

Quality and Accreditation Institute
Centre for Laboratory Accreditation



**POLICY AND PROCEDURES
FOR ASSESSMENT, ONGOING MONITORING
AND REASSESSMENT OF CAB**

Issue No.: 02

Issue Date: March 2021

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 1/11

CHANGE HISTORY

Sl. No.	Doc No.	Current Issue No.	Revised Issue No.	Date of Issue	Reasons
1	CLA 025	1	2	September 2021 (11 March 2021)	Biobank added to the list of CAB ISO 20387 added Hybrid/remote assessment added
	1				

CONTENTS

Sl. No.	Title	Page No.
1.	Preparing for CAB Accreditation	4
2.	Eligibility for applying for QAI Accreditation	4
3.	Accreditation Procedure	5
4.	Maintaining Accreditation	7
5.	Ongoing Monitoring	8
6.	Reassessment and Renewal of Accreditation	8
7.	Adverse Decisions	9
8.	Appeal	9
9.	Publicity	9
10.	Confidentiality	10
11.	Liability	10
12.	Amendments to the Policies and Procedures	10

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 3/11

1. Preparing for conformity assessment body (CAB) accreditation

In this document CAB means medical laboratory, testing laboratory and biobanks. CAB management should first decide about getting accreditation from QAI. It is important for a CAB to make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation. The person nominated should be familiar with CAB's services, functions and existing quality system, if any.

A request can be made to QAI Secretariat for procurement of relevant QAI documents against the payment, if any. All documents are free downloadable except printed copy of standards and guidance book. CAB must procure a copy of the relevant standard (ISO 15189 or ISO/IEC 17025). A list of QAI documents is given on the website under each programme and general documents. Clarifications on any document/ process may be obtained from QAI Secretariat in person, by post, on telephone or through e-mail. The CAB get fully acquainted with relevant documents and understand the assessment procedure & methodology of making an application.

Before an application is made, it is required that CAB do the self-assessment using self-assessment tool to ascertain whether CAB fulfilling QAI accreditation requirements, if find the gaps, take necessary measures to fill those gaps.

Relevant requirements for QAI accreditation should be discussed amongst concerned staff of the CABs. This will enable them to understand their weaknesses and strengths. The CAB must ensure that policies, procedures and other documents for various sections/ departments and services being provided are available and implemented.

The CAB interested in going for accreditation should understand the QAI assessment procedure and prepare accordingly.

2. Eligibility for applying for QAI Accreditation

The applicant CAB must comply with all clauses of ISO 15189 or ISO/ IEC 17025:2017 or ISO 20387 whichever is applicable and relevant regulatory/ statutory requirements.

The applicant CAB must have filled self-assessment tool kit against ISO 15189 or ISO/ IEC 17025:2017 or ISO 20387 before the submission of application. Self-assessment tool is a mechanism of ensuring compliance to standards by the CAB themselves and therefore it would be easier for the assessment teams to verify those compliances during assessments (on-site/ remote/ hybrid). It also gives confidence to CAB about documentation and implementation of the requirements.

The applicant CAB must have participated satisfactorily in the proficiency testing programme, wherever applicable, conducted by an accredited PT provider, APAC or any other national or international accredited/ recognised PT provider as per policy mentioned in CLA 005. If no suitable PT programme is available the CAB can initiate an inter-laboratory comparison with adequate number of accredited CABs 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 CAB must have conducted at least one internal audit and a management review before the submission of application.

3. Accreditation Procedure

3.1 Application for accreditation

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 4/11

The CAB shall apply to QAI in the prescribed application form, along with self-assessment tool and supporting documents of the CAB in accordance with relevant accreditation standard. The application shall be accompanied with the prescribed application fee as detailed in the information brochures.

3.2 Registration and Acknowledgements of application

Within 10 days of receipt of the application from an CAB, the following actions shall be taken:

- Review application to see for which accreditation programme application is made and accordingly allocate a Unique Registration Number
- Open a folder in the computer system and hard copy document file
- Update the database maintained
- Fee received is updated in database
- Performing completeness check of application including supporting documents and fee received on-line
- Examine the Self-Assessment tool/ Manuals to verify if all the requirements of standard have been adequately addressed
- Issue acknowledgement mentioning unique Registration number. If deficiencies are noticed, in application fees, application, or the self-assessment tool, it shall be recorded and the CAB be informed for corrective actions within 10 days.
- This unique Registration number shall be used for QAI's own recording system and also for correspondence with the CAB. All CABs are advised to use this registration number while communicating with QAI
- QAI shall maintain confidentiality of application submitted by CAB.

3.3 Appointment of Lead Assessor

The Lead assessor shall have the overall responsibility of conducting the assessment and shall be responsible for conducting the on-site/ remote/ hybrid assessment of the concerned CABs. 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 amends 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/ remote/ hybrid assessment visit is organised.

3.4 Assessment

Once the Lead Assessor has been selected, the concerned Officer shall constitute an assessment team for final assessment (on-site/ remote/ hybrid). The team shall include the Lead Assessor, assessor(s), technical expert(s) and observers or trainee assessors (if required) in order to cover the scope of accreditation. The CAB is informed about the team members and consent is taken to avoid any conflict of interest.

Thereafter the officer shall fix up dates for assessment of the CAB in consultation with the CAB and the assessment team. The Officer from QAI may also participate in the assessment as an observer/ coordinator during the assessment and convey his/ her observations to the Lead

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 5/11

Assessor. The Officer is also required to provide clarification on QAI requirements to the Lead Assessor and other assessors, whenever necessary.

The CAB is informed about the assessment team and date(s) and concurrence taken. A copy of this communication is marked to the members of assessment team, along with the requisite documents. The assessors are required to reach the place of assessment, preferably a day before the start of assessment.

The assessment team assess the CAB's services and functions and verifies its compliance with the applicable accreditation standards, for the purpose assessment team carries out various assessment activities documented management system, SOPs, work instructions, test methods and technical competence etc. The team will assess the extent of implementation of standards, the non-conformities, if identified are reported in the assessment report.

The assessors report shall be prepared in the formats prescribed by QAI as per the Assessors' Guide (QAI CLA 104, 114, 204 and 304) and to be sent by the Lead Assessor to QAI Secretariat, within 10 days of completion of assessment. The assessment team shall share the assessment report with the CAB representative after the assessment is over.

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 A copy of the report containing final summary, details of the non-conformities observed during the assessment is handed over to the CAB by the Lead Assessor.

3.5 Scrutiny of assessment report

The assessment report shall be examined by QAI and confirmed with the CAB that they have received a copy of the report. Officer shall seek any clarification, if required from assessment team or the CAB on the report. Officer shall communicate to CAB 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.

3.6 Decision Making

After satisfactory corrective action are submitted by the CAB and accepted by the assessment team, the assessment report shall be submitted to the Head of Division who is responsible to examine the report and comments of the assessment team and may seek clarification from the Lead Assessor/ Assessor/ CAB 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 CAB as per laid down appeal process.

3.7 Issue of accreditation certificate

The effective date of accreditation will be the date of Chairman's approval. When the recommendation of the assessment team results into accreditation, the officer concerned shall prepare an Accreditation Summary in the prescribed format provided in document QAI CLA 012. This accreditation summary along with scope of accreditation is submitted to Chairman for approval. Once Chairman has accorded his approval, the officer shall prepare the accreditation certificate and scope of accreditation. Accreditation certificate is digitally

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 6/11

signed using the scanned signatures of the CEO and the Chairman. Accreditation certificate bears the signatures of the CEO and the Chairman while scope of accreditation only bears the signatures of the CEO. A unique certificate number shall be allotted to CAB. Certificate shall carry name of CAB, effective date of accreditation, date of expiry and unique certificate number. If the certificate pertains to the already accredited facility (renewal cases), 'Date of first Accreditation' shall also be mentioned above the accreditation date. Final certificate containing information as described above and duly signed by the Chief Executive Officer and the Chairman, QAI CLA is issued to the CAB.

The applicant CAB must make all payments due to QAI CLA, before the certificate is issued to the CAB.

4. Maintaining Accreditation/ Recognition

4.1 Validity

The accreditation/ recognition certificate shall be valid for a period of two years. On grant of accreditation, the CAB can use QAI accreditation mark on its letterheads, brochures and any other material issued to its customers. The guidelines for using QAI Accreditation Mark are given in the document 'Policy and guidelines for use of QAI accreditation mark' (QAI CLA 013).

QAI shall conduct on-going monitoring every year in the middle of the accreditation cycle of the accredited CAB before the expiry of the accreditation certificate.

During the validity of accreditation, the CAB must continuously comply with the requirements of QAI Standards and 'Terms and condition for maintaining QAI accreditation' (QAI CLA 002).

4.2 Extension/ Reduction of Scope of Accreditation

The CAB during the validity of accreditation may enhance or reduce the scope of accreditation for which QAI shall organise reassessment or a supplementary/ special visit. The reduction of scope is only permitted if CAB ceases to provide services in that specific area.

4.3 Focus/ Surprise/ Verification/ Unannounced visit

Besides the regular (announced) reassessment, QAI may also organise Focus/ Surprise/ Verification/ unannounced visit at any time because of any of the following reasons:

- **Changes in the accreditation standards and requirements**

If there is a change in the general accreditation criteria, QAI shall inform the CAB of this in writing indicating the transition period, which shall be at least 6 months. On receipt of the aforesaid information, the CAB must confirm to QAI, its willingness to modify its quality system in accordance with the changes. On confirmation from the CAB, QAI may conduct a verification visit to assess the implementation of the same.

- **Changes affecting the CAB operations**

In the event of the CAB informing QAI about any changes in the information affecting the CABs activities and operations, such as equipment, accommodation, environment, scope of accreditation or changes in key managerial/ technical personnel, a verification visit may be conducted.

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 7/11

- **Misuse of accreditation mark**

Whenever any information regarding misuse of Accreditation Mark is received in QAI Secretariat, it shall be investigated and objective evidence of such misuse is collected and reported to the CEO QAI. Verification/ unannounced Verification visit shall be organised based on the severity of the outcome of the investigation.

- **Complaint against an CAB**

In case, a complaint has been received and the facts need to be verified. Complaint will be dealt with as per the policy.

5. **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/ ISO/IEC 17025:2017/ ISO 20387:2018) 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/ ISO/IEC 17025:2017/ ISO 20387:2018 and any other requirements prescribed by the QAI CLA since last on-site assessment"

Ongoing monitoring is aimed at examining whether the accredited CAB is maintaining the requirements of ISO Standards and other applicable criteria.

6. **Reassessment and Renewal of Accreditation**

QAI Secretariat shall remind the CAB 12 months before the expiry of accreditation for making application for renewal of accreditation to ensure that CAB applies for renewal.

The CAB may apply for renewal of accreditation by submitting an application in the prescribed form. The application shall be accompanied with the prescribed renewal fee, as detailed in

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 8/11

the information brochure. The CAB may request for extension of scope of accreditation, which should explicitly be mentioned in the application form.

The request for renewal must be submitted at least six months before the expiry of the validity of accreditation. If the CAB does not apply for renewal of accreditation, three months before the expiry of accreditation, it shall be presumed that the CAB is no longer interested in accreditation and the accreditation status of the CAB shall expire on the validity date mentioned in the certificate. In such a case the CAB shall have to apply afresh and the continuity of the certificate shall be disturbed.

Once applied within the time frame given above, the CAB must be prepared for assessment. QAI shall conduct the renewal assessment (on-site/ remote/ hybrid), based on situations anytime during this period to ensure that the decision on the renewal assessment can be arrived at before the expiry of the accreditation certificate. In circumstances, where the decision for renewal could not be arrived at before the expiry of the accreditation, QAI may take a decision to extend the certificate validity up to a period not exceeding three months.

The procedure for processing of renewal application is similar to that of first application. The procedure for the reassessment is similar to that of first assessment.

If the results of reassessment are positive and all non-conformities are addressed through an action plan and corrective actions before the expiry of the certificate, then the validity of the certificate is extended by another two year without any discontinuity.

A new certificate of accreditation is issued on renewal; however, the certificate number remains the same.

7. Adverse Decisions

QAI may take an adverse decision on the accredited CAB, if the CAB at any time during the validity of accreditation, does not fulfil the requirements of QAI Standards and other relevant criteria. The conditions of taking adverse decisions, like a reduction in scope of accreditation, abeyance, suspension and forced withdrawal is described in the document 'Policies & Procedures for Dealing with Adverse Decisions' (QAI CLA 022).

In case of adverse decisions like inactive, abeyance, suspension and forced withdrawal, the CAB shall ensure that the use QAI accreditation mark is as per policy. The suspension and forced withdrawal status shall also be publicised.

In case the CAB's accreditation has been withdrawn by QAI, it is debarred to participate in the accreditation programme for a period of at least one year. The CAB may apply afresh by giving valid justification for earlier withdrawal and paying all fees & expenses, as applicable at that time.

8. Appeal

All adverse decisions taken by QAI regarding accreditation shall be open to appeal by the CAB, to the Chairman QAI as per laid down policy.

9. Publicity

QAI on its website shall publish details of applicant and accredited CABs. Scope of accreditation & accreditation status with validity date of accreditation of the accredited CABs shall be made available on our website.

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 9/11

10. Confidentiality

The members of the Board, Assessors, Experts and QAI officials are required to maintain strict confidentiality of the information gathered regarding the CABs from their various documents and any other related information that might have been given by QAI, during the process of accreditation. QAI shall impose the same obligation of maintaining secrecy on those, whom they entrust the tasks of a confidential nature, as described above. All such persons who have access to confidential information sign a declaration of confidentiality.

11. Liability

QAI shall not be responsible for any damages, which the CAB may suffer as a result of any action or negligence by those who are carrying out the tasks on behalf of QAI and any failure to the grant of accreditation or abeyance/ suspension/ forced withdrawal of the accreditation.

12. Amendments to the Policies and Procedures

QAI may at any time amend the policies and procedures related to grant of accreditation, maintaining accreditation, ongoing monitoring, renewal of accreditation and the adverse decisions thereon. QAI shall inform the CABs regarding such amendments indicating the transition period set for compliance.

Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 10/11

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Quality and Accreditation Institute		
Centre for Laboratory Accreditation		
Doc. No.: QAI CLA 025	Policy and Procedures for Assessment, Ongoing Monitoring and Reassessment of CAB	
Issue No.: 02	Issue Date: March 2021	Page No.: 11/11