

Quality and Accreditation Institute

Centre for International Accreditation



Change Adapt Improve

INFORMATION BROCHURE FOR CALIBRATION LABORATORIES

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1. Laboratory Accreditation

Accreditation is the third-party attestation related to a Conformity Assessment Body (CAB) 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, reference material producers, management system certification, personnel certification, and product certification.

CAB 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- General requirements for the competence of testing and calibration laboratories and for medical are specified in the International Standard ISO 15189— Requirements for quality and competence, for Biobanking are specified in Biotechnology-Bio banking- General requirements for biobanking as per ISO 20387, for Proficiency Testing Provider-General requirements for the competence of proficiency testing providers as per ISO/IEC 17043, for Inspection Bodies are specified in ISO/IEC 17020 Conformity Assessment-Requirements for the Operation of Various Types of Bodies Performing Inspection and for Reference Material Producers specified in ISO 17034 General Requirements for the Competence of Reference Material Producers. 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 CABs and an assurance given by the accreditation body that the accredited CAB fulfils the accreditation criteria. Accredited CABs 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 CABs 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 are saved due to reduction or elimination of the need for retesting of product.
- Global recognition as it is based on International Standard ISO/IEC 17025.
- 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 International Accreditation (CIA)
- Centre for Accreditation of Veterinary Facilities (CAVF)

4. QAI's Centre for International Accreditation (CIA)

The organisation structure of QAI's Centre for International 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 CIA. CEO is the Member Secretary of the Board.

CIA operates its accreditation process through a structured framework of competent staff and pool of empaneled 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 CIA as per the relevant international accreditation criteria and subsequently empaneled 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.

QAI's CIA has been established with the objective of providing Government, Industry Associations and Industry in general with a scheme of accreditation for Conformity Assessment Bodies (CABs) including medical labs, testing labs, calibration labs and Biobanks as per below:

- Accreditation of **Testing laboratories** as per ISO/ IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories
- Accreditation of **Calibration laboratories** as per ISO/ IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories

- Accreditation of **Medical Laboratories** as per ISO 15189: Medical laboratories - Requirements for Quality and Competence,
- **Recognition of Medical Laboratories** as per the requirements of the Central Clinical Establishments Act.
- **Biobanking** Accreditation as per ISO 20387: General requirements for Biobanking. **(For the First time in India)**
- Accreditation of **Proficiency Testing Providers** as per ISO/IEC 17043: General Requirements for the competence of Proficiency Testing Providers
- Accreditation of **Inspection Bodies** as per ISO/IEC 17020: Conformity Assessment-Requirements for the Operation of Various Types of Bodies Performing Inspection
- Accreditation of **Reference Material Producers** as per ISO 17034: General Requirements for the Competence of Reference Material Producers

We offer accreditation services in a non-discriminatory manner. QAI-CIA has established its accreditation system in accordance with the international standard ISO/ IEC 17011 'Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies'. QAI CIA has achieved global recognition through APAC and ILAC MRA.

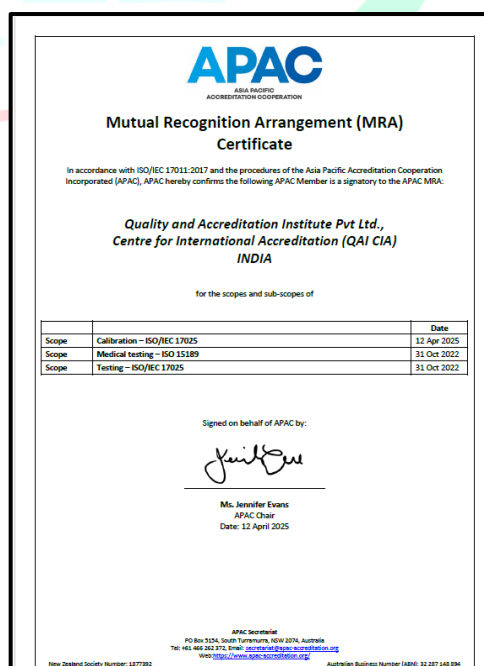
International Affiliations

QAI CIA is a Full Member/ MRA Signatory of the Asia Pacific Accreditation Cooperation (APAC) (<https://www.apac-accreditation.org/membership/full-member/>) for the following scopes:

Medical testing-ISO 15189 effective from 31 October 2022

Testing-ISO/IEC 17025 effective from 31 October 2022

Calibration-ISO/IEC 17025 effective from 12 April 2025

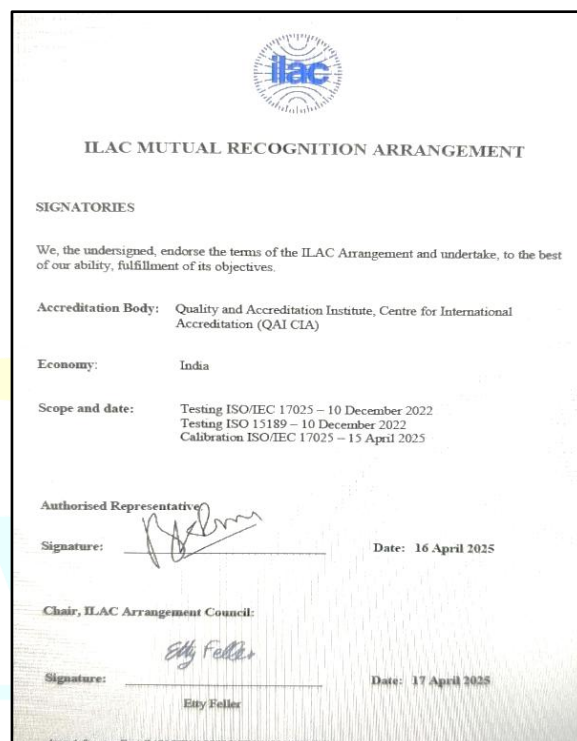


QAI CIA is a Full Member/ MRA Signatory of the International Laboratory Accreditation Cooperation (ILAC)
(<https://ilac.org/signatory-detail/?id=210>) for the following scopes:

Medical Testing-ISO 15189 effective from 10 December 2022

Testing-ISO/IEC 17025 effective from 10 December 2022

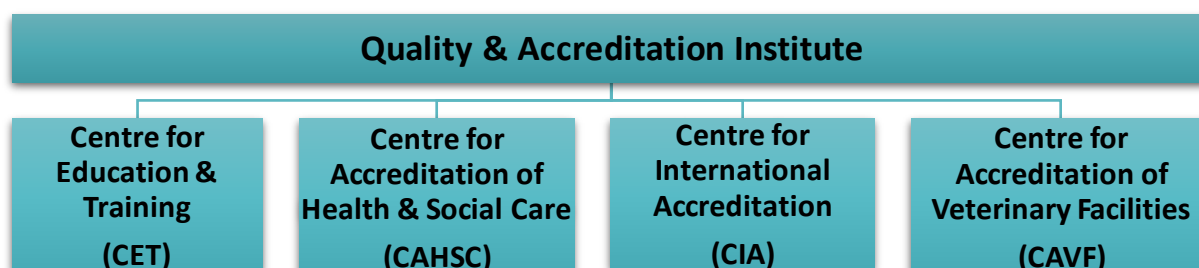
Calibration- ISO/IEC 17025 effective from 15 April 2025



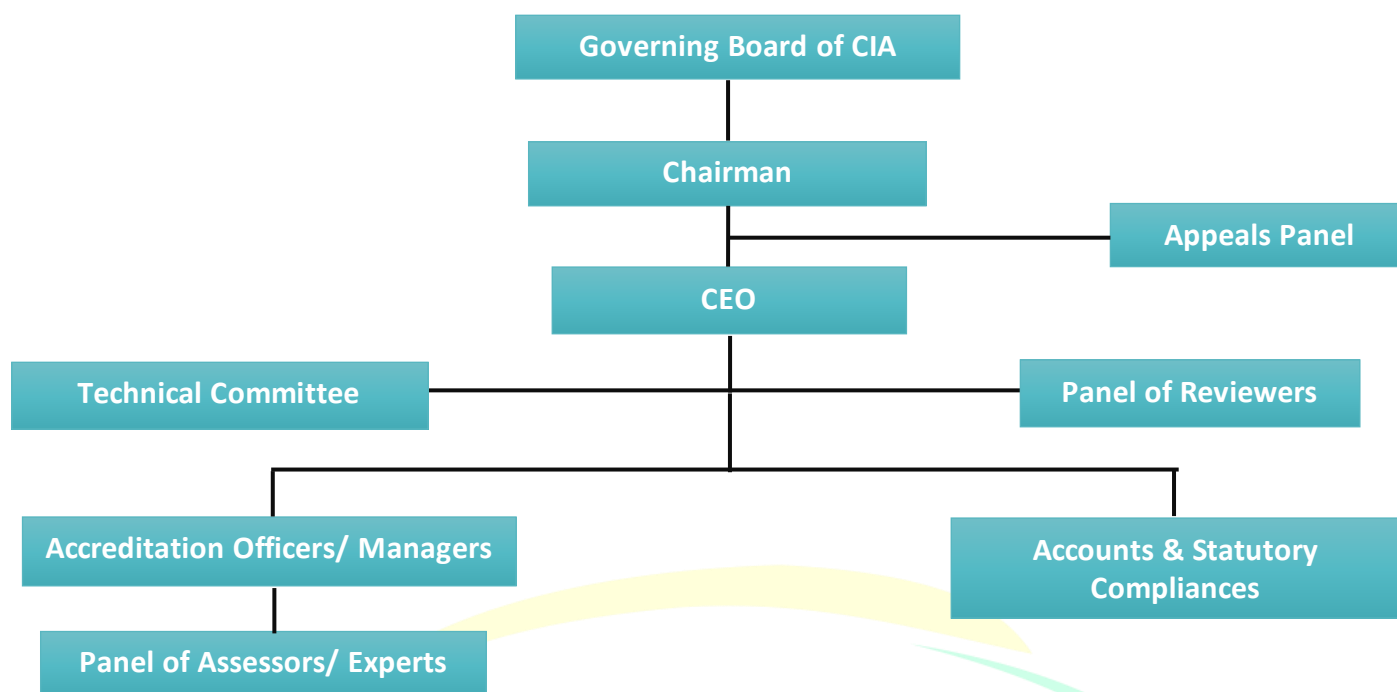
5. Organisation Structure

The organisation structure of QAI's centre for international 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 CIA. CEO, QAI is the member secretary of the board.

CIA 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 CIA 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 CIA



6. 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
- Optional pre-assessment to reduce turnaround 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/IEC 17025.
- Our process ensures continuous support to our clients in handling their queries as each lab is unique in itself.
- We support quality improvement journey on an ongoing basis.
- Rigorous assessor management system including a transparent monitoring and evaluation mechanism for all empaneled assessors.
- Open to hear the voice of all keeping 'Client First'.
- Harmonising local, national, regional and global framework.
- Blend of global strategy, experience and leadership.
- Fee structure based on the world bank's income- level classification of countries.
- Consolidated fee structure reducing number of transactions and cost effective compared to other accreditation bodies.
- Compliance to ISO/IEC 17011.
- Economic yet global model.

7. Scope of Accreditation

Accreditation is currently given in following disciplines:

Electro-Technical	
Alternating Current (<1 GHz)	Direct Current
RF/ Microwave (1 GHz and Above)	Time & Frequency
EMI/EMC	Electrical equipment
Temperature Simulation	Miscellaneous
Mechanical	
Acceleration & Speed	Acoustics
Density and Viscosity	Force
Dimension (Basic- Measuring Instrument, Gauges etc.)	Hardness & Impact
Mass	Volume
Dimension (Precision- Precision Instruments and Surface Topology)	Pressure & Vacuum
Torque Generating & Measuring Devices	Miscellaneous
Chemical	
Equipment/Devices	
Fluid-Flow	
Flow Measuring Devices	
Miscellaneous	
Thermal	
Specific Heat & Humidity	
Temperature	
Miscellaneous	
Optical	
Equipment	
Optical	
Miscellaneous	
Radiological	
Radiological Measurements	
Radio Isotope/Source Calibration	
Miscellaneous	
Medical Devices	
Discharge Equipment/ Devices	Patient Conditioning/ Maintenance
Monitoring Unit	Imaging/ Plotters
Medical Device Analyzer/ Simulator Equipment	Miscellaneous

8. Calibration Laboratory Accreditation Programme

8.1 Preparing for Accreditation

Management of the laboratory shall first decide about getting accreditation from QAI CIA. 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.

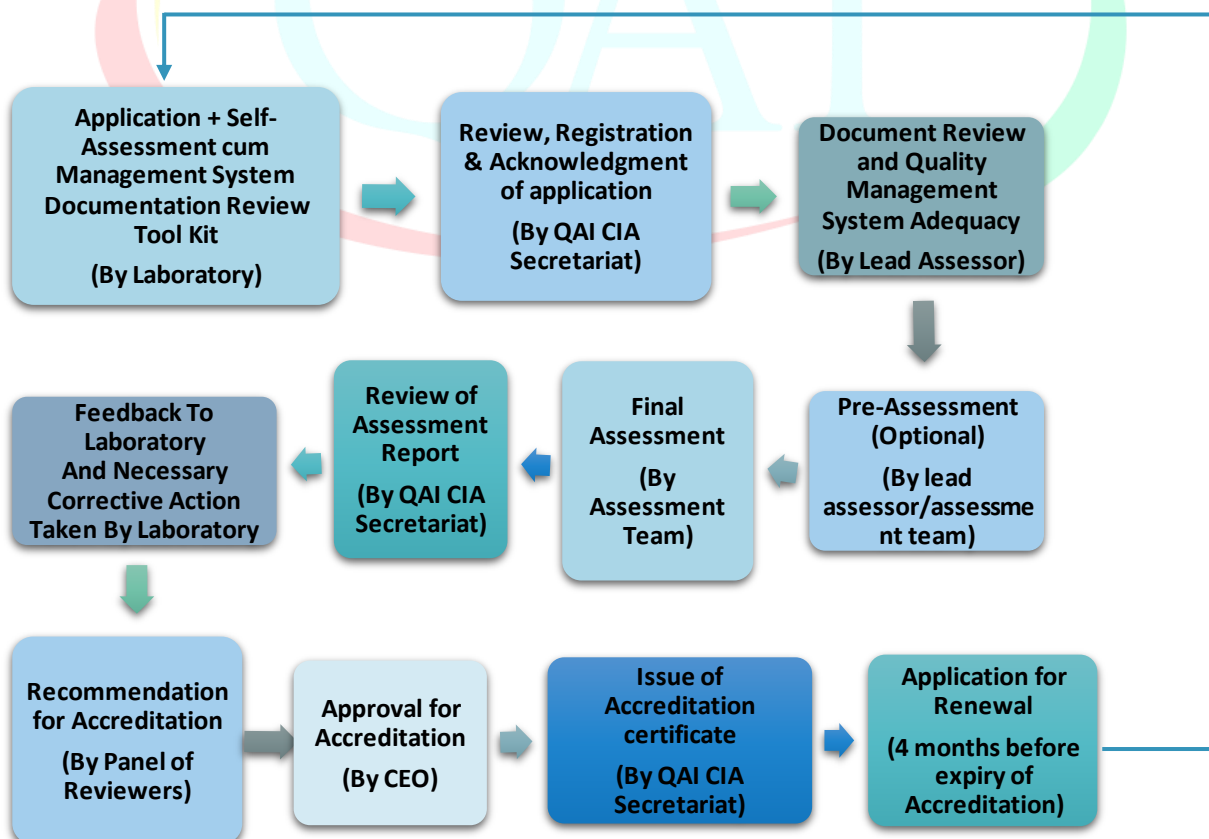
Laboratory must procure a copy of the relevant standard i.e., ISO/IEC 17025:2017. The laboratory looking for accreditation shall understand the QAI CIA assessment process. The laboratory shall ensure that all the requirements of the standard are implemented. For preparing the quality manual or verifying its contents, the laboratory may get its personnel trained in a training programme 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/ IEC 17025:2017. 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.

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:

- Soft copy of completed application form (available on website)
- Soft copy of Self-assessment cum management system documentation review tool kit along with referenced document
- Soft copy of Quality Manual/ Management system documentation
- Prescribed application fees
- Soft copy of signed QAI CIA 002 'Terms and Conditions for Maintaining QAI CIA Accreditation
- All the above information shall be sent to the given email ID: info@qai.org.in

Self-assessment cum management system documentation review tool kit is based on the requirements of the accreditation standard ISO/IEC 17025:2017. It gives an opportunity to the CAB 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

QAI CIA secretariat on receipt of application form, self-assessment cum management system documentation review tool, referenced documents and the fees reviews the application for its completeness, and a unique reference number is allocated which is used for correspondence with the laboratory. Secretariat reviews the self-assessment cum management system documentation review tool kit and referenced documents in accordance with the relevant standard and may ask for additional information/ clarification(s) at this stage, if found necessary.

9.3 Document Review and Quality Management System Adequacy

QAI CIA comprises a team of expert lead assessors. Once a laboratory submits the complete set of application documents, a lead assessor is appointed with the laboratory's consent. The complete set of documents along with self-assessment tool kit is then shared with the lead assessor for a review of the adequacy of the quality management system (QMS). Any gaps or deficiencies identified during this review are communicated to the conformity assessment body (CAB) for necessary incorporation. Following this, once the findings have been addressed and closed by the CAB, the pre-assessment or final assessment is scheduled accordingly.

9.4 Pre-Assessment (Optional):

QAI has introduced pre-assessment as optional. Those laboratories shall inform QAI while applying in case they wish to undergo pre-assessment. All laboratories are not required to undergo the same and can directly move to the final assessment. Appointed assessor or assessment team shall conduct the pre-assessment (remote/ hybrid/ on-site). Lead assessor shall submit the pre-assessment report to QAI. The laboratory shall take corrective actions on the non-conformities raised by the lead assessor/ assessment team. The laboratory shall be required to pay the pre-assessment fee as defined in the fee structure (programme wise).

9.5 Final Assessment

QAI CIA constitutes an assessment team. The team includes the lead and technical assessor(s)/ expert(s) in order to cover various fields within the scope of accreditation sought. QAI CIA may also nominate an observer which is either an assessor-in-training or a Secretariat staff. QAI CIA 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/ remote/ hybrid visit, the assessment team

reviews the documented management system and verifies its compliance with the requirements of ISO/ IEC 17025:2017 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 QAI CIA 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.

9.6 Review of Assessment Report

The assessment report is examined by the QAI CIA secretariat and follow up action as required is initiated. Laboratory has to take necessary corrective action and root cause analysis for non – conformities raised using 'QAI CIA 015-Corrective Action Summary for Non-Conformity Raised' and submit the same to the Secretariat within 30 days. Which means that submission of corrective actions and closure by the assessment team should be completed within 30 days.

In exceptional case if CAB is unable to submit the corrective actions within the stipulated timeline, it shall submit a formal request for an extension to the QAI CIA Secretariat through email, clearly stating the reasons for the delay. The QAI CIA secretariat shall review the request and obtain approval from the CEO before granting any extension for the submission of corrective actions.

9.7 Decision Making

After satisfactory closure of the corrective action submitted by the CAB the assessment team, submits its recommendation to the Secretariat.

Further the final assessment report along with corrective action and recommendation of the assessment team shall be reviewed by two or more assessors not part of the assessment team and the accreditation decisions are taken by the reviewer panel and approved by the CEO. QAI CIA always ensures that the decisions on accreditation are made by the competent persons. All decisions taken by QAI CIA regarding grant of accreditation are open to appeal by the CAB as per laid down appeal process.

Note- The laboratory shall submit the duly signed disclaimer (QAI CIA 014) on its letter head, two-year PT plan covering the recommended scope and the feedback for the assessment team through the feedback form (QAI CIA 010).

9.8 Issue of Accreditation Certificate and Scope

QAI-CIA issues an accreditation certificate and scope which has a unique certificate number, discipline, group, 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 CIA-Policy for use of QAI Accreditation mark.



ISO/IEC 17025:2017

Certificate No.

Example: QAI/CIA/CL/2022/0001

9.9 Maintaining Accreditation

Conformance to applicable standards and other requirements

The accredited laboratory at all times shall conform to the requirements of ISO/IEC 17025 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 CIA 002 'Terms & Conditions for Maintaining QAI CIA Accreditation. 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-CIA/ 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, CIA 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/ IEC 17025:2017) 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. Calibration Certificate

- D.1. One Calibration certificate released in every month since the grant of accreditation

E. 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.)

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

A statement "This is to declare that the laboratory has been complying to the requirements of ISO/IEC 17025:2017 and any other requirements prescribed by the QAI CIA since last on-site/ remote/ hybrid assessment"

9.10 Re-assessment

1. In general, QAI CIA accreditation cycle will be of two years. However, in exceptional cases, accreditation may be granted upto maximum of five years, based on the specific requirements of the international contract.

For a two-year accreditation cycle, 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 CAB has to apply four 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. In case of an accreditation cycle of over two years, it will be ensured that the requirements of ISO/IEC 17011 are complied with.

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 CIA 402). 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/quality management system. However, there will be adequacy check if there is a change in accreditation standard.

Applicant CAB is requested to submit the application to info@gai.org.in

2. Complaints and Appeals

Complaints

QAI-CIA 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-CIA is open to appeals from the applicant/ accredited laboratories against its decisions. The decisions against which appeals are entertained relate to adverse decisions like accepting 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'.

3. 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-CIA is obliged to make available information on scope of accreditation, validity dates for its accreditation certificate(s) and contact details to users of the laboratories. The laboratory has the right to object to appointment of specific member(s) of assessment team by giving valid reasons. QAI-CIA accredited laboratory has the right to use 'QAI Accreditation Mark' on the test reports issued by it as long as the test 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-CIA 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 shall 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.

4. Rights and Responsibilities of QAI-CIA

Rights

- QAI-CIA requires that all laboratories will conform to ISO/IEC 17025:2017 and any other requirement specified by QAI-CIA from time to time to maintain accreditation.
- QAI-CIA requires that all accredited labs abide by 'Terms and conditions for obtaining and maintaining accreditation.'
- QAI-CIA 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-CIA 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-CIA will communicate changes to the requirements of accreditation such as ISO/IEC 17025 through website.

5. 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.

6. QAI-CIA Publications

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





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