

**Quality and Accreditation Institute**  
**Centre for International Accreditation**



*Change Adapt Improve*

**INFORMATION BROCHURE**  
**FOR**  
**PROFICIENCY TESTING PROVIDERS**

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## 1. Proficiency Testing Providers (PTP) Accreditation

Proficiency Testing is one of the important tools to determine the technical competence of the Testing, Calibration and Medical Testing laboratories.

Proficiency Testing (PT) is the evaluation of participant performance against pre-established criteria by means of inter laboratory comparisons. For the purposes of ISO/IEC 17043:2010 or ISO/IEC 17043:2023, the term “proficiency testing” is taken in its widest sense and includes, but is not limited to:

- **Quantitative scheme** — where the objective is to quantify one or more measurands of the PT items;
- **Qualitative scheme** — where the objective is to identify or describe one or more characteristics of the PT items;
- **Sequential scheme** — where one or more PT items are distributed sequentially for testing or measurement and returned to the PTP at intervals;
- **Simultaneous scheme** — where PT items are distributed for concurrent testing or measurement within a defined time period;
- **Single occasion exercise** — where PT items are provided on a single occasion;
- **Continuous scheme** — where PT items are provided at regular intervals;
- **Sampling** — where samples are taken for subsequent analysis;
- **Data transformation and interpretation** — where sets of data or other information are furnished and the information is processed to provide an interpretation (or another outcome).

Note: “quantitative” and “qualitative” are not schemes in pure terms this is only the way statistics of a scheme will be handled. All schemes i.e., sequential, simultaneous, single occasion, continuous, sampling, data transformation and interpretation can be quantitative or qualitative.

Participation in PT schemes allow laboratories to assess their conduct of specific tests, measurements or calibrations compared to similar laboratories. The ongoing opportunity to compare data can minimise the risk of errors, biases or differences which may occur when operating in isolation.

Proficiency testing provides a chance to undertake comparisons and to have an independent appraisal of the laboratory’s data compared to reference values (or other performance criteria) or to the performance of similar laboratories. The results from such participation provide laboratory managers with either a confirmation that the laboratory’s performance is satisfactory or an alert that investigation of potential problems within the laboratory is required.

## 2. Benefits of Accreditation

Accredited PTPs with international criteria have following advantages:

- Comparison of the facility’s performance with that of other participating (peer) facilities
- Monitoring of the long-term performance of a facility.
- Improvement in the performance of tests/calibrations following investigation and identification of the cause(s) of unsatisfactory PT performance, and the introduction of corrective action to prevent re-occurrence.
- Staff education, training and competence monitoring.
- Evaluation of methods, including the establishment of method precision and accuracy.
- Contribution to the facility’s overall risk management system.

- Confidence building with interested parties, e.g., customers, accreditation bodies, regulators, specifiers.
- PTPs play an important role in the value chain for assurance of products and services. Being an accredited PTP in accordance with ISO/IEC 17043 gives the organisation credibility for their PT services.

### 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, Biobanks, PTP, Inspection, Reference Material Producers 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, and
- **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



**APAC**  
ASIA PACIFIC  
ACCREDITATION COOPERATION

**Mutual Recognition Arrangement (MRA)  
Certificate**

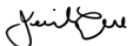
In accordance with ISO/IEC 17011:2017 and the procedures of the Asia Pacific Accreditation Cooperation Incorporated (APAC), APAC hereby confirms the following APAC Member is a signatory to the APAC MRA:

**Quality and Accreditation Institute Pvt Ltd.,  
Centre for International Accreditation (QAI CIA)  
INDIA**

for the scopes and sub-scopes of

Scope	Date
Medical testing – ISO 15189	31 Oct 2022
Testing – ISO/IEC 17025	31 Oct 2022

Signed on behalf of APAC by:



Ms. Jennifer Evans  
APAC Chair  
Date: 14 November 2023

APAC Secretariat  
PO Box 5154, South Turramurra, NSW 2074, Australia  
Tel: +61 486 262 372, Email: [apac@apac-accreditation.org](mailto:apac@apac-accreditation.org)  
Web: <https://www.apac-accreditation.org/>

New Zealand Society Number: 1877392 Australian Business Number (ABN): 52 287 148 894

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:

- Testing-ISO 15189 effective from 10 December 2022
- Testing-ISO/IEC 17025 effective from 10 December 2022





**ILAC MUTUAL RECOGNITION ARRANGEMENT**

**SIGNATORIES**

We, the undersigned, endorse the terms of the ILAC Arrangement and undertake, to the best of our ability, fulfillment of its objectives.

**Accreditation Body:** Quality and Accreditation Institute, Centre for International Accreditation (QAI-CIA)

**Economy:** India

**Scope and date:** Testing ISO/IEC 17025 – 10 December 2022  
Testing ISO 15189 – 10 December 2022

**Authorised Representative:**

Signature:  Date: 21 November 2023

**Chair, ILAC Arrangement Council:**

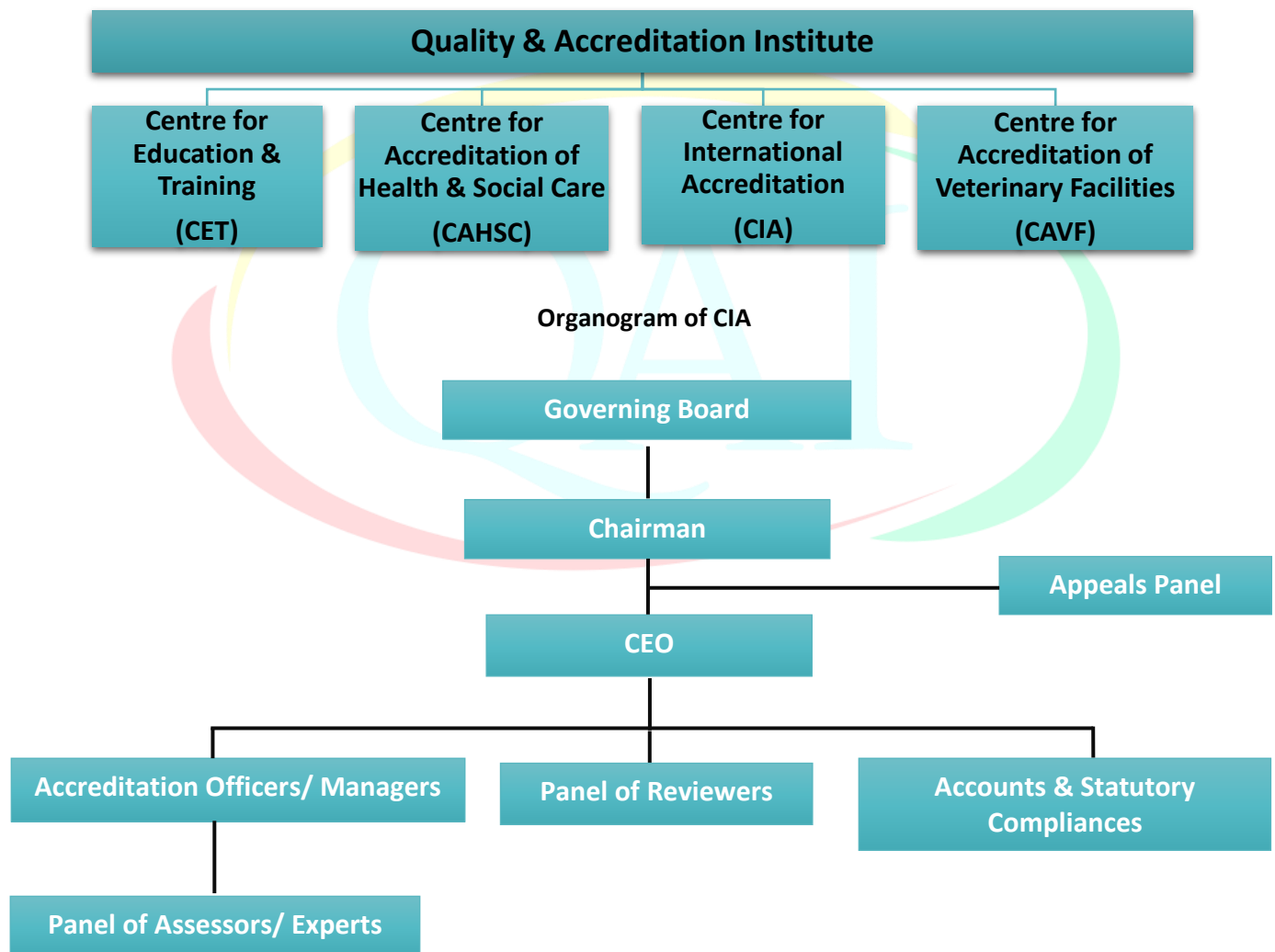
Signature:  Date: 23 November 2023  
Ety Feller

Annex A: Signature Sheet, ILAC MUTUAL RECOGNITION ARRANGEMENT

## 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.



## 6. Special Features of Proficiency Testing Provider (PTP) 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 CAB as per the intent of the standard
- No pre-assessment to reduce turnaround time.
- Introducing a new concept of self-assessment and document review replacing pre - assessment, and providing opportunity to PTP for a thorough review of their documentation and implementation of requirements of ISO/IEC 17043.
- Our process ensures continuous support to our clients in handling their queries as each PTP 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.
- PTPs in SAARC nations to enjoy same fee structure as for PTPs in India.
- Consolidated fee structure reducing number of transactions and cost effective compared to other accreditation bodies.
- Compliance to ISO/IEC 17011.
- Economic yet global model.

## 7. Scope of Accreditation

Accreditation is currently given in following disciplines:

- Testing
- Calibration
- Medical

Sub-discipline of Testing	
Biological	Mechanical
Chemical	Non-Destructive
Electrical	Optical photometry
Electronics	Radiological
Fluid-Flow	Forensic



Sub-discipline of Calibration	
Electro-Technical	Thermal
Mechanical	Optical
Fluid Flow	Radiological
Medical Device	Others

Sub-discipline of Medical	
Clinical Biochemistry	Haematology
Clinical Pathology	Histopathology
Microbiology & Infectious disease serology	Cytopathology
Flow Cytometry	Cytogenetics
Molecular testing	

## **8. Proficiency Testing Provider (PTP) Accreditation Programme**

### **8.1 Preparing for Accreditation**

Management of the PTP shall first decide about getting accreditation from QAI. It is important for the PTP 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 PT quality management system.

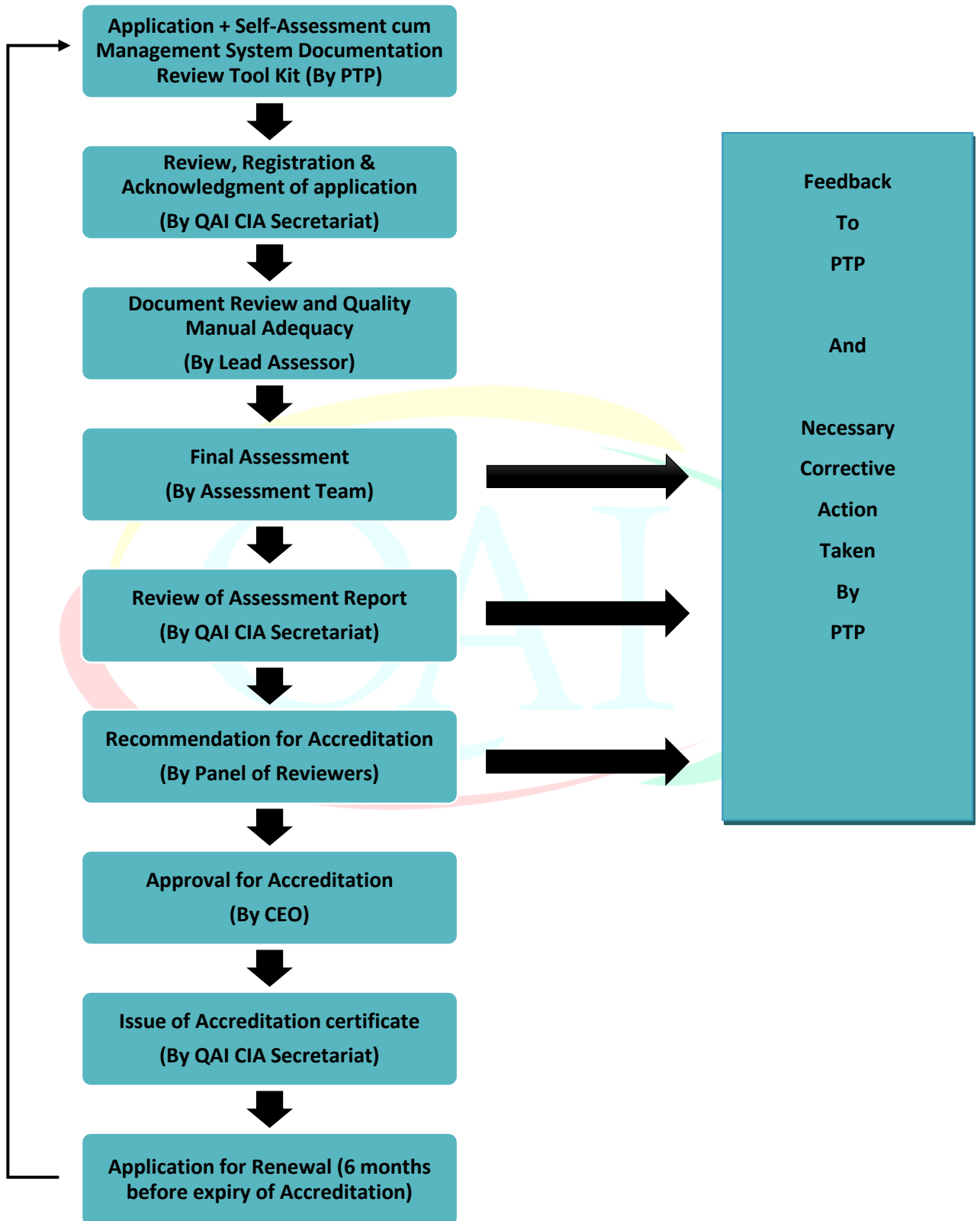
PTP must procure a copy of the relevant standard i.e., ISO/IEC 17043:2010 or ISO/IEC 17043:2023. The PTP looking for accreditation shall understand the QAI assessment process. The PTP shall ensure that all the requirements of the standard are implemented. For preparing the quality manual or verifying its contents, the PTP 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 PTP must comply with all clauses of ISO/IEC 17043:2010 or ISO/IEC 17043:2023.
- The PTP must have conducted at least one PT scheme in same/similar Matrix (PT item) in each group (e.g., building materials, metals and alloys, food and agricultural products etc.) with at least some of the critical parameters in accordance with ISO/IEC 17043 for the applied scope of accreditation.
- For PT Programme not conducted/not completed, at least PT design document (detailed document as how the programme will be conducted) shall have been prepared for entire scope of accreditation.
- The applicant PTP must have conducted at least one internal audit and a management review before the submission of application.
- In case of PT programmes for calibration laboratory, the Reference standard used for assigning the value of artifact (PT item) shall be calibrated against a standard which is directly traceable to National Metrological Institute (NMI).

9. Accreditation Process

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



### 9.1 Application for Accreditation

Applicant PTP 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 Obtaining and Maintaining Accreditation/ Certification'

Self-assessment cum management system documentation review tool kit is based on the requirements of the accreditation standard ISO/IEC 17043:2010 or ISO/IEC 17043:2023. It gives an opportunity to the PTP 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 kit, 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 PTP. 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 Final Assessment

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. CIA may also nominate an observer which is either an assessor-in-training or a Secretariat staff. CIA seeks PTP's acceptance for the proposed assessment team and dates for assessment. The PTP 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 PTP. During on-site/ remote/ hybrid visit, the assessment team reviews the documented management system and verifies its compliance with the requirements of ISO/IEC 17043 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 PTP. The report prepared by the assessment team is sent to CIA Secretariat. A copy of summary of assessment report and copies of non-conformities, if any, are provided to the PTP at the end of the assessment visit.

#### 9.4 Review of Assessment Report

The assessment report is examined by the Secretariat and follow up action as required is initiated. PTP 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 acceptance by the assessment team should be completed within 30 days.

#### 9.5 Decision Making

After satisfactory corrective action submitted by the PTP 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/PTP concerned.

Based on the recommendations of the assessment team, 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 PTP as per laid down appeal process.

#### 9.6 Issue of Accreditation Certificate

QAI-CIA issues an accreditation certificate which has a unique number, discipline, date of validity along with the scope of accreditation.

##### Accreditation Mark

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



**ISO/IEC 17043:2010**  
**Certificate No.**  
**Example: QAI/CIA/PTP/2023/0000**



**ISO/IEC 17043:2023**  
**Certificate No.**  
**Example: QAI/CIA/PTP/2023/0000**

## 9.7 Maintaining Accreditation

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

The accredited PTP at all times shall conform to the requirements of ISO/IEC 17043 as well as any other laid down requirements.

### **Terms and Conditions**

The accredited PTP is required to comply at all times with the terms and conditions given in CIA 002 'Terms & Conditions for Obtaining and Maintaining Accreditation/ Certification'. The PTP 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 CAB is informed of this giving an appropriate transition period to align its operations in accordance with the modified criteria.

### **Adverse decision against the PTP**

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

### **Ongoing Monitoring**

Accredited PTP is required to submit following information/documents/ records every year in the middle of the accreditation cycle. This is to ensure that the accredited PTP is continuously complying with the requirements of the applicable standard (ISO/IEC 17043:2010 or ISO/IEC 17043:2023) 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 of PTP 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 PTP has been complying to the requirements of ISO/IEC 17043:2010 or ISO/IEC 17043:2023 and any other requirements prescribed by the QAI CIA since last on-site assessment"

## 9.8 Reassessment

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

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

The renewal application is submitted in the prescribed form (QAI CIA 502). The PTP 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

## 10. Complaints and Appeals

### Complaints

QAI-CIA is open to receiving complaints for any of the activities performed by its officials, assessors and the accredited PTP. 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 PTP 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'.

## 11. Rights and Obligations of PTPs

### Rights of PTPs

PTPs are entitled to receive information related to Proficiency Testing accreditation. They can access our website [www.qai.org.in](http://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 PTPs. The PTP has the right to object to appointment of specific member(s) of assessment team by giving valid reasons. QAI-CIA accredited PTP 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 PTPs

An accredited PTP is obliged to fulfil requirements of relevant standard and any other requirements set by QAI-CIA at all times. The PTP 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 PTP 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 PTP is required to notify QAI of any change that may affect accreditation status, within 15 days. The PTP is required to pay necessary fees as determined by QAI from time to time.

## 12. Rights and Responsibilities of QAI-CIA

### Rights

- QAI-CIA requires that all PTPs will conform to ISO/IEC 17043:2010 or ISO/IEC 17043:2023 and any other requirement specified by QAI-CIA from time to time to maintain accreditation.
- QAI-CIA requires that all accredited PTPs abide by 'Terms and conditions for obtaining and maintaining accreditation/certification'.
- QAI-CIA has the right to:
  - effect changes in standards on which PTP accreditation is based in accordance with international norms
  - decide on policies related to accreditation in consultation with stakeholders
  - appoint assessment teams in consultation with PTP and the assessors
  - take appropriate action including adverse decisions against a PTP giving valid reasons for the same

### Duties

- QAI-CIA is obliged to make available relevant information to its applicant and accredited PTP. This information is provided on our web site [www.qai.org.in](http://www.qai.org.in).
- QAI-CIA will communicate changes to the requirements of accreditation such as ISO/IEC 17043 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 PTP and the charges are maintained at a reasonable level so that PTP 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 on the website.

## 14. QAI-CIA Publications

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





## Quality and Accreditation Institute

Centre for International Accreditation

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