Quality and Accreditation Institute

Centre for International Accreditation

Change Adapt Improve

GENERAL INFORMATION BROCHURE

QAI CIA 001

Issue No. 10 | Issue Date: February 2026

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1. Conformity Assessment Body (CAB) Accreditation

Accreditation is the third-party attestation related to a CAB conveying the formal demonstration of its competence to carry out specific conformity assessment task. CAB is an organisation providing the following conformity services: testing including medical, calibration, inspection, proficiency testing, 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 CAB or other organisations, to be considered competent to carry out testing (other than medical) and calibration are specified in the International Standard ISO/IEC 17025:2017, for medical are specified in the International Standard ISO 15189:2022, for Biobanking are specified in Biotechnology-Bio banking- General requirements for biobanking as per ISO 20387:2018, for Proficiency Testing Provider-General requirements for the competence of proficiency testing providers as per ISO 17043:2010 and ISO 17043:2023, for Inspection Bodies are specified in ISO 17020:2012 Conformity Assessment-Requirements for the Operation of Various Types of Bodies Performing Inspection and for Reference Material Producers specified in ISO 17034:2016 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 CAB with international criteria has following advantages:

- Increased confidence in Testing/ Calibration/Medical/Inspection/RMP/PTP/Biobanking Reports issued by the CAB.
- Better control of CAB operations and feedback to CABs 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 CABs are publicised by the Accreditation Body by putting their name on its website.
- Users of accredited CABs 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 Standards.
- 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, Biobanks, Proficiency Testing Providers, Inspection Bodies and Reference Material Producers 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 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

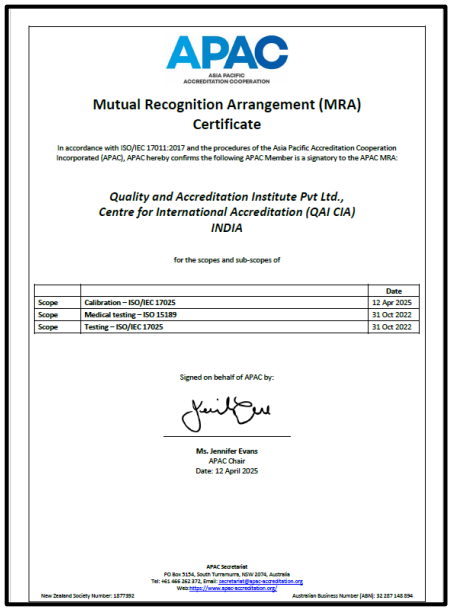
We offer accreditation services in a non-discriminatory manner. QAI-CIA has established its accreditation system in accordance with the international standard ISO/ IEC 17011 'Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies'. QAI CIA has achieved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

APAC
ASIA PACIFIC
ACCREDITATION COOPERATION



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

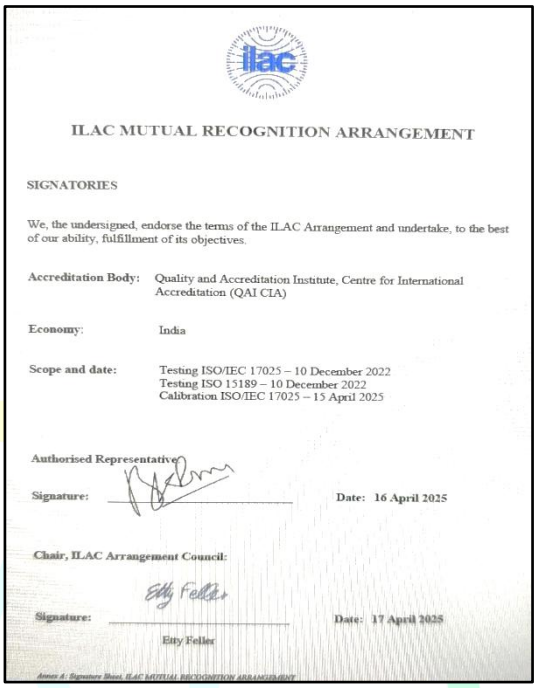
		Date
Scope	Calibration – ISO/IEC 17025	12 Apr 2025
Scope	Medical testing – ISO 15189	31 Oct 2022
Scope	Testing – ISO/IEC 17025	31 Oct 2022

Signed on behalf of APAC by:

Ms. Jennifer Evans
APAC Chair
Date: 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



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
Calibration ISO/IEC 17025 – 15 April 2025

Authorised Representative

Signature: Date: 16 April 2025

Chair, ILAC Arrangement Council:

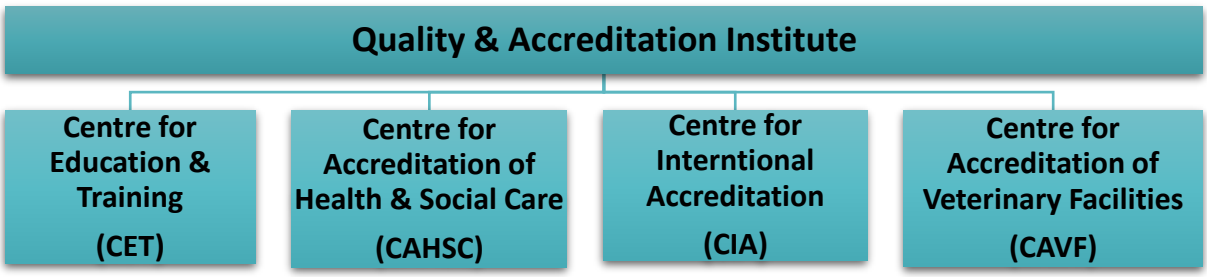
Signature: Date: 17 April 2025

Etty Feller

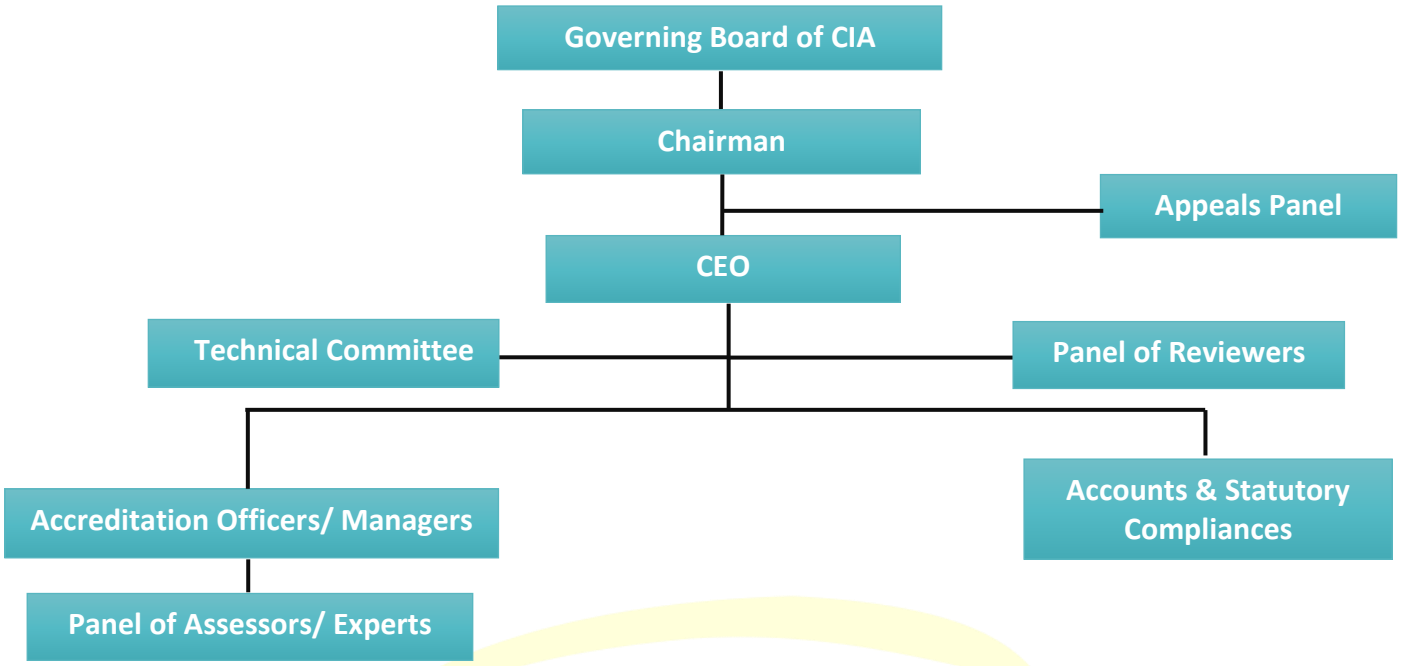
5. Organisation Structure

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 International 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
- Optional pre-assessment to reduce turnaround time.
- Introducing a new concept of self-assessment and document review replacing pre - assessment, and providing opportunity to CABs for a thorough review of their documentation and implementation of requirements of ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034.
- Our process ensures continuous support to our clients in handling their queries as each CAB 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:

7.1 Medical Laboratory

Clinical Biochemistry	Point-of-Care Testing (POCT) (ISO 22870)
Clinical Pathology	Cytopathology
Haematology & Immunohematology	Genetics including Molecular Diagnostics
Histopathology	Nuclear Medicine (*in-vitro* tests only)
Microbiology and Serology	

7.2 QAI-CIA Recognition for Basic Composite Medical Laboratory

Biochemistry	Haematology
Medical Microbiology and Immunology	

7.3 Testing Laboratory

Biological		
Food and Agricultural Products	Resistance to Microbial Attack	Antimicrobial Activity Products
Drugs and Pharmaceuticals	Biological Tests on Other Miscellaneous Test Items	Wild Life Forensic
Water	Biopesticides and Biofertilisers	AYUSH Products
Environment and Pollution	Toxicology	Biological Monitoring
Biocides	Identification/Enumeration of Microbial Pathogens	Biologicals Derived Pharmaceuticals
Cosmetics and Essential Oils	Residue Analysis	Cosmetics & Essential Oil
Industrial Cultures	Veterinary Testing	GM Products
Seed Testing	Nutraceuticals & Functional Foods	Marine /Aqua Culture Food Products
Plants and Plant Materials	Nutritional Supplements	Medical Accessories & Surgical Products
Cell Culture	Animal Food & Feed	Molecular Analysis

Chemical		
Adhesives	Hazardous & Restricted Chemicals	Petroleum and Products
Animal Food & Feeds	Industrial & Fine Chemicals	Plastic & Resins
AYUSH Products	Inks, dyes & pigments	Pollution & Environment
Atmospheric Pollution	Lac & lac products	Residues and Contaminants in Food and Agriculture Products

Chemical		
Building Material	Leather	Residues and Contaminants in Water
Cosmetics & Essential Oils	Lubricants	Rubber & Rubber Products
Corrosion Tests	Marine / Aqua culture Food Products	Soap Detergent & Toiletries
Drugs & Pharmaceuticals	Metallic coatings & treatment solutions	Soil and Rock
Explosives & Pyrotechnics	Metals & Alloys	Solid Fuels
Fertilisers	Nutraceuticals & Functional Foods	Textile (Woven & Non-woven)
Fire Fighting Equipment & Accessories	Ores & Minerals	Warfare Chemicals
Food & Agricultural products (Except Human Milk)	Paints & Surface Coating	Water
Gases	Paper and Pulp	Wood and Wood Products
Glass	Pesticide Formulations	Plants
Nutritional Supplements	Bio-stimulants	Packaging Material
Medical Devices	Miscellaneous	

Electrical	
Switchgear and Protective Equipment	Cells and Batteries
Rotating Electrical Machines	Power System Protection Relays
Inductors and Transformers	Measuring Instruments
Transmission Line Equipment and Accessories	Electrical Materials
Cables and Wires	High Voltage Test Facility
Capacitors	Short Circuit Test Facility
Lamps, Luminaries and Accessories	Electromagnetic Interference (EMI) / Electromagnetic Compatibility (EMC) Test Facility
Wiring Accessories	Environmental Test Facility
Domestic Electrical Appliances	Energy Efficiency of Domestic Electrical Appliances
Power Stabilisers and UPS	Safety Test Facility
Bridges and Potentiometers	Conductors and Conducting Materials
Electrical Indicating and Recording Instruments	Frequency and Time Measuring Instruments
Insulating Materials and Insulators	Magnetic Materials
Miscellaneous	Resistors, resistance boxes and Potential dividers
Energy Efficiency of Commercial/Industrial Appliances	

Electronics	
Audio Equipment	Equipment Used in Clinical Laboratory
Domestic Electronic Appliances & Accessories	Medical Electrical Equipment
Electronic Components & Equipment Sub-Assemblies	Power Supplies & Stabilisers
EMC Test Facility	Safety Testing Facility
Environmental Test Facility	Miscellaneous Products
IT Equipment	Telecommunication equipment (For TEC CAB Designation)
Energy Efficiency of Domestic Electronic Appliances	

Mechanical	
Automotive Components	Properties of Powder Metallurgical Products
Building, Infrastructure and Construction Materials	Rubber and Rubber Products
Heating, Ventilating, and Air Conditioning (HVAC)	Soil and Rock
Leather and Leather Products	Sub Assembly/Ancillaries/Accessories
Mechanical Properties of Metals	Textile Materials
Metallography Test	Toys and Similar Products
Noise & Vibration	Wood and Wood Products
Paper & Paper Products	Thermal Testing
Performance/Durability/ Safety Test	Solar Panel
Plastics and Plastic Products	Precious Stones
Soil-Basic	Soil- Advanced
Soil-Field	Rock-Basic
Rock-Advanced	Packaging Material
Medical Devices	Miscellaneous

Software & IT System	
Software Testing	

Radiological	
Radiation Monitors	Food and Agriculture Products
Radiation Sources	Water

Radiological/ Nucleonic Equipment	Soil
Environment (Radioactive contaminants)	Miscellaneous

Non-destructive Testing
Metals and Alloys
Building Materials
Reinforced Concrete Structures

Fluid- Flow
Air & Gases
Liquids
Miscellaneous

Photometry
Light Sources (Electric Lamp)
Luminaires
Glasses/Mirror
Miscellaneous

Veterinary Testing Laboratories

Clinical Biochemistry	Point-of-Care Testing (POCT) (ISO 22870)
Clinical Pathology	Cytopathology
Haematology & Immunohematology	Genetics including Molecular Diagnostics
Histopathology	Nuclear Medicine *including (in vitro tests only)*
Microbiology and Serology	Identification of micro-organisms
Miscellaneous	

Forensic Laboratories

Biological Science	Physical Science
Chemical Science	Crime Scene Management
Forensic Electronics and Computer Forensics	Forensic Psychology
Miscellaneous	

Diagnostic Radiology QA Testing

Radiography (X-ray -Fixed Portable, Mobile)	Computed Tomography (CT)
Mammography	Interventional Radiology & Fluoroscopy

7.4 Biobanking

Source of Biological Material	Type of Biological Material	Activities	Internal/ External Methods	Storage Conditions
Human	e.g. blood, tissues, body fluids, cell lines, gametes, genetic material, waste products	Collection, Acquisition, Preparation, Processing, Examination/ Testing/ Analysis, Preservation, Storage, Distribution, Disposal (of material beyond a defined storage period, if any)	e.g. reference to ISO standards, National standards, Industrial standards, Association standards, Biobank SOPs, etc.	e.g. -80 Freezer, Cryofreezer, Slides, etc.
Animal	e.g. blood, tissues, body fluids, gametes, cell lines, genetic materials			
Plant	e.g. whole plant, tissue, extracts, genetic materials			
Microorganism	e.g. culture, genetic materials			
Multicellular organism neither animal nor plant e.g., Fungi, Brown Seaweed	e.g. whole material, mycelium, spores, culture, genetic materials			

7.5 Calibration Laboratory

Chemical	
Equipment/Devices	

Electro-Technical	
Alternating Current (<1 GHz)	Direct Current
RF/ Microwave (1 GHz and Above)	Time & Frequency
EMI/EMC	Electrical equipment
Temperature Simulation	Oscilloscope
Miscellaneous	

Mechanical	
Acceleration & Speed	Acoustics
Density and Viscosity	Force
Dimension	Hardness and Impact
Mass	Measuring instruments

Mechanical	
Precision instruments	Pressure & Vacuum
Surface topography	Torque
Volume	Viscosity
Miscellaneous	

Fluid-Flow
Flow by Mass
Flow by Volume
Others

Thermal
Temperature
Specific heat & Humidity
Miscellaneous

Medical Devices
Discharge Equipment/ Devices
Patient Conditioning/ Maintenance
Monitoring Unit
Imaging/ Plotters
Medical Device Analyzer/ Simulator Equipment
Miscellaneous

Radiological
Radiological measurements
Radio Isotope/Source Calibration
Miscellaneous

Optical
Optical
Equipment

7.6 Proficiency testing Providers

- Testing
- Calibration
- Medical
- Inspection

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

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

Molecular testing	

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

Sub-discipline of Inspection	
NDT	Agriculture and agricultural products
Manufactured goods	Industrial equipment and machinery
Forensic inspection	Natural resources and refined products
IT products and services	Environment & Environmental protection products
Transport	Industrial and commercial construction & maintenance
Tourism accommodation	Technical regulation inspection
Health inspection	Building construction and maintenance
Factory inspection	Others

7.7 Inspection Body

The scope of accreditation may fall into any of the following fields (but not limited to). However, the final scope of accreditation would be defined based on the type of activity(ies) as described under item 15 of QAI CIA 601 document.

Sl. No.	Fields
1.	Agriculture & Fishing
2.	Forestry
3.	Mining and Quarrying
4.	Food products, beverages and tobacco
5.	Textiles and textile products
6.	Leather & Leather products
7.	Tanning & Dressing of Leather

Sl. No.	Fields
8.	Wood and wood products
9.	Pulp, paper
10.	Paper products
11.	Publishing Companies
12.	Printing companies
13.	Manufacture of coke and refined petroleum
14.	Nuclear fuel
15.	Chemicals, chemical products and fibres
16.	Pharmaceuticals
17.	Rubber products
18.	Plastic products
19.	Non-metallic mineral products
20.	Concrete, cement, lime, plaster etc.
21.	Basic Metal
22.	Fabricated metal products
23.	Machinery and equipment
24.	Electrical equipment
25.	Optical and precision equipment
26.	Medical and surgical equipment
27.	Shipbuilding
28.	Aerospace
29.	Other transport equipment
30.	Manufacturing not elsewhere classified
31.	Recycling
32.	Electricity supply
33.	Gas and Petroleum supply
34.	Water supply
35.	Construction
36.	Wholesale & retail trade;

Sl. No.	Fields
37.	Repair of motor vehicles, motorcycles and personal and household goods
38.	Hotels and Restaurant
39.	Transport, storage and communication
40.	Tele Communication
41.	Financial intermediation
42.	Real estate; renting
43.	Information technology
44.	Engineering services (like ERDMP)
45.	Other services
46.	Public Administration
47.	Education
48.	Health and social work
49.	Other social services

8. Eligibility and Preparation for Accreditation

8.1 Preparing for Accreditation

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

CAB must procure a copy of the relevant standard (ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034). The CAB looking for accreditation shall understand the QAI assessment process. The CAB shall ensure that all the requirements of the standard are implemented. For preparing the quality manual or verifying its contents, the CAB 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.

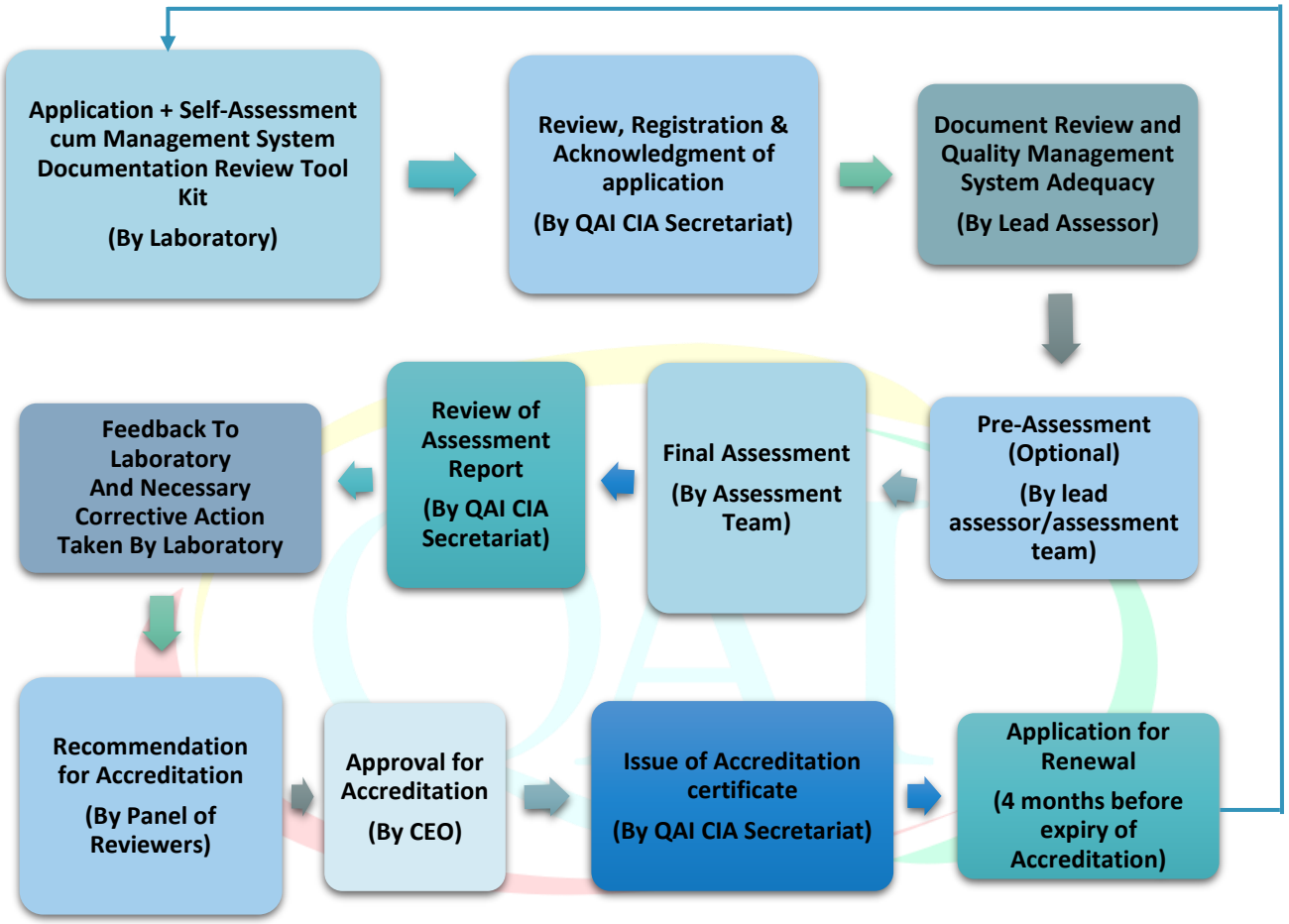
8.2 Eligibility for Accreditation

The applicant CAB must comply with all clauses of ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034. The applicant CAB must have participated satisfactorily in the 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 CAB can initiate an inter-laboratory comparison with adequate number of accredited CAB or engage into other types of internal quality control checks. The minimum

stipulated participation for CAB 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.

9. Accreditation Process

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



9.1 Application for Accreditation

Applicant CAB is requested to submit the following:

- Soft copy of completed application form (available on website)
- Soft copy of Self-assessment tool kit along with referenced documents
- 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'

Self-assessment cum management system documentation review tool kit is based on the requirements of the accreditation standard ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034. 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 CAB. 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 CABs shall inform QAI while applying in case they wish to undergo pre-assessment. All CABs 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 CAB shall take corrective actions on the non-conformities raised by the lead assessor/ assessment team. The CAB shall be required to pay the pre-assessment fee as defined in the fee structure (programme wise).

9.5 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 CAB's acceptance for the proposed assessment team and dates for assessment. The CAB 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 CAB. During on-site/ remote/ hybrid visit, the assessment team reviews the documented management system and verifies its compliance with the requirements of ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034 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 CAB. 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 CAB at the end of the assessment visit.

9.6 Review of Assessment Report

The assessment report is examined by the secretariat and follow up action as required is initiated. CAB 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.

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 CAB is authorised to use following accreditation mark subject to requirements specified in 'QAI CIA-Policy for use of QAI Accreditation mark'

MEDICAL LABORATORY

ISO 15189:2022
Certificate No.
Example: QAI/CIA/ML/2020/0000

TESTING LABORATORY

ISO/IEC 17025:2017
Certificate No.
Example: QAI/CIA/TL/2020/0000

BIOBANKING

ISO 20387:2018
Certificate No.
Example: QAI/CIA/BB/2021/0000

CALIBRATION LABORATORY

ISO/IEC 17025:2017
Certificate No.
Example: QAI/CIA/CL/2021/0000

PROFICIENCY TESTING

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

INSPECTION BODY

ISO/IEC 17020:2012
Certificate No.
Example: QAI/CIA/IB/2023/0000

REFERENCE MATERIAL PRODUCER

ISO/IEC 17034:2016
Certificate No
Example: QAI/CIA/RMP/2023/0000

9.9 Maintaining Accreditation

Conformance to applicable standards and other requirements

The accredited CAB at all times shall conform to the requirements of ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034 as well as any other laid down requirements.

Terms and Conditions

The accredited CAB is required to comply at all times with the terms and conditions given in CIA 002 ‘Terms & Conditions for Obtaining and Maintaining Accreditation’. The CAB 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 CAB

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

9.10 Ongoing Monitoring

Accredited CAB is required to submit following information/documents/ records every year in the middle of the accreditation cycle. This is to ensure that the accredited CAB is continuously complying with the requirements of the applicable standard (ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034) 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 two years
C.2 Details of participation in last one year
C.3 Details of action taken for any unsatisfactory results

D. Test Reports

D.1 One test/calibration report or certificate released in each 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 that the CAB has been complying to the requirements of ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034 and any other requirements prescribed by the QAI CIA since last on-site/hybrid/remote assessment"

9.11 Reassessment

In general, QAI CIA accreditation cycle will be of two years. However, in exceptional cases, accreditation may be granted up to 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. 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.

For the details of accreditation process of Inspection Bodies (IB), please refer to the CIA 601_Information Brochure for Inspection Bodies.

10. QAI-CIA Recognition for Medical Laboratories (QRML)

Quality and Patient Safety are the words we keep hearing every now and then. However, as a healthcare system, have we reached out to healthcare facilities those are providing services to patients but may not have an opportunity to check on how they are doing in terms of quality and patient safety. Moreover, they may not have even exposed to the concept of quality and patient safety. Many such healthcare facilities are medical laboratories both based in a hospital and standalone. Several hundred medical laboratories operating in India for several years were never exposed to this concept of quality and patient safety. It is high time to reach out to these laboratories to support them through education and capacity building to make them competent to just ensure reliability of test results they are producing.

To steer this agenda forward, QAI-CIA has initiated a recognition programme- QAI-CIA Recognition for Medical Laboratories (QRML). This recognition programme is based on the (1) requirements prescribed in Gazette Notification G.S.R.468 (E) dated 18th May, 2018 by Ministry of Health and Family Welfare, Government of India related to Clinical Establishments (Central Government) Rules, 2012 and (2) certain quality improvement principles. This programme is likely to serve several important underline purposes including encouragement to labs to meet minimum regulatory requirements, adopt quality & patient safety as core element of the business.

Labs would be encouraged to adopt ISO 15189 as they move forward in their quality journey.

11. Eligibility Conditions for Recognition Medical Laboratories

A Laboratory performing the tests covered (given below) under QAI Recognition for Medical Laboratory (Basic, Medium and Advance) in Gazette notification G.S.R. 468 (E) dated 18th May 2018 by MOHFW regarding Clinical Establishments (Central Government) Rules, 2012 is eligible to apply under this programme of QRML. A laboratory performing tests outside Medical Laboratory (Basic, Medium and Advance) scope can also apply subject to availability of required authorised signatory as per applicable regulation. (**Refer document CIA- 113**).

12. Recognition Process

For Detailed Information Please Refer CIA_111 Information Brochure for QAI Recognition for Medical Laboratories (QRML)-Basic/ Medium/Advance

Recognition Mark

Recognised Laboratory is authorised to use following mark subject to requirements specified in 'QAI CIA-013 Policy for use of QAI-CIA Accreditation mark'.

BML
Certificate No.
Example: QAI/CIA/BML/2020/0000

13. Complaints and Appeals

Complaints

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

14. Rights and Obligations of CAB

Rights of CAB

CAB are entitled to receive information related to laboratory/biobank/IB/PTP/RMP 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 CAB. The CAB has the right to object to appointment of specific member(s) of assessment team by giving valid reasons. QAI-CIA accredited CAB 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 CAB

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

15. Rights and Responsibilities of QAI-CIA

Rights

- QAI-CIA requires that all CAB will conform to ISO 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034 and any other requirement specified by QAI-CIA from time to time to maintain accreditation.
- QAI-CIA requires that all accredited CAB abide by 'Terms and conditions for obtaining and maintaining accreditation'.
- QAI-CIA has the right to:
  - ❖ effect changes in standards on which CAB accreditation is based in accordance with international norms
  - ❖ decide on policies related to accreditation in consultation with stakeholders
  - ❖ appoint assessment teams in consultation with CAB and the assessors
  - ❖ take appropriate action including adverse decisions against a CAB giving valid reasons for the same

Duties

- QAI-CIA is obliged to make available relevant information to its applicant and accredited CABs. 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 15189 or ISO/IEC 17025 or ISO 20387 or ISO/IEC 17043 or ISO/IEC 17020 or ISO 17034 through website.

16. 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 CAB and the charges are maintained at a reasonable level so that CAB 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.

17. QAI-CIA Publications

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

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