Quality and Accreditation Institute

Centre for International Accreditation

Change Adapt Improve

INFORMATION BROCHURE
FOR
BIOBANKING ACCREDITATION PROGRAMME

QAI CIA 301

Issue No. 05 | Issue Date: November 2023

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1. Introduction

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

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

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

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

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

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

2. Benefits of Accreditation

Accredited laboratories with international criteria have following advantages:

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

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:

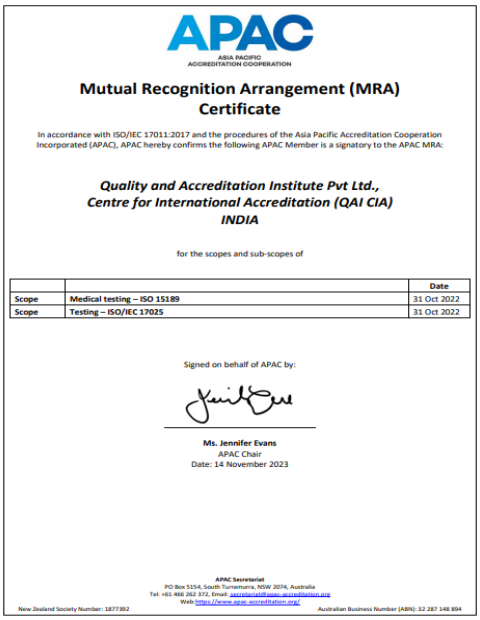
- Accreditation of **Testing laboratories** as per ISO/ IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories
- Accreditation of **Calibration laboratories** as per ISO/ IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories
- Accreditation of **Medical Laboratories** as per ISO 15189: Medical laboratories - Requirements for Quality and Competence, 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 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

		Date
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: 14 November 2023

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

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**
Etty Feller

Annex A: Signature Sheet, ILAC MUTUAL RECOGNITION ARRANGEMENT

5. Organisation Structure

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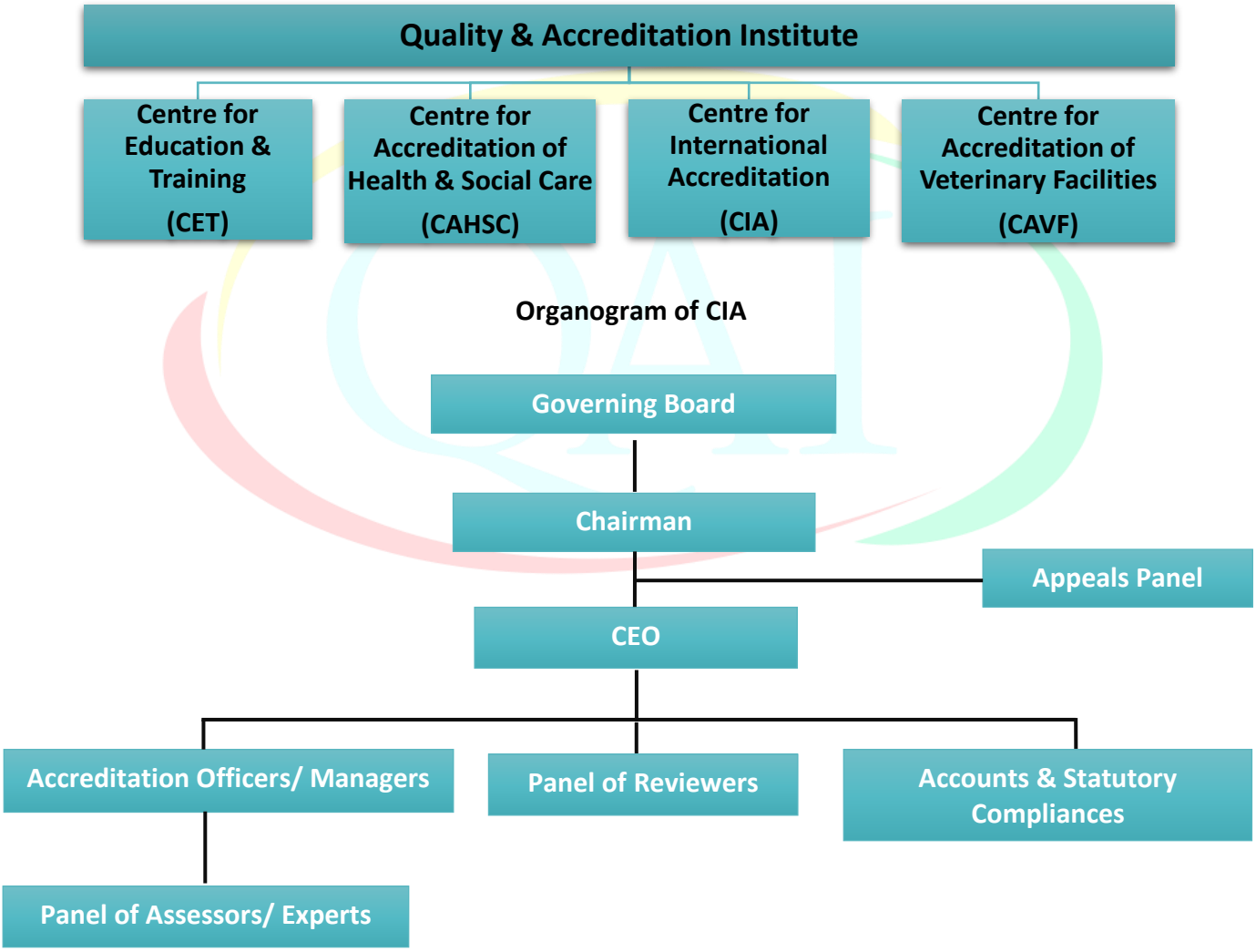


6. Special Features of Laboratory Accreditation Programme:

- 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
- No 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 20387.
- 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.
- CABs in SAARC nations to enjoy same fee structure as for labs 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:

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	Acquisition (required) Storage (required) Any one or more from the following: Collection, Preparation, Processing, Examination/ Testing/ Analysis, Preservation, 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. whole material, mycelium, spores,			

e.g., Fungi, Brown Seaweed	culture, genetic materials			

8. Biobanking Laboratory Accreditation Programme

8.1 Preparing for Accreditation

Management of the laboratory shall first decide about getting accreditation from QAI. 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 20387. The laboratory looking for accreditation shall understand the QAI 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.

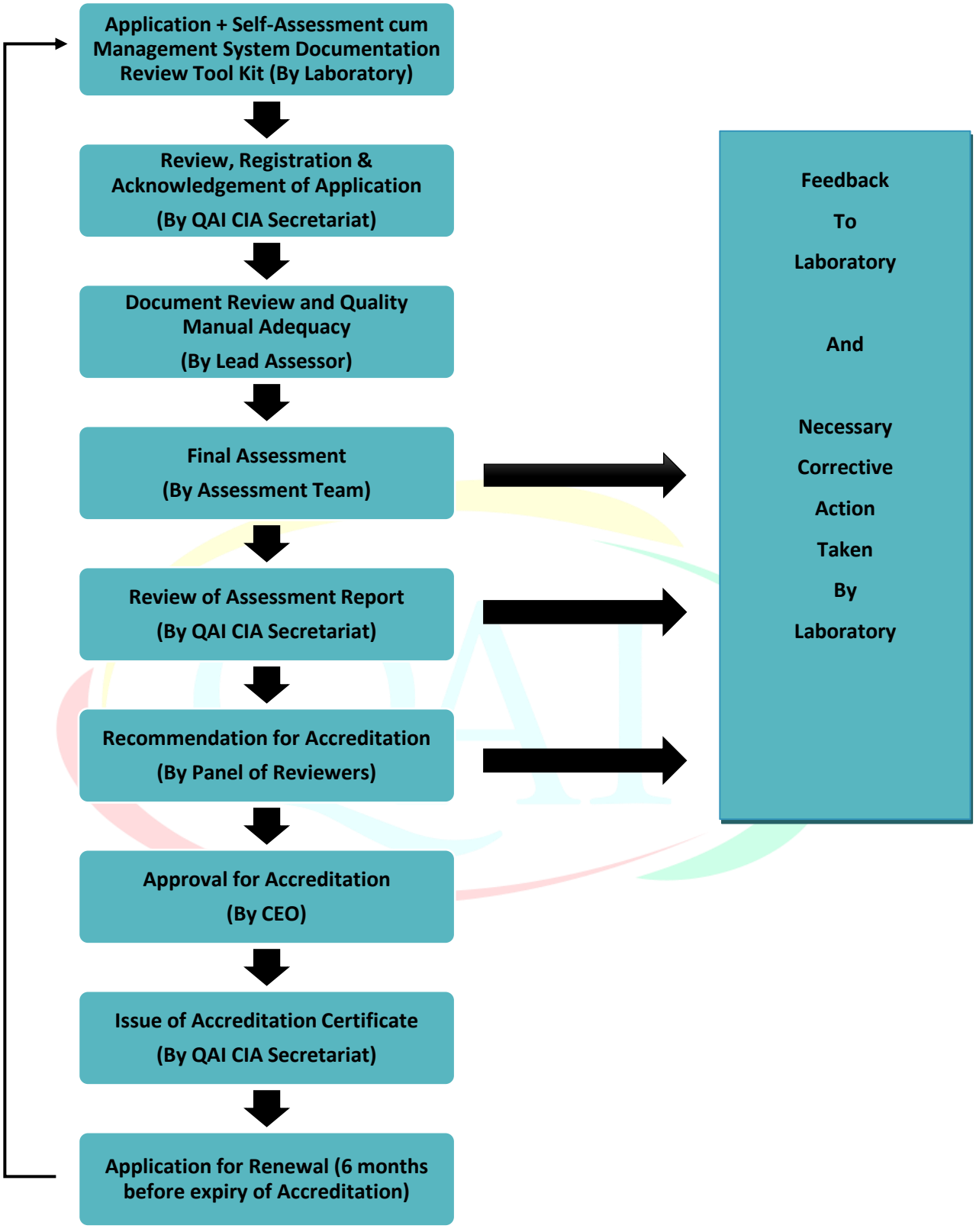
8.2 Eligibility for Accreditation

The applicant laboratory must comply with all clauses of ISO 20387 whichever is applicable. 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 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/ Certification'

Self-assessment cum management system documentation review tool kit is based on the requirements of the accreditation standard ISO 20387. It gives an opportunity to the laboratory 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 ID 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 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 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 20387 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 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.

9.4 Review of Assessment Report

The assessment report is examined by the 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 acceptance by the assessment team should be completed within 30 days.

9.5 Decision Making

After satisfactory corrective action submitted by the laboratory 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/ Laboratory 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 laboratory 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 Laboratory is authorised to use following accreditation mark subject to requirements specified in QAI CIA-Policy for use of QAI Accreditation/ Certification mark.

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

9.7 Maintaining Accreditation

Conformance to applicable standards and other requirements

The accredited laboratory at all times shall conform to the requirements of ISO 20387 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 Obtaining and Maintaining Accreditation/ Certification'. 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 20387) and any other requirements stipulated from time to time.

A. Internal Audit

A.1 Internal audit plan
A.2 Date of last internal audit
A.3 Summary of findings of last internal audit

B. Management Review

B.1 Management review plan
B.2 Date of last management review
B.3 Minutes of the last review

C. Proficiency Testing/ External Quality Assessment Schemes/ Inter-laboratory comparisons (ILC)/ Any other method (e.g., use of CRMs)

C.1 Proficiency testing plan to cover the accredited scope in a period of four years
C.2 Details of participation in last one year
C.3 Details of action taken for any unsatisfactory results

D. Major Changes, if any

Any major changes in last one year (e.g., change in legal status, change in management and senior staff, change in testing scope etc.)

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

A statement "This is to declare that that the laboratory has been complying to the requirements of ISO 20387 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 laboratory 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 102). 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. However, there will be adequacy check if there is a change in accreditation standard.

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 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'.

11. 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.

12. Rights and Responsibilities of QAI-CIA

Rights

- QAI-CIA requires that all laboratories will conform to ISO 20387:2018 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/certification'.
- 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 20387

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 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. 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

Quality and Accreditation Institute

Centre for International Accreditation

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