Quality and Accreditation Institute

Centre for International Accreditation

Change Adapt Improve

QAI RECOGNITION FOR MEDICAL LABORATORIES (QRML)- BASIC/ MEDIUM/ADVANCE

QAI CIA 111

Issue No. 08 | Issue Date: September 2024

CONTENTS

1. Laboratory Recognition

This recognition programme has been developed to promote medical laboratories to adopt quality and safety practices, and also to comply with minimum standards for medical laboratories as prescribed in Clinical Establishment Act in Gazette notification G.S.R. 468 (E) dated 18th May, 2018 and related amendment dated 14 February 2020 by Ministry of Health & Family Welfare (MOHFW), Government of India.

This recognition programme is not covered under APAC/ILAC MRA.

2. Benefits of Recognition

Recognised laboratories with international criteria have following advantages:

Benefits for Users/ Patients

Users/ patients are the biggest beneficiary among all the stakeholders. Test results are crucial for the management of a patient. Any error in the test results may lead to wrong diagnosis and thus wrong treatment. Recognition results in improving the quality of test results and patient safety.

Benefits for Laboratories

Recognition to a medical laboratory stimulates continuous improvement. It enables laboratories in demonstrating commitment to quality. It raises community confidence in the services provided by them.

Benefits for Staff

The staff in a recognised laboratory is satisfied as it provides for continuous learning, good working environment and leadership. It improves overall professional development of all the staff including medical and para medical staff.

Benefits for Regulators/ Payers/ Insurance Agencies

Regulators can rely on QAI recognition as Deemed Compliance to minimum standards prescribed in Clinical Establishment Act. In other words, regulators may not require additional inspection.

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
- **Recognition of Medical Laboratories** as per the requirements of the Central Clinical Establishments Act
- **Biobanking** Accreditation as per ISO 20387: General requirements for Biobanking. **(For the First time in India)**
- Accreditation of **Proficiency Testing Providers** as per ISO 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

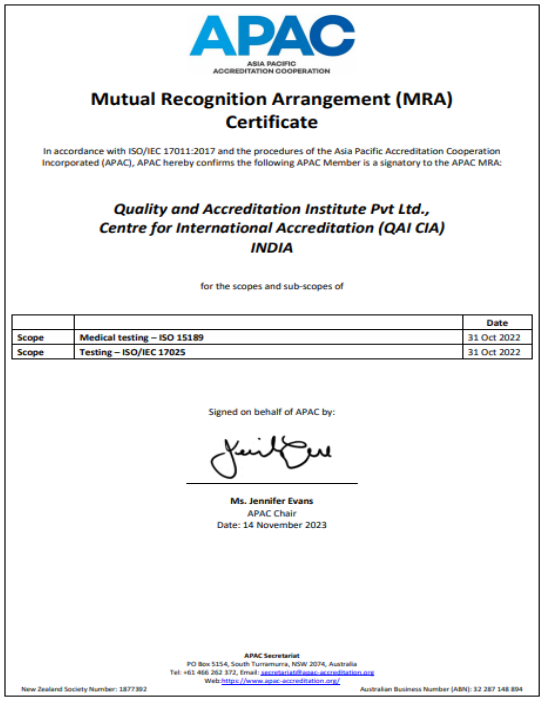
We offer accreditation/ recognition services in a non-discriminatory manner. QAI-CIA has established its accreditation system in accordance with the international standard ISO/ IEC 17011 'Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies'. QAI CIA has achieved global recognition through APAC and ILAC MRA. This recognition programme is not covered under APAC/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



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

APAC Secretariat
PO Box 5154, South Turramurra, NSW 2074, Australia
Tel: +61 466 262 372, Email: secretariat@apac-accreditation.org
Web:https://www.apac-accreditation.org/
New Zealand Society Number: 1877392 Australian Business Number (ABN): 32 287 148 894

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: Etty Feller **Date: 23 November 2023**

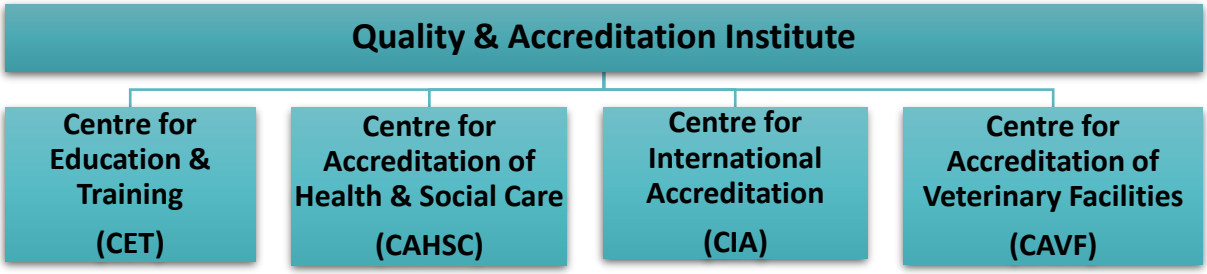
Etty Feller

Annex A: Signature Sheet, ILAC MUTUAL RECOGNITION ARRANGEMENT

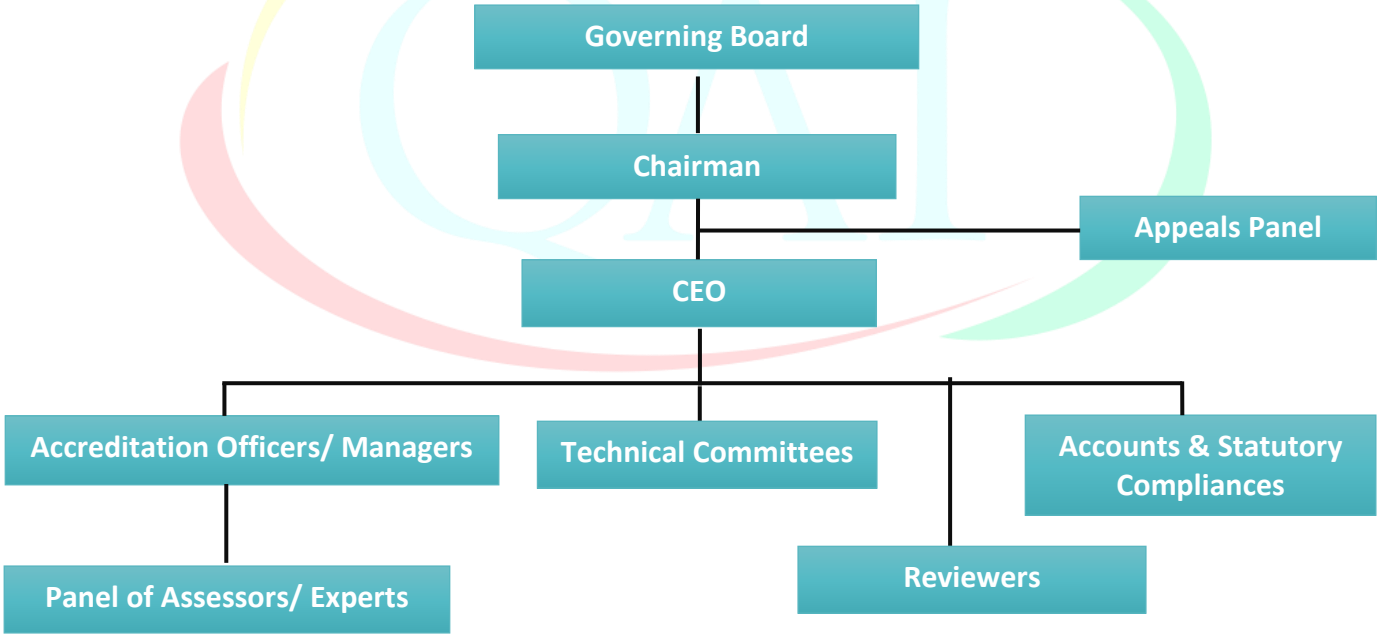
5. Organisation Structure

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.



Organogram of CIA

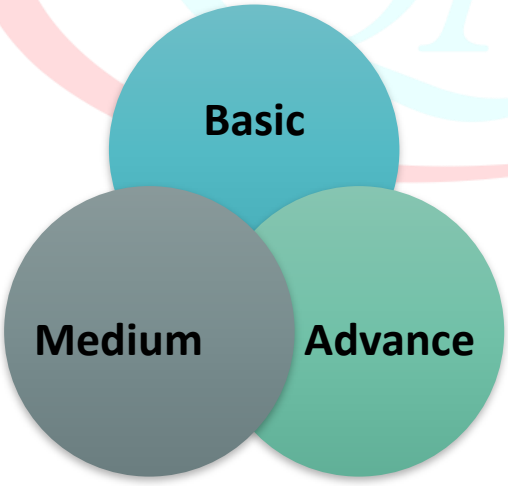


6. Special Features of Laboratory Recognition Programme:

- Quick turnaround time
- Comprehensive standard tool and document review process
- Rigorous Assessor Management System
- Blend of clear strategy, experience and leadership
- Increased reliability of laboratory results
- Earn a Recognition Mark
- Competitive advantage and public recognition
- Government / Regulator and insurance companies can rely on Recognition
- Recognition is based on minimum requirements stipulated in Central Clinical Establishment Act
- Follow the principle of All or None. Which means laboratory has to apply for all the scope of services available and cannot choose specific test(s) for recognition.

7. QAI Recognition for Medical Laboratories Framework

- Scope of Services
- Infrastructure
- Human Resource
- Instruments or Equipment or Drugs
- Legal or Statutory Requirements
- Record Maintenance and Reporting
- Standards on Basic Processes
- Continual Quality Improvement Practices (Internal audit and management review processes)



8. Scope of Services

Scope of Services for QAI Recognition for Medical Laboratories- Basic

a. **Biochemistry:** Routine Biochemistry tests like Blood Sugar, Renal Function Tests, Liver Function Tests, Amylase, Lipase, Lipid profile, Cerebro -Spinal Fluid (CSF) and other biological fluids (glucose and protein), Oral Glucose Tolerance Test, Electrolytes, Calcium or Phosphate, HbA1c, any bio chemistry based rapid test.
b. **Haematology:** Haemogram (CBC, Hb, TLC, DLC, Platelet Count, RBC Count, HCT, MCV, MCH, MCHC, ESR), Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching.
c. **Medical Microbiology & Immunology:** Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio cholerae, Stool for ova, cyst. All HIV positive rapid assays need to be confirmed from the next level diagnostic laboratory using confirmatory tests.

Scope of Services for QAI Recognition for Medical Laboratories- Medium

a. **Biochemistry:** Routine Biochemistry tests like Blood Sugar, Renal Function Tests, Liver Function Tests, Amylase, Lipase, Lipid profile, Cerebro-Spinal Fluid (CSF) and other biological fluids (glucose and protein), Oral Glucose Tolerance Test, Electrolytes, Calcium or Phosphate, HbA1c, any bio chemistry based rapid test, Hormone Bioassay, Tumor markers, plasma protein electrophoresis
b. **Haematology:** Haemogram (CBC, Hb, TLC, DLC, Platelet Count, RBC Count, HCT, MCV, MCH, MCHC, ESR), Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching, Coagulation Assay
c. **Histopathology:** May do, subject to availability of equipment and specialist
d. **Molecular Genetics:** May do, subject to availability of equipment and specialist
e. **Cytopathology:** PAP smear, Fine Needle Aspiration Cytology (FNAC), sputum and CSF cytology
f. **Medical Microbiology & Immunology:** Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio cholerae, Stool for ova, cyst. All HIV positive rapid assays need to be confirmed from the next level diagnostic laboratory using confirmatory tests. Serological tests for (viruses, bacteria, fungi, parasites), Cultural Sensitivity tests (Bacterial or fungal), Other special stains besides Gram's stain.

Scope of Services for QAI Recognition for Medical Laboratories- Advance

a. **Biochemistry:** Routine Biochemistry tests like Blood Sugar, Renal Function Tests, Liver Function Tests, Amylase, Lipase, Lipid profile, Cerebro -Spinal Fluid (CSF) and other biological fluids (glucose and protein), Oral Glucose Tolerance Test, Electrolytes, Calcium or Phosphate, HbA1c, any bio chemistry based rapid test, Hormone Bioassay, Tumor markers, plasma protein electrophoresis , coagulation profile, Drug monitoring and toxicology assay, Molecular genetics, tests for detection of inborn errors of metabolism.
b. **Haematology:** Haemogram (CBC, Hb, TLC, DLC, Platelet Count, RBC Count, HCT, MCV, MCH, MCHC, ESR), Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, blood grouping and matching, Coagulation Assay, all other Haematology tests also.
c. **Histopathology:** Histopathology Examination
d. **Molecular Genetics:** Molecular genetics
e. **Cytopathology:** PAP smear, Fine Needle Aspiration Cytology (FNAC), sputum and CSF cytology, Immuno Cytochemistry, Other biological fluid cytology; Ultrasound or CT guided FNAC.
f. **Immunohistopathology:** Immunohisto-chemistry
g. **Medical Microbiology & Immunology:** Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio cholerae, Stool for ova , cyst. All HIV positive rapid assays need to be confirmed from the next level diagnostic laboratory using confirmatory tests. Serological tests for (viruses, bacteria, fungi, parasites), Cultural Sensitivity tests (Bacterial, fungal, viruses), Other special stains besides Gram's stain, Real Time Polymerase Chain Reaction (RTPCR) tests. Tissue diagnosis test for infectious diseases.

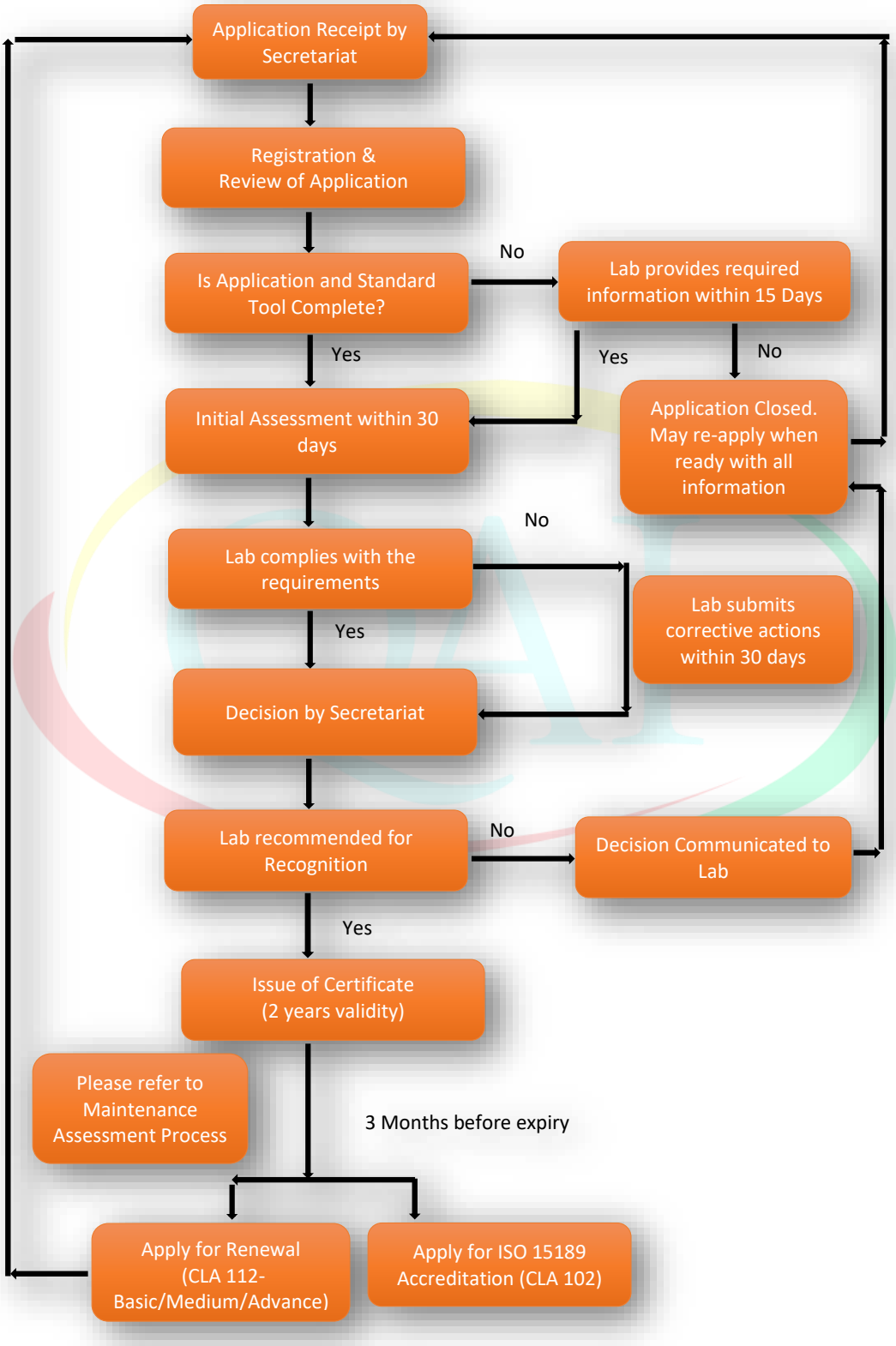
9. Eligibility and Preparation

A laboratory performing the tests covered (given in scope of services) under QAI Recognition for Medical Laboratory (Basic, Medium and Advance) in Gazette notification G.S.R. 468 (E) dated 18th May, 2018 and related amendment dated 14 February 2020 by MOHFW regarding Clinical Establishments (Central Government) Rules, 2012 is eligible to apply under this programme of QRML.

The laboratory seeking recognition shall understand the QAI assessment process. The laboratory shall ensure that all the requirements are implemented. The laboratory may get its personnel oriented/ trained in understanding and implementation of requirements of various sections. Such training programmes may be conducted by QAI from time to time.

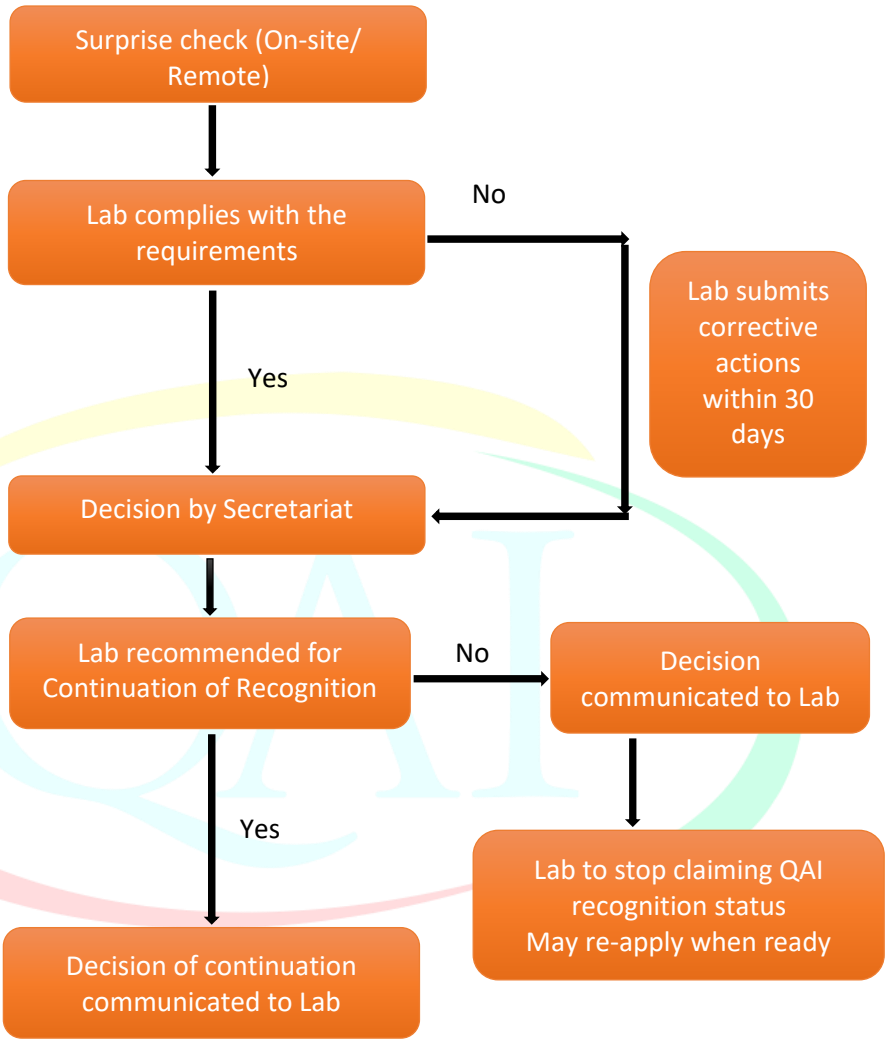
10. Recognition Process

Conceptualised a recognition process which is simple and efficient as shown below:



11. Surprise check (on-site/remote) process

QAI may conduct a surprise check (maintenance assessment) at any time during 2 years of the recognition cycle to ensure continued compliance of the standards.



12. Recognition Mark

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

Recognition Mark

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

Certificate No.
Example: QAI/CIA/RML/Year/0000

13. Reassessment

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

The renewal application is submitted in the prescribed form (QAI CIA 112). Rest of the process is same as for initial on-site/ remote/ hybrid assessment.

14. Complaints and Appeals

Complaints

QAI-CIA is open to receiving complaints for any of the activities performed by its officials, assessors and the accredited/recognised 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/recognition, reduction of scope of accreditation/recognition or abeyance/ suspension/ forced withdrawal of accreditation/recognition. The details are provided in a separate document 'Policy and Procedure for Dealing with Complaints and Appeals'.

15. Rights and Obligations of Laboratories

Rights of Laboratories

Laboratories are entitled to receive information related to laboratory recognition. They can access our website www.qai.org.in which gives information necessary. QAI-CIA is obliged to make available information on scope of accreditation/ recognition, validity dates for its accreditation/ recognition 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 recognised laboratory has the right to use 'QAI Recognition Mark' on the test reports issued by it as long as the test is included in its scope of recognition as per laid down policy. Detailed requirements governing use of 'QAI Recognition Mark' have been stated in a separate document.

Obligations of the Laboratories

A recognised 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. A recognised laboratory can claim recognition only for the scope for which it has been granted recognition and shall not claim recognition 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 recognition status, within 15 days. The laboratory is required to pay necessary fees as determined by QAI from time to time.

16. Rights and Responsibilities of QAI-CIA

Rights

- QAI-CIA requires that all laboratories will conform to requirements and any other requirement specified by QAI-CIA from time to time to maintain recognition.
- QAI-CIA requires that all recognised labs abide by 'Terms and conditions for obtaining and maintaining accreditation/recognition'.
- QAI-CIA has the right to:
    - ❖ effect changes in standards on which laboratory recognition is based
    - ❖ decide on policies related to recognition 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 recognised labs. This information is provided on our web site www.qai.org.in.
- QAI-CIA will communicate changes to the requirements of recognition

17. Finance and Fee Structure

Type of Laboratory	Application fee and assessment charges (non-refundable, to be paid along with the application) (Rs. 12000)		Recognition Fee for two years
	Application Fee	Assessment Charges	Rs. 10000
Basic Medical Laboratory	Rs. 2000	Rs. 10000	

Type of Laboratory	Application fee and assessment charges (non-refundable, to be paid along with the application) (Rs. 18000)		Recognition Fee for two years
	Application Fee	Assessment Charges	Rs. 16000
Medium Medical Laboratory	Rs. 2000	Rs. 16000	

Type of Laboratory	Application fee and assessment charges (non-refundable, to be paid along with the application) (Rs. 20000)		Recognition Fee for two years
	Application Fee	Assessment Charges	Rs. 18000
Advance Medical Laboratory	Rs. 2000	Rs. 18000	

In addition to the above-mentioned fee:

- **GST @18.0 % or as applicable from time to time**
- **Travel/ stay of the assessor/ expert**

18. QAI-CIA Publications

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

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