Quality and Accreditation Institute

Centre for International Accreditation

Change Adapt Improve

INFORMATION BROCHURE
FOR
REFERENCE MATERIAL PRODUCERS

QAI CIA 701

Issue No. 04 | Issue Date: February 2026

CONTENTS

1. Reference material producers (RMP) Accreditation

The Reference Material Producer (RMP) accreditation programme allows RMPs to demonstrate their competence in the production of certified reference materials and reference materials by complying with international criteria specified in ISO 17034:2016 'General Requirements for the competence of Reference Material Producer'. Reference Material Producer (RMP) accreditation activities are administered under the direction of the QAI, involving Assessment Team and Reviewers as recommending bodies.

Reference Material (RM): A Reference Material is a material sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Certified Reference Material (CRM): A certified reference material is a reference material characterized by a metrological valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

2. Benefits of RMP Accreditation

Accredited RMPs with international criteria have following advantages:

- Facilitate easy & timely availability of less expensive reference material in country.
- RMs offer the highest level of Quality assurance, accuracy and traceability.
- It gives complete confidence that results are reliable and reproducible.
- Offer market differentiation and leadership.
- Cost & time saving, because the RMs help optimise operations and avoid multiple testing.

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

- Accreditation of **Proficiency Testing Providers** as per ISO/IEC 17043: General Requirements for the competence of Proficiency Testing Providers
- Accreditation of **Inspection Bodies** as per ISO/IEC 17020: Conformity Assessment- Requirements for the Operation of Various Types of Bodies Performing Inspection
- Accreditation of **Reference Material Producers** as per ISO 17034: General Requirements for the Competence of Reference Material Producers

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

International Affiliations

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

Medical testing- ISO 15189 effective from 31 October 2022
Testing- ISO/IEC 17025 effective from 31 October 2022
Calibration- ISO/IEC 17025 effective from 12 April 2025

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

APAC Secretariat
PO Box 3154, 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
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

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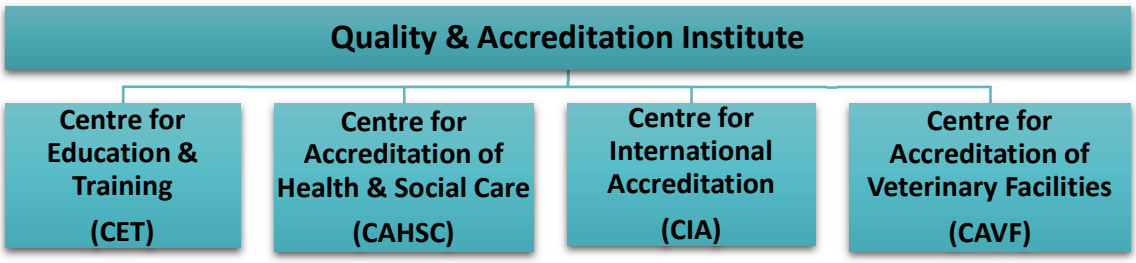
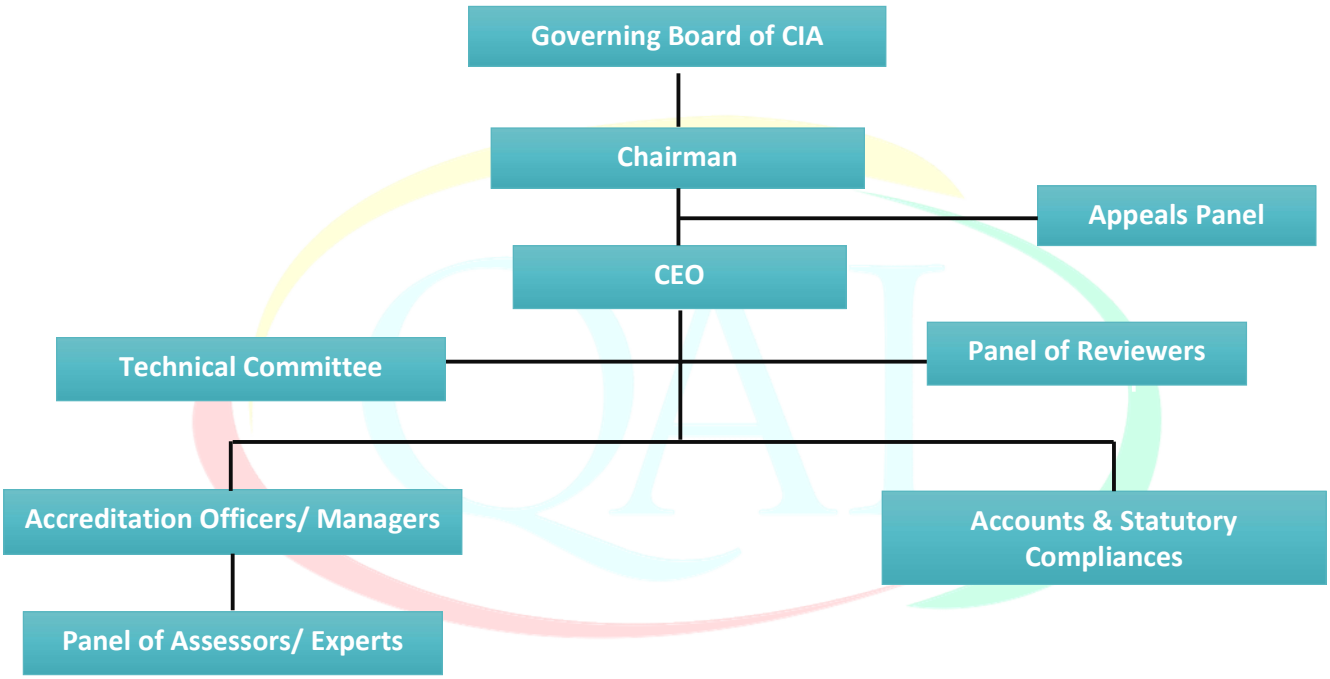


Organogram of CIA



6. Special Features of Reference material provider (RMP) 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 RMP 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 RMPs for a thorough review of their documentation and implementation of requirements of ISO 17034.
- Our process ensures continuous support to our clients in handling their queries as each RMP 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.
- RMPs in Low and Lower Middle Economies as per World Bank Classification to enjoy same fee structure as for RMPs 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 categories:

- Chemical Composition
- Biological and Clinical Properties
- Physical Properties
- Engineering Properties
- Miscellaneous Properties

Sub-Categories of Chemical composition	
Metal	Engine wear materials
Inorganic reference materials	Analysed gases
Organic reference materials	Forensic reference materials
Environmental reference materials	Ion activity
Health and industrial hygiene	

Sub-categories of Biological and Clinical Properties	
General Medicine	Parasitology
Clinical Chemistry	Bacteriology and Mycology
Tissue Pathology and Cytology	Virology
Hematology	Other biological and clinical reference Materials
Immunohematology	Forensic Reference Materials
Immunology	

Sub-categories of Physical Properties	
Reference Materials with Optical Properties	Reference Materials with Electrical and Magnetic Properties
Reference Materials for Frequency Measurements	Reference Materials for Radioactivity
Reference Materials for Thermodynamic Properties	Reference Materials for Physicochemical Properties
Reference Materials for Fibre Identification	Reference Materials for other properties

Sub-categories of Engineering Properties	
Surface Finish	Tensile Strength
Sizing	Elasticity
Nondestructive Testing	Creep
Hardness	Fire Research
Impact Toughness	

Sub-categories of Miscellaneous Properties	
Other	

8. Reference material producer Accreditation Programme

8.1 Preparing for Accreditation

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

RMP must procure a copy of the relevant standard i.e., ISO 17034:2016. The Reference Material Producer looking for accreditation shall understand the QAI assessment process. The RMP shall ensure that all the requirements of the standard are implemented. For preparing the quality manual or verifying its contents, the RMP may get its personnel trained in a training programme on quality management system organised by various institutes including QAI's Centre for

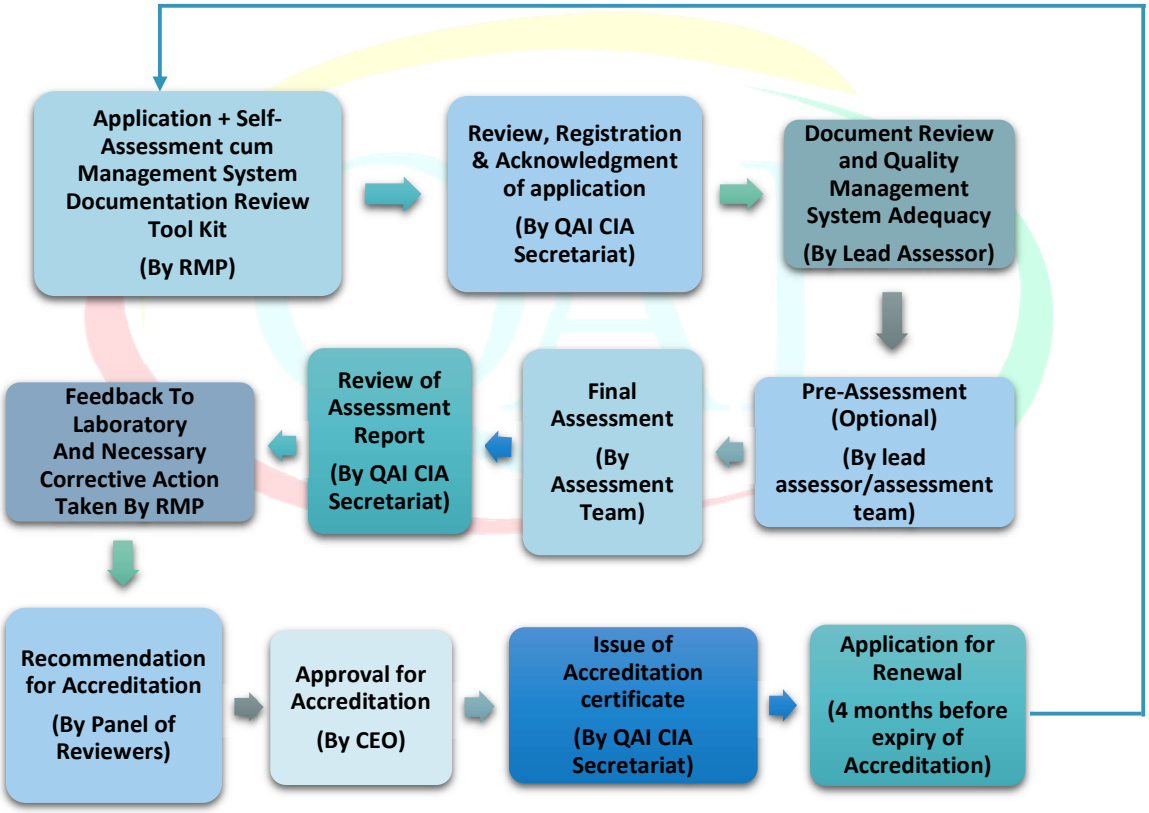
Education and Training. The proposed Quality manager shall have undergone a formal training on management system and internal audit based on relevant standard.

8.2 Eligibility for Accreditation

The applicant RMP must comply with all clauses of ISO 17034:2016. The applicant RMP 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 laboratories or engage into other types of internal quality control checks. The applicant RMP 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 RMP is requested to submit the following:

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

Self-assessment cum management system documentation review tool kit is based on the requirements of the accreditation standard ISO 17034:2016. It gives an opportunity to the RMP 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 RMP. 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 RMP submits the complete set of application documents, a lead assessor is appointed with the RMP'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 RMP, the pre-assessment or final assessment is scheduled accordingly.

9.4 Pre-Assessment (Optional):

QAI has introduced pre-assessment as optional. Those RMPs shall inform QAI while applying in case they wish to undergo pre-assessment. All RMPs 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 laboratory shall be required to pay the pre-assessment fee as defined in the fee structure (programme wise).

9.5 Final Assessment

QAI CIA constitutes an assessment team. The team includes the lead and technical assessor(s)/ expert(s) in order to cover various fields within the scope of accreditation sought. QAI CIA may also nominate an observer which is either an assessor-in-training or a Secretariat staff. QAI CIA seeks RMP's acceptance for the proposed assessment team and dates for assessment. The RMP 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 RMP. During on-site/ remote/ hybrid visit, the assessment team reviews the documented management system and verifies its compliance with the requirements of 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 RMP. 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 RMP 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. RMP 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 RMP 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 RMP as per laid down appeal process.

Note- The RMP 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

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

Accreditation Mark

Accredited Reference Material Producer is authorised to use following accreditation mark subject to requirements specified in QAI CIA-Policy for use of QAI Accreditation mark.

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

9.9 Maintaining Accreditation

Conformance to applicable standards and other requirements
The accredited RMP at all times shall conform to the requirements of ISO 17034 as well as any other laid down requirements.

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

Ongoing Monitoring
Accredited RMP is required to submit following information/documents/ records every year in the middle of the accreditation cycle. This is to ensure that the accredited RMP is continuously complying with the requirements of the applicable standard (ISO 17034:2016) 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 report of every month released since grant of accreditation

E. Major Changes, if any

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

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

A statement "This is to declare that the RMP has been complying to the requirements of ISO 17034:2016 and any other requirements prescribed by the QAI CIA since last on-site assessment"

9.10 Reassessment

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

For a two-year accreditation cycle, there will be an on-site/ remote/ hybrid reassessment conducted before the expiry of accreditation within 24 months from the date of accreditation. An accredited RMP has to apply four months before the expiry of accreditation in order to complete all formalities for renewal of accreditation before the expiry of the current accreditation cycle so that continuity of the accreditation is maintained. In case of an accreditation cycle of over two years, it will be ensured that the requirements of ISO/IEC 17011 are complied with.

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

The renewal application is submitted in the prescribed form (QAI CIA 702). The RMP will have an opportunity of requesting for an extension to the scope of accreditation, which should explicitly be mentioned in the application form. Rest of the process is same as for initial on-site/ remote/ hybrid assessment except there will be no adequacy of quality manual/quality management system. However, there will be adequacy check if there is a change in accreditation standard.

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

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 RMPs. 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 RMPs 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 RMPs

Rights of RMPs

RMPs are entitled to receive information related to Reference Material Producers 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 RMPs. The RMP has the right to object to appointment of specific member(s) of assessment team by giving valid reasons. QAI-CIA accredited RMP 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 Reference Material Producers

An accredited RMP is obliged to fulfil requirements of relevant standard and any other requirements set by QAI-CIA at all times. The RMP 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 RMP 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 RMP is required to notify QAI of any change that may affect accreditation status, within 15 days. The RMP 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 RMPs will conform to ISO 17034:2016 and any other requirement specified by QAI-CIA from time to time to maintain accreditation.
- QAI-CIA requires that all accredited RMPs abide by 'Terms and conditions for obtaining and maintaining accreditation/certification'.
- QAI-CIA has the right to:
    - ❖ effect changes in standards on which RMP accreditation is based in accordance with international norms
    - ❖ decide on policies related to accreditation in consultation with stakeholders
    - ❖ appoint assessment teams in consultation with RMP and the assessors
    - ❖ take appropriate action including adverse decisions against RMP giving valid reasons for the same

Duties

- QAI-CIA is obliged to make available relevant information to its applicant and accredited RMPs. 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 17034 through website.

13. Finance and Fee Structure

Finance

QAI derives its funds from the revenue generated through accreditation and training activities.

Fee Structure

A uniform fee structure is maintained for all RMPs and the charges are maintained at a reasonable level so that RMPs 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.

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

709, Wave Silver Tower, Sector 18, Noida 201301, India

Email: info@qai.org.in Website: www.qai.org.in

M: +91 8287841146

Ph No.: +91 120-6664981

LinkedIn |Twitter |Facebook |YouTube |Instagram