IQAS-001

General Information Brochure

AMENDMENT SHEET

Sr. No.	Page No.	Clause No.	Date of amendment	Reasons of amendment	Amendment details	Remarks	Approved by
1	--	--	28.10.2026	Periodic Review as per document control procedure	Detailing as part of periodic review	Replaces previous issue 03 dated 04.12.2024	R.S. Rana

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1. Objective

To provide an overview of the assessment activities taken by IQAS.

2. Scope

Details about the fields that are covered for accreditation.

3. Responsibility

All IQAS personnel

4. Reference

All clauses of quality manual

5. Terminology

Initial Assessment: The term initial assessment is used for first time applicant CAB.
Re-assessment: CABs already accredited are required to apply for re-assessment.

6. About IQAS

International Quality and Accreditation Services (IQAS) was established in the year 2021 with an objective to provide accreditation services to Conformity Assessment Bodies (CABs) engaged in the field of testing, calibration and medical testing. IQAS has been established to create a hassle-free but process driven accreditation service in a competitive environment to ensure measurement systems as per the ISO/IEC 17011:2017.

7. Accreditation schemes undertaken by IQAS

IQAS offer accreditation to CABs to the following standards:

7.1 ISO/IEC 17025:2017 for Testing and Calibration CABs
7.2 ISO 15189:2022 for Medical Testing CABs
7.3 ISO 17034:2016 for RMP CABs
7.4 ISO/IEC 17043:2023 for PTP CABs
7.5 ISO/IEC 17020:2026 for Inspection Bodies

8. Scope of Accreditation undertaken by IQAS

IQAS accreditation services for testing, calibration and medical testing CABs covers the following:

8.1 Testing CABs

- Biological
- Chemical
- Electrical
- Electronics
- Fluid Flow
- Forensic
- Mechanical
- Non-Destructive (NDT)
- Photometry
- Radiological
- Diagnostic Radiology QA Testing
- Software & IT System Testing

8.2 Calibration CABs

- Electro Technical
- Fluid Flow
- Mechanical
- Optical
- Radiological
- Thermal
- Medical Devices
- Chemical

8.3 Medical testing CABs:

- Clinical biochemistry
- Clinical pathology
- Cytopathology
- Cytogenetics
- Flow Cytometry
- Hematology
- Histopathology
- Microbiology and Infectious disease serology
- Molecular Testing
- Medical imaging

8.4 Reference Material Producer:

- Chemical composition
- Biological and Clinical properties
- Physical properties
- Engineering Properties
- Miscellaneous Properties

For Sub-category refer IQAS-026 (Information on Classification of Product Categories in Testing, Calibration Field & and Reference Materials)

8.5 Proficiency Testing Provider:

- Calibration
- Testing
- Medical

8.6 Inspection Bodies:

- Basic metals and fabricated metal products
- Machinery and equipment
- Electrical and optical equipment
- Chemicals, chemical products and fibers
- Rubber and plastic products
- Manufacturing not elsewhere classified
- Textiles and textile products
- Food products, beverages and tobacco
- Water supply
- Other transport equipment

For Sub-discipline refer IQAS-026 (Information on Classification of Product Categories in Testing, Calibration Field & and Reference Materials)

Note: In case of any query regarding to sub-groups, feel free to contact us on +91 11-43023577 or write to us at services@iqas.co.in

9. Application for accreditation

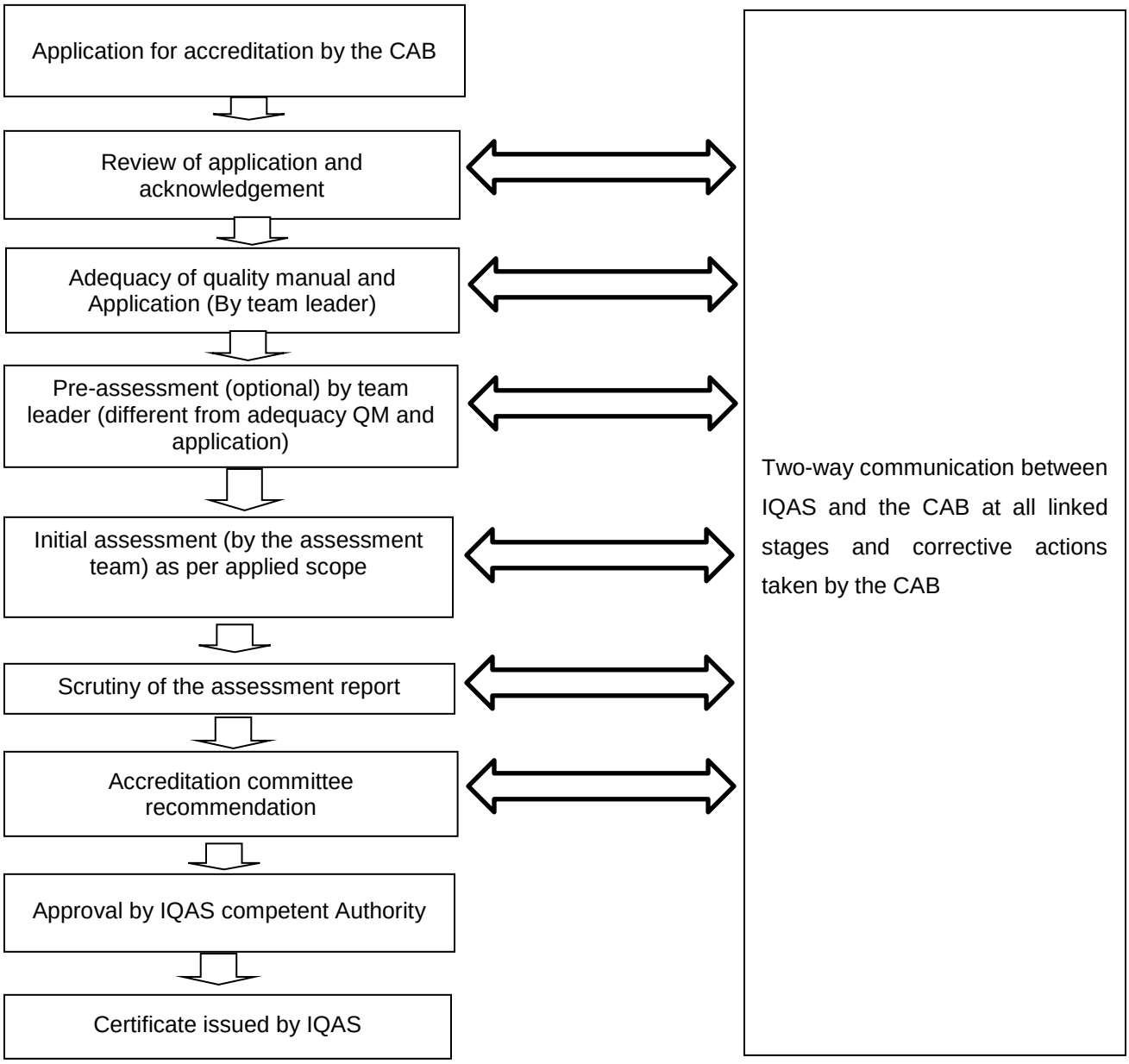
The CABs desirous for accreditation in the field of testing, calibration, medical testing, RMP,PTP and Inspection Bodies shall apply in the IQAS prescribed format of application IQAS-002, IQAS-003, IQAS-004, IQAS-036, IQAS-037 and IQAS 042 through mail on testing@iqas.co.in/ calibration@iqas.co.in/ medical@iqas.co.in / ptrmp@iqas.co.in /

ib@iqas.co.in respectively or through IQAS website.

10. Accreditation process

The applicant laboratory having applied for the required scope of accreditation in the prescribed format will pay the required fee. Various stages of the accreditation process are depicted in the flow diagram.

Stage wise accreditation process



10.1 Application for accreditation by CAB

The interested CAB shall apply in the prescribed format of application as per the scope of accreditation in testing, calibration, medical testing, RMP, PTP and Inspection Bodies complete in all aspect along with applicable fee.

10.2 Review of application and acknowledgement

The application is reviewed by IQAS for completeness and resources available within IQAS so that accreditation services can be offered to the applicant CAB. If IQAS has all resources for the applied accreditation and application is complete in all respect, it will be acknowledged with a unique ID number and communicated to the applicant CAB. If there is any inadequacy in the application, the same is informed to the CAB and the CAB shall take corrective actions for the same in the stipulated time period of one week.

10.3 Adequacy of Quality Manual and Application

The application with requisite complete information and the CAB's quality manual will be sent for adequacy compliance to the team leader or adequacy can be also be checked by IQAS officer. The team leader shall submit report of adequacy of quality manual and application within one-week to the concerned IQAS Accreditation Officer. The CAB has to take corrective actions on observed non-conformances (NCs) and close it within two weeks, failing to close the inadequacy within the timeline the IQAS can initiate the adverse action as per IQAS-013. The adequacy report will be communicated by IQAS dealing officer to the CAB

10.4 Preliminary visit (optional)

The CAB may opt for a preliminary visit. The preliminary visit is optional and it is up to the CAB, the visit is to preliminary review the availability of structure, resources, process and management system adequacy to recommend the team required to assess the CAB complying to ISO/IEC 17025:2017, ISO 15189:2022, ISO 17034:2016, ISO/IEC 17043:2023 and ISO/IEC 17020:2026. The visit report will be shared with the CAB. The CAB shall have to address or close the non-conformity, if any within 30 days.

10.5 Initial Assessment

Once NCs raised during the preliminary visit are closed by the CAB and corrective actions are accepted by the team leader or in the event that the CAB has directly opted for the initial assessment, concerned IQAS officer schedules initial assessment of the CAB. Based on the scope of accreditation applied for by the CAB, the assessment team comprises of a team leader and technical assessors and an observer (if deputed by IQAS). The assessment team composition and schedule are shared with the CAB and those are to be acceptable to the CAB and also to the Assessor(s). The assessment team submits the report of initial assessment in the prescribed forms and formats. The CAB needs to take the corrective action within 30 days for NCs if any and corrective action are reviewed by the respective assessor for its compliance keeping IQAS informed.

10.6 Accreditation Process for Inspection Bodies:

Assessment Programme:

Based on the draft assessment programme, IQAS prepares a detailed plan for the following three stages of the assessment.

a) Assessment of the documentation of the inspection body as per IQAS-CL-IB-06 (Document Review Report cum Adequacy Checklist).

b) (I) An optional preliminary assessment as per IQAS-FF-44 (to review the preparedness of IB to face the final onsite assessment)
(ii) Assessment of the office of the inspection body including branch offices/sub-contractors. The locations for assessment are chosen based on review of activities being performed at a location for the applied scope. All locations wherein key activities like planning of assessment, inspector qualifications, inspector monitoring, etc. are performed are would be assessed each year.

c) It is also ensured that each scope sector for which inspection body has applied are covered during the initial assessment.

d) Witness of the inspections being carried out by the inspection body (IQAS-FF-46 List of Forthcoming Inspection for Witness) A plan is given to IB for the same which includes witness assessments in annual surveillance.

The programme is provided to the applicant body for its agreement as per IQAS-FF-47-Assessment Programme as per ISO/IEC 17020.

10.6.1.1 Upon successful completion of office assessment, witness assessments are planned. At least two inspections are witnessed for initial accreditation of an inspection body for a particular group of scopes (or set of scopes as applicable) of accreditation. In case of critical scope sectors 2 witness assessments are planned. Critical scope sectors are listed in Annex II of IQAS-042 which describes the classification of groups.

10.6.1.2 During initial assessment inspection bodies declare about the activities being performed at each location and based on assessment of risk of each activity performed at each location, the locations for assessment are chosen. The assessment plan is provided based on inspection body informing about the activities. However, if during initial office assessment there is need felt to assess any other location same is informed to the inspection body and included in the assessment plan.

10.6.2 Initial Assessment

The initial assessment is carried out in three steps as per the assessment programme.

10.6.2.1 The documents are verified by the assessment team for compliance to the accreditation criteria as supported by the guidance documents, IQAS -043 (Supplementary Criteria for Inspection Bodies) and the scope applied for by the applicant. A summary report of any omissions of the criteria elements is forwarded by the team leader to IQAS.

10.6.2.2 The report is reviewed and a copy of report is forwarded to the applicant body for their comments and compliance. Depending on the nature of comments and changes made to the documentation, a second review of documents may be necessary. The applicant Inspection Bodies would be informed if a second review is needed. IQAS may consider charging 1 MD cost more in case there is are major changes observed during 1st iteration of the document review.

10.6.2.3 On receipt of confirmation of the compliance, including any evidence of implementation of changes to the system that may be necessary, by the applicant body, the applicant body is requested to forward required number of sets of the manual and procedures for the assessors.

10.6.2.4 A preliminary visit would be undertaken:

a) If requested by IB
b) When first document review report brings out gross deficiencies in the documentation system.

10.6.2.5 In case preliminary visit is not required, the office assessment would be planned and scheduled. The dates are in agreement by the Team Leader with the applicant body and the assessment team carries out the assessment of the implementation of the quality manual and procedures of the applicant body in the head office of the applicant body and if necessary, at other office sites / sub-contractors included in the accreditation application /

assessment programme. Initial assessment would be generally conducted within 30 days once satisfactory actions on document review report/preliminary visit non conformities are received. In case the same is delayed IB would be informed. In case information collected during the office assessment requires inclusion of other locations in the assessment programme, the applicant would be informed and the assessment programme would be modified to cover such locations.

10.6.2.6 The branch offices ı sub-contractors would be included in the assessment programme depending on the nature of activities carried out by them and the extent of control demonstrated by the applicant IB and risks associated. Normally branch offices carrying out activities like development of inspection methods and procedures, contract review, inspector qualification / approval, monitoring of inspectors, handling of inspection samples and items, preparation and issue of inspection reports/certificates would be included in the assessment programme. The offices, other than key locations may also get sampled and assessed during an accreditation cycle to ensure the competence is reviewed. The same is done based on risk review.

10.6.2.7 The assessment is to ensure the competence of the body in operating a sound inspection system.

10.6.2.8 During the assessment or on demand at any time, the applicant/accredited body provides unrestricted access to the documents that pertain to the inspection process and the scope applied for. Access is also provided to the records of the complaints, appeals and disputes along with corrective action and the method of verifying the effectiveness of the corrective actions. Inspection bodies have to also provide documents related to the review of Type status and its justification and risk analysis documentation for review by assessment team.

10.6.2.9 Any non-conformities and concerns observed during the office assessment shall be explained to the applicant body and are provided in the IQAS-FF-45 (P-VIII) format. Applicant has to respond within 30 days.

10.6.2.10 IQAS conducts witness assessment in case there is no NC observed during on site initial assessment which is related to competence or gross deviation in implementation of standard requirements. IQAS proceeds with the witness of the site inspections scheduled to be carried out by the applicant.

10.6.2.11 The nominated assessment team carries out the witness assessment of the inspections for a given scope (or a set of scopes) as per plan and identifies the non-conformities and concerns observed. Assessment team for witness assessment is selected based on their competence and is aware of the processes involved during the inspection.
IQAS uses the services of a technical expert during inspection, if required. Technical expert is accompanied with an assessor. Technical expert is used to ensure that the knowledge and skill required for conducting the assessment is available in the assessment team

10.6.2.12 The applicant is provided with the copy of the non-conformities and concerns observed for corrective action at the end of the witness assessment.

10.6.3 Assessment Report

10.6.3.1 The team leader prepares a summary report of all the aspects of the assessment of the office and on-site inspections. The assessment report is made in the following parts:

a) The non-conformities observed during various stages of the assessment.

b) A summary report indicating the conformity of the inspection body's management system to the particular accreditation requirements. The team also provides an opportunity for the applicant body to ask any questions about the findings and its basis during the closing meeting.

10.6.3.2 The team prepares a detailed report in the format listing the level of compliance to the requirement of the supplementary criteria of the IQAS and send for comments by IB The inspection body is invited to give technical comments on the report and agree for the corrective action within a defined time schedule.

10.6.3.3 The report is reviewed at IQAS official.

10.6.3.4 In case that the report sent has any difference from the information presented to the applicant body by the assessment team at the closing meeting, the same is highlighted and the explanation of the differences is enclosed.

10.6.3.5 IQAS may consider conducting a follow-up assessment (partial or verification) assessment in case of Major NC after discussion with Team Leader considering the NC.

10.6.3.6 After all the non-conformities have been closed by the applicant and verified to the satisfaction of the Team leader, a final summary of the assessment report including the details of the corrective actions taken by the applicant body is sent to IQAS. IQAS organizes an Accreditation Committee Meeting for conducting an independent technical review. The Committee is proposed by IQAS officer from empanelled members. It is also ensured during review of the report that the Committee has knowledge about the products and processes under review in the scope of applied for accreditation.

10.6.3.7 The process of closing the non-conformities and verification must be completed in the specified time. If the applicant body delays the process of acceptable corrective action beyond the limits specified by the IQAS, the IQAS will reserve the right to reject the application. The fees paid by such applicant will be forfeited.

10.6.3.8 The assessment team also submits a final consolidated report in the IQAS-FF-

45 format after compiling the contents of initial assessment report as well the witness assessment reports and final recommendation is provided to IQAS along with recommended scope in the specific format. The assessment team also provides justification for not recommending any scopes that the applicant IB had sought accreditation for.

10.6.7 Time Period for assessment process

a) The assessment process for any applicant must be completed within a maximum of one year. In the event that the process is not completed within this stipulated time, IQAS may grant additional period of further one-year subject to review of the progress of assessment process carried until then and after taking an undertaking from the applicant to complete the process at the earliest within this additional time. The grant of additional time shall be the prerogative of IQAS and will only be considered after clearing of all outstanding payments. In case, it is observed that the applicant is not progressing with the assessment process during the additional time, the application shall be closed by IQAS.

b) In the event of delay in getting witness assessment scheduled for different scope sectors that the applicant has applied for, IQAS in discussion with the applicant may decide to present the partial assessment results for accreditation decision for part of the scopes. This will be done after all the non-conformities observed during the earlier office assessment and part of the witness assessments completed, have been closed to the satisfaction of the assessment Team Leader.

10.7 Scrutiny of report by the IQAS officer

The initial assessment report is submitted to IQAS by the team leader with the recommendations of the final assessment. The concerned IQAS officer scrutinizes the assessment report for its completeness including expense claims, submitted in the prescribed form and format, of the Assessment Team.

10.8 Recommendations of Accreditation Committee

Once all the corrective actions are reviewed and accepted by the assessment team individually, the IQAS officer makes a summary of the assessment report and place it to the accreditation committee for its recommendation. The accreditation committee members, reviewing the assessment report, are independent and there is no conflict of interest in any manner.

10.9 Approval by competent authority

The accreditation committee findings and recommendation are approved by the competent authority of IQAS and are communicated to the CAB. The decision on accreditation is communicated to the CAB only after the approval and clarification, if any, asked by IQAS are satisfactorily submitted by the CAB.

10.10 Issuance of accreditation Certificate along with scope of accreditation

The certificate is issued to the CAB based on the recommendations and approval of IQAS. The certificate of accreditation contains,

- Name and address of the CAB
- Standard of accreditation;
  ISO/IEC 17025:2017 for testing and calibration
  ISO 15189:2022 for medical testing
  ISO 17034:2016 for RMP
  ISO/IEC 17043:2023 for PTP
  ISO/IEC 17020:2026 for Inspection Bodies
- Certificate no. for testing/calibration/medical testing/RMP/PTP /Inspection Bodies with issue and date of validity of the certificate.

The scope of accreditation for calibration laboratory defines:

- Details of accreditation certificate along with the discipline/group, measurand or reference material/type of instrument or material to be calibrated or measured/ quantity measured /instrument, calibration or measurement method or procedure measurement, range and additional parameters where applicable (range and frequency), calibration and measurement capability (CMC) (±)/facility.

The scope of accreditation for testing laboratory defines:

- Discipline/group, materials or products tested, component, parameter or characteristic tested/specific test performed/tests or type of tests performed, test method specification against which tests are performed and range of measurement/detection limit/or the techniques/equipment used.

The scope of accreditation for medical testing laboratory defines:

- Discipline, component, parameter or characteristic tested/ specific test performed/

tests or type of tests performed, test method specification against which tests are performed and range of testing/ or the techniques/equipment used

The scope of accreditation for Reference Material Producer defines:

- Types of reference materials (Certified Reference Materials, Reference Materials or both) Category & Subcategory, Reference Material Matrix or Artefact, Property / Properties Characterized, Approach used to assign property values/ Characterization Technique, Range of property, Assigned value, uncertainty and best reference value capability (as relevant), Activities being subcontracted (e.g. assessment of homogeneity, stability, characterization, testing, calibration, measurements etc. if any) etc.

The scope of accreditation for Proficiency Testing Provider defines:

- Proficiency Testing Scheme, Type of PT Item/ Matrix, Measurand/ Characteristic/ Type of measurand/ Type of characteristic/ Analyte/ Parameter, Range of Measurement (if applicable), Minimum Periodicity, Test method etc.

The scope of accreditation for Inspection Bodies defines:

- Inspection Bodies Scheme, IAF Scope Sector Classification Code, Inspection field and specific item(s), Stage and Range of Inspection(s), Inspection requirement(s) [Standards / Regulations / Methods/ Procedures], Office(s) where competence for each scope exists etc.

The certificate and scope of accreditation are signed by the competent authority of IQAS.

11. Maintenance of accreditation

The accredited CAB shall maintain and conform to the requirement of the relevant standard ISO/IEC 17025:2017, ISO 15189:2022, ISO 17034:2016, ISO/IEC 17043:2023 and ISO/IEC 17020:2026 and also the specific requirements of IQAS throughout the cycle of accreditation. The CAB shall also comply with the terms and conditions of obtaining and maintaining the accreditation IQAS-006 throughout the cycle of accreditation.

11.1 Desktop Surveillance/ Onsite surveillance

To monitor the compliance for accreditation, IQAS will perform the desktop surveillance and onsite surveillance during the cycle of accreditation.

The accreditation cycle will be 4 years, during the first year there will be desktop surveillance within 10th to 12th months and in the 2nd year there will be onsite surveillance from 20th -24th months. Again, in the third year there will be desktop surveillance within 32nd to 36th months. In the fourth year the CAB needs to apply three months prior to expiry of the accreditation cycle and there will be renewal assessment within the 46th to 48th months.

The scheduled assessment shall be as follows:

Year in accreditation cycle	Duration from the date of issue of accreditation certificate	Types of assessment
1st Year	10th to 12th months	Desktop Surveillance
2nd Year	20th to 24th months	Onsite Surveillance
3rd Year	32nd to 36th months	Desktop Surveillance
4th Year	46th to 48th months	Renewal assessment

Note: For PTP/RMP/Inspection Bodies the accreditation cycle will be one year and desktop surveillance/onsite surveillance is not applicable unless linked to investigation of complaint against the PTP/RMP/Inspection Bodies.

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11.2 Extraordinary Assessment

In case of valid complaint or changes or other matters that may affect the ability of CAB to fulfill the requirements of accreditation, an extraordinary assessment may be conducted.

11.3 Reassessment for renewal of accreditation

The accreditation cycle is of 4 years and there will be desktop surveillance in the first year, onsite surveillance in the second year and again there will be desktop surveillance in the third year. There will be reassessment for renewal of accreditation in the fourth year, as mentioned above in clause 11.1. For renewal of accreditation the CAB should apply for renewal six months prior to expiry of certificate. The process of accreditations followed is the same as the stage wise accreditation process. After getting application, the CAB ID will remain the same and the assessment is scheduled based on the scope of accreditation. The assessment team may be different from the previous assessment team. However, in some special case (s) the assessor(s) may be repeated provided no other assessor is/are available in the particular field, or in case some assessor had assessed different parameter in the previous onsite

assessment. Application submitted for renewal of accreditation along with requisite fees (refer cl 8 of IQAS-006) will be considered for renewal till a maximum period of three months from the expiry of the validity.

Other steps followed are similar to as for a new applicant laboratory. Only adequacy, preliminary assessment will not be conducted for the renewal of application/accreditation.

Note: For PTP/RMP and Inspection Bodies the accreditation cycle will be one year and CAB needs to apply three months in advance for renewal (i.e., three months prior to the expiry) of accreditation.

11.4 Modifications to the Accreditation Criteria

If the accreditation criteria are modified by ISO/ ILAC/ APAC/ IQAS, the CAB is informed of the same, giving a transition period of at least 6 months to align its operations in accordance with the modified criteria and IQAS to verify the same through assessment.

12. Other activities during the accreditation cycle of the CAB

12.1 Name change/ change in legal entity of the CAB under same ownership

In the case of name change under the same ownership, the CAB shall apply for the name change along with old and new legal entity documents of the CAB. Prescribed fee is to be paid for the name change. New accreditation certificate with earlier scope of accreditation is issued to the CAB bearing the new certificate number and a new issue date. However, the date of expiry remains the same as that on the original certificate.

12.2 Acquisition/merger/ change in ownership/sale purchase

The CAB shall inform IQAS and apply for fresh accreditation in the event of acquisition/merger/change in ownership/sale purchase/ of the CAB. If the key personnel of the laboratory have not changed, the process of simple name change is followed and the same is applicable to the CAB and the CAB needs to declare no change in the key personnel of the laboratory. In case, there is change in the key personnel along with change in the ownership, then CAB has to apply for fresh accreditation. The new application for fresh accreditation is processed by IQAS as per the procedure followed in clause 9 of this document.

12.3 Change in the premises

When a CAB changes its premises for any reason, the CAB needs to inform IQAS within 7 days and shall not use IQAS logo during the process of premises change until a fresh certificate at new premises is issued by IQAS. A supplementary visit is scheduled by IQAS in consensus with the CAB by deputing the assessor/assessment team. A fresh certificate is issued and issue date is the approval date of the accreditation committee recommendation approved by the competent authority of IQAS with the date of validity remaining the same.

12.4 Change in authorized signatory

The CAB may apply for additional authorized signatory (ies) and the same is reviewed by the assessor/ assessment team based on the number of authorized signatories through online or on-site visit. In case, when there is no authorized signatory available with the CAB due to any reason, the CAB shall inform IQAS within 7 days and shall not claim IQAS accreditation, in other words CAB shall not use IQAS symbol on test/calibration report until the new authorized signatory is approved by IQAS.

12.5 Change in test/calibration method

When there is a change in the test/calibration method due to change in the relevant national or international standard the CAB has to inform IQAS and request for change in the test/calibration method. If there is no significant change in the techniques of the test/calibration method, the revised certificate is issued based on the recommendation of technical assessor and approval by the competent authority of IQAS with note in the certificate indicating the reason of change of test/calibration method. When there is a significant change in the techniques of the test/calibration method, a supplementary visit is scheduled by the IQAS on the request of the CAB. The prescribed fee is also paid by the CAB.

12.6 Change in scope of accreditation

12.6.1 Scope Extension

The CAB may apply for scope extension during the cycle of accreditation. For scope extension, the CAB shall apply in the prescribed format of application for testing/calibration/medical testing/PTP/RMP/Inspection Bodies along with prescribed fee.

The assessment will be scheduled for scope extension, based on the parameters and discipline. IQAS will issue the revised scope based on the assessment report.

12.6.2 Withdrawal of scope

The CAB may withdraw part of the accredited scope during the cycle of accreditation due to any reason. For withdrawing the scope CAB shall write to IQAS and same shall reviewed by the Accreditation Committee and approved by the competent authority of IQAS. The revised scope of accreditation will be issued to CAB.

12.6.3 Reduction in scope

The scope can be reduced based on the recommendations of the accreditation committee for the following reasons:

- CAB is not found competent during the assessment.
- CAB has not taken the corrective actions on the NC/NCs raised during the assessment.
- CAB has failed to take corrective actions for the failure during the participation of PT/ILC for a particular parameter. The parameter may be reduced from the scope of accreditation.

Note: For any change in the accreditation certificate and scope of accreditation, the amendment date is mentioned on the certificate.

13. Complaints

Whenever any complaint is received by IQAS against the applicant or accredited CAB or IQAS or IQAS officers from any source, it will be investigated and if found valid the complaint will be processed as per the laid down procedure of IQAS-010.

14. Appeals

Whenever, CAB disagrees with the decision of IQAS the CAB may appeal to the authorized competent authority of IQAS. On acceptance of a valid appeal, the same will be processed as per the laid down procedure IQAS-011 for dealing with appeal(s).

15. Fee Structure

A CAB application once accepted by IQAS for fresh accreditation, renewal of accreditation

or any other activity; the fee paid by the CAB shall not be refunded. The fee for various activities is as below **(refer IQAS-026):**

Table:1

Field	Discipline	Product Groups (refer IQAS-026)	Application Fee (INR)	Annual Accreditation fee to be paid every year (INR) per discipline
Testing	Chemical	For 1 group	9000.00	20000.00
	Biological	For 1 group	9000.00	20000.00
	Mechanical	For 1 group	9000.00	20000.00
	Electrical	For 1 group	9000.00	20000.00
	Electronics	For 1 group	9000.00	20000.00
	Fluid Flow	For 1 group	9000.00	20000.00
	Forensic	For 1 group	35000.00	39000.00
	Non-Destructive (NDT)	For 1 group	9000.00	20000.00
	Photometry	For 1 group	9000.00	20000.00
	Radiological	For 1 group	9000.00	20000.00
	Thermal	For 1 group	9000.00	20000.00
	Diagnostic Radiology QA Testing	For 1 group	9000.00	20000.00
	Software & IT System Testing	For 1 group	35000.00	39000.00
Calibration	Mechanical (Group): i. Mass/Volume/ Balance	For 1 group	9000.00	20000.00
	ii. Density iii. Dimensions	For 2 groups	18000.00	
		For each additional	5000.00	

		group		
	Medical Devices	For 1 group	20000.00	20000.00
		For additional group	20000.00	
	Electro Technical	For all applied groups	23000.00	20000.00
	Fluid Flow	For all applied groups	18000.00	20000.00
	Thermal	For all applied groups	18000.00	20000.00
	Optical	For all applied groups	18000.00	20000.00
	Radiological	For all applied groups	18000.00	20000.00
	Chemical	For all applied groups	32000.00	20000.00
A Medical Testing CAB can apply either under Scheme A or Scheme B				
Medical (Scheme A)	Micro laboratories	(Up to 25 patients/ day)	5000.00+175 per SCF	5000.00+175 per SCF
	Mini Laboratories	(26 - 50 patients/ day)	8000.00+175 per SCF	8000.00+175 per SCF
	Small laboratories	(51 - 100 patients/ day)	15000.00+175 per SCF	16000.00+175 per SCF
	Medium laboratories	(101-400 patients/ day)	35000.00+175 per SCF	39000.00+175 per SCF
	Large laboratories	(401 - 1000 patients/ day)	88000.00+175 per SCF	96000.00+175 per SCF

	Very large laboratories (above 1000 patients/ day/location)	(Above 1000 patients/ day)	1,76,000.00+175 per SCF	1,92,000.00+175 per SCF
Medical (Scheme B)	Cl. Biochemistry Cl. Pathology Haematology Microbiology and Infectious Disease Serology Histopathology Cytopathology Flow cytometry Cytogenetic Molecular Testing	Up to 2 disciplines	9000.00	12000.00
		Total 3 disciplines	15000.00	18000.00
		Total 4 disciplines	21000.00	24000.00
		Total 5 disciplines	27000.00	30000.00
		Total 6 disciplines	33000.00	36000.00
		Total 7 disciplines	39000.00	42000.00
		Total 8 disciplines	45000.00	48000.00
		Total 9 disciplines	51000.00	54000.00
	Collection Center and Sample Collection Facility (SCF)	Up to 5 SCF	500.00	1000
	For each additional Collection Center/SCF	--	100.00	200.00
	Point of Care Testing (POCT)	each discipline	6000.00	6000.00
	Mobile Testing Facility	each discipline per mobile testing facility	6000.00	6000.00
Medical	1. Medical Imaging a. Projection Radiography and Fluoroscopy b. CT c. MRI d. Ultrasound and	--	9000.00	12000.00

	Colour Doppler e. Nuclear Medicine f. Interventional Radiology			

Field	**For Category/ Sub category (refer IQAS-026)**	**Application Fee (INR)**	**Annual Accreditation fee to be paid every year (INR) per discipline**
RMP	Per Category–up to 2 Sub - categories e.g., Metals & Organic Reference Materials under Chemical Composition	12500.00	13750.00
	For each additional sub-category in the same category	5000.00	

Field	**For Disciplines/ Sub disciplines (refer IQAS-026)**	**Application Fee (INR)**	**Annual Accreditation fee to be paid every year (INR)**
PTP	For one Sub discipline per discipline e.g., Chemical under Testing	12500.00	13750.00
	For each additional sub discipline in the same Discipline	5000.00	

Fee structure for Inspection Bodies

Description	**Annual Turnover of the IB as an Entity in India**		
	Less than 1 Crore	**1 Crore-5 Crore**	**Above 5 Crore**
Application Fee			
Application fee	70,000	1,40,000	1,80,000
Application Fee for Renewal of Accreditation	40,000	70,000	90,000
Application Fee for Extension of Scope (Anytime during accreditation cycle)			
Addition of Field	15,000	30,000	40,000
Addition of Sub Field within existing Field	8,000	15,000	20,000
Man-day Charges			
Assessors	15,000	20,000	20,000
Experts	15,000	15,000	15,000
Annual Accreditation Fee	70,000	1,15,000	1,80,000
Travel, Boarding and Lodging	On actuals		

Scope enhancement	Description	Fee (INR)
Testing	Any extension in the existing accredited scope per product group in each discipline of testing	5000.00
	For each additional product group in each discipline of testing	9000.00
Forensic	Forensic Laboratories and Software & IT system testing Any extension in the existing accredited scope	5000.00
	Medical Laboratories & Associated Sample Collection Centre/Facility (SCF) Any extension in the existing accredited scope	5000.00
	Any addition in Sample Collection Centre/Facility (SCF)	160 per collection center
Medical Testing	Any extension in the existing accredited scope in each discipline of testing	3000.00
	For each additional discipline	6000.00
Medical imaging	Any extension in the existing accredited scope of medical imaging	5000.00
	Any new group/ modality extension in the existing accredited scope of Medical Imaging.	9000.00
Calibration	Any extension in the existing accredited scope per group per discipline	5000.00
	For each additional product group per discipline (Except Medical Devices)	9000.00
	Medical Devices a) For each additional group	20000.00
	b) Addition of up to 2 equipment in existing accredited group	5000.00
PTP	Addition in existing Sub -discipline	2500.00
	Addition of sub discipline in the existing discipline	5000.00
RMP	For addition in existing subcategory	2500.00
	For each additional sub category	5000.00
Change in authorized signatory	**Description**	**Fee (INR)**
Testing (online/telephonic)	Additional authorised signatory other than scheduled assessment	5000.00

Calibration (online/telephonic)	Additional authorised signatory other than scheduled assessment	5000.00
Medical (online/telephonic)	Additional authorised signatory other than scheduled assessment	5000.00
PTP/RMP	Additional authorised signatory other than scheduled assessment	5000.00
Change in certificate	**Description**	**Fee (INR)**
Calibration, Testing, Medical Laboratories, PTP and RMP	Any change in the name and/ or premises/ address of the laboratory leading to issue of new accreditation certificate and / scope	5000.00
Onsite assessment for additional authorised signatory	Charges of assessor and additional charges	Assessor honorarium and overhead Charges as applicable
Online assessment for additional authorised signatory	Charges of assessor and additional charges	overhead Charges as applicable
Overhead charges for testing/calibration/medical testing/PTP/RMP CAB (other than assessor/assessment team charges)	Preliminary assessment	12000.00
	Initial Assessment	
	Re-assessment	
	Desktop Surveillance	
	Onsite Surveillance Note: at the time of onsite surveillance CAB to pay the full application fee which was paid at the time of initial application/renewal of application.	
	Supplementary visit	
Assessors' honorarium	Team leader	5500.00 per day
	Technical assessor	5000.00 per day
	Document review by team leader	3500.00

	Travel tickets (Air ticket in economy class for more than 300 km and second-class AC train ticket/AC bus) under 300 km travel, local transport up to 80 km (AC taxi) and food & accommodation in single occupancy AC room)- To be arranged by the CAB Note: In case assessors opts for his own vehicle for local transport up to 80 km, same to be reimbursed at the rate of Rs.12/ km.	As actuals.

Note: - Fee Structure for SAARC/Other countries in testing/calibration/medical testing/PTP/RMP/Inspection Bodies CABs - Request for quotation.