International Quality And
Accreditation Services Pvt. Ltd.
(Formerly International Quality And Accreditation Services LLP)
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IQAS-001

General information brochure

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. 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 (CAB) 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 for development of measurement systems in the country as per the ISO/IEC 17011:2017.

6. Accreditation schemes undertaken by IQAS

IQAS offer accreditation to CABs to the following standards:

6.1 ISO/IED 17025:2017 for Testing and Calibration CABs

6.2 ISO 15189:2012 for Medical Testing CABs

7. Scope of Accreditation undertaken by IQAS

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

7.1 Testing CABs

- Biological
- Chemical
- Electrical
- Electronics

- Fluid Flow
- Forensic
- Mechanical
- Non-Destructive (NDT)
- Photometry
- Radiological

7.2 Calibration CABs

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

7.3 Medical testing CABs:

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

Note: In case of any query regarding to sub-groups, feel free to contact us on +91 1135064124 or write to us at contact@iqas.co.in .

8. Application for accreditation

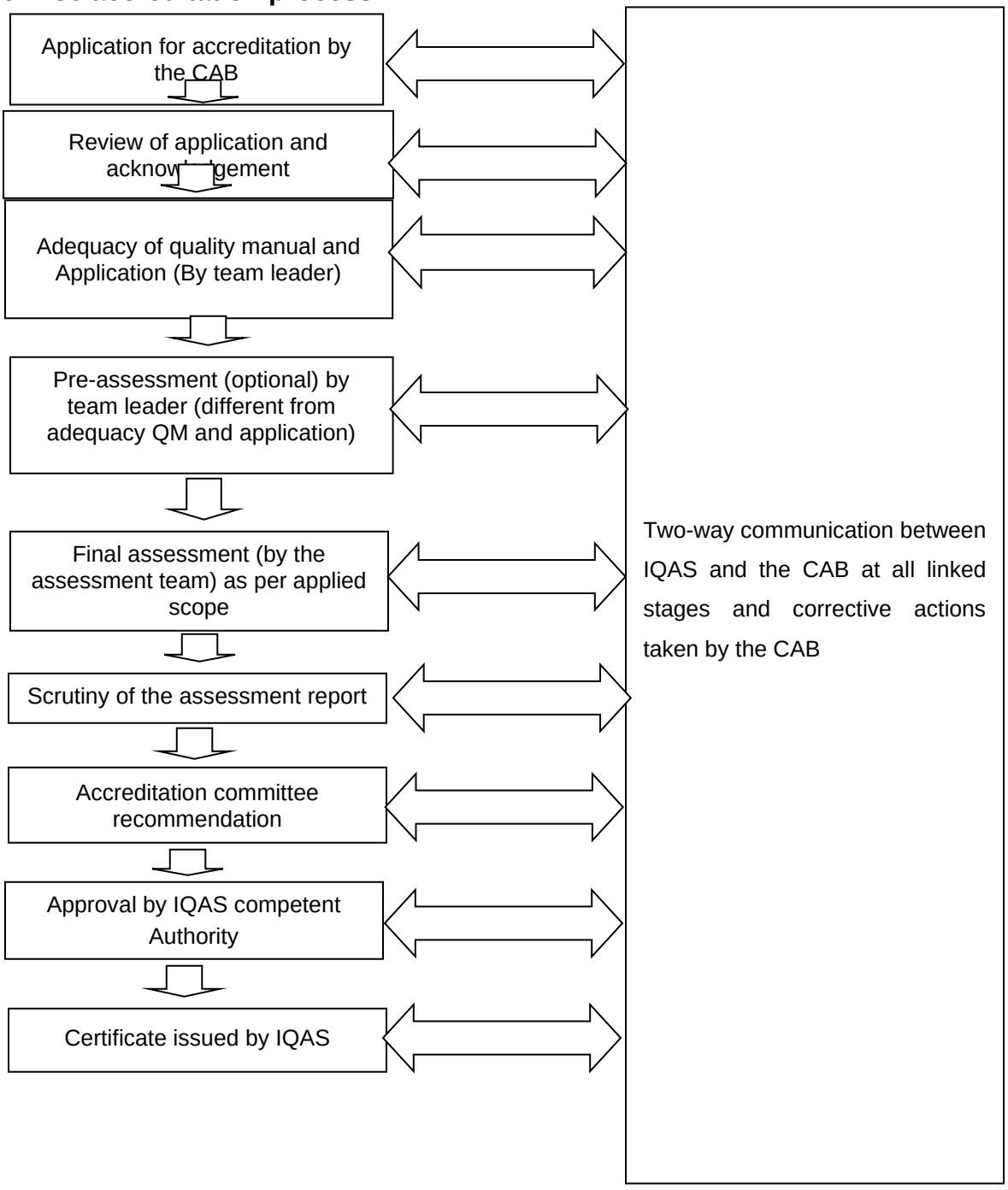
The CABs desirous of accreditation in the field of testing, calibration and medical testing shall apply in the IQAS prescribed format of application through mail on contact@iqas.co.in / info@iqas.co.in or through IQAS website. The concerned IQAS officer will get back with the required documents and forms and formats.

9. 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



9.1 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 or medical testing complete in all respect along with applicable fee.

9.2 Review of application and acknowledgement

The application is reviewed by IQAS official 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.

9.3 Adequacy of Quality Manual and Application

After satisfactory review of the application form, the CAB's quality manual and application will be sent for adequacy compliance to the team leader, the team leader shall submit report of adequacy of quality manual and application within one-week to the concerned IQAS officer. It is a requirement that the team leader submits the report to the IQAS officer but not directly to the CAB. An undertaking to this effect is to be submitted by the Team leader. The IQAS officer will share the report with the CAB and the CAB has to take corrective actions on observed nonconformances (NCs) within 30 days. The corrective actions will be reviewed by the team leader for the closure of inadequacies, if any.

9.4 Preliminary visit (optional)

Once the inadequacies raised, during scrutinising of quality manual and application by the team leader are closed, the CAB may opt for a preliminary visit. The preliminary visit is optional and it is up to the CAB, whether to opt for preliminary visit or to go directly for final assessment.

If the CAB opts for preliminary visit, the IQAS officer will plan the visit, generally lasting one day, by deputing a team leader. The preliminary visit schedule is shared with the CAB and the same is also to be accepted by the CAB. The team leader will submit the preliminary visit report, the CAB will take corrective actions to close the

NCs raised during the preliminary visit within one month. The corrective actions are reviewed by the team leader and after the closure of NCs raised during the preliminary visit the concerned IQAS officer schedules final assessment of the CAB.

9.5 Final 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 final assessment, concerned IQAS officer schedules final 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). If preliminary visit has been conducted for the laboratory, the team leader may be the same for final assessment. 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 final assessment in the prescribed forms and formats. The CAB needs to take the corrective action within 30 days for any and all NCs and all the corrective action are reviewed and accepted by the team leader.

9.6 Scrutiny of report by the IQAS officer

The final 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.

9.7 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 assessment committee for its recommendation. The assessment committee members, reviewing the assessment report, are independent and there is no conflict of interest in any manner.

9.8 Approval by competent authority

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

IQAS are satisfactorily submitted by the CAB.

9.9 Issuance of Certificate

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 and ISO 15189:2012 for medical testing
- Certificate no. for testing/calibration/medical testing with issue and expiry date 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/testing or measurement method or procedure measurement, range and additional parameters where applicable (range and frequency), calibration and measurement capability (CMC)(±).

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/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/or the techniques/equipment used

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

10. Maintenance of accreditation

The accredited CAB shall maintain and conform to the requirement of the relevant standard ISO/IEC 17025:2017 or ISO 15189:2012 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 throughout the cycle of accreditation.

10.1 Onsite surveillance

The onsite surveillance is scheduled when it is found during investigation of any complaint by client/interested party, that there is a gross negligence/nonconformity observed by the accreditation committee and the same is approved by the competent authority of IQAS.

10.2 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.

10.3 Reassessment for renewal of accreditation

The accreditation cycle is for one year and for renewal of accreditation the CAB should apply three months prior to expiry of certificate. The process of accreditation remains the same as that in the previous assessment and the stage wise accreditation process also repeat them. After getting renewal application, CAB ID remains the same and assessment is scheduled directly based on the scope of accreditation. The assessment team is different from the previous onsite assessment team. Only in some special cases the assessor may be repeated. The assessors may be repeated when no other assessor is available in the particular field or in case some assessor had assessed different parameter in the previous onsite assessment. Other steps followed are similar to that for a fresh applicant laboratory, only adequacy and preliminary assessment are not conducted for the renewal of application.

11. Other activities during the accreditation cycle of the CAB

Name change/ change in legal identity 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 changed revision date however, the date of expiry remain the same as that on the earlier certificate.

11.1 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/name change of the CAB. If the key personnel of the laboratory have not changed, the process of simple name change is followed and follows 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.

11.2 Change in the premises

When a CAB changes its premises for any reason, the CAB needs to inform IQAS and shall not use IQAS logo during the process of premises change until a fresh certificate at new premises is issued by IQAS. The CAB may change the premises and CAB shall apply for premises change to IQAS. A supplementary visit is scheduled by IQAS in consensus with the CAB by deputing the assessor/assessment team and the report of the assessment is reviewed by the accreditation committee for the premises change. 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 expiry remaining the same.

11.3 Change in authorised signatory

The CAB may apply for additional authorised signatory (ies) and the same is reviewed by the assessor/ assessment team based on the number of authorised signatories through online or on-site visit. The report of the assessment team is reviewed by the Accreditation Committee and approved by the competent authority of IQAS. In case, when there is no authorised signatory available with the CAB due to any reason, the CAB shall inform IQAS within 15 days and shall not use/claim IQAS accreditation, in other words CAB shall not use IQAS logo on test/calibration report until the new authorised signatory is approved by IQAS as per procedures followed for the additional authorised signatory.

11.4 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.

11.5 Change in scope of accreditation

11.6.1 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 along with prescribed fee. The assessment is scheduled for scope extension , based on the parameters and discipline. The report submitted by the assessor/assessment team is reviewed by the accreditation committee, which is approved by the competent authority of IQAS.

11.6.2 Withdrawal of scope

The CAB may withdraw 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 fresh scope of accreditation certificate is issued to CAB.

11.6.3 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.

12. Complaints

Whenever any complaint is received by IQAS against the applicant or accredited CAB from any source, it will first be investigated and if found authentic it will then be registered and complaint will be processed as per the laid down procedure of IQAS.

13. Appeals

Whenever, CAB disagrees with the decision of IQAS related to denial of accreditation, scope reduction, suspension, debar from applying for accreditation, the CAB may appeal to IQAS. The appeal so received will be first validated whether it could be accepted as an appeal or not. On acceptance the appeal will be processed as per the laid down procedure for dealing with appeal(s).

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

14. 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:

Type of CAB	**Discipline**	**Groups**	**Fee (INR)**	**Annual Accreditation fee to be paid every year (INR)**
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	8000.00	16000.00
	Food Testing	For 1 group	9000.00	20000.00
	Veterinary	For 1 group	20000.00	60000.00
	Laboratories under Integrated Assessment	For 1 group	20000.00	20000.00
Calibration	Mechanical (mass/volume and balance and density, two group and dimension additional group) total three groups	For 1 group	9000.00	19000.00
	Electro Technical	For all applied groups	27000.00	29000.00
	Fluid Flow	For all applied groups	18000.00	19000.00
	Thermal	For all applied groups	18000.00	19000.00
	Optical	For all applied groups	18000.00	19000.00
	Radiological	For all applied groups	18000.00	19000.00
	Medical Devices	For 1 group	20000.00	19000.00
	Chemical	For all applied groups	32000.00	29000.00
Medical Testing	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/	(Above 1000 patients/ day)	1,76,000.00+175 per SCF	1,92,000.00+175 per SCF

	day/location)			
	Medical Imaging CABs	For 1 group/ modality (e.g., Computed Tomography, Ultrasound and Colour Doppler)	9000.00	20000.00
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
		Any extension in the existing accredited product group per discipline under Integrated Assessment		20000.00
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 imaging conformity assessment body (MI-CAB)		Any extension in the existing accredited scope of MI-CAB		5000.00
		Any extension of new group/ modality in the existing accredited scope of MI-CAB		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

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
Change in certificate	**Description**	**Fee (INR)**
Calibration, Testing and Medical Laboratories and MI-CAB	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	As per rules
Overhead charges for testing/calibration/medical testing CAB (other than assessor/assessment team charges)	Preliminary assessment	9000.00
	Final Assessment	9000.00
	Re-assessment	9000.00
	Desktop Surveillance	9000.00
	Supplementary visit	9000.00
Change in certificate	**For testing/calibration/medical testing**	
Assessors' honorarium	Team leader	6000.00 per day
	Technical assessor	5000.00 per day
	Document review by team leader	3500.00
	Air ticket Economy Class, Train ticket 2nd class AC, AC Bus, Local travel, Accommodation in single occupancy AC room - **To be arranged by the CAB**	As actuals.