

## ACCREDITATION PROCEDURE

**Revision 08**

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## 1.0 PURPOSE

The purpose of this procedure is to describe the general procedures, responsibilities and action in the process of accreditation and arrangement for the smooth conduct of accreditation program.

## 2.0 SCOPE AND APPLICATION

This procedure is applicable to the accreditation schemes for CABs under ILAC and APLAC portfolios such as (but not limited to):

- 2.1 Testing Laboratories
- 2.2 Calibration Laboratories
- 2.3 Medical Laboratories
- 2.4 Inspection Bodies

## 3.0 REFERENCES

- 3.1 BAB Quality Manual (BQM)
- 3.2 ISO/IEC 17011- Conformity assessment -- Requirements for accreditation bodies accrediting conformity assessment bodies

## 4.0 PROCEDURE

Sec. No	Procedure / Action	Responsibility / Reference Document
<b>4.1 Application for CAB Accreditation</b>		
	BAB accredits CABs to applicable international and/or national standards and BAB requirements.	<b>AF01 Application Form for Testing and Calibration Laboratory</b>
	Applicant CABs submits two copies of the relevant application to BAB in a prescribed format, with two sets of Quality Manuals or equivalents (uncontrolled copy) and associated documents.	<b>AF02 Application Form for Medical Laboratory</b>
	The Quality Manual should respond to the requirements of applicable international and/or national standards. Prescribed fee is required to be submitted along with the application.	<b>AF03 Application Form for Certification Body</b>
	All publicly available accreditation information is available in the BAB website. The applicant CAB can visit the website for general information for the details of BAB functions, including accreditation schemes, accreditation process, obligations to the CABs, the fee schedule, details of associated expenditures and Terms and Conditions for accreditation. CAB can download informative documents, guidelines and application forms at free of cost from the BAB website. Applicant CAB can also collect the publicly available accreditation information from BAB office on request.	<b>AF04 Application Form for Inspection Body</b>
		<b>SP01 Terms and Conditions for CAB Accreditation</b>
		<b>SP02 Accreditation Fee Schedule</b>

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<b>4.2 Appointment of CASE officer (CO)</b>	Quality Manager/Director assigns the application to a Case Officer (CO). The BAB Case Officer is a BAB staff officer assigned to the applicant as the steward of the file. CO sends an acknowledgement letter (QF21) to applicant CAB as soon as possible.	<b>Quality Manager/Director Case Officer (CO) QF21 Acknowledgment Letter</b>
<b>4.3 Registration of Application and Resource Review</b>	CO opens a file with unique identification no. to be used for future correspondence and keep the application, (QF 36) Quality Manual and associated documents in the respective binder.	<b>CO Applicant CAB QF23 Checklist for Application Review QF36 Registry of CABs</b>
	CO examines the completeness of the application, including the application fee, PT information & completes Checklist for Application Review (QF23). In those cases where the application is incomplete the CAB concerned is informed for corrective measures.	
	CO reviews the BAB's ability considering its policy, competence and availability of suitable assessors and experts to conduct the assessment of the applicant CAB in timely manner.	
	In the event that the application is for a new field of accreditation or BAB is being asked to undertake a new type of accreditation because of the expressed desire of interested parties, BAB will:	<b>Director / QM</b>
	a) Conduct an analysis of its present competence, suitability of extension, resources, etc. in the new field,	<b>Director / QM</b>
	b) Determine the need and availability of employing expertise from other external sources, such as universities, industry associations, scientific community or other groups	<b>Director / QM</b>
	c) Determine the need for creating special requirements or guidance documents for the new field of accreditation,	
	d) Determine the need for identification, recruitment, training and selection of assessors for this new field of accreditation in accordance with AP11, and	<b>Director / QM AP 11 Selection of Assessor</b>
	e) Determine the need for any special training of BAB staff to support accreditations in the new field.	<b>Director / QM</b>
	Report to the DG on the suitability of BAB to undertake accreditations in the new field for final decision by the DG.	<b>Director / QM</b>

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<b>4.4 Formation of Assessment Team</b>		
	<p>Quality Manager/Director in consultation with Case Officer forms an assessment team consisting of a <b>Team Leader (TL)</b> and <b>Technical Assessors (TAs)</b> and/or <b>Technical Experts (TEs)</b> as team member by evaluating BAB listed assessors'/expert's profiles according to the requested scope of accreditation by CABs. Quality Manager assigns the team for the assessment using form no. QF 37</p> <p>CO informs the applicant CAB of the acceptance or rejection of the application and consent of the assessment team using QF22. The team starts work only after CAB's positive consent to BAB.</p> <p>If CAB objects to the assessment team or any member of the team BAB will give due considerations provided the reasons cited by the CAB are valid.</p>	<p><b>Director</b>  <b>CAB</b>  <b>Team Leader (TL)</b>  <b>Technical Assessor (TA)</b>  <b>Technical Expert (TE)</b></p> <p><b>AP03 Assessment Procedure</b>  <b>QF37 Assignment of Assessment</b></p> <p><b>QF22 CAB Consent to Assessor Nomination</b></p>
<b>4.5 Adequacy Audit</b>		
	<p><b>TL</b> examines the quality manual and seeks clarification on the issues/points from the CAB through CO when required.</p> <p><b>TL</b> does the adequacy audit of the CAB using the Adequacy Audit Checklists and Report Form (QF12) and submits the report to CO with his recommendations for pre-assessment or assessment.</p> <p>CO examines the report and informs the CAB of the recommendations of the <b>TL</b>, if any. After getting the responses from the applicant CAB, CO proceeds with the next steps.</p> <p>An Adequacy Audit only applies to a new applicant.</p>	<p><b>Team Leader (TL)</b>  <b>CAB</b>  <b>CO</b>  <b>QF12 Adequacy Audit Check List and Report Form</b>  <b>SP02 Accreditation Fee Schedule</b></p>

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<b>4.6 Pre-assessment</b>		
	<p>Pre-assessment is mandatory for new applicant CABs. For CABs accredited by an ILAC/IAF signatory, pre-assessment is optional.</p> <p>The CAB may request BAB for pre-assessment during application or later.</p> <p>Pre-assessment follows the same processes described in the section 4.8 below. An assessment is a must even if there are no findings in the pre-assessment.</p> <p>CAB is to respond to findings, if any, raised in the pre-assessment within the specified timeframe given on the assessment report. TL determines timeframe for responses to the findings in consultation with the applicant CAB. This is normally 90 days from the date of pre assessment. But extension of time is subject to the request from the CAB. CO receives the responses along with the evidence for actions taken and sends this report to the TL who closes out the findings and gives recommendation for assessment. CO in consultation with QM will take the decision. CAB in consultation with TL and CO, may request QM to include one or more TAs/ TEs in the pre assessment team.</p> <p>Pre-assessment activities are not for AC review.</p>	
<b>4.7 Document Review</b>		
	<p>The team reviews the documents at least 7 days before assessment and reassessment. If the applicant CAB is not interested to send the associated documents with the application, the assessment team will conduct on site document review. This is subject to the payment as per BAB Fee Schedule.</p> <p>But BAB encourages the CABs to send the associated documents with application.</p> <p>The requested scope(s) of accreditation are reviewed and agreed between the CAB and the CO at this point to determine the possibility of going further with the assessment.</p>	<p>CO            TL            AP03 Assessment Procedure</p>
<b>4.8 Assessment</b>		
	<p>CO is responsible to communicate with TL, TA/ TE and CAB. TL is responsible to organize the assessment. CO gives Assessor Kit (QF32) to fresh assessor/ expert. The team works following this and other relevant procedures. And submits their assessment report to the CO at BAB office in the prescribed form. CO duly informs Director/QM of the results of the assessment.</p>	<p>Director/QM            CO            TL            TA/TE            AP03 Assessment Procedure            AP02 Assessment Preparation            QF 32 Assessor Kit</p>

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<b>4.9 Joint Assessments</b>		
	<p>BAB occasionally works with other ILAC/IAF signatory accreditation bodies in the delivery of joint assessments. Normally, these assessments may result in two separate certificates of accreditation based on the work of the assessors from both bodies.</p>	<b>Director/QM</b> <b>CO</b>
	<p>In most instances, joint assessments are conducted by joint teams with assessors from both accreditation bodies and one designated as the <b>Team Leader (TL)</b>.</p>	<b>AP03 Assessment Procedure</b>
	<p>In all cases, BAB will forward its proposed scope of accreditation to the other accreditation body for review prior to completing its review of CAB responses.</p>	
<b>4.10 Acceptance of Responses</b>		
	<p>CAB is to respond to findings, if any, raised by the assessment team within the specified timeframe given on the assessment report. This is normally 90 days from the date of assessment of a new applicant CAB and 30 days for a reassessment.</p>	<b>CO</b> <b>TL/Assessor/Technical Expert</b> <b>QF04 Assessment Finding Form</b>
	<p>Every assessment finding is generally recorded as a single assessment finding in Assessment Finding Form (QF04). The CAB responds to BAB using this same form and sends it to the CO with the evidences for close out of NCs, if any. Additionally, the CAB duly signs and submits a summary of responses to the findings using Finding Response Form (QF38).</p>	<b>QF38 Finding Response Form</b>
	<p>CO receives the responses along with the evidence for actions taken and sends this report to the team members respective of whoever raised the findings during the assessment for close out and comments. The <b>TL</b> of the assessment team signs the report, provided meeting the requirements satisfactory, and sends it to CO. <b>TL</b> closes out the findings in consultation with the <b>Assessor/ Technical Expert</b>, if any in the team.</p>	
	<p>During closing out of findings by the team if more information need be, CO will communicate with CAB for further information. After successfully completion of findings CO accepts the response by signing off in the appropriate place in each QF04 assessment finding form and proceeds with the next steps.</p>	

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<b>4.11 Technical Review Followed by Decision Taken by Accreditation Committee (AC)</b>	<p>Director/QM in consultation with CO will select and appoint members for AC using of AC Terms of Reference (AD03).</p> <p>The primary function of AC is to ensure that the accreditation process has been conducted in accordance with procedures - AP01 and AP03, and the integrity of BAB accreditations is upheld. Secondly, it undertakes a technical review of accreditation files in question following the agreement of BAB staff and the CAB on the close out of all findings with responses the BAB staff and assessors deem appropriate. Finally, the committee makes decision in QF33 with a recommendation to be approved by DG for, or against, the accreditation of the CAB applicant based on the contents of the file being reviewed.</p> <p>AC should refrain from conducting their own “assessment” of the CAB being reviewed.</p> <p>The CO acts as Secretary and thus, compiles necessary documents and records into files from AC Meetings.</p> <p>For each individual accreditation case a separate AC may be formed or a single AC may review and decide on multiple cases on a single occasion.</p>	<p>Director/QM            CO            Accreditation Committee(AC)            AD03 AC ToR            QF33 Accreditation Committee Ballot            AP13 Accreditation Decision Making</p>
<b>4.12 Approval and Issue of Accreditation Information Document</b>	<p>The recommendation with decision of the AC is forwarded to the DG for approval and signing.</p> <p>On approval from the DG, CO prepares accreditation information documents i.e. accreditation certificate and scopes of accreditation according to the relevance of accreditation schemes (as described in clause 7.8.3 of ISO/IEC 17011:2017). Then QM checks both certificate and scope of accreditation and signs on the scope of accreditation.</p> <p>Then the file is forwarded to DG for signing the accreditation certificate.</p> <p>Before issuing the accreditation certificate CO shall ensure that all dues are paid by the CABs. Withholding accreditation is subject to the pending of dues.</p> <p>The CO informs the CAB of the accreditation decision and issuance of accreditation information documents as soon as practicable and arranges to publish those information on BAB website.</p>	<p>DG            QM            CO            CAB</p>



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<b>4.14 Yearly Surveillance Assessment</b>		
	<p>Though the accreditation given to a CAB is valid for three years, still BAB keeps a watch on its accredited CABs to ensure that they continue to abide by BAB's norms. It is for this reason to determine if the accredited CABs have been working on the basis of its approved quality system and have been abiding by the BAB's conditions for maintaining accreditation. BAB as per its policy organizes annual <b>surveillance assessment</b> for its accredited CABs.</p> <p>Surveillance assessment would be through either onsite visit or without visit (desktop). CO and TL in consultation with QM decide(s) on the mood of surveillance and the related method(s) (and sampling methods). Outcome of the surveillance assessment would be properly documented to justify the continuation of accreditation or any subsequent changes.</p> <p>Depending on the recommendations of <b>either</b> assessment team (more specifically TL), <b>CO and QM based on the outcome of surveillance assessment</b>, DG may continue, suspend or withdraw accreditation <b>partly or wholly</b>.</p> <p>BAB can also organize additional visits to the premises of the CAB if it has reasons to do so, for example; receiving information about unethical practices at the CAB and breaching of terms and conditions of accreditation.</p>	<b>CO</b> <b>QM</b> <b>AP03 Assessment Procedure</b> <b>CAB</b>  <b>DG</b>
<b>4.15 Validity of Accreditation</b>		
	<p>The accreditation given to the CAB is valid for three years, and the CAB is required to apply for accreditation at least TWO months in advance <b>of expiry</b> to make it possible for BAB to complete the reassessment and be able to communicate its decision to the applicant. If an application is not received two months in advance then it is quite possible that discontinuity in its accreditation status may result.</p>	<b>CO</b> <b>CAB</b> <b>DG</b> <b>SP01 Terms and Conditions for Accreditation</b>
<b>4.16 Reassessment</b>		
	<p>Procedure for reassessment remains the same as of assessment. See section 4.8 Assessment.</p> <p>Section 4.10-4.13 would be applicable after reassessment in order to continue, suspend or withdraw accreditation including reduction of scopes.</p> <p>CAB can also voluntarily request for a reduction, suspension, or extension of scope of accreditation during or before reassessment.</p>	<b>Director/QM</b> <b>CO</b> <b>TL</b> <b>Assessor/Technical Expert</b> <b>AP03 Assessment Procedure</b> <b>AP02 Assessment Preparation</b> <b>QF 32 Assessor Kit</b>
<b>4.17 Extraordinary Continuation of Accreditation</b>		
	<p>In the event that an accreditation is in jeopardy of expiry, through no fault of the CAB, the DG may extend it for up to 60 days, based on the recommendation of the CO and QM.</p>	<b>DG</b> <b>QM</b> <b>CO</b>

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<b>4.18</b>	<p><b>Extraordinary Visits</b></p> <p>BAB may conduct an extraordinary visit (verification <b>assessment</b>) to a CAB in the event that it undergoes any significant changes, such as a move of the lab or other changes in the structure or operating environment of the CAB that may have significant impact on the test results.</p> <p>Verification visits may also be warranted for cause in the event that information has been received by BAB, concerning the CAB, which may result in a loss of confidence regarding its conformance to requirements.</p> <p>Verification visits follow the processes contained in Sections 4 through 10 above and the CAB is expected to respond to any findings raised in order to retain its accreditation within 30 days from the date of verification visit.</p> <p>Any changes to the scope of accreditation that may be necessitated by a verification visit will follow the procedures for the examination of the process by <b>AC</b> described above in Sections 11 above.</p> <p>If the verification visit results in no changes to the scope of accreditation of the CAB, it may be concluded by the DG on the recommendation of the CO and QM.</p>	<p><b>CO</b>  <b>AP03 Assessment Procedure</b>  <b>CAB</b>  <b>TL/TATE</b>  <b>QF04 Assessment Finding Form</b></p>
<b>4.19</b>	<p><b>Scope Extension</b></p> <p>On request from a CAB for extension of accreditation scope, BAB either can do it in the next reassessment, if reassessment is <b>not within next three months; BAB may</b> arrange assessment for extension of accreditation scope prior to next reassessment.</p> <p>Scope extensions will normally require the complete set of visit and follow up activities described in Sections 4.4 through 4.10 above. In the event that the <b>CAB</b> has requested to add something for which a visit may not be needed, or which is simple extension of competence already demonstrated, then the DG may approve such a minor extension on the basis of a recommendation from the CO and QM.</p>	<p><b>CO</b>  <b>AP03 Assessment Procedure</b>  <b>CAB</b></p>

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<b>4.20 Complaints, Disputes and Appeals</b>		
	<p>CABs may submit a complaint for any issue that concerns them. See QP04 – Feedback.</p> <p>If a CAB is not satisfied with any adverse decisions made by BAB officials &amp; assessors, they may submit a dispute or appeal in accordance with AP05 – Disputes and Appeals.</p> <p>BAB has appointed the <b>Director/QM</b> to investigate all disputes and appeals. Where the <b>Director/QM</b> is not independent of the subject of the appeal, another staff member is appointed to fill the role.</p> <p>All disputes and appeals would be handled by the procedure. See QP05- Disputes and Appeals.</p> <p>For all appeals, an Appeal Panel is convened to adjudicate it. The <b>Director/QM</b> serves as secretary to this panel and:</p> <ul style="list-style-type: none"> <li>• will advise the CAB of the final decision(s) of BAB</li> <li>• Implements follow-up action where required. and</li> </ul> <p>The decision of the Government shall be final for the appeal under this section.</p> <p>The <b>Director/QM</b> decides on the dispute and the decision is reviewed by the DG.</p>	<p><b>QP04 Feedback</b></p> <p><b>QP05 Disputes and Appeals</b></p> <p><b>Chairman [of the Board]</b></p> <p><b>DG</b></p> <p><b>Government [Ministry of Industry]</b></p>
<b>4.21 Records</b>		
	<p>BAB maintains records for its accredited CABs for as long as the CAB remains accredited by BAB. Records of its accredited CABs <b>for the last</b> term of accreditation are archived and retained for ten years. Also BAB maintains the records for any CABs that are no longer accredited for five years and these are destroyed thereafter. BAB retains such records as long as it is required in those cases where there is any dispute between BAB and a CAB. After retention time the records are destroyed as per respective procedure.</p> <p>BAB publishes a directory of accredited CABs along with scope of accreditation on its website and it is updated regularly as and when needed.</p>	<p><b>CO</b></p> <p><b>QM</b></p> <p><b>QP08 Handling and Control of Records</b></p>