

**GENERAL INFORMATION
FOR
LABORATORY ACCREDITATION**

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1.0 LABORATORY ACCREDITATION

Laboratory accreditation is a procedure by which an authoritative body gives formal recognition of technical competence for specific tests/ measurements, based on third party assessment and following international standard and if any, national standards.

In the current global scenario an essential pre-requisite of trade is that any product or service accepted formally in one economy must also be free to circulate in other economies without having to undergo extensive re-testing. WTO recognizes that non acceptance of test results and measurement data is a Technical Barrier to Trade. Global sourcing of components calls for equivalence of measurement, which can be facilitated by a chain of accredited calibration laboratories. Accreditation is considered as the first essential step for facilitating mutual acceptance of test results and measurement data.

Confidence in accreditation is obtained by a transparent system of control over the accredited laboratories and an assurance given by the accreditation body that the accredited laboratory fulfils the accreditation criteria, at all times.

Accredited laboratories can objectively state conformance of product or service to specified requirements. It is important for the purchaser, regulator, government, and the public to be able to identify accredited testing and calibration laboratories.

Laboratory accreditation plays an important role in social sectors such as Medical, Food, Environmental and Forensic Science testing laboratories and in export sectors where products and goods are necessitated to test prior to exporting.

2.0 KINDS OF LABORATORY ACCREDITATION:

- Testing and Calibration Laboratory According to ISO/IEC 17025
- Medical Laboratory According to ISO 15189

3.0 BENEFITS OF ACCREDITATION

Formal recognition of competence of a laboratory by an Accreditation body in accordance with international criteria has many advantages:

- Increased confidence in Testing/ Calibration Reports issued by the laboratory.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- Potential increase in business due to enhanced customer confidence and satisfaction.
- Customers can search and identify the laboratories accredited by BAB for their specific requirements from the BAB Directory of Accredited Laboratories.
- Users of accredited laboratories will enjoy greater access for their products, in both domestic and international markets, when tested by accredited laboratories.
- Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.

4.0 ABOUT BAB

Bangladesh Accreditation Board (BAB) is an autonomous body with the aegis of Ministry of Industries, Government of Bangladesh by the Bangladesh Accreditation Act, 2006.

BAB has been established with the objective to provide Government, Industry Associations and Industry in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories Government of Bangladesh has authorized BAB as the sole accreditation body for Testing and Calibration laboratories and Medical laboratories.

In order to achieve this objective, BAB provides laboratory accreditation services to laboratories that are performing tests/ calibrations in accordance with ISO/IEC 17025. (General Requirements for the Competence of Testing and Calibration Laboratories) & medical laboratory based on ISO 15189. These services are offered in a non-discriminatory manner and are accessible to all testing and calibration laboratories in Bangladesh and abroad, regardless of their ownership, legal status, size and degree of independence.

BAB has established its Accreditation System in accordance to ISO/IEC 17011 and international MRA requirements.

6.0 INTERNATIONAL LINKAGES

BAB maintains its linkages with the international bodies like Asia Pacific Laboratory Accreditation Cooperation (APLAC), the International Laboratory Accreditation Co-operation (ILAC), the Pacific Accreditation Cooperation (PAC), and the International Accreditation Forum (IAF).

BAB is a Full Member of APLAC and Affiliate Member of ILAC. BAB has been signatory to the APLAC/ILAC Mutual Recognition Arrangements (MRA) for its following scheme(s):

- Testing and Calibration Laboratory According to ISO/IEC 17025 Since 2015

BAB has applied for the MRA for Medical Testing Laboratory (ISO 15189) and Inspection Body (ISO/IEC 17020) and that is in process.

In order to achieve the objective of the acceptance of test/ calibration data across the national borders, BAB operates and is committed to update its laboratory accreditation system as per international norms.

7.0 POLICY FORMULATION ORGANS OF BAB

7.1 The Board

BAB is constituted by 14 members from different ministries and professional bodies. The Board is headed by a Chairman whose responsibilities include presiding over meetings of the Board and maintaining a general oversight of the organization to ensure implementation of policies and decisions. Chairman is nominated by the government.

Functions are:

- Responsible for the overall accreditation program.
- Set policies and approval of rules and regulations for its operation.
- Responsible to ensure that the financial affairs of the organization are under control and properly reported.
- May appoint sub-committees for specific tasks and may also appoint technical committees to provide technical advices and recommendations for various sectoral activities.

To see updated list, please visit www.bab.org.bd

7.2 Organizational Structure

- **BAB Secretariat**

BAB Secretariat coordinates the entire activities of accreditation services for laboratories and its office are located at: Ministry of Industries 5th Floor, 91 Motijheel C/A, Dhaka-1000.

- **Team Leader (TL)**

The Lead Assessor is overall responsible for conducting the assessment of the applicant laboratory including evaluating the adequacy audit, conducting pre-assessment, final assessment & for submission of the assessment report to BAB.

- **Technical Assessor (TA)**

BAB has empanelled experts in various fields of testing and calibration and medical testing from organizations all over Bangladesh. These experts are trained by BAB or by equivalent APLAC/ILAC MRA member AB's on laboratory accreditation and audit techniques. BAB assessors evaluate the Technical Competence and Quality System of the laboratories for its compliance to ISO/IEC 17025, ISO 15189 and supplementary explanations.

- **Technical Review Panel**

Technical Review Panel (TRP) evaluates the assessment reports submitted by **Team Leader (TL)**. For different field of accreditation, different TRP will be responsible.

- **Technical Committee**

The Technical Committees (TC) examines the assessment reports prepared by the **Team Leader (TL)** and already assessed by Technical Review Panel (TRP). TC makes recommendation to the DG, BAB regarding the Accreditation of the laboratory concerned. It has been created in a manner so as to maximize the uniformity of interpretation and judgment. Balance of interest is kept in mind while framing such committee.

- **Appeals Committee**

When the complaints and disputes raised against BAB have not been to the satisfaction of laboratory, they are having the option to raise a dispute or an appeal to the BAB. The board may constitute a committee to look in to the grievances of the appellant. The Committee is impartial and its resolutions are binding on both the parties.

8.0 SCOPE OF ACCREDITATION

BAB gives accreditation to the **TESTING & CALIBRATION LABORATORIES** according to ISO/IEC 17025 for the following fields. (Also mentioned in AF01)

Fields of Testing	
	Biological Testing
	Chemical Testing
	Construction Materials Testing
	Electrical Testing
	Electro-technical Measurements Testing
	Food and Microbiological Testing
	Textile Testing
	Pharmaceutical testing
	Information and Communications Technology Testing
	Environmental Testing
	Mechanical Testing
	Mechanical Measurements Testing
	Non-destructive Testing
	Plant Health Testing
	Forensic Testing
	Veterinary Testing
	Metrology
	Optics & radiometry
	Heat & Temperature measurement
	Acoustic & vibration measurement
Fields of calibration	
	Mechanical Calibration
	Electro-technical Calibration
	Thermal Calibration

BAB gives accreditation to the **MEDICAL LABORATORIES** according to ISO 15189 for the following fields. (Also mentioned in AF02)

Fields of Accreditation	
	Clinical Biochemistry
	Clinical Pathology
	Hematology and Immunology
	Clinical Microbiology
	Clinical Chemistry
	Serology and Immunology
	Histopathology
	Cytopathology
	Genetics
	Nuclear Medicine (in-vitro tests only)

The accreditation granted to a laboratory shall remain valid for a period of 3 years subject to satisfactory annual **surveillance assessment**. Laboratory has an option to widen the scope of accreditation in terms of specific tests and calibration, at any time. **BAB conducts annual surveillance through reassessment for medical laboratory.**

BAB has established policies and procedures for granting, suspending and withdrawal of accreditation in accordance with ISO/IEC 17011.

Directory of BAB Accredited Laboratories is available in the website www.bab.org.bd, which contains laboratories' contact details and information on their Scope of Accreditation.

9.0 ASSESSMENT CRITERIA

The laboratories seeking accreditation are assessed on the basis of its capacity to perform test(s)/ calibration(s) and provide accurate and reliable results, in accordance with ISO/IEC 17025 and ISO 15189 and relevant BAB requirements.

A laboratory wishing to be accredited by BAB must have a documented Quality System, satisfying the requirements as described in various clauses of ISO/IEC 17025 for testing and calibration laboratory and ISO 15189 for medical laboratory.

Quality System documentation and its implementation by the laboratories shall be verified by the Assessors for its compliance in accordance with the relevant standards.

The laboratory shall be able to demonstrate to the BAB Assessment Team that all requirements as laid down in the ISO/IEC 17025 and ISO 15189, BAB requirements and other Guidelines.

10.0 MODIFICATION TO THE ACCREDITATION CRITERIA

If the accreditation criteria are modified by ILAC/APLAC/BAB, the laboratory shall be informed of this in writing giving a transition period agreed internationally to align itself in accordance with the modified criteria.

11.0 PREPARING FOR ACCREDITATION

Laboratory management should first decide about getting accreditation for its laboratory from BAB. It is important for a laboratory to make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation. The person nominated should be familiar with laboratory's existing quality system.

A request can be made to BAB Secretariat for procurement of relevant BAB documents. Clarifications on the document to be procured may be obtained from BAB Secretariat in person, by post/ or on telephone. The laboratory should get fully acquainted with all BAB documents and understand the assessment procedure & methodology before making an application.

Laboratory needs to ascertain the status of its existing quality system and technical competence with regards to requirements for BAB.

- Is your existing documented quality system adequate or does it need modification?
- Do you need to build the quality system from scratch?

12.0 PREPARING FOR ACCREDITATION

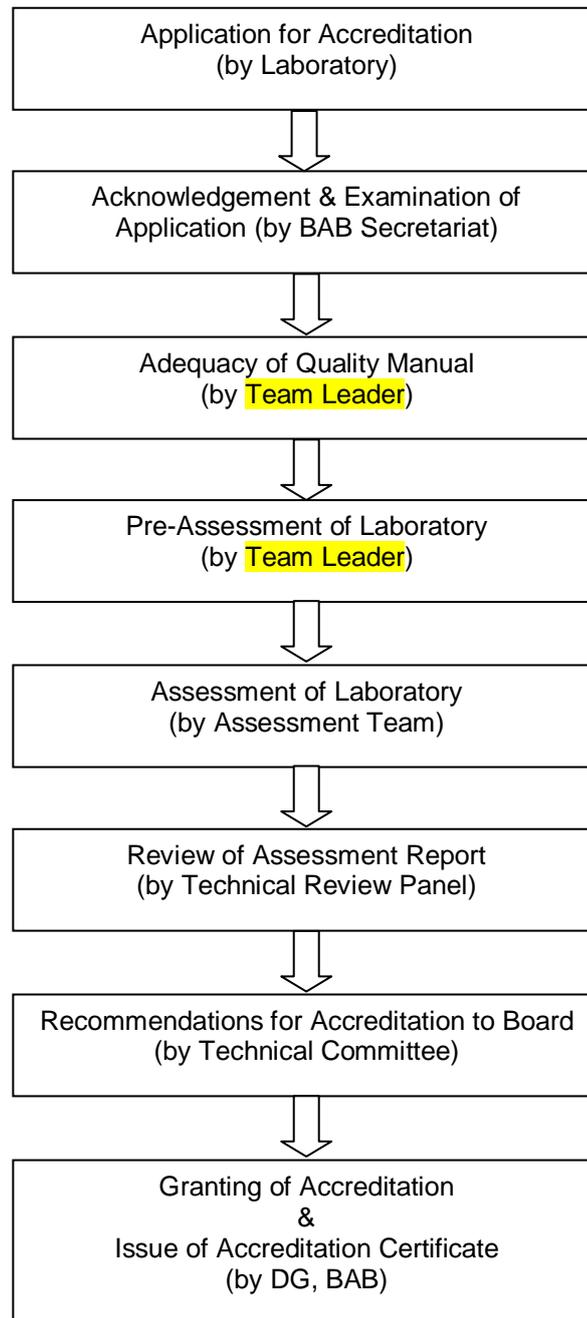
- It must be remembered that quality manual is a policy level document, which has to be supplemented by a set of other documents like procedural manuals, work instructions etc. to align the quality system in accordance with the standards and BAB supplementary explanations.
- Relevant requirements for BAB accreditation should be discussed amongst concerned staff of the laboratory. This will BAB them to understand their weaknesses and strengths.
- The laboratory must ensure that the procedures described in the Quality Manual and other documents are being implemented.

For preparing the quality manual or verifying its contents, the laboratory may get its technical personnel trained on quality system management and internal audit based on the relevant standards.

13.0 ELIGIBILITY FOR ACCREDITATION

	Testing and Calibration laboratories	Medical laboratories
Must comply with all clauses of International Standard	ISO/IEC 17025- General requirements for the competence of testing and calibration laboratories	ISO 15189- Medical laboratories -- Particular requirements for quality and competence
Participation in proficiency testing (PT)/ External Quality Assurance (EQA)/ Interlaboratory Comparisons (ILC) program recognized by BAB	Prior to grant of accreditation: At least one parameters/ type of test per discipline	Prior to grant of accreditation: At least one parameters/ type of test per discipline
NOTE: The satisfactory performance shall be defined in term of Z score (testing) and En number (calibration). For unsatisfactory performance, the laboratory shall take corrective action and inform BAB.	To maintain accreditation: At least one parameter/ type of test/ calibration per discipline per year.	To maintain accreditation: At least one parameters/ type of test per discipline in every quarter (03 months)
FURTHER REFERENCE(S): <ul style="list-style-type: none"> • ISO/IEC 17043, and • AP08 BAB PT Policy 	However, wherever possible, full scope shall be covered in entire accreditation cycle.	However, wherever possible, full scope shall be covered in entire accreditation cycle.
Internal Audit (Must have been conducted before the submission of application)	At least one	At least one
FURTHER REFERENCE(S): ISO 19011-Guidelines for auditing quality system		
Management Review (Must have been conducted before the submission of application)	At least one	At least one

14.0 ACCREDITATION PROCESSES



15.0 FINANCIAL TERMS & CONDITIONS

Please see “SP02 Accreditation Fees Schedule” available on BAB website www.bab.org.bd

16.0 CONTACT ADDRESSES:

Secretariat:

Ministry of Industries building (5th Floor)
91, Motijheel C/A
Dhaka-1000
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Tel: 880 - 2 – 9513223-6
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