Accreditation Process

Part 1

INTRODUCTION

Accreditation is defined as a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry specific tests, calibrations or inspections. Accreditation is available to any type of testing laboratory (including medical), calibration laboratory and inspection body.

The general requirements for accreditation are the following international standards:

- PNS ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories
- PNS ISO/IEC 17020:2012 Conformity Assessment- Requirements for the operation of various types of bodies performing inspection
- PNS ISO 15189:2012 Medical Laboratories – Requirements for quality and competence

Additional requirements for specific fields (e.g. calibration, chemical testing, etc.) or specific programs, which are necessary to meet particular user needs, complement these general requirements.

The PAB accreditation covers the following field:

Chemical Testing	Medical/Clinical Testing
Biological Testing	Calibration
Electrical Testing	
Mechanical Testing	

Users of accredited laboratories and inspection bodies are advised to obtain the Scope(s) of Accreditation from the accredited laboratory and inspection body or from PAB. The Scope(s) of Accreditation identifies the specific tests or types of tests or calibration capability for which the laboratory or inspection body is accredited.

Part 2

CONDITIONS FOR ACCREDITATION

In order to attain and maintain accreditation, laboratories and inspection bodies must comply with the PAB Conditions for Accreditation.

The applicant laboratory's inspection body's Authorized Representative must agree to the conditions for accreditation and must attest that all statements made on the application are correct to the best of his/her knowledge and belief. He/she must accomplish Acceptance of Accreditation Conditions (LA/SF27) and submit to PAB together with the other application requirements.

An accredited laboratory's Authorized Representative is responsible for ensuring that all of the relevant conditions for accreditation are met. During the on-site assessment, the assessor will determine that the Authorized Representative and a deputy are knowledgeable about the

accreditation requirements and require that the Authorized Representative and a deputy sign a statement that the Conditions for Accreditation will be upheld.

Part 3

ACCREDITATION PROCESS

3.1 The First Step

When considering to seek PAB accreditation, laboratory or inspection body management should examine this document LA/GD01 – Accreditation Process, the international standards mentioned in Part 1 of this document, Supplementary Requirements and other Guidance Documents (GDs) issued by PAB in the relevant field of testing, calibration and inspection.

Laboratory or inspection body management is encouraged to hold discussion (personal, thru e-mail or phone call) with the PAB technical staff before lodging an application for accreditation. If a pre-assessment is desired at this stage, an informal review of the major elements of the laboratory's resources, procedures and documentation is undertaken. A completed assessors' briefing (LA/SF06) and application form (LA/SF03) should be submitted for review together with the laboratory's Quality and Procedures manuals.

3.2 Application for Accreditation

Applications for accreditation may be made only by legally identifiable organizations. A laboratory or inspection body applying for accreditation shall submit the necessary forms and documents:

- Application for Accreditation/Reaccreditation
- Quality Manual and Procedures Manual
- Test Method/Calibration Method/Inspection Method (for In-House Methods)
- Application for Signatory Approval with updated CVs and summary of trainings
- Assessors' Briefing and associated document required
- Acceptance of Accreditation Conditions

Only complete application will be schedule for assessment. For PAB schedule of fees refer to LA/GD20.

3.3 Authorized Representative

The applicant or accredited laboratory/inspection body should nominate the authorized representative who should represent the organization in all matters relating to the accreditation. This person is the official contact of the laboratory/inspection body.

3.4 Scope of Accreditation

An application should clearly define the scope and in the form of a series of classes of test or parts thereof. Each field of testing has been divided into a series of classes of test. The classes of test are listed in relevant reference material. For tests, the scope of accreditation is normally identified in terms of standard test methods prepared by national, international, and professional standards writing bodies. For calibrations, the scope of accreditation is described typically in terms of measurement parameter, range of measurement and best attainable uncertainties (calibration measurements capabilities).

3.5 Assessment

The Team Leader/Lead Assessor in coordination with the Program Manager/Accreditation Officer shall organize an assessment team. The Director/Officer-in-Charge appoints the assessment team. The assessment team reviews the quality manual and related documentation before assessment can begin.

Compliance of an applicant laboratory/inspection body with the accreditation requirements is determined primarily by an assessment of its resources, procedures and documentation. The basic objective of the assessment is to establish whether a laboratory or inspection body can competently perform the tests for which accreditation is sought.

Assessment is carried out by a team, which begins with an opening meeting, led by a Team Leader/Lead Assessor who may be a PAB Accreditation Assessor or a qualified external assessor. The team includes technical assessor/expert (s), selected for the relevance of expertise and freedom from conflict of interest.

Assessments are conducted in a day and may extend to more and include detailed discussions with laboratory/inspection body management and personnel, inspection of equipment and premises, and examination of documentation and records. Assessors normally witness some or all of the tests/calibration/inspection activity covered by the accreditation or applied for accreditation.

A closing meeting is held at the completion of the assessment. The authorized representative is provided with a written report on the on-site assessment findings, including details related to any corrective action required before accreditation can be granted.

3.6 Deficiencies

During assessment, assessors may observe deficiencies. A deficiency is any nonconformity to accreditation requirements. Refer to LA/GD 06: Guidelines on Grading of Non-conformities.

3.6.1 During the presentation of the report to the laboratory/inspection body, all non-conformities and any observations shall be fully discussed, including the time scales agreed to or set by the Team Leader/Lead Assessor for implementation of the corrective actions on the non-conformities.

3.6.2 The laboratory/inspection body is informed that corrective actions to assessment findings shall be submitted two (2) months from the date of the on-site assessment. Subsequent corrective actions if required by the assessors shall be completed by the laboratory/inspection body, evaluated and cleared by the assessors within four (4) months from the date of initial assessment. Entire accreditation process must be completed within five (5) months.

3.6.3 The laboratory/inspection body is given opportunity to clarify the findings and to offer alternative suggestions. At the close of the meeting, mutually acceptable date for completion of corrective actions is agreed, sufficient to bring the laboratory's/inspection body's technical and/or management systems into compliance with the criteria for accreditation.

3.7 Accreditation Decisions

The Officer-in-Charge/Director approves the accreditation upon the recommendation by the Laboratory Accreditation Committee (LAC). This is based on the laboratory's or inspection body's complete assessment documentations and assessment report endorsed by the assessment team through the Division Manager/Program Manager.

3.8 Proficiency Testing

Proficiency testing is a process for checking actual laboratory testing performance, usually by means of inter-laboratory test data comparisons or measurement audit for calibration. For many tests and calibrations, results from proficiency testing are very good indicators of competence. Proficiency testing programs may take many forms and standards for satisfactory performance can vary depending on the field and is used to compliment on-site assessment in evaluating laboratory performance. Satisfactory performance is a condition for granting accreditation. For details on the requirements for proficiency testing refer to LA/SR09: Supplementary Requirements on Proficiency Testing.

3.9 After Accreditation

An accredited laboratory must continue to comply with the requirements in the documents listed in Section 1, including their revisions.

The authorized representative is required to notify the PAB immediately of:

- Any changes in name or ownership of the laboratory;
- Changes on duties, resignations of staff; or
- Significant changes to accommodation or equipment,
- Relocation of laboratory/inspection body facilities

Accredited laboratories/inspection bodies are subject to two (2) surveillance visits. The first surveillance visit is done within twelve (12) months from the date of initial assessment. The second surveillance visit is conducted not later than the 22nd month after the first surveillance visit.

There will only be two surveillance assessments within 5 years but during the 2nd and 4th year of the accreditation, the accredited laboratory/inspection body shall be required to submit their internal audit report, management review report, proficiency testing (PT) participation and their results and (PT) proficiency testing plan one (1) month after the conduct of laboratory's/inspection body's management review.

The PAB may conduct additional visit when the following scenarios occur:

- Request from the laboratory or inspection body
- Unsatisfactory result in proficiency testing participation
- No action plans formulated during the management review

3.10 Reassessment and Renewal of Accreditation

Accredited laboratories/inspection bodies are subject to reassessment every five (5) years. Accredited laboratory/inspection body that intends to renew its accreditation shall file application for renewal six (6) months before the validity expires. Application documents are specified in 3.2 of this document.

A reassessment of a laboratory/inspection body resembles an initial assessment in all aspects except on the review of previous assessment findings; in that, it is a full assessment of the laboratory's/inspection body's operations and procedures.

3.11 Extension or Variation to the Scope of Accreditation and Additional Signatory

An accredited laboratory/inspection body may request for increase of its scope of accreditation or add approved signatory at any time and shall officially notify PAB of its intention including the following documents:

For additional scope or subscope, an accredited laboratory/inspection body shall submit the following:

- Application for Special Assessment
- Assessors' Briefing
- Application for Signatory Approval with updated CV and summary of training
- Test Method/Calibration Method/Inspection for In-House Methods
- Application for Signatory Approval with updated CV and summary of training

For additional signatory, an accredited laboratory/inspection body shall submit the following:

- Application for Special Assessment
- Application for Signatory Approval with updated CV and summary of training

PAB makes the necessary adjustments and changes in the Directory of Accredited Laboratories/Inspection Bodies based on amendments in scope of accreditation or list of approved signatories.

3.12 Laboratory Reference to PAB Accredited Status

The requirements pertaining to the use of the PAB symbol and to any other reference to PAB accreditation are outlined in the LA/SR11 (PAB Requirements for the Use of PAB Laboratory Accreditation and Inspection Body Accreditation Symbols). Failure to comply with these requirements may result in suspension or revocation of a laboratory's accreditation.

3.13 Suspension of Accreditation

3.13.1 The following are the grounds for suspension of accreditation:

a) When an accredited laboratory/inspection body signifies that it is temporarily unable to comply with the accreditation requirements.
b) When an assessment reveals that an accredited laboratory/inspection body has failed to comply with the requirements for accreditation and corrective action cannot be taken/ submitted within the specified time to achieve full compliance. (Note: Submission of corrective actions is one (1) month for surveillance visit and special assessment; two (2) months for initial and renewal assessment)
c) When the accredited laboratory/inspection body fails to submit its annual reports (i.e. Internal Audit Report, Management Review, annual PT plan and participation results).
d) When the accredited laboratory/inspection body have two (2) consecutive unsatisfactory PT results due to ineffective corrective actions on the affected scope.
e) Inappropriate use of PAB accreditation symbol (Refer to LA/SR11 PAB Requirements for the Use of PAB Laboratory Accreditation and Inspection Body Accreditation Symbols).

f) When the laboratory or inspection body fails to pay its Billing Statements two (2) months from its due date, this includes Assessment Fees, Annual Fees, and Accreditation Fees.

3.13.2 A accredited laboratory or inspection body whose accreditation is suspended is still required annual accreditation fees and any special assessment fees associated with the reactivation of accreditation.

3.13.3 A accredited laboratory or inspection body whose accreditation is suspended shall be directed to remove from public view Certificates of Accreditation, Scope of Accreditation, and cease issuing endorsed reports. The laboratory or inspection body shall also be directed to cease referring to itself as a PAB Accredited laboratory or inspection body in any documents, brochures, catalogues, correspondence, etc, that it issues within the period of suspension. Refer to LA/SR11 PAB Requirements for the Use of PAB Laboratory Accreditation and Inspection Body Accreditation Symbols.

3.13.4 When accreditation is suspended or withdrawn, all reference to the accredited laboratory or inspection body shall be deleted from any subsequent directories of accredited laboratories or inspection bodies issued by PAB.

3.13.5 Suspended accreditation can be reactivated only after the laboratory/inspection body has submitted to PAB proof that it is able to comply with the accreditation criteria, or after PAB has verified compliance.

3.14 Withdrawal of Accreditation

Accreditation shall be withdrawn if the laboratory/inspection body fails to achieve full compliance, declines to take appropriate corrective action within six (6) months from the date of the suspension; does not intend to renew its accreditation at the end of the accreditation period; and voluntarily declares non-interest in accreditation within the accreditation period.

An accredited laboratory/inspection body whose accreditation is withdrawn shall return to PAB the Original Certificate of Accreditation, List of Approved Signatories and Scope of Accreditation.

The laboratory/inspection body shall be directed to immediately cease referring to itself as a PAB accredited laboratory/inspection body in any documents, brochures, catalogues, correspondence, etc. that it issues after the date of withdrawal of accreditation.

The laboratory/inspection body shall also be directed to notify all customers and all other persons who may have been previously notified of its accreditation that its accreditation has been withdrawn.

Reactivation of accreditation shall be done only after a full assessment is conducted and the laboratory is found to comply with the accreditation criteria. The laboratory/inspection body shall reapply and pay all the required fees and other costs that may be entailed during the assessment.

A laboratory/inspection body whose accreditation is suspended or withdrawn may appeal this decision.

3.15 Confidentiality Policy

All information provided by the laboratory in connection with a preliminary inquiry or an application for accreditation and all information obtained in connection with an assessment or proficiency test is confidential. PAB Accreditation Officers/staff, assessors and experts who examine such information are made aware of its confidentiality and are required to sign a confidentiality agreement with the PAB.

Documents necessary to convey information about accredited laboratories and their scopes of accreditation are not confidential.

3.16 Conflict of Interest Policy

Consistent with principles set forth in ISO/IEC 17011:2004 - General requirements for accreditation bodies accrediting conformity assessment bodies, it is vital that PAB accreditation services be impartial and objective, uninfluenced by the private interests of individuals acting for PAB. Accordingly, any person directly involved in actions relating to the PAB accreditation process shall avoid direct participation in PAB actions that may involve an actual or apparent conflict of interest.

Part 4

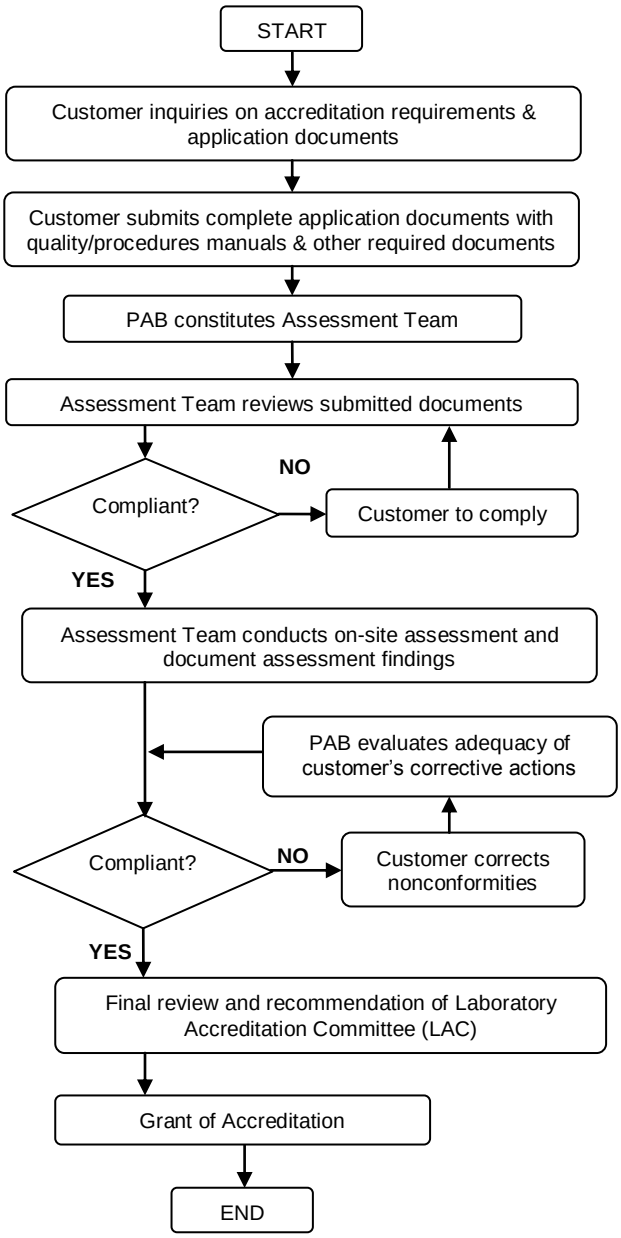
APPROVED SIGNATORY

An Approved Signatory is any laboratory/inspection body personnel who have satisfied the criteria listed in LA/GD07 Guidelines for Laboratory Personnel and Approved Signatories and have been granted signatory approval by the PAB.

PAB-endorsed documents shall be signed by a PAB approved signatory. The validity and completeness of endorsed documents are the responsibility of the Approved Signatory.

Part 5

ACCREDITATION PROCESS



ISSUE AND AMENDMENT RECORD

Title	Issue	Date	Amendments
Accreditation Process	01	January 2015	Initial Issue