

Accreditation Process

Foreword

This Philippine Accreditation Bureau Laboratory Accreditation Guidance Document for Accreditation Process was developed to provide clear guidelines in processing an accreditation based on a specific scheme under the Laboratory Accreditation Division.

The 8th issuance of this document was made to reflect the following updates:

- Inclusion of Hybrid assessment in the accreditation process*
- Alignment of accreditation process with ARTA requirements*

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 Conformity Assessment Bodies (CABs) - testing laboratory (including medical), calibration laboratory, inspection body *and proficiency testing provider*.

The general requirements for accreditation are the following international standards:

- ISO/IEC 17025 (General Requirements for the Competence of Testing and Calibration Laboratories)
- ISO/IEC 17020 (Conformity Assessment- Requirements for the operation of various types of bodies performing inspection)
- ISO 15189 (Medical Laboratories – Requirements for quality and competence)
- ISO/IEC 17043 (Conformity assessment – General requirements for proficiency testing)

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

CONDITIONS FOR ACCREDITATION

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

CABs should nominate an Authorized Representative who will represent the organization and will be the official contact person of PAB in all matters relating to the accreditation. The 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 knowledge and belief. The Authorized Representative must accomplish Acceptance of Accreditation Conditions (PAB/SF06) and submit to PAB together with the other application requirements.

The CABs 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.

ACCREDITATION PROCESS

When seeking for PAB accreditation, CABs management should be aware of this document, applicable international standards, supplementary requirements and guidance documents issued by PAB.

CABs are encouraged to discuss with a PAB technical staff before lodging an application for accreditation. A preliminary visit may be conducted with the agreement of the CAB. Normally, a preliminary visit is conducted due to a new applicant CAB or a new scope is being applied to verify the activity/process. A preliminary visit form *should* be used to indicate the evaluation.

Application for Accreditation

Application for accreditation shall be made only by legally identifiable organizations. CABs applying for accreditation shall submit the necessary forms and documents:

- Application for Accreditation (LA/SF02) together with the supporting documents
- Applicable Assessment Checklist
- Acceptance of Accreditation Conditions (PAB/SF06)
- Uncertainty Budget Computation for the scopes applied (for Calibration)
- Management and Technical Documents (See Annex A of LA/SF01 Application Requirements)

Only complete application shall be processed for document review. If there are any findings during document review, applicant CAB shall respond to these findings and can only be endorsed for assessment once cleared and/or completed. Applicant CAB will only be scheduled for assessment when document review is done.

At any point in the application or assessment process, if there is any violation in the Terms and Conditions of PAB Accreditation. PAB shall reject the application or terminate the assessment process.

Scope of Accreditation

CABs should clearly define the scope and described in more detail and usually include reference to specific determinations/matrix type, analytical techniques and relevant standard/in-house methods. (Refer to Classification of Scopes). For calibrations, the scope of accreditation is described typically in terms of measurement parameter, range of measurements and best attainable uncertainties (calibration measurement capabilities). Accreditation for these scopes may be granted that is suitable to the concerned authority.

On-site/ Remote / Hybrid Assessment

The Accreditation Officer in consultation with the concerned Program Manager/Accreditation Officer will organize an assessment team and approved by the Director. The assessment team reviews the application documents submitted before assessment can begin.

Compliance of CAB with the accreditation requirements is determined primarily by an assessment of its activity/process, resources, and implemented management system. The basic objective of the assessment is to establish whether a CAB can demonstrate technical competence in the scope applied and have sound quality management system.

Assessment is carried by a team, which begins with an opening meeting, led by a Team Leader. The team includes technical assessor/expert (s) selected for the relevance of expertise and free from any conflict of interest. The assessor/expert(s), shall undertake their assessment based on their assignments.

Note: CAB has the opportunity to oppose any particular team members or observers. CAB shall provide a formal letter indicating the reason with supporting justification and this will be reviewed accordingly by the *Division Chief* for approval.

Assessments are conducted *within* a day and may *be extended depending on the applied scopes of accreditation and signatories*. Technical assessor/expert(s), *should* witness some or all the scope of activities covered by the accreditation.

A closing meeting is held *to conclude* the assessment. The authorized representative is provided with a report on the assessment findings, including details related to any corrective actions required before accreditation be granted.

Refer to LA/GD09 – Guidance Document for Remote/*Hybrid* Assessments for the specific guidelines on the conduct of remote/*hybrid* process.

Assessment Findings and Evaluation

During assessment, assessment team may observe some deficiencies. A deficiency is any nonconformity to accreditation requirements. (Refer to LA/GD02 Guidelines on Grading of Nonconformities).

During the presentation of the report, all nonconformities and observations shall be fully discussed including the agreed timeframe for implementation of the corrective actions on the findings raised. CABs are given opportunity to clarify the findings.

CABs are informed that corrective actions with *root* cause analysis and objective evidence to assessment findings shall be submitted thirty (30) calendar days from the date of closing meeting. Subsequent corrective actions, if required by the assessors, shall be completed including evaluation and clearance made by the assessment team within the prescribed period. Entire accreditation process *should* be completed within six (6) months. Exceeding the six (6) months processing *may* either discontinue the assessment or suspend the accreditation of CABs.

Accreditation Decision

The Director approves the accreditation upon the recommendation from the final evaluation process. This is based on the CABs complete assessment documentations and assessment report endorsed by the assessment team.

Surveillance Visits

Accredited CABs are subject to surveillance visits. First surveillance visit will be conducted fifteen (15) months after the date of granting the accreditation. Succeeding surveillance visit will be conducted with a *fifteen* month scheduled interval from the date of granting of accreditation.

Renewal of Accreditation

Accredited CABs are subject to reassessment every five (5) years. Accredited CABs that intends to renew its accreditation shall file application for renewal at least seven (7) months before the validity of accreditation. Required documents to be submitted are the same as listed in the application for accreditation.

Extension of Scope of Accreditation and/or Additional Signatory

Accredited CABs may request for additional scope of accreditation or additional signatory approval at any time.

For additional scope or sub-scope and additional signatory, an accredited CAB shall submit the Application for Accreditation (LA/SF02) together with the supporting documents.

PAB updates the list of accredited CABs in PAB website.

CABs Reference to PAB Accreditation Status

The requirements pertaining to the use of the PAB symbol and to any other reference to PAB accreditation are outlined in the LA/SR03 (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.

Also, the Authorized Representative is required to notify PAB immediately when the following circumstances occur:

- Any changes in the name or ownership that affects the legal identity of CAB;
- Changes on duties, resignation of PAB approved signatory;
- Significant changes to accommodation or equipment; and
- Relocation of CABs facilities.

Suspension of Accreditation

The following are the grounds for suspension of accreditation:

- When CABs signifies that it is temporarily unable to comply with the accreditation requirements;
- When an assessment reveals that accredited CABs failed to comply with the requirements for accreditation and corrective action cannot be completed within the specified time to achieve full compliance;
- When accredited CABs have two (2) consecutive unsatisfactory results in PT participation due to ineffective corrective actions on the affected scope (*for ISO/IEC 17025 and ISO 15189*);
- Inappropriate use and reference to the PAB Accreditation status and symbol;
- When accredited CABs failed to settle its billing statements one (1) month from its due date, including assessment fees, annual fees and accreditation fees, without justifiable reason.

An accredited CAB whose accreditation is suspended is still required *to settle its* annual accreditation fees and any special assessment fees associated with the reactivation of accreditation.

Suspended CABs shall be directed to remove from public view their certificates and cease on issuing endorsed reports. CABs shall also be directed to cease referring to itself as a PAB accredited CAB in any documents, brochures, catalogues, correspondence, etc. within the period of suspension.

Suspension of accreditation shall be lifted based on *any of* the following *as applicable*:

- CABs shall apply for a special assessment *within three (3) months from the date of suspension* and be recommended for continued accreditation *within six (6) months from the conduct assessment* (i.e. satisfactorily and adequately comply with the accreditation requirements);
- Nonconformities on the misuse of PAB accreditation symbol shall be cleared *within one (1) month from the date of suspension*; and
- Payments *obligation* shall be settled *within six (6) months* from the date of suspension.

Withdrawal of Accreditation

Accreditation shall be withdrawn if the CABs fail to achieve full compliance, declines to take appropriate corrective action and/or settle payment *obligation* 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.

CABs 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. Also, CABs 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.

Accreditation shall be done only after a full assessment is conducted and found to comply with the accreditation criteria. CABs shall apply *for initial assessment* and pay all the required fees and other costs that may be entailed during the assessment.

CONFIDENTIALITY

All information provided by CAB in connection with a preliminary inquiry or an application for accreditation and all information obtained in connection with an assessment are confidential. All personnel who examine such information are made aware of its confidentiality and are required to *abide with the* confidentiality agreement with the PAB.

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

CONFLICT OF INTEREST

Consistent with principles set forth in ISO/IEC 17011 (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 that may involve an actual or apparent conflict of interest.

ANNEX: ACCREDITATION PROCESS

