# INTRODUCTION

1. Purpose

This checklist is prepared for the following purposes:

* 1. To assist both the staff of the Conformity Assessment Body (CAB) and the assessment team in checking that all criteria for accreditation are satisfied.
	2. To index documentation of the quality system and use as part of the preparation for the introduction of ISO/IEC 17020:2012 and an assessment; and
	3. To provide essential background information for briefing PAB assessment team and relevant information during the assessment process.
1. Structure and Use of the Checklist
	1. Compliance with PAB General Requirements
	2. All PAB accredited CABs are required to comply with the accreditation requirements and the basic technical and management system requirements for CAB based on ISO/IEC 17020:2012.
	3. PAB needs to obtain and maintain information on the specific technical resources available in the laboratory and to be aware of the desired scope of the accreditation by PAB (the approved classification of scopes) and for approved signatories (the specific people authorized to sign PAB endorsed test reports).
2. Preparation of Documented Management System
	1. Each accredited CAB is required to implement a documented quality management system as one of the fundamental conditions for PAB accreditation.
	2. The documented quality management system includes all the policies and operational procedures established to meet requirements for accreditation.
	3. The manner in which a documented quality system is structured is the choice of the CAB. The purpose of the documentation is primarily to advice the staff of the policies and procedures expected by its management to be implemented by all staff.
	4. Typically, a quality management system is documented in a Quality Manual and supporting procedures and records. In some cases, a Quality Manual includes supporting procedures. In other cases, some of the subjects of a Quality Manual may be incorporated in an organization’s more general Quality Manual or procedures.

| **Clause** | **Requirements** | **Reference to CAB’s Documents and/or Information on the Implementation**(to be completed by the CAB) | **PAB Remarks** |
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| **4** | **General requirements** |
| **4.1** | **Impartiality and independence** |
| 4.1.1 | Inspection activities shall be taken impartially. |  |  |
| 4.1.2  | The inspection body shall be responsible for the impartiality of its inspection activities. |  |  |
| 4.1.3  | The inspection body shall identify risk to its impartiality on an ongoing basis. |  |  |
| 4.1.4  | The inspection body shall be able to demonstrate how it eliminates or minimizes risk. |  |  |
| 4.1.5  | The inspection body shall have top management commitment to impartiality. |  |  |
| 4.1.6 | Independent to the extent that is contractually required |  |  |
| a) | **Type A Inspection Body**Fully independent of all consulting, manufacturing involvement |  |  |
| b) | **Type B Inspection Body**A separate and identifiable part of an organization, established to supply inspection services to its parent organization only |  |  |
| c) | **Type C Inspection Body**A separate and identifiable part of an organization, may supply inspection services to other parties not being its parent organization |  |  |
| **4.2** | **Confidentiality** |
| 4.2.1  | Confidentiality and propriety rights Shall be legally responsible for the management of all information obtained or created during the performance of inspection activities. |  |  |
| 4.2.1   | IB shall inform the client of the information it intends to place in the public domain. |  |  |
| 4.2.1 | All information (except information that the client makes publicly or agreed between the IB and the client) are regarded as confidential. |  |  |
| 4.2.2  | The client of individual concern shall be notified if the IB is required by law or authorized by contractual commitment to release confidential information. |  |  |
| 4.2.3  | Information obtained from sources other than the shall be treated confidential. |  |  |
| **5.1** | **Administrative requirements** |
| 5.1.1 | The inspection body shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for all its inspection activities. |  |  |
| 5.1.2 | An inspection body that is part, of a legal entity involved in activities other than inspection shall be identifiable within that entity. |  |  |
| 5.1.3 | The inspection body shall have documentation which describes the activities for which it is competent. |  |  |
| 5.1.4 | The inspection body shall have adequate provision (eg insurance or reserves) to cover liabilities arising from its operations |  |  |
| Insurance | Insurer | Policy Number | Value | Expiry |
| Prof. Indemnity |  |  |  |  |
| Public liability |  |  |  |  |
| Other |  |  |  |  |
| 5.1.5 | The inspection body shall have documentation describing the contractual conditions under which it provides the inspection, except when it provides inspection services to the legal entity of which it is a part |  |  |
| **5.2** | **Organization and management** |
| 5.2.1 | The inspection body shall be structured and managed so as to safeguard impartiality. |  |  |
| 5.2.2 | The inspection body shall be organized and managed so as to enable it to maintain the capability to perform its inspection activities. |  |  |
| 5.2.3 | The inspection body shall define and document the responsibilities and reporting structure of the organization. |  |  |
| 5.2.4 | Where the inspection body forms a part of a legal entity performing other activities, the relationship between these other activities and inspection activities shall be defined. |  |  |
| 5.2.5 | The inspection body shall have available one or more person(s) as technical manager(s) who have overall responsibility to ensure that the inspection activities are carried out in accordance with this international Standard. |  |  |
| Where the inspection body has more than one technical manager, the specific responsibilities of each manager shall be defined and documented. |  |  |
| 5.2.6 | The inspection body shall have one or more named person(s) who will deputize in the absence of any technical manager responsible for ongoing inspection activities. |  |  |
| 5.2.7 | The inspection body shall have a job description or other documentation for each position category within its organization involved in inspection activities. |  |  |
| **6**  | **Resource requirements** |
| **6.1**  | **Personnel** |
| 6.1.1 | The inspection body shall define and document the competence requirements for all personnel involved in inspection activities, including requirements for education, training, technical knowledge, skills and experience, |  |  |
| 6.1.2 | The inspection body shall employ, or have contracts with, a sufficient number of persons with the required competencies, including, where needed, the ability to make professional judgements, to perform the type, range and volume of its inspection activities, |  |  |
| 6.1.3 | The personnel responsible for inspection shall have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the inspections to be carried out.  |  |  |
| 6.1.4 | The inspection body shall make clear to each person their duties, responsibilities and authorities. |  |  |
| 6.1.5 | The inspection body shall have documented procedures for selecting, training, formally authorizing, and monitoring inspectors and other personnel involved in inspection activities. |  |  |
| 6.1.6 | The documented procedures for training (see 6.1.5) shall address the following stages:a) an induction period; b) a mentored working period with experienced inspectors; c) continuing training to keep pace with developing technology and inspection methods. |  |  |
| 6.1.7 | The training required shall depend upon the ability, qualifications and experience of each inspector and other personnel involved in inspection activities, and upon the results of monitoring (see 6.1.8). |  |  |
| 6.1.8 | Personnel familiar with the inspection methods and procedures shall monitor all inspectors and other personnel involved in inspection activities for satisfactory performance. Results of monitoring shall be used as a means of identifying training needs (see 6.1.7). |  |  |
| 6.1.9 | Each inspector shall be observed on-site, unless there is sufficient supporting evidence that the inspector is continuing to perform competently. |  |  |
| 6.1.10 | The inspection body shall maintain r6cotds of monitoring, education, training, technical knowledge, skills, experience and authorization to each member of its personnel involved in inspection activities, |  |  |
| 6.1.11 | The personnel involved in inspection activities shall not be remunerated in a way that influences the results of inspections. |  |  |
| 6.1.12 | All personnel of the inspection body, either internal or external, that could influence the inspection activities shall act impartially. |  |  |
| 6.1.13 | All personnel of the inspection body, including sub-contractors, personnel of external bodies, and individuals acting on the inspection body's behalf, shall keep confidential all information obtained or created during the performance of the inspection activities, except as required by law. |  |  |
| **6.2** | **Facilities and equipment** |
| 6.2.1 | The inspection body shall have available, suitable and adequate facilities and equipment to permit all activities associated with the inspection activities to be carried out in a competent and safe manner. |  |  |
| 6.2.2 | The inspection body shall have rules for the access to, and the use of, specified facilities and equipment used to perform inspections. |  |  |
| 6.2.3 | The inspection body shall ensure the continued mentioned in 6.2.1 for their intended use. |  |  |
| 6.2.4 | All equipment having a significant influence on the results of the inspection shall be defined and, where appropriate, uniquely identified |  |  |
| 6.2.5  | All equipment (see 6.2.4) shall be maintained in accordance with documented procedures and instructions. |  |  |
| 6.2.6 | Equipment which have significant influence on the results calibrated before being put into service and calibrated according to an established program |  |  |
| 6.2.7 | Calibration program designed and operated so that applicable measurements are traceable to national and international standards of measurement |  |  |
| 6.2.8 | Reference standards used for calibration only, Reference standards calibrated providing traceability to a national or international standards of measurement |  |  |
| 6.2.9 | Equipment subjected to in-service checks between regular recalibrations |  |  |
| 6.2.10 | Reference materials traceable to national or international standard reference materials |  |  |
| 6.2.11 | Where relevant, procedures for:* Selection and approval of suppliers
* Verification of incoming goods
* Ensuring storage facilities
 |  |  |
| 6.2.12 | Stored items assessed at appropriate intervals to detect deterioration |  |  |
| 6.2.13 | Computers/automated equipment used in connection with inspections ensure:1. Computer software adequate
2. Procedures established and implemented for protecting integrity and security of data
3. Computer and automated equipment maintained
 |  |  |
| 6.2.14 | Procedures for dealing with defective equipment including examining the effect of defects on previous inspections |  |  |
| 6.2.15 | Equipment identification, calibration and maintenance records |  |  |
| **6.3** | **Subcontracting** |
| 6.3.1 | Where an inspection body subcontracts any part of the inspection, it shall ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in this International Standard or in other relevant conformity assessment standards. |  |  |
| 6.3.2 | Inform client of the intention to subcontract part of the inspection |  |  |
| 6.3.3 | Whenever subcontractors. Carry out \*work that forms part of an inspection, the responsibility for any determination of conformity of the inspected item with the requirements shall remain with the inspection body. |  |  |
| 6.3.4 | Record and retain subcontractors’ competence and conformity with applicable requirements of ISO/IEC 17020 or in other relevant conformity assessment standards |  |  |
| Maintain a register of all subcontractors |  |  |
| **7**  | **Process requirements** |
| 7.1  | Inspection methods and procedures |
| 7.1.1 | Use methods and procedures which are defined in the requirements against which inspection is to be performed |  |  |
| When methods and procedures are not defined, develop specific methods and procedures to be used |  |  |
| Inform client if method proposed by client is inappropriate |  |  |
| 7.1.2 | Use adequate documented instructions on inspection planning and on sampling and inspection techniques |  |  |
| Where applicable, have sufficient knowledge of statistical techniques |  |  |
| 7.1.3 | Non-standard methods or procedures used appropriate and fully documented |  |  |
| 7.1.4 | Instructions, standards or written procedures, worksheets, checklists and reference data maintained up to date and readily available |  |  |
| 7.1.5 | Contract or work order control system ensures:1. Work is within available expertise and adequate resources
2. Requirements adequately defined and special conditions understood so that unambiguous instructions can be issued to personnel
3. Work is controlled by regular review and corrective action
4. Requirements of the contract or work have been met
 |  |  |
| 7.1.6 | Verify integrity of information supplied by any other party as part of the inspection  |  |  |
| 7.1.7 | Observations or data obtained recorded in a timely manner |  |  |
| 7.1.8 | Calculations and data transfers subjected to appropriate checks |  |  |
| 7.1.9 | Documented instructions for carrying out inspection in a safe manner |  |  |
| **7.2** | **Handling inspection items and samples** |
| 7.2.1 | Ensure items and samples to be inspected are uniquely identified |  |  |
| 7.2.2 | Establish item to be inspected has been prepared |  |  |
| 7.2.3 | Apparent abnormalities recorded  |  |  |
| Contact the client about doubts as to the item’s suitability or where item does not conform to the description provided |  |  |
| 7.2.4 | Have documented procedures and appropriate facilities to avoid deterioration or damage to inspection items. |  |  |
| **7.3** | **Inspection records** |
| 7.3.1 | Maintain a record system to demonstrate the effective fulfilment of the inspection procedures and comply with applicable regulationsConsider:1. Contract review negotiations
2. Client/work instructions
3. All original notes and calculations taken by the inspector and/or other staff during an inspection
4. Original copies or negatives of photographs
5. The identity of the staff undertaking part(s) or the whole of the inspection
6. Computer data files and/or software programs
7. Reports on sampling, tests and measurements including copies of reports on sub-contracted inspection, sampling and/or testing work conducted
8. A copy of the inspection report and a record of its distribution
9. Records of all discussions with clients during or after the inspection relevant to the preparation of the inspection report
10. Date and time of inspection

Consider management of electronic records |  |  |
| Sufficient information to permit satisfactory evaluation of the inspection report |  |  |
| 7.3.2 | Inspection report or certificate traceable to the inspector(s) who performed the inspection |  |  |
| **7.4** | **Inspection report and inspection certificates** |
| 7.4.1 | Retrievable inspection report or inspection certificate |  |  |
| 7.4.2 | Inspection report/certificate include the following:1. Identification of the issuing body
2. Unique identification and date of issue
3. Date(s) of inspection
4. Identification of the item(s) inspected
5. Signature or other indication approval, by authorized personnel
6. A statement of conformity where applicable
7. The inspection results, except where detailed in accordance with 7.4.3

Optional elements of inspection reports and certificates:1. Designation of the document (i.e. as inspection report or inspection certificate)
2. Identification of the client
3. Description of the inspection work ordered
4. Information on what has been omitted
5. Identification or brief description of the inspection method(s) and procedure(s) used, mentioning the deviations
6. Identification of equipment used for measuring/testing
7. Reference to or description of the sampling method and information on where, when, how and by whom the samples were taken
8. Information on where the inspection was carried out
9. Information on environmental conditions during the inspection
10. A statement that the inspection results relate exclusively to the work ordered or the item(s) or lot inspected
11. A statement that the inspection report should not be reproduced, except in full
12. The inspector’s mark or seal
13. Names (or unique identification) of the personnel members who have performed the inspection and, in cases when secure electronic authentication is not undertaken, their signature
 |  |  |
| 7.4.3 | Issue an inspection certificate that does not include the inspection results only when inspection report containing the inspection results can be produced, and when both the inspection certificate and inspection report are traceable to each other |  |  |
| 7.4.4 | All information reported correctly, accurately, and clearly |  |  |
| Results supplied by subcontractors clearly identified in the inspection report or inspection certificate. |  |  |
| 7.4.5 | Record corrections or additions to an inspection report or inspection certificate |  |  |
| Identify the report or certificate replaced in amended report or certificate |  |  |
| **7.5** | **Complaints and appeals** |
| 7.5.1 | Documented process to receive, evaluate and make decisions on complaints and appeals |  |  |
| 7.5.2 | Description of the handling process for complaints and appeals available to interested  |  |  |
| 7.5.3 | Confirm whether the complaint relates to inspection activities and deal with it |  |  |
| 7.5.4 | Be responsible for all decisions at all levels of the handling process for complaints and appeals |  |  |
| 7.5.5 | Investigation and decision on appeals does not result in any discriminatory actions |  |  |
| **7.6** | **Complaints and appeals process** |
| 7.6.1 | Handling complaints and appeals include the following:1. Process for receiving, validating, investigating the complaint or appeal and deciding actions to be taken
2. Tracking and recording complaints and appeal, including actions undertaken
3. Appropriate action is taken
 |  |  |
| 7.6.2 | Responsible for gathering and verifying information to validate complaint or appeal |  |  |
| 7.6.3 | Acknowledge receipt of complaint or appeal and provide the complainant or appellant progress reports and outcome |  |  |
| 7.6.4 | Decisions communicated to the complainant or appellant are reviewed and approved by individuals not involved in the original inspection activities in question |  |  |
| 7.6.5 | Give formal notice of the end of the complaint and appeals handling process to the complainant or appellant |  |  |
| **8**  | **Management system requirements** |
| 8.1.1 | Establish and maintain a management system capable of achieving the consistent fulfilment of the requirements of ISO/IEC 17020 in accordance with either Option A or Option B |  |  |
| 8.1.2 | Option AThe management system shall address the following:* Management system documentation ( e.g. manual, policies, definition of responsibilities)
* Control of documents ( see 8.3)
* Control of records ( see 8.4)
* Management review ( see 8.5)
* Internal audit ( see 8.6)
* Corrective actions ( see 8.7)
* Preventive actions ( see 8.8)
* Complaints and appeals ( 7.5 and 7.6)
 |  |  |
| 8.1.3 | Option BIB that has established and maintains a management system in accordance with the requirements of ISO 9001 and is capable of supporting and demonstrating the fulfilment of ISO/IEC 17020 fulfills the management system clause requirements ( see 8.2 to 8.8 ) |  |  |
| 8.2.1 | Top management establish, document, and maintain policies and objectives  |  |  |
| Ensure policies and objectives are acknowledged and implemented at all levels  |  |  |
| 8.2.2 | Top management provide evidence of commitment to the development and implementation of the management system and its effectiveness |  |  |
| 8.2.3 | Top management appoint a member of management with the responsibility and authority that include the following:1. Ensuring that processes and procedures are established, implemented and maintained
2. Reporting to top management on the performance of the management system and any need for improvement
 |  |  |
| 8.2.4 | All documentation, processes, systems, records are included, referenced, or linked to documentation of the management system. |  |  |
| 8.2.5 | All personnel involved in inspection activities have access to the parts of the management system documentation and related information applicable to their responsibilities. |  |  |
| **8.3** | **Control of documents ( Option A )** |
| 8.3.1 | Establish procedures to control documents |  |  |
| 8.3.2 | Procedures define the controls needed to:1. Approve documents for adequacy prior to issue
2. Review and update and re-approve documents
3. Ensure that changes and the current revision status of documents identified
4. Ensure relevant versions are available at points of use
5. Ensure that documents remain legible and readily identifiable
6. Ensure that documents of external origin are identified and distribution controlled
7. Prevent unintended use of obsolete documents, apply suitable identification if retained for any purpose
 |  |  |
| **8.4** | **Control of records ( Option A )** |
| 8.4.1 | Establish procedures to define controls needed for identification, storage, protection, retrieval, retention time and disposition of records |  |  |
| 8.4.2 | Establish procedures for retaining records for a period consistent with its contractual and legal obligations |  |  |
| Access to records consistent with the confidentiality arrangements |  |  |
| **8.5** | **Management review ( Option A )** |
| 8.5.1 | General |  |  |
| 8.5.1.1 | Top management establish procedures to review its management system at planned intervals |  |  |
| 8.5.1.2 | Management review conducted at least once a year. Complete review broken into segments be completed within a 12-month time frame. |  |  |
| 8.5.1.3 | Records of review maintained |  |  |
| 8.5.2 | Review InputsThe input include the following:1. Results of internal and external audits
2. Feedback from clients and interested parties
3. Status of preventive and corrective actions
4. Follow-up actions from previous management review
5. Fulfilment of objectives
6. Changes that could affect the management system
7. Appeals and complaints
 |  |  |
| 8.5.3 | Review outputsManagement review outputs include decisions and actions related to:1. Improvement of the effectiveness of the management system and its processes
2. Improvement of the inspection body
3. Resource needs
 |  |  |
| **8.6** | **Internal audits ( Option A )** |
| 8.6.1 | Establish procedures for internal audits |  |  |
| 8.6.2 | Planned audit programme taking into consideration the importance of processes and areas audited, as well as results of previous audits |  |  |
| 8.6.3 | Conduct periodic internal audits covering all procedures |  |  |
| 8.6.4 | Internal audits performed at least once every 12 months |  |  |
| 8.6.5 | Ensure that:1. Internal audits are conducted by qualified personnel
2. Auditors do not audit their own work
3. Personnel responsible for the area audited are informed of the outcome of the audit
4. Any actions resulting from internal audits are taken in a timely and appropriate manner
5. Any opportunities for improvement identified
6. The results of the audit are documented
 |  |  |
| **8.7** | **Corrective actions ( Option A )** |
| 8.7.1 | Establish procedures for identification and management of nonconformities  |  |  |
| 8.7.2 | Take actions to eliminate the causes of nonconformities in order to prevent recurrence |  |  |
| 8.7.3 | Corrective actions appropriate to the impact of the problems encountered |  |  |
| 8.7.4 | Procedures define requirements for the following:1. Identifying nonconformities
2. Determining the causes of nonconformity
3. Correcting nonconformities
4. Evaluating the need for actions to ensure that nonconformities do not recur
5. Determining the actions needed and implementing them in a timely manner
6. Recording the results of actions taken
7. Reviewing the effectiveness of corrective actions
 |  |  |
| **8.8** | **Preventive actions ( Option A )** |
| 8.8.1 | Establish procedures for taking preventive actions |  |  |
| 8.8.2 | Preventive actions appropriate to the probable impact of the potential problems |  |  |
| 8.8.3 | Procedures for preventive actions define the requirements for the following:1. Identifying potential nonconformities and their causes
2. Evaluating the need for action to prevent the occurrence of nonconformities
3. Determining and implementing the action needed
4. Recording the results of actions taken
5. Reviewing the effectiveness of the preventive actions taken
 |  |  |

| **PAB Supplementary Requirements** | **Reference to CAB’s Documents and/or Information on the Implementation**(To be completed by the CAB) | PAB Remarks |
| --- | --- | --- |
| LA/SR 01 (Supplementary Requirements for Participation to Proficiency Testing) |  |  |
| LA/SR 02 (Supplementary Requirements on Traceability of Measurement) |  |  |
| LA/SR 03 (Supplementary Requirements on the Use of PAB Laboratory and Inspection Body Accreditation Symbol) |  |  |
| ILAC-P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies |  |  |