



**MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA**

**ACCREDITATION POLICY 4 (AP 4) -
POLICY ON THE REQUIREMENTS FOR KEY PERSONNEL
OF CONFORMITY ASSESSMENT BODIES**

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**JABATAN STANDARD MALAYSIA
DEPARTMENT OF STANDARDS MALAYSIA**

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Introduction

This document provides requirements to Conformity Assessment Bodies (CABs) on management of key personnel. The purpose of this document is to provide assurance that personnel involved in issuing and authorising reports and conducting audits are competent.

1 Scope

1.1 This document outlines the policy of the Department of Standards Malaysia (JSM) with regards to requirements of key personnel of applicants and accredited CABs.

1.2 This document shall be read in conjunction with other related accreditation criteria and applicable to all JSM accreditation schemes but not limited to as follows:

- a) *Skim Akreditasi Makmal Malaysia (SAMM)* for testing and calibration laboratories;
- b) The Scheme for the Accreditation of Certification Bodies (ACB);
- c) Malaysia Inspection Bodies Accreditation Scheme (MIBAS);
- d) Malaysia Proficiency Testing Provider Accreditation Scheme (MyPTP);
- e) The Scheme for the Accreditation of Validation and Verification Bodies (MyV&V).

1.3 The requirements related to key personnel for SAMM Medical Testing laboratories will refer to SC 2 – Specific Criteria for Accreditation in the Field of Medical Testing and SC 2.1 – Specific Criteria for Accreditation in the Field of Medical Molecular Testing.

1.4 The requirements related to key personnel for Primary Healthcare Laboratory Accreditation Scheme (PHLAS) will refer to its manual.

2 Normative reference

2.1 ISO/IEC 17011 - Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.

Note: Unless otherwise specified, reference to the latest edition of the document applies.

3 Definition

3.1 Key personnel

Internal or external individuals authorised by the CAB to carry out conformity assessment activities. For the purpose of this document, key personnel refer to any of the following functions, where applicable:

- a) Approved signatory
- b) Auditor
- c) Validator
- d) Verifier

3.2 Approved signatory

A person who is formally approved by the CAB responsible for the issuance and authorisation of reports performed by an accredited CAB. An approved signatory may be a resident or non-resident signatory.

Note: Approved signatory is not applicable for ACB Scheme and MyV&V.

3.3 Resident signatory

A signatory working full-time in the accredited CAB or in another section/department within the same organisation at the same location.

3.4 Non-resident signatory

A signatory who is a part-time employee of the accredited CAB or a signatory from another branch of the accredited CAB. A non-resident signatory has contractual arrangements with the accredited CAB.

3.5 Auditor

A person who conducts an audit for certification body.

[Source: ISO/IEC 17021-1:2015]

4 Approved signatory

4.1 The report issued by a CAB for conformity assessment activities conducted shall be reviewed and authorised by an approved signatory.

4.2 An approved signatory is responsible for the technical validity and accuracy of all information contained in the report.

4.3 It is the responsibility of the CAB to ensure the competency and the authorisation of approved signatory. The CAB shall have a procedure for determining the competence criteria and the approval process of the signatories.

4.4 The qualification and competency of the signatory that has been approved by the CAB shall be verified by the assessment team during the assessment.

4.5 The CAB shall maintain the list of their current approved signatories indicating their status as resident or non-resident. It is the responsibility of the CAB to ensure that the CAB has an approved signatory for each scope it is accredited at any time.

4.6 When significant changes occur, (i.e. no signatory available for the accredited scope that affects accreditation status) JSM shall be promptly notified. The status of accreditation shall be made inoperative if there is no approved signatory for specific fields.

4.7 Approved signatory is not considered as a personnel qualification and is not transferable from one accredited organisation to another. The CAB shall withdraw the status of approved signatory when the personnel leave the organisation.

4.8 For conformity assessment activities regulated by regulatory authorities, the approved signatory shall comply with the relevant requirements set by the regulatory authorities.

4.9 The CAB shall maintain the necessary records and make it readily available when requested by JSM.

4.10 The CAB shall ensure the competency of the approved signatory taken into account the following attributes:

- a) Relevant qualification and work experience (see 4.11);
- b) Position in organisation structure;
- c) Familiarity with the principles of CAB services or operation;
- d) Knowledge of accreditation standards and other related requirements;
- e) Understanding of the methods/protocols/specifications for specific accreditation scheme /field;
- f) Familiarity with the management system of the CAB;
- g) The evaluation of measurement uncertainties for the accreditation sought or held, where applicable;
- h) Knowledge of the procedure for recording, reporting and reviewing results; and
- i) Knowledge of the need to maintain integrity and impartiality in conduct of conformity assessment activities.

4.11 Qualification and work experience of approved signatory

4.11.1 Generally, the education, professional qualification and work experience of the approved signatory are stated in the respective accreditation criteria for the specific accreditation schemes/fields.

4.11.2 Where the education, professional qualification and work experience of the approved signatory are not stated in the respective accreditation criteria for the specific accreditation schemes/fields, the CAB shall ensure the approved signatory possess the following education qualification and working experience:

- a) SPM or equivalent in science or technical stream, with at least eight (8) years of experience working in the relevant fields; or
- b) STPM or diploma in science or equivalent discipline, with at least three (3) years working experience in relevant fields; or and
- c) Degree holders in science or equivalent discipline with at least six (6) months relevant working experience in relevant fields.

4.11.3 Working at least three (3) months in the current CAB.

4.11.4 For MIBAS, clause 4.11.2 is not applicable. The competence criteria for approved signatory with regard to qualification, training, experience and knowledge of the requirements of the inspection activities shall be determined by the inspection body.

4.12 Continual professional development

The approved signatory shall participate in continual professional development through in-house and external activities at least sixteen (16) hours in a year for example method development and validation, review and update of test procedure, training, presentation of papers, attending seminars and lectures etc.

4.13 Legal requirements for authorisation of report

4.13.1 These requirements shall be read in conjunction with any other legal requirements relating to the authorisation of report. Authorisation of approved signatory does not absolve the signatory and the CAB from complying with legal requirements relating to the authorisation of the report. Compliance with legal requirements shall be the sole responsibility of the signatory and the CAB.

4.13.2 The CAB shall maintain the necessary records and make it readily available when requested by JSM.

4.14 Non-resident signatory

4.14.1 Generally, approved signatories are resident signatories. The CAB may appoint a non-resident signatory, if the need arises.

4.14.2 An accredited CAB shall only appoint a non-resident signatory if the accredited CAB has a resident signatory.

4.14.3 Should the accredited CAB lose the service of the resident signatory, the CAB may continue its use of the non-resident signatory for a maximum of 6 months from the date of the resident signatory leaves the organisation. The status of accreditation shall be made inoperative if no replacement is made after the stipulated period.

4.14.4 A non-resident signatory shall have effective communication with the CAB and is aware of the CAB's current operation. The CAB shall maintain records of communication such as dates, topics and issues discussed, interaction with on-site staff and recommendations, advice or instruction given are kept.

4.14.5 Formal arrangement between the CAB and the non-resident signatory shall be established. The arrangement shall define the functions, responsibilities and authority in particular those of an approved signatory shall be clearly defined.

4.14.6 For MIBAS, clause 4.14 non-resident signatory is not applicable.

5 Certification Bodies' (CBs) auditor

5.1 Generally, the requirements for key personnel follow the requirements specified in the respective standards or International Accreditation Forum (IAF) Mandatory Documents (MD). However, the scheme owner may define additional requirements.

5.2 The following programmes have additional requirements as specified by the scheme owner:

- a) Food Safety Management Systems (FSMS),
- b) Hazard Analytical Critical Control Point (HACCP),
- c) Good Manufacturing Practice (GMP), and
- d) Anti-Bribery Management Systems (ABMS).

5.3 Requirements for FSMS, HACCP and GMP auditors

5.3.1 Initial assessment

- a) CB auditors are required to participate and pass the Ministry of Health (MOH) food safety training as follows:

Programme	Training on ACB-GMP	Training on ACB-HACCP
Good Manufacturing Practices for Food	✓	Not applicable
HACCP Systems	✓	✓
Food Safety Management Systems (FSMS)	✓	✓

- b) Qualified auditors will be issued a certificate by MOH that is valid for three (3) years.

5.3.2 Maintenance of accreditation

- a) The certificate issued by MOH is renewable without re-examination subject to the auditor's having conducted a minimum of three (3) audits per programme within the certificate validity. The auditor is required to submit their audit log and other relevant documentation to MOH for renewal of certificate.
- b) Qualified auditors that have not conducted the minimum three (3) audits as per 5.3.2 a) within the three (3) year validity period, shall re-take and pass the MOH food safety training.

5.3.3 Schedule of accreditation

JSM will issue the schedule of accreditation with a link that contains a list of auditors whom have successfully passed the MOH training. The CB shall update the list immediately when there are any changes to the list of auditors.

5.4 Requirements for Anti-Bribery Management Systems (ABMS) auditors

5.4.1 Competence requirements

In addition to the requirements as stated in the related accreditation criteria, the CB shall comply with the following requirements:

a) Integrity vetting (*Tapisan keutuhan*)

- i) During application, the CB shall submit the name of their auditors (permanent and contract) to JSM for Malaysian Anti-Corruption Commission (MACC)'s integrity vetting.
- ii) The CB shall ensure that auditors undergo integrity vetting every three (3) years. It is the responsibility of the CB to submit the name of their auditors to JSM when the three (3) years are due.
- iii) The CB shall inform JSM of any changes in their auditors. The CB shall also ensure that all new auditors have undergone integrity vetting prior to ABMS auditing for the CB.

b) Training/course for auditor of CB

- i) The auditors shall attend in-class training in Malaysia Anti-Corruption Academy (MACA) which the training includes the:
 - Introduction of MS ISO 37001 Anti-Bribery Management System;
 - Malaysian Anti-Corruption Commission Act 2009;
 - Penal Code, Criminal Procedure Code;
 - Anti-Money Laundering;
 - Anti-Terrorism Financing and Proceeds of Unlawful Activities Act 2001 (AMLATFPUAA);
 - Case studies;
 - Internal control; and
 - Corruption Risk Management (CRM) etc.
- ii) The auditors shall attend any training conducted by MACC if there is any new development of the mentioned areas.
- iii) During extraordinary circumstances, MACC or MACA may decide to conduct the training online.

5.4.2 Schedule of accreditation

JSM will issue the schedule of accreditation with the link that contains a list of auditors whom have successfully attended the MACA training and passed the integrity vetting. The CB shall update the list immediately when there are any changes to the list of auditors.

6 Liabilities

An accredited CAB shall assume full liability on all reports/certificates issued.