



# DEPARTMENT OF STANDARDS MALAYSIA SCHEME FOR THE ACCREDITATION OF CERTIFICATION BODIES (The ACB Scheme)

# ACB 1

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# TERMS AND CONDITIONS GOVERNING THE SCHEME FOR THE ACCREDITATION OF CERTIFICATION BODIES (ACB)

**Authority To Issue** 

Director General Department of Standards Malaysia

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#### 1. INTRODUCTION

- 1.1 The Terms and Conditions Governing the Scheme for the Accreditation of Certification Bodies (ACB Scheme) are applicable to all accredited certification bodies and applicants.
- 1.2 ACB gives formal recognition to certification bodies that have been independently assessed and found to comply with the criteria established by Department of Standards Malaysia (Standards Malaysia). Accreditation is granted for specific certification activities of a certification body.
- 1.3 This document shall be read in conjunction with the relevant ACB accreditation criteria:
  - a) Act 549 Standards of Malaysia Act 1996 incorporating latest amendment Act A1425 of the year 2012
  - b) ISO/IEC 17011 Conformity assessment Requirements for accreditation bodies accrediting conformity assessment bodies
  - c) IAF MD 7 IAF Mandatory Document for Harmonization of Sanctions to be applied to Conformity Assessment Bodies
  - d) CAB 1 Confidentiality
  - e) CAB 2 Complaints
  - f) CAB 3 Appeals
  - g) CAB 4 Suspension and Withdrawal of Accreditation
  - h) ACB Policy series, ACB accreditation criteria and/or other documents that may be issued/endorsed as ACB requirements relating to specific certification activities of certification bodies.

NOTE: For dated references, only the edition cited applies. For undated references the latest edition of the referenced document (including amendments) applies.

#### 2. **DEFINITIONS**

- 2.1 For the purpose of this document, in addition to the definitions in the relevant ISO standards, the following definitions and abbreviations shall also apply.
  - (a) **Accreditation**: Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
  - (b) Certificate of accreditation A certificate issued by the Director-General of Standards Malaysia under Act 549 to a certification body that the certification body is recognized as competent to perform audit on specific programmes under ACB.
  - (c) **Schedule:** A schedule issued with a certificate of accreditation listing those accredited scopes under accreditation programmes that

Standards Malaysia has recognized the certification body is competent to perform.

- (d) ACB accreditation criteria: Includes the appropriate accreditation standard, and all Standards Malaysia approved policies and procedures at the time of application, and those approved from time to time subsequent to accreditation, that are applicable to the accreditation programmes.
- (e) ACB Symbol: Symbol issued by Standards Malaysia under the Scheme for the Accreditation of Certification Bodies (ACB Scheme) to be used by accredited certification bodies to indicate they are accredited.
- (f) **Assessment**: Process undertaken by an accreditation body to determine the competence of a CB, based on standard(s) and / or other normative documents for a defined scope of accreditation.
- (g) **Assessor**: Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a CAB.
- (h) **Certification:** Third-party attestation related to products, process, system or persons.
- (i) Malaysian Standards and Accreditation Council, MSAC (hereinafter referred to as the Council): An independent advisory council who advises the Minister and approves all accreditation schemes, criteria and programmes.
- (j) National Accreditation Committee (NAC): A committee established by the MSAC and has been delegated by the MSAC to perform specific functions relating to accreditation and to make recommendations on specific matters to the MSAC.

## 3. AUTHORITY FOR GRANTING OF ACB ACCREDITATION

# 3.1 General

- 3.1.1 Under the ACB Scheme, the Director General of Standards Malaysia is responsible for all policies and decisions affecting the accreditation of certification bodies including the granting, maintaining, extending, renewal reducing, suspending, withdrawing and reinstatement of accreditation.
- 3.1.2 The Director General of Standards Malaysia grants, maintains and renews accreditation to certification bodies which:
  - (a) are legally identifiable and operational;
  - (b) enters into a legally enforceable agreement with Standards Malaysia;
  - (c) complies with the ACB requirements, accreditation criteria and any other undertakings as Standards Malaysia may require; and

(d) pay such fees as are due to Standards Malaysia in the manner prescribed by Standards Malaysia Fee Schedule.

# 3.2 Criteria of competence, procedure and amendment of conditions:

- 3.2.1 Standards Malaysia reserves the right to:
  - (a) prescribe relevant policies and procedures and criteria against which the certification body shall be assessed.
  - (b) set the relevant accreditation criteria based on international standards, such as ISO or IEC, adopted or directly used, or other international harmonized documents, against which a certification body shall be assessed. Standards Malaysia reserves the right, if necessary, to formulate its own guidelines or to adopt/use the relevant international interpretive guidelines for assessment of compliance.
  - (c) specify procedures for which application for accreditation shall be made, the conditions for <u>granting</u>, maintaining, extending, renewing, reducing, suspending, <u>withdrawing</u> or <u>reinstating</u> accreditation.
  - (d) amend any part of ACB criteria, if in the opinion of Standards Malaysia such amendments are necessary to maintain the credibility of the ACB Scheme. In the event of such amendments, reasonable time shall be given to certification bodies to carry out the necessary adjustments to their management system in order to comply with the amended criteria.
    - Unless otherwise specified, a period of six (6) months from the date of notification of change by Standards Malaysia shall be given for certification bodies to carry out the necessary adjustments to their system.
  - (e) select any assessor to form an assessment team as part of a mechanism to maintain Standards Malaysia's impartiality.

# 3.3 Processing and granting of accreditation

- 3.3.1 The process and granting of accreditation are as follows:
  - (a) Applicants shall submit necessary documents as required by Standards Malaysia for the purpose of application for accreditation;
  - (b) An application for accreditation is valid for two (2) years from the date of acceptance of application and lapses by the end of the two-year period if accreditation has not been successful;
  - (c) Upon written request by the applicant certification body, Standards Malaysia reserves the right to extend the application period, as it deems appropriate;
  - (d) To proceed with compliance assessment, the certification body shall have certified at least three (3) clients;

- (e) Standards Malaysia will only consider the granting of accreditation upon satisfactory discharge of all nonconformities raised during the assessment:
- (f) Standards Malaysia will furnish an ACB Certificate of Accreditation and a Schedule of Accredited Scopes of Certification to certification bodies after it is satisfied that the certification bodies comply with these conditions and all ACB criteria:
- (g) Upon granting of accreditation, the certificate of accreditation is valid for five (5) years from the date of approval by the Director General of Standards Malaysia;
- (h) Under special circumstances, Standards Malaysia may also consider procedures and conditions under which accreditation may be transferred from one legal entity to another legal entity such as in a situation resulting from organizational restructure. Application for transfer will be considered on a case to case basis;
- (i) Standards Malaysia may consider changes/amendments to the certificate/schedule of accreditation such as, but not limited to:
  - i. Change of the name of the certification body or its organization structure:
  - ii. Change in its legal status;
  - iii. Change of address or premises;
  - iv. Merger or acquisition of an accredited certification body;
  - v. Change or increase in the number of standards covered under accreditation;
  - vi. Request for change in scope; and
  - vii. Change involving addition of branch offices in different geographical locations.

If in the opinion of Standards Malaysia or its authorized representatives, these changes constitute significant changes to the certification body's management system or affect its competence, Standards Malaysia reserves the right to conduct verification assessment or other forms of evaluation to confirm its continued compliance with ACB accreditation criteria;

- (j) All accredited certification bodies are listed in a directory of accredited certification bodies in Standards Malaysia website. The directory indicates the current accreditation status of the certification body;
- (k) At any point in the application or initial assessment process, if there is any evidence of fraudulent behavior, if the certification body intentionally provides false information or if the certification body conceals information, Standards Malaysia reserves the right to reject the application or terminate the assessment process; and
- (I) If the certification body is withdrawn or the application is terminated due to evidence of fraudulent behavior, the certification body is not allowed to reapply within two (2) years.

# 3.4 Reduction, Suspension and Withdrawal of Accreditation

- 3.4.1 Standards Malaysia may, at its discretion, reduce or suspend accreditation for the following:
  - (a) Violation of any terms and conditions of accreditation;
  - (b) Failure to comply with ACB requirements;
  - (c) Failure to provide cooperation or facilities for Standards Malaysia, its assessors and/or its authorized representatives to discharge their official duties:
  - (d) Non-payment of accreditation fees;
  - (e) Failure to submit satisfactory evidence of non-conformity(ies) in agreed time frame;
  - (f) Negative outcome of a complaint investigation;
  - (g) Abuse of sub-contracting;
  - (h) Abuse of the use of Standards Malaysia accreditation symbol or reference to Standards Malaysia accreditation;
  - (i) Significant change to the CAB's personnel that seriously affects the competence of the body as an accredited CAB;
  - (j) Failure to complete the total number of witness audits for one cycle of accreditation; or
  - (k) CAB is providing certification to any standard used as a basis for accrediting CABs (e.g. ISO/IEC 17025, ISO/IEC 17020 or ISO 15189).
- 3.4.2 Standards Malaysia may, at its discretion, withdraw accreditation for the following:
  - (a) Non-payment of accreditation fees;
  - (b) Bankruptcy or closure of business of the accredited certification body;
  - (c) Voluntary withdrawal of a certification body;
  - (d) Abuse of sub-contracting;
  - (e) No satisfactory action taken after suspension;
  - (f) As a result of frequent suspension of more than three (3) times;
  - (g) Proven evidence of fraudulent behavior, or the CAB intentionally provides false information;
  - (h) CAB is providing certification to any standard used as a basis for accrediting CABs (e.g. ISO/IEC 17025, ISO/IEC 17020 or ISO 15189); or

- (i) Where, in the view of Standards Malaysia an accredited certification body has made irresponsible use of sub-contracted certification;
- 3.4.3 In cases where minor nonconformities are not closed satisfactorily within 3 months from the date of assessment, Standards Malaysia will initiate suspension or withdrawal by issuing a notice to the accredited certification body requiring 14 working days from the date the certification body is informed, to show cause why the certificate of accreditation (all or part of the accredited scope/for the affected scope) should not be suspended or withdrawn.

If no response is received by Standards Malaysia against the notice of suspension or withdrawal, Standards Malaysia, on expiry of the notice will suspend or withdraw the accreditation and inform the certification body in writing upon approval by the Director General.

- 3.4.4 A certification body whose accreditation has been <u>reduced</u> or suspended shall inform their clients on their <u>reduction</u> or suspension of Standards Malaysia accreditation and the associated consequences without undue delay.
- 3.4.5 A certification body whose accreditation has been withdrawn shall return the certificate of accreditation to Standards Malaysia immediately and inform their clients on their withdrawal from Standards Malaysia accreditation and the associated consequences without undue delay.
- 3.4.6 A certification body under <u>reduction</u>, suspension or has withdrawn shall not issue accredited certificates for the <u>reduced</u>, suspended or withdrawn programme or scope.
- 3.4.7 The suspension period is determined on a case-to-case basis and shall not exceed the expiry date of accreditation. Accreditation resumes after satisfactory action to close the suspension has been taken. If the action taken is unsatisfactory or if there is no action within the period of suspension, Standards Malaysia may proceed to initiate the withdrawal process.
- 3.4.8 Should the <u>reduced</u>/suspended/withdrawn certification body wish to appeal against the decision, it shall do so in writing within seven (7) working days from the date of <u>reduction</u>/suspension/withdrawal letter.
- 3.4.9 Standards Malaysia reserves the right to publicly inform on the <u>reduction</u>, suspension or withdrawal status of the accreditation status of its CABs. If necessary, Standards Malaysia also notifies the International Accreditation Forum (IAF) Secretariat, who may proceed to notify other accreditation bodies.

# 3.5 Appeal

An appeal shall be made in writing. When such an appeal is received, Standards Malaysia will consider the explanations given, and provide the accredited certification body an opportunity to be heard. Appeals are handled within the accreditation system in an impartial and independent manner. Refer to CAB 3 – Appeals for Standards Malaysia policy on appeals.

# 3.6 Inoperative Accreditation

- 3.6.1 If an accredited certification body is unable to comply with any of the ACB requirements and notifies Standards Malaysia and in the opinion of Standards Malaysia, such failure to comply is of a temporary nature, Standards Malaysia retains the right to hold the accreditation as inoperative in part or for the whole accredited scope covered in the schedule of accreditation of the certification body.
- 3.6.2 While accreditation is under inoperative, no accredited certificates shall be issued for the inoperative scope. Failure to comply with the above conditions shall result in mandatory suspension.
- 3.6.3 The inoperative period shall be determined on a case-to-case basis and shall not exceed the expiry of accreditation. Accreditation is restored after satisfactory verification of compliance with ACB requirements, otherwise accreditation is lapsed after the expiry date.
- 3.6.4 Standards Malaysia at its discretion may consider specific exceptions to the requirements of the inoperative status, upon consultation with relevant parties where necessary.

# 3.7 Confidentiality

- 3.7.1 All information gained by Standards Malaysia, its assessors and authorized representatives in the processing, granting, maintaining, extending, renewing, reducing, suspending, reinstating or withdrawal of accreditation are treated as confidential between Standards Malaysia and the certification body. Such information will be handled within Standards Malaysia on a strict 'need to know' basis and will not, unless required by the law and regulations enforced in the country, be divulged without the prior written consent of the certification body.
- 3.7.2 Except for the following information, which is published in Standards Malaysia website, all information is treated as confidential:
  - a) Name, address and contact details;
  - b) ACB number:
  - c) Scope of accreditation; and
  - d) Status of accreditation.
- 3.7.3 MSAC and MyNAC members, Standards Malaysia personnel, members of Accreditation Review Panel (ARP), <u>Technical Working Group</u>, Appeals Panel, Standards Malaysia's assessors, and authorized representatives shall be made aware of, and abide by this requirement for confidentiality.

#### 4. ELIGIBILITY

4.1 Any certification body in Malaysia willing to demonstrate compliance with the criteria and requirements for accreditation of Standards Malaysia may apply for accreditation. Whether a certification body operates on a "profit" or "not for profit" basis shall not be a consideration for the purpose of determining eligibility.

#### 5. OBLIGATIONS OF CERTIFICATION BODIES

# 5.1 General

- 5.1.1 Accreditation under the ACB scheme does not in any way exempt organizations/certification bodies from or diminishes their responsibilities in observing/complying with existing laws and regulations currently enforced in the country.
- 5.1.2 Accreditation should not be regarded as in any way diminishing the normal contractual responsibilities between the certification body and its client. While accreditation is an indication of the integrity and competence of the certification body, it cannot be taken to constitute a guarantee by which the certification body always maintains a particular level of performance.
- 5.1.3 Arrangements for charging of fees between a certification body and its client are in no way the responsibility of, and are not subject to the control of Standards Malaysia.

# 5.1.4 The certification body shall:

- (a) commit to fulfill continually the requirements for accreditation for the scope for which the accreditation is sought or granted and to commit to provide evidence of fulfilment. This includes the agreement to adapt to changes in the requirements for accreditation;
- (b) cooperate as is necessary to enable Standards Malaysia to verify fulfilment of requirements for accreditation;
- (c) provide access to certification body personnel, locations, equipment, information, documents and records as necessary to verify fulfilment of requirements for accreditation;
- (d) arrange the witnessing of conformity assessment activities when requested by Standards Malaysia and <u>provide the assessment team</u> with suitable personal protective equipment (PPE) whenever necessary;
- (e) have, where applicable, legally enforceable arrangements with their clients that commit the clients to provide, on request, access to Standards Malaysia assessment teams to assess the certification body's performance when carrying out conformity assessment activities at the client's site;
- (f) claim accreditation only with respect to the scope for which it has ben granted;
- (g) commit to follow Standards Malaysia policy for the use of the accreditation symbol;
- (h) not use its accreditation in such a manner as to bring Standards Malaysia into disrepute:

- (i) inform Standards Malaysia without delay of significant changes related to its accreditation;
- (j) pay fees as determined by Standards Malaysia;
- (k) commit to allow Standards Malaysia to conduct the assessment in a safe environment. Standards Malaysia does not tolerate any unprofessional conduct towards the assessment team. The assessment team will not hesitate to discontinue the assessment. When such incidents are reported, this may lead to suspension; and
- (I) retain all records as stated in the accreditation standard as required by law, or national guidelines or at least 10 years.

# 5.2 Impartiality and integrity

- 5.2.1 The certification body and its personnel shall be free from any commercial, financial and other pressures or inducement which might influence their judgement.
- 5.2.2 The certification body shall not allow persons or organizations external to the certification body to influence the certification decision.
- 5.2.3 The certification body shall not engage in any activity that may endanger the trust in its independence of judgement and integrity in relation to its certification activities.

# 5.3 Cooperation with Standards Malaysia

- 5.3.1 The certification body shall afford Standards Malaysia, its assessors and its authorized representatives such reasonable accommodation and cooperation as necessary, to enable Standards Malaysia to monitor the competence with the terms and conditions and relevant accreditation criteria. This cooperation shall include:
  - (a) offer Standards Malaysia and its representatives such reasonable accommodation and cooperation as necessary, to enable Standards Malaysia to monitor compliance with the Accreditation Criteria. This shall apply to all premises where the conformity assessment services take place;
  - (b) provide Standards Malaysia access to information, documents and records as necessary for the assessment and maintenance of accreditation, including those that provide insight into the level of independence and impartiality of the certification body from its related bodies, where applicable. When requested, the records of all complaints, appeals and subsequent actions shall also be made available to Standards Malaysia;
  - (c) arrange for the witnessing of certification body's auditing of its client when requested by Standards Malaysia; and

- (d) assist Standards Malaysia or its authorized representatives in the investigation and resolution of any properly authenticated complaints received by Standards Malaysia. These complaints may be made by third parties or interested parties of the certification bodies accredited certification activities.
- (e) After the CB is notified of an assessment or has committed to a witnessing assessment and the CB is unable to proceed without valid justification on the agreed date, Standards Malaysia reserves the right to impose a penalty, whereby the CB shall reimburse any expenses occurred (e.g. flight tickets, hotel reservations etc).

#### 5.4 Liabilities

- 5.4.1 An accredited certification body shall have full control of the issue of accredited certificates subject to these terms and conditions. It shall therefore assume full liability in the issue of all its certificates.
- 5.4.2 The certification body where relevant shall carry adequate third-party indemnity insurance covering its certification / registration activities.

#### 6. NOTIFICATION OF CHANGE

- 6.1 The certification body shall inform Standards Malaysia immediately of any changes bearing on the certification body's compliance with these Terms and Conditions and the accreditation criteria, or otherwise affecting the certification body's capability or scope of activity.
- 6.2 The certification body shall inform Standards Malaysia immediately of any intended changes to its:
  - (a) legal, commercial, ownership or organizational status;
  - (b) organization, top management and key personnel;
  - (c) policies or procedures, where appropriate;
  - (d) premises and resources:
  - (e) scope of accreditation; and
  - other such matters that may affect the ability of the certification body to fulfill requirements for accreditation.
- 6.3 The certification body shall have procedures to ensure that the information supplied to Standards Malaysia is kept up-to-date.
- 6.4 A certificate of accreditation may be relinquished by an accredited certification body in writing to Standards Malaysia.
- Any notice or other communication given or sent by Standards Malaysia to a certification body shall be made in the form of post, e-mail or facsimile to the address of the certification body last known to Standards Malaysia.

### 7. ENFORCEMENT

Standards of Malaysia Act 1996 (Act 549) incorporating latest amendments of Act A1425, year 2012 enables Standards Malaysia to perform enforcement activities for the misuse of reference to accreditation status as cited in Part V, clause 18(1) as follows:

#### Any person who -

- (a) Makes any statement or representation, whether in writing or otherwise, with reference to any conformity assessment that conveys or is likely to convey the impression that a person who is not accredited under this Act with reference to that conformity assessment activity is so accredited;
- (b) Makes any statement or representation, whether in writing or otherwise, that conveys or is likely to convey the impression that a conformity assessment complies with the requirements of accreditation when it does not so comply; or
- (c) Having been accredited to use the accreditation symbol, uses the accreditation certificate after its withdrawal, or during its suspension, or otherwise in contravention of the terms and conditions of the accreditation certificate.

Shall be guilty of an offence and shall on conviction be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding five years or to both and, for a second or subsequent offence, to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding ten years or to both.

[Subs. Act A1425 of the year 2012]

#### 8. MISCELLANEOUS

- Standards Malaysia reserves the right not to disclose any information on a complainant.
- b) Standards Malaysia shall not accept or accredit more than one application from a certification body which has a different legal entity but has a similar management system, human resources, and facilities at the same location.