



STANDARDS
MALAYSIA

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

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THE CONDUCT OF ACCREDITATION ASSESSMENTS

Authority To Issue

**Director General
Department of Standards Malaysia**

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1. INTRODUCTION

- 1.1 This policy explains the operational activities and responsibilities of Standards Malaysia and Certification Bodies (CBs) accredited by Standards Malaysia. Other activities and responsibilities of Standards Malaysia and its accredited CBs may be described in additional guidelines and administrative documents.
- 1.2 The main function of Standards Malaysia as a national accreditation body is to accredit, following successful assessment, those certification bodies found to be competent and impartial to manage a certification system appropriate to its scope, type and volume of its accreditation activities.
- 1.3 The main function of assessment is to determine whether the Certification Body complies with the standards as well as general criteria and requirements published by Standards Malaysia and its related bodies such as the Asia Pacific Accreditation Cooperation (APAC) and International Accreditation Forum (IAF).
- 1.4 Any information acquired by Standards Malaysia's assessment team during assessment visits will be treated confidential and is not under any circumstances to be divulged to any other party. All Standards Malaysia Assessors are bound by an undertaking of confidentiality and Code of Ethics.

2. SCOPE

- 2.1 This document prescribes general guidance and procedures for the conduct of accreditation assessment of certification bodies under the Standards Malaysia accreditation system.
- 2.2 This document should be read in conjunction with the relevant published criteria, policies and procedures governing the ACB scheme

3. DEFINITIONS

- 3.1 For the purpose of this document, definitions in the relevant ISO standards and the relevant ISO/IEC Guides shall apply. The following definitions and abbreviations shall also apply.

Accreditation: Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Accredited Certification Body: A body that has been accredited by Standards Malaysia in accordance with specific criteria, procedures and requirements to operate, on a continuing basis, as a certification body.

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 program under which accreditation is sought..

Accreditation Reviewer: An experienced individual approved by Standards Malaysia and may be chosen from the assessor pools or Scheme Managers or any relevant

experts as and when necessary, to review assessment reports/ pertinent issues related to accreditation, to perform an independent and impartial evaluation and to make the appropriate recommendation to the Director General for accreditation decisions.

Accreditation Review Panel (ARP): A panel of three or more members constituted from experienced individuals approved by Standards Malaysia and may be chosen from the assessor pools or any relevant experts as and when necessary, to review assessment reports/ pertinent issues related to accreditation, to perform an independent and impartial evaluation and to make the appropriate recommendation to the Director General for accreditation decisions.

Accreditation system: A system that has its own rules of procedure and management for the conduct of assessment and for granting of accreditation.

Assessment: Process undertaken by an accreditation body to determine the competence of a CAB, based on standard(s) and / or other normative documents and for a defined scope of accreditation.

Assessor: Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of CAB

Conformity Assessment Body (hereinafter referred to as CAB): Body that performs conformity assessment services and that can be the object of accreditation

Certification system: A system having its own rules of procedure and management for carrying out conformity certification.

Director General: The Head of Department oversees the overall operation and executive functions of the department as stipulated in Act 549.

Malaysian Standards and Accreditation Council, MSAC (hereinafter referred to as the Council): An Advisory Council established under Section 13 of the Standards of Malaysia Act 1996 with delegated functions under the said Act in advising the Minister on policies, criteria and procedures for the administration of a national accreditation system.

National Accreditation Committee (NAC): A Committee of the Council established by MSAC under Section 13 of the Standards of Malaysia Act 1996 and act on behalf of the Council for discharging the duties and functions of the Council in connection with accreditation matters.

Nonconformity: The absence of, or the failure to implement and maintain, one or more requirements of the Standards Malaysia Accreditation Criteria, or a situation which would, on the basis of available objective evidence raise significant doubt as to the credibility of the certificates issued by the applicant body.

- a) **Major nonconformity** - may be an individual nonconformity or a number of minor but related nonconformities, which when considered in total are judged to contribute to an overall system failure.
- b) **Minor nonconformity** - a single failure to comply with Standards Malaysia Accreditation Criteria, or with the CB's own documented quality system, or if a series of minor but related discrepancies are observed, which together are

judged to be a quality risk, without constituting an overall system failure in the area concerned.

Observation: An assessment finding that does not warrant nonconformity but is identified by the assessment team as an opportunity for improvement. The CB is strongly recommended to take corrective actions to indicate commitment to continual improvement.

Reassessment: A periodic accreditation assessment activity designed to re-evaluate conformity of products, services or systems with criteria specified by Standards Malaysia.

Surveillance assessment: A periodic accreditation assessment activity to monitor the continued fulfillment by accredited CBs of requirements for accreditation.

Unscheduled assessment: An assessment outside of the scheduled assessment as a result of certain matters that may affect the ability of the CB to fulfill requirements of accreditation.

4. APPLICATION

4.1 Application for accreditation:

4.1.1 Information about Standards Malaysia accreditation process and application forms are available on Standards Malaysia's website www.jsm.gov.my.

4.1.2 A Certification Body (CB) interested to be accredited by Standards Malaysia shall submit a prescribed application form, duly signed by its authorized representative and providing details of its name, addresses, legal structure, and accompany with the following:

- (i) General features of the CB, including legal entity, name, address(es), legal status as well as human and technical resources;
- (ii) General information concerning its relationship in a larger corporate entity, if any, and addresses of all its physical location(s) and information on activities conducted at all locations including virtual site(s);
- (iii) A clearly defined scope of accreditation sought for which the CB seeks accreditation, including limits of capability where applicable;
- (iv) A completed competence analysis for the scope sought;
- (v) Its published rules or terms and conditions governing the certification scheme operated by the CB;
- (vi) Information that provides a description of the certification services it undertakes, and a list of standards, methods or procedures for which it seeks accreditation including limits of capability where applicable, as describe in the application form;
- (vii) Its Quality Manual and/or relevant associated documents and records;
- (viii) Information on the size or volume of its current activities, and its current human and technical resources; and
- (ix) agreement as commitment to fulfil the requirements for accreditation and the other obligations of the CB

4.2 Acceptance of Application

4.2.1 The following are the requirements for acceptance of application:

- (i) Applicant is from a formally constituted body and is legally identifiable;
- (ii) Applicant has provided all information required by Standards Malaysia for processing application;
- (iii) Declaration of undertakings duly signed by authorized representative of CB;
- (iv) CB must be operational, rather than a proposed system;
- (v) CB must have a minimum level of operational experience and has a minimum number of three (3) certified clients;
- (vi) CB must have a full-time secretariat;
- (vii) Information on its regional / branch offices, if any; and
- (viii) Information on existing Mutual Recognition Arrangements or existing relationship with similar bodies.

4.2.2 Acknowledgement is sent once application is received. Application of documents are checked for completeness. Once satisfactory, a letter of acceptance and invoice for the application fee is sent to the applicant.

4.2.3 The accreditation process will not commence further until payment is received. Application is valid for two years from the date of the acceptance of application.

4.2.4 At any point in the application, if there is evidence of fraudulent behavior, if the CB intentionally provides false information or if the CB conceals information, Standards Malaysia reserves the right to reject the CB's application whenever, it deems necessary.

5 CONDUCT OF ASSESSMENT

5.1 Composition of Assessment Team

Following acceptance of a CB's application, Standards Malaysia appoints an assessment team to conduct assessments. An assessment team is usually made up of a lead assessor, that acts as the team leader, and a team of assessor(s). Where applicable, a technical expert and/or observer may accompany the assessment team. Standards Malaysia will ensure that the expertise of the assessment team as a whole for each assessment is appropriate.

After assembling a team, Standards Malaysia informs the CB of the name of the member(s) of the assessment team and the organization they belong to for the CB to accept. Should the CB object to any appointment of the assessment team, the CB shall lodge the objection with valid reasons, in writing, to Standards Malaysia.

Standards Malaysia reserves the right to overrule such objections where insufficient reasoning for objection is provided.

5.2 Initial assessment (For applicants)

5.2.2 General

Under Standards Malaysia system, the initial accreditation assessment consists of two (2) stages, which come under the responsibilities of a Standards Malaysia assessment team. These are:

5.2.3 Stage 1: Documentation Review

This stage involves carrying out an “adequacy audit” on-site to review the CB’s documentation and its compliance with Standards Malaysia accreditation criteria. Depending on a particular circumstance, Accreditation Officer may also assist in this system assessment exercise.

Documentation review is to ensure that the CB is in a position that will enable Standards Malaysia assessors to evaluate the management of all certification system components including that component on the witnessing of CB’s auditors in action.

During this stage, Standards Malaysia can decide not to proceed with further assessment. If this situation occurs, Standards Malaysia will be reported to the CB in writing.

5.2.4 Preliminary Assessment (optional)

This stage is carried out based on request by the CB or as recommended by the Team Leader based on results of the documentation review carried out in Stage 1. A preliminary assessment shall not be carried out more than 1 time.

5.2.5 Stage 2: Compliance Assessment

The compliance assessment of the accreditation process will not proceed until the CB is in a position that enables Standards Malaysia assessors to evaluate the management of all the certification system components.

This stage involves the assessment of the CB’s headquarters and other locations (if applicable), whereby, visits are made to all other premises of the CB from which one or more key activities are performed, and which is covered by the scope of accreditation.

An important component of this compliance assessment involves the witnessing of CB’s auditors carrying out audits on their clients. Generally, Standards Malaysia witnesses the CB’s auditor(s) performing a certification audit prior to granting accreditation. Standards Malaysia requires a witnessing of at least ONE (1) compliance audit or ONE (1) recertification audit or TWO (2) surveillance audits of the CB’s client. However, where a specific programme warrants specific witnessing arrangements, the requirements are to be followed.

(For further information on witnessing, please refer to ACB 4).

5.2.6 General Conduct of Assessment – Assessment Techniques

5.2.6.1 Documentation Review

As and when deemed necessary, Standards Malaysia may request a documentation review to be performed on a CB. The CB is notified of such a

need and shall prepare the necessary documentation for the assessment to be carried out. The documentation review is carried out by a Standards Malaysia's lead assessor. The Accreditation Officer may assist where needed.

5.2.6.2 Office Assessment

An office assessment involves the assessment team conducting an on-site assessment at the CB's premises. The office assessment shall include the following:

- a) Opening meeting
 - i. Opening meeting is conducted by the Team Leader whereby, he introduces the assessment team, explains the objectives of the assessment, the accreditation criteria that will be assessed, the assessment plan, assessment techniques and confirmation of the CB's scope;
 - ii. The Team Leader also confirms guides that will accompany each assessment team member;
 - iii. This meeting also provides an opportunity for the CB to seek clarification with regards to the assessment, and request for any changes to the assessment plan to suit the CB's operations;
 - iv. It is advisable for the CB's top management to be present during this meeting.

- b) Progress of assessment
 - i. The assessment team assesses the competence, consistency in operation as well as the impartiality of the CB through various assessment techniques which include but are not limited to the following:
 1. on-site assessment;
 2. document review;
 3. file review;
 4. interviewing.
 - ii. These techniques are used to ascertain the CB's compliance with:
 1. Requirements of the relevant standard(s);
 2. International Accreditation Forum (IAF) or Asia Pacific Accreditation Cooperation (Formerly known as Pacific Accreditation Cooperation) documents;
 3. Standards Malaysia policy and criteria.
 - iii. The CB shall assist in providing any necessary information for the assessment team to determine compliance.
 - iv. Any findings that may impact on the CB's accreditation shall be brought up during the closing meeting.

- c) Closing meeting
 - i. Closing meeting is conducted by the Team Leader, whereby he presents to the CB in an objective manner, a brief summary of the results of the assessment, to inform the CB of the assessment team's recommendation and to highlight any findings that may call for the condition of accreditation.
 - ii. Any nonconformities raised are presented to the CB and a timeframe for response is provided;
 - iii. The CB shall ensure that the summary report, scope and findings are signed, and a copy of those documents are kept (if through e-accreditation, the documents are accepted);

- iv. The CB may seek clarification from the Team Leader, if necessary. Any diverging opinions regarding the conclusion or nonconformities between the assessment team and CB shall be discussed and resolved, where possible.

5.2.6.3 Where office assessment is not possible due to unavoidable circumstances, Standards Malaysia may consider other methods of assessment.

5.2.6.4 The areas assessed are on a sampling basis and may not be representative of the whole operation of the CB.

6 GRANTING ACCREDITATION

6.1 Subject to the assessment team's findings and closure of non-conformities raised, Standards Malaysia presents the reports to the Accreditation Review Panel (ARP), an independent panel made up of assessors and technical experts not involved in the assessment for their review and recommendation.

6.2 If all Standards Malaysia's conditions are met, the ARP proposes recommendation for granting of accreditation to the Director-General through the Director of Accreditation.

6.3 If the ARP decides against accreditation, or requires further information prior to the granting of accreditation, the ARP communicates with the officer-in-charge for them to proceed to the appropriate next steps.

6.4 The CB has the right to appeal against any decision by the Director-General. Information about appeals can be found in CAB 3.

7 MAINTAINING ACCREDITATION

7.1 Administrative support by Accreditation Officer

7.1.2 Upon accreditation, each CB is appointed an Accreditation Officer in charge of coordinating and monitoring their accreditation. The Accreditation Officer assists in the following:

- a) Arrangement of accreditation assessment(s) including assessment team, dates, duration, and fees;
- b) Confirmation of criteria which will be used in the assessment process such as, ISO/IEC 17021 and all other additional criteria and requirements which will be made known to all parties and agreed to by the CB;
- c) Ensure the scope of accreditation is up-to-date;
- d) Obtain information such as CB auditors and their competence, subcontracting arrangements, a list of current MoUs or MRAs the CB has with other similar bodies;
- e) Obtain additional information from the CB as and when necessary.

7.2 Accreditation Cycle

- 7.2.1 Upon granting of accreditation, the CB is provided with an assessment programme outlining the CB's activities including the scheduled assessments and witnessing assessment, that will be assessed throughout the accreditation cycle.
- 7.2.2 The purpose of the accreditation cycle is to determine whether a CB continues to comply with the accreditation criteria. Clause 5.2.6 describes the general approach followed for the conduct of surveillance or reassessment. Any failure on the part of the CB to do so may result in a reduction of scope, suspension or withdrawal of accreditation.
- 7.2.3 Scheduled assessments are planned to take into account other activities such as;
- a) Enquiries from Standards Malaysia to the CB on aspects concerning the accreditation;
 - b) Reviewing the declarations of the CB with respect to what is covered by the accreditation;
 - c) Requests to the CB to provide documents and records (e.g. audit reports, personnel files, results of internal audits, complaints records, management review records); and
 - d) Monitoring the performance of the CB.
- 7.2.4 Standards Malaysia practices a 5-year accreditation cycle. The first accreditation cycle after granting of accreditation is as follows:
- i) Surveillance I : 11 months after the renewal of its Certificate of Accreditation
 - ii) Surveillance II : 11 months from Surveillance I
 - iii) Surveillance III : 11 months from Surveillance II
 - iv) Surveillance IV : 11 months from Surveillance III
 - iii) Re-assessment: 5 months before expiry of certificate
- 7.2.5 After the first accreditation cycle, the frequency of surveillance may be reduced as follows:
- i) Surveillance I : 15 months after the renewal of its Certificate of Accreditation
 - ii) Surveillance II : 20 months from Surveillance I
 - iii) Reassessment : 5 months before expiry of certificate
- 7.2.6 However, Standards Malaysia reserves the rights to conduct unscheduled assessments due to certain cases such as recommendation of the Team Leader in his recommendation report or by the ARP/Accreditation Reviewer. The unscheduled assessments may be carried out without prior warning, for example, if there is reason to believe that standards may have deteriorated.

- 7.2.7 The accreditation cycle will also include yearly witnessing of audits carried out by CB's auditors as determined by **Annex 1**.
- 7.2.8 A reassessment provides the opportunity for a more comprehensive examination of a CB's performance. Prior to reassessment, the CB shall submit a checklist provided by Standards Malaysia at least 1 month before reassessment. Failure to submit the checklist within the stipulated timeline may result in an additional man-day. The CB shall also ensure that all witnessing of audits have been completed prior to expiry of accreditation.
- 7.2.9 The Team Leader at the conclusion of a scheduled assessment, as with an initial assessment, will be required to make a proposal on the continuing accreditation of the CB. Depending on the number and seriousness of any nonconformity found the Team Leader proposes whether accreditation should be:
- (a) Maintained/renewed unconditionally (this recommendation will only be made when no nonconformities have been found);
 - (b) Maintained/renewed on the understanding that any nonconformity found are corrected within a specified period (refer to clause on findings);
 - (c) Maintained/renewed with a reduction in scope (i.e. scope has been dormant for one cycle or insufficient auditor's with competency in mentioned scope)
 - (d) Suspended until the CB has corrected the nonconformities found within a specified time period (a recommendation that the accreditation of a CB is suspended will almost certainly require a further visit to confirm that the nonconformities have been corrected); or
 - (e) Withdrawn (a recommendation that accreditation be withdrawn will involve the CB in having to make a new application and undergoing a further full assessment if it wishes to regain its accreditation).

7.3 Witnessing Of CB's Auditors Conducting Audits

- 7.3.1 During the drawing up of the CB's assessment programme, the Accreditation Officer plans the number and scope of witnessing audits to be performed on the CB's auditors. The CB shall accommodate and arrange the witnessing audits according to the assessment programme. CB shall ensure that:
- (i) The CB to seek prior agreement of any client concerned and shall explain the reason for the presence of the Standards Malaysia assessors, and assure that the team's presence will have no bearing on the outcome of the CB's own audit.
 - (ii) Once consent is given, the CB shall communicate to the CB's client together with a list of essential information required by the Standards Malaysia assessment team and such information shall be given to the Assessor well in advance of each visit.
- 7.3.2 Standards Malaysia requires applicants and accredited certification bodies to have an enforceable arrangement with clients holding a certificate accredited by certification bodies which shall include:

- (i) An arrangement which shall provide, on request, access to Standards Malaysia assessment teams to witness the certification body's audit team performing an audit at the organization's site.

If the CB client refuses Standards Malaysia witnessing, in order to avoid sanctions, the CB shall withdraw the existing accredited certificate, or, if not yet certified, the CB will not be allowed to place the accreditation logo on the future certificate, unless the refusal is duly justified and accepted by Standards Malaysia.

(Note: This does not apply to clients holding certificates issued by certification bodies accredited by other accreditation bodies)

- 7.3.3 Certification Bodies and certified organization should be aware, that failure to witness an audit or an auditor in a particular scope sector may ultimately lead to Standards Malaysia removing that scope sector from the accreditation scope.
- 7.3.4 Preparation for a witness audit by the CB to Standards Malaysia shall include the following:
 - (i) Particulars of client (Name of client, address, client background, etc.)
 - (ii) NACE Sector/Category code/Technical areas
 - (iii) Audit plan (Including audit team and team code holder)
 - (iv) Other information (e.g. previous audit report, personnel file), if requested.
- 7.3.5 Standards Malaysia assessor(s) follows the CB's auditor(s) during the whole of the audit, he will take notes, examine documents or other items, but will ask no questions and make no comment until after the closing meeting between the CB's auditors and the client.
- 7.3.6 The CB shall allocate time after the closing meeting of the audit for the assessor to brief on any findings raised during the witness audit.
- 7.3.7 If at any time during the assessment of a CB audit, the assessor observes a potential condition considered to be an imminent risk of high severity (e.g. health and safety or the environment), the assessor reserves the right to request a private meeting with the CB's team leader to inform him/her of the potential threat, with the expectation that the CB's team leader will address the threat with the organization according to the CB's policies and procedures.
- 7.3.8 The total number of witness audits for the CB concerned shall be completed before the expiry date of accreditation. Should the CB be unable to do so, Standards Malaysia reserves the right to initiate sanctions (e.g. suspension or withdrawal depending on severity).
- 7.3.9 The Guidelines for the Selection of Witnessing of Audits are as per outlined in ACB 4.

7.4 Verification Assessment

- 7.4.1 Verification assessments may be conducted but not limited to, in the following:
 - a) Case of any unresolved/pending issues with regards to non-conformities that require further verification (e.g. ARP feedback), a verification

assessment can be conducted at the CB's premises. Accreditation is not to be granted or maintained until all nonconformities have been corrected and the correction verified;

- b) Investigation of complaint(s); and
- c) A sudden surge in number of CB's clients (increment by 10) after granting of accreditation.

8 EXTENSION OR REDUCTION OF SCOPE

- 8.1 The scope of a CB is unambiguously defined, according to the function performed and the fields concerned by the operation of these functions. This ensures that clients are provided with an accurate and unambiguous description of the areas of capability within which the certification body is accredited.
- 8.2 For an extension of scope, accredited CB shall formally apply to Standards Malaysia using the official application form as well as the auditor's technical sector competence and competence analysis. Each request for an extension of scope is individually reviewed and a decision on whether or not the extension of scope requires additional assessment will be determined by Standards Malaysia.
- 8.3 Standards Malaysia reserves the rights to redefine or reduce the scope of accreditation.
- 8.4 The precise details of the accredited scope will be identified on a schedule accompanying Standards Malaysia Certificate of Accreditation.

9 FINDINGS

- 9.1 Findings under the ACB Scheme are divided into three (3) categories:

MAJOR NON-CONFORMITY: A major non-conformity shall be closed in a period not exceeding ONE (1) month.

MINOR NON-CONFORMITY: A minor non-conformity shall be closed in a period not exceeding THREE (3) months

OBSERVATION: CB to submit a corrective action plan in a period not exceeding THREE (3) months that will be verified in the upcoming assessment.

Note: The definition of nonconformities can be found in Clause 3.

- 9.2 For non-conformities, whether major or minor, the CB is required to submit a root cause analysis.

10 FACTORS AFFECTING RECOMMENDATION FOR ACCREDITATION

- 10.1 In deciding on his proposal for accreditation, the Team Leader will consider the following:

- (a) The number and seriousness of the individual nonconformities found during the assessment;
- (b) The adequacy of control of the CB's management to operate its certification system and reach proper conclusion as to awarding certificate; and
- (c) The range of knowledge and experience of the assessed CB relevant to the scope of accreditation sought.

11. DECISION ON ACCREDITATION

- 11.1 The decision on whether or not to grant accreditation shall remain with Standards Malaysia and such authority cannot be delegated. The decision on accreditation are based on the assessment findings and the recommendation of the ARP.

12. SUSPENSION OR WITHDRAWAL OF ACCREDITATION

- 12.1 Standards Malaysia initiates suspension of withdrawal among others subject to dissatisfaction of the assessment team's or ARP's findings in complying with Standards Malaysia's policies and procedures. The procedure for suspension or withdrawal of accreditation is as outlined in CAB 4.

13 SPECIFIC EXCEPTIONS

- 13.1 The Director of Accreditation, at his discretion, may grant specific exceptions to the requirements of this document or impose other requirements upon consultation with relevant parties.