



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

**ACCREDITATION POLICY 2 (AP2) -
TERMS AND CONDITIONS GOVERNING
THE DEPARTMENT OF STANDARDS MALAYSIA'S
ACCREDITATION SCHEMES**

Issue 1, 01 November 2023



**JABATAN STANDARD MALAYSIA
DEPARTMENT OF STANDARDS MALAYSIA**

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Introduction

This document describes the policy of the Department of Standards Malaysia (JSM) for the terms and conditions governing all accreditation schemes offered by JSM.

1 Scope

1.1 This document outlines the policy of JSM with regards to the terms and conditions governing the accreditation schemes for applicant and accredited CABs that carry out conformity assessment activities. The conformity assessment bodies (CABs) which include but are not limited to testing including medical testing and calibration laboratories, certification bodies, inspection bodies, proficiency testing providers and validation and verification bodies.

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 the following:

- a) *Skim Akreditasi Makmal Malaysia (SAMM)*;
- 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) Primary Healthcare Laboratory Accreditation Scheme (PHLAS);
- f) The Scheme for the Accreditation of Validation and/or Verification Bodies Scheme (MyV&V).

2 Normative reference

2.1 Act 549 - Standards of Malaysia Act 1996

2.2 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 Terms and definition

For the purpose of this document, the following definitions shall apply:

a) Terms related to accreditation in general

3.1 Department of Standards Malaysia (JSM)

The accreditation body established under the Standards of Malaysia Act 1996 (Act 549).

3.2 Accreditation

Third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities.

[Source: ISO/IEC 17011:2017]

3.3 Conformity Assessment Body (CAB)

Body that performs conformity assessment activities, excluding accreditation.

3.4 Accredited Conformity Assessment Body (CAB)

A body that has been accredited by JSM in accordance with specific JSM criteria, procedures and requirements to operate, on a continuing basis, as a conformity assessment body.

3.5 Accreditation body logo

Logo used by JSM to identify itself.

3.6 Accreditation symbol

Symbol issued by JSM to be used by an accredited CAB to indicate that they are accredited under the JSM's accreditation schemes.

b) Terms related to accreditation status

3.7 Inoperative

Accreditation status of all or part of the accredited scope held in abeyance for a temporary period at the request of the laboratory until effective corrective action has been taken.

3.8 Reinstatement

The process of re-establishing/regaining the accreditation status of a laboratory.

3.9 Suspension

Accreditation status of all or part of the accredited scope held in abeyance by JSM until effective corrective action has been taken.

[Source: ISO/IEC 17011:2017]

3.10 Withdrawal

Partial or full cancellation of accredited scope by JSM or as requested by an accredited laboratory. For full withdrawal, the certificate of accreditation shall be returned to JSM.

[Source: ISO/IEC 17011:2017]

3.11 Appeal

Request by a CAB for reconsideration of any adverse decision made by JSM related to its desired accreditation status.

[Source: ISO/IEC 17011:2017]

c) Terms related to personnel

3.12 Assessor

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

3.13 Accreditation reviewer

An experienced individual approved by JSM and may be chosen from the assessor pools or Scheme Managers or any relevant experts as and when necessary, to review assessment reports or 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.

3.14 Evaluation panel

A panel of three (3) or more members constituted from experienced individuals approved by JSM 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.

3.15 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

Note: Key personnel shall be as defined and approved under SAMM in accordance to the requirements in SC 2: Specific Criteria for Accreditation in the Field of Medical Testing.

3.16 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 does not apply to SAMM (Medical Testing), ACB and MyV&V.

d) Terms related to accreditation information

3.17 Certificate of accreditation

A certificate issued by the Director General of JSM under the [Act 549] to a CAB attesting that the CAB is recognised as competent to perform specific conformity assessment activities under respective accreditation scheme.

3.18 Schedule of accreditation

A schedule issued by JSM as a supporting document to the certificate of accreditation listing specific conformity assessment activities for which accreditation has been granted. The schedule of accreditation is to be read together with the certificate of accreditation.

Note: Schedule of accreditation also known as scope of accreditation.

e) Other terms related to accreditation

3.19 Accreditation criteria

Include the appropriate accreditation standard, and all JSM approved policies and procedures at the time of application, and those approved from time to time subsequent to accreditation, that are applicable to the respective accreditation programmes.

3.20 Central Conformity Assessment Body

The premise where the management system is managed and administered. A Central CAB may or may not conduct conformity assessment activities. The Central CAB manages one or more branches and/or sites at which conformity assessment activities are carried out. All branches or sites are under the same legal entity with the Central CAB and implement the same management system.

3.21 Branch

Branch is a premise at a different location conducting conformity assessment activities, which is controlled and managed by the Central CAB. Branch implements the same management system and is owned by the same legal entity as the Central CAB. Branch may manage one or more sites.

3.22 Site

Any location where conformity assessment activity is conducted by CAB, on a temporary or permanent basis. Site also includes mobile facilities.

Note: For mobile facilities, please refer to AP 3 Policy for the Accreditation of Branches or Sites of Conformity Assessment Bodies.

f) Terms related to assessment

3.23 Assessment

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

3.24 Unscheduled assessment

An assessment outside of the scheduled assessment as a result of certain matters that may affect the ability of the CAB to fulfil requirements of accreditation.

Note: Examples of unscheduled assessment include extension of scope, extension of branch, verification of findings and verification of complaint.

3.25 Remote assessment

Assessment of the physical location or virtual site of a conformity assessment body, using electronic means.

Note: A virtual site is an online environment allowing persons to execute processes, e.g., in a cloud environment.

3.26 Finding

A nonconformity or observation identified as a result of an assessment.

3.27 Category 1 Nonconformity

Non-fulfilment of a requirement. Nonconformity that affects the capability of the conformity assessment body to achieve the intended results and contributes to a system failure. System failure may be limited to a part or the whole scope of accreditation and affects either the competency, impartiality and/or consistency of operation.

3.28 Category 2 Nonconformity

Non-fulfilment of a requirement. A single failure to comply with JSM's accreditation criteria, or with the CAB's own management system, or if a series of minor or significant but related discrepancies are observed, which together are judged to be a risk to the management system, impartiality, competency, and consistency of operation, without constituting a system failure in the area concerned.

3.29 Category 3 Observation

Finding that is not a nonconformity but is identified as an opportunity for improvement.

For other terms not listed, the relevant definitions in ISO/IEC 17000 and the International Vocabulary of Basic and General Terms in Metrology shall apply.

4 Accreditation of Conformity Assessment Bodies

4.1 Authority to accredit Conformity Assessment Bodies (CABs)

4.1.1 In carrying out its function under the Standard of Malaysia Act 1996 [Act 549], the Director General of JSM is responsible for all policies and decisions affecting the accreditation schemes, including the granting, maintaining, extending, renewal, reducing, suspension, inoperative, withdrawal or reinstatement of accreditation.

4.1.2 The granting, maintaining, extending, renewal, reducing, suspending, inoperative, withdrawal or reinstatement of accreditation shall be granted only to a CAB which:

- a) is legally identifiable and operational;
- b) complies with accreditation criteria;
- c) pays such fees (as prescribed in the Fee Schedule) as are due to JSM; and
- d) enters into a legally enforceable arrangement with JSM.

4.1.3 An Accreditation Reviewer or an Evaluation Panel, constituted from experienced and competent individuals approved by JSM to review assessment reports and make recommendations to the Director General on accreditation decisions.

4.2 Accreditation criteria and procedures

4.2.1 JSM reserves the right to:

- a) prescribe the relevant accreditation criteria based on international standards, or other internationally recognised requirements, or any national standards against which CAB shall be assessed;
- b) specify the procedures by which application for accreditation shall be made, the conditions for granting, maintaining, extending, renewal, reducing, suspension, inoperative or withdrawal of accreditation, and the conditions under which CAB accreditation may be refused, reduced, suspended, withdrawn, or reinstated;
- c) formulate its own policies and procedures or to adopt/use the relevant international requirements for accreditation activities;
- d) amend any part of accreditation criteria, if in the opinion of JSM such amendments are necessary to maintain the credibility of CABs. In the event of such amendments, reasonable time shall be given to CABs to carry out the necessary adjustments to their management system in order to comply with the amended accreditation criteria. Unless otherwise specified, a period of six (6) months from the date of notification of change by JSM shall be given for the CAB to carry out the necessary adjustments to their system; and
- e) appoint competent assessors to conduct assessment on behalf of JSM. JSM may rotate the assessors involved in the assessment of the CABs as part of a mechanism to maintain impartiality.

4.3 Application process and granting of accreditation

4.3.1 Applicants shall submit the necessary documents as required by JSM for the purpose of application for accreditation.

4.3.2 For SAMM testing laboratory, it is JSM's policy to accredit a laboratory conducting sampling only when the output of sampling is subject to testing undertaken by the same laboratory.

4.3.3 An application for accreditation shall be valid for two (2) years from the date of acceptance of application and shall be deemed unsuccessful after the application validity. Upon written request by the applicant CABs, JSM reserves the right to extend the application period, as it deems appropriate.

4.3.4 An applicant CAB shall be operational, rather than a proposed system. The conformity assessment process as per the requirements of the accreditation scheme needs to be completed in order to apply for accreditation.

4.3.5 For applicant certification bodies, to proceed with compliance assessment, the certification body shall have certified at least three (3) clients. JSM reserves the right to decide the minimum number of clients for specific programme.

Note: From herewith client also refers to customer.

4.3.6 JSM shall assess the applicant CAB by performing:

- a) **Documentation review:** A review of the applicant documentation to ascertain that the relevant standards and accreditation requirements are adequately addressed.

CABs under the same legal entity and sharing the same documentation may be exempted from multiple documentation review at JSM's discretion.

- b) **Pre-assessment:** A preliminary assessment of the CAB's management system and its implementation to determine its readiness for the compliance assessment.

CABs under the same legal entity, having a similar management system, applying for the same field of conformity assessment activity and meeting the other exemption criteria as set out by JSM, may be exempted from multiple pre-assessment at JSM's discretion.

Pre-assessment is optional for ACB and MyV&V Schemes. However, JSM may require the CB or the validation and/or verification bodies (VVBs) to proceed to pre-assessment in case of unsatisfactory closure of documentation review finding.

- c) **Compliance assessment:** An assessment to establish whether a CAB is competent to perform the conformity assessment activities for which it seeks accreditation and make recommendation on accreditation which is subject to the approval by JSM.

4.3.7 JSM may require the CAB to repeat the assessment if the outcome of the assessment is unsatisfactory.

4.3.8 JSM shall only consider the granting of accreditation upon satisfactory closure of all nonconformities raised during the assessments and completion of witnessing assessment(s). Refer clause 4.9 - witnessing.

4.3.9 JSM shall grant accreditation by issuing a Certificate of Accreditation and a Schedule of Accreditation to a CAB upon approval by the Director General. The accreditation status shall be valid for five (5) years. The validity of accreditation status will be specified in the Schedule of Accreditation.

4.3.10 The Certificate of Accreditation shall not be transferable. Under special circumstances, JSM may consider conditions under which accreditation may be changed from one legal entity to another legal entity such as in a situation resulting from merger or acquisition.

4.3.11 JSM may consider changes/amendments to the Certificate/Schedule of Accreditation such as, but not limited to the following:

- a) change of name of CAB or its organisation structure;
- b) change in its legal status;
- c) change of address or premises/branch office/site;
- d) request for change in scope; and/or
- e) other significant editorial changes shall be considered by JSM.

If in the opinion of JSM or its authorised representatives, these changes constitute significant changes to the CAB's management system or affect its technical competence, JSM reserves the right to conduct unscheduled assessment or other forms of evaluation to confirm its continued compliance with the JSM accreditation criteria.

4.3.12 All accredited CABs shall be listed in a directory available on JSM's website. The directory shall indicate the current accreditation status of the CABs.

4.3.13 At any point in the application or initial assessment process, if there is evidence of fraudulent behaviour or if the CABs provides false information or if the CABs conceals information, JSM shall reject the application or terminate the assessment process.

4.3.14 If the accreditation status of a CAB is withdrawn or the application is terminated due to evidence of fraudulent behaviour, the CAB or the personnel involved is not allowed to reapply within two (2) years.

4.4 Frequency of internal audit and management review

4.4.1 Internal audits shall be performed at least once every 12 months. However, the frequency of internal audits may be reduced if the CAB can demonstrate that its management system continues to be effectively implemented according to respective accreditation standards and has proven stability. The maximum interval for internal audit shall not exceed 18 months.

4.4.2 The CAB's management review shall be conducted at least once a year.

4.5 Maintaining of accreditation

4.5.1 JSM shall monitor the compliance of the CABs to the relevant accreditation criteria.

4.5.2 JSM shall schedule assessments of the accredited CABs according to the following **Table 1** and **Table 2**. However, JSM reserves the right to revert the cycle of accreditation depending on the performance of the CABs arising from the results of the assessment.

Table 1: First cycle of accreditation

Surveillance 1	Approximately 10 months from date of granting/renewal of certificate
Surveillance 2	Approximately 15 months from date of Surveillance 1
Surveillance 3	Approximately 15 months from date of Surveillance 2
Reassessment	Approximately 5 months before date of expiry

Table 2: Subsequent cycle of accreditation

Surveillance 1	Approximately 15 months from the date of last expiry
Surveillance 2	Approximately 20 months from the date of Surveillance 1
Reassessment	Approximately 5 months before date of expiry

4.5.3 The accreditation cycle shall also include witnessing according to the respective accreditation scheme.

4.5.4 CABs shall adhere to the assessment programme unless otherwise determined by JSM. If the CABs is unable to proceed with the assessment on the agreed date, it shall notify JSM.

4.5.5 After the assessment notification is issued and CAB is unable to proceed with the assessment, on the agreed date, JSM reserves the right to impose a penalty and the CABs shall reimburse any expenses incurred (e.g., flight tickets, non-refundable hotel deposit).

4.5.6 JSM reserves the right to conduct the assessments unannounced/unscheduled due to certain cases such as recommendation of the Team Leader in his recommendation report or by the Evaluation Panel/Accreditation Reviewer or investigation of complaints. The unscheduled assessments may be carried out without prior notice.

4.6 Extension of scope (EOS)/branch (EOB) for accreditation

4.6.1 CABs may apply for extension of scope (EOS)/branch (EOB). An application for EOS/EOB shall be valid for **one (1) year** from the date of acceptance and shall expire if accreditation has not been successful.

4.6.2 JSM only accepts new applications for extension of scope/branch upon completion of the earlier EOS/EOB application. Only **one (1) application** for EOB and/or EOS is allowed at one time.

Note: CAB may refer to Accreditation Policy (AP) 3 - Policy for the Accreditation of Branches or Sites of Conformity Assessment Bodies.

4.7 Reduction of accreditation scopes

4.7.1 A scope of accreditation may be reduced from the Schedule of Accreditation in the following situations:

- a) Request from the CAB; or
- b) As a result of an assessment or outcome of investigation of a complaint or recommendation by an Accreditation Reviewer or Evaluation Panel.

4.7.2 JSM reserves the rights to redefine or reduce the scope of accreditation.

4.8 Unscheduled assessment

4.8.1 JSM or its authorised representative reserves the right to carry out unscheduled assessment to applicant or accredited CABs.

4.8.2 The unscheduled assessments may be conducted but not limited to the following:

- a) verification on the implementation of the corrective actions;
- b) unsatisfactory outcome of an assessment;
- c) extension of scope;
- d) extension of branch;
- e) verification of significant changes in the CABs (e.g., relocation, renovation, restructuring, etc.);
- f) verification of key personnel (signatory/auditors);
- g) investigation of complaints;
- h) a sudden surge in number of certification body's (CB's) clients (increment by ten (10)) after granting of accreditation (only applicable for ACB scheme);
- i) unannounced assessment;
- j) others, when necessary.

4.9 Witnessing of conformity assessment bodies activities

4.9.1 Witnessing of CAB's activities is an essential part of the JSM assessment.

- a) For SAMM, witnessing of test/calibration shall be conducted during JSM assessment.
- b) For MyPTP, witnessing of proficiency testing activities may be conducted, where necessary.
- c) For MIBAS, witnessing is particularly important when the inspection bodies (IB) is performing inspections of such a nature where the inspector's professional judgment is crucial to the outcome of inspection. This witnessing may be conducted during the assessment or conducted separately. The details of the witnessing of IB process are stated in **Annex A1**.
- d) For the ACB and MyV&V Schemes, the accreditation cycle will also include yearly witnessing of audits/validation and/or verification carried out by certification body (CB's) auditors/validators and/or verifiers as determined by **ACB 4**. Details of the witnessing of CB/VB process are stated in **Annex A2**.

4.9.2 Where witnessing assessments are carried out outside of scheduled assessments, the CAB shall also ensure that all witnessing assessments have been completed prior to expiry of accreditation and in accordance with the relevant accreditation scheme.

4.10 Remote assessment

4.10.1 JSM may conduct remote assessment due to extra ordinary circumstance. An extraordinary circumstance refers to a circumstance beyond the control of the organisation, commonly referred to as “Force Majeure” or “act of God”. Examples are but not limited to war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters.

4.10.2 The general principles for the conduct of remote assessments are as follows:

- a) the CAB is able to provide documents and records electronically;
- b) the CAB is able to provide a suitable remote platform;
- c) the CAB is able to demonstrate competency to JSM's assessment team remotely (i.e., through witnessing of CAB's personnel conducting conformity assessment activities); and
 - i) witnessing activities are mandatory, where applicable; and
 - ii) witnessing should be conducted in real time. If it is not possible to be conducted in real time, with justification, the CAB in agreement with the assessment team may allow for recording of CAB conducting Conformity Assessment activity.
- d) if at any point of the remote assessment, JSM's assessment team is dissatisfied with the conduct of remote assessment, JSM's assessment team may terminate the remote assessment or request for a verification on-site.

4.11 Categorisation of findings

4.11.1 JSM's categorisation of findings is as defined in Accreditation Policy (AP 7) - Policy on Grading of Assessment Findings.

4.11.2 Should the CAB wish to express dissatisfaction with the findings raised, the dissatisfaction shall be lodged as a formal complaint in accordance to CAB 2 - Complaints.

4.12 Suspension and withdrawal of accreditation

4.12.1 JSM shall **suspend the scope of accreditation** whether partial or full, depending on the severity of the situation, as per the following:

- a) violation of the terms and conditions of accreditation;
- b) failure to comply with accreditation requirements;
- c) category 1 nonconformity raised during assessment;
- d) failure to close out nonconformity which was raised during assessment within stipulated time frame;
- e) fraudulent practices, which include but are not limited to deception of claims and alteration of CABs certificate/report;
- f) proven evidence of fraudulent behaviour, or the CABs provides false information;
- g) failure to provide cooperation or facilities for JSM, its assessors and/or its authorised representatives to discharge their official duties;
- h) unprofessional conduct/harassment toward JSM officer and/or assessment team
- i) where, in the view of JSM an accredited CABs has made irresponsible use of externally provided services;
- j) non-payment of accreditation fees;

- k) abuse of sub-contracting/external service provider/outsourcing;
- l) misuse of accreditation symbol or reference to JSM accreditation;
- m) significant change to the CAB's personnel that seriously affects the competence of the body as an accredited CAB;
- n) failure to complete the total number of witness audits/inspection for one cycle of accreditation;
- o) CB is providing certification to any standard used as a basis for accrediting CABs (e.g., ISO/IEC 17025, ISO/IEC 17020 or ISO 15189);
- p) an individual of CAB's sole proprietorship is declared bankrupt or enter into a composition with his creditors; and/or
- q) accredited CAB being a company, enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purposes of reconstruction) or enters into receivership.

4.12.2 JSM shall **withdraw accreditation** as per the following:

- a) no satisfactory action taken after suspension;
- b) non-payment of accreditation fees;
- c) bankruptcy or closure of business of the accredited CABs;
- d) voluntary withdrawal of a CAB;
- e) abuse of sub-contracting/external service provider/outsourcing;
- f) as a result of frequent suspension of more than three (3) times within two (2) accreditation cycles (10 years);
- g) proven evidence of fraudulent behaviour, or the CAB provides false information; and/or
- h) CB is providing certification to any standard used as a basis for accrediting CABs (e.g., ISO/IEC 17025, ISO/IEC 17020 or ISO 15189).

4.12.3 JSM will suspend or withdraw by issuing a notice to the accredited CABs. Should the suspended/withdrawn CABs wish to appeal against the decision, it should do so in writing within seven (7) working days from the date of the suspension/withdrawal letter. Please refer to CAB 3 for the appeals process.

4.12.4 The CABs needs to inform its affected clients of the suspension, reduction or withdrawal of its accreditation and the associated consequences without undue delay.

4.12.5 A CABs that has been suspended or withdrawn shall not issue CABs certificate/reports for the suspended or withdrawn scope/programme. Failure to comply with the above conditions shall result in legal actions.

4.12.6 The suspension period shall be determined on a case-to-case basis and shall not exceed 24 months or the expiry date of accreditation, whichever comes first. The accreditation status is considered lapsed and no longer valid after the suspension period has ended and no action has been taken. Accreditation shall resume upon approval by JSM Director General after satisfactory action has been taken. The procedure for suspension or withdrawal of accreditation as outlined in CAB 4: Suspension and Withdrawal of Accreditation.

4.12.7 JSM reserves the right to publicly inform on the suspension or withdrawal status of the accreditation status of its CABs. If necessary, JSM also notifies the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) Secretariat, who may proceed to notify other accreditation bodies.

4.13 Inoperative accreditation

4.13.1 Accreditation status of all or part of the accredited scope held in abeyance for a temporary period at the request of the CAB until effective corrective action has been taken. The maximum time for inoperative is not more than 24 months or expiry date of the CAB's accreditation, whichever comes first.

4.13.2 If an accredited CAB is unable to comply with any of the JSM accreditation requirements, and notifies JSM and in the opinion of JSM, such failure to comply is of a temporary nature, JSM retains the right to hold the accreditation on inoperative for part or all of the accredited scope covered in the schedule of accreditation of that CABs.

4.13.3 While accreditation is under inoperative, no endorsed reports/certificates shall be issued for the inoperative scope. Failure to comply with the above conditions shall result in mandatory suspension.

4.13.4 The inoperative period shall be determined on case-to-case basis and shall not exceed 24 months or the expiry date of accreditation, whichever comes first. Accreditation shall be restored after satisfactory verification and reinstatement by JSM, otherwise accreditation shall be withdrawn.

4.13.5 Director of Accreditation at its discretion may consider specific exceptions to the requirements of the inoperative status, upon consultation with relevant parties where necessary.

4.14 Appeal

4.14.1 An appeal shall be in writing. When such an appeal is received, JSM shall consider the explanations given, and provide the accredited CABs an opportunity to be heard. The appeals process is prescribed in CAB 3: Appeals.

4.14.2 Upon acknowledgement of the CAB's letter of appeal by JSM, the appellant will be issued an invoice for a non-refundable appeal fee as per the Standards of Malaysia (Fees) Regulation 2018.

4.15 Confidentiality

4.15.1 All information gained by JSM, its assessors and authorised representatives in the processing, granting, maintaining, extending, renewal, reducing, suspension, inoperative or withdrawal of accreditation will be treated as confidential between JSM and the accredited CAB. Such information will be handled on a strict "need to know" basis and will not, subject to the law of Malaysia, be disclosed without the written permissions of the CABs.

4.15.2 Except for the following information, which are published in JSM website, all information are treated as confidential:

- a) name, address and contact details;
- b) accreditation number;
- c) scope of accreditation; and
- d) status of accreditation.

4.15.3 All JSM related personnel including the Malaysian Standards and Accreditation Council (MSAC) members, the National Accreditation Committee (NAC) members, Evaluation Panel (EP), Technical Committees, Appeals Panel, JSM's assessor and personnel shall be made aware of and abide by this requirement for confidentiality.

4.16 Non-discriminatory condition

4.16.1 Any CABs operating in Malaysia whether on a profit or not for profit basis and able to demonstrate compliance with JSM accreditation criteria may apply for accreditation.

4.16.2 All government and non-governmental CABs are eligible to apply for an accreditation regardless of the size of CAB.

4.17 Fraudulent behaviour

4.17.1 JSM does not tolerate fraudulent behaviour.

4.17.2 Fraudulent behaviour is defined as one of the following:

- a) violation of any laws and regulations currently enforced in Malaysia;
- b) intentionally providing false information or concealing information;
- c) fabrication or falsification of documentation;
- d) deliberately violating accreditation policies and criteria;
- e) unethical conduct of conformity assessment activities; or
- f) involvement in bribery and corruption.

4.17.3 Taking into consideration the impact on the credibility and reputability of JSM accreditation, this policy covers fraudulent behaviour perpetrated by the following:

- a) applicant CABs and accredited CABs; and
- b) clients of applicant and accredited CABs.

4.17.4 If there is a report of fraudulent behaviour on CABs or on clients of applicant or accredited CABs:

- a) JSM will investigate reports and take actions of fraudulent behaviour in line with CAB 2 - Complaints and CAB 4 - Suspension and Withdrawal; and
- b) In addition, JSM will require the CAB to provide a show cause letter on why it shall absolve responsibility of involvement with the fraudulent behaviour of the client.

4.17.5 At any point in the application or initial assessment process, if there is evidence of fraudulent behaviour, if the CAB intentionally provides false information or if the CAB conceals information, JSM shall reject the application or terminate the assessment process.

4.17.6 JSM reserves the right to suspend or withdraw the CAB's accreditation if it is proven that the CAB has been involved in the mentioned fraudulent behaviour.

4.17.7 If a CAB is withdrawn or the application is terminated due to evidence of fraudulent behaviour, the CAB or the personnel involved is not allowed to re-apply for accreditation within two (2) years.

4.17.8 JSM will not hesitate to report to the International Accreditation Forum (IAF) and/or International Laboratory Accreditation Cooperation (ILAC) on the sanctions carried out by JSM.

4.17.9 JSM also reserves the right to take legal action for any violation of regulations of laws currently in force.

4.18 Unprofessional conduct

4.18.1 Factors that might indicate unprofessional conduct are as follows but not limited to:

- a) language that is harassing, hostile, abusive, obscene, racist, ageist, or otherwise discriminatory, offensive or threatening language in written or verbal communications;
- b) language that is combined with accusations and insults; and
- c) attempts to coerce or intimidate JSM officers/assessment team, or to abuse/distress them via language, tone of voice, body language or other behaviour, during written or verbal communications.

4.18.2 At any point in the application or initial assessment process, if there is evidence of unprofessional conduct by the CAB, JSM reserves the right to reject the application or terminate the assessment process.

4.18.3 JSM reserves the right to suspend or withdraw the CAB's accreditation if it is proven that the CAB has been unprofessional towards JSM officer/assessment team.

4.18.4 JSM also reserves the right to take legal action for any violation of regulations of laws currently in force.

5 Obligations of the conformity assessment bodies

5.1 General

5.1.1 Accreditation under the JSM accreditation schemes does not in any way exempt CABs from or diminishes their responsibilities in observing/complying with existing laws and regulations currently enforced in the country and international requirements where applicable.

5.1.2 Arrangements for charging of fees between a CAB and its client are in no way the responsibility of, and are not subject to the control of JSM.

5.1.3 The CAB shall, at its own risk, cost and expense, carry out the following obligations:

- a) fulfil all the requirements for accreditation imposed by JSM;
- b) arrange for the verification of the fulfilment of requirements for accreditation whenever requested by JSM;
- c) provide access to all relevant information, documents, records and systems as necessary to JSM's personnel and to verify the fulfilment of requirements for accreditation;

- d) arrange the witnessing of conformity assessment activities whenever requested by JSM;
- e) have, where applicable, legally enforceable arrangements/agreements with CAB's clients that commit the clients to provide, on request, access to JSM's assessment team to assess the conformity assessment 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 been granted;
- g) comply with all JSM's policy for the use of the accreditation symbol and/or combined ILAC MRA/IAF MLA mark;
- h) not use its Accreditation in such a manner as to bring the accreditation into disrepute;
- i) inform JSM without delay of any significant changes relevant to its accreditation;
- j) pay fees as determined by JSM;
- k) assist in the investigation and resolution of any accreditation-related complaints about the Conformity Assessment Body referred to by JSM;
- l) commit to be professional towards JSM's assessment team during the assessment as any unprofessional conduct may result in the assessment team discontinuing the assessment which may lead to suspension of the accreditation granted to CAB upon the incidents being reported and validated by JSM;
- m) provide JSM assessment team with suitable personnel protective equipment (PPE) whenever necessary; and
- n) retain all records as stated in the accreditation standard as required by law, or national guidelines or at least five (5) years.

5.2 Impartiality and integrity

5.2.1 The CABs and its personnel shall be free from any commercial, financial and other pressures or inducement, which might influence their technical judgment. This includes, but not limited to:

- a) the remuneration of the personnel engaged in conformity assessment activities shall not depend on the number of conformity assessment results;
- b) the CABs shall not allow persons or organisations external to the CABs to influence the results/decision of its conformity assessment activities performed by the CABs' personnel; and
- c) the CABs shall not engage in any activity that may endanger the trust in its independence of judgment and integrity in relation to its conformity assessment activities. For example, when products are tested by bodies, (e.g., manufacturers) who have been concerned with their design, manufacture or sale, a clear separation of different responsibilities shall be made known in the CAB's documented information.

5.3 Report or certificate issued by accredited conformity assessment bodies

5.3.1 CABs shall refer to Accreditation Policy 1 (AP 1) - Policy on the Use of Accreditation Symbol and Reference to Accreditation for the use of accreditation symbol and reference to accreditation.

5.3.2 All accredited report or certificates shall not be reproduced except in full without written approval of the accredited CAB to provide assurance that parts of a report/certificates are not taken out of context.

5.3.3 Reporting statement of conformity in report or certificate (applicable to SAMM testing and calibration laboratories)

5.3.3.1 The laboratory is required to establish a policy if the laboratory does not provide statement of conformity on their test report or calibration certificate.

5.3.3.2 The laboratory shall comply to clause 7.8.6 of MS ISO/IEC 17025 if the laboratory provides statement of conformity. The laboratory may refer to relevant latest edition of guidelines such as ILAC G8 Guidelines on Decision Rules and Statements of Conformity and JCGM 106 Evaluation of measurement data - The role of measurement uncertainty in conformity assessment or ISO/IEC Guide 98-4 Uncertainty of measurement Part 4: Role of measurement uncertainty in conformity assessment.

5.3.3.3 Where an accredited laboratory provides statement of conformity on their report or certificate this is not regarded as being part of opinions and interpretations.

5.3.4 Reporting opinion and interpretation in report or certificate (applicable to SAMM laboratories)

5.3.4.1 A SAMM accredited report or certificate shall not contain any expression of expert opinion as to serviceability of the sample, batch or consignment or its suitability for a specific purpose provided:

- a) any expression of expert opinion shall be qualified by a disclaimer that it is not under the scope of accreditation under SAMM; and
- b) any such expression of expert opinion be provided in a separate unendorsed document.

However, for medical testing reports, any expression of expert opinion, shall refer to SC 2: Specific Criteria for Accreditation in the Field of Medical Testing.

5.4 Cooperation with JSM

5.4.1 The CABs shall afford JSM, its assessors and its authorised representatives cooperation which shall include:

- a) reasonable access to relevant areas of the CAB for the assessment of the management system and witnessing of conformity assessment activities;
- b) provide facilities such as meeting room, internet connection, etc as necessary during assessment. This shall apply to all premises where the conformity assessment services take place;
- c) provide access to information, documents and records as necessary including the records of all complaints, appeals and subsequent actions shall be made available to JSM, where applicable for the assessment or throughout the accreditation period; and
- d) assisting in the investigation and resolution of any valid complaints received by JSM. These complaints may be made by third parties or interested parties on the conformity assessment activities.

5.5 Liabilities

5.5.1 An accredited CABs shall have full control of the issue of accredited reports or certificates subject to these terms and conditions. It shall have full liability on the issue of all reports or certificates.

5.5.2 The CABs shall have arrangements to cover the liability as stated in the accreditation standard or as required by law. It is advised that the CAB acquires professional indemnity insurance against risks that may arise from the use of the reports or certificates of the conformity assessment it performed.

5.6 Notification of change

5.6.1 The CABs shall inform JSM promptly any change bearing on its compliance with these terms and conditions and other requirements affecting the CABs' capability, competence, integrity, independence or scope of accreditation activities.

5.6.2 The CABs shall have arrangement to ensure that the information supplied to JSM is kept up to date. The CABs shall inform JSM immediately of any intended significant changes to its:

- a) legal, commercial, ownership or organisational status or structure;
- b) scope of accreditation;
- c) policies or procedures, where appropriate;
- d) address, premises, facilities, equipment or other resources, for example relocation and major renovation affecting the validity of results;
- e) CAB management or persons which has overall responsibility for the management and technical operation of the CAB, and key personnel including approved signatories; and
Note: Where relevant, if the CAB loses its sole approved signatory, the accreditation status of the CAB will be inoperative.
- f) other such matters that may affect the ability of the CABs to fulfil requirements for accreditation.

5.6.3 Under circumstances where an accredited CABs' capability or competence is affected by one or more of the above significant changes that reduced the confidence of CABs accredited scope, the CABs, at its discretion may make voluntarily request to JSM for the CABs to be placed under inoperative accreditation. After the appropriate actions have been completed to comply fully with JSM accreditation criteria and requirements, it shall notify JSM for a verification assessment to restore accreditation.

5.6.4 Failure to notify the significant changes to JSM may lead to suspension or withdrawal of accreditation.

5.6.5 A certificate of accreditation may be relinquished by an accredited CABs in writing to JSM.

5.6.6 Any notice or other communication shall be made in the form of post or email to the last known address of the accredited CABs.

6 Enforcement

6.1 Standards of Malaysia Act 1996 (Act 549), incorporating latest amendment of Act A1425 of year 2012 enables JSM to perform enforcement activities for misuse reference of 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]

7 Specific exception

7.1 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.

8 Miscellaneous

8.1 Accreditation shall not be regarded in any way diminishing the normal contractual responsibilities between the CAB and the clients.

8.2 While accreditation will normally be a sound indicator of the quality of service offered by the CAB, it cannot be taken to constitute a guarantee by JSM that the CAB always maintains a particular level of performance.

8.3 Fee arrangements between the CABs and its clients are not under the purview of JSM.

8.4 JSM reserves the right not to disclose any information on the complainant.

8.5 JSM does not accept or accredit more than one application from CABs, which has different legal entity but having a same management system, human resources and facilities at the same location.

8.6 Accreditation does not absolve the CABs from complying with relevant legal requirements relating to its conformity assessment activities. Compliance with legal requirements shall be the sole responsibility of the CABs. The CABs shall maintain the necessary records and make it readily available when requested by JSM.

Annex A

(Normative)

Witnessing process for conformity assessment bodies

A1 Witnessing inspection conducted by inspection bodies under MIBAS

A1.1 Witnessing of inspections is an essential part of the JSM assessment of inspection bodies. This is particularly important when the inspection body is performing inspections of such a nature where the inspector's professional judgment is crucial to the outcome of inspection.

A1.2 When deciding on the types of inspection to be witnessed, consideration will be taken of the following:

- a) variety of products, services, processes and plant covered by the inspection activities;
- b) skills needed by inspector;
- c) any regulatory requirements;
- d) the extent to which inspectors are required to exercise professional judgment.

A1.3 As a minimum, one inspection process will be assessed on-site for each of the fields/types of inspection activities as in scope of accreditation.

A1.4 The most critical contribution to inspections decision is the inspectors. Following this, inspectors shall be witnessed while performing inspections. Some of the consideration in determining the amount of witnessing include but not limited to the following:

- a) numbers of fields or inspection activities as in scope of accreditation;
- b) the extent to which inspectors are required to exercise professional judgements;
- c) total number of inspectors;
- d) frequency of each type of inspection;
- e) number of branches of the inspection body;
- f) history of performance during previous surveillance/reassessment;
- g) personnel certification or other formal qualifications held by inspectors;
- h) the training programme of the inspection body;
- i) effectiveness of internal monitoring of inspectors;
- j) organisational stability and risk awareness of the inspection body;
- k) any statutory requirements.

A1.5 If none of the inspectors can cover the entire scope of a specific field then more than one inspector will be assessed for that field. Where there is any evidence which casts doubt on the competence of inspection staff, the sample size of inspectors assessed on site may be increased.

A1.6 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an inspector operates remotely, this examination will be arranged at a mutually acceptable location.

A1.7 JSM assessor will ensure that their role during on-site witnessing of inspections is as one of observer and they will not influence or interfere with the inspection being performed.

A1.8 The assessment team will be assessing to ensure that as a minimum:

- a) the inspector has the competence for the inspection performed;
- b) the inspector's competence is consistent with the records;
- c) the inspector has been supplied with all necessary documented inspection methods and procedures;
- d) the procedures are up-to-date;
- e) the inspector implements the procedure in full and correctly i.e., no shortcuts, no personalised application where it is not permissible to do so;
- f) records of all observations are made while on site as required by the procedure;
- g) records clearly identify what has been inspected, using what method/procedure and when;
- h) all records are signed/initialled, as applicable;
- i) all findings that indicate immediate or urgent action are reported as required to the client whilst on site;
- j) reports comply with the inspection body requirements, MS ISO/IEC 17020 as amplified by ILAC P15 and relevant regulatory requirements;
- k) facilities and equipment are fit for the inspection purpose.

Annex A
(Normative)

Witnessing process for conformity assessment bodies

A2 Witnessing of certification body's auditors conducting audits under ACB Scheme

A2.1 The number of witnessing is as per the CB's assessment programme. The CB shall accommodate and arrange the witnessing audits according to the assessment programme.

A2.2 The CB to seek prior agreement of the client concerned and shall explain the reason for the presence of the JSM assessors, and assure that the team's presence will have no bearing on the outcome of the CB's own audit.

A2.3 CB and certified organisation should be aware that failure to witness an audit or an auditor in a particular scope sector may ultimately lead to JSM removing that scope sector from the accreditation scope.

A2.4 JSM 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.

A2.5 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.

A2.6 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 organisation according to the CB's policies and procedures.

A2.7 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, JSM reserves the right to initiate sanctions (e.g., suspension or withdrawal depending on severity).