



DEPARTMENT OF STANDARDS MALAYSIA ACCREDITATION OF CONFORMITY ASSESSMENT BODIES

CAB 4 SUSPENSION AND WITHDRAWAL OF ACCREDITATION

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1 PURPOSE

- 1.1 This document is to inform on the conditions for suspension and withdrawal of accreditation for which the Department of Standards Malaysia (Standards Malaysia) observes and operates under as part of the process of establishing and maintaining the competence and integrity of the national accreditation system, hereinafter referred to as the Accreditation System.
- 1.2 This document is applicable to all accreditation schemes operated by Standards Malaysia and their related terms and conditions.
- 1.3 Suspension due to the operation of SAMM Policy 10/ ACB 7/ MIBAS Policy 3/ MyPTP Policy 3 requires specific follow-up action as described in section 5.2 and 5.3 of this document.

2 **REFERENCES**

- 2.1 Standards of Malaysia Act 1996, (Act 549)
- 2.2 RoP MSAC: Rules of Procedures for the Malaysian Standards and Accreditation Council
- 2.3 SAMM Policy 1: Terms and Conditions Governing the Laboratory Accreditation Scheme of Malaysia
- 2.4 SAMM Policy 10: Policy on Grading of Non-conformities
- 2.5 ACB 1: Terms and Conditions Governing the Scheme for the Accreditation of Certification Bodies
- 2.6 ACB 7: The Conduct of Accreditation Assessments
- 2.7 MIBAS Policy 1: Terms and Conditions Governing the Malaysia Inspection Bodies Accreditation Scheme.
- 2.8 MIBAS Policy 3: Policy on Grading of Non-conformities
- 2.9 MyPTP Policy 1: Terms and Conditions Governing the Malaysia Proficiency Testing Provider Accreditation Scheme
- 2.10 MyPTP Policy 3: Policy on Grading of Non-conformities
- 2.11 CAB 3: Appeals
- 2.12 IAF MD 7 IAF Mandatory Document for Harmonisation of Sanctions to be Applied to Conformity Assessment Bodies

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

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

Accredited Conformity Assessment 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 conformity assessment body.

Evaluation Panel: A Panel i.e. Laboratory Accreditation Evaluation Panel (LAEP), Accreditation Review Panel (ARP), Inspection Accreditation Evaluation Panel (IAEP) or Proficiency Testing Accreditation Panel (PAEP) with appropriate members drawn from a pool of experienced individuals in the relevant accreditation scheme i.e. SAMM, ACB, MIBAS or MyPTP, to perform an independent and impartial evaluation and make appropriate recommendations to the Director General on the acceptability of conformity assessment bodies for accreditation.

Conformity Assessment Body (hereinafter referred to as CAB): Body that performs conformity assessment activities and that can be the object of accreditation, e.g. testing and calibration laboratories, certification bodies, inspection bodies and proficiency testing providers.

Director General: Director General of Standards Malaysia as the Head of Department who is appointed in accordance with Section 9 of the Act 549 and responsible to oversee the overall operation and executive functions of the department as stipulated in Subsection 10 of the Act 549.

4 GENERAL

The terms and conditions in SAMM Policy 1, ACB 1, MP1 and MyPTP1 governing the respective accreditation schemes prescribe the rights and responsibilities of Standards Malaysia in operating and administrating accreditation schemes. This includes the right to suspend or withdraw certificate of accreditation by the Director General of Standards Malaysia if any terms and conditions of the respective accreditation scheme has been breached.

5 SUSPENSION

- 5.1 Circumstances that may lead to suspension include any breach of the terms and conditions as described in the respective accreditation scheme. In addition, the following circumstances may also lead for suspension;
 - i) outcome of any assessment;
 - ii) non-payment of accreditation fees after issuance of reminder letters.;
 - iii) failure to submit the evidence of corrective action within the agreed time frame;
 - iv) negative outcome into a complaint;
 - v) abuse of sub-contracting / external providers;

- vi) abuse of the use of Standards Malaysia accreditation symbol or reference to Standards Malaysia accreditation;
- vii) if a certification body fails to complete the total number of witness audits for one cycle of accreditation (for ACB scheme only);
- viii) violation of any terms and conditions of Standards Malaysia accreditation schemes;
- ix) prolonged lapses in Surveillance /Re-assessment;
- x) failure to address outlier in proficiency testing (for SAMM and MIBAS);
- xi) 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) (For ACB Scheme only); or
- xii) other circumstances for suspension as determined by the respective accreditation schemes from time-to-time.
- 5.2 For SAMM/MIBAS/MyPTP scheme:
 - a. Where suspension is recommended by a Team Leader due to the issuance of a Category 1 NCR during an assessment under SAMM/MIBAS/MyPTP, the conditions described in SAMM Policy 10/MIBAS Policy 3/MyPTP Policy 3 shall apply.
 - b. In this case, the summary report with any relevant documents are compiled and submitted to the Director General for approval. The Director of Accreditation will notify the affected CAB in writing of the suspension and the condition(s) for reinstatement of accreditation.
 - c. Where the issues at hand are highly technical in nature, the Director of Accreditation may call for an Evaluation Panel meeting for recommendation prior to approval by the Director General.
 - d. The suspension may be part of the scope of accreditation or the entire CAB accreditation status.
- 5.3 For ACB Scheme:
 - a. When there are situations that necessitate suspension, the relevant supporting documents are compiled and submitted to the Director General for review and approval.
 - b. Where the issues at hand are highly technical in nature, the Director of Accreditation may call for an Evaluation Panel meeting for recommendation prior to review and approval by the Director General.
 - c. The suspension may be part of the scope of accreditation or the entire certification body accreditation status.
- 5.4 The affected CAB is notified accordingly. Notification of suspension to the CAB also informs the reason(s) for suspension, actions to be taken during suspension, conditions for reinstatement of accreditation and the CAB's right to appeal as provided under the Terms and Conditions of the respective scheme.

- 5.5 The period of suspension is decided by the Director General based on the types and seriousness of non-conformities or breach to the terms and conditions of accreditation. **Table 1 as in Annex 1** provides some general guidance.
- 5.6 Standards Malaysia will make available information on the suspension of its CAB in its website. Standards Malaysia also reserves the right to inform the relevant secretariat under which Standards Malaysia is a signatory to on the status of suspension of a CAB and the reason(s) resulting in the suspension.
- 5.7 The CAB shall inform its affected clients of the suspension of its accreditation and the associated consequences without undue delay.
- 5.8 Accreditation officer assigned to take responsibility on suspended CAB monitors the performance including corrective actions of the CAB concerned.
- 5.9 At the end of the suspension period, or when informed by the CAB, Standards Malaysia accreditation assessor / officer may carry out a verification assessment and to review the status of suspension. An assessment report will be prepared and submitted to Standards Malaysia.
- 5.10 When the accreditation assessor / officer has confirmed that satisfactory corrective actions have been implemented effectively, then a recommendation for reinstatement of accreditation is prepared and forwarded to the Director General of Standards Malaysia.
- 5.11 Upon the approval of the Director General, the CAB is informed on the reinstatement of accreditation.
- 5.12 If no corrective actions have been implemented by the CAB, Scheme Manager initiates action to withdraw accreditation and adheres to the procedure of withdrawal.
- 5.13 Any other matters related to suspension actions or that may arise or any inadequacy that become apparent in the course of implementing this is referred to the Evaluation Panel for the relevant schemes for advice and resolution.

6 WITHDRAWAL

- 6.1 Circumstances that may lead for withdrawal of accreditation are as follows:
 - i) outcome of any assessment;
 - ii) negative outcome of a complaint;
 - iii) non-payment of accreditation fees after issuance of a reminder and a final warning letter, if after suspension, no action is taken;
 - iv) bankruptcy or closure of business of the accredited CAB;
 - v) voluntary withdrawal of a CAB;
 - vi) abuse of subcontracting / external providers;
 - vii) failure to reinstate accreditation status after suspension;
 - viii) consecutive three (3) times suspension within a period of three (3) years;
 - ix) proven evidence of fraudulent behavior, or the CAB intentionally provides false information;

- 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) (For ACB Scheme only); or
- xi) other circumstances for withdrawal as determined by the respective accreditation schemes from time-to-time.
- 6.2 If a recommendation for withdrawal of accreditation is received from the assessment team, the recommendation is first reviewed by an accreditation officer.
- 6.3 The report with the file of the affected CAB is further reviewed by the Scheme Manager in charge of that particular scheme and verified by the Director of Accreditation.
- 6.4 Where the issues at hand are highly technical in nature, the Director of Accreditation may call for Evaluation Panel meeting for recommendation prior to approval by the Director General.
- 6.5 After fully satisfied that there is sufficient evidence for breach of any term and condition that necessitate withdrawal, recommendation for withdrawal is forwarded to the Director General for final decision.

On the other hand, if the Director General is not satisfied with the report, he/she will request the Accreditation Division to re-examine the recommendation. If the evidence submitted is weak or unsubstantiated, the recommendation for withdrawal is dropped. The affected CAB is notified accordingly.

- 6.7 The affected CAB for withdrawal has the right to appeal as provided under the terms and conditions of the respective accreditation scheme.
- 6.8 When accreditation certificate is withdrawn the CAB is to be reminded on its obligation including to return the certificate of accreditation to Standards Malaysia and to refrain from making claim in writing or otherwise of its accreditation. The CAB shall inform its affected clients of the withdrawal of its accreditation and the associated consequences without undue delay.
- 6.9 Standards Malaysia will make available information on the withdrawal of accreditation of its CAB in its website. Standards Malaysia also reserves the right to inform the relevant secretariat under which Standards Malaysia is a signatory to on the withdrawal of a CAB and the reason(s) resulting in the withdrawal.

Annex 1

Nature of Non-conformities or breach of terms and conditions	Suspension Period
a) Failure to pay any fee after 2 months invoice issued	1 month Withdrawal after 1 month suspension period ends and there is no payment received
 b) Abuse of subcontracting/ external provider c) Abuse on the use of Standards Malaysia accreditation symbol or reference to Standards Malaysia accreditation 	3 months Withdrawal initiated after 3 subsequent cases of abuse
 d) NCR Cat. 1 issued (applicable to SAMM, MIBAS and MyPTP) Note: Suspension entire accreditation status if NCR related to a CAB's accreditation system or partial scope of accreditation if NCR related to specific scope only 	Start: Suspension from the date of assessment End: Upon satisfactory closure of nonconformity or at the expiry of accreditation, whichever comes first
 e) Failure to submit satisfactory evidence of non- conformity Cat. 2 and Cat. 3 (applicable to SAMM, MIBAS and MyPTP) Note: Suspension entire accreditation status if NCR related to CAB accreditation system or partial scope of accreditation if NCR related to specific scope only 	Start: 3 months from the date of assessment End: Upon satisfactory closure of non- conformity(ies) or at the expiry of accreditation, whichever comes first
f) Failure to submit satisfactory evidence of non- conformity(ies) in specified time frame (applicable to ACB only)	Minimum suspension period of at least 3 months Start: End of the time frame End: After 3 months period and upon satisfactory closure of non-conformity(ies) or at the expiry of accreditation, whichever comes first
g) Significant change of CAB's personnel that seriously affect the competence of the body as an accredited CABh) Violation of any terms and conditions of	Start: Upon receiving information on changes End: Upon satisfactory verification or at the expiry of accreditation, whichever comes first At the discretion of Standards Malaysia on a
respective accreditation scheme	case to case basis

Inoperative	Inoperative Period
Inoperative occur when a CAB requests a temporary suspension of its accreditation status due to relocation, resignation of signatory, restructuring or other similar situation.	Start: Effective date of notification by CAB. End: Upon satisfactory verification or action implemented by CAB, or lapse of accreditation on the expiry date, whichever comes first.