



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

**ACCREDITATION POLICY 7 (AP 7) -
POLICY ON GRADING OF ASSESSMENT FINDINGS**

Issue 2, 29 August 2023



**JABATAN STANDARD MALAYSIA
DEPARTMENT OF STANDARDS MALAYSIA**

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Introduction

Accreditation provides formal recognition to Conformity Assessment Bodies (CABs) which comply with specific standards that define the requirements for competency, impartiality and consistent operation.

Department of Standards Malaysia (JSM) conducts an assessment to determine the competence of a CAB, based on standard(s) and/or other normative documents and for a defined scope of accreditation. During the assessment, JSM may raise findings for the CAB to take appropriate action.

1 Scope

1.1 This document outlines the policy of the JSM with regards to the grading of findings and the appropriate actions to be taken by applicant and accredited CABs, according to the category of findings raised.

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

- 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 Verification Bodies (MyV&V).

2 Normative references

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 Definition

3.1 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.

3.2 Accreditation criteria

Includes 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.

3.3 Conformity Assessment Bodies (CABs)

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

3.4 Finding

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

3.5 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.

3.6 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.

3.7 Category 3 Observation

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

4 Grading of findings

4.1 An assessment is conducted to determine the competence, impartiality, and consistent operation of CABs. This assessment process requires the professional judgement of the assessor or assessment team. Where the CABs activities are not in compliance with accreditation criteria, findings will be raised.

4.2 Category of findings

JSM will consider the nature of findings, as well as the objective evidence and categorise the findings as category 1 nonconformity, category 2 nonconformity or category 3 observation.

4.2.1 Category 1 Nonconformity

4.2.1.1 Where a non-conformity is very serious the accreditation of the CAB is suspended immediately. The effective date of suspension shall be the date of the finding raised by the assessment team.

4.2.1.2 The CAB shall provide analysis of the extent and cause (e.g. root cause analysis) of the nonconformities, description and appropriate corrective action for the assessment team to review and satisfactorily close the nonconformities. The assessment team may conduct a verification assessment to verify corrective action and satisfactory close the Category 1 Nonconformity.

4.2.1.3 Suspension will only be uplifted once the nonconformity is satisfactorily closed. Accreditation is reinstated upon approval by the Director General.

4.2.1.4 The affected scope of accreditation is withdrawn if no corrective action is received within 2 years or after the expiry date of accreditation, whichever comes first. JSM issues a letter of termination to the CAB.

4.2.1.5 A CAB whose accreditation is suspended/withdrawn shall not issue accredited reports/certificates or make reference to JSM accreditation for those scopes for which accreditation has been suspended/withdrawn in accordance with AP 1. Failure to comply with these conditions shall result in legal actions against CABs as stipulated in Act 549, Standards of Malaysia Act 1996.

4.2.2 Category 2 Nonconformity

4.2.2.1 Where nonconformity is significant, analysis of the extent and cause (e.g. root cause analysis) of the nonconformities, description and corrective action shall be submitted to JSM within three (3) months. If the CAB fails to submit corrective action for ALL nonconformities raised, JSM may initiate suspension.

4.2.2.2 The CAB shall ensure that all the nonconformities are satisfactorily closed out within five (5) months from the last date of assessment, or until the date of expiry, whichever comes first. Failure to satisfactorily close out the nonconformities within the stipulated time, results in the following:

- a) If the nonconformities are not satisfactorily closed out within five (5) months and the accreditation is still valid, JSM may initiate suspension of the CAB's accreditation;
- b) If the nonconformities are not satisfactorily closed until the date of expiry, the CAB's accreditation is considered lapsed.

4.2.2.3 For reassessment, it is the responsibility of the CAB to ensure that assessment is carried out with sufficient time to close any findings raised. If the CAB conducts reassessment less than three (3) months before the expiry, the CAB shall ensure ALL nonconformities are satisfactorily closed within three (3) months. Failure to close the nonconformities within the stipulated time will result in lapse of accreditation.

4.2.2.4 The assessment team may conduct a verification assessment to verify corrective action to satisfactory close the nonconformities.

4.2.2.5 Suspension will only be uplifted once nonconformities are satisfactorily closed. Accreditation is reinstated upon approval of the Director General.

4.2.2.6 The accreditation status of the CAB is withdrawn if no corrective action is received within 2 years or after the expiry date of accreditation, whichever comes first.

4.2.2.7 Category 1 Nonconformity may be raised in the next assessment if the same Category 2 Nonconformity recurs.

4.2.3 Category 3 Observation

An assessment finding that is not a nonconformity but is identified by the assessment team as an opportunity for improvement. It is not mandatory for the CAB to respond to the observation; however, the CAB is strongly recommended to take appropriate action to indicate commitment for continual improvement.

4.3 New applicant and applicant for extension of branch/scope

4.3.1 For applicant CABs or accredited CABs seeking extension of branch/scope, the following shall apply:

- a) Findings raised are categorised based on clause 4.2 to indicate to the CAB the severity of the finding. However, the timeline for submission of findings as defined above does not apply.
- b) Nonconformities (i.e. Category 1 and Category 2) raised shall be closed within the application validity (i.e. 2 years for applicants and 1 year for extension of branch/scope).
- c) If submission of corrective action exceeds 6 months from the date of assessment, JSM may conduct a verification assessment.