

MINISTRY OF INVESTMENT, TRADE AND INDUSTRY DEPARTMENT OF STANDARDS MALAYSIA

# ACCREDITATION POLICY 3 (AP 3) -POLICY FOR THE ACCREDITATION OF BRANCHES OR SITES OF CONFORMITY ASSESSMENT BODIES

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# 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 accreditation of branches or sites of conformity assessment bodies (CABs) which includes but not limited to testing and calibration laboratories, certification bodies, inspection bodies and proficiency testing providers.

#### 1 Scope

1.1 This document outlines the policy of the JSM with regards to requirements for applicant and accredited CABs that carries out its conformity assessment activities:

- a) at or from a permanent branch location; or
- b) at or from a site.

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 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 Scheme (MyV&V).

#### 2 Normative reference

2.1 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 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.

#### 3.2 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.

# 3.3 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.

## 3.4 Initial assessment

The assessments conducted after acceptance of application until granting of accreditation. The initial assessment includes documentation review, pre-assessment (if applicable) and compliance assessment.

# 3.5 Site

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

## 3.6 Mobile facilities of laboratory or inspection body

Fully equipped vehicle or purpose-built transportable facilities (laboratory or inspection body).

# 4 General requirements

4.1 The categorisation of Central, branches or sites of CAB depends on the key activities carried out as follows:

- a) Legal entity;
- b) Management representative;
- c) Field/programme of accreditation;
- d) Management system;
- e) Development of policy, process, procedure;
- f) Contract review/review of requests;
- g) Planning of CAB's activities;
- h) Reviewing or authorising of CAB's results;
- i) Issuing CAB's certificates/reports
- j) Management of records
- 4.2 The CAB shall manage the key activities as per **Table 1**.

# Table 1 – Comparison of Central, Branch and Site

Items	Central CAB	Branch CAB	Site
a) Legal Entity	Shall be a legal entity Has legal rights and is responsible for the Central CAB and its branches/sites	Having the same legal entity as the Central CAB	Having the same legal entity as the Central CAB

Items	Central CAB	Branch CAB	Site
b) Management Representative	Appoints Central Coordinator	Appoints Branch Coordinator or managed by the Central Coordinator	Managed by Central/Branch Coordinator
c) Field/ Programme of Accreditation	May apply for any programme or field	May apply for same/different programme or field as Central CAB	May apply for same/ different programme or field as Central CAB
d) Management System	Establishes the management system. If the Central CAB conducts conformity assessment activities, it shall also operate under the same management system	Operates under the same management system as the Central CAB	Operates under the same management system as the Central CAB
e) Development of Policy, Process, Procedures	Responsible to develop relevant policy, process and procedures	May develop its own policy, process, and procedure or directly implements Central CAB's policy, process and procedures	Does not develop its own policy, process, and procedures. Directly implements Central CAB's and/or branch policy, process and procedures
f) Contract Review / Review of requests	Performs contract review/review of requests for Central CAB/branch/site	May perform contract review/ review of requests for branch	Does not perform contract review/ review of requests
g) Planning of CAB activities	Planning for Central CAB and/or branch/site	May plan for branch or follow Central CAB's plan	Does not plan. Planning is done by the Central CAB and/or branch
h) Reviewing or Authorising of CAB results	Reviews and authorises central CAB results and or branch/site results	Reviews and authorises branch results only. Reviews and authorisation of branch results may be done by Central CAB	Reviews and authorises site results only. Reviews and authorisation of site results may be done by Central CAB or Branch

Items	Central CAB	Branch CAB	Site
i) Issuing CAB certificates/ reports	Issues CAB certificate or report from Central CAB	CAB certificate or report is issued by the Central CAB or issued directly by the branch	CAB certificate or report is issued by the Central CAB or Branch CAB or issued directly by the site
j) Management of records	Managed by the Central CAB	Managed by the Branch CAB	Managed by the Site CAB

- 4.3 In addition to Table 1, the CAB/branch/site shall demonstrate the following: -
- a) All branches or sites are included in the internal audit programme and management review process of the Central CAB;
- b) For laboratory and inspection body, all branches have satisfactorily participated in proficiency testing (PT) activity in accordance with JSM accreditation criteria;
- c) All branches shall have sufficient personnel including at least one (1) resident signatory/key personnel responsible for managerial and technical role for each field/programme of accreditation; and
- d) All sites shall have sufficient competent personnel responsible for each field/ programme of accreditation.
- e) Where the conformity assessment activities performed by other branches or sites or external providers, relevant requirements related to external providers shall apply. Record of the review of request shall be retained.
- f) Result of conformity assessment activities shall be clearly indicated when it is performed by other branches or sites or external providers.

## 5 Accreditation process

#### 5.1 Application

5.1.1 An applicant that has several branches or sites may obtain a single accreditation, provided that the conditions specified by JSM are fulfilled. The applicant shall clearly identify the Central CAB. If the Central CAB has conformity assessment activities, it shall be accredited. A Central Coordinator shall be appointed by the Central CAB as an authorised representative.

5.1.2 All applications for a branch shall be made by the Central CAB. If the Central CAB is an applicant, it may submit the application for accreditation for the Central CAB together with a maximum of two (2) branches in one (1) application. There is no limit on the number of sites that can be applied in one (1) application. The Central CAB shall indicate the range of scopes for each branch or site in the application.

5.1.3 The Central CAB shall apply for Extension of Branch (EOB) for addition of branch and apply for Extension of Scope (EOS) for addition of site.

5.1.4 For EOB, a maximum of three (3) branches are allowed in one (1) application. There is no limit for addition of sites under EOS.

5.1.5 Only one (1) application for EOB and/or EOS is allowed at one time. The EOB and/or EOS application will be valid for one (1) year from the date of acceptance.

# 5.2 Initial assessment

5.2.1 Generally, JSM will assess all branches or sites during initial assessment.

5.2.2 Initial assessment will be conducted together with the Central CAB. Documentation Review and Preassessment will be conducted at the Central CAB. The conduct of Compliance Assessment will involve both the Central CAB and branches or sites.

5.2.3 During the assessment at the Central CAB, JSM may need to access records of activities, which are being carried out at different branches or sites.

5.2.4 Any nonconformity raised at the Central CAB or at any one of the branches or sites; the corrective action procedure shall apply to all branches or sites where applicable.

#### 5.3 Maintenance of accreditation

5.3.1 For maintenance of accreditation (i.e. surveillance or reassessment), branches or sites shall be assessed in accordance with the assessment programme of Central CAB for each accreditation cycle.

5.3.2 Generally, JSM will assess all branches or sites during each scheduled assessment. JSM reserve the right to increase or reduce the frequency and number of branches or sites to be assessed based on a risk assessment which includes but not limited to:

- a) The number of personnel at each branch or site;
- b) Maturity of the CAB's management system;
- c) Complexity of CAB's documentation;
- d) Logistics (Conformity assessment activities are carried out at more than one (1) location);
- e) Number and complexity of scope of accreditation;
- f) Records of complaints on the CAB;
- g) Records of appeals made by the CAB to JSM;
- h) Results of CAB's internal audit and/or management review;
- i) Results of CAB's previous assessments (e.g. significant weakness or inconsistency in the implementation of the management system); and
- j) Other reasonable factors which may affect the management system of the CAB.

5.3.3 For MIBAS, branches or sites having similar activities may be assessed on a sampling basis. This will be determined based on the key activities as well as risk associated mentioned in 5.3.2.

5.3.4 JSM shall be notified of any changes to branch or site location and activities. The need for assessment shall be reviewed and assessment may be carried out during surveillance, reassessment or in a separate assessment where necessary.

5.3.5 Suspension and withdrawal may occur in the following circumstances:

- a) If the failure to comply with JSM criteria is at the Central CAB, the overall accreditation may be suspended or withdrawn including branch and site;
- b) If the failure to comply with JSM criteria is at the branch or site due to the lack of control by the Central CAB, the overall accreditation may be suspended or withdrawn including branch and site;
- c) If the failure to comply with JSM criteria is at the branch or site, the branch or site may be suspended or withdrawn from the scope of accreditation.

#### 6 Scope of accreditation

All branches or sites shall be issued with the same accreditation number as the Central CAB.

#### 7 Use of accreditation symbol and reference to accreditation

In line with JSM accreditation criteria, the CAB shall only use the accreditation symbol and/or make reference to accreditation on any branch or site which has been accredited and included in the scope of accreditation.

#### 8 Accreditation fees

8.1 All fees for branch/site CAB shall be charged according to Standards of Malaysia (Fees) Regulation 2018.

8.2 Matters related to accreditation fees shall be coordinated by the Central CAB.