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**SAMM CIRCULAR 1/2018**  
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**POLICY ON SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)**

**REQUIREMENTS FOR THE ACCREDITATION OF BRANCH OR  
SATELLITE LABORATORIES**

**1. Introduction and Scope**

This circular provides Standards Malaysia policy on the requirements for the accreditation of branch or satellite laboratories.

Standards Malaysia policy allows for an organisation to combine branch or satellite laboratories under one accreditation. All applicants and accredited laboratories intending to apply for the above scope are required to comply with the requirements of this circular.

Satellite laboratory is only applicable for medical testing laboratories seeking accreditation/accredited to MS ISO 15189.

**2. Implementation Date**

This circular will be implemented effective immediately.

**3. Definitions**

**3.1 Central laboratory/office**

The headquarters where the management system is administered. The headquarters may or may not be a laboratory.

**3.2 Branch laboratory**

(A) laboratory(ies) at a different location managed by the central laboratory/office with the same management system and owned by the same legal entity.

**3.3 Satellite laboratory** (for MS ISO 15189 accreditation only)

(A) physically separate laboratory(ies) (from the main laboratory) that is allowed to place their testing or calibration capabilities on the main laboratory's scope (with a footnote to reference their location) as long as the satellite laboratory is:

- i. not performing any 'key activities' (i.e. policy formulation, process and/or procedure formulation); and
- ii. in close proximity to the main laboratory (usually within the same state, unless special exception is granted by Standards Malaysia);

**4. Accreditation Criteria and requirements**

**4.1 Conditions to apply for branch laboratory(ies) or satellite laboratory(ies)**

4.1.1 The central laboratory/office shall be clearly identified. If the central is a laboratory, the central laboratory shall be accredited.

4.1.2 A central coordinator shall be appointed by the central laboratory/office as an authorised representative.

4.1.3 For medical testing, each accreditation (with the same SAMM number) shall only be made for either branch laboratory or satellite laboratory.

4.1.4 In addition to 3.2 and 3.3, each branch or satellite laboratory shall comply with the following:

- i. Under the same legal entity as the central laboratory/office;
- ii. Operate under the same management system;
- iii. Have conducted at least ONE (1) internal audit and management review included under the central laboratory/office before application;
- iv. Undergone proficiency testing (PT) activity in accordance with SP4; and
- v. Have sufficient personnel and at least ONE (1) resident signatory/key personnel for each field of accreditation.

4.1.5 Accreditation of branch or satellite laboratory shall comply with all current SAMM accreditation policies and criteria.

4.1.6 For branch laboratory(ies), one accreditation number can only cover a maximum of five (5) branch laboratories including central laboratory (if any).

4.1.7 For satellite laboratory(ies), there is no limitation to number of laboratories.

## **4.2 Application process for branch or satellite laboratory(ies)**

- 4.2.1 The central laboratory/office shall apply for an additional branch or satellite laboratory(ies) under the extension of scope/branch application (LA 202EXT).
- 4.2.2 For branch laboratory(ies) application, a separate application must be completed for each laboratory.
- 4.2.3 The Extension of Branch (EOB) application will be valid for one (1) year from the date of assessment conducted.
- 4.2.4 New EOB application can only be made once existing EOB application has been accredited.

## **4.3 Assessment Process for branch or satellite laboratory(ies)**

- 4.3.1 A compliance assessment shall be conducted at each branch or satellite laboratory to confirm competence and operation is under the same management system as the central laboratory.
- 4.3.2 Branch or satellite laboratory(ies) shall follow the same accreditation schedule as the central laboratory/office. Subsequent scheduled assessments shall cover all branches or satellite laboratory(ies).
- 4.3.3 For any nonconformities raised, if the nonconformity relates to the management system, the corrective action shall be applied across all branches. If a nonconformity is at a particular branch or satellite laboratory is identified as major, it may lead to suspension or withdrawal of the accreditation of the branch or satellite laboratory.
- 4.3.4 The central laboratory/office shall notify Standards Malaysia of any changes of personnel or branch that may affect its accreditation. Depending on the significance of the change, a verification assessment may be conducted to ensure continued compliance with Standards Malaysia accreditation requirements and criteria.

## **4.4 Scope of Accreditation**

- 4.4.1 All branch or satellite laboratory shall be issued with the same accreditation number.

## **4.5 Accreditation fees**

- 4.5.1 All fees for branch laboratories shall be charged according to Standards of Malaysia (Fee) Regulation 2018.
- 4.5.2 Accreditation fees shall be managed by the central coordinator.

#### **4.6 Special exception**

The Director of Accreditation, at his discretion, may grant specific exceptions to the requirements for branch or satellite laboratory.

Approved by,  
**Director of Accreditation**  
**Department of Standards Malaysia**  
Date: 2 March 2020