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SAMM CIRCULAR 2/2021

**POLICY ON THE QUALITY MANAGEMENT SYSTEM (QMS)
UNDER THE PURVIEW OF ONE LEGAL ENTITY
FOR MEDICAL TESTING LABORATORIES**

1. Introduction and Scope

This circular outlines Standards Malaysia policy on the requirements for the accreditation of medical testing laboratories with more than one Quality Management System (QMS) for MS ISO 15189 under the purview of one legal entity.

2. Policy on the Quality Management System (QMS) under the Purview of One Legal Entity for Medical Testing Laboratories

Standards Malaysia policy allows for an organisation to have more than one laboratory implementing the same QMS under one accreditation i.e. same SAMM number.

All applicants and accredited laboratories who wish to have separate QMS in one organisation, shall apply for accreditation individually.

If the accredited laboratory having more than one QMS with the same SAMM number, the laboratory needs to decide the option as follows:

- a) **Option 1** - Merge the QMS under one SAMM number; or
- b) **Option 2** - Maintain more than one QMS with separate SAMM number, under the same legal entity

3. Criteria for Option 1 and Option 2

<u>Option 1</u>	<u>Option 2</u>
Merge the QMS under one accreditation SAMM number, this is only applicable for existing accredited laboratory sharing same SAMM number but having separate QMS. This option is not applicable to new applicants.	Maintain more than one QMS with separate SAMM number, under the same legal entity

<u>Option 1</u>	<u>Option 2</u>
<p>a) One accreditation number used by more than one department which led by different laboratory director/head of department and report to the same top management. Standards Malaysia may issue accreditation certificate to each department/laboratory where necessary.</p> <p>b) The departments/laboratories which implement the same QMS shall be coordinated by representatives of the departments/laboratories and the interrelationship shall be documented.</p> <p>c) Laboratories shall use one Laboratory Quality Manual and the same Quality Procedures. The laboratory may establish specific procedures for each department/laboratory, where applicable.</p> <p>d) Standards Malaysia will only charge for one accreditation based on Standards Malaysia (Fee) Regulation 2018.</p> <p>e) A Team Leader will be appointed for the organisation.</p> <p>f) Only one assessment will be conducted according to Standards Malaysia assessment schedule.</p>	<p>a) The departments/laboratories implement individual QMS and procedures. The departments/laboratories shall ensure that access control, confidentiality and impartiality between each other comply with MS ISO 15189 requirements especially where the shared resources (e.g. personnel, equipment, facilities etc.) are used.</p> <p>b) The organisation shall decide among the departments/laboratories which will maintain the existing accreditation number and the other department/laboratory shall submit a new application for accreditation. Hence, the applicant laboratory will start full application process for accreditation i.e. Adequacy Audit> Pre-Assessment> Compliance Assessment.</p> <p>c) Granting of accreditation will be given according to the application for the respective departments/laboratories.</p> <p>d) Standards Malaysia will charge the departments/laboratories individually according to SAMM number, based on Standards Malaysia (Fee) Regulation 2018.</p> <p>e) A Team Leader will be appointed for each department/laboratory.</p> <p>f) Separate assessments will be conducted for each department/laboratory according to Standards Malaysia assessment schedule.</p>

4. This circular will be implemented effective immediately.

Approved by,

**Director of Accreditation
for the Director General
Department of Standards Malaysia**

Date: 25 February 2021