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SAMM Medical Testing Laboratories and Assessors  
Accreditation Officers



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**SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)**  
**SAMM CIRCULAR 3/2019**  
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**GUIDELINE FOR THE DETERMINATION OF ASSESSMENT MAN-DAYS OF  
ACCREDITATION ASSESSMENT FOR MEDICAL TESTING LABORATORIES  
(SAMM MS ISO 15189)**

**Scope**

This guideline is applicable to applicants and accredited SAMM Medical Testing Laboratory.

**Implementation Date**

This circular will be implemented effective immediately.

**Guidelines for the Determination of Assessment Man-Days**

Types of Assessment	Activities During Assessment	Medical Testing Assessor	
		Team Leader	Technical assessors
Adequacy Audit	Review on: <ul style="list-style-type: none"> <li>Structure of Laboratory Operation</li> <li>Documentation Structure</li> <li>Lab Policy</li> <li>Completeness of Procedure for QMS</li> <li>Adequacy of Forms</li> <li>Preparation of Adequacy Audit report</li> </ul>	One Day	NIL
Pre-Assessment /Compliance Assessment /Surveillance /Renewal	On-site assessment  Review on: <ul style="list-style-type: none"> <li>Structure of Laboratory Operation</li> <li>Documentation Structure</li> <li>Lab Policy</li> <li>Completeness of Procedure for QMS</li> <li>Adequacy of Forms</li> </ul> During Assessment: <ul style="list-style-type: none"> <li>Review implementation records/QC/EQA/PPM</li> </ul>	1-3 Days	1-3 Days*

Types of Assessment	Activities During Assessment	Medical Testing Assessor	
		Team Leader	Technical assessors
	<ul style="list-style-type: none"> <li>• Interview personnel</li> <li>• Witnessing personnel performing test</li> <li>• Scope confirmation</li> <li>• Witnessing report</li> <li>• EQA/QC evaluation</li> <li>• Assessment findings and observation</li> <li>• Preparation of assessment report</li> </ul>		
Assessment for Extension of Scope/ Verification Assessment	<p>On-site assessment</p> <p>During Assessment:</p> <ul style="list-style-type: none"> <li>• Review implementation records/QC/EQA/PPM</li> <li>• Interview personnel</li> <li>• Witnessing personnel performing test</li> <li>• Scope confirmation</li> <li>• Witnessing report</li> <li>• EQA/QC evaluation</li> <li>• Assessment findings and observation</li> <li>• Preparation of assessment report</li> </ul>	0.5 Day to Two Days	0.5 Day to Two Days*

**\* Notes:**

Minimum one technical assessor will be appointed for an assessment per discipline/field of scope accreditation. However, the number of technical assessors appointed for each discipline is determined by the complexity of scope of accreditation e.g.: Specialised and Routine Test, Bacteriology & Serology

The completeness of the assessment activity above includes the following:

- a) Prior Assessment:
- (i) Review Scope/Method/Personnel under accreditation
  - (ii) Previous Assessment report
  - (iii) Documentation preparation
- b) Post Assessment:
- (i) Review and acceptance evidence of corrective action
  - (ii) Preparation of assessment report (where necessary)

Approved by:

**Director of Accreditation**  
**Department of Standards Malaysia**  
Date: 1 November 2019