



STANDARDS
MALAYSIA

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA

**SAMM POLICY 6 (SP 6) – REQUIREMENTS FOR
SAMM APPROVED SIGNATORY**

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MS ISO/IEC 17025

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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1 Introduction

- 1.1 The approved signatory under *Skim Akreditasi Makmal Malaysia* (SAMM) is as defined in SAMM Policy 1 (SP 1) – Terms and Conditions Governing the Laboratory Accreditation Scheme of Malaysia.
- 1.2 The presence of SAMM symbol or reference to SAMM accreditation in the test reports or calibration certificates is a formal recognition of the technical competence of the laboratory and the evidence of its compliance with MS ISO/IEC 17025 and SAMM requirements.
- 1.3 This policy document should be read in conjunction with other SAMM requirements.

2 Scope

- 2.1 This document specifies the policy and requirements for SAMM signatory approval for use by SAMM laboratories, assessors and other interested parties.
- 2.2 This policy is applicable to SAMM accredited and applicant laboratories under MS ISO/IEC 17025.

3 Requirements of MS ISO/IEC 17025

- 3.1 Clause 6.2.2 of MS ISO/IEC 17025 requires,
“The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.”

NOTE: The laboratory shall document competence requirements for the signatory(ies).

- 3.2 Clause 6.2.5 of MS ISO/IEC 17025 requires,
*“The laboratory shall have procedure(s) and retain records for:
a) determining the competence requirements;”*

NOTE: Records for all technical personnel including approved signatory(ies) shall be maintained.

- 3.3 Clause 6.2.6 of MS ISO/IES 17025 requires,
*“The laboratory shall authorise personnel to perform specific laboratory activities, including but not limited to, the following:
a) development, modification, verification and validation of methods;
b) analysis of results, including statements of conformity or opinions and interpretations;
c) report, review and authorisation of results.”*

NOTE: Such personnel as in Clause 6.2.6 c) shall be SAMM approved signatory for SAMM endorsed test reports or calibration certificates.

- 3.4 Clause 7.8.1.1 of MS ISO/IEC requires,
“The results shall be reviewed and authorised prior to release”

NOTE: The results shall be reviewed and authorised by approved signatory(ies).

- 3.5 Clause 7.8.2.1 (o) of MS ISO/IEC 17025 requires that each report shall bear the identification of the person(s) authorising the report.

NOTE: Referring to the Clause 7.8.1.2 of MS ISO/IEC 17025, report means a test report or a calibration certificate or report of sampling.

4 SAMM Policy on approved signatory

- 4.1 A report issued by SAMM accredited laboratories for accredited test or calibration shall be reviewed and authorised by signatory(ies) approved by Standards Malaysia. An approved signatory is responsible for the technical validity and accuracy of all information contained in the report.
- 4.2 The nominated signatory shall be assessed on-site by the assessment team for compliance with Clause 5 of this document.
- 4.3 The signatory shall hold a position within the organisation, which provides authority over the testing or calibration activities and to reject results when he/she considers them to be inadequate.
- 4.4 Signatory approval by Standards Malaysia is granted to personnel for specific scopes for which he/she has been assessed to be technically qualified and competent.
- 4.5 Signatory approval under Standards Malaysia is not a personal qualification and is not transferable from one laboratory to another. The approved signatory status is deemed to be terminated when the personnel leaves the organisation.
- 4.6 Signatory approval by Standards Malaysia may also be granted to personnel registered under the regulatory authorities/organisations providing recognition. Such personnel may be employed or contracted full-time or part-time, provided that the requirements of Clause 4 of this document are met.

NOTE 1 Resident signatory means a signatory working full-time in the accredited laboratory or in another section/department within the same organisation at the same location.

NOTE 2 Non-resident signatory means a signatory who is a part-time employee of the accredited laboratory or a signatory from another branch providing covering duties to the accredited laboratory.

4.7 Non-resident signatory

4.7.1 A non-resident signatory can only be approved if the accredited laboratory has a permanent resident signatory.

4.7.2 Should the accredited laboratory lose the service of the permanent resident signatory the laboratory shall apply to Standards Malaysia to continue its use of the non-resident signatory. Standards Malaysia at its discretion may grant approval on the continual use of the non-resident signatory for a specified period.

4.7.3 It is the responsibility of the laboratory to ensure that the laboratory has a replacement for the permanent resident signatory.

4.7.4 A non-resident signatory shall have direct interaction with the laboratory on-site at least once a month.

4.7.5 Formal agreement between the laboratory and the non-resident signatory shall be established. The agreement shall ensure that:

- i) the functions, responsibilities and authority in particular those of an approved signatory shall be clearly defined.
- ii) records of input including dates and duration of on-site visits, topics and issues discussed, interaction with on-site staff and recommendations, advice or instruction given are kept.
- iii) the non-resident signatory shall attend:
 - a) the management review meeting; and
 - b) SAMM assessments unless specific exemption is granted by Standards Malaysia.
- iv) the non-resident signatory shall:
 - a) review and authorise report; and
 - b) review quality control records and relevant technical records.

4.8 Continual professional development

4.8.1 The SAMM approved signatory shall maintain his/her technical competence to ensure his/her ability to evaluate the report results.

- 4.8.2 The SAMM approved signatory shall participate in continual professional development through in-house and external activities e.g.: method development and validation, review and update of test procedure, training, presentation of papers, attending seminars and lectures etc.

5 Requirements for signatory approval

5.1 Legal requirements

5.1.1 These requirements shall be read in conjunction with any other legal requirements relating to the signatory of report. Granting of SAMM signatory does not absolve the signatory and laboratory from complying with legal requirements relating to the signatory of report. Compliance with legal requirements shall be the sole responsibility of the signatory and laboratory.

5.1.2 The laboratories shall provide necessary information and documentary evidence to Standards Malaysia for compliance with the necessary legal requirements.

5.2 Qualification and experience

5.2.1 Education qualification and working experience:

- i) SPM or equivalent in science or technical stream, with at least eight (8) years of experience working in the relevant fields; or
- ii) STPM or diploma in science or equivalent discipline, with at least three (3) years working experience in relevant fields; or
- iii) Degree holders in science or equivalent discipline with at least six (6) months relevant working experience in relevant fields; and
- iv) Other requirements as stipulated in the relevant specific technical requirements.

5.3 Technical and operational requirements

5.3.1 Knowledge and understanding of the technical and laboratory operational requirements:

- i) Requirements of MS ISO/IEC 17025 and all related SAMM requirements (e.g.: SP series, SC and STR) and relevant regulatory requirements.
- ii) The principles of testing, calibration or measurement.

- iii) The standards, methods and specifications for accreditation sought or held.
- iv) The estimation of measurement uncertainties for the accreditation sought or held.

5.3.2 Working at least three (3) months in the current laboratory and be knowledgeable of its management system.

5.4 Specific Exceptions

5.4.1 The Director of Accreditation, at his discretion, may grant specific exceptions to the requirements for approved signatory or impose other requirements upon consultation with relevant parties.

6 Liabilities

6.1 An accredited laboratory shall assume full liability on all reports issued.

Abbreviations:

- 1) SAMM – *Skim Akreditasi Makmal Malaysia*
- 2) SC – Specific Criteria
- 3) SP – SAMM Policy
- 4) STR – Specific Technical Requirements