



STANDARDS
MALAYSIA

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

**SAMM POLICY 8 (SP8) – REQUIREMENTS FOR THE
ACCREDITATION OF SITE TESTING AND
CALIBRATION LABORATORIES**

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MS ISO/IEC 17025

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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1 Introduction

- 1.1 SAMM Accreditation Standard (MS ISO/IEC 17025) set forth the criteria of competence for accreditation of testing / calibration performed by a laboratory or an organisation that carries out testing and/or calibration:
- (a) at or from a permanent location;
 - (b) at or from a temporary facility; or
 - (c) in or from a mobile facility.
- 1.2 The accreditation requirements and procedures applicable to a permanent laboratory need no further explanation.
- 1.3 This policy document should be read in conjunction with other SAMM requirements.

2 Scope

- 2.1 This document sets forth the requirements for accreditation of three (3) categories of site testing / calibration described in clause 3.11 of this document.
- 2.2 The requirements of this document apply to a large cross-section of testing / calibration laboratories and service organisations that perform testing / calibration of measurement equipment at customers' premises or sites.

3 Definitions

- 3.1 **Permanent laboratory (base laboratory):** A laboratory or organisation that performs testing and/or calibration at a permanent location or premises.
- 3.2 **Site testing / calibration:** Testing / calibration (including sampling where it forms part of the documented test procedure) performed by staff of an organisation outside the premises / grounds in which the permanent laboratory or the permanent base of the organisation is located.

NOTE: The location in which the permanent facilities are sited shall be defined. Any testing / calibration outside this location shall be considered as site testing / calibration.

- 3.3 **Site:** Any location where site testing / calibration as defined in 3.2 above is performed, e.g. manufacturers' premises, construction sites, dockyards, buildings and open spaces.

NOTE: For the purpose of assessment, sites shall be accessible to SAMM assessors during testing / calibration.

- 3.4 **Site laboratory:** A testing / calibration laboratory set up in a dedicated area on site on a short-term basis until the completion of a contract.
- 3.5 **Mobile laboratory:** Fully equipped van or purpose-built transportable testing / calibration laboratory. If a mobile laboratory is left permanently on one site it will be subject to the same terms of accreditation as a site laboratory.
- NOTE: Laboratory may consult with Department of Standards Malaysia (Standards Malaysia) on the categorising site testing / calibration appropriate to the laboratory's application. For this purpose applicants are advised to provide an estimated period for which the site laboratory or mobile laboratory will be sited in a location.
- 3.6 **Pre-assessment:** A preliminary assessment of the laboratory's management system and its implementation to determine its readiness for the compliance assessment. Pre-assessment will be conducted at an applicant's testing / calibration laboratory and if applicable, its testing / calibration sites prior to compliance assessment.
- 3.7 **Compliance Assessment:** An initial on-site assessment conducted by an assessment team at the premises of a laboratory and if applicable, its testing / calibration sites for verifying, by means of an independent, impartial and objective assessment and ascertaining full compliance with SAMM accreditation criteria and requirements. Compliance assessment is also conducted prior to award of accreditation.
- 3.8 **Surveillance Assessment:** One or more on-site assessments, conducted by assessment team(s), at periodic intervals at the premises of an accredited laboratory and if applicable, its testing / calibration sites for verifying, by means of an independent, impartial and objective assessment the continued compliance of the laboratory management system with SAMM accreditation criteria and requirements.
- 3.9 **Re-assessment:** An on-site assessment conducted normally prior to expiry of an accreditation certificate, by an assessment team at the premises of a laboratory and if applicable, its testing / calibration sites for verifying, by means of an independent, impartial and objective assessment and ascertaining full compliance with SAMM accreditation criteria and requirements. The conduct of reassessment may also be applicable to a request or procedure for restoration of an inoperative accreditation, or for restoration of a suspended accreditation.
- 3.10 **Organisations (including companies, consultancies, partnerships):** legal entity comprising one or more individuals who do not have a permanent laboratory but who measure, examine, test, calibrate or otherwise determine the characteristics or performance of equipment, materials or products on site.
- 3.11 **Site testing / calibration categories.** Three (3) categories of site testing / calibration have been identified and defined as follows:-
- a) **Category I:** Site testing / calibration is performed by staff sent out on-site by a permanent laboratory that holds SAMM accreditation.

- b) **Category II:** Site testing / calibration is performed in a site laboratory or mobile laboratory, (or by staff sent out by a site laboratory or mobile laboratory), which is under the responsibility of the permanent laboratory that holds SAMM accreditation.
- c) **Category III:** Site testing / calibration is performed on site by testing / calibration personnel of an organisation that does not have a permanent testing / calibration laboratory under Category III, testing / calibration may be performed using:
 - i) portable test equipment;
 - ii) a site laboratory;
 - iii) a mobile laboratory; or
 - iv) equipment from a mobile or site laboratory.

4 Accreditation criteria and requirements

- 4.1 The accreditation criteria and requirements applicable to any of the above three (3) categories of laboratories are identical to those applicable to the permanent laboratory.

These requirements are as documented in MS ISO/IEC 17025, SAMM policies and other SAMM documents.

- 4.2 Laboratory quality manual shall address the requirements contained in this document. Procedures shall exist and address the nature of site testing / calibration and it shall include the application of quality assurance system in such activities providing technical confidence and integrity in the same way test / calibration data are generated in a permanent laboratory.

5 Application for accreditation of site testing / calibration

5.1 Categories I and II

- a) an organisation operating a permanent laboratory already holding SAMM accreditation may submit application for extension of accreditation for site testing / calibration under **Category I or II** as defined in this document.
- b) an organisation operating a permanent laboratory that also performs **Category I or II** site testing / calibration may submit simultaneous applications for accreditation for both the permanent laboratory and site testing / calibration.
- c) However, if there are reasons to expect that administrative, operational or logistic problems are likely to be encountered in the assessment of both the permanent and site laboratories, Standards Malaysia will normally recommend that application for site testing / calibration be deferred after the permanent laboratory has gained SAMM accreditation.

NOTE: Application for accreditation solely for site testing / calibration under **Categories I and II** will not be accepted from an organisation that does not hold SAMM accreditation for its permanent laboratory if that organisation has a permanent laboratory for the same testing / calibration activities.

- d) an organisation is required to make a separate application for accreditation for site testing / calibration even though the permanent laboratory has been accredited for the same scope.

5.2 Category III

An organisation not possessing a permanent laboratory may submit application for accreditation under **Category III**. Applicants under this Category should familiarise themselves with and understand the requirements of MS ISO/IEC 17025, SAMM Policies and other relevant SAMM documents. Failure to comply with the requirements of these documents would result in failure in obtaining accreditation or would cause unnecessary delay in the processing of application.

6 Accreditation procedures

6.1 Categories I, II and III for site testing / calibration

- a) Application details

In addition the following requirements apply:

- i) a list of the tests / calibration for which accreditation for site testing / calibration is sought.
- ii) the types of site testing / calibration, site location involved, description of site / location (e.g. as detailed in contract) and a register of current site testing / calibration activities.
- iii) in the case of **Category II**, description and identification of each site or mobile laboratory and the nature of site testing / calibration.
- iv) in the case of **Category III**, an applicant must provide a description and identification of each mobile laboratory, if any, and provide details of the nature of business or organisation.

NOTE: For **Categories I and II**, relevant section(s) of the laboratory quality manual covering the quality assurance / control arrangements for site testing / calibration should be submitted with the application. For **Category III**, a copy of quality manual should be submitted. These arrangements shall satisfy the requirements of the MS ISO/IEC 17025, SAMM Policies and other relevant documents.

6.2 Assessment

- a) On receipt of application, SAMM officer will check the application information for completeness. Once application could be accepted, applicant will be invoiced for the appropriate application fees.
- b) Lead Assessor will:
 - i) perform adequacy assessment and examine the relevant controlled documents held in the organisation;
 - ii) perform as appropriate pre-assessment and/or compliance assessment and evaluate both the operation of the quality system and the testing / calibration competence on, as the case may be, the permanent, site (including customer's site), and mobile laboratory(ies).

7 Award or extension of accreditation

- 7.1 Award or extension of accreditation for site testing / calibration will be granted:
- a) after all non-conformities identified during initial assessment have been satisfactorily discharged and documented evidence submitted to Standards Malaysia.
 - b) for specific tests / calibrations or types of tests / calibrations considered to be within the competence of the staff of the permanent laboratory.

8 Certificate of accreditation and schedule

- 8.1 For **Category I and II** site testing / calibration, where the application has been submitted simultaneously with the application for the permanent laboratory, a certificate of accreditation will be issued with separate schedules for accredited tests / calibrations in the permanent laboratory and for those in the site category.
- 8.2 For **Category I and II** site testing / calibration, where the application has been submitted as an extension of accreditation after the permanent laboratory has gained accreditation, a revised schedule will be issued.
- 8.3 For **Category III** site testing / calibration, a certificate of accreditation bearing the SAMM accreditation number and permanent business address of the organisation will be issued together with a schedule listing the relevant information.
- 8.4 The certificate for any of the categories shall bear the address of the permanent laboratory or organisation. The accompanying schedule however will give outline details of the sites (for **Categories II and III**) which testing / calibration is performed.

9 Maintenance of accreditation (surveillance or reassessment)

- 9.1 Site testing / calibration activities will be subject to periodic assessment by SAMM assessment teams in accordance with established practice as described in SAMM Policy 1 to ensure continuing compliance with the MS ISO/IEC 17025.
- 9.2 Assessment to one or more testing / calibration sites will be additional to those made to the permanent laboratory. Documents relating to site activities which are held in permanent laboratory will be examined.
- 9.3 Maintenance of accreditation may be supplemented by a requirement to participate in nominated proficiency testing programme.
- 9.4 Should SAMM have reasons to believe that the SAMM requirements are not being observed, sites may be visited at random with short or without notification.
- 9.5 Assessors will make recommendations to Standards Malaysia after assessment to site and/or permanent laboratory premises. They may recommend:
 - a) that accreditation be maintained if no non-conformities are identified or if the laboratory discharges any non-conformities identified during assessment within the agreed time-scale.
 - b) that accreditation be reduced or withdrawn for the site testing / calibration concerned and that a suitably revised site testing / calibration Accreditation Schedule is issued.
 - c) that accreditation be withdrawn for the test(s) / calibration(s) concerned from the Accreditation Schedules issued for testing / calibration on site and in the permanent laboratory.
 - d) that accreditation for site testing / calibration be withdrawn completely.
 - e) that accreditation of the permanent laboratory be suspended or withdrawn as a result of failure to comply with SAMM accreditation criteria when testing / calibration on site. (This would automatically result in withdrawal of accreditation for site testing / calibration or mobile laboratory).

10 Notification of change

- 10.1 In the event of the closure of a **Category II or III** site laboratory or the cessation of the use of a site testing / calibration facility or a mobile laboratory it will be the responsibility of the permanent laboratory or organisation to notify Standards Malaysia with the necessary details.
- 10.2 The permanent laboratory or organisation shall at all times maintain an up-to-date register of site testing / calibration, site laboratory(ies) and/or mobile laboratory(ies). The register shall be available for review by SAMM assessment team upon request.