

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

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**SI 1**

**AN INTRODUCTION OF SAMM TO  
CALIBRATION AND TESTING LABORATORIES**

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**JABATAN STANDARD MALAYSIA  
DEPARTMENT OF STANDARDS MALAYSIA (DSM)**

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## **1. INTRODUCTION**

**1.1** Accreditation scheme in Malaysia, in particular Laboratory accreditation scheme was launched in July 1987. The scheme was then an institutional scheme administered by the Standard and Industrial Research Institute of Malaysia. At that time, there were other organizations that administered so called accreditation schemes based on various criteria and requirements.

Recognising the need and eventual demand for accredited laboratories, the Government established in 1990, the National Laboratory Accreditation Scheme of Malaysia known as *Skim Akreditasi Makmal Malaysia (SAMM)*. It was operated by a National Council, which assesses, accredits and monitors laboratories according to the stringent requirements of ISO/IEC Guide 25 (1990).

On 30 March 1994, the Government established the Malaysia Accreditation Council (MAC). This Council was given the power to accredit laboratories as well as to accredit registrars/certification bodies that operate the ISO 9000 management system schemes.

Eventually in 1996, a department known as the Department of Standards Malaysia (DSM) was set up by the Government under the Standards of Malaysia Act 1996, Act 549. It continues to carry on the duties and responsibilities of accreditation that was under the Malaysia Accreditation Council (MAC).

The Department has formally established its office on 28 August 1996. It reports to the Ministry of Science, Technology and Innovation.

## **2. OBJECTIVES OF SAMM**

The objectives of the SAMM scheme are:-

- to grant formal recognition to laboratories with proven capability and competence in specific fields of calibration/testing.
- to reduce and eliminate the need for multiple assessments on laboratories.
- to upgrade the status and standard of calibration and testing laboratories in the country.
- to promote the acceptance, both in Malaysia and overseas, of calibrations and tests performed by SAMM-accredited laboratories.
- to enhance the quality, acceptability and reputation of Made-in-Malaysia goods in domestic and overseas markets.

## **3. ACCESSIBILITY OF THE ACCREDITATION SYSTEM**

The SAMM accreditation system is open to any testing or calibration laboratory that wants to be recognized as competent, operating to MS ISO/IEC 17025 "*General requirements for the competence of calibration and testing laboratories*" or MS ISO 15189 "*Medical Laboratories-Particular Requirements for Quality and Competence*" criteria for both its technical capability and competence and its management system.

The scheme is accessible to all laboratories in Malaysia, performing first, second or third party testing, measurement and calibration. These may include laboratories from the private and public sectors, commercial testing services, in-house testing facilities, site testing

operation or mobile testing facilities. Participation in the scheme is voluntary. However, users of test or calibration services throughout the world are increasingly demanding that testing or calibration data should be from those complying with MS ISO/IEC 17025 or MS ISO 15189 requirements.

#### **4. FIELDS OF TESTING AND CALIBRATION**

4.1 The SAMM scheme covers accreditation of both testing and calibration laboratories under the following fields and accreditation programmes.

<b><u>Field of testing</u></b>	<b><u>Field of calibration</u></b>
Chemical testing	Heat and temperature measurements
Microbiological testing	Mechanical, mass and force measurements
Electrical testing	Electrical measurements
Mechanical / physical testing	Flow, pressure, viscosity and density measurements
Non-destructive testing	Length and dimensional measurements
Thermal	Acoustic and vibration measurements
Radioactivity testing	Radioactivity measurement
Bioefficacy of Household Pesticide	
Toxicity	
Genetically Modified Organism (GMO)	
Veterinary	
Electromagnetic Compatibility (EMC)	
Medical	

Please refer to Leaflet 1 and Leaflet MT for further details.

#### **5. ACCREDITATION CRITERIA AND REQUIREMENTS**

The accreditation criteria adopted for the SAMM scheme is MS ISO/IEC 17025 “*General requirements for the competence of calibration and testing laboratories*”. This is supplemented by other published SAMM accreditation requirements. Meanwhile, for accreditation of medical labs, the criteria adopted is MS ISO 15189 “*Medical Laboratories-Particular Requirements for Quality and Competence*”.

Other technical requirements are those as defined in the appropriate test methods, procedures or those specific to a particular testing and calibration technology.

The use of MS ISO/IEC 17025 or MS ISO 15189 requirements for assessment implies that laboratories will be assessed for both its technical competence as well as its documented management system.

Assessment of its technical competence include interviewing of all levels of technical staff involved in testing and calibration.

## 6. INITIAL PREPARATION FOR APPLICATION

6.1 The laboratory must prepare itself for application for accreditation by some of the following means:

Utilize internal resources to train laboratory personnel in the understanding and implementation of a laboratory management system consistent with MS ISO/IEC 17025 or MS ISO 15189 and SAMM policy requirements. In the absence of the above, the laboratory concerned may encourage its personnel to attend public or in-house training courses offered by training bodies or professional organizations, or by consultants who are well-versed with MS ISO/IEC 17025 or MS ISO 15189 and SAMM policy requirements.

6.2 The laboratory should give priority in documenting its Management System and formalising it in a **Quality Manual**. However, if a Quality Manual is already available, the laboratory should draw up or employ a suitable checklist to identify and remedy any element or item lacking in the Quality Manual.

6.3 The laboratory should also get on to prepare (a) its Procedure Manual to address procedures or arrangements required or specified under MS ISO/IEC 17025 or MS ISO 15189; (b) test or calibration procedure manual relevant to the scope of accreditation sought.

6.4 No application will be accepted without the application form being accompanied with:

- (a) the laboratory Quality Manual,
- (b) Quality System Procedure Manual and
- (c) the scope of accreditation sought and CV of nominated signatory(ies).

6.5 In advancing the preparatory phase from documentation to actual implementation of the intended or proposed management system, the laboratory concerned should also prepare to employ trained staff to carry out internal audits on the progress and effectiveness of the laboratory management system. The laboratory should have a documented procedure for the conduct of internal audits.

6.6 Results of internal audits, feedback and the corrective actions taken to improve and to prevent future recurrence of nonconformities are important and useful inputs for the conduct of management review. The conduct of management review is the responsibility of top management. The laboratory should have a documented procedure for the conduct of management reviews.

6.7 The laboratory should have been participating in local or interlaboratory proficiency testing programmes or similar comparison programmes relevant to their testing activities or more specifically, relevant to the scope of accreditation sought.

6.8 By going through each and every clause of MS ISO/IEC 17025 or MS ISO 15189, the laboratory management should know what would be expected to be assessed by DSM and therefore should make the appropriate preparation for supplying documented evidence, records, performance data and their analysis to DSM assessors during their forthcoming assessment visit.

6.9 It is the policy of DSM not to consider accreditation if applicant laboratory has not performed its internal audits and management review.

## **7. SAMM ACCREDITATION PROCEDURES**

### **7.1 Receiving application**

The laboratory desiring to be accredited shall make application in writing to DSM.

Application for accreditation may only be made by way of application form **LA 202T/C**.

All applications must be accompanied by applicant's quality manual and the relevant supporting documentations such as procedure manuals and a master listing of all its documentations.

### **7.2 Processing of Application (Administrative)**

7.2.1 Application will be checked for basic requirements and for completeness, i.e. to ensure that all required documentations are attached.

7.2.2 Application will be acknowledged. An invoice will be sent requesting the applicant for payment of appropriate application fee (See SAMM Fees Schedule enclosed with application form).

Note: Application fee is non-refundable. An application is considered lapsed if the applicant failed to obtain accreditation within two years from the date of acceptance of application.

7.2.3 In cases of significant deficiency in basic requirements and incomplete documentation, DSM Accreditation staff will normally seek additional information/documentations before application could be accepted. The applicant will then need to resubmit the re-adjusted documentation to ensure its completeness.

7.2.4 The applicant will be asked to respond on the acceptability of members of the assessment team.

### **7.3 Adequacy Audit**

7.3.1 A SAMM accreditation staff or an appointed lead assessor will be assigned to perform on site documentation review on the applicant's quality manual and associated documents. Generally, this involves:-

(a) assessing the adequacy of applicant's documented management system against accreditation criteria MS ISO/IEC 17025 or MS ISO 15189 and SAMM requirements.

(b) the "Adequacy Audit Report" will document any deficiencies in the documentation which should be addressed before the process of pre-assessment could commence.

7.3.2 the applicant shall respond to the written comment by Lead Assessor and make the necessary adjustments to DSM.

7.3.3 However, if the documentation review report indicates that the applicant has adequately addressed all system elements of the SAMM criteria and requirements, the Lead Assessor will arrange for the conduct of an on-site pre-assessment which is described below. The timing of such assessment would be arranged by way of written request from the laboratory or any subsequent discussion with the applicant to ensure mutual agreement.

## **7.4 Assessment**

7.4.1 Assessment of a laboratory is divided into two phases, the preliminary assessment and the compliance assessment.

The aim of the assessment is to establish whether a laboratory can competently perform those calibrations / tests for which accreditation is sought.

The assessment of the laboratory is achieved by the use of qualified SAMM assessors and other technical assessors who have been selected on the basis of their calibration / testing expertise and experience. Their qualifications are also supplemented by knowledge gained from appropriate training in laboratory accreditation.

An assessment may take a day, and may extend to a number of days, depending on the operation, complexity and size of the laboratory.

An assessment takes the form of detailed discussion between calibration / testing staff and the assessors, together with an inspection of the premises, record system, internal quality control schemes, the equipment, including an examination of any calibration information and records of internal assessment. The assessors normally witness the performance of some routine calibration / testing. Laboratories will be checked and assessed on their performance in any related proficiency testing programme available in the country or overseas.

### **7.4.2 On-site Compliance Assessment**

7.4.2.1 At this stage in the processing of the application, a formal compliance assessment of the applicant laboratory shall be carried out by DSM assessment team. The timing of such a visit would be arranged by way of written request from the laboratory or any subsequent discussion with the applicant to ensure mutual agreement.

7.4.2.2 An assessment plan will include arrangements for the witnessing of the laboratory's testing or calibration staff in the actual performance of test or calibration.

7.4.2.3 The applicant will be also be invoiced on the costs of the assessors based on the current fees schedule.

7.4.2.4 The applicant and DSM must confirm the scope of testing sought and must also resolve all outstanding issues and problems, if any, before compliance assessment could proceed.

7.4.2.5 The purpose of the formal on-site compliance assessment is to verify, firstly, the laboratory's technical competence and, secondly, the effectiveness and maturity of the management system implemented.

For these reasons, the managerial, technical and administrative staff shall be interviewed and test / calibration records and overall record system, files, training records, validation or test performance data, proficiency testing records, investigation and resolution record and other related documentation will be examined by the assessment team.

Nominated signatories of test / calibration report will also be interviewed, supporting records checked and their technical competence confirmed and verified.

7.4.6 The applicant's organization will be given the opportunity to correct any area or item identified by the assessment team as not complying with the requirements for accreditation. When an applicant fully complies with the criteria of accreditation and confidence in its

technical competence is established, the assessment team will normally recommend accreditation.

7.4.7 The above procedure applies both for pre-assessment and compliance assessment.

## **7.5 Review of Assessment Report**

7.5.1 The assessment team will then prepare an assessment and recommendation report for deliberation by a Laboratory Accreditation Evaluation Panel (LAEP) selected from a pool of experienced and qualified persons established by the Director General of DSM.

7.5.2 The impartial and independent LAEP will review the assessment team's recommendation that is submitted for the final approval by the Director General.

7.5.3 The final decision of the Director General will be communicated to the applicant in writing. In case of rejection of an application for accreditation, the reasons shall be provided.

## **7.6 Award of Accreditation**

7.6.1 Once a favourable decision is taken by the Director General in granting accreditation, the Accreditation Certificate will be awarded. The certificate is valid for three (3) years and shall be renewable subject to regular surveillance at about nine-month intervals and to the terms and conditions governing the operation of the SAMM scheme.

## **7.7 Procedure Flow Chart and Summary of Accreditation Process**

A flow chart identifying the foregoing sequence of activities is shown in Appendix 1 and Table 1.

## **8. APPEALS**

In the event that an applicant laboratory / accredited laboratory lodges an appeal against any application / accreditation related decision, an Appeals Panel will be constituted to action such appeals. An Appeals Panel will be established on each occasion that an appeal has to be heard. The Appellant will be given an opportunity to object to any members of the Appeal Panel with valid reasons. To meet the impartiality, independence and no conflict of interest requirements, the Appeals Panel is constituted from three members drawn from the Malaysian Standards and Accreditation Council and its Accreditation Committee.

## **9. SAMM ACCREDITATION REGISTER**

A register of accredited laboratories will be maintained by the DSM for public inspection. Information on the accredited laboratories will also be available in DSM Homepage or through its regular publications.

## **10. ROUTINE COMMITMENT AFTER ACCREDITATION - (Maintenance of Accreditation)**

The responsibility and obligation on the part of a SAMM accredited laboratory are to maintain and improve the laboratory management system so as to comply with SAMM requirements at all times. The onus for maintenance of its accreditation status lies with the laboratory. For details, please see relevant SAMM policy requirements.

Routine commitments expected of an accredited laboratory include:

a) maintenance of calibration/testing practices in accordance to the laboratory's management system including the conduct of internal audits and management system review;

It is a mandatory requirement for the laboratory management to conduct internal audits and management reviews. Non-performance of these quality activities will eventually lead to withdrawal of accreditation by DSM.

b) notification of changes in the laboratory management (equity changes, resignations, transfers, etc.);

c) notification of changes or resignation of SAMM approved signatories;

d) notification of significant changes in accommodation or equipment;

e) adherence to the necessary requirements for the periodic re-calibration of equipment;

f) participation in nominated or available proficiency testing programme and implementing calibration or test checks.

This shall include participation in available proficiency testing programmes such as APLAC programmes and other forms of comparison testing or studies. Results of participation on interlaboratory cross-checks, or other forms of comparative testing including corrective actions must be taken.

## **11. SURVEILLANCE AND RE-ASSESSMENT**

11.1 DSM will conduct surveillance assessments of the accredited laboratories at about nine (9) to eleven (11) months after accreditation granting to confirm adherence to the criteria and requirements for accreditation. It is the responsibility of the laboratories to advise DSM of any change in the organization's policies, procedures, test report signatories, key personnel, facilities or change in legal structure which would affect compliance with the MS ISO/IEC 17025 or MS ISO 15189 criteria and requirements for accreditation. Failure to notify DSM of any significant change will constitute a non-conformity to SAMM requirements.

11.2 Reassessment will be carried out before the expiry of the accreditation certificate.

## **12. EXPANSION OF SCOPE OF ACCREDITATION**

SAMM accredited calibration / testing laboratories may apply to add new field(s) of calibration / testing and / or to extend the scope of accreditation in the existing accredited field(s). Application may be made to DSM on **Form LA 202EXT**.

## **13. CONFIDENTIALITY**

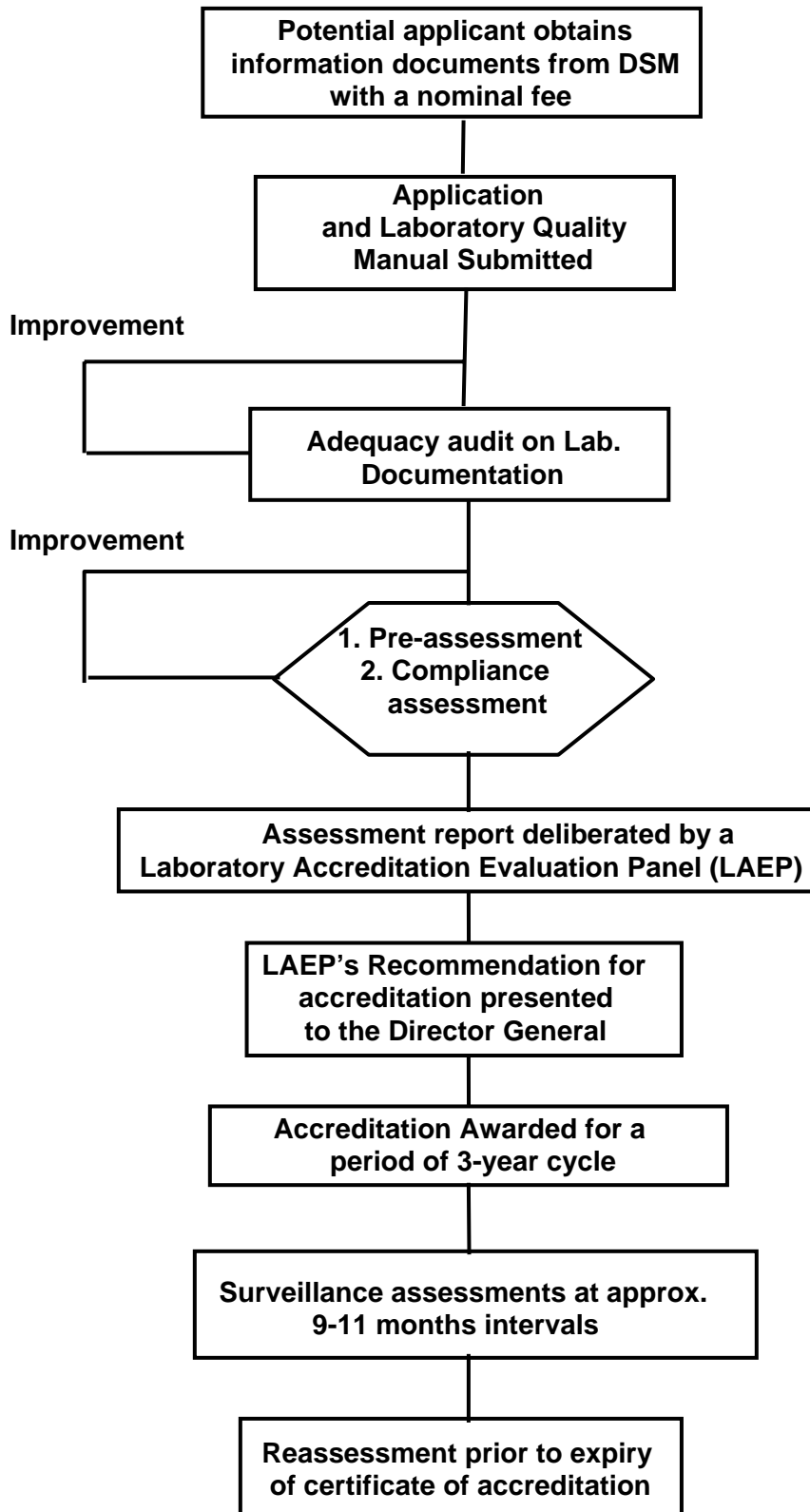
It is the policy of DSM to require its staff members and its assessors to maintain confidentiality of information and documentation belonging to the applicant / accredited laboratories. No assessor would be allowed to carry out any assessment unless he or she has signed an official letter of undertaking of confidentiality. In addition SAMM assessors are also required to abide by DSM code of ethics for assessors.

## **14 SAMM FEES AND ASSESSMENT CHARGES**

A current SAMM accreditation fee structure will be enclosed with every application form. The accreditation fees / charges are however subject to review by DSM from time to time.

Appendix 1

ACCREDITATION PROCEDURE FLOW CHART



**Table 1: Summary of accreditation process**

(i)	Submission of application	Formal application is received and processed. Application checked for basic information. Applicant invoiced and payment made. Application accepted.
(ii)	Adequacy audit on laboratory quality manual and associated documentations	A review of the Applicant's documentation is undertaken against MS ISO/IEC 17025 or MS ISO 15189 and SAMM Accreditation requirements
(iii)	Preliminary assessments (pre-assessment) (including witnessing of actual laboratory operations)	<p>Applicant laboratory sends in request form in advance for a pre-assessment to be carried out.</p> <p>It involves assessing the implementation of the management system intended by the laboratory against SAMM accreditation criteria and requirements. Basically it is no different from a compliance assessment except for the following:</p> <ul style="list-style-type: none"> <li>• No recommendation for accreditation is made at the end of a pre-assessment.</li> <li>• Pre-assessment may be exempted with conditions under certain circumstances such as the branch laboratories of an accredited main laboratory.</li> <li>• The aim of pre-assessment is for the laboratory to acquaint and familiarize itself with assessment against MS ISO/IEC 17025 or MS ISO 15189 requirements</li> <li>• It gives an opportunity to the assessment team to view the actual operation of the laboratory and to evaluate the actual resources required for the performance of a thorough compliance assessment.</li> <li>• With prior arrangements, measurement audits may be carried out on applicant calibration laboratories.</li> </ul>

(iv)	Compliance assessments (including witnessing of actual laboratory actual operations)	<p>Applicant laboratory sends in request form in advance for a compliance assessment to be carried out when it is fully ready.</p> <p>A thorough assessment is carried out.</p> <p>At the closing meeting, the assessment team will present recommendation whether accreditation be granted conditionally or unconditionally, be deferred or rejected.</p>
(v)	Corrective action on nonconformities	<p>Very often and in fact in almost all cases, nonconformities to SAMM criteria and requirements or nonconformities to the laboratory own management system are raised.</p> <p>It is imperative that laboratory undertakes to correct all nonconformities and submit proper and organized documented evidence that all nonconformities have been corrected and corrective actions implemented.</p> <p>The onus is on the laboratory to clear such nonconformities and to present proper, traceable and auditable documented evidence to DSM.</p> <p>DSM assessment team leader would require documented evidence to be supplied to him / her for the discharge of nonconformities and to proceed for the writing of final assessment report for submission to DSM.</p> <p>As long as this step is still outstanding, the accreditation process stage could not be advanced to the next step.</p>
(vi)	Review of Assessment Report	<p>Assessment Report deliberated by an impartial and independent Laboratory Accreditation Evaluation Panel (LAEP) and recommendation for accreditation by the assessment team is reviewed.</p>
(vii)	Decision or approval on Accreditation	<p>Director General makes final decision on accreditation based on recommendation of LAEP and relevant information</p>

(viii)	Award of Accreditation on successful application	Accreditation Certificate is prepared and granted to successful Applicant
(ix)	Surveillance Assessment approximately once in seven months	Accredited laboratory will be subjected to surveillance assessments to ensure continuing compliance with SAMM accreditation criteria and requirements
(x)	Re-assessment	Accreditation certificate expires at the end of third year. Prior to expiry, comprehensive re-assessment is conducted on accredited laboratory's management system and technical competence.