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

SI 1

AN INTRODUCTION OF SAMM TO TESTING AND CALIBRATION LABORATORIES

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JABATAN STANDARD MALAYSIA
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1. INTRODUCTION

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 organisations 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 (Standards Malaysia) was set up by the Government under the Standards of Malaysia Act 1996, Act 549. It continued 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. Governed by the Ministry of International Trade and Industry (MITI) since 19 October 2018, Standards Malaysia operates as the National Standards and Accreditation Body in the country. Previously Standards Malaysia was governed by Ministry of Energy, Science, Technology, Environment and Climate Change and Innovation (MESTECC).

2. OBJECTIVES OF SAMM

The objectives of SAMM are:-

a) to grant formal recognition to laboratories with proven capability and competence in specific fields of testing/calibration.

b) to reduce and eliminate the need for multiple assessments on laboratories.

c) to upgrade the status and standard of testing and calibration laboratories in the country.

d) to promote the acceptance, both in Malaysia and overseas, of tests and calibrations performed by SAMM accredited laboratories.

e) 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 recognised as competent, operating to MS ISO/IEC 17025 *"General Requirements for*

the Competence of Testing and Calibration Laboratories" or MS ISO 15189 "*Medical Laboratories- 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/calibration services, in-house testing/calibration facilities, site testing/calibration operation or mobile testing/calibration 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

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

Field of testing	**Field of calibration**	**Field of medical testing**
Chemical	Heat and Temperature	Cytopathology
Biological	Electrical	Histopathology
Electrical	Dimensional	Chemical pathology
Thermal	Acoustic and Vibration	Haematology
Mechanical / Physical	Radioactivity	Medical microbiology
Non-destructive Testing	Optical and Photometric	Medical microbiology (Virology)
Radioactivity	Mass and Mass Related Quantities (density, pressure, force, torque, hardness, viscosity, flow & volume)	Cytogenetics
Bioefficacy of Household Pesticide		Assisted Reproductive Technology (ART)
Toxicity		Medical Molecular Testing
Veterinary		
Genetically modified organism (GMO)		
Electromagnetic Compatibility (EMC)		
Nucleic Acid		
Forensic Science		
Information Technology Security Testing		
Software Testing		

5. ACCREDITATION CRITERIA AND REQUIREMENTS

The accreditation criteria adopted for the SAMM is MS ISO/IEC 17025 *"General Requirements for the Competence of Testing and Calibration Laboratories"*. This is supplemented by other published SAMM accreditation requirements. Meanwhile, for accreditation of medical laboratories, the criteria adopted is MS ISO 15189 "*Medical Laboratories - 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 includes 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:

> Utilise 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 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 organisations, or by consultants who are well versed with MS ISO/IEC 17025 or MS ISO 15189 and SAMM requirements.

6.2 The laboratory should give priority in documenting its Management System and formalising it in a laboratory documented information.

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 documented information that covers the following:
   i) Company profile and information about the laboratory including legal entity and its activities;
   ii) Structure/Organisation chart;
   iii) Policies and objectives;
   iv) Identified management personnel who is responsible for the laboratory's activities (name and responsibility); and

v) Risk assessment analysis/report.

b) Quality System Procedure Manual
c) The scope of accreditation sought and CV of nominated signatory(ies)/ key personnel(s)
d) Proficiency testing information
e) Internal Audit Report
f) Management Review Minutes

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. Internal audits shall be performed at least once every 12 months. However, the frequency of internal audits may be reduced if the laboratory can demonstrate that its management system continues to be effectively implemented according to MS ISO/IEC 17025 and has proven stability. The interval period of the internal audit may be extended but shall not exceed 18 months.

6.6 Results of internal audits, feedback, and the corrective actions as well as root cause analysis 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 laboratory management. The laboratory's management review shall be conducted at least once a year.

6.7 The laboratory should have been participating in proficiency testing activities 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 Standards Malaysia and therefore should make the appropriate preparation for supplying documented evidence, records, performance data and their analysis to Standards Malaysia assessors during their forthcoming assessment visit.

6.9 It is the policy of Standards Malaysia 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 Standards Malaysia.

Application for accreditation may only be made by way of application form **LA 201 C/T** or **LA 201 MT** for medical testing**.**

All applications must be accompanied by applicant's laboratory documentation 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 in accordance to Standards Malaysia (Fees) Regulation 2018.

Note: Application fee is non-refundable. An application is considered lapsed if the applicant failed to obtain accreditation within **two (2) years** from the date of acceptance of application.

7.2.3 In cases of significant deficiency in basic requirements and incomplete documentation, Standards Malaysia 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 Once the application is completed, the acceptance letter will be issued as well as username of e-Accreditation system. The applicant is required to complete all the necessary application information in the e-Accreditation system.

Note: All types of assessment such as adequacy audit, pre-assessment, compliance, surveillance, re-assessment, extension of scope and etc., will be conducted through e-Accreditation system.

7.2.5 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 documentation review on the applicant's laboratory documented information 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 Standards Malaysia.

7.3.3 However, if the documentation review report indicates that the applicant has adequately addressed all system elements of SAMM criteria and requirements, the Lead Assessor will arrange for the conduct of 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 Initial Assessment

7.4.1 Pre-assessment

7.4.1.1 Initial assessment of a laboratory is divided into two phases, the preliminary assessment and the compliance assessment.

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

7.4.1.3 The assessment of the laboratory is conducted by selected qualified SAMM assessors on the basis of their testing / calibration expertise and experience. Their qualifications are also supplemented by knowledge gained from appropriate training in laboratory accreditation.

7.4.1.4 An assessment may take a day, and may extend to a number of days, depending on the operation, complexity and size of the laboratory. Determination for assessment man-days, please refer Accreditation Circular 1/2019 or SAMM Circular 3/2019 for medical testing.

7.4.1.5 An assessment takes the form of detailed discussion between testing / calibration 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 testing/calibration. Laboratories will be checked and assessed on their performance in any related proficiency testing activities available in the country or overseas.

7.4.1.6 The assessment fee will be invoiced to the applicant laboratory based on the current fee schedule.

7.4.1.7 The applicant and Standards Malaysia should confirm the scope of accreditation sought and must also resolve all outstanding issues and problems, if any, before compliance assessment can proceed.

7.4.2 Compliance Assessment

7.4.2.1 Compliance assessment will be conducted after the completeness of pre-assessment. The timing of such assessment would be arranged by way of written request from the applicant or after 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 purpose of the formal on-site compliance assessment is to verify the laboratory's technical competence and 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/key personnel of test / calibration report will also be interviewed, supporting records checked and their technical competence confirmed and verified.

7.4.2.5 The applicant's organisation 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.

7.4.2.6 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).

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.

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 accreditation is valid for three (3) years and shall be renewable subject to regular and compliance to the terms and conditions governing the operation of SAMM.

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

8.1 In the event that an applicant / accredited laboratory lodges an appeal against any application / accreditation related to decision made by Director General, 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.

8.2 An appeal should be lodged in writing to the Director General of Standards Malaysia, no later than thirty (30) days after notification to the laboratory of the decision or measure made by Standards Malaysia.

8.3 The appellant is required to submit a letter of appeal and will remit a non-refundable appeal fee as per Standards Malaysia (Fees) Regulation 2018 - made payable to "Ketua Pengarah Jabatan Standard Malaysia" to cover any costs which might be incurred in respect of the appeal. Please refer to CAB 3: Appeals for detailed information.

9. SAMM ACCREDITATION REGISTER

A register of accredited laboratories is publicly available and maintained in Standards Malaysia website.

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 requirements.

Routine commitments expected of an accredited laboratory include:

a) maintenance of testing / calibration 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 Standards Malaysia.

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

c) notification of changes or resignation of SAMM approved signatories/key personnel;

d) notification of significant changes in accommodation or equipment;

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

f) to pay all fees and costs connected with the accreditation process;

g) participation in proficiency testing activities as specify in SAMM Policy 4 (SP4) - *Policy for Participation in Proficiency Testing Activities*.

11. SURVEILLANCE AND RE-ASSESSMENT

11.1 Standards Malaysia will conduct surveillance assessments of the accredited laboratories at about nine (9) to twelve (12) months after accreditation granting to confirm adherence to the criteria and requirements for accreditation.

Schedule 1 (Cycle 1)

a. **Surveillance 1:** Approximately 9 months from date of granting of accreditation certificate.

b. **Surveillance 2:** Approximately 12 months from date of Surveillance 1.

c. **Re-assessment:** Approximately 3 months before date of certificate expiry.

Schedule 2 (Subsequent cycle)

a. **Surveillance:** Approximately 12 months from date of last certificate expiry.

b. **Re-assessment:** Approximately 6 months before date certificate expiry.

However, Standards Malaysia may change any assessment interval schedule depending on the performance of the laboratory at our discretion.

11.2 It is the responsibility of the laboratories to advise Standards Malaysia of any change in the organisation's policies, procedures, approved 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 Standards Malaysia of any significant change will constitute a non-conformity to SAMM requirements.

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

12. EXTENSION OF SCOPE/BRANCH/SATELLITE LABORATORY OF ACCREDITATION

SAMM accredited laboratories may apply to add new field(s)/branch of testing / calibration, satellite laboratory for medical testing and / or to extend the scope of accreditation in the existing accredited field(s). Application may be made to Standards Malaysia using **LA 202EXT Form** or **LA 202EXT-MT** for medical testing**.**

The Extension of Scope/Branch/Satellite Laboratory application will be valid for **one (1) year** from the date of assessment conducted.

13. CONFIDENTIALITY

It is the policy of Standards Malaysia 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 Standards Malaysia code of ethics for assessors.

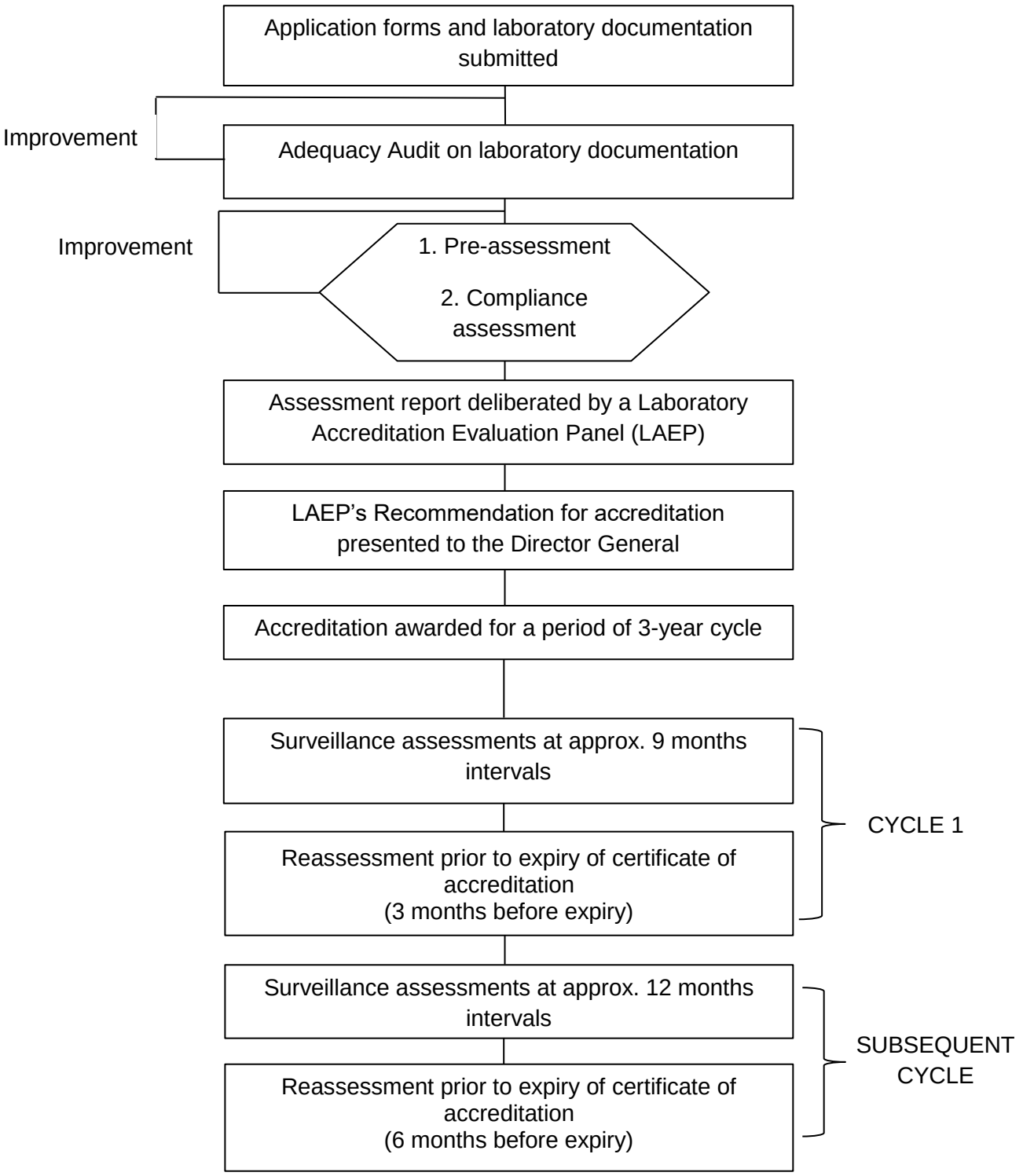
14 SAMM FEES AND ASSESSMENT CHARGES

The current SAMM accreditation fee structure is as per the Standards Malaysia (Fees) Regulation 2018. The accreditation fees / charges are however subject to review by Standards Malaysia from time to time.

Failure to pay up fees may result in suspension / withdrawal of accreditation.

Appendix 1

ACCREDITATION PROCEDURE FLOW CHART



However, Standards Malaysia may change any assessment interval schedule depending on the performance of the laboratory at our discretion.

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 documented information 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)	Applicant laboratory sends in request form in advance for a pre-assessment to be carried out. 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: • No recommendation for accreditation is made at the end of a pre-assessment. • Pre-assessment may be exempted with conditions under certain circumstances such as the branch laboratories of an accredited main laboratory. • 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 • 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. • With prior arrangements, measurement audits may be carried out on applicant calibration laboratories.
(iv)	Compliance assessments (including witnessing of actual laboratory actual operations)	Applicant laboratory sends in request form in advance for a compliance assessment to be carried out when it is fully ready. A thorough assessment is carried out. At the closing meeting, the assessment team will present recommendation whether accreditation be granted conditionally or unconditionally, be deferred or rejected.

(v)	Corrective action on nonconformities	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. It is imperative that laboratory undertakes to correct all nonconformities, conduct root cause analysis and submit proper and organised documented evidence that all nonconformities have been corrected and corrective actions implemented. The onus is on the laboratory to clear such nonconformities and to present proper, traceable and auditable documented evidence to Standards Malaysia. Standards Malaysia 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 Standards Malaysia. As long as this step is still outstanding, the accreditation process stage could not be advanced to the next step.
(vi)	Review of assessment report	Assessment report deliberated by an impartial and independent Laboratory Accreditation Evaluation Panel (LAEP) and recommendation for accreditation by the assessment team is reviewed.
(vii)	Decision or approval on accreditation	Director General makes final decision on accreditation based on recommendation of LAEP and relevant information.
(viii)	Award of accreditation on successful application	Certificate of accreditation is prepared and granted to successful applicant.

(ix)	Surveillance Assessments	Accredited laboratory will be subjected to surveillance assessments to ensure continuing compliance with SAMM accreditation criteria and requirements. **<u>Schedule 1 (Cycle 1)</u>** **Surveillance 1:** Approximately 9 months from date of granting / renewal **Surveillance 2:** Approximately 12 months from date of surveillance **<u>Schedule 2 (Subsequent cycle)</u>** **Surveillance:** Approximately 12 months from date of last certificate expiry.
(x)	Re-assessment	Certificate of accreditation expires at the end of third year. Prior to expiry, comprehensive re- assessment is conducted on accredited laboratory's management system and technical competence approximately 3 months (Cycle 1) or 6 months (Subsequent cycle) before date of expiry.