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1 **Introduction and Scope**

1.1 The Terms and Conditions Governing SAMM (hereinafter referred to as "SAMM Conditions") are applicable to SAMM accredited testing/calibration laboratories and applicant laboratories.

1.2 These terms and conditions shall be read in conjunction with SAMM accreditation criteria:

   a) **MS ISO/IEC 17025** - General Requirements for the Competence of Testing and Calibration Laboratories; or
   b) **MS ISO 15189** - Medical Laboratories - Requirements for Quality and Competence;
   c) **Act 549** - Standards of Malaysia Act 1996;
   d) **CAB 3** - Appeals;
   e) **CAB 4** - Suspension and Withdrawal of Accreditation; and
   f) **SAMM Policy** (SP series), other specific criteria (SC) and specific technical requirements (STR) or other documents that may be issued/endorsed as SAMM requirements relating to specific testing, measurement and quality assurance activities in testing/calibration laboratories.

The undated references indicate the latest edition of the referenced document (including any amendments) applies.

2 **Definition**

2.1 For the purpose of this document, the following definitions shall apply:

   a) Accreditation status
   i) **Accredited laboratory**: A testing/calibration laboratory to which SAMM accreditation certificate has been granted.
   ii) **Inoperative**: Accreditation status of all or part of the accredited scope held in abeyance for a temporary period at the request of the laboratory until effective corrective action has been taken.
   iii) **Suspension**: Accreditation status of all or part of the accredited scope held in abeyance by Standards Malaysia until effective corrective action has been taken.
   iv) **Withdrawal**: Partial or full cancellation of accredited scope by Standards Malaysia or as requested by an accredited laboratory. For full withdrawal, the certificate of accreditation shall be returned to Standards Malaysia.
   v) **Reinstatement**: The process of re-establishing / regain the accreditation status of a laboratory.

   b) Personnel
   i) **Approved signatory (for testing/calibration laboratory)**: A person recognised and approved under SAMM to sign SAMM endorsed test
ii) **Key personnel (applicable to medical laboratory):** Key personnel shall be as defined and approved under SAMM in accordance to the requirements in SC 2: Specific Criteria for Accreditation in the Field of Medical Testing.

c) **Certificates**

i) **Certificate of accreditation:** A certificate issued by the Director General of Standards Malaysia under Act 549 to a testing/calibration laboratory attesting that the laboratory is recognised as competent to perform specific test/calibration or types of measurements/tests under SAMM.

ii) **Schedule:** A schedule issued with a certificate of accreditation listing those accredited scopes of calibration, tests and/or measurements that Standards Malaysia recognises a testing/calibration laboratory is competent to perform.

iii) **Calibration report/certificate:** A document that presents the calibration or measurement results and other information relevant to the calibration or measurement.

iv) **Test report/certificate:** A document that presents the test or measurement results and other information relevant to the test or measurement.

v) **SAMM endorsed test and calibration report/certificate:** A report/certificate that bears a SAMM symbol or a statement that a testing/calibration laboratory is accredited for the test/calibration reported and that the test or calibration has been performed in accordance with SAMM requirements and conditions.

d) **Others**

i) **Accreditation:** Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

ii) **Appeal:** Request by a laboratory for reconsideration of any adverse decision made by Standards Malaysia related to its desired accreditation status.

iii) **Department of Standards Malaysia (referred to as Standards Malaysia):** The accreditation body established under the Standards of Malaysia Act 1996 (Act 549).

iv) **Laboratory:** Body that performs one or more of the following activities:
- testing;
- calibration;
- sampling, associated with subsequent testing or calibration.
v) **SAMM (Skim Akreditasi Makmal Malaysia):** The Laboratory Accreditation Scheme of Malaysia is a national laboratory accreditation scheme administered by Standards Malaysia.

vi) **SAMM accreditation criteria:** Includes the appropriate accreditation standard, and all Standards Malaysia approved policies and procedures at the time of application, and those approved from time to time subsequent to accreditation, that are applicable to the respective accreditation programmes.

vii) **Branch:** A permanent laboratory at a different location managed by the central laboratory/office with the same management system and owned by the same legal entity.

For other terms not listed, the relevant definitions in ISO/IEC 17000 and the International Vocabulary of Basic and General Terms in Metrology shall apply.

3 **Authority for the Granting of SAMM Accreditation**

3.1 **General**

Under Skim Akreditasi Makmal Malaysia (SAMM), the Director General of Standards Malaysia is responsible for all policies and decisions affecting the accreditation of testing/calibration laboratories, including the granting, maintaining, extending, renewal, reducing, suspending, withdrawing or reinstatement of accreditation.

The granting, maintaining, extending, renewal, reducing, suspending, withdrawing or reinstatement of accreditation shall be granted only to a testing/calibration laboratory which:

a) is legally identifiable and operational;

b) complies with SAMM conditions and the relevant SAMM accreditation criteria and any other undertakings as Standards Malaysia may require;

c) pays such fees (as prescribed in the Fee Schedule) as are due to Standards Malaysia; and

d) enters into a legally enforceable arrangement with Standards Malaysia.

3.2 **Criteria of Competence, Procedure and Amendment of Conditions**

a) Standards Malaysia shall have the right to prescribe the relevant criteria of competence against which a testing/calibration laboratory shall be assessed.

b) The accreditation requirements set out in 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 and any applicable criteria prescribed at the discretion of Standards Malaysia, shall be taken as the criteria for assessing the competence of a testing/calibration laboratory.

c) Standards Malaysia shall specify the procedures by which application for accreditation shall be made, the conditions for granting, maintaining, extending, renewal, reducing, suspending or withdrawing of accreditation,
and the conditions under which SAMM accreditation may be refused, reduced, put under suspension, withdrawal, or reinstatement.

d) Standards Malaysia reserves the right to amend any part of SAMM conditions, if in the opinion of Standards Malaysia such amendments are necessary to maintain the credibility of SAMM.

e) In the event of such amendments, reasonable time shall be given to laboratories to carry out the necessary adjustments to their management system in order to comply with the altered terms and conditions.

Unless otherwise specified, a period of six (6) months from the date of notification of change by Standards Malaysia shall be given for testing/calibration laboratories to carry out the necessary adjustments to their system.

f) Standards Malaysia reserve the right to rotate the assessor involved in the assessment team of the laboratory as part of mechanism to maintain Standards Malaysia impartiality.

3.3 Processing and Granting of Accreditation

a) Applicants shall submit necessary documents as required by Standards Malaysia for the purpose of application for accreditation.

b) It is Standards Malaysia policy to accredit a laboratory conducting sampling only when the output of sampling is subject to testing undertaken by the same laboratory.

c) An application for accreditation shall be valid for two (2) years from the date of acceptance of application and shall lapse at the end of the two-year period if accreditation has not been successful.

d) On written request by the applicant laboratory, Standards Malaysia reserves the right to extend application period, as it deems appropriate.

e) Standards Malaysia shall assess the applicant laboratory by performing:

i) **Adequacy audit**: A review of its documentation to ascertain that the SAMM requirements are addressed.

Laboratories under the same legal entity and sharing the same documentation may be exempted from multiple adequacy audits at Standards Malaysia’s discretion.

ii) **Pre-assessment**: A preliminary assessment of the laboratory’s management system and its implementation to determine its readiness for the compliance assessment.

Laboratories under the same legal entity, having a similar management system, applying for the same field of activity and meeting the other exemption criteria as set out by Standards Malaysia, may be exempted from multiple Pre-assessment at Standards Malaysia’s discretion.
iii) **Compliance assessment**: An assessment to establish whether a laboratory can competently perform the test/calibration for which it seeks accreditation and make recommendation on accreditation which is subject to the approval by Standards Malaysia.

f) Standards Malaysia shall only consider the granting of accreditation upon satisfactory discharge of all nonconformities raised during the assessments.

g) Standards Malaysia shall grant a SAMM Certificate of Accreditation and a Schedule of Accredited tests and/or calibration to a laboratory after it is satisfied that the laboratory complies with these conditions and all the SAMM criteria.

h) The Certificate of Accreditation shall be valid for three (3) years from the date of approval by the Director General of Standards Malaysia.

i) The Certificate of Accreditation shall not be transferable.

j) Subject to such limitations as laid down in SAMM conditions, changes/amendments to the Certificate/Schedule of accreditation such as:

   i) change of name of a laboratory or its organisation structure;
   ii) change in its legal status;
   iii) change of address or premises;
   iv) change(s) in approved signatories of test/calibration reports or key personnel (for medical testing laboratory); or
   v) other significant editorial changes

   shall be considered by Standards Malaysia.

If in the opinion of Standards Malaysia or its authorised representatives, these changes constitute significant changes to the laboratory management system or affect its technical competence, Standards Malaysia reserves the right to conduct verification assessment or other forms of evaluation to confirm its continued compliance with the SAMM accreditation criteria.

k) All accredited laboratories shall be listed in a directory of accredited laboratories in Standards Malaysia’s website. The directory shall indicate the current accreditation status of the laboratories.

l) At any point in the application or initial assessment process, if there is evidence of fraudulent behaviour, if the laboratory intentionally provides false information or if the laboratory conceals information, Standards Malaysia shall reject the application or terminate the assessment process.

m) If a laboratory is withdrawn or the application is terminated due to evidence of fraudulent behaviour, the laboratory is not allowed to re-apply within two (2) years.
3.4 Frequency of Internal Audit and Management Review

3.4.1 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 maximum interval for internal audit shall not exceed 18 months.

3.4.2 The laboratory’s management review shall be conducted at least once a year.

3.5 Extension of Scope/Branch for Accreditation

3.5.1 Accredited laboratory may apply for extension of scope/branch. An application for extension of scope/branch shall be valid for one (1) year from the date of assessment conducted and shall lapse if accreditation has not been successful.

3.5.2 Standards Malaysia only accepts new application for extension of scope/branch upon granting of the previous extension of scope/branch application.

3.6 Surveillance and Reassessment of Accredited Laboratory

a) Standards Malaysia shall monitor the compliance of the laboratories to the relevant SAMM accreditation criteria.

b) Standards Malaysia shall schedule assessments of the accredited laboratories according to the following table:

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<th>Table 2: Subsequent cycle of accreditation</th>
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<td>Surveillance</td>
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However, Standards Malaysia reserves the right to revert the cycle of accreditation depending on the performance of the laboratory arising from the results of the assessment.

c) Laboratories shall adhere to the assessment schedule as fixed by Standards Malaysia unless otherwise determined. If the laboratory is unable to proceed with the assessment on the agreed date, it shall notify Standards Malaysia.

d) After the assessment notification is issued and laboratory is unable to proceed with the assessment, on the agreed date, Standards Malaysia
reserves the right to impose a penalty and the laboratory shall reimburse any expenses incurred (e.g. flight tickets, non-refundable hotel deposit).

e) Standards Malaysia reserves the right to conduct the assessments unannounced or without prior notice.

3.7 Unscheduled Assessment

Standards Malaysia or its authorised representative reserves the right to carry out unscheduled assessment to applicant or accredited laboratories.

Examples of such unscheduled assessments are as listed below:

i) verification on the implementation of the corrective actions;

ii) extension of scope;

iii) extension of branch;

iv) verification of significant changes in the laboratory (e.g. relocation, renovation etc.);

v) verification of signatory/key personnel;

vi) investigation of complaints;

vii) unannounced assessment;

viii) others, when necessary.

3.8 Suspension and Withdrawal of Accreditation

a) Standards Malaysia shall suspend or withdraw accreditation in the light of:

i) violation of the terms and conditions of accreditation;

ii) failure to comply with SAMM requirements;

iii) fraudulent practices, which includes but are not limited to: deception of claims and alteration of SAMM certificate;

iv) failure to provide cooperation or facilities for Standards Malaysia, its assessors and/or its authorised representatives to discharge their official duties;

v) where, in the view of Standards Malaysia an accredited laboratory has made irresponsible use of externally provided testing/calibration;

vi) an individual of sole proprietorship laboratory is declared bankrupt or enter into a composition with his creditors;

vii) accredited laboratory, being a company, enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purposes of reconstruction) or enters into receivership.

b) In cases where NCR category 2 and category 3 are not closed satisfactorily within three (3) months from the date of assessment, Standards Malaysia may initiate suspension or withdrawal by issuing a notice to the accredited laboratory requiring it within 14 working days from the date the laboratory is informed, to show cause why the certificate of accreditation (all or part of the accredited scope/for the affected scope) should not be suspended or withdrawn.

If no response is received by Standards Malaysia against the notice of suspension or withdrawal, Standards Malaysia shall on expiry of the
notice, suspend or withdraw the accreditation and inform the laboratory in writing upon approval by the Director General.

c) A laboratory whose accreditation has been withdrawn shall return the certificate of accreditation to Standards Malaysia immediately.

d) A laboratory that has been suspended or withdrawn shall not issue SAMM endorsed test reports or calibration certificates for the suspended or withdrawn scope. Failure to comply with the above conditions shall result in legal actions.

e) The laboratory needs to inform its affected customers of the suspension, reduction or withdrawal of its accreditation and the associated consequences without undue delay.

f) The suspension period shall be determined on a case-to-case basis and shall not exceed the expiry date of accreditation. Accreditation shall resume after satisfactory verification/closure of all nonconformities/payment of outstanding fees as prescribed in CAB 4: Suspension and Withdrawal of Accreditation.

g) Should the suspended/withdrawn laboratory wish to appeal against the decision, it should do in writing within seven (7) working days from the date of the suspension/revocation letter.

3.9 Appeal

An appeal shall be in writing. When such an appeal is received, Standards Malaysia shall consider the explanations given, and provide the accredited laboratory an opportunity to be heard. A policy on appeals can be referred to CAB 3: Appeals.

3.10 Inoperative Accreditation

If an accredited laboratory is unable to comply with any of SAMM requirements, and notifies Standards Malaysia and in the opinion of Standards Malaysia, such failure to comply is of a temporary nature, Standards Malaysia retains the right to hold the accreditation on inoperative for part or all of the accredited scope covered in the schedule of accreditation of that laboratory.

While accreditation is under inoperative, no SAMM endorsed test reports/calibration certificates shall be issued for the inoperative scope. Failure to comply with the above conditions shall result in mandatory suspension.

The suspension period shall be determined on case-to-case basis and shall not exceed the expiry date of accreditation. Accreditation shall be restored after satisfactory verification/closure of all nonconformities, otherwise accreditation shall be withdrawn after the expiry date.

Standards Malaysia (Director of Accreditation) at its discretion may consider specific exceptions to the requirements of the inoperative status, upon consultation with relevant parties where necessary.
3.11 Confidentiality

3.11.1 All information gained by Standards Malaysia, its assessors and authorised representatives in the processing, maintaining, extending, renewal, reducing, suspending or withdrawing of accreditation will be treated as confidential between Standards Malaysia and the accredited laboratory. Such information will be handled on a strict "need to know" basis and will not, subject to the law of Malaysia, be disclosed without the written permissions of the testing/calibration laboratory.

3.11.2 Except for the following information, which is published in Standards Malaysia website, all information are treated as confidential:

   a) Name, address and contact details;
   b) SAMM number;
   c) Scope of accreditation; and
   d) Status of accreditation.

3.11.3 MSAC and Committee members, Standards Malaysia staff members, members of Laboratory Accreditation Evaluation Panels, Technical Committees and Sub-committees, Appeals Panel, Standards Malaysia’s assessors and authorised representatives shall be made aware of and abide by this requirement for confidentiality.

4 Obligations of the Testing/Calibration Laboratories

4.1 General

Participation in SAMM does not in any way exempt organisations/laboratories from or diminishes their responsibilities in observing/complying with existing laws and regulations currently enforced in the country.

The testing/calibration laboratory shall:

a) commit to fulfil continually the requirements for accreditation for the scope for which accreditation is sought or granted and to commit to provide evidence of fulfilment. This includes agreement to adapt to changes in the requirements for accreditation;

b) cooperate to enable the Standards Malaysia to verify fulfilment of requirements for accreditation;

c) provide access to laboratory personnel, locations, equipment, information, documents and records as necessary to verify fulfilment of requirements for accreditation;

d) provide Standards Malaysia assessment team with suitable personnel protective equipment (PPE) whenever necessary;

 e) arrange the witnessing of testing/calibration activities when requested by Standards Malaysia;

 f) have, where applicable, legally enforceable arrangements with their customers that commit the customers to provide, on request, access to Standards Malaysia assessment teams to assess the laboratory’s
performance when carrying out testing/calibration activities at the customer’s site;

g) claim accreditation only with respect to the scope for which it has been granted;
h) commit to follow the Standards Malaysia policy for the use of the accreditation symbol;
i) not use its accreditation in such a manner as to bring the Standards Malaysia into disrepute;
j) inform the Standards Malaysia without delay of significant changes relevant to its accreditation;
k) pay fees as determined by Standards Malaysia;
l) commit to be professional towards the assessment team during the assessment. Standards Malaysia does not tolerate any unprofessional conduct and assessment team will not hesitate to discontinue the assessment. When such incidents are reported and validated, this may lead to suspension of accreditation;
m) retain all records as stated in the accreditation standard as required by law, or national guidelines or at least six (6) years.

4.2 Impartiality and Integrity

The laboratory and its personnel shall be free from any commercial, financial and other pressures or inducement, which might influence their technical judgment. This includes, but not limited to:

a) The remuneration of the personnel engaged in testing or calibration activities shall not depend on the number of tests or calibrations carried out nor on the results of such tests or calibrations;
b) When products are tested by bodies, (e.g. manufacturers) who have been concerned with their design, manufacture or sale, a clear separation of different responsibilities shall be made known in the laboratory’s documented information.

4.3 SAMM Endorsed Test Reports and Calibration Certificates

a) All SAMM endorsed test reports or calibration certificates shall be signed or approved by Standards Malaysia approved signatory or key personnel (for medical laboratory). Approved signatory or key personnel shall be identifiable in the test reports or calibration certificates.
b) SAMM endorsed test report/calibration certificate shall not be reproduced except in full without written approval of the accredited laboratory.
c) All SAMM endorsed test reports or calibration certificates shall use the SAMM endorsement in the form of SAMM symbol and the identification of accreditation certificate number. Alternatively, they shall use the endorsement in the form of a statement that the laboratory is accredited under SAMM and identified by its accreditation certificate number.
d) The accredited laboratory may issue a SAMM endorsed test report or calibration certificate that includes test or calibration result from competent external provider in accordance with MS ISO/IEC 17025 requirements and SAMM Policy 3 (SP 3): Policy on the Use of SAMM Accreditation Symbol and Combined ILAC MRA Mark or Reference to SAMM Accreditation.

For medical laboratories, results from external referrals laboratory shall be in accordance with MS ISO 15189 requirements.

e) A SAMM endorsed test report or calibration certificate shall not contain any expression of expert opinion as to serviceability of the sample, batch or consignment or its suitability for a specific purpose provided:

i) Any expression of expert opinion shall be qualified by a disclaimer that it is not under the scope of accreditation under SAMM.

ii) Any such expression of expert opinion be provided in a separate unendorsed document.

However, for medical testing reports, any expression of expert opinion, shall refer to SC 2: Specific Criteria for Accreditation in the Field of Medical Testing.

4.4 Cooperation with Standards Malaysia

The testing/calibration laboratory shall afford Standards Malaysia, its assessors and its authorised representatives such reasonable accommodation and cooperation as necessary, to enable Standards Malaysia to monitor compliance with the terms and conditions and relevant accreditation criteria. This cooperation shall include:

a) affording Standards Malaysia or its authorised representatives reasonable access to relevant areas of the testing/calibration laboratory, for the assessment of the management system and witnessing of calibration or tests

b) undertaking any reasonable check, test or measurement audits to enable Standards Malaysia or its agents to verify the testing/calibration capability of the laboratory

c) preparation, packaging and dispatch, at the expense of the testing/calibration laboratory of test pieces, artefacts, samples or other items needed by Standards Malaysia or its authorised representatives for verification purposes, such as, for the conduct of inter-laboratory comparison testing or proficiency testing

d) participation in any appropriate programme of proficiency testing/measurement audit or inter-laboratory comparison testing that Standards Malaysia may reasonably deem to be necessary

e) permitting scrutiny by Standards Malaysia or its authorised representatives of the results of the testing/calibration laboratory's own internal audits, the performance results of measurement audits or proficiency tests
f) assisting Standards Malaysia or its authorised representatives in the investigation and resolution of any properly authenticated complaints received by Standards Malaysia. These complaints may be made by third parties or interested parties on the laboratory’s accredited tests or calibrations.

g) providing any information, document or records related to operational and management of laboratory (e.g.: cost/charges of testing/calibration services provided) when requested.

4.5 Liabilities

a) An accredited laboratory shall have full control of the issue of accredited test reports or calibration certificates subject to these terms and conditions. It shall therefore assume full liability on the issue of all test/calibration results and reports.

b) The laboratory is hereby advised to acquire professional indemnity insurance against risks that may arise from the use of the results of test/calibration performed.

4.6 Notification of Change

a) An accredited laboratory shall inform Standards Malaysia promptly any change bearing on its compliance with these terms and conditions and other requirements affecting the testing/calibration laboratory’s capability, competence, integrity, independence or scope of activity. Such changes in an accredited laboratory include:

i) changes in the laboratory management or persons which has overall responsibility for the management and technical operation of the laboratory (e.g. Head of laboratory);

ii) any significant changes in activity of the accredited scope;

iii) any significant change in the laboratory’s organisational and management structure;

iv) change of approved signatory(ies);

Note: If the laboratory loses its sole approved signatory, the accreditation status of the laboratory will be suspended.

v) relocation and major renovation affecting the quality of test/calibration results;

vi) any change in the laboratory's legal status;

vii) significant changes in the laboratory's documented policies and/or procedures. The laboratory shall provide Standards Malaysia with copies of the changes.

b) Under circumstances where an accredited laboratory’s capability or competence is affected by one or more of the above significant changes that reduced the confidence of SAMM accredited test/ calibration reports,
the laboratory, at its discretion may make voluntarily request to Standards Malaysia for the laboratory to be placed under inoperative accreditation.

After the appropriate actions have been completed to comply fully with Standards Malaysia accreditation criteria and requirements, it shall notify Standards Malaysia for a verification assessment to restore accreditation.

c) A certificate of accreditation may be relinquished by an accredited laboratory in writing to Standards Malaysia.

d) Any notice or other communication shall be made in the form of post, e-mail or facsimile to the last known address/number of the accredited laboratory.

5 Enforcement

Standards of Malaysia Act 1996 (Act 549), incorporating latest amendment of Act A1425 of year 2012 enables Standards Malaysia to perform enforcement activities for misuse reference of accreditation status as cited in Part V, clause 18(1) as follows:

Any person who—
(a) makes any statement or representation, whether in writing or otherwise, with reference to any conformity assessment that conveys or is likely to convey the impression that a person who is not accredited under this Act with reference to that conformity assessment activity is so accredited;
(b) makes any statement or representation, whether in writing or otherwise, that conveys or is likely to convey the impression that a conformity assessment complies with the requirements of accreditation when it does not so comply; or
(c) having been accredited to use the accreditation symbol, uses the accreditation certificate after its withdrawal, or during its suspension, or otherwise in contravention of the terms and conditions of the accreditation certificate,

shall be guilty of an offence and shall on conviction be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding five years or to both and, for a second or subsequent offence, to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding ten years or to both.

[Subs. Act A1425 of the year 2012]

6 Miscellaneous

a) Accreditation shall not be regarded in any way diminishing the normal contractual responsibilities between the laboratory and the users of its test or calibration data.

While SAMM accreditation will normally be a sound indicator of the quality of testing/calibration service offered by the laboratory, it cannot be taken to constitute a guarantee by Standards Malaysia that the laboratory always maintains a particular level of performance.

b) Accreditation does not, of itself, qualify the laboratory to approve any particular product, process or system.
Note: Accreditation may be a relevant factor enabling approval and certification authorities to decide whether to use a given laboratory in connection with their own activities, or whether to delegate approval or certification authority to a particular laboratory.

c) Charging arrangements between the laboratory and its customers are not under the purview of SAMM accreditation and of these terms and conditions.

d) Standards Malaysia reserves the right not to disclose any information on complainant.

e) Standards Malaysia does not accept or accredit more than one application from a laboratory, which has different legal entity but having a similar management system, human resources and facilities at the same location.