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DEPARTMENT OF STANDARDS MALAYSIA
MINISTRY OF INTERNATIONAL TRADE AND INDUSTRY


MANUAL FOR *PRIMARY HEALTHCARE* LABORATORY ACCREDITATION SCHEME (PHLAS)

Issue 1, 4 January 2021

MASTER COPY


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1.0 SCOPE

- 1.1 This manual describes the management system for the accreditation of primary healthcare laboratories or *Primary Healthcare Laboratory Accreditation Scheme (PHLAS)* including the related procedure.
- 1.2 This manual also describes the organisation of Department of Standards, Malaysia (hereafter known as Standards Malaysia) with respect to this accreditation scheme.
- 1.3 The accreditation scheme is voluntary scheme open to any primary healthcare laboratories that provides conformity assessment services for medical testing such as Haematology, Chemical Pathology, Medical Microbiology and others.
- 1.4 This manual is established based on the requirements of ISO/IEC 17011: "Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies".-
- 1.5 The scheme is part of the overall accreditation infrastructure set up by the Government and operates under an Act of Parliament, the Standards of Malaysia Act 1996 (Act 549) and Amendment 2012 (Act A1425).


2.0 NORMATIVE REFERENCES

In preparing this manual, references are made to the following documents:

- 2.1 Act 549, Standards of Malaysia Act 1996 and Amendment 2012 (Act A1425)
- 2.2 ISO/IEC 17011 – Conformity assessment – Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
- 2.3 ISO/IEC 17000 - Conformity assessment - Vocabulary and General Principles
- 2.4 ISO 19011 – Guidelines for Auditing Management Systems
- 2.5 WHO Laboratories Quality Standards and their Implementations 2016
- 2.6 MS 2702 Primary Healthcare Laboratories - Requirements for Quality and Competence

Note 2:

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

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3.0 (A) TERMS AND DEFINITIONS


For the purpose of this manual, the terms and definitions given in ISO/IEC 17000, MS 2702 and ISO/IEC 17011 apply.

Specifically, terms used in this manual are defined as follows:

- 3.1 **Accreditation:** Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment task.
- 3.2 **Accreditation body:** Authoritative body that performs accreditation.
- 3.3 **Accreditation certificate:** Formal documentation or a set of documents, stating that accreditation has been granted for the defined scope.
- 3.4 **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.
- 3.5 **Accreditation symbol:** Symbol issued by an accreditation body to be used by accredited PHLs to indicate they are accredited.
- 3.6 **Primary Healthcare Laboratory:** is medical testing laboratory that provides testing services for primary healthcare in both public and private sectors
- 3.7 **Scope of accreditation:** Specific conformity assessment services for which accreditation is sought or has been granted.
- 3.8 **Assessor:** A person who is competent to conduct assessment.

(B) ACRONYM

MITI	Ministry of International Trade and Industry
MSAC	Malaysian Standards and Accreditation Council
NAC	National Accreditation Committee
QMS	Quality Management Systems
PHL	Primary Healthcare Laboratory

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4.0 ACCREDITATION BODY

4.1 Legal entity

4.1.1 Background

- a) **Standards Malaysia** was set up by the Malaysian Government on 28 August 1996 under an Act of Parliament, Act 549, the Standards of Malaysia Act 1996 and Amendment 2012 (Act A1425). It is placed under the Ministry of International Trade and Industry (MITI) and is government funded. Standards Malaysia operates as the national accreditation body in the country for conformity assessment activities. The Accreditation Division of Standards Malaysia carries out this specific task.
- b) Standards Malaysia has taken over all accreditation functions and activities of the Malaysian Accreditation Council, which was set up earlier by the Malaysian Government on 30 March 1994 [Cabinet Paper Ref. No. H089/94 and Cabinet Paper Ref. No. 462/1734/90].
- c) As stipulated in Act 549, Standards Malaysia is the national standards and accreditation body which is responsible to develop and promote standards, and to accredit conformity assessment bodies as a means of advancing the national economy, promoting industrial efficiency and development, benefiting the health and safety of the public, and the environment, protecting the consumers, facilitating domestic and international trade and furthering international cooperation in relation to standardisation and accreditation activities.


4.1.2 Office address

- a) Further information on Standards Malaysia accreditation services can be obtained from:

Director General
Department of Standards Malaysia
Level 4, 5, 6 & 7, Tower 2
Menara Cyber Axis
Jalan Impact, Cyber 6
63000 Cyberjaya, Selangor, Malaysia
Tel: +(603) 8008 2900 Fax: +(603) 8008 2901
Homepage: <http://www.ism.gov.my>
- b) The Accreditation Division is located at Level 4 and 5 of the above address.

4.2 Accreditation agreement


- 4.2.1 Standards Malaysia has established agreement which is duly signed upon application whereby the PHL agrees to the terms and conditions set by Standards Malaysia as mentioned below and application forms (PHLAS-P001):

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- a) to 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 of accreditation;
- b) to cooperate as is necessary to enable Standards Malaysia to verify fulfilment of requirements for accreditation;
- c) to provide access to PHL personnel, locations, equipment, information, documents and records as necessary to verify fulfilment of requirements for accreditation;
- d) to arrange the witnessing of conformity assessment activities when requested by Standards Malaysia;
- e) to have, where applicable, legally enforceable arrangements with their clients that commit the clients to provide, on request, access to Standards Malaysia assessment teams and observers to assess the PHL's performance when carrying out conformity assessment activities at the client's site;
- f) to claim accreditation only with respect to the scope for which it has been granted;
- g) to commit to follow Standards Malaysia's policy for the use of the accreditation symbol;
- h) not to use its accreditation in such manner as to bring Standards Malaysia into disrepute;
- i) to inform Standards Malaysia without delay of significant changes relevant to its accreditation but not limited to:
 - i. its legal, commercial, ownership or organizational status;
 - ii. the organisation, top management and key personnel;
 - iii. resources and location(s);
 - iv. scope of accreditation;
 - v. other matters that can affect the ability of the PHL – to fulfil requirements for accreditation;
- j) to pay fees as determined by Standards Malaysia; and
- k) to assist in the investigation and resolution of any accreditation-related complaints about the PHL referred to it by Standards Malaysia.


4.3 Use of accreditation symbols and other claims of accreditation

- 4.3.1 Standards Malaysia takes effective measures to ensure that the accredited PHL conforms fully to the requirements of Standards Malaysia for the use of accreditation symbol as required in Accreditation Policy 1 (AP1).
- 4.3.2 Standards Malaysia accreditation symbols are trademarked with the Intellectual Property of Malaysia (MyIPO). Misuse of accreditation symbol can be an offence under the Standards of Malaysia Act 1996 (Act 549).
- 4.3.3 Standards Malaysia conducts regular monitoring during office assessments and through random selection to ensure correct use of accreditation symbol.
- 4.3.4 If there are incorrect references to accreditation status, or misleading use of accreditation symbols found in advertisements and catalogues suitable actions include corrective action need to be in place which withdrawal of accreditation, publication of the transgression and, if necessary, other legal action.

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4.4 Impartiality requirements

- 4.4.1 Standards Malaysia and its operation are established to safeguard the objectivity and impartiality of its activities.
- 4.4.2 Standards Malaysia takes responsibility for the impartiality of its accreditation activities and does not allow commercial, financial and other pressures to compromise impartiality. Standards Malaysia has established a decision making process to ensure its accreditation activities are impartial and not influenced by other activities.
- 4.4.3 Standards Malaysia's top management has endorsed an impartiality policy which is made available on Standards Malaysia's official website, www.jsm.gov.my.
- 4.4.4 All personnel and committees of Standards Malaysia (Assessors, trainees, observers, staff of Standards Malaysia and members of the MSAC, NAC, EP, Appeal Panel, TWG and all of whom having access to Standards Malaysia files or PHL's files) are responsible, accountable and free from any undue commercial, financial and other pressures that could compromise impartiality, which might influence the results and decisions of the accreditation process. Standards Malaysia requires all individuals involved in its accreditation activities to sign the relevant AF 109 for maintaining confidentiality and impartiality and declaration of no conflict of interest.
- 4.4.5 If there are any risks to impartiality identified, Standards Malaysia ensures necessary measures are taken to eliminate or minimise the identified risk.
- 4.4.6 Standards Malaysia policies and procedures, their administration and implementation shall not discriminate, inhibit or impede in any way against any PHL, who wishes to seek accreditation that falls within Standards Malaysia accreditation activities. No application for accreditation shall be rejected without valid reasons.
- 4.4.7 Standards Malaysia accreditation services are accessible to all applicants whose requests for accreditation fall within the activities and limitations as defined within its policies and rules. Access shall not be conditional upon the size of the applicant PHL or membership of any association or group, nor shall Standards Malaysia accreditation be conditional upon the number of PHLs already accredited by Standards Malaysia.
- 4.4.8 Fee schedules for the various schemes are made available in Standards Malaysia website, www.jsm.gov.my. Other than the approved and published fees, there are no other undue financial conditions imposed.
- 4.4.9 Standards Malaysia does not offer or provide any service that affects its objectivity and impartiality, such as those conformity assessment services that PHLs perform, or consultancy.
- 4.4.10 Promotional talks, briefings, seminars, workshops and public training may be organised by Standards Malaysia.

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4.4.11 Standards Malaysia is not linked to any organisation that offers or provides any service that affect its objectivity and impartiality, such as those conformity assessment services that PHLs perform, or consultancy.

4.4.12 Standards Malaysia has ensured that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality of its accreditations. Standards Malaysia has considered the following when analysing its relationship with related bodies (PHLAS-R010) to avoid possible conflict of interest:

- a) different top management for the activities;
- b) personnel different from those involved in the decision-making processes of accreditation;
- c) distinctly different name, logos and symbols; and
- d) effective mechanisms to prevent any influence on the outcome of any accreditation activity

4.5 Financing and Liability

4.5.1 Financial resources required for the operation of Standards Malaysia are financed by an annual budget allocation from the Government.

4.5.2 Standards Malaysia is a Government body and therefore the Government of Malaysia has adequate arrangements and resources to cover liabilities arising from its accreditation operations and related activities, as referred in the two acts as follows;

- a) **Act 198: Public Authorities Protection Act (1948)**
An Act relating to the protection of persons acting in the execution of statutory and other public duties.
- b) **Act 359: Government Proceedings Act (1956)**
An Act relating to proceedings by and against the Federal Government and the Governments of the States.


4.5.3 Outsourced personnel upon agreement to work for Standards Malaysia need to sign an undertaking whereby the personnel ensure that they have made sufficient arrangements to cover liabilities not covered by the Government of Malaysia.

5.0 STRUCTURAL REQUIREMENTS

5.1 Accreditation Personnel

5.1.1 This manual is consisting of structure, policies dan procedures to ensure the smooth implementation of PHLAS activities. Separate procedure may be established if necessary.

5.1.2 Standards Malaysia's organisation and Unit PHLAS structure are described in (Appendix 1 and Appendix 3) of this manual.

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5.1.3 The MT Unit, Accreditation Division whom is in charge of carrying out PHLAS accreditation activities is part of Standards Malaysia.

5.1.4 Standards Malaysia description of its legal status is as per mentioned in Clause 4.1.1.

5.1.5 Under the Act 549, Director General is the authority that decides on the granting of accreditation or otherwise. The Director General may, in writing, delegate to any of Standards Malaysia Director, this function in the event of his absence from office when necessary.

5.1.6 Standards Malaysia management system has been established, documented, implemented and maintained to give confidence in its ability to operate an accreditation system in an effective manner.

5.1.7 Director General

Director General of Standards Malaysia as the head of department who is appointed in accordance with Section 9 and responsible to oversee the overall operation and executive functions of the department as stipulated in Subsection 10 of the Act 549 and reports to the Minister of **MITI** through the Secretary General of the Ministry. In performing his duties, he is assisted by one (1) Senior Director and three (3) Directors.

The Director of Accreditation is responsible for overseeing the operation of all accreditation including regional and international accreditation / compliance matters. The organisation chart of the Accreditation Division is as shown in (Appendix 2) respectively.


5.2 Council and Committees

5.2.1 Malaysian Standards and Accreditation Council (MSAC)

- a) The Malaysian Standards and Accreditation Council (MSAC or the Council) is an independent advisory council who advises the Minister and approves all accreditation schemes, criteria and programmes.
- b) The terms of reference, memberships and rules of procedure of MSAC are described in document **RoP-MSAC**.

5.2.2 National Accreditation Committee (NAC)

- a) The NAC is established by the MSAC and has been delegated by the MSAC to perform specific functions relating to accreditation and to make recommendations on specific matters to the MSAC.
- b) The terms of reference, memberships and rules of procedure of NAC are described in document **RoP-NAC**.

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5.3 Appeals Panel


- a) As and when required, an independent and impartial panel is established for each appeal to be heard.
- b) Standards Malaysia policies and procedures for the resolution of complaints and appeals received from customers or other parties about accreditation or related matters are covered by documents **RoP-AP** and related procedures.

5.4 Evaluation Panel (EP)

- a) The member of Evaluation Panel (EP) is appointed from assessor pool as when necessary.
- b) The function of EP is to review assessment reports and to make the appropriate recommendation to the Director General for accreditation decisions.
- c) The selection of EP members, for a meeting, Standards Malaysia shall take into consideration the following risks and take appropriate action to minimize the risk:
 - a) Members shall not be selected from the assessment team for which the assessment report is the subject of EP deliberation;
 - b) Members shall not have any involvement with the PHL in any way (offered consultancy / internal auditor, employment) within the last two (2) years (PHLAS-P005-3);
 - c) Members from the same organisation with PHL;
 - d) Members from PHL competitor;
 - e) Members who do not declare the relationship with the PHLs and PHL's personnel;
 - f) Ensure competency of member appoint is matching with PHL activities;
- d) Standards Malaysia to select at least three (3) members for a meeting. At least one (1) EP member should has similar technical competency to the field of accreditation sought by the PHL. Standards Malaysia also needs to consider geographical location and availability of the EP members.
- e) Lead Assessor may be invited to summarize the overall operation of the PHL to the panel members.

5.5 Technical Working Groups (TWG)

- a) As and when necessary, the NAC may establish a TWG for the purpose of developing / reviewing any supplementary accreditation criteria and/or discussing any technical matters.
- b) The NAC has delegated the appointment of TWG members to the Director of Accreditation.
- c) The terms of reference and guidance for the appointment of members for TWG are described in documents **RoP-TWG** and **QP 107**.


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5.6 Assessor

The scheme shall have sufficient number of assessors, which include Lead Assessors and Technical Assessors to cover all of its PHLAS accreditation activities. Standards Malaysia maintains a pool of these resources.

5.6.1 SELECTION, APPOINTMENT AND MONITORING OF ASSESSOR

- 5.6.1.1 Standards Malaysia ensure that an adequate number of competent technical personnel are appointed to carry out PHLAS accreditation activities. The assessment will be led by a lead assessor/team leader that is responsible for the conduct of assessment, opening meeting, report findings and closing meeting. Assessors assigned will perform assessment wherever necessary. The names of the assessors and their organisation will be maintained in Standards Malaysia assessor database.
- 5.6.1.2 The competence of an assessor is determined based on tertiary education in a recognised academic institution with relevant working experience and training in MS 2702 / MS ISO 15189. In addition, the candidate shall have working experience in field of science relevant under the PHLAS scope. Potential assessors may submit application by using form (PHLAS-R004).
- 5.6.1.3 The candidate shall be appointed as a Trainee Technical Assessor by the Director of Accreditation based on recommendation by the PHLAS Manager upon satisfactory evidence provided show fulfilment of the education and working experience requirements.
- 5.6.1.4 The Trainee Technical Assessor is to undergo a PHLAS assessor training programme or SAMM Assessor Workshop. The aim is to equip the Trainee Technical Assessor with adequate knowledge of PHLAS requirements and appropriate skills for conduct of assessment under this scheme.
- 5.6.1.5 A Trainee Technical Assessor shall be considered for appointment as a Technical Assessor after completing at least one (1) observation of assessment and one (1) supervised assessment. Existing assessor in SAMM MT may be appointed for PHLAS and exempted from above requirements.
- 5.6.1.6 Lead Assessor is a person with good managerial and leadership skills in communication, planning, organising, conducting and reporting of the inspection/study audit including dealing with conflicts and decision-making. He shall attend assessor course organised by Standards Malaysia on MS 2702 Primary Healthcare Laboratories - Requirements for Quality and Competence. A PHLAS Lead Assessor shall be considered for appointment as a Lead Assessor, after completing at least five (5) assessment. Existing assessor in SAMM MT may be appointed for PHLAS and exempted from above requirements.
- 5.6.1.7 PHLAS TTA/LA shall be evaluated during the first conduct of assessment by using PHLAS Evaluation Report (PHLAS-R006). Re-Evaluation/monitoring of assessor to be performed every three (3) years.

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5.6.1.8 A person is authorized to carry-out as PHLAS Technical Assessor or Lead Assessor only after the appointment letter (PHLAS-R005) has been signed by PHLAS Manager.

5.6.1.9 The PHLAS assessors shall participate in seminars, courses, workshops, attachments, observations etc. for continuous improvement of their knowledge and skill related to accreditation and technical competency.

6.0 PROCESS REQUIREMENTS

6.1 Accreditation requirements

6.1.1 The general criteria used for accreditation of PHL are those set out in MS 2702 requirements and PHLAS accreditation criteria.

6.1.2 PHLAS accreditation is intended to ascertain whether PHL have implemented requirements as described in MS 2702 and PHLAS accreditation criteria (if any) and conform its competency in conduct of medical testing. The accreditation process includes Preliminary Visit, Compliance Assessment, Surveillance Assessment and Extra Ordinary Assessment (where applicable). The assessment process is demonstrated in the flow chart as in (Appendix 4).

6.2 Application for accreditation

6.2.1 PHLAS is a voluntary program. The mechanism for obtaining this accreditation is by submitting application form (PHLAS-P001) and related documents to Standards Malaysia.

The PHL details shall be registered in database (PHLAS-R001).

6.2.2 The adequacy of the information and documents submitted by the applicant are reviewed by the designated accreditation officer. Where required, further information may be requested from the applicant PHLs. A Lead Assessor is appointed to conduct assessment via dossier (PHLAS-P002).


Acceptance letter will be issued to laboratory by (PHLAS-P003).

6.2.3 At any point during application staged, if there is evidence of fraudulent behaviour, if the PHL intentionally provides false information or if the PHL conceals information, the Standards Malaysia shall reject or terminate application process.

6.3 Assessment Process

6.3.1 For the purpose of the assessment, Standards Malaysia provides the assessment team with appropriate and up-to-date criteria documents, previous assessment records, relevant documents and records of the PHL.

6.3.2 Standards Malaysia ensures that the PHL is agreeable to the date(s) and plan before the assessment notification letter, assessment plan and Delivery Order (for invoice) are issued.

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6.3.3 During conduct of assessment, the assessment team especially Team Leader to pay particular attention on the following items:

- a) Verification of corrective actions on NC raised in the previous assessment;
- b) Proficiency Testing, participation, results and related activities;
- c) Observe performance of medical testing;
- d) Customer complaints and appeals-handling and resolution;
- e) Internal audits, management review and follow up of conclusions resulting from internal audits and reviews;
- f) The effectiveness of the PHL's operations with regard to achieving the objectives of Standards Malaysia criteria.

6.3.4 Assessors must conduct in-depth assessments so as to draw conclusion of the effectiveness of PHL's management system, its operation.

6.3.5 Assessment team analyses all relevant information and evidence gathered during assessment to determine the extent of competence and conformity of the PHL with the requirements for accreditation. Observations for possible improvements may also be reported to the PHL, but consultancy is not provided.

6.3.6 Description of assessment category are as follows:

- a) Preliminary Visit
- b) Compliance Assessment
- c) Surveillance Assessment
- d) Extra ordinary assessment
(e.g: Extension of Scope/Verification Assessment)

6.3.6.1 (a) Preliminary visit


Preliminary visit will be conducted where necessary, within 30 days upon receiving completed application documents including information on:

- a) the type, size and layout of the PHL;
- b) the workload;
- c) the management structure of the laboratory including CVs, job description of key personnel; and
- d) scope of accreditation sought

This preliminary visit is normally carried out within one day to familiarize and to verify that the PHL has implemented requirements in MS 2702 and has adequate resources in respect of management structure, physical layout of buildings and documentation.

Notification of preliminary visit (PHLAS-P004) will be sent to the PHL before date of assessment. This notification contains assessment plan, name of team members, date and time of assessment team arrival, the objective of their visit and assessment duration. This shall allow the PHL to ensure that the appropriate personnel and documentation are available.

It is recommended that Top Management or its representative and key personal be present at the Preliminary visit.

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Some areas of the PHL will be visited, including overview of operations activities. During this visit, the normal work could be slightly disturbed, documents and records may be asked.

The result arising from the Preliminary visit shall be presented in (PHLAS-P008). The PHL is required to submit feedback and accepted by Team Leader before propose date of compliance assessment.

Compliance assessment is scheduled within 3 to 6 months from the date of application accepted. If the PHL is still not ready for the compliance assessment Standards Malaysia will consider to be removed from the scheme.

6.3.6.1 (b) Assessment (Compliance/Surveillance/EOS)

The compliance assessment will involve verification and observation of implementation against MS 2702 including competency of personnel. The compliance assessment would normally be conducted at least one (1) day depending on the number of scopes of accreditation sought by the PHL.

Standards Malaysia shall notify the PHL the assessment team by using Notification of Compliance/Surveillance/EOS Assessment (PHLAS-P004) sufficiently in advance to provide the PHL to lodge of objection to the appointment will supporting justification. This notification contains assessment plan, name of team members, date and time of assessment team's arrival, the objective of their visit and assessment duration. The assessment team will be assigned based on discipline of accreditation sought.

It is absolutely necessary that top management or its representative, and key personnel are present at the opening and closing meeting. During the assessment it is desirable that key personnel to accompany the assessors. As far as possible, the team leader assesses the general operation/quality management system of the PHL whereas the technical assessor will assess the technical aspects. During the assessment, assessors may interview laboratory personnel.


At the opening meeting, the team leader will introduce the assessment team, inform the purpose, outline the scope and assessment criteria to the PHL top management and its personnel.

Assessment team will use to this Assessor's Notes (PHLAS-P011) for recording observations.

During the closing meeting on the last day of the assessment, the team leader will present the findings in the assessment report PHLAS Assessment Report (PHLAS-P008) to the laboratory personnel and acknowledged by laboratory management.

6.3.6.1 (c) Surveillance Assessment

First and second surveillance assessment will be conducted annually for the first two years after the date of granting. The next surveillance assessment will be conducted every two (2) years based on granting date. The process used for the surveillance assessment is similar to what has been described under 6.3.1.6 (b)

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6.3.6.1 (d) Extra ordinary assessment (e.g: Extension of Scope/Verification Assessment)

Extension of Scope/Verification Assessment shall be carried out for the following situation but not limited to:

- a) verification on the implementation of the corrective actions
- b) extension of new test/discipline
- c) significant changes in the laboratory (e.g changes of address, relocation, renovation etc)
- d) others where necessary.

The process used for the Extra Ordinary Assessment as described under **6.3.1.6 (b)**

6.3.7 PHL shall allow Standards Malaysia assessor access to the PHL specify area, resources, operations, procedures, records and personnel, so that the assessors can effectively assess the PHL system and activities.

6.3.8 PHL shall make available a room for examination document and other activities during the assessment.

6.4 FOLLOW UP TO ASSESSMENT

6.4.1 Classification of Non-Conformity (NC)

During the assessment, the assessment team may come across areas/issues which are not in compliance with the MS 2702, PHLAS Manual and accreditation criteria. Such non-conformity is classified into following categories.

6.4.2 Major Non-Conformity


Major non-conformity is defined as deviation from the MS 2702 requirements, PHLAS and PHL's procedure that threatens the integrity of quality system.

6.4.2.1 Major Non-Conformity During Compliance Assessment

When major is raised during compliance assessment, appropriate corrective action shall be taken by the applicant. The corrective action period shall not exceed one (1) month from the last date of assessment, but another delay of one (1) month can be permitted if PHL can justify the delay. The applicant shall not receive accreditation certificate until corrective action has been handled satisfactory and accepted by assessment team. In case if the PHL fails to take satisfactory actions within the specified time, Standards Malaysia may consider verification assessment or remove from the scheme.

6.4.2.2 Major Non-Conformity During Surveillance/Extraordinary Assessment

When Major is observed during Surveillance/Extraordinary Assessment, the PHL is to take appropriate measures within a specified time frame of one (1) month, to resolve the issues. If corrective action is not submitted within the time frame, the team leader will make recommendation to Standards Malaysia whether part or entire part of PHLAS scope of accreditation suspend and/or remove from the scheme. The PHL is given 14 working days to response to the Standards Malaysia from the letter of suspension.

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If the PHL wish to re-enter into the scheme, they need to submit a new application.

6.4.3 Minor Non-Conformity

During the assessment, the assessor may come across non-conformity that have significant impact to the quality of management system or to validity of test results. Such non-conformity is normally observed in isolated areas.

6.4.3.1 Minor Non-Conformity During Compliance Assessment

When minor is observed during compliance assessment, appropriate corrective action shall be taken by the applicant. The corrective action period shall not exceed 3 months from the date of last assessment. The applicant shall not receive accreditation certificate until corrective action has been handled satisfactory and accepted by assessment team. In case if the PHL fails to take satisfactory actions within the specified time, Standards Malaysia may consider verification assessment or remove from the scheme.

6.4.3.2 Minor Non-Conformity During Surveillance/Extraordinary Assessment

During the Surveillance/Extraordinary Assessment, the laboratory will be given 3 months to take corrective action of such deviations. However, if the laboratory fails to take satisfactory action within the duration mentioned, then Standards Malaysia will suspend its accreditation status or may consider removing it from the scheme.

For Minor non-conformity, corrective action and root cause analysis of the nonconformities shall be submitted to Standards Malaysia and closed out satisfactorily within three (3) months. Should the nonconformity unable to be closed out within three (3) months, Standards Malaysia may initiate suspension of the laboratory's accreditation. The PHL is given 14 working days to response to the Standards Malaysia from the letter of suspension.

6.4.4 Observation

During the compliance and surveillance assessment, observations may be raised as an opportunity for PHL to consider possible improvement.


6.5 Accreditation Decision Making

6.5.1 Final approval of assessment reports

6.5.1.1 The assessment team will review and accepts the corrective action submitted by PHL. The team leader will complete the assessment report and forward to Standards Malaysia for approval. The assessment report will be reviewed by the PHLAS Manager and authorized by Director of Accreditation before tabled to evaluation panel for recommendation of approval. Appointment of panel meeting will be using (PHLAS-P005).

*Note: Panel meeting – Frequency monthly @ as necessary

6.5.1.2 Director of Accreditation will forward the recommendation by evaluation panel for Director General approval using (PHLAS-P005-2) and (PHLAS-P006).

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6.6 Status of Accreditation


- 6.6.1 The Director General makes the decision on whether to grant, continue, suspend and remove accreditation based on an evaluation of all information provided.
- 6.6.2 If PHL comply with all accreditation requirements, the Director General of Standards Malaysia will make decision on accreditation status against Accreditation to MS 2702 (PHLAS-P008) and a notification Letter on Accreditation (PHLAS-P007) will be issued to the laboratory.
- 6.6.3 The certificate (PHLAS-P010) issued contains a statement of accreditation status to show the PHL assessed is competent and comply with MS 2702. Scope schedule (PHLAS-P009) will also be issued based on the approval by Director General.
- 6.6.4 If, a PHL has been removed from the scheme, it shall not make any claim on accreditation status.

6.7 Accreditation Information

- 6.7.1 Each accredited PHL is provided with Certificate of Accreditation signed by the DG. Each Certificate of Accreditation is uniquely numbered and identifies the following:
- Standards Malaysia's logo;
 - Name of accredited PHL and the name of legal entity, if different;
 - scope of accreditation;
 - locations of the PHL;
 - unique accreditation number of the accredited PHL;
 - effective date of granting of accreditation;
 - a statement of conformity and a reference to the standard(s) or normative document(s), including issue or revision used for assessment of the PHL.
- 6.7.2 The effective date of Standards Malaysia accreditation is the date of approval by the DG.
- 6.7.3 The scope of accreditation also identifies the following:
- issue date;
 - materials or specimen tested;
 - parameter or characteristic tested;
 - tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used; and
 - signatory(ies)

7.0 Suspension and Removal

- 7.1 Standards Malaysia shall decide on suspension and/or withdrawal of accreditation when an accredited PHL has persistently failed to meet the requirements of accreditation or to abide by the rules for accreditation. There may be circumstances where the PHL may ask for temporary inoperative or withdrawal of accreditation

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7.2 Whenever it comes to Standards Malaysia's knowledge of fraudulent behaviour by a PHL, Standards Malaysia shall conduct an investigation to gather information. If there is sufficient evidence, Standards Malaysia shall remove from the scheme.

8.0 Complaints

8.1 Standards Malaysia has established procedures for dealing with complaints from the general public and its customers to ensure that any shortcomings of the accreditation activities and its accredited PHL's are reviewed and corrective actions taken to prevent recurrence.

8.2 Formal notice of complaint outcome will send to complainant at the end of complaint.

8.3 Complaints made to Standards Malaysia shall not in any way result in discriminatory actions against the complainant.

9.0 Appeals

9.1 Standards Malaysia has also established procedures to address appeals by PHLs. The appeal will be registered and forwarded to the Chairman of the Malaysian Standards and Accreditation Council (MSAC) for resolution in accordance with RoP-Appeal and related procedures.

9.2 Standards Malaysia provides PHL with the right to appeal against any decision made by Standards Malaysia.

9.3 Standards Malaysia is responsible for all decisions at all levels of the handling process for appeals.


9.4 Appeals made to Standards Malaysia shall not in any way result in discriminatory actions against the appellant.

9.5 Standards Malaysia shall provide formal notice to the appellant of the appeals outcome.

10.0 Records on PHL

10.1 It is Standards Malaysia's policy to retain records relating to PHL for two (2) accreditation cycle.

10.2 As a minimum, records on PHL include relevant correspondences, assessment records and reports, records of deliberations of EP and other committees where applicable, accreditation decisions and copy of accreditation certificate and scope.

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11.0 Fee

11.1 The following fees are payable by the PHL according to Standards Malaysia Fee Regulation 2018.

Application	RM 2000.00
Type of Assessment: i) Preliminary ii) Compliance Assessment iii) Surveillance Assessment iv) Extraordinary/Others	Lead Assessor: RM 1000/ man day Technical Assessor/Expert: RM 800/ man day
Annual renewal fee	RM 1000.00
Annual branch fee	RM 500.00
Appeal	RM 1500.00

12. Rights & Duties

- a) Standards Malaysia ensures its assessors including those sourced externally are impartial and without any conflict of interest with regard to an assessment assigned to them as described in Clause 4.4 of this manual.
- b) To ensure compliance to Standards Malaysia criteria and PHLAS Accreditation requirements, informing PHL of procedures to assess their competence. These information are publicly available on Standards Malaysia website, www.ism.gov.my/accreditation.
- c) Where the assessment team cannot reach a conclusion about a finding, the team shall refer back to Standards Malaysia for clarification. Standards Malaysia has established working mechanism to handle this situation, including appointing a competent committee to review the findings concluded by the assessment team.
- d) An accredited PHL is required to inform Standards Malaysia without delay of any significant changes in any aspects of its status or operation that may affect its capability or conformance with the requirements and other relevant criteria specified by Standards Malaysia.
- e) Significant change may includes:
 - a. changes in personnel, equipment, or scope of activity of an accredited;
 - b. laboratory;
 - c. any change in the laboratory's organisation and management,


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- d. e.g. Head of laboratory, Technical Manager or Quality Manager, any change, transfer, redesignation of duties, resignation of laboratory key personnel, approved signatory, authorised representative and other senior laboratory staff,
 - e. changes of duties of approved signatories,
 - f. significant changes in address, premises, laboratory calibration testing environment, facilities, equipment or other resources,
 - g. any change in the laboratory's legal, commercial or organisational status,
 - h. changes in the laboratory's policy and procedures.
- f) Standards Malaysia shall made publicly available information about the current status of the accreditations that it has granted to PHL including whether the PHLs accreditation status is active, suspended or withdrawn. This information is updated regularly as and when required. The information includes at least the name and address of each accredited PHL, the date of granting/suspension/withdrawal of accreditation and the scope of accreditation.

13.0 INFORMATION REQUIREMENTS

13.1 Confidential information

- 13.1.1 Standards Malaysia procedures provide adequate arrangement; consistent with laws of Malaysia, to safeguard confidentiality of the information obtained in the course of its accreditation activities at all levels within the organisation.
- 13.1.2 Standards Malaysia keeps records on PHL securely to ensure confidentiality. The security of information/records communicated through email shall be ensured at all times. Standards Malaysia staff is required to refer to the Guidance on Procedural Use of Internet and Electronic Mail at Government Agencies (*PKPA Bil. 1 Tahun 2003 – Garis Panduan Mengenai Tatacara Penggunaan Internet dan Mel Elektronik di Agensi-Agensi Kerajaan*).
- 13.1.3 The Government General Orders and the Official Secret Act provide that any person found contravening with the above requirements are guilty of an offence and on conviction are liable to a fine, or to imprisonment or to both.
- 13.1.4 Except as required in its documented system, information (not including information in the public domain) about a particular PHL shall not be disclosed to a third party without the written consent of the PHL in question. Where the law or authorised by contractual arrangements requires information to be disclosed to a third party, the PHL shall be informed, in writing, accordingly.
- 13.1.5 Information about the PHL obtained from sources other than the PHL (e.g. complainant, regulators) shall be confidential between the PHL and Standards Malaysia. The provider (source) of this information shall be confidential to Standards Malaysia and shall not be shared with the PHL, unless agreed by the source.

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14.0 List of Appendices

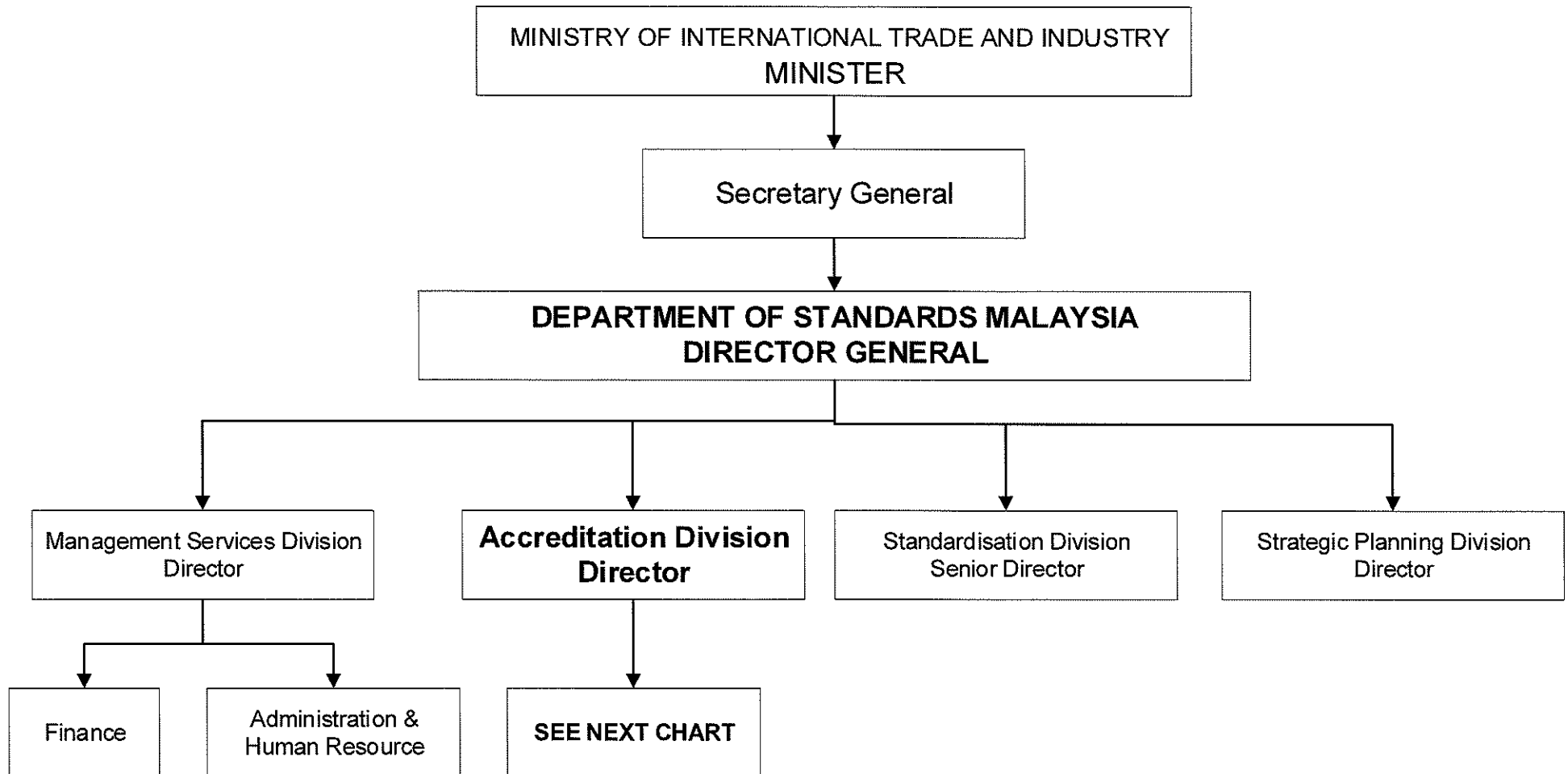
	NAME	APPENDIX NO.
1.	Organisation Chart of Standards Malaysia	1
2.	Organisation Chart of Accreditation Malaysia	2
3.	Organisation Chart of PHLAS Unit	3
4.	Flowchart of PHLAS Unit Process	4

15.0 List of Forms

	NAME	FORMS
1.	Application Form	PHLAS-P001
2.	Dossier for Undertaking Laboratories	PHLAS-P002
3.	Letter of Accepting Laboratories	PHLAS-P003
4.	Notification and Plan of Assessment	PHLAS-P004
5.	Notification PHLAS Evaluation Panel	PHLAS-P005
6.	PHLAS Evaluation Panel Report	PHLAS-P005-2
7.	PHLAS Evaluation Panel Attendance List	PHLAS-P005-3
8.	MEMO Approval Compliance (Granting / Continuity)	PHLAS-P006
9.	Letter of Granting / Continuity	PHLAS-P007
10.	Assessment Report	PHLAS-P008
11.	Scope of Accreditation	PHLAS-P009
12.	Certificate of PHLAS	PHLAS-P010
13.	Assessors Note	PHLAS-P011
14.	Database of PHLAS	PHLAS-R001
15.	Undertaking of Confidentiality	PHLAS-R002
16.	Code of Ethics for Assessors	PHLAS-R003
17.	Assessor Registration Forms	PHLAS-R004
18.	Appointment TTA/TA/LA	PHLAS-R005
19.	Assessor Evaluation Report	PHLAS-R006
20.	Checklist Appointment of Assessor	PHLAS-R007
21.	Checklist Approval of Assessor	PHLAS-R008
22.	Checklist of Assessor Approval	PHLAS-R009
23.	Analysis of Related Body Relationship	PHLAS-R010

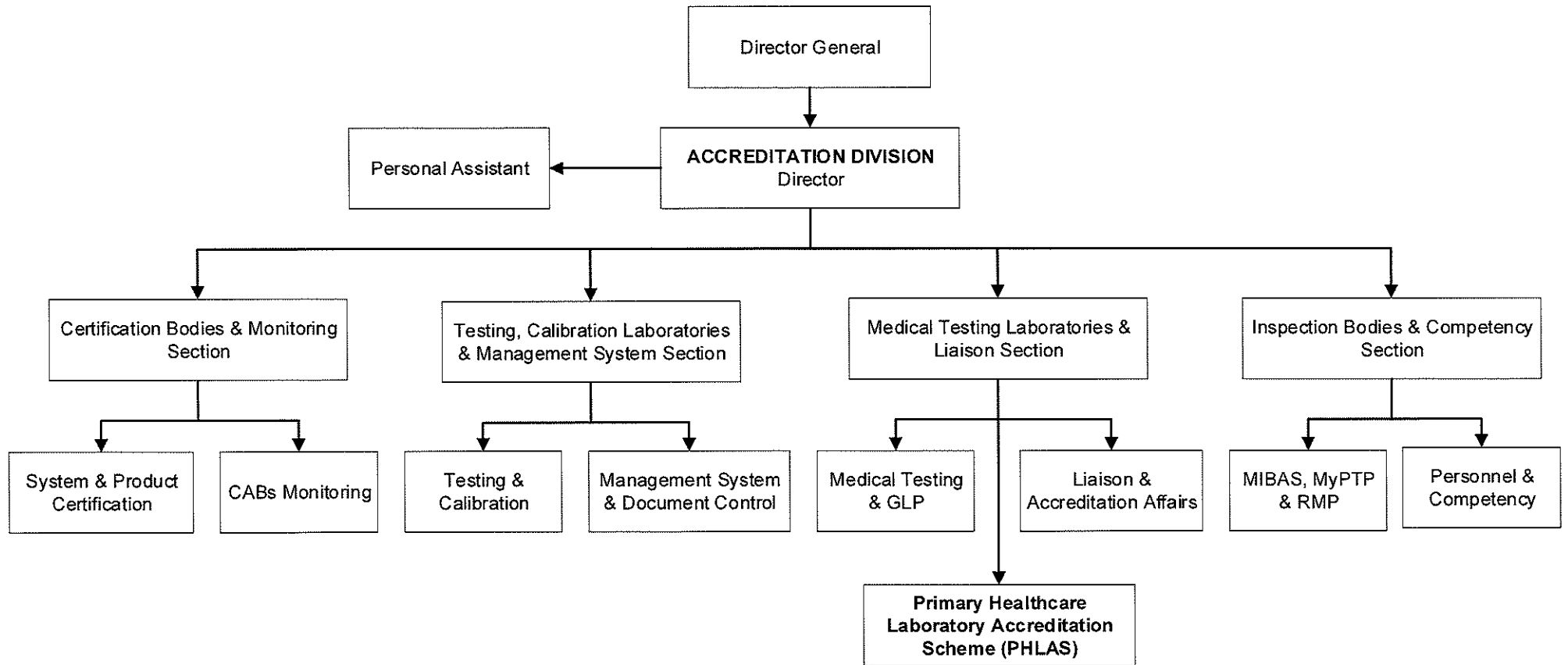
APPENDIX 1

ORGANISATION CHART – DEPARTMENT OF STANDARDS MALAYSIA



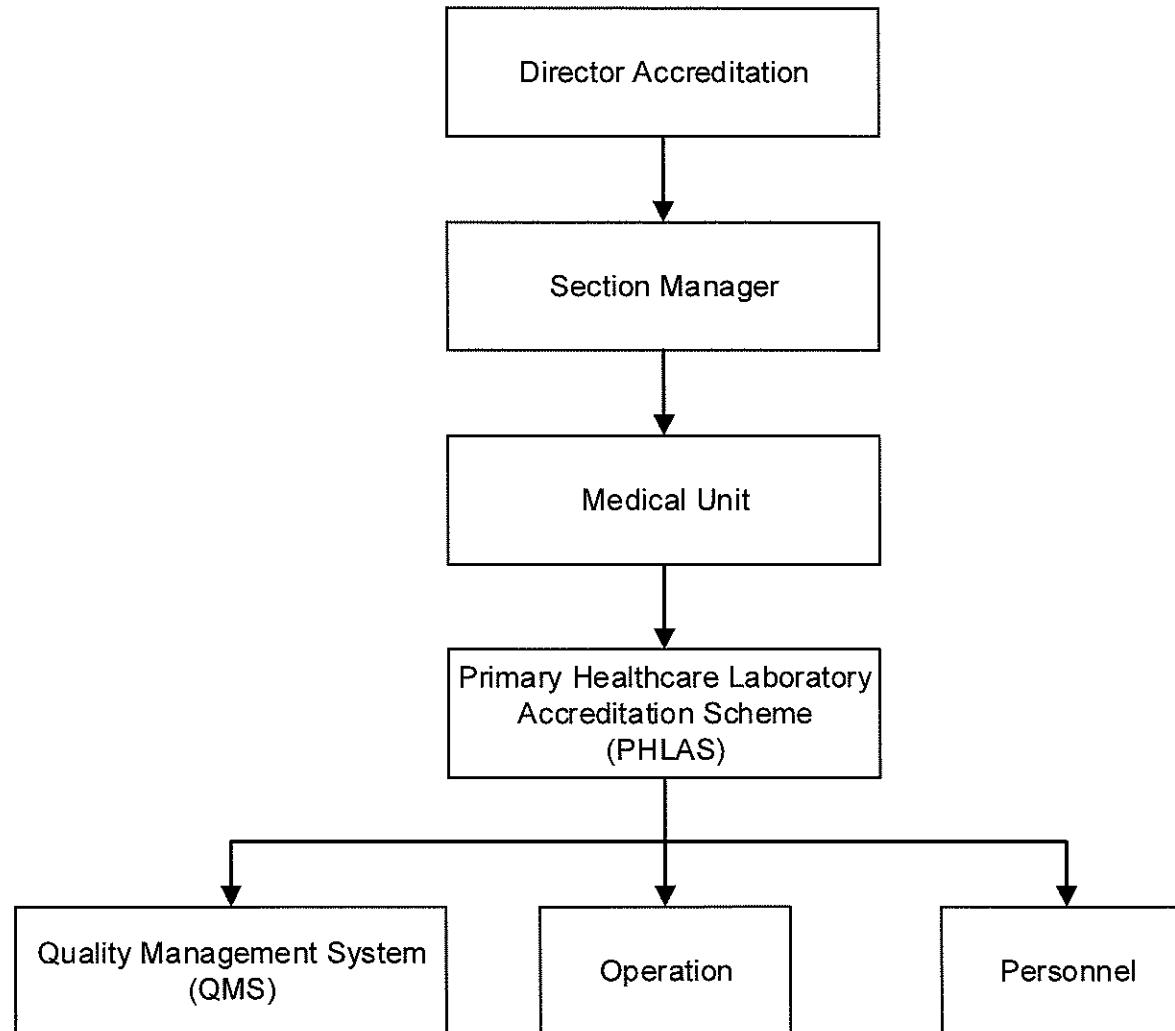
APPENDIX 2

ORGANISATION CHART – ACCREDITATION DIVISION (OPERATIONAL)



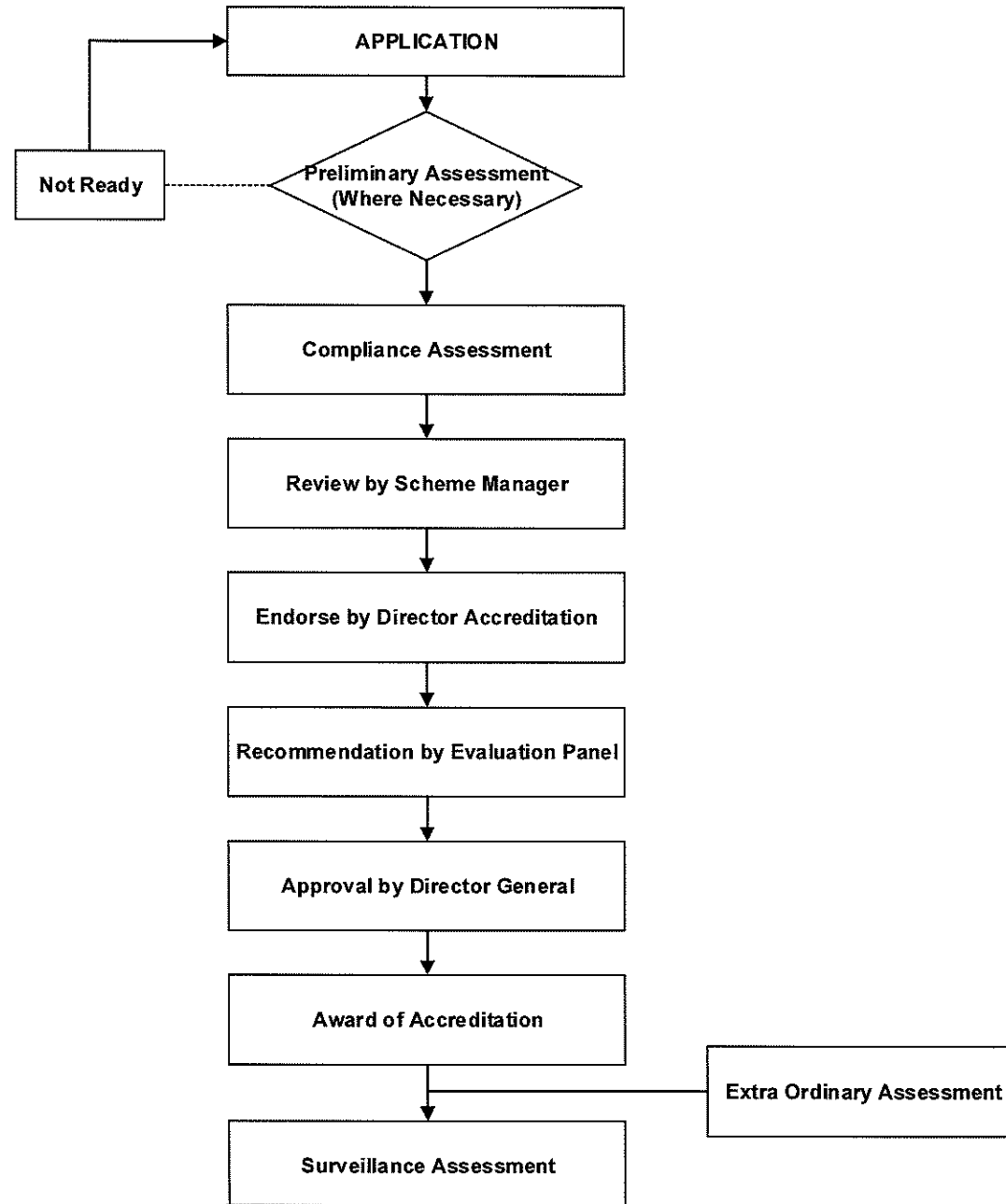
APPENDIX 3

ORGANISATION CHART – PHLAS UNIT



APPENDIX 4

FLOWCHART OF ACCREDITATION PHLAS PROCESS





**PRIMARY HEALTHCARE LABORATORY
ACCREDITATION SCHEME**

APPLICATION FORM

1. ORGANIZATION DETAILS

Name:.....
(Indicate exactly how the name of the organisation is to appear on the certificate)

Address:.....
.....
.....

Tel. no.:..... Fax. No.:.....

Website: E-mail:

Contact person:..... Designation:.....

2. LABORATORIES DETAILS

(If different from above)

Name:.....
(Indicate exactly how the name of the laboratory is to appear on the certificate)

Address:
.....
.....

Tel. No.: Fax. No.:

Website: E-mail:.....

Contact person:..... Designation:.....

Date of establishment :

Legal status :
(e.g. Govt. Dept., Pte/Ltd, etc)

4. GENERAL BACKGROUND OF APPLICANT KLINIK KESIHATAN LABORATORY

(Please provide as much as possible details such as organisation charts, extracts from quality manual, organisation's latest annual report or publicity brochure)

a) Major activities of laboratory:

b) Structure of laboratory:

(Please provide the organisation chart showing the line of authority within the laboratory and if relevant, the laboratory's position in the overall structure of the parent organization. If it is available in the Quality Manual, please state the relevant section of the location of the laboratory's structure)

c) Laboratory's main quality documents:

(Please tick in the appropriate boxes)

1. Quality manual *	
2. Standard operating procedure (SOP) *	
3. Test method *	
4. Working instructions (WI)	
5. Forms	
6. Reference documents	
Others, please state:	

Note: Documents marked with * are to be submitted to Standards Malaysia

d) Field of medical testing for which accreditation is sought

(Please tick in the appropriate boxes)

Chemical Pathology	
Haematology	
Medical Microbiology	
Virology	
Others: (please state e.g.: immunology, etc)	

5. SCOPE OF ACCREDITATION SOUGHT

(Please specify as precisely as possible the scope of accreditation sought)

Field:

Specimen Tested	Type of Tests / Properties Measured	Test Method, Specification/ Equipment/Techniques Used

Specimen Tested	Type of Tests / Properties Measured	Test Method, Specification/ Equipment/Techniques Used

Note: Photocopies/retyped schedules are acceptable.

6. LIST OF KEY PERSONNEL

(Please attach CV and provide details of the office bearers below and please use extra sheet if necessary)

Laboratory Key Personnel:

	Name	Designation
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

7. DECLARATION

- I have read, understood and will comply with MS 2702 and PHLAS requirements:
 - a) to 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 of accreditation;
 - b) to cooperate as is necessary to enable Standards Malaysia to verify fulfilment of requirements for accreditation;
 - c) to provide access to PHL personnel, locations, equipment, information, documents and records as necessary to verify fulfilment of requirements for accreditation;
 - d) to arrange the witnessing of conformity assessment activities when requested by Standards Malaysia;
 - e) to have, where applicable, legally enforceable arrangements with their clients that commit the clients to provide, on request, access to Standards Malaysia assessment teams and observers to assess the PHL's performance when carrying out conformity assessment activities at the client's site;
 - f) to claim accreditation only with respect to the scope for which it has been granted;
 - g) to commit to follow Standards Malaysia's policy for the use of the accreditation symbol;
 - h) not to use its accreditation in such manner as to bring Standards Malaysia into disrepute;
 - i) to inform Standards Malaysia without delay of significant changes relevant to its accreditation but not limited to:
 - i. its legal, commercial, ownership or organizational status;
 - ii. the organisation, top management and key personnel;

- iii. resources and location(s);
- iv. scope of accreditation;
- v. other matters that can affect the ability of the PHL to fulfil requirements for accreditation;

j) to pay fees as determined by Standards Malaysia; and

k) to assist in the investigation and resolution of any accreditation-related complaints about the PHL referred to it by Standards Malaysia.

- I hereby, give my consent on behalf of the laboratory to abide requirements by Standards Malaysia.
- I hereby, declare that the information furnished above is correct.
- I have to pay all fees and costs connected with the accreditation process irrespective of the eventual granting of PHLAS compliance.
- I will provide access to those documents that provide insight into the level of independence and impartiality of the test facility from its related bodies, where applicable; and;
- I agree to allow Standards Malaysia assessors access to the laboratories specify area, resources, operations, procedures, records and staff so that the assessors can effectively access the laboratory system and activities. I understand that the failure to allow the above access will lead to the removal of my laboratory application.

Signature:

Date:.....

Name of laboratories Representative:.....

Organisation's Stamp / Seal:

Please return completed forms to:

Director General
Department of Standards Malaysia
Aras 4, 5, 6 & 7, Tower 2
Menara Cyber Axis
Jalan Impact, Cyber 6
63000 Cyberjaya
Attention: Director of Accreditation
Tel : +(603) 8008 2900
Fax : +(603) 8008 2901

Acknowledgement Receipt

To:
.....
.....
.....

I, hereby confirmed that we have received your application form and will proceed to further action i.e. to assign Lead Assessor, issuing assessment notification, plan etc.

Name & Designation: Signature:.....

Date:



PHLAS-P002: DOSSIER FOR UNDERTAKING LABORATORIES
(Original to be kept by Lead Assessor & photocopy to be kept in applicant file)

A) Laboratories details:-

Name:

Address:

.....

Contact person: Email:

Tel. No.:

File No.:

B) Proposed Team Leader

Name of proposed Team Leader

Signature: Date:

C) Approval (PHLAS Manager)

Approved / Not Approved *

Comment:

.....

Name of officer in-charge

Signature: Date:

* Delete which is not applicable

To:	<Lead Assessor's name> <Address>
	Tel: _____ Email: _____

Scope of accreditation: All requirements of MS 2702 and manual PHLAS documents.

Action required from you:

- 1) Please prepare to conduct the Pre-Assessment, Compliance and Surveillance Assessment on the documents submitted and take appropriate action and submit all report to the Standards Malaysia.

Important Note:

- 1) All forms used and report generated shall be in the current format prepared by Standards Malaysia (where appropriate).
- 2) Please contact Standards Malaysia should you have any enquiries, problem/s associated with the assessment of the Laboratories assigned to you.
- 3) In accordance with Standards Malaysia's policy as declared by you in the code of ethics, every member of the team must inform Standards Malaysia, prior to the assessment, about any existing, former and envisaged future link between themselves or their organisations and the Laboratories to be assessed.
- 4) Assessor, who have any existing link between themselves or their organisations and the Laboratories to be assessed, in such a way that the objectivity of the assessment, including independence, impartiality and no-conflict of interest requirements may be compromised, shall be relieved from performing assessment on that particular Laboratories on Standards Malaysia's behalf.

Declaration:

Are you free from any commercial (have not offered consultancy to this Laboratories within 2 years), financial or other pressures or conflicts of interest that might cause you to act in other than an impartial or non-discriminatory manner?

YES NO

If YES, please proceed to accept this assignment.

Accepted:

Name: Signature:
(Lead Assessor)

Date:

Ref. File no: JSM/AD-700/06/01/01/
Date:

PHLAS-P003
Issue 1, 4 Jan 2021

«Name_of_TF»
«Address_1»
«Address_2»
«Address_3»
«Address_4»
(Attn:)
Tel:

Dear Sir/Madam,

PARTICIPATION IN PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME

With reference to the above and your application-dated dd-mm-yyyy to the Department of Standards Malaysia (Standards Malaysia), we wish to inform you that, Standards Malaysia has examined and accepted the application submitted.

As for conduct any assessment, Standards Malaysia has proposed **Ms./Mr.** _____ as the Lead Assessor. We will conduct preliminary visit / compliance assessment for you laboratory.

You are advised to reply to Standards Malaysia on the acceptance of the above Lead Assessor. Kindly inform us in writing, with valid reason/s should you wish to appeal against the use of this Lead Assessor and any of the Assessor/s proposed in the future. We wish to draw your attention that such appeal and its resolution are provided in Standards Malaysia procedures.

Our Lead Assessor will contact your laboratory for the commencement of assessment, confirmation of date and his/her assessment team.

Please be informed that your file reference number is **JSM/AD-700/06/01/01/**(), for any communication to Standards Malaysia, please quote this reference number.

If you have any enquiries, kindly contact the officer in-charge, **Ms. Rohasmizah binti Ismail** by phone at 03 – 8008 2817 or email rohasmizah@jsm.gov.my.

Thank you.

Yours faithfully,

(FARIZA WAN ABDULLAH)
Accreditation Division
for the Director General
Department of Standards Malaysia



Ref. File no.: JSM/AD-700/06/01/01/
Date: dd-mm-yyyy

PHLAS-P004
Issue 1, 4 Jan 2021

<name of laboratories >
<address>

(Attn: Mr.)

Tel:

Dear Sir/Madam,

PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME: PRE-ASSESSMENT / COMPLIANCE / SURVEILLANCE DATE: <dd-mm-yyyy>

With reference to the above, please note that the above assessment of your laboratory is scheduled on the date as confirmed. The purpose of this assessment is to verify compliance to the MS 2702 and PHLAS requirements.

The assessment team will comprise the following:

	<u>Name</u>	<u>Organisation</u>
Team Leader:		
Assessor:		

You are advised to reply to Standards Malaysia on the acceptance of the above assessor/s.

Kindly inform us in writing, with valid reason/s should you wish to appeal against the use of any of the above assessor/s. We wish to draw your attention that such appeal and its resolution are provided in Standards Malaysia procedures.

Please be informed that it is desirable for your top management representative to be present at both the opening and closing meeting. Assessment findings and provisional report will be presented at the closing meeting.

Enclosed please find the assessment plan for your kind attention. Standards Malaysia will invoice you in accordance to Standards Malaysia (Fees) Regulation 2018 for this assessment.

Thank you.

Yours faithfully,

(FARIZA WAN ABDULLAH)
PHLAS Manager
for the Director General
Department of Standards Malaysia
c.c. All Assessor

ASSESSMENT PLAN

Day 1, Date: day/month/year (DAY)

<u>TIME</u>	<u>EVENT</u>
09.00 a.m.	Opening meeting with laboratory management Introduction of Standards Malaysia team To confirm: a) scope of tests b) applicable standard/criteria/requirement c) review of assessment plan including witnessing of test d) assessment of method/standard/procedure e) auditee's applicable documents and their status f) interview of personnel and suitability of signatory
09.45 a.m.	Briefing by auditee on change in the organisation/quality system
10.00 a.m.	Commencement of assessment - Verification of effectiveness of corrective action and update of quality system - Assessment of the laboratory including examination of documents/record, interview of staff and witnessing of tests
01.00 p.m.	Lunch break (Note: The time for lunch break may be adjusted to fit in with the laboratory's operations)
02.00 p.m.	Continuation of assessment proper (visiting of site where appropriate)
03.30 p.m.	Meeting of assessors to discuss findings of the assessment and report preparation
04.30 p.m.	End of 1 st day assessment Closing meeting and presentation of assessment findings and summary report to laboratory management

Day 2, Date: day/month/year (DAY) – IF APPLICABLE

09.00 a.m.	Meeting with laboratory management if necessary
09.30 a.m.	Continuation of assessment
01.00 p.m.	Lunch break (Note: The time for lunch break may be adjusted to fit in with the laboratory's operations)
02.00 p.m.	Continuation of assessment proper (visiting of site where appropriate)
03.30 p.m.	Meeting of assessors to discuss findings of the assessment and report preparation
04.30 p.m.	Closing meeting and presentation of assessment findings and summary report to laboratory management

Note:

- The times indicated are subject to adjustment forward or backward depending on the progress of the assessment.
- It is desirable for top management to be present at both opening and closing meetings.
- Please make a copy of assessment findings, summary report and endorsed scope for your retention.



JABATAN STANDARD MALAYSIA
Kementerian Perdagangan Antarabangsa dan Industri
Tingkat 4, 5, 6 & 7, Tower 2, Menara Cyber Axis
Jalan Impact, Cyber 6, 63000 Cyberjaya, Selangor

DEPARTMENT OF STANDARDS MALAYSIA
Ministry of International Trade and Industry
Level 4, 5, 6 & 7, Tower 2, Menara Cyber Axis
Jalan Impact, Cyber 6, 63000 Cyberjaya, Selangor

STANDARDS
MALAYSIA

Tel: +603-8008 2900
Fax: +603-8008 2901
E-mail: central@jsm.gov.my

PHLAS-P005
Issue 1, 4 Jan 2021

File ref. no.: JSM/AD-700/06/01/01/
Date: dd-mmm-yyyy

PANEL 1
Address
Email:

PANEL 5
Address
Email:

PANEL 2
Address
Email:

PANEL 6
Address
Email:

PANEL 3
Address
Email:

PANEL 7
Address
Email:

PANEL 4
Address
Email:

Dear Sir/Madam,

**PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME EVALUATION
PANEL MEETING**

I wish to confirm that the PHLAS Evaluation Panel meeting for reviewing and evaluation of assessment's report of laboratory(ies), has been scheduled as follows:

Date : ddmmyyyy (day)
Time : am/pm
Venue : Level 1, Accreditation Discussion Room, Standards Malaysia
Agenda : -Explanation by the Scheme Manager or Officer in charge of laboratory.
-Consideration of the compliance / extension of scope assessment's report of laboratory(ies) as follows :

1. name of laboratory (type of assessment)

2. name of laboratory (type of assessment)

Kindly inform us should you have any involvement (consultancy/internal auditor/ employment within the last two (2) years) with the laboratory(ies) as listed above. Your attendance is essential and your cooperation is highly appreciated.

Thank you.

Yours faithfully,

(Officer in charge)
Accreditation Division
for the Director General
Department of Standards Malaysia

DEPARTMENT OF STANDARDS MALAYSIA (STANDARDS MALAYSIA)
PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME (PHLAS)

PHLAS EVALUATION PANEL REPORT

Name & address of laboratory:

--

File ref. no.: JSM/AD-700/06/01/01/

Field of Accreditation:

Review Summary		REMARK (if any)
1. Are all applicable assessment documents and other evidence of assessment conducted available?	Yes / No*	
2. Was the assessment conducted according to PHLAS Manual? <i>(i.e. in the form of evidence in assessment planning, assessment program/schedule, attendance list of opening and closing meetings)</i>	Yes / No*	
3. Are all outstanding NCRs satisfactorily discharged as a condition for accreditation? <i>(Look for individual as evidenced in tabulated NCRs / corrective actions)</i>	Yes / No*	
4. Is the assessment team's proposed for accreditation? <i>(Request to view PHLAS-P005)</i>	Yes / No*	
5. Agree with scope of accreditation and key personnel proposed by the Assessment Team?	Yes / No*	

* Delete whichever is not applicable

File ref. no.: JSM/AD-700/06/01/01/

<u>RINGKASAN PENYEMAKAN</u> <i>Review Summary</i>		<u>REMARK (if any)</u>
6. Has laboratory participated in Interlaboratory Comparison (ILC) or PT program or other comparisons conducted by them? Are the results satisfactory, and if not have they taken appropriate action?	Yes / No*	
7. Has the whole assessment process been conducted in a way that ensures impartiality, independence, no conflict of interest and technical integrity? <i>(Please check and ask questions on the composition of members of assessment team against the scope of accreditation)</i> <ul style="list-style-type: none"> • Selection of assessors and lead assessor in accordance to PHLAS manual • Files of individual assessors and their records • Signed letters of undertaking confidentiality /STANDARDS MALAYSIA's assessors' code of ethics • Agreement to or opportunity to appeal against use of assessors 	Yes / No*	
8. Is a verification visit to the laboratory necessary? (Any doubt on 1 - 6 above) <ul style="list-style-type: none"> • To weigh all circumstances based on clearance of NCRs and the statement of satisfactory / non-satisfactory discharge of NCRs by Lead Assessor / Assessor / STANDARDS MALAYSIA project officer 	Yes / No*	
9. Recommendation for Accreditation	Yes / Yes with conditions / No*	Comment:

* Delete whichever is not applicable

File ref. no.: JSM/AD-700/06/01/01/

Name:

PANEL CHAIRPERSON

Signature

Date

Name:

MEMBER

Signature

Date

Name:

MEMBER

Signature

Date

Name:

MEMBER

Signature

Date

Note: Minimum 3 panel members of PANEL

MEETING NO. 1/2020 (Issue x, date/month/year)

**PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME
EVALUATION PANEL**

DATE :
TIME :
VENUE :

PART 1

Attendance list & Undertaking of confidentiality, impartiality and declaration of no conflict of interest

I confirm that there are no commercial (have not offered consultancy / internal audit to the laboratory(ies) within 2 years and not involved as an assessment team for the assessment report table in this meeting), financial or other pressures or conflict of interest that prevents me from performing the work of the PHLAS Evaluation Panel.

I hereby declare that I have complied with Standards Malaysia policies and I agreed to accept this work:

NO	NAME	SIGNATURE
1.		
2.		
3.		
4.		

PART 2

NO	NAME OF LABORATORY	DATE OF ASSESSMENT	LEAD ASSESSOR
1.			
2.			
3.			
4.			

NO	NAME OF LABORATORY	FEEDBACK TO LABORATORY
5.		
6.		
7.		
8.		

MEMO FOR APPROVAL

From : Director of Accreditation
To : Director General, Standards Malaysia
File : JSM/AD-700/06/01/01/
Copy : JSM/AD-700/06/01/01/
Date : date month year

Dear Sir,

APPROVAL FOR GRANTING / CONTINUITY OF PHLAS ACCREDITATION

With reference to the application for PHLAS accreditation / to the continuity of PHLAS accreditation certificate, a compliance/surveillance assessment was conducted on this particular laboratory by a group of assessors on dd-mm-yyyy.

The assessment report was analysed and found to be complete and in order. Based on this report, the PHLAS Evaluation Panel which sat on dd-mm-yyyy has reached an agreement that the laboratory has met all MS 2702 and PHLAS requirements. The PHLAS Evaluation Panel has given its recommendation for accreditation.

Hence, this granting/continuity for accreditation is for your approval.

<u>Laboratory</u>	<u>Certificate No.</u>	<u>Field(s)</u>
«Name_of_lab»	PHLAS	
«Address_1»		
«Address_2»		
«Address_3»	Attached PHLAS-P005-2 (PHLAS Evaluation Panel Report)	
«Address_4»		
	Officer in charge:	

Thank you.

Yours sincerely,

(WAN RUKIMAN BIN WAN MAMAT)

*** Granting for accreditation is hereby approved / not approved.**

(SHAHARUL SADRI BIN ALWI)
Director General
Department of Standards Malaysia

Date:

* Delete where necessary

File ref. no.: JSM/AD-700/06/01/01/
Date: date month year

PHLAS-P007
Issue 1, 4 Jan 2021

«Name_of_Lab»
«Address_1»
«Address_2»
(Attn:)

Dear Sir/Madam,

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM) - LETTER OF GRANTING/CONTINUATION ACCREDITATION

Certificate no.: PHLAS 000, issue date: date month year

We are pleased to inform you that your application for accreditation of your laboratory has been approved by the Department of Standards Malaysia (Standards Malaysia).

>> With reference to the continuity of PHLAS accreditation certificate, a surveillance assessment was conducted on your laboratory on day-month-year. The assessment report was analysed and found to be complete and in order. <<

>> We wish to draw your attention that the accreditation granted/approve by the Director General of Standards Malaysia is subject to your laboratory's continued compliance with all MS 2702 and PHLAS requirements. <<

Please find enclosed the original copy of the certificate of accreditation for your attention and retention. Kindly acknowledge the receipt of the certificate using the receipt note as below and return it to Standards Malaysia for our further action. The scope of accreditation can be downloaded from www.jsm.gov.my/cab-directories.

>> You may refer to the schedule below for better view and understanding of the assessment schedule. However, Standards Malaysia may change any assessment interval schedule depending on the performance of the laboratory, at our discretion. <<

Surveillance Assessment (I)	Surveillance Assessment (II)	Surveillance Assessment (III)	Surveillance Assessment (IV)
8 November 2021	8 November 2022	8 November 2024	8 November 2026

We would like to congratulate and thank you for your participation and interest in obtaining PHLAS Accreditation.

Thank you.

Yours faithfully,

(WAN RUKIMAN WAN MAMAT)
Accreditation Division
for the Director General
Department of Standards Malaysia

.....
(RECEIPT NOTE)

I confirmed that I have received the certificate of accreditation as above.

Signature:

Date:

Name:

Laboratory's stamp:



STANDARDS
MALAYSIA

**PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME (PHLAS)
DEPARTMENT OF STANDARDS MALAYSIA**

ASSESSMENT REPORT

LABORATORY

ADDRESS:

FILE NO: JSM/AD-700/06/01/01/

DATE OF ASSESSMENT: date month year

HEAD OF LABORATORY

TEAM LEADER:

TECHNICAL ASSESSOR:

Classification used in this report:

Obs For Compliance assessment, it is recommendation or suggestion for improvement.

For Surveillance Assessment, it is recommendation or a reminder for follow-up/review at next assessment.

Minor For Compliance Assessment, the applicant shall submit the evidence of corrective action within 3 months from the last date of assessment. In case if the PHL fails to take satisfactory actions within the specified time, Standards Malaysia may consider verification assessment or remove from the scheme.

For Surveillance Assessment, corrective action and root cause analysis of the nonconformities shall be submitted to Standards Malaysia and closed out satisfactorily within three (3) months from the last date of assessment or Standards Malaysia may initiate suspension of the laboratory's accreditation.

Major For Assessment, the applicant shall submit the evidence of corrective action within one (1) month from the last date of assessment.

For Surveillance Assessment, the laboratory would be given an opportunity to make appropriate measures within a specified time frame of one (1) month, to resolve the issues. If corrective action is not submitted within the time frame, the team leader will make recommendation to Standards Malaysia whether part or entire part of PHLAS scope of accreditation suspend and/or remove from the scheme.

SCOPE OF ASSESSMENT:

The laboratory was assessed for compliance with the requirements MS 2702: Primary healthcare laboratories - Requirements for quality and competence; and PHLAS requirements.

PREVIOUS ASSESSMENT: <<Compliance / Surveillance / Extra-ordinary Assessment>>
Assessment of the laboratory was conducted on xx MM YY. Findings and evidence of corrective actions were reviewed and accepted.

FIELD OF TESTING:

Chemical pathology
Haematology
Medical Microbiology

SUMMARY:

Generally the quality system implemented in laboratory found to be compliance with the requirements MS 2702: Primary healthcare laboratories- Requirements for quality and competence and PHLAS requirements except for findings raised in this inspection report.

Recommendation for granting accreditation status will be made subject to action taken being satisfactorily accepted.

CONCLUSION (to be completed by Team Leader)		
Summary of PHLAS non conformity : Major <input type="checkbox"/> Minor <input type="checkbox"/> Observation <input type="checkbox"/>		
Proposal by Assessment Team		
The assessment team agree to propose:		
a. Granting of accreditation with or without changes in scope b. Continuation of accreditation with or without changes in scope c. Suspension fully / partially the scope accreditation d. Others (to specify):	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
If granting / continuation not possible, please explain:		
Name: _____ (Team Leader)	Signature: _____	
	Date: _____	
Acknowledgement by laboratory:		
Name: _____	Signature: _____	Date: _____

* Delete where necessary

Reviewed by PHLAS Manager:

Result of review: *Satisfactory / Unsatisfactory

Comments:

Name:

Signature:

Date:

Authorised by Director of Accreditation

***Approved / Not Approved**

Comments:

Name:

Signature:

Date:

Authorised by Director of Accreditation

***Approved / Not Approved**

Comments:

Name:

Signature:

Date:

Schedule

Issue date: XX XX XXXX
Valid until: XX XX XXXX



PHLAS NO:

PHLAS-P009
Issue 1, 4 Jan 2021
Page: 1 of 1

LABORATORY LOCATION:



LABORATORY NAME
COMPANY NAME
FULL ADDRESS
MALAYSIA

FIELD(S) OF TESTING:

FIELD 1
FIELD 2
FIELD 3

The standard used for assessment of this laboratory is MS 2702:2020 Primary Healthcare Laboratories: Requirements For Quality And Competence

A medical laboratory's fulfillment of the requirements of MS 2702:2020 means the laboratory meets both the technical competence requirements and the management system requirements necessary for it to consistently deliver technically valid test results.

SCOPE OF MEDICAL TESTING: FIELD 1

Specimen Tested	Type of Test/ Properties Measured/	Test Methods, Specifications/ Equipment/Techniques Used

Key Personnel:

	Name	Position/Bidang
1.		
2.		

Scan this QR Code or visit www.ism.gov.my/cab-directories for the current scope of accreditation



Certificate of Primary Healthcare Laboratory Accreditation Scheme

No: PHLAS 00X

Dates of Assessment: date month year

NAME & ADDRESS OF LABORATORY

Field of medical testing :

The Director General of Department of Standards Malaysia hereby, endorses the Primary Healthcare Laboratory has been assessed and found to be operating in compliance to the MS 2702 and PHLAS. The assessment will be conducted at regular basis with respect of the scope of accreditation as described in the schedule.

(SHAHARUL SADRI BIN ALWI)
Director General
Department of Standards Malaysia

Date of issue: date month year

DEPARTMENT OF STANDARDS MALAYSIA (STANDARDS MALAYSIA)
PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME (PHLAS)

ASSESSOR'S NOTES

- Note: 1. Original to be handed to STANDARDS MALAYSIA after the assessment.
2. Photocopy may be kept by assessor for purpose of report writing.

Name of laboratory: File ref. no.: JSM/AD-700/06/01/01/ PHLAS no.:	Preliminary / Compliance / Surveillance / Extra ordinary of scope * Others () * - Delete as appropriate Date: Page: of
Laboratory representative:	Name of assessor:

REFERENCE	OBSERVATIONS	REMARK

* - delete as appropriate

DEPARTMENT OF STANDARDS MALAYSIA (STANDARDS MALAYSIA)
PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME (PHLAS)

ASSESSOR'S NOTES

- Note:**
1. Original to be handed to STANDARDS MALAYSIA after the assessment.
 2. Photocopy may be kept by assessor for purpose of report writing.

Name of laboratory: File ref. no.: JSM/AD-700/06/01/01/ PHLAS no.:	Preliminary / Compliance / Surveillance / Extra ordinary of scope * Others () * - Delete as appropriate Date: Page: of
Laboratory representative:	Name of assessor:

REFERENCE	OBSERVATIONS	REMARK

* - delete as appropriate



UNDERTAKING OF CONFIDENTIALITY

DEPARTMENT OF STANDARDS MALAYSIA

This undertaking is to safeguard confidentiality of any information at all levels obtained in the course of accreditation activities under Primary Healthcare Laboratory Accreditation Scheme (PHLAS).

Hereby, I (name)..... [NRIC:]
declare that;

- (i) I will not disclose any information gained during the execution of my duties to any person or organisation;
- (ii) I am fully aware of the ownership and confidentiality requirement for the protection intellectual property right;
- (iii) I have no financial or other interest in the laboratories assessed, the study audited or the firm sponsoring such study; and
- (iv) I have completed this undertaking prior to taking part in any preparation for or actual PHLAS accreditation activity or to have access to any document of the PHLAS.

Signature:

Date:.....



DEPARTMENT OF STANDARDS MALAYSIA

CODE OF ETHICS FOR ASSESSORS

In the context of their inspection activities under PHLAS, the assessor undertake to comply with the rules below, which concern the actual activity of assessment as well as the assessors' attitude to the laboratories assessment, third parties and the Department of Standards Malaysia (Standards Malaysia). They must:

- a) present the facts objectively, honestly, equitably and accurately to all the parties concerned.
- b) constantly maintain an attitude that welcomes dialogue, avoid arbitrary or authoritarian behaviour and keep their language courteous.
- c) inform Standards Malaysia of any relation that may exist or have existed in the past two years with the organisation to be assessed and which might cause doubt concerning the independence of their judgment.
- d) neither accept, nor authorise any member of the assessment team under their responsibility to accept for themselves or their entourage any payment, gift, commission or other advantage, even if it is non-pecuniary, from the laboratories assessment, their representative or any other party involved or otherwise, to avoid casting doubt on their independence during the assessment.
- e) take every precaution to avoid informing third parties, whether directly or indirectly as a result of their actions or those of the people under their responsibility, of documents or information which may come to their knowledge in the context of their assessment activities without written authorisation from the parties concerned.
- f) share their experience with the members of the assessment team with whom they may be called upon to work.
- g) behave in a manner that does not damage the reputation or interests of the client of the Standards Malaysia the organisation assessed.
- h) act to preserve a positive image of the Standards Malaysia and the quality of assessment.
- i) cooperate with any requests for information or formal examination procedure if violation of this code is alleged.
- j) not take part in any assessment which exceeds PHLAS purposes /their professional abilities.
- k) make every effort to improve their own expertise and the effectiveness and quality of their services.
- l) keep a record of the assessment performed and the training courses attended and to transmit copies of these to their files at Standards Malaysia.
- m) know the rules of the PHLAS policies and contribute to maintaining the reputation of the PHLAS accreditation activities.
- n) accept that the Standards Malaysia's staff or authorized representative observes their performance during an assessment carried out after being informed by Standards Malaysia and with the agreement of the laboratories concerned.

I hereby understand and undertake to comply with the above code of ethics:

Name: Signature:

Date:

To be filed by Standards Malaysia:

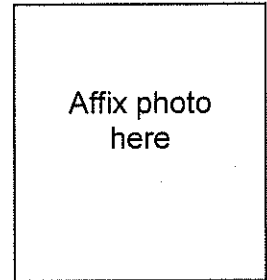


CONFIDENTIAL

STANDARDS
MALAYSIA

PHLAS- R004
Issue 1, 4 Jan 2021

For Standards Malaysia's Use Only. File Ref No: JSM/AD-700/06/01/01/



PARTICULARS OF ASSESSOR

1. PERSONAL PARTICULARS

Name: Title:
(Use Capital Letter and Underline Surname) (Mr/Miss/Dr/Prof. etc.)

Identity Card No: Sex: Male/ Female

Address (Office):.....
.....
.....

E-mail:

Tel: Fax:

H/p:

Address for Correspondence (If different from above):
.....
.....

Tel (Home):

2. ACADEMIC OR PROFESSIONAL QUALIFICATIONS

Qualification	Principal Subject	Institution Attended	Date of Award	Cert Attached (✓)

(Please provide photocopy of certificate(s))

3. PROFESSIONAL EXPERIENCE

(A) Present job* from Date:

Position/Post	Nature of Work

(B) Previous job(s)*

Position /Post	Year	Nature of Work

4. TRAINING COURSES ATTENDED*

(Relevant to PHLAS and/or Quality Management Systems)

Year Attended	Name of Training Course & Duration	Training Course Organised By	Cert Attached (√)

(Please Provide Photocopy of Relevant Certificate/s)

5. SPECIALISED TRAINING*
(IN SPECIFIC EQUIPMENT AND/OR TECHNIQUE)

Year Attended	Equipment/ Technique

(Please provide evidence of such specialised training where necessary)

NOTE* IF SPACE PROVIDED IS INSUFFICIENT, PLEASE ATTACH EXTRA SHEET IF NECESSARY (IF HARD COPY USE)

6. I HEREBY CONFIRM / RECONFIRM MY EXPERTISE IN THE FOLLOWING NON-CLINICAL STUDIES/ TESTING:

(Please tick the appropriate)

Management System	
NON-CLINICAL STUDIES/ TESTING CATEGORIES	FIELD OF EXPERTISE (<input checked="" type="checkbox"/>)
1. Physical-Chemical Testing	
2. Toxicity	
3. Mutagenicity	
4. Environmental Toxicity	
5. Bioaccumulation; Behaviour In Water, Soil, Air	
6. Residue	
7. Effect on Mesocosms and Natural Ecosystems	
8. Analytical and Clinical Chemistry	
9. Worker Exposure	
Others:	

Note*: Each field of competence declared must be supported by objective evidence (e.g. certificate) or information of working experience, training etc.

7. STATEMENT OF UNDERTAKING:

I hereby undertake to:

- (a) undergo training regardless of my background, experience and qualification by attending PHLAS training course organised or recognised by the Department of Standards Malaysia (Standards Malaysia);
- (b) make the necessary arrangements with my office of employment to be available for undergoing training or performing inspections;
- (c) perform inspections when called upon to do so;
- (d) sign a letter of confidentiality to treat in confidence all discussions, information and observations pertaining to inspection of laboratories;
- (e) familiarise myself with OECD Guidelines and Standards Malaysia manual for PHLAS Compliance Monitoring Program for the conduct of inspection and all other relevant documents.
- (f) operate a standard of inspection so as to upgrade and maintain my acceptability as a inspector.

8. Curricular Vitae and Qualification Certificate

I attach herewith my Curricular Vitae, details of academic/ professional/ technical qualifications, training, working experience, field of expertise and relevant copy of certificate for your further action.

Name:.....

Signature:..... Date:.....

Please return to:

<p>DIRECTOR GENERAL</p> <p>Department of Standards Malaysia Aras 4, 5, 6 & 7, Tower 2 Menara Cyber Axis Jalan Impact, Cyber 6 63000 Cyberjaya</p> <p>Tel : +(603) 8008 2900 Email : phlas@jsm.gov.my</p>



JABATAN STANDARD MALAYSIA
Kementerian Perdagangan Antarabangsa dan Industri
Tingkat 4, 5, 6 & 7, Tower 2, Menara Cyber Axis
Jalan Impact, Cyber 6, 63000 Cyberjaya, Selangor

DEPARTMENT OF STANDARDS MALAYSIA
Ministry of International Trade and Industry
Level 4, 5, 6 & 7, Tower 2, Menara Cyber Axis
Jalan Impact, Cyber 6, 63000 Cyberjaya, Selangor

STANDARDS
MALAYSIA

Tel: +603-8008 2900
Fax: +603-8008 2901
E-mail: central@jst.gov.my

PHLAS-R005
Issue 1, 4 Jan 2021

File ref. no.: JSM/AD-700/06/01/01/
Date: date month year

«Assessor name»
«Address_1»
«Address_2»
«Address_3»
«Address_4»

Dear Sir/Madam,

APPOINTMENT AS TRAINEE TECHNICAL ASSESSOR (TTA) / TECHNICAL ASSESSOR (TA) / TRAINEE LEAD ASSESSOR (TLA) / LEAD ASSESSOR (LA) UNDER PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME (PHLAS)

We are pleased to inform you that you have been appointed as a Trainee Technical Assessor / Technical Assessor / Trainee Lead Assessor / Lead Assessor under PHLAS.

In order to ensure a systematic and consistent approach in the conduct of assessment you are required to refer to PHLAS for Manual which can be accessed from our website www.jst.gov.my

As a confirmation that you have received this letter and agree to the appointment, kindly reply to Standards Malaysia using the attached form. We would like to thank you for your interest and participation in PHLAS.

Thank you.

Yours faithfully,

(WAN RUKIMAN BIN WAN MAMAT)
Director of Accreditation
for the Director General
Department of Standards Malaysia

Receipt note appointment of TTA

To: Director General
Department of Standards Malaysia
Level 4, 5, 6 & 7, Tower 2
Menara Cyber Axis
Jalan Impact, Cyber 6
63000 Cyberjaya
(Attn: Pn. Rohasmizah binti Ismail)

Fax No: 03 – 8008 2901
Tel No: 03 – 8008 2819
Email: rohasmizah@jstn.gov.my

APPOINTMENT AS A TRAINEE TECHNICAL ASSESSOR (TTA) / TECHNICAL ASSESSOR (TA) / TRAINEE LEAD ASSESSOR (TLA) / LEAD ASSESSOR (LA) UNDER PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME (PHLAS)

Dear Sir/Madam,

I hereby **accept / do not accept** * appointment as the Trainee Technical Assessor / Technical Assessor and confirm that I have received the appointment letter dated <<date month year>> regarding the above.

I also agree to provide contribution to PHLAS and abide by the conditions as stated in "Code of ethics for assessors" and "Undertaking of maintaining confidentiality, impartiality and declaration of no conflict of interest".

Signature :

Name :

Date :

**PRIMARY HEALTHCARE LABORATORY ACCREDITATION SCHEME COMPLIANCE
PROGRAMME
DEPARTMENT OF STANDARDS MALAYSIA**

***LEAD ASSESSOR/ TECHNICAL ASSESSOR / TRAINEE ASSESSOR EVALUATION REPORT**

Name of evaluated assessor : _____	
Date of assessor : _____	Type of assessor : _____
Role in the assessor : _____	
Name of laboratories: _____	

Classification of Evaluation:

A = Acceptable, B = Needs Improvement, NA = Not applicable

EVALUATION

Criteria	A	B	NA	Comment
1. Effective planning, preparation and briefing				
2. Punctuality <ul style="list-style-type: none"> • the assessor was on time 				
3. Conduct of opening meeting:				
<ul style="list-style-type: none"> • introduction 				
<ul style="list-style-type: none"> • scope and objectives 				
<ul style="list-style-type: none"> • reconfirm the standard 				
<ul style="list-style-type: none"> • assures the maintenance & undertaking of confidentiality 				
<ul style="list-style-type: none"> • clarifies the assessment plan 				
<ul style="list-style-type: none"> • provides the opportunity for everyone to ask questions 				
<ul style="list-style-type: none"> • responds effectively to questions and remarks 				
4. Audit skills:				
<ul style="list-style-type: none"> • remained in scope 				
<ul style="list-style-type: none"> • objective 				
<ul style="list-style-type: none"> • conclusions based on objective evidence 				
<ul style="list-style-type: none"> • alert 				
<ul style="list-style-type: none"> • act ethically 				
<ul style="list-style-type: none"> • good time management 				
<ul style="list-style-type: none"> • ability to understand operation in a broad perceptive 				
5. Conduct of closing meeting:				
<ul style="list-style-type: none"> • inspection findings clearly presented and explained 				
<ul style="list-style-type: none"> • category and significant of non-compliance explained 				
<ul style="list-style-type: none"> • confirmation of the scope of studies 				

Criteria	A	B	NA	Comment
6. Presentation of assessment findings <ul style="list-style-type: none"> assessment findings and non-compliance raised clearly presented and explained 				
7. Knowledge of assessment criteria / requirements (MS 2702 & PHLAS Requirement)				
8. Compliance with assessment procedure (PHLAS Manual & MS 2702)				
9. Appearance				
10. Oral communication skills				
11. Clear and concise reporting				
12. Relationship with team				
13. Relationship with customer				
14. Personal attributes:				
<ul style="list-style-type: none"> ethical, versatile 				
<ul style="list-style-type: none"> open minded, mature 				
<ul style="list-style-type: none"> diplomatic, observant 				
<ul style="list-style-type: none"> decisive, self-reliant 				

Report by evaluator

Result of evaluation: Satisfactory / Unsatisfactory *

Summary comments:

Name: _____ Signature: _____ Date: _____

Acknowledgement by evaluatee

Name : _____ Signature: _____ Date: _____
(Lead Assessment/Technical Assessor/Trainee Assessor*)

Reviewed by PHLAS Manager

Result of review: Satisfactory / Unsatisfactory *

Comments:

Name: _____ Signature: _____ Date: _____

Approval by Director of Accreditation

Approved / Not Approved*

Comments:

Signature: _____ Date: _____

Note: * Delete whichever not applicable

CHECKLIST FOR APPOINTMENT OF PHLAS ASSESSOR

1. Name of candidate: _____
2. Organisation: Department of Standards Malaysia
3. Summary of compliance to Section 5.6 of PHLAS Manual
4. File ref. no.: JSM/AD-700/06/01/01/

SECTION A: PHLAS Trainee Assessor

No	Criteria/Requirements	Compliance	
		Yes / No	Remark
1.	Have tertiary education in a recognized academic institution.		
2.	Have working experience in field of science relevant to area of expertise under the PHLAS.		

SECTION B: Competence/ expertise in the following scope(s):

Categories of Test Item / Products:	Area of expertise:

Recommendation

Based on fulfillment of Section 5.6 of PHLAS Manual, it is recommended that above personnel to be approved as PHLAS Assessor under PHLAS.

Prepared by:

PHLAS Officer
Name:

Signature:

Date:

Recommendation by:

PHLAS Manager
Name:

Signature:

Date:

Approval by Director of Accreditation

Approved / not approved*

Signature:

Date:

CHECKLIST FOR PHLAS ASSESSOR APPROVAL

1. Name of candidate: _____
2. Organisation: Department of Standards Malaysia
3. Summary of compliance to Section 5.6 of PHLAS Manual
4. File ref. no.: JSM/AD-700/06/01/01/

PHLAS Assessor / PHLAS Lead Assessor

No	Criteria/Requirements	Compliance	
		Yes / No	Remark
1.	Have undergo a PHLAS Assessor and MS 2702 training programme: -		
	a) Attending PHLAS course or workshop organized by or Standards Malaysia / MS 2702		
	b) Completing 40 hours of observation or PHLAS Assessment.		
2.	Performance in conducting supervised assessment and preparing assessment report has evaluated by assigned assessor / Lead Assessor.		
3.	Participate in seminars, courses, workshops, attachments or observations related with PHLAS for continuous improvement.		
4.	Have an in-depth knowledge in the PHLAS requirement.		
5.	Have managerial and leadership skills for PHLAS Assessment		
6.	Performance as Trainee Technical Assessor (TTA) / Technical Assessor (TA) / Trainee Lead Assessor (TLA) / Lead Assessor (LA) evaluated by PHLAS Manager or Director of Accreditation.		

Recommendation

Based on fulfillment of Section 5.6 of PHLAS, it is recommended that above personnel to be approved as PHLAS Assessor / PHLAS Lead Assessor under PHLAS.

Prepared by: _____ **Recommendation by:** _____

PHLAS Officer
Name:

PHLAS Manager
Name:

Signature:

Signature:

Date:

Date:

Approval by Director of Accreditation

Approved / not approved*

Signature:

Date:

C O N F I D E N T I A L

ASSESSOR APPROVAL

Category: *Trainee Technical Assessor/Technical Assessor/ Lead Assessor

1. Name of candidate:

2. Organisation:

3. Summary of compliance to PHLAS Manual

4. Ref file: JSM/AD-700/06/01/01/

Cat.	No	Criteria/Requirements	Compliance	
			Yes / No	Remark
TTA	1.	Qualified in a relevant scientific or technological discipline by either a degree or equivalent academic/professional qualification or diploma or equivalence qualification.		
	2.	Technically competent in specific field(s) of medical testing. Minimum of five (5) years (for degree holder) and ten (10) years (for diploma holder) full time working experience involving calibration / testing or inspection.		
	3.	Have initial training provided/attended (briefing etc.)		
TA	1.	Have been appointed as Trainee Technical Assessor (TTA)		
	2.	Have the following knowledge & skills: i) Standards Malaysia accreditation criteria, regulations, MS 2702 and PHLAS requirements, procedures and processes; ii) assessment principles, practices and techniques; iii) general management system principles and tools; iv) accreditation and accreditation scheme requirements and relevant guidance and application documents; v) conformity scheme requirements, other procedures and methods used by the CAB; vi) risk based assessment principles; vii) practices and processes of the CAB business environment; viii) general regulatory requirements related to the conformity assessment activities. ix) communication skills appropriate to all levels within CAB; x) note-taking, report writing, interviewing and assessment management skills		
	3.	Ability to function effectively in conducting technical assessment as member of an assessment team lead by a Lead Assessor-		
	4.	Ability to present assessment findings / summary in writing in an objective way and to write formal report on technical assessment performed		
	5.	Capability to communicate, both in writing and verbally		
	6.	Participated in at least one (1) observation of assessment and one (1) supervised assessment under supervision of Lead Assessor and evaluated by Lead Assessor / Evaluator.		
LA	1.	Have been appointed as Technical Assessor.		
	2.	Have a combination of qualifications and necessary experience to function effectively as leader / coordinator of assessment teams		
	3.	Competent in management system applicable to CAB where he / she is required to exercise judgment during an assessment with the application of quality assurance concepts		

Cat.	No	Criteria/Requirements	Compliance	
			Yes / No	Remark
	4.	Have the following knowledge and skills (PHLAS requirements and MS 2702): i) Standards Malaysia accreditation criteria, regulations, requirements, procedures and processes; ii) assessment principles, practices and techniques; iii) general management system principles and tools; iv) accreditation and accreditation scheme requirements and relevant guidance and application documents; v) conformity scheme requirements, other procedures and methods used by the CAB; vi) risk based assessment principles; vii) practices and processes of the CAB business environment; viii) general regulatory requirements related to the conformity assessment activities; ix) note-taking, report writing, interviewing, assessment management and communication skills; x) opening and closing meeting skills		
	5.	Ability to present assessment findings / summary in writing in an objective way and to write formal assessment report		
	6.	Ability to talk to CAB management in a fair but firm manner regarding matters which require the CAB management's attention		
	7.	Have satisfactorily completed: a) The MS ISO 15189 and Lead Assessors Training Course accepted by Standards Malaysia and; b) MS 2702:2020		
	8.	Completed at least five (5) assessment. Existing assessor in SAMM MT may be appointed for PHLAS and exempted from above requirements.		
	9.	Satisfactorily conducted one (1) assessment of compliance / surveillance as Lead Assessor under guidance/supervision and evaluated by the Evaluator / Scheme Manager.		

TTA-Trainee Technical Assessor TA-Technical Assessor LA-Lead Assessor

Competence/ expertise in the following field(s): borang permohonan

NO	FIELD	TICK ()
1.	QUALITY MANAGEMENT SYSTEM	
2.	CHEMICAL PATHOLOGY	
3.	HAEMATOLOGY	
4.	MEDICAL MICROBIOLOGY	

Recommendation:

Based on fulfillment of PHLAS Manual, it is recommended that above candidate to be approved as *Trainee Technical Assessor / Technical Assessor / Lead Assessor under PHLAS

PHLAS OFFICER

Name:

Signature:

Date:

PHLAS MANAGER

Name:

Signature:

Date:

Approval by Director of Accreditation

Approved / not approved*

Signature:

* Please delete whichever is not applicable

Date:

ANALYSIS OF RELATED BODY RELATIONSHIP WITH STANDARDS MALAYSIA

Note:

Analysis on related body shall be completed if applicant comes from Government Department / Agency / Statutory Body etc.

Background of Applicant

- a) Name of applicant:
- b) Status of applicant : Government Department / Agency / Statutory Body
- c) Parent organisation :
- d) Applicant's activity :

No	Analysis of related body relationship with Standards Malaysia	Remark Yes / No
1	Having different top management for:	
	a) development of policies	
	b) supervision of implementation of policies and procedures	
	c) supervision of finances	
	d) decisions on accreditation	
	e) contractual arrangement	
	f) delegation of authority to committees or individuals	
2	Personnel different from those involved in the decision-making processes of accreditation	
3	Have no influence on the outcome of an assessment for accreditation	
4	Different name, logos and symbols	

Prepared by

Name:

Signature:

Review & confirmation by PHLAS Manager

- 1) I hereby confirmed that this applicant complies / does not comply * with the requirement on the relationship of related body with Standards Malaysia,
- 2) This application is accepted / not acceptable *
(Note: advise applicant, application is not acceptable)

Signature:

Date:

* Delete whichever not applicable