



Reminder

We are now promoting the organisation as

STANDARDS
MALAYSIA

since 20 November 2006

The acronym **DSM** is **obsolete**.

We are **not using** the acronym **SM**.

However the legal entity is still
Department of Standards Malaysia

or

Jabatan Standard Malaysia

SAMM updates

Contents:

1. International Accreditation Day
2. SAMM Statistics
3. New Field
4. New Documents
5. Technical Working Group (TWG)
6. Assessment in December
7. APLAC Peer Evaluation 2010
8. PT Programme 2010
9. Updated Information: ILAC MRA Mark
10. Reminder
11. Assessment Fees
12. Upcoming Event
13. Staff Strength of STANDARDS MALAYSIA

3

World Accreditation Day

**Global
Acceptance**
World Accreditation Day
9 June 2010



10th Anniversary ILAC MRA | 12th Anniversary IAF MLA

June 9th 2010 will mark World Accreditation Day

9 June is the **World Accreditation Day**, a global initiative jointly established by the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) to raise awareness of the importance of accreditation-related activities.

4

World Accreditation Day

Theme: **Global Acceptance**

Internationally-agreed standards and accreditation play an important role in the support of competitive markets and cross border trade. This is increasingly important as supply chains are ever extending to new overseas markets as businesses seek to lower costs or satisfy contract terms, whilst maintaining a level of confidence that products are technically compatible, to specification, and safe.

Global acceptance of accredited certificates is a central pillar of accreditation as the harmonization of assessment requirements and processes at a worldwide level, provides businesses and regulators with confidence that products entering the market conform to specification, meet national legal and regulatory requirements, and will therefore serve to protect public interests in general.

5

World Accreditation Day

Programmes by STANDARDS MALAYSIA

- 1** Forum with SMM laboratories
19 July 2010
Putrajaya
- 2** Forum with certification bodies
26 July 2010
Putrajaya

6

SAMM Statistics (as of 30 June 2010)

Accredited:

Active:

Testing Laboratories	:	301
Calibration Laboratories	:	51
Calibration & Testing Laboratories	:	13
Medical Laboratories	:	15
TOTAL	:	380

Voluntary withdrawal:

Testing Laboratories	:	62
Calibration Laboratories	:	24
Calibration & Testing Laboratory	:	1
TOTAL	:	87

Inoperative/suspension/termination:

Testing Laboratories	:	6
Calibration Laboratory	:	3
Medical Testing	:	2
TOTAL	:	11

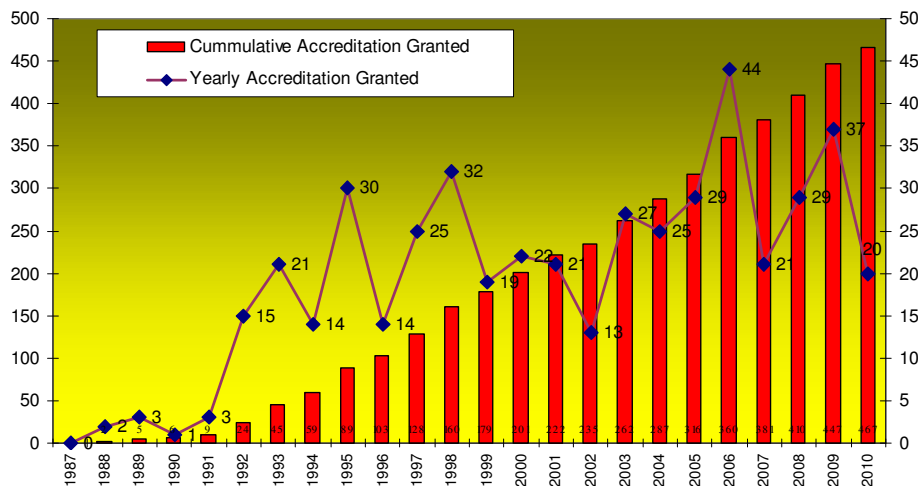
Number of SAMM Certificates issued : 467 (since 1987)

Applicant:

Testing Laboratories	:	52
Calibration Laboratories	:	13
Medical Laboratories	:	18
TOTAL	:	83

7

SAMM Statistics (as of 30 June 2010)



8

New Fields

TESTING

1. Accreditation of Information Technology Security Evaluation and Testing: Common Criteria

- To increase Malaysian competitiveness in quality assurance of information security using the Common Criteria standard, and to build consumer confidence in Malaysian information security products and systems
- Launched in December 2009
- CyberSecurity Malaysia accredited on 15 March 2010

9

New Fields

FORENSIC SCIENCE TESTING

2. Accreditation of Analysis of Dangerous Drugs And Other Controlled Substances for Forensic Science Testing Laboratories

3. Accreditation of Trace Evidence for Forensic Science Testing Laboratories (will be available in STANDARDS MALAYSIA website in Q3)

Documents for new fields can be downloaded from www.standardsmalaysia.gov.my > accreditation > Skim Akreditasi Makmal Malaysia (SAMM) > SAMM Publication

10

New documents

1. **STR 1.11** – Specific Technical Requirements for Accreditation of Analysis of Dangerous Drugs And Other Controlled Substances for Forensic Science Testing Laboratories
2. **STR 1.12** – Specific Technical Requirements for Accreditation of Trace Evidence for Forensic Science Testing Laboratories (pending for approval by the Minister, will be available in Q3 of the year)
3. **SC 1.3** – Specific Criteria for Accreditation in the Field of Microbiology (pending for approval by the Minister, will be available in Q3 of the year)
4. **SC 1.4** – Specific Criteria for Accreditation in the Field of Electrical Testing (pending for approval by the Minister, will be available in Q3 of the year)

These documents can be downloaded from www.standardsmalaysia.gov.my > accreditation > Skim Akreditasi Makmal Malaysia (SAMM) > SAMM Publication

11

Technical Working Groups

TWG	DOCUMENT	STATUS
22	SG 3 – Guidelines for determination of calibration intervals of measuring instruments	No update
27	SC for Microbiology Testing	Final draft document is ready to be tabled to MyNAC meeting for approval by the Minister
32	SP 1 – Terms and Conditions Governing The Laboratory Accreditation Scheme of Malaysia	10 th meeting on 21 May 2010. Final draft is still being polished.
33	SC for Electrical Testing	Final document is pending for approval by the Minister
34	SP 4 – Policy on Proficiency Testing Requirements for SAMM Laboratories	2 nd meeting

12

Technical Working Groups

TWG	DOCUMENT	STATUS
35	STR for Trace Evidence for Forensic Science Testing (FST)	Plan: Announcement in website by August, in progress to finalise and submit for Ministry approval by this month
36	STR for Toxicology for FST	On hold
37	STR for Firearms for FST	On hold
38	SC for Mechanical Testing	Comments received
40	SC for Calibration	2 nd meeting in Q3

13

Technical Working Groups

TWG	DOCUMENT	STATUS
41	Review of SC 2 document (Medical Testing)	2 nd meeting in August
42	Review of STR 2.3 document (Chemical Pathology)	1 st meeting in August
43	Review of STR 2.4 document (Haematology)	1 st meeting in August
44	Review of STR 2.1	1 st meeting in August

14

Assessment in December

As far as possible, assessments will not be scheduled in December.

Any scheduled assessment (forward plan schedule) which falls in December will be rescheduled in November / January the following year.

15

APLAC Peer Evaluation 2010

STANDARDS MALAYSIA has been re-evaluated by APLAC peer evaluators from 21 - 25 June 2010

Evaluation team was led by Mr. Isao Fujita (IA JAPAN, Japan)

Team members are;

- Ms. Anne Hofstra (IANZ, New Zealand)
- Mr. Alok Jain (NABL, India)
- Ms. Yi Fang PAN (TAF, Chinese Taipei)

16

APLAC Peer Evaluation 2010

The evaluation was conducted in accordance with, and against the requirements specified in APLAC MR 001 (Procedures for Establishing and Maintaining Mutual Recognition Agreements Between Laboratory Accreditation Bodies) & the requirements of ISO/IEC 17011 (Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies)

- (a) STANDARDS MALAYSIA operates its testing laboratory, calibration laboratory and medical laboratory (ISO 15189) accreditation programmes in accordance with the requirements of ISO/IEC 17011 and ILAC/IAF A5
- (b) Laboratories accredited by STANDARDS MALAYSIA have been assessed against the requirements of ISO/IEC 17025

17

APLAC Peer Evaluation 2010

- (c) Medical testing laboratories accredited by STANDARDS MALAYSIA have been assessed against the requirements of ISO 15189
- (d) STANDARDS MALAYSIA adopts and substantially implements the International Laboratory Accreditation Cooperation (ILAC) policy on traceability of measurement results (ILAC-P10), and the Malaysian national measurement system can provide satisfactory measurement support to STANDARDS MALAYSIA accredited laboratories in the basic physical units

18

APLAC Peer Evaluation 2010

9 laboratories with different stages of assessment were visited

Testing

- 1 surveillance assessment of a chemical/microbiological laboratory
- 1 extension assessment of a chemical/microbiological laboratory
- 1 surveillance assessment of a mechanical/chemical laboratory
- 1 compliance assessment of a mechanical laboratory

Medical Testing

- 1 compliance assessment
- 1 surveillance/extension assessment

Calibration

- 1 surveillance assessment of an electrical laboratory
- 1 re-assessment of a dimensional/mechanical laboratory

Testing & Calibration

- 1 re-assessment of an electrical laboratory

19

APLAC Peer Evaluation 2010

Laboratories involved in APLAC Peer Evaluation 2010

1. Ceramic Research Company (M) Sdn. Bhd., Klang
2. TekMark Sdn. Bhd., Kuala Lumpur
3. Makmal Perkhidmatan Perjangkaan, TNB, Petaling Jaya
4. ALS Technichem (M) Sdn. Bhd., Shah Alam
5. Mitutoyo (Malaysia) Sdn. Bhd., Shah Alam
6. Makmal Kesihatan Awam Kebangsaan, Sungai Buloh
7. University of Malaya Medical Centre, Kuala Lumpur
8. Applicant Lab in Shah Alam
9. Applicant Lab in Cheras

20

APLAC Findings

- All the assessments witnessed were, without exception, of a high standard in terms of their scope and depth.
- The evaluation team was impressed with the expertise of staff and assessment teams; the quality and thoroughness of assessments; knowledge of and adherence to procedures.
- No nonconformity, two concerns, and six comments were raised by the evaluation team.

21

APLAC Findings

No.	Concerns
1.	<p>Minimum PT participation requirement of STANDARDS MALAYSIA is “at least one proficiency activity relating to each major sub-area of major disciplines of a laboratory’s scope of accreditation every four years.” STANDARDS MALAYSIA does not have a documented definition of “major sub-area of major disciplines”. Laboratories and assessors were not clear on what constituted a major sub-discipline and therefore the recommended minimum of one activity relating to each major sub-discipline within four years was not always applied.</p> <p><i>[ILAC P9: 2005; 4.2]</i></p>
2.	<p>Three members are usually selected from the pool of Laboratory Accreditation Evaluation Panel (70 members) to review assessment reports and make a recommendation on accreditation to Director General of STANDARDS MALAYSIA. Some of the members are from private and governmental laboratories, and the others are from other governmental agencies, private consulting companies and retirees from governmental agencies. Although a declaration form on impartiality and confidentiality has been collected from these members, there may be potential conflict of interests and issues of confidentiality between the selected panel members and the applicant laboratory. STANDARDS MALAYSIA should establish a mechanism to avoid these issues.</p> <p><i>[ISO/IEC 17011:2004; 4.3.4&4.4]</i></p>

22

APLAC Findings

No.	Comments
1.	During the assessment process, the technical assessors select tests to be carried out by the laboratory staff and witnessed by the relevant technical assessor. While this is planned in agreement with the laboratory being assessed and is dependent on the testing planned during the course of the assessment, STANDARDS MALAYSIA <u>has no documented guidelines</u> on how this is to be managed <u>to ensure the same types of testing are not selected at each assessment.</u> It is recommended that STANDARDS MALAYSIA have such detailed procedures or guidance in order <u>to ensure that the representative number of examples is consistently</u> selected by all assessment teams.
2.	Before an on-site assessment, an assessment team is provided with the previous summary assessment report, and if any, non-conformity and observation reports. However, the summary report does not include detailed information about the previous assessment. It is recommended that more information such as tests witnessed at the previous assessment and PT performance be provided to the assessment team before the on-site assessment so that the next assessment team can prepare for assessment more effectively; e.g. planning for witnessing.

23

APLAC Findings

No.	Comments
3.	STANDARDS MALAYSIA has established the procedure to evaluate the assessor's performance on-site every 3 years. In addition, the procedure allows the evaluation of the assessors be carried out by the APLAC peer evaluators. However the responsibility for the evaluation of assessors lies with STANDARDS MALAYSIA and it is recommended that the reference to the possible APLAC evaluator's role in this process is removed from the procedures (SOP 502 section 4.3.2).
4.	Specific criteria documents are available for most testing laboratories i.e. chemical, medical etc. STANDARDS MALAYSIA had not yet published a Specific Criteria document for the Biological testing laboratories. The STANDARDS MALAYSIA staff advised this was in progress. It is recommended that this is completed in the near future.

24

APLAC Findings

No.	Comments
5.	SAMM Policy 7 (SP7), Issue 2, 28 February 2007 – “Specific Requirements on the issue of SAMM endorsed calibration certificates” requires accredited calibration laboratories to include “the appropriate statement of the confidence probability or the appropriate statement on number of standard deviation” in their calibration certificates. For convenience of their customers, it is preferable that at least the coverage factor be given in calibration certificates. STANDARDS MALAYSIA may consider reviewing this document, including changing terminologies.
6.	STANDARDS MALAYSIA has only one APLAC lead evaluator. Although he has been active in APLAC MRA activities, STANDARDS MALAYSIA may consider contributing more in this area.

25

Survey: Peranan Akreditasi dalam Meningkatkan Perniagaan Makmal

[Survey.ppt](#)

26

PT Programme 2010

PT Programme organised by STANDARDS MALAYSIA

	Programme	No. of Labs
PT 1-2	DC Voltage	13
PT 1-13	Power Sensor	4
PT 2-12	PT100	11
PT 2-13	Thermocouple	15
PT 3-2	Gauge Blocks	4
PT 3-11	Mass	12
PT 3-12	Caliper	22

27

PT Programme 2010

APLAC PT Programme organised by STANDARDS MALAYSIA

Programme	Status
APLAC PT M025 Pressure	Artefact circulation

28

PT Programme 2009-2010

International and Regional PT Programme organised by other Accreditation Bodies

Programme	Organiser	No. of SAMM Labs
Heavy Metals in Crustacean Seafood	Government Laboratory of Hong Kong	3
Fertiliser	National Accreditation Body of Indonesia	1
Food – Artificial colour and sweetener	National Accreditation Body of Indonesia	2
APLAC T070 - Determination of PBDE in ABS	Taiwan Accreditation Foundation	4
APLAC T071 - Melamine in Milk	Hong Kong Accreditation Services	1

29



ILAC MRA MARK

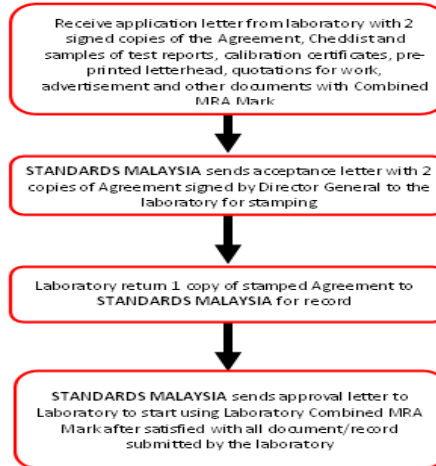
- Laboratory **shall not use** Combined ILAC MRA Mark before receiving a written approval from STANDARDS MALAYSIA.
- Application form is available in STANDARDS MALAYSIA website since August 2009
 - LA 1101-2 – Document checklist
 - Sub License Agreement (color printing/ black and white printing)
- www.standardsmalaysia.gov.my> Accreditation > Skim Akreditasi Makmal Malaysia (SAMM) > Application for Combined ILAC MRA Mark
- Applications from 60 laboratories have been approved by STANDARDS MALAYSIA

30



ILAC MRA MARK

Application Procedure for Combined ILAC MRA Mark



31

Reminder (Misuse of symbol)

Act 549 - STANDARDS OF MALAYSIA ACT 1996

Miscellaneous offences

18. (1) Any person who –

- (a) makes any statement or representation, whether in writing or otherwise, or uses any mark with reference to any commodity, process, practice or service that conveys or is likely to convey the impression that a person who is **not registered or certified to use a mark of conformity with reference** to that commodity, process, practice or service is so registered or certified or is otherwise entitled to use a mark of conformity;
- (b) makes any statement or representation, whether in writing or otherwise, or uses any mark that conveys or is likely to convey the impression that a **commodity, process, practice or service complies with a standard specification when it does not so comply;**
- (c) having been registered or certified to use a mark of conformity, **uses that mark of conformity after the revocation or during the suspension** of his registration or accreditation certificate or otherwise than in accordance with the terms and conditions of his registration or accreditation certificate;

32

Reminder (Misuse of symbol)

- (d) makes any statement or representation, whether in writing or otherwise, with reference to any commodity, process, practice or service that conveys or is likely to convey the impression that a person who is not accredited under this Act with reference to that commodity, process, practice or service is so accredited;
- (e) makes any statement or representation, whether in writing or otherwise, that conveys or is likely to convey the impression that a commodity, process, practice or service complies with the requirements of accreditation when it does not so comply; or
- (f) having been registered or accredited, uses the registration or accreditation certificate after its revocation, or during its suspension, or otherwise than in accordance with the terms and conditions of the registration or accreditation certificate,

33

Reminder (Misuse of symbol)

..... shall be guilty of an offence and shall on conviction be liable to a fine not exceeding one hundred thousand ringgit (RM100,000) and, in the case of a continuing offence, to a further fine not exceeding one thousand ringgit (RM1000) for every day on which the offence is continued.

34

Reminder (NCR submission)

- **Intended corrective action**

Laboratories are required to submit intended corrective action to STANDARDS MALAYSIA **within 10 (working) days** from the date of assessment.

- **NC category 2**

Corrective action must be submitted and **closed out satisfactorily** to STANDARDS MALAYSIA within **3 months** from the date of assessment.

Failure to comply with this policy, STANDARDS MALAYSIA may **suspend** the laboratory's entire/partial scope of accreditation. STANDARDS MALAYSIA will send reminder letter if we do not receive any corrective action after 2 months of assessment. (refer SP 10 document - SP10 – Grading of non-conformities)

Corrective action report is preferably to be submitted to STANDARDS MALAYSIA, if you are sending direct to the Lead Assessor, please copy to STANDARDS MALAYSIA

35

Reminder (Assessment)

- **Application for extension of scope**

(a) must attach **test method and CV** of proposed signatory(ies).

(b) do not submit your application at the last minute. **(at least 2 weeks before assessment, do not apply during the day of assessment)**

- **New proposed signatory(ies)**

Laboratory must inform STANDARDS MALAYSIA on any new proposed signatory(ies) before assessment. **(do not apply during the day of assessment)**

- **Resignation of approved signatory(ies) / QM / TM**

Laboratory must **notify** STANDARDS MALAYSIA of the changes e.g.: change of resident / non-resident approved signatory status

- **Rotation of Lead Assessor**

Fresh view of the laboratory system

- **Postpone assessment**

Absence of QM/TM **is not a reason** to postpone the assessment.

36

Reminder (Assessment)

Request for change of assessor

STANDARDS MALAYSIA will not entertain any request for change of assessor without valid reason(s)

Draft certificate of accreditation

Must **check carefully**

Any changes to the scope after confirmation will be charged RM100 (to amend the scope)

Inoperative / suspension status

Laboratory has to pay assessment / annual fees

37

Reminder (Assessment)

Compliance assessment / extension of scope

After submitting the corrective action, STANDARDS MALAYSIA may need time to proceed for granting accreditation. **(DO NOT EXPECT TO RECEIVE THE CERTIFICATE OF ACCREDITATION IMMEDIATELY AFTER SUBMITTING THE CORRECTIVE ACTION)**

PT organised / coordinated by STANDARDS MALAYSIA

For outlier PT result, the laboratory is required to submit corrective action report **within 1 month** from the date of letter.

38

New Assessment Fee

Will be in the new regulation

Type of fee	Current fee	Revised fee
Application fee	RM 3500 for first field, RM 200 for each subsequent field	RM 3000 for first field, RM 200 for each subsequent field
Annual renewal fee	RM 3000 for first field, RM 200 for each subsequent field	RM 2500 for first field, RM 200 for each subsequent field
Assessment fee	<u>Lead Assessor:</u> RM 600 / assessor / assessment visit <u>Technical Assessor:</u> RM 600 / assessor / assessment visit	<u>Lead Assessor:</u> RM 800 / assessor for 1 st day, RM 400 for each subsequent day <u>Technical Assessor:</u> RM 600 / assessor for 1 st day, RM 300 for each subsequent day

39

New Assessment Procedure

Witnessing

STANDARDS MALAYSIA will establish new procedure for selection of witnessing of test/lab activity

Laboratory to maintain/keep a copy of the witnessing report

40

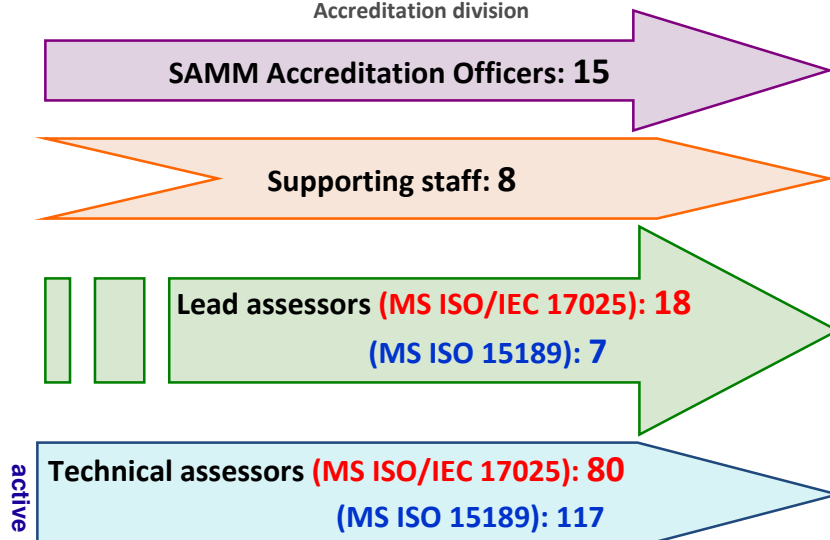
Upcoming events

Training/Programme/Course/Workshop/ Forum	Date & venue
Majlis Anugerah Standard dan Akreditasi 2010	Nov 2010 - Putrajaya
PT Post Implementation Workshop for Calibration Laboratories	Nov 2010 - Shah Alam
Forum with SMM Assessors	Oct 2010 - Putrajaya
Forum with SMM MT Assessor	Dec 2010 - Putrajaya
Training on Measurement Uncertainty for Microbiology Laboratories	Dec 2010 - Cyberjaya
ILAC & IAF Annual Meetings	20 - 29 Oct 2010 - Shanghai, People's Republic of China
APLAC General Assembly and Technical Meetings	4 - 10 Dec 2010 - Osaka, Japan

41

Staff strength

Accreditation division



42

STANDARDS MALAYSIA

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