

▶ **JAWAPAN BERKENAAN ISU-ISU  
BERTULIS YANG DITERIMA  
UNTUK FORUM JABATAN  
STANDARD MALAYSIA  
BERSAMA MAKMAL SAMM  
2013**

## General Issue

No	Issue	Response
1.	- Memohon wakil Standard Malaysia untuk hadir bersama-sama dengan assessor pada proses pengauditan dijalankan.	-STANDARDS MALAYSIA has taken note and will take into consideration in the future.
2.	- Perkembangan terbaru dan terkini SAMM.	- To be brief during SAMM Update session.
3.	- Tawaran yuran akreditasi secara 'group package' untuk makmal-makmal yang ada cawangan untuk kurangkan kos.	-STANDARDS MALAYSIA in the process to review fee regulation for accreditation. This issue has been taking into consideration during preparation of this regulation.
4.	- Sekiranya makmal sedia ada (telah akreditasi) akan berpindah ke bangunan lain, bagaimanakah dengan proses ISO17025:2005 & SAMM, adakah makmal perlu memulakan segalanya daripada proses 'pre-assessment'	- Lab needs to inform STANDARDS MALAYSIA before the relocation and accreditation status will be held inoperative. STANDARDS MALAYSIA will do verification for the reinstatement of accreditation status.
5.	- Status/ Accreditation stage for lab.	- Information can be easily obtained from officer in charge of your laboratory.

## Proficiency Testing / Interlab Comparison

No	Issue	Response
6.	- To extend PT program to include more oleochemicals products/ samples.	- STANDARDS MALAYSIA understands that there are areas in which PT is non-existence. STANDARDS MALAYSIA take note on the issue and will update laboratory in Oleochemicals Industries on any PT offered in this field in the future. Kindly be informed that the information on PT in the website has been improved to provide more links to accredited PT Provider. Meanwhile laboratory may conduct or participate in interlaboratory comparisons activities to demonstrate competence if PT is not available.
7.	- Bolehkah PT dilaksanakan 2 tahun sekali?	- Accredited laboratory shall participate in at least one available PT activity relevant to its scope of accreditation for each field within one accreditation cycle. The laboratory shall achieve satisfactory performance in all the PT activities it has participated.  To be further explained during briefing of SP 4

## Proficiency Testing / Interlab Comparison

No	Issue	Response
8.	- The laboratory currently participates in PT and obtains good result. However a certain regulatory body complained that the laboratory is not performing the test methods accordingly. How does the laboratory address this issue?	- STANDARDS MALAYSIA will further discuss this matter with related Regulatory Body.
9.	- <b>SP4 May 2013 draft</b> With reference to amendments in the new SP4 draft, and in relation to Issue (1), there are no PT programs/ activities for specific assays that we wish to include in the accreditation scope, be they PT, ILC or EQA. What other activity/ alternatives can these assays undergo to comply with SP4 in order to be included in the accreditation scope?	- To be discussed during SP 4 briefing session.

## SAMM / Reference Documents

No	Issue	Response
10.	- Status SP14, adakah dokumen lain yang menggantikannya?	- For information, S14 document is obsolete and irrelevant to be used as a guidance to determine the calibration interval of significant test and measuring instruments. User should specify the calibration interval depend on the usage of respective instruments and intermediate check shall be performed periodically to ensure validity of the result.  Laboratories are encouraged to refer to ILAC G 24: Calibration Interval for Measuring Equipment, which can be downloaded for free from ILAC website. <a href="http://www.ilac.org">www.ilac.org</a> .
11.	S14 replacement document which standard is the best to refer.	Laboratories are encouraged to refer to ILAC G 24: Calibration Interval for Measuring Equipment, which can be downloaded for free from ILAC website. <a href="http://www.ilac.org">www.ilac.org</a>

## SAMM / Reference Documents

No	Issue	Response
12.	- Mohon penjelasan isu tentang 'approved signatory'. Isu: Terdapat makmal yang senarai 'approved signatory' dicatatkan dalam sijil di bawah skop umum iaitu analisis kimia atau analisis mikrobiologi berbanding di sesetengah makmal yang senarai 'approved signatory' dicatatkan dalam sijil bawah skop khusus seperti analisis drug vet, analisis mikotoksin, analisis aditif dan sebagainya.	- Signatory approval by STANDARDS MALAYSIA is granted to personnel for specific scopes for which he/she has been assessed to be technically qualified and competent (SP6, Clause 3.4). Approved signatory will be granted for general analysis if the personnel are competent to perform the test.

## SAMM Assessors

No	Issue	Response
13.	- Menambah bilangan lead auditor dan technical auditor untuk 'critical field'.	- STANDARDS MALAYSIA has taken note on the suggestion.
14.	- Pemilihan auditor- pelanggan @ konsultan tidak boleh jadi auditor.	- Laboratory need to inform STANDARDS MALAYSIA if any conflict of interest arose with the appointed assessor as stated in notification letter.
15.	- Mohon penjelasan lanjut mengenai proses jika perlu menukar khidmat Lead Assessor sedia ada.	- Any laboratories which request to change the lead assessor need to provide relevant justification in writing to STANDARDS MALAYSIA. STANDARDS MALAYSIA will review and decide the relevancy to change the lead assessor. The replacement of lead assessor will be effective on the next assessment or cycle.

## SAMM Assessors

No	Issue	Response
16.	- Menambah bilangan juru audit bagi membolehkan proses audit berjalan lebih lancar.	- Assessment team will be form based on: <ol style="list-style-type: none"> <li>Type of fields</li> <li>Capacity of the fields (number of test)</li> </ol>
17.	<ol style="list-style-type: none"> <li>Kekurangan Lead Assessor</li> <li>ii. Lead Assessor sentiasa tiada di SAMM untuk dihubungi (tiada email address)</li> </ol>	<ol style="list-style-type: none"> <li>STANDARDS MALAYSIA is in the process of recruiting more assessors.</li> <li>ii. Lead Assessor is on the job basis and performed assessment based on the prepared scheduled. Lab may contact their respective Lead Assessor through phone for matter pertaining to accreditation only or liase with the officer-in-charge if lab are not able to contact the Lead Assessor</li> </ol>

## STANDARDS MALAYSIA Website

No	Issue	Response
18.	- Tidak dapat access SAMM Publication daripada website Standard Malaysia.	- STANDARDS MALAYSIA's website is currently being upgraded and there will be some problem accessing the website. However, this will be temporary in nature. STANDARDS MALAYSIA will brief laboratories on how to navigate through our website during SAMM Update session
19.	- Penerangan berkenaan dengan Laman Web Rasmi Jabatan Standard Malaysia.	
20.	-Segala maklumat terkini tidak dapat diakses dan dipertonton di ruang utama website DSM.	

## SAMM Training / Workshop / Seminar

No	Issue	Response
21.	- Kursus dan latihan oleh STANDARDS MALAYSIA memilih peserta SAMM untuk sama-sama menimba pengalaman ISO di luar negara.	- The invitation received for seminar/ training/ workshop usually will be funded by organizer or government with limited budget. However, if the laboratories willing to bear all the cost, STANDARDS MALAYSIA will consider to invite laboratory attending the relevant seminar/ training/ workshop.
22.	Makluman kursus/ latihan yang disediakan perjumpaan berkala untuk perbincangan.	- STANDARDS MALAYSIA noted and will take into consideration in the future.
23.	- Mengadakan latihan secara praktikal mengenai ujikaji/ analisis yang mengikut standard.	- It is the responsibilities of laboratory to seek relevant training.

## SAMM Training / Workshop / Seminar

No	Issue	Response
24.	- Menyediakan dan memperbanyakkan latihan/ kursus ISO (awarenes internal audit training).	- STANDARDS MALAYSIA has taken note and will take into consideration in the future.  For information, STANDARDS MALAYSIA has provide general training such as Measurement Uncertainty for Microbiology Training, Statistical method in Proficiency testing based on needs.

## Miscellaneous

No	Issue	Response
25.	- Calibration Load Column >3000kN.	- Please provide more details and to be discussed during Clinic SAMM
26.	- To formulate/ develop a standard list of testing methods that is acknowledged by the regulatory body from APHA so that all relevant method). For regulatory purposes, laboratory labs are doing the same test despite the fact there are more one option to perform the test.	- STANDARDS MALAYSIA accredits any test method applied by laboratory (in-house/standard regulatory body from APHA so that all relevant method). For regulatory purposes, laboratory needs to refer to the relevant Regulatory Body.
27.	- To develop a list of competent consultant with regards to ISO17025 related program training.	- STANDARDS MALAYSIA is Accreditation Body which provides accreditation services based on MS ISO/IEC 17011. STANDARDS MALAYSIA as Accreditation Body cannot provide/involve in any matters related consultancy services.

## Miscellaneous

No	Issue	Response
28.	- Memberi hadiah kepada makmal yang aktif menambah skop akreditasi pada setiap tahun sebagai insentif kepada makmal-makmal yang mengamalkannya.	- Extending scope is a voluntary process and requested by the laboratories based on their necessities.
29.	- Tindakan-tindakan yang boleh ambil sekiranya laporan ujian makmal yang diakreditasi tidak diterima oleh agensi.	- Laboratory need to inform STANDARDS MALAYSIA if such issues arise. We will discuss with the related agencies.

## Miscellaneous

No	Issue	Response
30.	- Prepare more benefits for those accredited Laboratory under DSM such as: a) free participation at any international exhibition. b) DSM manages training to enhance technical knowledge for laboratory.	- Some of the benefits that can obtain through accreditation are as follows: i. Tax deduction for the costs such as Assessment Fee, Annual Fee and other Fee imposed by STANDARDS MALAYSIA. ii. Promote accredited laboratories services to industries and stakeholders (examples through directories in website, promotional activities and during meeting with relevant stakeholders). iii. STANDARDS MALAYSIA do organize trainings (eg. through smart partnership with organisation such as IKM) from time to time and will extend the invitation to relevant laboratories.
31.	- Validation performance of autoclave	- Please provide more details and to be discussed during Clinic SAMM.

## Miscellaneous

No	Issue	Response
32.	- Apakah perbezaan permohonan akreditasi ISO17025: 2005 antara makmal Asid Nukliekdengan makmal Halal?	- For information, if the laboratory interested to apply for halal testing, fields offered at the moment are Nucleic Acid, chemical, microbiology etc. where applicable. STANDARDS MALAYSIA does not have specific requirement document for Halal testing. However, STANDARDS MALAYSIA may develop if we received suggestion and proposal from interested parties.