



SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
SAMM CIRCULAR 4/2017

TRANSITION TO ISO/IEC 17025:2017
GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND
CALIBRATION LABORATORIES

1. INTRODUCTION

The third edition of the ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories* was published in November 2017. This third edition of the ISO/IEC 17025:2017 cancels and replaces ISO/IEC 17025:2005.

The standard applies to testing and calibration laboratories. International Organization for Standardization (ISO) and International Laboratory Accreditation Cooperation (ILAC) have agreed on a (3) three-year transition period from the date of publication of the ISO/IEC 17025:2017 for laboratories to bring their operations and processes in line with the requirements of the new standard. As such, Standards Malaysia will require all of its accredited laboratories to conform to the new standard by **30 November 2020**.

2. OBJECTIVE

This circular is aimed to inform the related Standards Malaysia accredited laboratories on the transition process that will be implemented by Standards Malaysia for the transition to the new standard, ISO/IEC 17025:2017 within the transition deadline, i.e. by or before **30 November 2020**.

3. STANDARDS MALAYSIA REQUIREMENTS FOR TRANSITION TO ISO/IEC 17025:2017

3.1 Applicant Laboratory

3.1.1 Any applications for laboratory accreditation in accordance with ISO/IEC 17025 submitted to Standards Malaysia after **1 January 2018** shall be based on and assessed using ISO/IEC 17025:2017.

3.1.2 For existing application, the applicant is required to document and submit the plan for the transition to Standards Malaysia by **1 July 2018**. The plan shall indicate the transition process by using the attached template (**Annex 1**). Starting **1 January 2019**, the applicant laboratory shall be assessed using ISO/IEC 17025:2017.

3.2 Accredited Laboratory

- 3.2.1 Laboratory is advised to train its laboratory's personnel, review the new standard, conduct a gap analysis, establish a transition plan to incorporate the changes into their management system and determine the time frame required to execute them. Laboratory is required to document and submit the plan for the transition to Standards Malaysia by **1 July 2018**. The plan shall indicate the transition process by using the attached template (**Annex 1**).
- 3.2.2 Beginning **1 January 2018**, the laboratory may request for their assessment to be conducted using ISO/IEC 17025:2017. The laboratory shall request in writing to Standards Malaysia, and submit a transition plan as well as evidence of transition as in Clause 3.6 of this document (**Annex 2**).
- 3.2.3 Starting **1 January 2019**, all scheduled assessments (Surveillance/Re-Assessment) shall be conducted using ISO/IEC 17025:2017. The laboratory shall submit evidence of transition as in Clause 3.6 of this document (**Annex 2**) to Standards Malaysia at least **one month** before assessment.
- 3.2.4 For any assessment that due after July 2020, the transition assessment to the new ISO/IEC 17025:2017 shall be conducted during the previous assessment.
- 3.2.5 Findings to the new ISO/IEC 17025:2017 shall be raised as non-conformities or observations. Corrective actions for the non-conformities shall be verified and closed out before the recommendation for transition of accreditation to ISO/IEC 17025:2017 is granted.
- 3.2.6 If a laboratory fails to comply with ISO/IEC 17025:2017 by **30 November 2020**, the laboratory shall be suspended for a maximum period of 3 months. After the suspension, failure of the laboratory to take any action would result in withdrawal of accreditation.

3.3 Extension of Scope

Beginning **1 January 2019**, application for extension of scope shall only be processed after the laboratory has successfully transitioned to ISO/IEC 17025:2017.

3.4 Summary of the deadlines

Date	Item	Remarks
1 January 2018	All new applications submitted after 1 January 2018 will be assessed using ISO/IEC 17025:2017	Applicable to new applicants
	Accredited laboratories may request in writing for assessment transitioning to ISO/IEC 17025:2017	All accredited laboratories
1 July 2018	All existing applicants and accredited laboratories to submit Transition Plan to Standards Malaysia	All existing applicants and accredited laboratories

Date	Item	Remarks
1 January 2019	Existing applicants (before 1 January 2018) and accredited laboratories shall be assessed to ISO/IEC 17025:2017	All existing applicants and accredited laboratories
30 November 2020	End of transition period	All laboratories

3.5 Accreditation Certificate and/or Schedule

- 3.5.1 The accreditation certificate and/or scope of accreditation will be adapted/amended to reflect accreditation to ISO/IEC 17025:2017 after the assessment to the new standard is completed and accreditation is granted.
- 3.5.2 The SAMM number and the accreditation validity period shall remain unchanged.

3.6 Documented information (laboratory document) based on ISO/IEC 17025:2017

The laboratory shall submit documented information to Standards Malaysia as an evidence compliance to ISO/IEC 17025:2017 using the attached template (**Annex 2**) covering the following:

- a) Company profile and information about the laboratory including legal entity and its activities;
- b) Structure/Organisation chart;
- c) Policies and objectives;
- d) Identified management personnel who is responsible for the laboratory's activities (name and responsibility);
- e) Risk assessment analysis/report;
- f) Internal audit report; and
- g) Management review minutes.

3.7 Frequency of Internal Audit based on ISO/IEC 17025:2017

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

3.8 Frequency of Management Review based on ISO/IEC 17025:2017

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

4. VALIDITY OF ISO/IEC 17025:2005

The status of accreditation to ISO/IEC 17025:2005 will remain valid until the laboratory achieves the transition or until the end of the transition period, i.e. 30 November 2020.

5. SPECIFIC EXCEPTIONS

The Director of Accreditation, at his discretion, may grant specific exceptions to the requirements for the transition to ISO/IEC 17025:2017, subject to valid justifications from the laboratory.

REFERENCES:

1. Joint ILAC-ISO Communiqué on the recognition of ISO/IEC 17025 during a Three-Year Transition
[http://isotc.iso.org/livelink/livelink/fetch/-8853493/8853511/8853520/15760064/Joint_ILAC-ISO_Communicu%C3%A9 -
_ISO IEC 17025 transition.pdf?nodeid=19392772&vernum=-2](http://isotc.iso.org/livelink/livelink/fetch/-8853493/8853511/8853520/15760064/Joint_ILAC-ISO_Communicu%C3%A9_-_ISO_IEC_17025_transition.pdf?nodeid=19392772&vernum=-2)
2. Joint ISO-ILAC-IAF Communiqué on the Management System Requirements of ISO/IEC 17025, General Requirements for the competence of testing and calibration laboratories
<http://ilac.org/about-ilac/partnerships/international-partners/iso/>
3. Resolutions of the Twentieth ILAC General Assembly, New Delhi, India, 2 and 4 November 2016
<http://ilac.org/publications-and-resources/ga-resolutions/>

ANNEX 1

TRANSITION PLAN BY LABORATORY FOR ISO/IEC 17025:2017

The laboratory shall submit this Transition Plan to Standards Malaysia by **1 July 2018**.

Laboratory Name:		
SAMM No:		
Proposed date of transition: (preferably during schedule assessment)		
Processes:		Planned Date (DD MM YYYY)
1.	Gap analysis	
2.	Documentation updated to meet ISO/IEC 17025:2017 requirements	
3.	Implementation of the revised management system	
4.	Internal audit conducted based on ISO/IEC 17025:2017	
5.	Management review conducted based on ISO/IEC 17025:2017	
6.	Others (Please specify)	

Prepared by laboratory's authorised personnel (however named)

Name:

Signature:

Date:

ANNEX 2

TRANSITION CHECKLIST

Laboratory Name:

SAMM No:

Proposed date of transition:

(preferably during schedule assessment)

Note: Please complete and submit this checklist, together with the following documents to Standards Malaysia at least **one month** before assessment.

No.	Particulars	Yes √	No √	Remark, if any
1	Company profile and information about the laboratory including legal entity and its activities			
2	Structure/Organisation chart			
3	Policies and objectives			
4	Identified management who responsible for the laboratory activities (name and responsibility)			
5	Risk assessment analysis/report			
6	Internal audit report			
7	Management review minutes			

Confirmed by laboratory's authorised personnel (however named)

Name:

Signature:

Date: