

# MINISTRY OF INVESTMENT, TRADE AND INDUSTRY DEPARTMENT OF STANDARDS MALAYSIA

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# MALAYSIA PROFICIENCY TESTING PROVIDERS (MYPTP) ACCREDITATION SCHEME

### **MYPTP CIRCULAR 1/2023**

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# TRANSITION TO ISO/IEC 17043:2023 - CONFORMITY ASSESSMENT – GENERAL REQUIREMENTS FOR THE COMPETENCE OF PROFICIENCY TESTING PROVIDERS

#### 1 INTRODUCTION

The second (2nd) edition of the ISO/IEC 17043:2023 - Conformity Assessment - General Requirements for the Competence of Proficiency Testing Providers was published in May 2023. This new ISO/IEC 17043:2023 cancels and replaces ISO/IEC 17043:2010.

The standard applies to proficiency testing providers. International Laboratory Accreditation Cooperation (ILAC) have agreed on a three (3) year transition period from the date of publication of the new ISO/IEC 17043:2023 standard for proficiency testing providers to bring their operations and processes in line with the requirements of the new standard. As such, the Department of Standards Malaysia (JSM) will require all of its accredited and applicant proficiency testing providers to conform to the new standard by 31st May 2026. However, during this transition period, it is important to note that both ISO/IEC 17043:2010 and ISO/IEC 17043:2023 are equally valid and applicable.

#### 2 OBJECTIVE

This circular is aimed to inform all JSM applicants and accredited proficiency testing providers on the transition process that will be carried out by JSM for the transition to the new ISO/IEC 17043:2023 standard, within the transition deadline, by or before **31**st **May 2026**.

### 3 JSM REQUIREMENTS FOR TRANSITION TO ISO/IEC 17043:2023

Proficiency testing providers are advised to train its personnel to the new standard, review the changes of the new standard, conduct a gap analysis, establish a transition plan (**Annex 1**) to incorporate the changes into their management system and determine the time frame required to execute them.

# 3.1 Applicant Laboratory

### **New Applicant**

3.1.1 For proficiency testing providers, whose application is received by JSM after **15**<sup>th</sup> **June 2023**, the proficiency testing providers will be assessed based on the new ISO/IEC 17043:2023 standard.

#### **Existing Proficiency Testing Providers Applicants**

- 3.1.2 For applicants, whose application is ongoing, the proficiency testing providers can be assessed against the ISO/IEC 17043:2010 standard until **31**<sup>st</sup> **December 2024.**
- 3.1.3 For applicants, whose accreditation is awarded/granted by 31st December 2024, the first surveillance assessment shall be conducted approximately ten (10) months after the date of granting, based on the new ISO/IEC 17043:2023 standard.
- 3.1.4 Beginning 1st January 2025, all applicants shall be assessed against the new ISO/IEC 17043:2023 standard. At least three (3) months prior to the applicable assessment stage (i.e.: preassessment or compliance), the applicant is required to submit the documents and Annex 1 to JSM.

## 3.2 Accredited Proficiency Testing Providers

- 3.2.1 The proficiency testing providers are required to document and submit its transition plan **Annex 1** to JSM by **1**<sup>st</sup> **January 2024**. The transition plan indicates the transition process required.
- 3.2.2 Beginning 1st June 2024, all scheduled assessments (i.e.: surveillance or reassessment) shall be conducted against the new ISO/IEC 17043:2023 standard. The proficiency testing providers shall submit documents to JSM according to Annex 2 (Transition ISO/IEC 17043:2023 Checklist) at least one (1) month before the scheduled assessment.
- 3.2.3 Assessment findings to the new ISO/IEC 17043:2023 standard during the transition period, shall be raised as non-conformities and will require corrective actions from the proficiency testing providers. Corrective actions for the non-conformities shall be verified and closed out before the recommendation for transition of accreditation to the new ISO/IEC 17043:2023 standard is approved.
- 3.2.4 If a proficiency testing provider fails to transition to the new ISO/IEC 17043:2023 standard by **31**<sup>st</sup> **May 2026**, the proficiency testing providers shall be suspended for a maximum period of 3 months. Failure to take the required action within the suspension period would result in withdrawal of accreditation.

#### 3.3 Extension of Scope (EOS)

Beginning **1st June 2024**, any EOS application can only be made after the proficiency testing provider has successfully transitioned to the new ISO/IEC 17043:2023 standard.

## 3.4 Schedule of Accreditation (scope)

- 3.4.1 The scope of accreditation will be amended to reflect the transition of accreditation to the new ISO/IEC 17043:2023 standard.
- 3.4.2 The MyPTP number and the accreditation validity period remain unchanged.

# 3.5 Documented information (proficiency testing providers document) based on ISO/IEC 17043:2023

The proficiency testing provider shall submit documented information to JSM as evidence of compliance to the new ISO/IEC 17043:2023 standard using the transition checklist (**Annex 2**), which covers the following:

- a) Company profile and information about the proficiency testing provider including legal entity and its activities;
- b) Structure / organisation chart;
- c) Policies and objectives;
- d) List of key personnel including name and responsibility in accordance the new ISO/IEC 17043:2023 standard;
- e) Risk assessment analysis/report;
- f) Internal audit report; and
- g) Management review minutes.

# 3.6 Frequency of internal audit based on ISO/IEC 17043:2023

The proficiency testing provider's internal audit shall be conducted at least once a year and shall be reported in the management review meeting.

#### 3.7 Frequency of management review based on ISO/IEC 17043:2023

The proficiency testing provider's management review shall be conducted at least once a year.

#### 4 SPECIFIC EXCEPTIONS

The Director of Accreditation, at his discretion, may grant specific exceptions to the requirements for the transition to the new ISO/IEC 17043:2023 standard, subject to valid justifications from the proficiency testing provider.

Thank you.

#### **Director of Accreditation**

#### **ANNEX 1**

# **TRANSITION PLAN FOR ISO/IEC 17043:2023**

The proficiency testing provider shall fill up and submit this transition plan to JSM at email <a href="mailto:mahadir@jsm.gov.my">mahadir@jsm.gov.my</a>, 3 months prior to transition proposed date (applicant proficiency testing provider) or latest by 1<sup>st</sup> January 2024 (accredited proficiency testing provider).

Proficiency Testing Provider Name:				
MYPTP No:				
Proposed date of transition assessment: (Refer Assessment Programme LA 1401)				
Processes to comp		ply to ISO/IEC 17043:2023	Planned Date (dd/mm/yyyy)	
1	Gap analysis			
2	Documentation approval (e.g.: policy and procedure documents)			
3	Implementation of management system			
4	Internal audit conduct			
5	Management review conduct			
6	Others (Please specify)			
Confirmed by Proficiency Testing Provider's authorised personnel (however named)				
Signature:				
Name:				
Date:				

# **ANNEX 2**

# TRANSITION ISO/IEC 17043:2023 CHECKLIST

Profic	ciency Testing Provider Name:		
MYPI	P No:		
-	osed date of transition assessment:r Assessment Programme LA 1401)		
	Please complete this checklist and submit docur <b>h</b> before assessment.	nents to	JSM at least one (1)
No.	Particulars	Yes (✔)	Remark, if any
1	Company profile and information about the proficiency testing provider including legal entity and its activities		
2	Structure / Organisation chart		
3	Policies and objectives (e.g.: policy and procedure documents)		
4	List of key personnel including name and responsibility in accordance to ISO/IEC 17043:2023		
5	Risk assessment analysis / report		
6	Internal audit report		
7	Management review minutes		
	rmed by proficiency testing provider's authoris	ed pers	onnel
Signa	ture:		
Name	:		
Date:			