MINISTRY OF INTERNATIONAL TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

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SAMM CIRCULAR 1/2023

TRANSITION TO ISO 15189:2022 MEDICAL LABORATORIES – REQUIREMENTS FOR QUALITY AND COMPETENCE

1 INTRODUCTION

The fourth (4th) edition of the ISO 15189 Medical Laboratories - *Requirements for Quality and Competence* was published in December 2022. This new ISO 15189:2022 cancels and replaces ISO 15189:2012.

The standard applies to medical testing laboratories. International Organization for Standardization (ISO) and International Laboratory Accreditation Cooperation (ILAC) have agreed on a three (3) year transition period from the date of publication of the new ISO 15189:2022 standard for laboratories 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 laboratories to conform to the new standard by **31st December 2025**. However, during this transition period, it is important to note that both ISO 15189:2012 and ISO 15189:2022 are equally valid and applicable.

2 OBJECTIVE

This circular is aimed to inform all JSM applicants and accredited medical testing laboratories on the transition process that will be carried out by JSM for the transition to the new ISO 15189:2022 standard, within the transition deadline, by or before **31st December 2025.**

3 JSM REQUIREMENTS FOR TRANSITION TO ISO 15189:2022

Laboratory is advised to train its laboratory 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 medical laboratories, whose application is received by JSM after 1st January 2023, the laboratories will be assessed based on the new ISO 15189:2022 standard.

3.1.2 The applicant whose application was received by JSM before 1st January 2023, the application will be put on hold up to 12 months for the transition preparation. Three (3) months prior to the adequacy audit, the applicant is required to submit the documents and **Annex 1** (Transition Plan for ISO 15189:2022) to JSM.

Existing Medical Testing Laboratory Applicants

3.1.3 For applicant, whose application is ongoing, the laboratory can be assessed against the ISO 15189:2012 standard until December 2023. However, beginning 1st January 2024, all applicants shall be assessed against the new ISO 15189:2022 standard. At least three (3) months prior to the applicable assessment stage (e.g.: preassessment or compliance), the applicant is required to submit the documents and **Annex 1** to JSM.

3.1.4 For applicant, whose accreditation is awarded/granted in 2023, the first surveillance assessment shall be conducted approximately ten (10) months after the date of granting, based on the new ISO 15189:2022 standard.

3.2 Accredited Medical Testing Laboratory

3.2.1 The laboratory is required to document and submit its transition plan to JSM by **1st July 2023**. The transition plan indicates the transition process required.

3.2.2 Beginning **1st January 2024**, all scheduled assessments (e.g.: surveillance or reassessment) shall be conducted against the new ISO 15189:2022 standard. The laboratory shall submit documents to JSM according to **Annex 2** (Transition ISO 15189:2022 Checklist) at least one (1) month before the scheduled assessment.

3.2.3 Findings to the new ISO 15189:2022 standard shall be raised as non-conformities. All non-conformities raised during the transition period against the requirements of the new standard ISO 15189:2022 standard will require corrective actions from the laboratory. Corrective actions for the non-conformities shall be verified and closed out before the recommendation for transition of accreditation to new ISO 15189:2022 standard is approved.

3.3 If a laboratory fails to migrate to the new ISO 15189:2022 standard by **31st December 2025**, the laboratory 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.

3.4 Extension of Scope (EOS)

Beginning **1st January 2024**, any EOS application can only be made after the laboratory has successfully transitioned to the new ISO 15189:2022 standard.

3.5 Schedule of Accreditation (scope)

3.5.1 The scope of accreditation will be amended to reflect the transition of accreditation to the new ISO 15189:2022 standard.

3.5.2 The SAMM number and the accreditation validity period remain unchanged.

3.6 Documented information (laboratory document) based on ISO 15189:2022

The laboratory shall submit documented information to JSM as evidence of compliance to the new ISO 15189:2022 standard using the transition checklist (**Annex 2**), which covers 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) List of key personnel including name and responsibility in accordance the new ISO 15189:2022 standard;
e) Risk assessment analysis/report;
f) Internal audit report; and
g) Management review minutes.

3.7 Frequency of internal audit based on ISO 15189:2022

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

3.8 Frequency of management review based on ISO 15189:2022

The laboratory'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 15189:2022 standard, subject to valid justifications from the laboratory.

Note: Validity of accreditation status based on **MS ISO 15189:2014 which is identical to ISO 15189:2012** will remain valid until the end of the transition period, by 31st December 2025. After 31st December 2025, accreditation granted against ISO 15189:2012 is no longer valid.

REFERENCES:

ILAC Resolution GA 26.08 (https://ilac.org/latest_ilac_news/iso-151892022-for-medical-labs-published/)

ANNEX 1

TRANSITION PLAN FOR ISO 15189:2022

The laboratory shall fill up and submit this transition plan to JSM at email mtteam@jsm.gov.my, 3 months prior to transition proposed date (applicant laboratory) or latest by 1st July 2023 (accredited laboratory).

Laboratory Name:	
SAMM No:	
Proposed date of transition assessment: (Refer Assessment Programme LA 1401)	

	Processes to comply to ISO 15189:2022	**Planned Date (dd/mm/yyyy)**
1	Gap analysis (may refer to the comparison table Annex B in ISO 15189:2022)	
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 laboratory's authorised personnel (however named)

Name: …….

Signature: ……..…..

Date: ……..……..

ANNEX 2

TRANSITION ISO 15189:2022 CHECKLIST

Laboratory Name:

SAMM No:

Proposed date of transition assessment:
(Refer Assessment Programme LA 1401)

Note: Please complete this checklist and submit documents to JSM at least **two months** before assessment. Hard copy documents can be couriered to the below address.

Accreditation Division
Department of Standards Malaysia
Aras 4, 5, 6 & 7, Tower 2, Menara Cyber Axis
Jalan Impact, Cyber 6
63000 Cyberjaya
Selangor
(Attn: Ms. Fariza Wan Abdullah)

No.	Particulars	Yes (✓)	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 (e.g.: policy and procedure documents)		
4	List of key personnel including name and responsibility in accordance to ISO 15189:2022		
5	Risk assessment analysis/report		
6	Internal audit report		
7	Management review minutes		

Confirmed by laboratory's authorised personnel (however named)

Name: …….

Signature: ……..…..

Date: ……..