

Transition Schedule for ISO 15189:2022

ISO 15189:2022 'Medical Laboratories – Requirements for quality and competence' was published in December 2022. The International Laboratory Accreditation Cooperation (ILAC) has endorsed a three-year transition period for the implementation of this new standard. Thus, the deadline for accredited medical laboratories to transition to ISO 15189:2022 will be **31 December 2025**. All HKAS accreditations based on 2012 version will become invalid after this date.

1. New applicants

HKAS Executive will accept applications based on ISO 15189:2022 from **1 July 2023**. HKAS Executive recommends medical laboratories submitting new applications based on this edition. Applications based on ISO 15189:2012 will NOT be accepted after **31 December 2023**.

Applications based on ISO 15189:2012

From **1 July 2023**, for assessments based on ISO 15189:2012, nonconformities against the requirements of ISO 15189:2012 will be, as usual, raised as 'Nonconformities (NCs)'. Obvious nonconformities against the new requirements of ISO 15189:2022 will be raised as 'Recommendations' *. Accreditation to ISO 15189:2012 will be granted when an applicant rectifies all critical and significant NCs to the satisfaction of HKAS Executive and commits to rectify all minor NCs prior to the next reassessment.

To ensure a smooth transition to the new standard, all new medical laboratories accredited to ISO 15189:2012 shall prepare a transition plan and submit to HKAS Executive *within one month* from the date of obtaining the accreditation.

(Please refer to Appendix I for a sample transition plan)

If accreditation based on ISO 15189:2012 of any new application cannot be granted by **31 December 2024**, HKAS Executive will suspend processing the application. The applicant shall implement the requirements of ISO 15189:2022 before HKAS Executive resumes the application process. Another assessment to confirm the conformity with the requirements of the new standard shall be conducted. Please note that other accreditation regulations relevant to an initial application still apply.

Applications based on ISO 15189:2022

Applications based on ISO 15189:2022 will be processed according to established accreditation procedures.

All assessed medical laboratories shall provide a plan for resolving all NCs identified in the assessment to HKAS Executive *within one month* after the assessment visit. Accreditation to ISO 15189:2022 will be granted when an applicant rectifies all critical and significant NCs to the satisfaction of HKAS Executive and commits to rectify all minor NCs prior to the next reassessment.

2. Accredited medical laboratories

To ensure a smooth transition to ISO 15189:2022, all accredited medical laboratories shall prepare a transition plan and submit to HKAS Executive by **1 July 2023**.

(Please refer to Appendix I for a sample transition plan)

From **1 July 2023** to **31 December 2024**, assessments can be based either on 2012 or 2022 edition of ISO 15189, depending on the transition plan submitted by the accredited medical laboratory. HKAS Executive will confirm the accreditation standard to be used prior to the assessment. In an assessment based on ISO 15189:2012, obvious nonconformities against the new requirements of ISO 15189:2022 will be raised as 'Recommendation' *. From 1 January 2025, assessments will only be based on ISO 15189:2022.

If an accredited medical laboratory prefers to transition to ISO 15189:2022 on an occasion other than the routine assessment visit, it may request HKAS Executive to carry out an extraordinary assessment but it shall bear the cost of such a visit.

3. Issue of Certificate of Accreditation referring to ISO 15189:2022

Certificate(s) of Accreditation referring to ISO 15189:2022 will be issued free of charge to replace the one(s) based on ISO 15189:2012 when an accredited medical laboratory demonstrates conformity with the new standard to the satisfaction of HKAS Executive. Any additional certificates will be charged according to the fee schedule.

*Note: * Addressing the 'Recommendations' does not imply conformity to ISO 15189:2022. Conformity to ISO 15189:2022 will be assessed in a separate assessment.*

HKAS Executive
1 March 2023

Appendix I

The transition plan should contain, at least, the following information:

Registration Number:	HOKLAS 8XXP		
Monitoring Plan	A / B / C		
Gap analysis			Before DD MM YYYY
Management system updated to meet ISO 15189:2022			Before DD MM YYYY
Implementation of the revised management system			From DD MM YYYY
Internal audit of the updated management system			Before DD MM YYYY
Year	Assessment type	Due dates	Standard to be used
2023	Reassessment	March 2023	ISO 15189: 2012
2024	1st surveillance	March 2024	ISO 15189: 2022
2025	2nd surveillance	March 2025	ISO 15189: 2022