

IAS TRANSITION POLICY FOR INTERNATIONAL STANDARD ISO 15189:2022

September 22, 2023

This policy applies to all IAS-accredited Medical Laboratories (MLs) and covers the following aspects in the transition process to ISO 15189:2022: Medical Laboratories- Requirements for quality and competence, published in December 2022.

IAS-accredited Medical Laboratories are required to comply with the requirements of this policy to maintain accreditation with IAS. As per ILAC General Assembly Resolution (ILAC GA 26-08), the International Laboratory Accreditation Cooperation (ILAC) has agreed to a three-year transition period from the date of publication of the standard. Further, ILAC GA 26.08 noted that the requirements for Point of Care Testing (POCT) contained in ISO 22870:2016 have been incorporated into the revised ISO 15189, ISO 22870:2016 in conjunction with ISO15189:2012 will still be recognized as a Level 4 standard for POCT for the duration of the transition period. At the end of the transition period, accreditation of a medical laboratory to ISO 15189:2012 and accreditation of POCT to ISO 22870:2016 in conjunction with ISO15189:2012 will not be recognized under the ILAC Arrangement.

The three-year transition period is **from 2022-12-06 to 2025-12-31** and at the end of the period, accreditation of a facility to ISO 15189:2012 will no longer be recognized and valid under the ILAC arrangement.

In order to ensure the implementation of this transition policy, IAS defined the following transition timelines.

Accepting applications for the new standard ISO 15189:2022	From 2023-10-01
Carry out Assessments as per the new standard ISO 15189:2022	From 2023-12-01
IAS will not accept new applications as per the previous standard ISO 15189:2012	From 2024-12-31
IAS will conduct all medical laboratory assessments as per the new standard ISO 15189:2022	From 2024-06-01
All IAS-accredited medical laboratories to the previous standard ISO 15189:2012 shall undergo a re-assessment as per the new standard ISO 15189:2022	Before 2025-11-05 and completed the process before 2025-12-31

All applicants who submitted applications to the previous version up to 2024-12-31 and were granted accreditation shall also complete a reassessment to the new standard.	Before 2025-11-05 and completed the process before 2025-12-31
Applicants to the previous standard before 2024-12-31 and not completed the initial assessment shall submit a new application to ISO 15189:2022	After 2024-12-31
Any accredited laboratory to ISO 15189:2012 fails to transfer its management system to the new standard ISO 15189:2022 and before 2025-11-06 will be suspended and accreditation status will be canceled	With effect from 2025-12-31

Availability of Accreditation Documents

All IAS-accredited medical laboratories are required to purchase a copy of the new International Standard ISO 15189:2022 from relevant standard bodies.

Assessment and Documentation

The IAS website will contain application documents for both standards until 2023-12-31 and thereafter, application documents related to previous standards will be removed from the website.

Assessment report formats, checklists, and other assessment-related documents for both new and previous standards will be provided to IAS assessors until 2024-12-31. Assessors are strictly advised to remove the assessment formats relevant to the previous standard from their computers/ folders unless required to keep them for considerable time due to justifiable reasons.

Stakeholder Training and Client Engagement

All ongoing communication and updates critical to the successful conclusion of the transition to ISO 15189:2022 will be posted on the following IAS website links: –
<https://www.iasonline.org/services/medical-laboratories>

IAS is offering training events and online webinars to the new standard. Please consult the IAS website (<https://www.iasonline.org/training>) for training dates and venues. If interested in obtaining training to the new version of ISO 15189, please contact IAS at training@iasonline.org

Guidance on the transition process for laboratories

1. Plan your transition process to the new version of the standard based on the IAS transition policy as outlined above.

2. Personnel responsible for the transition and implementation of their laboratory management system to the new version of the standard will need to be trained.
3. All relevant personnel need to understand, interpret, and implement the requirements of the new version of the standard.
4. Perform a gap analysis between the existing laboratory management system and the requirements to the new version of the standard.
5. Update laboratory management system documentation including existing policies and procedures as required.
6. Establish an internal training plan and schedule awareness training for relevant laboratory personnel. • Contact IAS to arrange for a transition assessment visit.

Note: Assessment visits relating to transitioning can be combined with the laboratory scheduled reassessments if they are within accepted time frames as stated in this policy.

Contact Information

Further information can be obtained by contacting Mr. Mohan Sabaratnam, Senior Vice President at msabaratnam@iasonline.org.