EGAC TRANSITION POLICY

On the accreditation of medical laboratories according to ISO 15189:2022
Medical laboratories - Requirements for quality and competence

Introduction

EGAC accredited and applicant medical laboratories are required to comply with the requirements of this policy commencing 31 July, 2023. This policy based on The ILAC Arrangement Management Committee (AMC) that is responsible for monitoring the implementation of transition periods for the Level 3 standards used by the accreditation bodies under the ILAC MRA and ILAC Resolution– Transition Period for ISO 15189:2022.
ILAC General Assembly endorses the recommendation of the AIC that a transition period of 3 years from the date of publication be adopted.

Noting that the requirements for Point of Care Testing (POCT) contained in ISO 22870:2016 have been incorporated into the revised ISO 15189:2022, 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 implementation of this transition period for ISO 15189:2022 by the signatories to the ILAC MRA for the accreditation of medical laboratories will be monitored by the ILAC AMC to ensure the deadline is achieved.

Purpose

This policy is to describe EGAC approach regarding the processes of handling transition to, and effective implementation of ISO 15189:2022.

The new ISO 15189:2022 Medical laboratories - Requirements for quality and competence standard was published on the 06 December 2022 and will replace ISO 15189:2012 and ISO 22870: 2016. The agreed transition period is 3 years from the date of publication. This means that all medical laboratories will need to have successfully transferred to the new standard within 3 years from the publication date.

EGAC Transitional Assessments

1. Transitional assessments shall consist of at least an assessment of the medical laboratories (ML) documented system in line with the new ISO 15189:2022.

2. These transitional assessments will be performed as far as possible with the scheduled annual assessments in order to avoid extra costs for the medical laboratories.

3. The following transitional provisions shall apply for the effective implementation of ISO 15189:2022:
   - EGAC shall conduct all pre-assessment, initial, in line with the requirements of ISO 15189:2022 from 01 June, 2024;
   - EGAC shall conduct all Consecutive assessments, extension and re-assessments visits in line with the requirements of ISO 15189:2022 from 01 August, 2024;
   - We will start receiving new application & transition action plan from medical labs on May 2023 depend on the lab cross reference;
   - On 31 December, 2023, the Cut-off date for receiving new CAB according to ISO 15189:2012. Starting from 01 January, 2024, only ISO 15189:2022 new applications are to be accepted;
   - All constitutive assessments scheduled to take place from 31 July, 2024, for accredited Medical Labs will also be conducted against ISO 15189:2022;
   - Findings (Corrective Action records and Comments) raised against the ISO 15189:2012 standard requirements during assessments conducted during the transition period require a response to EGAC within 1 – 3 months from the assessment visit. Findings raised against ISO 15189:2022 Standard must be resolved before 31 December, 2025.

4. All accredited and applicant medical laboratories should provide EGAC with revised quality system documentation addressing all new requirements of ISO 15189:2022 and return a completed self-assessment checklist, prior to their next assessment. All accredited and applicant medical laboratories will be provided with this checklist prior to assessment or upon request.

5. All accredited medical laboratories shall submit their transition action plan to EGAC by no later than 01 October 2023. The action plan must demonstrate how the medical laboratories has analyse the new standard and its implications to their quality system and operations. The action plan shall also indicate how the medical laboratories will effectively implement all the changes, system and technical, needed to comply before the transition date.

   - As ~~a~~ minimum, the plan should include:
     i) All specific actions to be taken to implement the changes;
     ii) The timelines and a significant stage for completion of actions;
     iii) The persons responsible for every action;
     iv) Ways to measure progress, implementation, effectiveness and completion of the actions.
   - All records and documented changes in line with the new standard will be reviewed and assessed during the scheduled annual visits and records shall demonstrate the following as a minimum:

     i) The internal audit and management review findings are aimed at ensuring effective implementation of ISO;
     ii) The actions in the Medical Laboratories established transition plan are adhered to and monitored to ensure timely transition;
     iii) The necessary changes made to documentation are implemented; and
     iv) All changes are implemented in all fixed-office locations/branches, where applicable.

6. Before 30 September, 2025, all medical labs quality system documentation must demonstrate compliance with the new ISO 15189:2022 standard in order to maintain EGAC accreditation, EGAC Staff will notify the delayed labs.

7. Medical laboratory that has not demonstrated full compliance with ISO 15189: 2022 Standard by 31 December, 2025, is subject to withdrawal of their accreditation.

8. All current EGAC accreditation certificates based on ISO 15189:2012 will expire on / before 31 December, 2025.

9. Medical laboratories demonstrating full compliance with the requirements of ISO 15189:2022 Standard will be issued a certificate listing accreditation to the new standard.

10. EGAC intends to conduct transitional assessments at the same time of the medical laboratory annual consecutive visit or re-assessment visit includes witnessing activities. It is therefore important to incorporate transition arrangements for these standards in the transition action plan as required above.
11. Once the medical laboratories have demonstrated successful transition and effective implementation of ISO 15189:2022 and the decision by the EGAC Accreditation Committee is for the continuation/maintenance/ renewal of accreditation, the Schedule and certificate of Accreditation will be updated to reflect ISO 15189:2022.

Availability of Accreditation Documents

EGAC-accredited and applicant medical laboratories are required to obtain a copy of the new international standard which may be purchased from the relevant standard development organization.

Training and Documentation Notes

A. All EGAC Medical laboratories assessors will be trained on the new standard prior to conducting assessments.
B. EGAC will be scheduling training events on the new standard according transition plan, Please consult the EGAC website regularly for training dates.

Accreditation Procedure

The current EGAC Accreditation Policy and guidance for Accreditation of Medical Laboratories (PB6M) and Regulation (R1G) will be revised to meet the requirements of the new standard.

EGAC Staff and Assessors Training

To facilitate the transition process, EGAC staff and assessors will receive training on the requirements of ISO 15189:2022 Standard. Training will also include guidance on the EGAC Transition Plan and a detailed overview the ISO 15189:2022 Standard so that assessors will be able to answer your questions. Assessor training will also include any new or revised administrative tools (e.g., forms, checklists, procedures, etc.) as required.

Medical Laboratories Engagement

Awareness about the transition and summary of ISO 15189:2022 changes will be arranged, and updates critical to the successful conclusion of the transition to ISO 15189:2022 by accredited and applicant Medical will be discussed during communication meetings.