

Transition Plan to ISO 15189: 2022

Sr.	Activity	Date	Comment
1	Publication date of standard (ISO 15189:2022)	December 06, 2022	Three years' transition period starts from December 06, 2022 and ends December 31, 2025.
2	Awareness for EGAC Assessors, staff, Technical and accreditation Committees members who are representing medical scheme on the new version ISO 15189: 2022.	(One Day) January, 2023 February, 2023	Awareness will include gap analysis between ISO 15189: 2012 and ISO 15189: 2022; also, ILAC requirements for transition and EGAC transition policy and plan. We will deal with reintroducing LQMS, the changes made in the new version, the impact of the changes and transition, and perspectives from Accrediting Bodies.
3	First , awareness for CAB's (medical labs accredited and not accredited) on new version, changes and transition ISO 15189:2022.	(One Days) February, 2023	Awareness will include gap analysis between ISO 15189: 2012 and ISO 15189:2022; also, ILAC requirements for transition and EGAC transition policy and plan. We will deal with reintroducing LQMS, the changes made in the new version, the impact of the changes and transition, and perspectives from Accrediting Bodies.
4	EGAC will send official e-mail to all CABs asking them to send their Transition Action Plan.	March, 2023	EGAC Medical Department will send e-mail for all CABs asking them for transition action plan to apply ISO 15189:2022 in their system.
5	Assessors Training Course according to ISO 15189:2022 for technical assessors, technical and accreditation committees members.	April, 2023 (3-4 days)	The training will include details and interpretation of every clause of ISO 15189:2022 (3-4 days).
6	EGAC department start to prepare documentation system according to ISO 15189: 2022 and ILAC requirements from the following:- - EGAC new policy. - EGAC new procedures. - EGAC new regulations. - EGAC new publications. - Self assessment checklist. -Technical and management checklists	June, 2023	Technical advisory committees will review the EGAC Medical department documentation system, then send it to the quality department to be get approved and published on the EGAC website
7	EGAC Medical Department will	June, 2023	EGAC Medical Department will start

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	start receiving new applications & transition Action Plans from medical labs (CABs).		receiving new applications and QMS according to ISO 15189:2022. CABs has to submit transition action plan and EGAC staff and assessors will verify the implementation onsite during the next scheduled visit.
8	Training course for Assessors, technical committee members awareness about EGAC new checklists, publication documents of policy, procedures, and Regulation according to new version ISO 15189:2022.	August, 2023 (One Day)	Training will include transition action plan ISO 15189:2022 and its application on: - EGAC new policy. - EGAC new procedures. - EGAC new Regulation. - EGAC new publication. - Checklist of reporting and document review.
9	<u>Second</u> , awareness for accredited CABs according to ISO 15189:2022 new version and transition action plan.	September, 2023 (One Day)	Training will include transition action plan of ISO 15189:2022 and its application on: - EGAC new policy. - EGAC new procedures. - EGAC new Regulation. - EGAC new publication. - Self assessment checklist.
10	EGAC will send official letters/ E-mail to all CABs to ask them send their transition action plan.	April - June, 2023	EGAC Medical Department will send letter E-mail for all CABs E-mail to ask them for transition action plan for applying ISO 15189:2022 for their system.
11	Review transition action plan received from medical labs and re-adjust the annual consecutive assessments visits and re-assessment plan for medical Lab.	June, 2023	EGAC will start receiving and reviewing CAB's transition action plan from June, 2023 for all accredited CABs according to ISO 15189:2022
12	Cut-off date of receiving new CAB according to ISO 15189:2012.	December 31, 2023	Starting from December 31, 2023, only ISO 15189:2022 new applications to be accepted.
13	Accredited Labs Assessments against ISO 15189:2022 from July 31, 2024{ Confirming transition for accredited (Consecutive assessments & reassessment) according to ISO 15189:2022} before the end date by ILAC (31 December. 2025)	From July 31, 2024 and before November 2025	Consecutive assessments & reassessment visits shall be done against ISO 15189: 2022 from July 31 2024, on all already accredited Medical labs that accredited before against ISO 15189: 2012

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14	Assessments for all medical labs (CABs) accredited or not accredited medical labs	July, 2025	All assessments to have been conducted against ISO 15189: 2022 for all accredited or not accredited medical labs.
15	All medical labs quality system documentation must demonstrate compliance with the new ISO 15189:2022 standard	Before 30 September 2025	in order to maintain EGAC accreditation All medical labs quality system documentation must demonstrate compliance with the new ISO 15189:2022 standard, EGAC Staff will notify the delayed labs
16	Transition Cut-off date	December 31, 2025	CABs that were unable to transit successfully will be automatically withdraw after the December 31, 2025.