



TRANSITION TO ISO 15189:2022 FOR MEDICAL LABORATORIES

The long-awaited ISO 15189:2022 - Medical Laboratories – Requirements for Quality and competences standard was published on the 06th of December 2022. All Medical Laboratories are to undergo a three-year transition period in line with the directive issued by the International Laboratory Accreditation Cooperation (ILAC), the transition period will end on the 06th of December 2025.

SANAS will commence with the transition process for all the Medical Laboratories accredited to ISO 15189:2012 in line with the SANAS P-32 'Transition to a new/revised Standard, Normative Document or Accreditation Scheme' policy from December 2022.

The key changes to the Standard are as follows:

- The ISO 15189:2022 is now aligned to ISO/ IEC 17025:2017;
- The revised standard is risk based, and increased the focus on the welfare of the patient by planning and encouraging continuous improvement within medical laboratories;
- It has incorporated the requirements for Point of Care Testing (POCT) - ISO 22870:2016.



The transition roll-out plan is scheduled as follows:

ACTIVITY	TIMELINES
Last day for ISO 15189:2012 standard applications	31 st January 2023
Assessor workshops conducted	February 2023
TG-67 “Transitional Guidelines for ISO 15189:2022 Medical Laboratories, Blood Transfusion Facilities and Point of Care Testing” published	March 2023
ISO 15189:2022 Assessment Checklists reviewed and published	March 2023
ISO 15189:2022 Assessment to commence <i>Note: CABs that are ready before the set date can inform SANAS about their readiness for provision to be made for assessments to be carried out.</i>	From 01 st October 2023
CABs are to submit the Annexure B of TG 67 <i>Note: The transition plans must be in place prior to undertaking the transition and this will be assessed on-site.</i>	Two months prior to scheduled assessment
Cut-off date for the completion of all transitions <i>Note: Failure to transition by the cut-off date will result in the suspension of the CABs.</i>	06 December 2025

The SANAS Knowledge Transfer department will arrange and announce the transition workshop for Medical Laboratories Conformity Assessment Bodies (CABS), further details will be available on the website. Once the ISO 15189:2022 assessment is concluded, and approval granted by the Approval Committee, the certificates will updated and aligned to the revised standard.

We will continue to issue communication regarding the transition during the implementation period.