



INAB Transition plan for ISO 15189:2022

NF39

Introduction and scope:

This communication is applicable to all applicant and accredited medical testing laboratories.

The accreditation standard ISO 15189:2022 “Medical laboratories — Requirements for quality and competence” was published on 6th December 2022. Standard ISO 15189:2022 replaces ISO 15189:2012.

In February 2024 EN ISO 15189:2022 was referenced in the Official Journal of the EU (L series on 20.02.2024) - therefore the standard is now harmonised. Harmonised standards are a special set of European Standards which are used to underpin EU product legislation and are given a legal basis by Regulation (EC) 765/2008.

According to Article 2 of the Commission Implementing Decision (EU) 2024/581 of 16 February 2024, EN ISO 15189:2012 is withdrawn from the Official Journal of the European Union, as and from **20th August 2025**.

All INAB-accredited laboratories will be required to have completed the transition to ISO 15189:2022 by this date.

All new laboratory applications for accreditation must be to ISO 15189:2022.

INAB began transition assessments of existing accredited laboratories to ISO 15189:2022 in January 2024. The transition assessments will take place with the scheduled annual assessment (surveillance or reassessment). If there are any nonconformities these will be recorded, classified, and managed through the normal INAB processes. Additional assessment time will be required to ensure all clauses of the new standard are covered at the assessment.

Assessment to the new standard is optional for any laboratories whose annual assessment (surveillance or reassessment) is scheduled from January – June 2024. Assessments to the new standard for existing accredited laboratories will be mandatory from July 2024. INAB will issue a revised accreditation certificate and scope of accreditation following a successful assessment according to ISO 15189:2022 and after a positive decision in that respect.

If the laboratory has not successfully completed their transition to ISO 15189:2022 before **20th August 2025**, then the existing accreditation for ISO 15189:2012 will be withdrawn on this date. Laboratories that have not transitioned to the 2022 version by this date will no longer be able to claim accreditation for their laboratory activities.

Accredited Point of Care Testing (POCT)

The requirements for Point of Care Testing (POCT) contained in ISO 22870:2016 have been incorporated into the revised ISO 15189:2022, and ISO 22870:2016 has been withdrawn. For the

duration of the transition period ISO 22870:2016 in conjunction with ISO15189:2012 will still be recognised as a Level 4 standard for POCT. At the end of the transition period, the accreditation of POCT to ISO 22870:2016 in conjunction with ISO15189:2012 will not be recognised. POCT systems will be assessed against ISO 15189:2022 as part of the laboratory transition assessment.

If you have any further queries, please contact your INAB Assessment Manager.

INAB Transition Arrangements and key dates:

2023		
1	New applications to ISO 15189:2022	<ul style="list-style-type: none"> Applications for accreditation to the new standard accepted from July 2023
2	Existing accreditations to ISO 15189:2012	<ul style="list-style-type: none"> 2023 annual surveillance or re-assessment to ISO 15189:2012 POCT systems assessed to ISO 22870:2016
3	Existing accreditations to ISO 15189:2012	<ul style="list-style-type: none"> Gap analysis and transition plan submitted by 1st November 2023 (see below)
2024		
4	Existing accreditations to ISO 15189:2012 If your annual surveillance or reassessment visit is due January - June 2024	<p>The CAB has two options. Please inform assessment manager as part of your gap analysis and transition plan</p> <ul style="list-style-type: none"> (a) Option to be assessed to ISO 15189:2012, and POCT systems will be assessed to ISO 22870:2016 (b) Option to be assessed to ISO 15189:2022 and POCT systems will be also be assessed to ISO 15189:2022
5	Existing accreditations to ISO 15189:2012 If your surveillance or reassessment visit is due July 2024 onwards	<ul style="list-style-type: none"> Assessment will be to ISO 15189:2022 (mandatory) POCT systems will be also be assessed to ISO 15189:2022
6	Existing accreditations to ISO 15189:2012 who apply for extension to scope to include POCT	<ul style="list-style-type: none"> If you apply for an extension to scope to include POCT you will be assessed as above, depending on the version of ISO 15189 the rest of your laboratory is accredited to
7	Existing accreditations to ISO 15189:2012 who apply for extension to scope for new disciplines	<ul style="list-style-type: none"> If you apply for an extension to scope to include new disciplines you will be assessed against whichever version of ISO 15189 the rest of your laboratory is accredited to

Laboratory Transition Plan:

In order to facilitate a smooth transition to the new standard, INAB requests existing accredited laboratories to submit a transition action plan to their INAB assessment manager before **1st November 2023**. At minimum the plan should include:

- Changes identified within the laboratories own quality system.
- Details of specific actions planned to implement any changes necessary.
- The timeframe for completion of such actions.
- The persons responsible for the actions.
- Process in place to monitor progress and completion of the actions.
- Staff training on ISO 15189:2022
- Confirmation on which option above is selected (4a, 4b, 5)

Information on ISO 15189:2022

<https://european-accreditation.org/publication-of-the-new-iso-15189/>

https://ilac.org/latest_ilac_news/iso-151892022-for-medical-labs-published/