

ISO 15189:2022 – Guidance on JAS-AU Transition Plan for Accredited and Applicant Medical Laboratories

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Following the publication of ISO 15189:2022, JAS-AU established this document to provide medical laboratories and stakeholders on the process and overall timelines for transition of JAS-AU accreditation to new version of the standard.

Date	Milestone/Activity
6 December 2022	ISO 15189:2022 issued
December 2022 to July 31 2023	JAS-AU Preparation
1 March 2023 to 30 June 2023	Submission of Action Plans by Medical Laboratories
1 August 2023	JAS-AU aims to be ready to start assessing to ISO 15189:2022
1 August 2023 to 31 Dec 2024	Laboratories that have their surveillance/reassessment on-site visit within this period can choose to be assessed to the 2022 or 2012 version. <u>In case the laboratory chooses to have their assessment of the 2022 version a document review will be conducted.</u>
1 August 2023 onwards	New applications for accreditation shall only be accepted to ISO 15189:2022
1 January 2024 onwards	Application for reassessment will only be accepted to ISO 15189:2022
1 January 2025 onwards	All annual surveillance / reassessments visits shall be conducted according to ISO 15189:2022. A document review will be performed.
6 December 2025	<u>After This date Accreditations to ISO 15189:2012 ceases to be valid.</u> Laboratories that have not transitioned to the 2022 version by this date will be automatically suspended and only accreditation to the 2022 version will be valid.

Transition process for accredited medical laboratories

JAS-AU plans to start the process of beginning Transition of JAS-AU accredited medical laboratories to ISO 15189:2022 from 31 July 2023. However, Initial assessments to the requirements of ISO 15189:2022 will be mandatory starting on 1st January 2024.

During the period of 1 August 2023 to the end of December 2024 Laboratories that have their surveillance/reassessment (onsite assessment) within this period can choose to be assessed to the 2022 or 2012 version by formally informing JAS-AU prior to the visit and in case the laboratory chooses to have their assessment on 2022 version a document review will be conducted.

All application signed based on ISO 15189:2012 before 1 August 2023 can proceed on the 2012 version and the laboratory have the option to choose to have the onsite assessment based on ISO 15189:2022 given that an additional document review on ISO 15189:2022 will be conducted.

Application for reassessment will only be accepted to ISO 15189:2022 from 1 January 2024.

Accredited medical laboratories are required to complete and submit a Transition Action plan to JAS-AU during the period (1 March 2023 to 30 June 2023). Accredited medical laboratories wishing to transit into ISO 15189:2022 are required to complete and submit Gap analysis to JAS-AU at least 1 month prior to the assessment, it is the responsibility of the laboratory to consider the extent and impact of these changes to meet the revised and new requirements in ISO 15189:2022.

Laboratories that have not transitioned to the 2022 version by 6 December 2025 will be automatically suspended after this date and only accreditation to the 2022 version will be valid. The accreditation will be suspended for up to six months until they can demonstrate that they meet the requirements of ISO 15189:2022.

Transition process for applicant medical laboratories

Medical laboratories that have already applied for ISO 15189:2012 accreditation and have not yet had their accreditation granted, may continue with the accreditation process to ISO 15189:2012 (after being granted accreditation, the Laboratory shall abide by the transition process for accredited medical laboratories).

If the assessment has not been conducted by 1st January 2024, then the applicant will need to change to, and be assessed against, the requirements of ISO 15189:2022, with any mandatory findings being satisfactorily addressed before accreditation can be granted.

Laboratories that are considering applying for accreditation under ISO 15189 are encouraged to develop their systems and processes in accordance with ISO 15189:2022. Those that have already prepared an application against the 2012 version can still submit it, but should be aware of the dates specified above, and that they will then need to transition to the 2022 version before the deadline.

JAS-AU will not accept any new applications for accreditation to ISO 15189:2012 starting from 1 August 2023.