Technical Bulletin: ISO 15189:2022 - Guidance for accredited and applicant medical laboratories

23 December 2022

Following the publication of ISO 15189:2022, this bulletin has been produced to update medical laboratories and stakeholders on the process and overall timelines for transition of UKAS accreditation to this new version of the standard.

Timeline:

Date	Milestone/Activity
6 December 2022	ISO 15189:2022 issued
December 2022 to March 2023	UKAS preparation
1 April 2023	UKAS aims to be ready to start assessing to ISO 15189:2022
1 April 2023 to 31 Dec 2023	Laboratories that have their annual surveillance/reassessment within this period can choose to be assessed to the 2022 version or remain with the 2012 version. In any case reports may highlight major deviations from the new standard.
1 July 2023 onwards	New applications for accreditation will only be accepted to ISO 15189:2022
1 January 2024 onwards	All initial assessments will be to ISO 15189:2022
1 January 2024 onwards (Assessment visits should be completed by 31 May 2025)	Mandatory Stage: All annual surveillance / reassessments will be to ISO 15189:2022
6 December 2025	Accreditations to ISO 15189:2012 cease to be valid. Laboratories that have not transitioned to the 2022 version by this date will no longer be able to claim accreditation for their laboratory activities.

UKAS transition process for accredited medical laboratories

UKAS aims to be ready to begin the transition of its accredited laboratories to ISO 15189:2022 from 1st April 2023. However, assessments to the requirements of ISO 15189:2022 will not be mandatory until 1st January 2024. Therefore, during the period of April 2023 to the end of December 2023 laboratories will be given the option of either deferring their transition until the following year or deciding to bring it forward to 2023. It is proposed that the transition assessments be undertaken with the scheduled annual UKAS assessment.

When arrangements are being made for the 2023 assessment, laboratories will need to inform UKAS if they wish the assessment to be conducted to the 2022 version of the standard. UKAS will contact customers directly; there will be no need for a formal application requesting transition to be completed.

If a laboratory does not wish to transition early, its UKAS assessment team, from April 2023 onwards, will continue to assess against the 2012 version, but may highlight any areas that will need to be addressed in order to comply with the revised version – these shall be recorded as recommendations.

From the beginning of 2024, all UKAS assessments of accredited laboratories will be conducted against the requirements of ISO 15189:2022: These will be combined with the laboratory's annual assessment visits.

In preparation for the transition assessment each accredited provider will be required to complete an 'assessment readiness' gap analysis proforma and return it to UKAS at least 1 month prior to the assessment. This proforma will be provided by UKAS at the time the transition assessment is arranged, although it will also be made available on the UKAS website early in the new year.

The proforma will identify where changes have been made in ISO 15189, and it will be the responsibility of the laboratory to consider the extent and impact of these changes, and to complete the form to state what changes (where necessary) it has made in order to meet the revised and new requirements in ISO 15189:2022.

Additional office time will be required by UKAS to review the changes made by the laboratory, as highlighted in the proforma. Subject to the extent of the changes made by the laboratory, it is not anticipated that additional site time will be required for most laboratories. The additional time required as part of the transition will be chargeable, with a fee to cover the desktop assessment, primarily of the assessment readiness questionnaire and submitted supported documentation. This will vary depending on the size/complexity of the laboratory and hence the expected time to complete the review: This is likely to be 1.25 day for laboratories with very small scopes of accreditation, to 1.75 day for larger scopes and possibly more for those that are more complex (e.g. multi-site).

Any additional site visits arranged to specifically assess the transition to ISO 15189:2022 will need to cover changes to both the management system and technical requirements for laboratory accreditation and, as such, will require input from both UKAS Lead and Technical Assessors. Such visits will be chargeable at the rate in force at the time (see UKAS Terms of Business) and will require more effort (assessment days) than if combined with the annual assessment.

The effectiveness of the changes shall be verified by the assessment team during the site visit. If areas are identified that do not adequately fulfil the requirements, then these will be raised as findings, with a one-month deadline for evidence submission. All mandatory findings must be addressed by the laboratory via the normal process before accreditation can be formally transitioned to ISO 15189:2022.

The deadline for transition to the new version has been internationally agreed as three years from the date of publication, meaning that from 6 December 2025 only accreditation to the 2022 version will be valid. It is therefore imperative that all accredited medical laboratories are fully transitioned before this date, and the UKAS transition timeline is based around this.

A new certificate and schedule of accreditation referencing ISO 15189:2022 shall be issued to each customer following the successful decision on its transition. Annual visit dates, current year in the accreditation cycle, initial accreditation dates and UKAS reference number will remain unchanged.

The accreditation of medical laboratories that fail to transition by the deadline of 6 December 2025 will cease to be valid from that date: Their accreditation will be listed as 'suspended' for up to six months until such time that they can demonstrate to UKAS that they meet the requirements of ISO 15189:2022.

UKAS transition process for applicant laboratories

Medical laboratories that have already applied to UKAS for accreditation to ISO 15189:2012 but have not yet had their accreditation granted, may continue with the accreditation process to ISO 15189:2012 (following grant of accreditation these laboratories will need to transition to ISO 15189:2022 before 06 December 2025). However, 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 to UKAS for accreditation under ISO 15189 should now 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.

UKAS will not accept any new applications for accreditation to ISO 15189:2012 after 30th June 2023.

Further details and contact

Further details on the transition of ISO 15189:2022, including how to obtain a copy of the new version, can be found in the **Medical Laboratory Accreditation** customer area of the UKAS website.

Queries regarding the transition process should be directed to the medical laboratory's appointed Assessment Manager.