Technical Bulletin: ISO 15189:2022 Transition process guidance

16 January 2023

Following publication of the UKAS technical bulletin on 23rd December 2022, outlining the UKAS transition plan for customers who want to be accredited to ISO 15189:2022, this bulletin gives further details of the process to be followed.

The first step is for each accredited or applicant customer to hold a copy of the ISO 15189:2022 standard, which is available from BSI **here**, identify any gaps between the policies and processes currently in place compared to the requirements of ISO 15189:2022, and develop an action plan for implementing any new requirements. UKAS has created a **gap analysis template** to support customers in this process.

Accredited customers (ISO 15189:2012 only)

Accredited customers can choose to be assessed against ISO 15189:2022 from 1st April 2023, although assessment to the new standard only becomes mandatory from 1st January 2024. It is anticipated that most customers will use 2023 to review the new standard and implement any necessary changes to their service and opt to undergo their transition assessment in 2024.

Transition assessments will usually be undertaken with the scheduled annual assessment. When arrangements are being made for the 2023 annual assessment, customers will need to inform UKAS if they wish to be assessed to ISO 15189:2022. This will be undertaken as part of the assessment booking process; *there is no requirement for a formal transition application to be submitted to UKAS*.

If customers are waiting until their 2024 assessment to be assessed to ISO 15189:2022, they do not need to notify UKAS of this decision, as all assessments from 1st January 2024 will be to ISO 15189:2022.

One month before the transition assessment takes place, customers shall provide UKAS with a completed **gap analysis** detailing identified gaps and actions taken. As part of the gap analysis, customers shall provide evidence (for example, updated documents/policies/records) to demonstrate the actions they have taken to comply with ISO 15189:2022.

Failure to provide the gap analysis and supporting documentation one month prior to the start date of the assessment risks additional costs and delays to the transition assessment.

The UKAS assessment team will review the submitted gap analysis and documentation and use these to identify key areas to assess during the associated surveillance/reassessment. Following the surveillance/reassessment visit, the UKAS assessment team will annotate the gap analysis provided by each customer, to include comments on compliance or non-compliance with ISO 15189:2022. Where non-conformities are identified, these will be recorded on an Improvement Action Report (IAR), and the finding will be referenced in the annotated gap analysis.

Following the on-site assessment, in addition to the routine annual assessment report(s), the customer shall be provided with a copy of the annotated gap analysis (now the transition assessment report, which shall also include a recommendation on the transition to ISO15189:2022 and a summary of the transition assessment) and any associated IAR (if findings relating specifically to the transition are raised).

Mandatory findings will be given a one-month deadline for evidence submission. Clearance of all findings (both annual assessment and transition assessment) permits the submission of all documentation to an independent UKAS decision maker to review and grant accreditation under ISO 15189:2022. If a customer has cleared all findings relating to ISO 15189:2012 but is having difficulty clearing findings raised against the new requirements of ISO 15189:2022, UKAS may maintain/renew accreditation to ISO 15189:2012 while the customer continues to implement the requirements of ISO 15189:2022. In this case, extra assessment activity (remote or on-site) may be required before the transition is granted, in order to provide UKAS with assurance that the customer is compliant to ISO 15189:2022.

When accreditation to ISO 15189:2022 is granted, UKAS will issue an updated accreditation schedule and e-certificate.

Customers who have not transitioned their accreditation to ISO 15189:2022 by 06 December 2025 will have their accreditation under ISO 15189:2012 suspended for a maximum of 6 months. If a customer fails to address the remaining actions required to complete the transition process within this timeframe, accreditation under ISO 15189:2012 shall be withdrawn, and the customer will need to reapply for accreditation.

Accredited customers (ISO 22870:2016 in conjunction with ISO 15189:2012)

Customers providing a Point of Care Testing (POCT) service accredited to ISO 22870:2016 in conjunction with ISO 15189:2012 will follow the same transition process detailed above.

When accreditation to ISO 15189:2022 is granted, the UKAS schedule will no longer reference ISO 22870:2016, but the accredited POCT service activities will still be listed. Accreditation for POCT activities will be under ISO 15189:2022.

New applicants

Applicants for accreditation under ISO 15189 who have already submitted an application form for accreditation to ISO 15189:2012 but have not yet been assessed need to consider the timeframes in which they wish to be assessed and accredited.

If they wish to be assessed before 01 April 2023, this will be to ISO 15189:2012, then they will need to follow the transition process detailed above in 2024.

If they wish to be assessed between 01 April 2023 and 31 December 2023, they can choose whether to be assessed against ISO 15189:2012 or ISO 15189:2022. If they choose to be assessed against ISO 15189:2012, they will need to follow the transition process detailed above in 2024.

If they wish to be assessed from 01 January 2024 onwards, this will be against ISO 15189:2022.

UKAS will stop accepting applications to ISO 15189:2012 after 30th June 2023.

The UKAS Training Academy is developing an ISO 15189:2022 transition training course for customers already accredited to ISO 15189:2012, and a new Medical Laboratories Awareness – ISO 15189:2022 course for new providers considering applying for accreditation for the first time. The Point of Care Testing course has been updated to replace the requirements of ISO 22870:2016 with those of ISO 15189:2022. For more information, see the UKAS website **here**.

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

*Queries from providers interested in applying for accreditation for the first time should be directed to **apps@ukas.com**.*