

Technical Bulletin: ISO 15189:2022 transition update

03 January 2024

Following the publication of ISO 15189:2022 in December 2022, the first year of the three-year transition period is now complete.

UKAS spent 2023 training Assessment Managers and Technical Assessors in the requirements of ISO 15189:2022, and sharing information about the updated standard and UKAS transition process through presentations at numerous events across the country and online, writing articles for digital and print journals, and developing the [UKAS ISO 15189:2022 transition hub](#).

As per the UKAS transition plan, all assessments due to take place 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) which shall be embedded in the gap analysis document on the appropriate line to which they correspond, to demonstrate the actions they have taken to comply with ISO 15189:2022. The information provided to UKAS should be more than just a reference to the documented procedure and should explain what has been changed and actions taken by the laboratory.

A number of gap analysis reviews and transition assessments have already been completed with good detail being provided in most cases. There has however been evidence of a trend with regards to data being submitted as detailed below:

Gap analyses often include action plans and statements such as “SOP xxx will be updated” but there is a lack of evidence being provided by laboratories to demonstrate how the appropriate documentation will be updated and that the requirements of ISO 15189:2022 have actually been *implemented*. UKAS cannot grant accreditation on intent; organisations shall make the necessary changes and have implemented these prior to the transition assessment.

UKAS expects laboratories to have updated relevant policies, procedures, SOPs and processes by the time of their transition assessment to demonstrate that the new version of the ISO 15189 has been understood. There shall be evidence of implementation of the new requirements, with particular focus on the major changes between ISO 15189:2012 and ISO 15189:2022 identified via each laboratory’s gap analysis.

The UKAS transition plan involves completion of all transition assessments in 2024. This will allow time in 2025 for laboratories to close any non-conformities raised in assessments in late 2024, UKAS to complete the required decision making to grant accreditation to ISO 15189:2022 to any remaining laboratories, and to perform any repeat assessments required.

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.

Useful links

[UKAS ISO 15189:2022 transition hub](#)

UKAS ISO 15189:2022 [gap analysis](#)

The ISO 15189:2022 standard is available from BSI [here](#)

