

Technical Bulletin: LAB 51 UKAS Accreditation of Laboratories Performing Analysis of Toxicology Samples - ACTION REQUIRED

Issue 2 - 14 June 2021 (Issue 1 - 01 June 2021): Dates revised as highlighted

Organisations undertaking the analysis of toxicology samples are working within a rapidly changing environment. For example, there have been advances in technology that have prompted changes to the analytical processes that have been traditionally applied. This has led to benefits from improvements in equipment such as automated sample processing, enhanced sensitivity and increased confidence in the identification of target substances. However, there have also been questions raised over the integrity of reported toxicology data which have, in some circumstances, led to the withdrawal of cases from the Criminal and Civil Justice Systems, and led to criminal prosecutions.

In response to these changes in methodology and concerns over data integrity, in 2018 UKAS undertook a review of all accredited laboratories within this sector. The review highlighted several areas where improvement was needed and initially resulted in changes to information detailed in the schedules of accreditation of the organisations conducting toxicology analysis (2019). These changes provided greater clarity of the sectors and matrices to which the methods apply and include more detail on the application of the methodologies e.g. associated cut-off concentrations and concentration ranges for the individual drugs being analysed.

The review also highlighted that the consistency of approach between laboratories in respect to areas such as selection, verification and validation of methods, ensuring on-going validity of results and control of data would benefit from further clarification by UKAS in regard to the expectations for compliance to ISO/IEC 17025 and ISO 15189 within this sector.

To this end UKAS has consulted with the sector and produced a new publication, LAB 51 *UKAS Accreditation of Laboratories Performing Analysis of Toxicology Samples*. This UKAS publication is available from the UKAS website (www.ukas.com) from the 1st June 2021.

This bulletin should be considered as a formal notification of the existence of this new UKAS publication which is directly relevant to the accredited activities of laboratories performing analysis of toxicology samples – a letter has also been sent directly to those organisations currently accredited for this testing.

In conjunction with the release of LAB 51, each affected organisation has been sent a [Gap Analysis Form \(F573\)](#) to complete and return to UKAS. The gap analysis lists the individual sections of LAB 51 and has been designed to assist in the identification of areas where processes may require amendment. **It is requested that this gap analysis is completed and returned to Kimberley Brumpton (kimberley.brumpton@ukas.com) by 02 August 2021.**

A further implementation period of one month has been assigned to allow organisations to address any gaps that have been highlighted prior to the completion of the [LAB 51 Declaration Form \(F572\)](#). **This Declaration Form is required to be completed and returned to Kimberley Brumpton (kimberley.brumpton@ukas.com) prior to 31 August 2021 to enable organisations to confirm processes have been updated (where necessary) and are in compliance with the expectations of LAB 51.**

All assessments from **01 September 2021** will incorporate assessment against the expectations of LAB 51. This will require additional assessment effort by UKAS, to ensure that compliance can be demonstrated and that any changes required have been appropriately implemented.

Assessment Managers will be in touch in due course to clarify the arrangements in relation to the next assessment and the additional effort that will be needed to review the implementation of LAB 51. This additional assessment effort will either be added to an existing routine assessment or an additional assessment will be carried out during 2021 (where visits have already been completed for this year). In addition, it may also be necessary to introduce a different Technical Assessor to your Assessment Team.

If you have any further queries, please do not hesitate to contact your Assessment Manager (*please do not contact Kimberley Brumpton for queries*).