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LAB51-UKAS Accreditation of Laboratories Performing Analysis of Toxicology Samples

Providing Consistency of Approach to Toxicology Analysis

20th July 2021

Background

- Following Concerns regarding Data Integrity and Quality, UKAS undertook a review of Toxicology Providers which was completed in June 2018

- An independent review of the outcomes was completed in January 2019

- The review provided three main Recommendations:

Toxicology Review - Recommendations

- Further definition of Market Sectors (and therefore the purpose of the analysis) for the accredited scope including whether tests are applied for Screening, Confirmation or Quantitative purposes COMPLETED 2019

- Revise Accreditation Schedules to include both the defined cut-off level (or Critical Level of Interest); the [Lower] Limit of Quantification and the [Upper] Limit of Quantification (as applicable). COMPLETED 2019

- Ensure a consistent and robust approach in areas such as validation, quality control, system suitability and batch acceptance –
    - Addressed through internal guidance documents for the Assessment team with further training of Technical Assessors through internal workshops (2019)

Toxicology - Requirement for LAB51

- Since this original review further data integrity issues (2020) have required UKAS involvement, and these have led to cases being withdrawn or adjourned within the Criminal Justice system:
    - A Certificate for a drug CRM re-issued by the manufacturer due to an error in estimated Measurement Uncertainty for the material
    - Erroneous acceptance of system and batch suitability prior to reporting

- Routine assessment visits have also noted significant differences and suitability of the approach to batch acceptance between Laboratories which may lead to inconsistencies in the measurement uncertainty and validity of results reported

Toxicology - Requirement for LAB51

- Drive for a consistent and Defensible approach to Toxicology Analysis

UKAS Technical Documentation –LAB51 UKAS Accreditation of Laboratories Performing Analysis of Toxicology Samples **(Published June 2021)**

- To be applied to all relevant Toxicology analyses accredited to ISO/IEC 17025 (Testing) and ISO 15189
    - provide consistency between market sectors

- Separate initiative to that being driven by the Forensic Science Regulator [FSR] concerning 'The Analysis and Reporting of Specimens in Relation to s5A Road Traffic Act 1988' as embodied in the draft FSR-C-133 Guidance Document.

LAB 51 - UKAS Accreditation of Laboratories Performing Analysis of Toxicology Samples June 2021

- Draft For Consultation (Based on existing guidance to Technical assessors within UKAS internal procedures and taking into account lessons learnt from previous reviews) – Issued March 2021

- Consultation Period closed April 2021

- Feedback Reviewed and Final revisions made May 2021

- LAB51 Published June 2021

LAB 51 – Consultation Feedback; Overview

- 20 Responses – 384 Comments were received
- ALL comments were collated and considered for revision of the draft based on their technical justification
- Due to the number of responses with similar technical themes, the changes made to the draft were based around those themes rather than reflecting each individual comment.
- The revised document was published June 2021

LAB 51 – Consultation Feedback

- Section 1 - Introduction (32 Comments)
  - Clarification regarding the Scope of Toxicology Analysis to include:
    - Workplace testing for drugs and drug metabolites (blood, urine, hair, oral fluids and other associated matrices)
    - Custody cases
    - Drink / drug driving (S5a Road Traffic Act 1988)
    - Forensic medical examination in cases of alleged sexual assault
    - Post-mortem work where criminal investigation is the primary purpose of test request
  - Clarification regarding the Scope of Toxicology Analysis to exclude:
    - Analysis for clinical or therapeutic diagnostic purposes

LAB 51 – Consultation Feedback

- Section 2 – Facilities and Environmental Conditions (22 Comments)
    - Suggested changes to wording in section 2.2-2.4 adopted for better clarity of requirements regarding Environmental monitoring
- Section 3 - Equipment (101 Comments)
    - Definition of Batch included (3.2)
    - Matrix matched calibration clarified for instances where actual matrix cannot be sourced e.g. post-mortem samples (3.3)
    - Calibration procedures for Presumptive Screening, Confirmation and Quantitative analyses clarified and adopted (3.4-3.6)
    - Addition of criteria for maximum error of calibration points (3.7)
    - Frequency of calibration check standards provided (3.8) based on risk assessment approach

LAB 51 – Consultation Feedback

- Section 4 - Metrological Traceability (13 Comments)
    - Comments regarding Section 4.4 adopted to reflect “prolonged” step changes on introduction of new reference standards
- Section 5 – Requests Tenders and Contracts (13 Comments)
    - No material changes adopted - laboratories shall have procedures to ensure requirements are adequately defined, documented and understood
- Section 6 - Selection, Verification and Validation of methods (71 Comments)
    - Comments regarding chromatographic confirmatory and quantitative analyses using MS techniques adopted (6.2)
    - Comments regarding published performance data adopted for clarity purposes (6.4/6.6.7)
    - Section 6.6.9 modified to remove ambiguity regarding concentration range
    - Section 6.10 modified to reflect comments regarding matrices and their complexity for better understanding

LAB 51 – Consultation Feedback

- Section 7 - Handling of Test items (20 Comments)
    - Comments regarding Section 7.2 adopted to reflect circumstances where freeze-thaw exercises may not be possible due to matrix type
- Section 8 – Technical Records and Control of Data (5 Comments)
    - Section 8.2 – minor update for clarity regarding recording and authorisation of laboratory batch data checks
- Section 9 - Measurement Uncertainty (10 Comments)
    - No material changes other than minor clarification in section 9.3

LAB 51 – Consultation Feedback

- Section 10 - Ensuring the validity of results (38 Comments)
    - Comments regarding Section 10.5 adopted to reflect circumstances where it may not be possible to matrix match all controls
    - Further clarity provided for less frequent analyses (10.7)
    - Section 10.13 modified to reflect concerns within comments raised regarding proficiency scheme participation coverage for competent analysts and required frequency
- Section 11 – Reporting Test Results (22 Comments)
    - Section 11.8 – updated to reflect comments received to include any contractual arrangements.
- Section 12/13 – References and Terminology (25 Comments)
    - Some required additions included

LAB51-Next Steps

- The completed Form 573 – "Toxicology Testing Laboratory LAB 51 Gap Analysis Customer Template" to be sent to UKAS by 2nd August 2021

- Any gaps identified are to be addressed by 31st August 2021

- Form 572 - LAB 51 Toxicology Requirements Declaration Form to be completed by 31st August 2021

- All subsequent assessments from 1st September 2021 will incorporate the expectations of LAB51 to drive consistency of approach and ensure that the analysis is performed appropriately and traceably.

LAB51-Assessment Approach

- Additional Technical/Lead assessors will be incorporated into existing assessment teams at the next planned visit (where possible) or, as an additional assessment visit.

- The effort assigned will be dependent on the size and complexity of the accredited scope:
  - Sectors serviced
  - Number of matrices
  - Different instrumentation/assays
  - Types of analyses – screening; confirmation; quantitative

- Quotes and dates for the required additional effort for these assessments will be agreed and provided following this webinar (all assessments to be completed prior to 30th March 2022).

LAB51-Assessment Approach

- The original customer gap analysis will be reviewed by the assessors prior to the assessment
- Based on this review the team will divide the responsibilities to review compliance to the expectations of LAB51
- Where non conformity is noted this will be raised as a finding against ISO/IEC 17025 or ISO 15189 (as applicable) and the clause within LAB51
- The time allotted for clearance of findings raised will depend on their significance on a case by case basis, to enable laboratories the time required to address any issues raised.
- Review of LAB51 scheduled for 6 months from issue – further feedback will be considered at this point

LAB51

Q&A

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Thank you

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