Questions raised before and during the Webinar held on 20th July 2021 relating to LAB 51- UKAS Accreditation of Laboratories Performing Analysis of Toxicology Samples

Q: LAB 51 was issued June 2021 but the version on the UKAS website is dated May 2021, has there been another release?

A: The issue on the website (dated May 2021) is the current issue which was amended post-consultation. The publication was formally issued on the 1st June 2021.

Q: When are laboratories going to get a formal written response addressing all comments raised during the consultation process? Feedback on LAB 51 was requested by UKAS and laboratories spent a great deal of time reviewing and supplying comments. Responses are required to allow the laboratory to interpret the requirements successfully and implement appropriate changes.

A: It is not UKAS policy to provide feedback to comments that are received in relation to the consultation on a publication. As there were a number of responses in relation to LAB 51 a webinar was held to outline the themes of the comments and to indicate the changes that were made to the publication as a result of the consultation.

Q: How can we submit questions after the webinar, if, due to time restraints, all questions cannot be addressed at the webinar, or if following the webinar, further questions come to light?

A: Additional questions can be directed through your Assessment Manager or the Technical Focal Point for Toxicology Analysis - Fran Bilby.

Q: You have referenced a group who will discuss post-mortem toxicology - can you explain what this group is and who will be involved. I think that all casework toxicology inclusion should be discussed.

Q: What toxicology input (i.e. from case working toxicologists) has there been on LAB 51 or what consultation with practitioners has occurred?

Q: Are we going to be given the option of an open discussion when we can openly talk back and forth and respond to the answers given - this meeting has not allowed this.

All three questions answered below:

A: UKAS will be setting up a further meeting with relevant professional bodies (AFSP, UKIAFT, LTG, RCPath, CSFS) to discuss any further queries in relation to the application of LAB 51, this will include an opportunity to highlight any specific issues, for example, casework toxicology.

Q: Why have Forensic Toxicology cases, where there is no legal limit specified (i.e. work outside Section 5A) been included within the scope of this document? Have you considered whether the requirements outlined in the document are fit for purpose for this type of work, and the impact it will have on providing this type of work i.e. the impact of increased cost for implementation and ongoing running costs which may affect viability?

A: The content of LAB 51 is not new, rather it provides specific interpretation and guidance for aspects of ISO/IEC 17025 and ISO 15189, the document therefore mirrors these standards. It is not intended to be specific to any one of the areas of toxicology but presents the underlying principles that will provide consistent quality of output, irrespective of the application of the results.

Q: Why has LAB 51 been made applicable to all toxicology sectors including workplace testing? LAB 51 appears to be written primarily to apply to Forensic laboratories (and specifically Section 5A road traffic testing) where for Criminal Law the burden of proof is beyond a reasonable doubt. It does not appear to take into consideration other sectors where toxicological analysis is undertaken e.g. in the Workplace sector where the burden of proof is on the balance of probabilities, or Drug Treatment, where drug identification alone is sufficient as the purpose of testing is to prove compliance and / or to signpost to appropriate support mechanisms.

A: The implication of unsatisfactory data quality can often be equally as life changing for cases heard in the civil courts as for those heard in the criminal court. The purpose of LAB 51 is to ensure that all analysis conducted in toxicology laboratories is to a technically appropriate standard and that users of the services of these laboratories can have confidence in the results produced.

Q: Why are ISO 15189 accredited laboratories offering workplace and forensic toxicology services, exempt from LAB 51? ISO/IEC 17025 laboratories may be disadvantaged by the additional accreditation requirements while customers may not be able to distinguish between identical toxicology services that are compliant or not compliant, to LAB 51?

A: ISO 15189 laboratories are not exempt from meeting the expectations of LAB 51 if they are conducting analysis that falls under the scope of the publication i.e. *'This publication has been prepared by UKAS and sets out how the requirements of ISO/IEC 17025,* ***ISO 15189****, ILAC G19 and UKAS shall be applied for organisations undertaking testing for drugs and drug metabolites in blood, urine, hair, oral fluids and other associated matrices for forensic, workplace, medical legal, or pathology (specialised toxicology) services'.*

Q: Post-mortem work appears to have been removed from the scope except where criminal investigation is the primary purpose of test request. Why is this? Coroners' cases may lead to criminal investigations as the case progresses and more information comes to light.

A: Post-mortem work is an area that remains under review to make sure we have targeted the right analyses to be included and/or excluded and that the complexities of this area of work are subject to the appropriate degree of scrutiny. LAB 51 will be subject to periodic review and this aspect will be considered at these times.

Q: Why was this removed from the scope but the remaining legal cases with non-specified limit have been left within scope?

A: All currently accredited analytical work that may affect results reported within either the civil or criminal courts has remained part of LAB51.

Q: Can you confirm if alcohol is exempt from LAB 51?

A: The analysis of alcohol is included within the scope of LAB 51, however, due to the history of this type of analysis there is already a large degree of consistency and compliance in the manner in which this is undertaken across the sector.

Q: If LAB 51 is just a clarification of ISO/IEC 17025 requirements then why is additional audit time required?

A: Routine UKAS assessments, by their nature, are sampling exercises where all aspects of the standards and all methods on the schedule of accreditation may not be reviewed at each assessment due to the allocated time available. Therefore, additional effort is required in the first instance to ensure that the expectations enshrined within LAB 51 have been applied to all of the methods / techniques, as appropriate, throughout each laboratory.

Q: In Scotland all post-mortem toxicology is considered necessary to determine cause of death. There is no initial distinction between "suspicious" and more routine. So, LAB 51 applies to all our casework, or none?

A: Since LAB 51 is providing clarification of the expectations to meet requirements of ISO/IEC 17025 and ISO 15189, if an organisation holds accreditation for a relevant activity, it would be best practice to apply the expectations of this document e.g. to all post-mortem work. However, at present UKAS have only included post-mortem work where criminal investigation is the primary purpose of the test request. within the scope of LAB 51. LAB 51 will be subject to periodic review and this aspect will be considered at these times.

Q: Are you expecting all laboratories to declare compliance with LAB 51 when providing evidence in court? If so, will non-compliance to LAB 51 be used to dismiss any provided toxicology results on all drugs/toxins stated on a submitted report, even if they were measured via methods compliant with ISO 15189 or ISO/IEC 17025?

A: LAB 51 is no different to any other UKAS LAB publication in that they support the relevant standard to which they apply. There is no expectation from UKAS that compliance to LAB 51 is included within any reports or evidence presented to court.

Q: What is the impact of not claiming compliance to LAB 51? Laboratories all around the world hold accreditation to ISO/IEC 17025 (without LAB 51) so can UK labs maintain accreditation to the unchanged standard and state that they do not claim compliance to LAB 51?

A: LAB 51 is a clarification of requirements for compliance to ISO/IEC 17025 Testing in the toxicology sector. UKAS will include compliance to LAB 51 within relevant assessments and will raise any findings, as appropriate, within the assessment framework. As with any other assessment all findings must be addressed in order for accreditation to maintained.

Q: How does this impact methods that are bespoke and not UKAS accredited - but we obviously state as a lab we are accredited to ISO/IEC 17025 etc. As long as we don't say those methods are accredited, are they exempt from LAB 51 requirements?

A: During assessments UKAS will only review compliance with ISO/IEC 17025 / ISO 15189 for methods that are on the schedule of accreditation (or applied for as an extension to scope) for that organisation. Therefore, compliance with LAB 51 (or ISO/IEC 17025 / ISO 15189) will not be reviewed for methods that are not on the schedule of accreditation (or applied for as an extension to scope). Accredited laboratories can only claim accreditation for methods that are within the accredited scope as defined on the schedule of accreditation and should make the accreditation status of a method clear to any customers that make a request for work.

Q: Why is the UK acting alone in changing the requirements for ISO/IEC 17025 accreditation. ISO/IEC 17025 is a global standard and UK based laboratories will have different accreditation requirements to other countries which may negatively impact on their competitiveness in a global market.

A: Issues within the toxicology sector are not restricted to the UK, for example, currently the USA are in consultation over a draft document related to toxicology analysis that is very similar to LAB 51, although it has been produced independently. All of the technical aspects of LAB 51 come within the remit of ISO/IEC 17025 or ISO 15189 Testing and merely provide a clear indication of those requirements in relation to laboratories accredited by UKAS.

Q: How can UKAS be the owner, accreditation body and dispute adjudicator for LAB 51? There appears to be no independent body involved to address dispute cases.

A: UKAS is the National Accreditation Body for the United Kingdom and a signatory to international recognition agreements and as such is subject to Peer Evaluation against the requirements of the International Standard for the operation of accreditation bodies (ISO/IEC 17011). UKAS also has processes for Complaints, Feedback and Appeals more detail of which can be found on our website www.ukas.com.

Q: The use of the word cut-off/critical concentration is not suitable for Toxicology work outside the Section 5A work. Can you confirm why it has been included for general toxicology?

A: All analyses, whether quantitative or qualitative, have a critical concentration otherwise the analysis would have no meaning. For qualitative methods, this is usually the concentration at which a presence/absence, detected/not detected is defined. Without knowledge of performance at these critical levels it cannot be determined whether the performance is satisfactory for the method's purpose.

Q: The "similar approach" being adopted in the US - are you aware of the transition timescales being applied? I understand this is over 12 months from initial release.

A: The accreditation infrastructure within the US is different from that within the UK. We understand that the timescales to be applied will be determined by the individual Accreditation Bodies.

Q: The transition period adopted to the change-over for ISO/IEC17025 from v.2005 to v.2017 was 18 months (January 2018 to June 2020). This was later extended to June 2021 under an ISO/ILAC communique dated 11 June 2020. If the transition period allowed for ISO/IEC17025 was 1.5 - 2.5 years (mostly requiring risk assessment and minimal analytical method revalidation), why has a transition period of 3 months been applied to LAB 51 – a new publication where adherence requires significant method re-validation for many operatives.

A: The timescales defined for the implementation of LAB 51 were set on the basis that the core expectations within the publication clarified the requirements within ISO/IEC 17025 an ISO 15189 and that therefore these had already been included within UKAS assessments as part of the review of compliance and as such it is not anticipated that there would be significant issues with demonstrating compliance.

Q: Why is it suggested that 'standards' should be swabbed? If you are swabbing the preparation area where standards are made this should not be required?

A: The laboratory has to demonstrate the suitability of its environmental monitoring strategy – there is no requirement to swab standards. Planned environmental swabbing should include areas where the potential for contamination is present (e.g. standard preparation areas; storage areas of samples; extraction equipment).

General questions relating to Calibration

The following questions were asked during the webinar in relation to Calibration. Answers to these can be found below each set of questions.

Q: HS-GC/FID for the analysis of Alcohol (3.3) - This section stipulates matrix-matches calibrators must be used – this is the case for all test methods used within our laboratory except for alcohol (ethanol). Please can you clarify if the use of aqueous calibrators for alcohol (ethanol) will be considered acceptable, if matrix-matched blood and urine QCs are used?

A: Whilst matrix matching is preferred for calibrators [and is essential for validation samples] this section does not preclude other solutions for calibration preparation where justified and used throughout the validation experiments.

Q: Presumptive Screening (3.4) vs Confirmatory Analyses (3.5) Definitions (13)

A: Presumptive screening covers qualitative analyses such as ELISA, or initial Chromatographic identification. Confirmatory analysis is where the drug presence is confirmed by a secondary analytical method such as MS with qualifier ion identification.

Q: Can you explain why there is reference to a full calibration requirement for screening - if it is just a screen then why is a full calibration required - it becomes a quantification then. Q: How does that apply to purchased commercial kits that only have one cal standard e.g. immunoassay? Q: What is meant by a full calibration for instrumental presumptive screening procedures?

A: This is a calibration across the range in use to ensure that the critical level of interest remains within the instrumental range of applicability.

Q: For confirmation methods - why do you need 3 calibration points? What is wrong with one point and independent checks with QCs standards? It is fit for purpose for reporting as Detected or an estimated concentration.

A: Qualitative analysis defines potential presence; confirmation analyses define presence with the lowest possible chance of a false positive. When confirming a qualitative result is above or below the cut-off/critical level of interest then the measurement uncertainty of this identification needs to be suitable for this purpose.

Q: What is the justification for no more than 20% of calibrators removed? Q: The original document read at least 4 calibrators should remain...? Q: What about if you have 7 calibrators? Can you remove two and still have the 5 required but more than 20%?

A: In order to ensure that sufficient calibrators remain to provide a robust calibration curve fit. Removal of multiple points from a calibration, that was originally defined by many points, would suggest that there is an underlying issue with the calibration.

Q: Reporting of results >ULOQ (3.6) This section stipulates that results >ULOQ shall be reported as >ULOQ or diluted to fall within the calibration range. Would it be considered acceptable, on occasion, to justify reporting a concentration >ULOQ?

For example, post-mortem blood alcohol concentration (BAC) >500 mg/100mL, estimating at 510 mg/100mL, which is within measurement uncertainty for test method. More error could be generated by repeating analysis than reporting original result.

A: This approach is not precluded but would require clarification with the customer regarding Measurement Uncertainty at concentrations >ULOQ.

Q: 3.6 The methods should be fit for purpose and how the end user is using the results. If an approximate value is required - a smaller number of points is fit for purpose. Please can we request further justification for this to provide full context?

A: What is meant by an 'approximate value'? This is just a value with a higher level of UoM and if a quantitative value is reported, then calibration is required

Q: Does your QC not do the job of the calibration check standard?

Q: Is a calibration check standard not a QC?

Q: With regards to the calibration check standard, are you expecting this in addition to Quality Control Standards that are run at the end of an instrument sequence?

Q: If QC samples are run at beginning, middle and end of batch can these not be used to show there has been no calibration drift? In this case a calibration check standard would be excessive.

Q: If the QC samples that are run at the beginning of the batch are also run at the end of the batch, can these be used to assess the calibration drift instead of running an extra calibration check standard?

Q: Please can UKAS clarify for what test method types these 'calibration check standards' are expected to be used. Is their use expected for quantitative analysis where the calibration is used for more than one batch of samples? If so, are these expected to be used in addition to QCs? At what concentration point on curve? From same source as Calibrators or QCs? Etc.

Q: What is a calibration check standard - does this refer to a Quality Control standard?

Q: What is meant by the term calibration check standards? Is this Quality Controls run alongside the batch of samples?

Q: 'Calibration check standards' to me is still unclear - the terminology defines them as 'calibrants' - are they included in the calibration curve or not? Or are they effectively just QCs? If we run calibration curves at beginning and end of a batch, does that not cover drift?

A: A calibration check standard is analysed to confirm the continuing suitability of the current calibration curve e.g. to check for drift during an analytical batch (calibration standards are not always matrix matched). An internal QC sample is generally an independent spiked sample or reference sample that has gone through the whole analytical process and is reflective of the sample analyses undertaken. If the QC samples mirror the calibration standard in matrix then these could be a substitute for the calibration check at the end of the run (Note: these would need plotting however on the relevant QC chart).

Q: There is a requirement to specify acceptance criteria for ion source parameters. The ion source parameters are within the instrument method, and do not have such 'acceptance criteria' - if the ion source parameters are not reached, the method should not run..?

A: These acceptance criteria are set by the laboratory and are normally recorded on instrument tune reports where the acceptance criteria are stated. If the defined acceptance criteria are not met, then the laboratory should investigate the root cause of the lack of compliance and take appropriate action, this may include not running the method.

Q: RE ion source parameters: MS tuning (m/z tuning) does not include ion source parameters. If an ESI source setting is, say, 4,000 V, then when the method runs, the instrument should only acquire data when this ions source setting is reached. Does 3.9 not currently read that the lab should provide 'acceptance criteria' for this setting, say 3,800-4,200 V? Note, these settings might be very different from the ion source settings used for the instrument calibration standard/mix.

A: Yes - these acceptance criteria are set by the laboratory and are normally recorded on instrument tune reports where the acceptance criteria are stated.

Q: Minor one - Selected Reaction Monitoring vs Multiple Reaction Monitoring. SRM is used by one vendor, MRM by most others.

A: We appreciate the similarity and will review to include both as necessary.

Q: 3.11 For 'system suitability checks' please can UKAS clarify what level of trend monitoring is expected and for what parameters of the check? Do UKAS expect the use of something like Shewhart charts for on-going monitoring?

A: The trending of system checks is a tool to identify whether the system is showing signs of deterioration which can be halted by pre-emptive maintenance. The tools used for this trending are for the laboratory to select and define as there are many possible ways that this can be done.

Q: Validation Experiments – Frequency (6.7) This section stipulates that 10 degrees of freedom for each validation exercise should be obtained using data produced from at least five batches analysed on separate days. Do UKAS expect this number of days for parameters such as Recovery and Matrix Effects? Or does this just refer to parameters such as Precision/Bias etc.

A: The actual validation exercises are defined by the laboratory, but precision/bias and subsequent calculations of measurement uncertainty are to be defined with a minimum of 10 degrees of freedom to provide a robust approach to the exercise undertaken.

Q: 6.6.5/6.6.6 - Matrix effect and recovery - why are these validation parameters necessary? What will this experiment add to the overall fitness for purpose of the method, if the sensitivity, accuracy and precision is robust and fit for purpose, as demonstrated throughout validation?

A: Matrix effect and recovery are essential tools within development of robust methodologies as recognised in many published reference documents. They are also expectations listed within the Forensic Science Regulators Codes of Practice. They provide an indication that the method is sound and providing sufficient sensitivity to provide the required performance that has been specified in the validation plan.

Q: 6.10 - This refers to the maximum value of the limit of detection usually regarded as being fit for purpose is 10% of the concentration of the critical level of interest or cut-off value and ideally the lower limit of quantification should be at least three times the LoD. Can you confirm that where this isn't possible, the current acceptable validation will be acceptable (i.e. for drugs like THC, LSD)?

A: The text in LAB 51 indicates that this is the 'usually' accepted demonstration of fitness for purpose. It is for the laboratory to review the data generated during the validation and to review this in terms of the purpose of the method and the user requirements and therefore to justify fitness for purpose.

Q: 6.3 - Full details of the method and method validation procedures shall be made available to the customer if requested is listed as a requirement. Why do you think full method details are needed by the customer and has commercial confidentiality been considered?

A: This information is only provided on request from the customer for clarification purposes. The information provided shall be such that the customer can evaluate if the method

validation process and outcome is suitable for the sample matrix that they wish to have analysed; this can be provided with due regard for commercial confidentiality, for example, in summary form.

Q: 6.6.12 - Please confirm whether you consider acceptable QCs run in each batch as evidence of 'Derivatisation Efficiency'?

A: Yes - as long as they have been hydrolysed/derivatised in a similar fashion to the samples.

Q: 7.0 - Why is this necessary to be included for ISO/IEC 17025 when the scope is outside the control of the laboratory and all scenarios cannot be investigated?

A: The laboratory needs sufficient information to be able to provide guidance to customers on the method of provision of samples in order to minimise degradation or potential contamination of samples prior to receipt. This is also required in order to identify any deviating sample (see UKAS Publication TPS 63 UKAS Policy on Deviating Samples).

Q: 7.3 - This is not easily applicable to actual post-mortem material that could be compromised due to a number of factors pre-analysis (i.e. bacterial contamination). Stability freeze/thaw studies are difficult to perform on post-mortem material that is subject to the Human Tissue Act.

A: It is stated within 7.2 that where these are not possible (e.g. post-mortem samples) an appropriate substitute biological matrix can be used wherever possible.

Q: 8.3 - This should provide an audit trail that can trace the changes made to the individual analyst responsible for the change. These changes shall be subsequently authorised prior to release of sample data for final reporting. Can it be confirmed that a data process and data checker fulfils this requirement and that if a data checker amends something - this doesn't require further authorisation?

A: Yes; where these are documented.

Q: Why is there a requirement for an annual statistical review of Quality Control data to provide an on-going estimate of the method precision for each accredited drug / matrix combination? Why is this necessary to be included for ISO17025 when the scope is outside the control of the laboratory and all scenarios cannot be investigated? Have the implications of this change been fully considered i.e. what would be the mechanism to respond to a significant change if identified at review?

A: This is to ensure that the on-going measurement uncertainty has not changed significantly since validation was conducted and that the method remains fit for purpose. Where significant change is noted these would be investigated on a case-by-case basis for cause of the change and whether this is acceptable and whether the method remains fit for use.

Q: Critical Levels of Interest / Cut-Offs and Measurement Uncertainty - For post-mortem toxicology, please can UKAS clarify at what points the

measurement uncertainty (MU) is expected to be calculated for quantitative analyses. The LOD, LLOQ and ULOQ are decision points in the assay, but are not critical levels of interest for the case work. Do UKAS expect the MU to be calculated at all three points?

A: The calibration line will define the concentrations of interest in these cases, with initial measurement uncertainty at the LLOQ and at the concentration where results are anticipated (usually defined as 50-75% of the calibration range and is the concentration that is also used for quality control purposes).

Q: 10.7 - Suggestion of infrequent methods employing a greater degree of QC with each sample batch is unrealistic.

A: Even if a method is run infrequently it must still be demonstrably reliable and therefore a robust and appropriate QC regime must be in place. See TPS 68 UKAS Policy on Accreditation of Infrequently Performed Conformity Assessment Activities for further information. Additionally, ILAC G19:08/2014 Modules in a Forensic Science Process refers to the use of infrequently performed tests in 3.10.

Q: Why are target control limits not acceptable for infrequent analyses as recommended by Nordtest?

A: 'Infrequent analysis' is open to interpretation, but where less than 20 QC data sets are available across a year then the on-going validity of the method may require justification on an "as used" basis (see ILAC G19:08/2014 Modules in a Forensic Science Process 3.10 in relation to infrequently performed tests).

Q: 10.9 - F test and T test comparisons? Is this advice from a statistician?

A: Yes, there is published reference documentation that use F and T tests for such comparison.

Q: We are interested on the application of Westgard rules. Westgard were elaborated for automated chemistry applications, focussing on single analytical runs with its usefulness and applicability relevant to pathology laboratories where acceptable total allowable error are significantly lower in comparison to those in hair testing. The single Westgard rule is widely accepted as best applicable when commercially available QCs with long term stability are monitored and they are independently prepared. This is not the case considering the biological variance of testing drugs in hair is high due to the fact that there are many factors that affect drug levels in hair samples (such as composition of the hair, hair colour, metabolism, cosmetic hair treatment, sun exposure etc...). In our opinion and experience, multiple rules rather than a single strict single rule, would be more appropriate and would not inflate the numbers of rejections of acceptable data.

Q: Westgard rules are relevant to acceptable Total Error. The strict single rule will be not in harmony. Yes, maybe for blood or oral fluid, but lots of acceptable data will be thrown out. There are paper regarding derived Westgard rules that will be in harmony with hair testing.

A: LAB 51 indicates that procedures shall be based on recognised statistical models such as Westgard Rules or the NORDTEST Handbook to provide guidance on statistical control of the analytical process for varying matrices. These are recognised throughout analytical industries as valid rules for identifying loss of statistical control, which would reflect on the validity of results reported.

Q: 11.4 - Can you please clarify what is meant by the following: The decision rule shall consider the level of risk associated with the decision rule employed and apply this to the result (where the decision rule is prescribed by regulation a further consideration of the level of risk is not necessary).

A: Decision Rules are required by ISO/IEC 17025:2017 and ILAC G8 and, where not specified within regulation, are to be defined and applied to the result to take into consideration the risk associated within the decision rule. For further information see UKAS Publication LAB 48 Decision Rules and Statements of Conformity.

General questions: LAB 51 Timeline to Implementation

The following questions were asked during the webinar in relation to LAB 51 Timeline to Implementation. Answers to these can be found at the end of each section.

Q: Why is the current compliance timeline so short? The August timeframe is unrealistic and UKAS's approach to this document release is very different to that taken for ISO 17025:2017 transition where sufficient time was allocated with support from UKAS via training events etc.

Q: Could you please explain the urgency behind the process and the short response timeframes associated with each step?

Q: Apologies for revisiting but please can I ask if by stating LAB 51 is ISO/IEC 17025 reiterated that it appears to give specifics to the standard to be achieved as opposed to allowing the provider to apply ISO/IEC 17025 as a standard.

Q: I'm concerned about the number of GAPs we have identified and the time allowed to complete them. Considering I thought we were complying with ISO/IEC 17025. It is the considerable additional resource required at this already stretched time which is a concern.

Q: I think we're all concerned, particularly those operating within the CJS, of ensuring compliance with what is and feels by most, a very tight deadline. We all fully embrace and welcome this proactive change to mitigate against future quality issues/failures, but it does add significant burden on a sector which is already under strain.

Q: The assumption that it will have no impact is incorrect. We have UKAS accredited methods that are fit for purpose however are not compliant with LAB 51 - particularly for casework toxicology. These issues have never been raised at previous audits.

Q: We welcome answers to all the questions, but whilst we wait for this document surely the timeframes should be put on hold, otherwise it's just shortening the time labs have to try and comply?

Q: Do UKAS feel there is a risk that laboratories will move away from offering a full range of accredited analyses due to the implications of LAB 51 and therefore posing a potential risk to the CJS by labs operating outside of accreditation?

Q: I understand you will do a review in a few months however if labs need to become compliant in September then they need to spend resource on this now. If this is then to change in a few months this is a waste of critical marketplace resource at a time when the risk to the marketplace is significant.

Q: My assessment of the meeting is that FSPs see the value of this work in managing risk to the CJS and are supportive. However, it is the consultation exercise and implementation timescales that are the challenges being made to UKAS, which perhaps need some reflection.

Q: Why wasn't there any opportunity to respond or discuss the changes added to the version of the document that was released?"

Q: How have you assessed the impact of both the requirements and the timeline on the marketplace - in terms of service provision.

Q: With the short implementation date, how will a meeting with the professional bodies, which may result in some amendments be reflected in the document?

Q: Current casework capacity is being impacted by the LAB 51 change. FSP's are having to divert expertise to review the gap analysis. This is at a time when forensic toxicology capacity is already constrained. Hence policing and the CJS are being impacted now by this change.

Q: Can you detail how exactly you have assessed impact of implementation of LAB 51 and how you have defined the timeline based on that assessment - are you expecting capacity to be lost from the marketplace as implementation is completed?

Q: The impacts will have been realised prior to the review period - has that been taken into account?

A: As discussed within the webinar it is pertinent to reflect on the reasons that led to the introduction of LAB 51. UKAS completed a review of toxicology providers in 2018, that was prompted by significant data integrity issues within the toxicology sector. This review identified a number of recommendations to take forward. One of which was to create a document to be used by UKAS Technical Assessors to ensure consistency and rigour within our assessments of toxicology laboratories. Unfortunately, since our initial review further data integrity issues and quality incidents have been escalated to UKAS by providers in the sector, some of which have led to cases being withdrawn or adjourned within the Criminal Justice System. Therefore, the decision was made to publish the existing guidance used by our Technical Assessors into the public domain to allow the organisations within the sector to proactively review their methods / process for compliance with the UKAS expectations in areas such as validation, quality control, system suitability and batch acceptance and if required make the necessary changes to drive the necessary improvement within the sector.

It is evident that there is a need for a consistent approach to toxicology analyses throughout the sector to give confidence in the results reported, which may have significant consequences for the donors of those samples. It is imperative that results reported within this sector can be relied upon and cannot be subject to technical challenge once released. It is essential that this document was issued as soon as possible, however, as with any UKAS document, periodic reviews will take place and any identified changes will be made as and when required. Due to the nature of this publication the first formal review of the document is scheduled for 6 months from the date of issue.

Q: You say flexibility in timescales but expect us to sign a compliance document which we can't sign, knowing we don't currently comply. I think this is why people are asking what happens if they don't sign and don't submit it.

A: Where an organisation identifies through their Gap Analysis that they are not as yet fully compliant with LAB 51 they should not sign the Declaration of Compliance. In these instances, the laboratory should contact their Assessment Manager who can set up a short meeting to discuss the potential gaps and significance of these and identify a suitable way forward.

Q: Glad to see recognition of the requirement for flexibility in timeframes but the timeline of implementation seems set in stone despite more meetings that may take place which could impact on the content of the document. Q: So do we do that with our assessment managers? Q: If the gap assessment identifies remediation work that will take months how can a lab sign the compliance statement by the end of August? Q: You say flexibility in timescales but expect us to sign a compliance document which we can't sign, knowing we don't currently comply. I think this is why people are asking what happens if they don't sign and don't submit it.

A: Where this may be the case the laboratory is requested to discuss this with their Assessment Manager who can set up a short meeting to discuss the potential gaps and significance of these.

Q: Are UKAS inferring anything from the volume of feedback received?

A: UKAS appreciated the level of feedback received and the desire within the industry to apply the principles within LAB51.