Forensic Science Regulator

Overseeing Quality

Forensic Science Regulator Codes of Practice and Conduct

The Analysis and Reporting of Whole Blood Specimens in Relation to s5A Road Traffic Act 1988 (Drug Driving)

FSR-C-133

Issue 5

1. Introduction

1.1.1 This document is published by the Forensic Science Regulator to establish the requirements for, and a common approach to, the analysis and reporting of the concentrations of certain drugs in relation to offences under s5A Road Traffic Act 1988 (drug driving).

1.1.2 The requirements and approach set out in this document have been established after discussions with the following.

a. The Home Office.
b. The Department for Transport.
c. The Crown Prosecution Service.
d. The United Kingdom and Ireland Association of Forensic Toxicologists.
e. Forensic units delivering analytical services for the s5A offence.
f. United Kingdom Accreditation Service.

1.1.3 At the time the drafting of this document was initiated the s5A offence was not operational in Scotland or Northern Ireland. [1] However, the approach contained within this document was discussed with the devolved authorities and forensic science providers in those jurisdictions with the aim of ensuring, should the legislation become operational, a level of consistency.

1.1.4 At the point of implementation of the s5A offence the Home Office, in conjunction with the Department for Transport, issued a specification for those undertaking this form of analysis at the instruction of the police or a prosecuting authority in England and Wales. This document does not replace or detract from the requirements set out in the specification for work done in England and Wales.

[1] The Road Traffic Act 1988 covers the United Kingdom but the provisions of s5A were initially brought into effect for England and Wales only. See the Crime and Courts Act 2013 (Commencement No. 1) (England and Wales) Order 2014. They were subsequently brought into effect in Scotland by The Crime and Courts Act 2013 (Commencement No. 1) (Scotland) Order 2018.

2. Scope

2.1.1 This document applies to analysis of whole blood [2] samples where the results may be employed for a prosecution of an offence under s5A Road Traffic Act 1988 in England or Wales. This relates to the offence of drug driving.

2.1.2 In this document the term 'prosecution of an offence' includes those acting for the prosecution and the defence.

3. Implementation

3.1.1 This version of the document is effective as of 1 December 2021.

4. Modification

4.1.1 Issue 5 is a significant re-write and, as a result, changes from the previous version are not marked.

4.1.2 The modifications made to create Issue 5 of this document were to ensure compliance with The Public Sector Bodies (Websites and Mobile Applications) (No. 2) Accessibility Regulations 2018.

4.1.3 The Regulator uses an identification system for all documents. In the normal sequence of documents this identifier is of the form 'FSR-#-###' where (a) the '#' indicates a letter to describe the type or document and (b) '###' indicates a numerical, or alphanumerical, code to identify the document. For example, the Codes are FSR-C-100. Combined with the issue number this ensures each document is uniquely identified.

4.1.4 In some cases, it may be necessary to publish a modified version of a document (e.g. a version in a different language). In such cases the modified version will have an additional letter at the end of the unique identifier. The identifier thus becoming FSR-#-####.

4.1.5 In all cases the normal document, bearing the identifier FSR-#-###, is to be taken as the definitive version of the document. In the event of any discrepancy

[2] Although s5A Road Traffic Act 1988 refers to both blood and urine the Regulations made under the Act only set limits for blood. As a consequence, this document has been drafted to deal only with the analysis of blood.

between the normal version and a modified version the text of the normal version shall prevail.

5. Provisions

5.1 Legal Position

5.1.1 Section 56 of the Crime and Courts Act 2013 inserted a new s5A into the Road Traffic Act 1988. Section 5A makes it an offence for a person to drive, attempt to drive or be in charge of a motor vehicle while the concentration of certain drugs in the person's blood or urine is above a specified limit.

5.1.2 The limits (in whole blood) for sixteen drugs were established by The Drug Driving (Specified Limits) (England and Wales) Regulations 2014 [SI 2868 of 2014]. [3] These Regulations were subsequently modified by The Drug Driving (Specified Limits) (England and Wales) (Amendment) Regulations 2015 [SI 911 of 2015] to create a limit for amphetamine. [4]

5.2 Legal Requirements

5.2.1 The s5A offence is relatively new and, at the time of production of this document, there were no appellate judgments dealing with the analytical aspects of this offence. However, the s5A offence mirrors the wording of the longstanding s5 offence (the equivalent drink driving offence) and there have been a number of judgments in relation to that offence.

5.2.2 The judgments in relation to the s5 offence include the following.

a. R. v. Coomaraswamy; Court of Appeal (Criminal Division); (1976) 62 Cr. App. R. 80; [1976] R.T.R 21; [1976] Crim. L.R. 260.
b. Thomas v. Henderson; Queen's Bench Division; [1983] R.T.R. 293.
c. Gordon v. Thorpe; Queen's Bench Divisional Court; [1986] R.T.R 358; Crim. L.R. 61.

3 These Regulations came into effect on 2nd March 2015.

4 These Regulations came into effect on 14th April 2015.

5.2.3 The position set out in these cases is that the prosecution does not have to prove a particular concentration of alcohol in the blood but does have to prove the concentration was above the legal limit.

5.2.4 The approach adopted assumes this is also the position for the offence under s5A.

5.3 Home Office Specification

5.3.1 The Home Office, in conjunction with the Department for Transport, issued a specification for the analysis of blood in relation to s5A when it is undertaken at the instruction of the police or prosecuting authorities in England and Wales. This document does not replace or detract from the specification in relation to work done in England and Wales.

5.4 Terminology

5.4.1 The analytical method is required to report the concentration of a drug in a sample as the mean of the result of a number of analyses. To ensure clarity the term ‘standard deviation’ shall mean the standard deviation derived using the results of the individual analyses or on the basis of reporting individual analyses. The term ‘standard deviation of the mean’ (SDM) shall mean the standard deviation calculated using the mean of the results of multiple analyses as the reported result for a sample or on the basis that the reported result will be the mean of multiple analyses. In some texts the SDM is referred to as the ‘standard error’ or the ‘standard error of the mean’.

5.5 Sample Storage

5.5.1 The drugs covered by the s5A offence may be subject to degradation over time. The forensic unit shall use storage methods which demonstrably minimise such degradation.

5.5.2 The forensic unit should consider the storage of samples prior to submission and may advise whether analysis is likely to be worthwhile; and may provide customers with advice as to how to store samples to maintain their integrity for analysis.

5.6 Requirements for Analysis

5.6.1 Any forensic unit undertaking analysis of whole blood where the results may be used for a prosecution under s5A Road Traffic Act 1988 shall meet the following requirements.

Quality Standards etc.

5.6.2 The forensic unit shall maintain the following standards.

a. It shall be accredited to:

   i. ISO/IEC 17025 [1] with the additional requirements set out in the Codes of Practice and Conduct [2]; or

   ii. ISO 15189 [3] with the additional requirements set out in the Codes of Practice and Conduct [2].

b. The analysis of whole blood samples for s5A Road Traffic Act 1988 shall be specifically listed in the scope of accreditation.

c. A forensic unit should have the drugs it analyses for in relation to s5A listed in the relevant section of its scope within 18 months of the later of (a) this document coming into effect or (b) a limit being established for that drug in the jurisdiction within which the laboratory operates. [5] [6]

d. The forensic unit shall comply with the provisions of this document in relation to all drugs analysed for the purposes of section 5A regardless of whether they are listed in the schedule of accreditation.

e. It shall comply with the Codes of Practice and Conduct [2].

5.6.3 The forensic unit should consider the guidance on general forensic toxicology issued by the United Kingdom and Ireland Association of Forensic Toxicologists (UKIAFT) [4] in developing analytical processes. Compliance with this guidance is not mandatory and its contents do not override the requirements of the Codes of Practice and Conduct [2] or the United Kingdom Accreditation Service (UKAS).

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5 The date on which limits were first established for each drug are provided in Annex A.

6 The forensic unit is responsible for ensuring those commissioning its services in relation to s5A are aware of the drugs which will be analysed for either in general or in any sample where the general provisions are not applicable.

Environmental Requirements

5.6.4 The following environmental requirements shall be addressed.

a. Analysis for the purpose of s5A shall be conducted separately from work involving bulk drugs. This means that bulk drug cases shall not be conducted in the same laboratory or analytical batch as s5A analysis.

b. Analysis of samples for the purpose of s5A casework shall be conducted separately, in terms of both space and analytical batch, from batches of other toxicological case work (other than s5A or s4) that may contain high levels of drugs (for example suspected overdose cases in post mortem casework). Separation may be achieved by management of space employed to ensure the risk of contamination is minimised by separating work in time and carrying out appropriate environmental checks.

c. Environmental monitoring shall be conducted to determine the presence and approximate level of any drugs being tested for in relation to s5A in the laboratory in which the sample preparation and analysis are undertaken, in particular for cocaine, amphetamine and methylamphetamine. This should include the use of the matrix blank samples. The appearance of a drug in a sample (e.g. QC sample or blank) where that drug should not have been present will also be monitored. The presence of a drug in a solvent blank where that drug was present in the case sample analysed immediately before the solvent blank will be taken to be the result of carry over as opposed to contamination.

d. The data produced by environmental monitoring shall be reviewed to ensure the level, if any, of drugs in the environment is managed.

Analytical Requirements

5.6.5 The analytical method shall, for each drug the laboratory analyses in relation to a potential s5A offence, achieve the following requirements.

a. The analysis shall be sufficiently specific for each drug such that the results can be relied on as measuring the concentration of the drug.

b. The analytical method shall ensure the results can be attributed to the sample from which they are believed to come from. This will include

procedures to ensure traceability as well as address the potential for carry over.

c. To protect against the risk of carry over a solvent blank shall, subject to the following point, be run before each case sample and the results from this blank shall not show the presence of any relevant drugs. This requirement will not require a solvent blank between two case samples where they are aliquots from the same case sample.

d. The forensic unit shall have a policy on the nature and frequency of the calibration of the method to ensure the results are robust.

e. For any part of the analysis employing a chromatographic method the forensic unit:

   i. Shall ensure that QCs are extracted and analysed alongside the case samples which will form the batch to check that the instrument calibration is still valid;

   ii. Shall ensure that data points generated from calibrators are only omitted from the generation of the 'calibration curve' in exceptional circumstances and if this is allowed by an in-house policy on identification of 'outliers' which complies with UKAS LAB 51 [5];

   iii. Shall ensure any omission of calibration data from the generation of the 'calibration curve' is justified and recorded;

   iv. Shall have requirements for an acceptable 'calibration curve' which implement the requirements of UKAS LAB 51 [5];

   v. Shall ensure manual integration of peaks is only undertaken as allowed by an in-house policy, which is scientifically justified and applied consistently through a batch; [7]

   vi. Shall ensure manual integration of peaks is recorded and justified; and

   vii. Where manual integration has been used on a case sample and this has caused the result to be reported as over the legal limit, where

[7] Manual integration of a peak shall not be undertaken solely to ensure an MRM ratio passes or to improve the calibration curve (i.e. R2 value).

this would not have happened without the use of manual integration, this must be made clear when the results are reported.

f. For any part of the analysis employing a mass spectroscopic method the forensic unit shall have a policy on the acceptable ion ratios in calibrators, QC and case samples.

   i. This policy should, subject to the point below, be based on the guidelines issued by World Anti-Doping Agency (WADA) [6].

   ii. The forensic unit may have an in-house policy setting out the acceptable results for peaks above the ULOQ which deviates from the WADA guidance.

g. Subject to 5.7 below, a blank human blood sample (which is analysed through the whole extraction alongside case work) must be run on each analytical batch. For each drug being analysed the concentration must be less than the LOD. [8]

h. The method shall involve monitoring for analytical results which suggest there may have been a contamination event (e.g. the presence of cocaine without BZE or drugs appearing where not expected).

i. The reported result of the method [9] shall be the mean of the analysis of at least two aliquots from the sample. There shall be at least two results generated from separate extraction (i.e. the extraction of at least two aliquots) and analysis of aliquots taken from the sample. This requirement applies to case samples and all QC samples.

j. For the mean of a number of analytical results to be acceptable all of the analytical results (i.e. drug concentrations in any case sample, calibrator or QC) shall be in the range ±20% of the mean. [10] Forensic units may adopt alternative approaches so long as they do not allow a greater difference from the mean.

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8 Forensic units may wish to consider the use of blank composed of a blood samples ‘spiked’ with the internal standard as well.

9 The term “reported result of the method” shall be used to refer to the final output of the analytical method (normally the mean of a number of analyses) which will be used to calculate the “not less than” figure.

10 The use of a ±20% check is a safeguard based on current practice. Given the uncertainty of measurement of the methods the fact that two analytical results are >20% from the mean does not, by itself, indicate any problem with the analysis.

k. For each drug the analytical method shall achieve the following.

i. It shall have a lower limit of quantification (LLOQ) at a concentration equal to or lower than half of the legal limit.

ii. It shall, subject to point iii, have an upper limit of quantification (ULOQ) at a concentration at least 25% higher than the Common Reporting Threshold (CRT) (see below).

iii. For Diazepam, Flunitrazepam, Lorazepam, Oxazepam and Temazepam (where the sample and QCs may require dilution to bring them within the calibration range) the forensic unit shall have a ULOQ appropriate to the method used.

iv. It shall use data points for calibration which ensure the calibration curve is optimised over the range of interest (that being from the LLOQ to the ULOQ).

v. The acceptable range of recovery of the internal standard shall be determined. During the validation of the method the forensic unit shall determine the range of recovery of the internal standard (as applied on a batch basis) over which the method is reliable and, in particular, over which the uncertainty of measurement requirements in this document can be achieved.

vi. It shall have a relative bias (the correct term may be trueness but the term bias is routinely used in the field) of less than 20%. [11] [12]

vii. It shall have the bias monitored on a regular basis (that being at least every three months).

viii. The method shall, subject to 5.6.7, ensure the correction of any positive bias, but negative bias shall not be corrected. [13]

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11 The bias of the method cannot be determined from a single batch so the bias shall be determined as part of the validation or specific study.

12 There are approaches to dealing with bias which allow it to be addressed as part of the determination of the uncertainty of measurement.

13 In normal analytical methods bias would be corrected regardless of whether it was positive or negative. In this area correction of negative bias would involve increasing the analytical results which is not considered appropriate.

l. The forensic unit shall be able to achieve the uncertainty of measurement requirements set out in 5.9.19 and 5.9.23 below. These requirements shall be maintained in routine work.

5.6.6 The forensic unit shall, for each drug, establish the uncertainty of measurement in a manner consistent with accepted guidance [7] [8] and accounting for all variables which may affect the results (e.g. different operators, analysis in different batches, analysis on different dates).

5.6.7 If a forensic unit has an uncertainty of measurement which is lower than the Forensic Science Regulator Expanded Uncertainty (FSREU) and the correction for bias and deduction of the forensic unit's uncertainty of measurement would lead to a 'Not Less than Figure' (NLTF) equal to or higher than that created by deducting the FSREU there shall be no correction for bias.

Positive Quality Control

5.6.8 The forensic unit shall undertake ongoing quality control monitoring using, subject to 5.7 below, human blood spiked at the critical drug driving limits for each drug. The results shall be trended in an appropriate manner (which is a Shewhart Chart) and subjected to suitable statistical rules (e.g. the Westgard Rules) for action. Results shall only be reported as valid if obtained while the method is under control.

5.6.9 The quality control monitoring shall use sufficient QC samples, at suitable concentrations, in each batch to ensure the reliability of results can be assured. Forensic units should use a level of QC samples of at least 5% of the samples in the batch.

5.6.10 To be considered reliable each casework must be 'bracketed' by acceptable QC results. To be acceptable the QC samples before and after the sample (with concentrations above and below the analytical results for the case sample – where these exist) are valid.

5.6.11 The quality control matrix will, subject to 5.7 below, use human blood. The drugs will be spiked into this matrix at the legal limits for each drug.

5.6.12 The quality control data shall be plotted on a Shewhart chart with statistically derived control limits. The standard deviation or standard deviation of the mean

used for the control lines will be derived from statistical analysis of QC data (a minimum of 20 data points, excluding outliers) for set up of preliminary quality control chart limit monitoring purposes.

5.6.13 The control lines for the warning limits shall be derived using the mean of the QC data and:

a. Where the QC results are plotted as individual analytical results; ±2 standard deviations of the forensic unit's method; or
b. Where the QC results are plotted as the mean of analytical results ±2 standard deviations of the mean of the forensic unit's method.

5.6.14 The control lines for the action limit shall be derived from the mean of the QC data and:

a. Where the QC results are plotted as individual analytical results; ±3 standard deviations of the forensic unit's method; or
b. Where the QC results are plotted as the mean of analytical results; ±3 standard deviations of the mean of the forensic unit's method.

5.6.15 An appropriate investigation, the nature of which is to be determined by the forensic unit, shall be carried out and corrective action taken, where relevant, when any 1 point exceeds the action limit.

5.6.16 An appropriate investigation, the nature of which is to be determined by the forensic unit, shall be carried out (or comment made on the case file if not detrimental to the CJS) and corrective action taken when 2 consecutive points are between the warning and the action limits.

5.6.17 The forensic unit shall establish rules for the monitoring of trends in the QC data (for example, an appropriate investigation to be carried out when 9 consecutive points fall on one side of the mean, 6 consecutive increasing points, or 6 consecutive decreasing points).

5.6.18 The forensic unit shall review the QC data and re-establish the mean, warning and action limits from the QC data once 60 data points have been obtained to set up initial limits. [14] The data on the charts shall be reviewed thereafter at

[14] This means that the preliminary values established at the point of validation shall be reviewed and updated in light of casework use.

intervals of no more than three months and the data on the charts statistically compared to that data used to establish these initial limits. Where there is a statistically significant difference, [15] or other reason such as a new QC standard being used or the instrument requiring cleaning, between the latest set of QC data and the initial set of data, the limits shall be reset. The new values shall apply only to analyses after resetting of the values.

5.6.19 Where the monitoring indicates the laboratory is no longer complying with the requirements in relation to uncertainty (see 5.6.5) work shall stop. A non-conforming work investigation shall be carried out and corrective action shall be taken to return the method to control.

5.6.20 Where a new lot of a certified reference material (CRM) is introduced it shall be compared, by experiment, against the existing CRM to determine whether there might be a change in the operation of the method.

5.7 Human Blood

5.7.1 The requirements in the section above requiring the use of human blood shall not apply where:

a. There are exceptional circumstances making the use of human blood impractical;
b. The method involving the use of non-human blood is fully validated; and
c. UKAS has accepted that the method using non-human blood is acceptable.

5.7.2 The use of non-human blood shall only continue for so long as the exceptional circumstances require it.

5.8 Contamination

5.8.1 Analysis for the purpose of s5A can involve detection and quantification of low concentrations of drugs. Further, even low levels of contamination could have an impact on a case.

[15] This would typically be done by using F [precision] and Student's t [bias] statistical tests.

5.8.2 Forensic units shall monitor for potential contamination events. Examples include, but are not limited to, drugs appearing in blanks, drugs appearing in calibrators or reference material which should not include them and unlikely results such as the presence of cocaine without its metabolite BZE.

5.8.3 Any contamination event shall be treated as non-conforming work and there shall be an appropriate investigation and action.

5.8.4 Forensic units shall address the potential for sporadic contamination [16] events in the reported results (see section 5.9.13 et seq below).

5.9 Reporting of Results

Units

5.9.1 Results shall be reported in units of micrograms per litre to facilitate comparison against the legal limits and avoid any confusion. Results for drugs with a legal limit below 10 µg/L shall be reported to one decimal place. Results for a drug with a legal limit equal to, or greater than, 10 µg/L shall be reported to integer values only.

Calculation

5.9.2 Where analytical results include a value above the ULOQ the mean shall be calculated using (a) the analytical result which is below the ULOQ and the ULOQ for the result which is above the ULOQ. The actual figure may not represent the true mean but the NLTF figure derived from it is still worthwhile. It is acceptable to note that the mean is less than the true mean as a result of the use of the ULOQ.

5.9.3 Where both analytical results are above the ULOQ the mean shall be reported as above the ULOQ. The ULOQ shall be used for the calculation of the NLTF.

5.9.4 Where analytical results include a value below the LLOQ and above the LOD the value should be reported as too low to report a meaningful concentration. The forensic unit shall determine a form of words to use in such cases.

[16] Sporadic contamination is the introduction of an analyte of interest into the blood sample or analytical method (other than from the source of the blood) in an unknown and unpredictable way.

5.9.5 The result shall be reported by use of a NLTF unless all results are above the ULOQ. The NLTF shall be calculated as follows.[17]

5.9.6 The FSREU shall be deducted from the mean of the analytical results. The figure generated shall be rounded down to the number of decimal places noted above. [18]

5.9.7 To illustrate, consider an example of a sample with concentrations of amphetamine in replicate one of 315 µg/L and replicate two of 323 µg/L leading to a mean of 319. µg/L. The FSREU is 20% so the deduction would be 63.8 producing 255.2 µg/L. This would be rounded down to 255 µg/L.

5.9.8 Where both results are above the ULOQ the normal reporting calculation as detailed above shall be carried out, but the figure should be reported as 'greater than ###'. For example, if the ULOQ for BZE is 250 µg/L, and both analytical results exceed this figure, 20% should be deducted from 250, and the result reported as' greater than 200 µg/L'.

5.9.9 The results shall be interpreted on the basis that the figure as rounded is the relevant figure for comparison against the legal limit.

Limits

5.9.10 Where the analytical results are all below the LOD the result may be reported as no drug detected.

5.9.11 Where the drug is detected but the NLTF is equal to or less than the legal limit for the drug the results may be reported as the drug present, but it cannot be reported as being over the limit.

5.9.12 Where the NLTF is above the legal limit the concentration of the drug may be reported as above the legal limit. The report may provide both the mean of the analytical results and the NLTF figure or just the NLTF.

Sporadic Contamination

5.9.13 This section applies where a forensic unit:

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17 Although a specific calculation is provided in the text, mathematically equivalent approaches can be adopted.

18 Rounding down is not normal scientific practice but in this area, it is seen as appropriate to avoid values being increased.

a. Issues a report including a NLTF for any drug which is above the legal limit for that drug; and
b. Has experienced a sporadic contamination event related to the drug being reported with an NLTF above the relevant legal limit.

5.9.14 In the circumstances set out in paragraph 5.9.13 the highest concentration attributed to sporadic contamination in that forensic unit for the drug of interest shall be provided in the report.

5.9.15 In this section the term report includes a SFR1.

Analysis at the Instruction of Police or Prosecution

5.9.16 To justify a prosecution the results of the method shall allow the scientist to state those results support the proposition that the concentration of the drug was above the legal limit. To assess the extent to which the results of the method support the proposition the uncertainty of measurement shall be accounted for.

5.9.17 Without a standard approach established centrally there could be variability in how measurement uncertainty is accounted for in forensic units leading to the potential for different outcomes from analysis of the same sample by different laboratories. That could lead to the decision to prosecute being determined by which forensic unit performed the analysis.

5.9.18 The use of the FSREU gives rise to the concept of a Common Reporting Threshold (CRT) - the lowest measured concentration at which the result can be reported as being above the legal limit. The CRT for each drug is also given in Annex A. A forensic unit will only report a result as above the legal limit when the reported result of the method is greater than or equal to the CRT for the relevant drug.

5.9.19 The forensic unit shall only provide a figure, which will be the “not less than” figure referred to above, if its expanded uncertainty of measurement is equal to or less than the FSREU.

5.9.20 This document covers the process by which the analytical result is produced and a conclusion reported as to whether the concentration of the drug in the sample was above the relevant legal limit. The use of an agreed uncertainty and

resultant common minimum reporting threshold does raise some additional points.

a. Any report/statement on an analysis shall make clear:

   i. That the determination of the "not less than" figure used centrally set expanded uncertainty; and

   ii. The forensic unit's calculated uncertainty for the analysis was no greater (worse) than the FSREU.

b. The requirements in paragraph a above can be achieved by reference to this document being complied with.

Challenges

5.9.21 The use of the FSREU for the determination of the "not less than" figure provides a consistent approach to the Criminal Justice System (CJS). However, any consideration of the reliability of the results (e.g. in response to a challenge) should address the issue of the probability of the analytical results being obtained had the sample been on the legal limit. This should be on the basis of the forensic unit's true uncertainty of measurement. Otherwise the CJS will not be provided with an accurate description of the robustness of the evidence. [19]

Analysis at the Instruction of the Defence

5.9.22 The need for consistency in decisions to prosecute, which led to the adoption of the CRT, does not apply to those forensic units instructed by the defence. However, there is a requirement of the CJS for the work undertaken on behalf of the defence to be to appropriate quality standards. Therefore, those instructed by the defence shall comply with this document.

5.9.23 It is clear that forensic units acting at the instruction of the defence using methods with high uncertainty of measurement could have an adverse impact on the CJS (e.g. by providing inaccurate or misleading results). The forensic

[19] In a case where the FSREU is 30% but a forensic unit has an expanded uncertainty of 20% and a challenge is made on the basis that the results are close to the limit it is sensible for the court to be advised that the 30% deduction was far more than required and the results are, in fact, not as close to the limit as it might appear.

units expanded uncertainty at the 99.7% coverage probability (as determined in compliance with 5.6.6) shall be less that the FSREU.

6. Acknowledgements

6.1.1 The Forensic Science Regulator acknowledges the invaluable assistance of the following in the preparation of this document.

a. Home Office.
b. Department for Transport.
c. Forensic science providers involved in the service.
d. The UK and Ireland Association of Forensic Toxicologists.
e. The United Kingdom Accreditation Service.

7. References

[1] International Organization for Standardization, “ISO/IEC 17025:2017; General requirements for the competence of testing and calibration laboratories”.

[2] Forensic Science Regulator, “Codes of Practice and Conduct for forensic science providers and practitioners in the Criminal Justice System,” [Online]. Available: www.gov.uk/government/collections/forensic-science-providers-codes-of-practice-and-conduct. [Accessed 17 October 2021].

[3] International Organization for Standardization, “ISO 15189:2012; Medical laboratories — Requirements for quality and competence”.

[4] S. P. Elliott, D. W. Stephenson and S. Patterson, “The United Kingdom and Ireland Association of Forensic Toxicologists Forensic Toxicology Laboratory Guidelines,” *Science and Justice,* pp. 335-345, 2018.

[5] United Kingdom Accreditation Service, “LAB 51: Accreditation Requirements for Toxicology Laboratories”.

[6] World Anti-Doping Agency, “Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for Doping Control Purposes - Technical Document – TD2021IDCR”.

[7] United Kingdom Accreditation Service, “M3003: The Expression of Uncertainty and Confidence in Measurement,” [Online]. Available: www.ukas.com/download/publications/publications-relating-to-laboratory-accreditation/M3003-Expression-of-Uncertainty-and-Confidence-in-Measurement-Edition-4-October-2019.pdf. [Accessed 17 October 2021].

[8] S. Ellison and A. Williams, “EURACHEM/CITAC Guide: Qualtifying Uncertainty in Analytical Measurement,” [Online]. Available: www.eurachem.org/index.php/publications/guides. [Accessed 17 October 2021].

8. Review

8.1.1 This document is subject to review at regular intervals.

8.1.2 If you have any comments please send them to the address or e-mail set out on the Internet at URL: www.gov.uk/government/organisations/forensic-science-regulator.

9. Abbreviations and Acronyms

Text	Meaning
BS	British Standards
CITAC	Co-Operation on International Traceability in Analytical Chemistry
CJS	Criminal Justice System
Cr. App. R.	Criminal Appeal Reports
Crim. L.R.	Criminal Law Review
CRT	Common Reporting Threshold
EN	European Standard
FSR	Forensic Science Regulator
FSREU	Forensic Science Regulator Expanded Uncertainty
IEC	International Electrotechnical Commission
ISBN	International Standard Book Number
ISO	International Organization for Standardization
LLOQ	Lower Limit of Quantification

Text	Meaning
LOD	Limit of Detection
MRM	Multiple Reaction Monitoring
NLTF	Not Less Than Figure
QC	Quality Control
R.T.R.	Road Traffic Reports
SD	Standard Deviation
SDM	Standard Deviation of the Mean
SI	Statutory Instrument
ULOQ	Upper Limit of Quantification
WADA	World Anti-Doping Agency

Annex A: Limits Uncertainty and Reporting Thresholds for England and Wales

10. Legal Limits and Related Data

10.1.1 The legal limits, FSR expanded uncertainty and the CRT for each drug are set out below. [20] [21]

Controlled Drug	Legal Limit (µg/L)	FSR expanded uncertainty (%)	CRT (µg/L)	Date limit first established
Amphetamine	250	20	314	14 April 2015
Benzoylecgonine	50	20	64	2 March 2015
Clonazepam	50	20	64	2 March 2015
Cocaine	10	35	17	2 March 2015
Delta-9-Tetrahydrocannabinol	2	30	3	2 March 2015
Diazepam	550	20	689	2 March 2015
Flunitrazepam	300	25	402	2 March 2015
Ketamine	20	20	27	2 March 2015
Lorazepam	100	25	135	2 March 2015
Lysergic Acid Diethylamide	1	45	2	2 March 2015
Methadone	500	25	668	2 March 2015
Methylamphetamine	10	40	19	2 March 2015
Methylenedioxymeth-amphetamine	10	25	15	2 March 2015
6-Monoacetylmorphine	5	35	8	2 March 2015
Morphine	80	25	108	2 March 2015
Oxazepam	300	20	377	2 March 2015
Temazepam	1000	20	1252	2 March 2015

[20] All concentrations are quoted in micrograms per litre (µg/L) as the legal limits are specified in this unit and consistent use of one unit avoids confusion when the results are employed by non-scientists.

[21] The calculation of the CRT is on the basis that deduction of the FSREU from the CRT will produce a figure which (when rounded down to the number of decimal places the results are reported to) is one unit (i.e. 01. µg/L or 1 µg/L) higher than the relevant legal limit.

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