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The United Kingdom and Ireland association of forensic toxicologists forensic toxicology laboratory guidelines (2018)

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ABSTRACT

In 2010, the United Kingdom and Ireland Association of Forensic Toxicologists (UKIAFT) created forensic toxicology laboratory guidelines. This represents a revision of those guidelines as a result of the changing toxicological and technical landscape.

1. Introduction

The UK & Ireland Association of Forensic Toxicologists (UKIAFT) consists of representatives from each of the main laboratories in the United Kingdom and Ireland offering Forensic Toxicology Services. In the absence of national guidelines for forensic toxicology, the UKIAFT approached the board of the Society of Forensic Toxicologists [10] with a view to amending the Laboratory Guidelines published jointly by SOFT and the American Academy of Forensic Sciences (AAFS). The SOFT/AAFS Forensic Toxicology Laboratory Guidelines (Version 2006) were reviewed and amended to better reflect toxicology standards and practices within the UK & Ireland. This resulted in the publication of the first UKIAFT laboratory guidelines in 2010 ([1], "The United Kingdom and Ireland Association of Forensic Toxicologists Forensic toxicology guideline (2010)", Sci Justice. 50:166–176). Since then, there have been various changes in laboratory testing, not least the wider use of liquid chromatography mass spectrometry, including high resolution mass spectrometry and is reflected in this revision.

The UK & Ireland Association of Forensic Toxicologists Forensic Toxicology Laboratory Guidelines (version 2018) acknowledge the following international standards:

- BS EN ISO/IEC 17025:2017 for testing laboratories,
- ILAC G-19:8/2014 guidelines for forensic science laboratories and,
- BS EN ISO/IEC 15189:2012 for medical laboratories

These guidelines do not necessarily reflect opinions about the minimum requirement for any laboratory, nor do they have any regulatory purpose; rather, they are intended to assist laboratories engaged in the practice of forensic toxicology in achieving future goals. These guidelines are also in the processing of forming an Appendix for forensic toxicology in the UK Forensic Regulator's Codes of Practice and Conduct for forensic science providers and practitioners in the Criminal Justice System [8].

A list of the organisations from the United Kingdom and Ireland that have contributed to the UKIAFT Forensic Toxicology Laboratory Guidelines 2018 is found in Appendix 1.

2. Scope

These guidelines are primarily for use in the practice of Forensic Toxicology encompassing post-mortem toxicology, human performance toxicology and criminal toxicology. There are separate guidelines available in relation to workplace drug-testing in the UK and Europe [5].

3. Definitions

Forensic Toxicology - determining the presence or absence and role of alcohol, drugs and their metabolites as well as other toxic substances in human fluids and tissues for Court and other legal purposes (including medico-legal matters).

Post-Mortem Toxicology - the determination of toxicological elements in death investigations.

Human Performance Forensic Toxicology - used to elucidate the absence or presence of substances modifying human performance or behaviour.

Criminal Toxicology - the determinants or toxicological factors in the investigation of criminal offences.

Reference Material (RM) - a material or substance containing target

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analyte(s), one or more properties of which, such as analyte concentration(s) are established sufficiently well to be used for calibration of an apparatus, assessing a measurement or assigning values to material. (AOAC Official Methods of Analysis (1984)).

Certified Reference Material (CRM) - a reference material, one or more of whose properties are certified by a valid procedure, or accompanied by or traceable to a certificate or other documentation which is issued by a certifying body (AOAC Official Methods of Analysis (1984)).

Standard - a reference material containing target analyte(s) possessing one or more properties such as analyte concentration(s) that are sufficiently well established so that it can be used to prepare calibrators.

Calibrator - a solution containing target analyte(s), either prepared from the reference material or purchased, used to calibrate the assay. Where possible, calibrators should be prepared in a matrix similar to that of the specimens to be analysed.

Quality Control (QC) - a solution containing target analyte(s) either prepared from the reference material (separately from the calibrators; that is, weighed or measured separately), purchased, or obtained from a pool of previously analysed samples subject to ethical approval and in accordance with the Human Tissue Act. Controls from any of these sources are used to determine the validity of the calibration; that is, the stability of a quantitative determination over time. Where possible, controls should be matrix-matched to specimens and calibrators, as indicated above.

4. Personnel

Due to the variety of forensic toxicology service providers in the UK & Ireland, it is not possible to provide a prescriptive line-management structure for all laboratories and titles for generic roles may differ across the various organisations. However, the UKIAFT (through member consultation) has published recommendations for establishing best practice for professional training & development in forensic toxicology ([2], “The United Kingdom and Ireland Association of Forensic Toxicologists; establishing best practice for professional training & development in forensic toxicology”, Sci Justice. 57(1):63–71). Best practice is proposed using a blend of modular foundation knowledge training, continuing professional development, academic study, research & development and ongoing analytical practice. The need for establishing a professional career structure is also discussed within the publication along with a suggested example of a suitable model.

4.1. Head of toxicology service

The forensic toxicology laboratory should be directed by a person who is qualified by reason of appropriate education and experience to assume the required professional, organisational, educational, managerial and administrative responsibilities.

4Acceptable qualifications include a doctoral degree in one of the natural sciences and at least three years of full-time laboratory experience in forensic toxicology; or a Master's degree in one of the natural sciences and at least five years of full-time laboratory experience in forensic toxicology; or a Bachelor's degree in one of the natural sciences and at least seven years of full-time laboratory experience in forensic toxicology.

The Head of Toxicology Service should also have documented training and/or experience in the forensic applications of analytical toxicology (such as court testimony, research, participation in continuing education programmes, and/or peer review of appropriate manuscripts in the field), including a knowledge of evidentiary procedures that apply when toxicological specimens are acquired, processed, stored and disposed and when toxicological data are submitted as part of a legal proceeding.

The Head of Toxicology Service should be ultimately responsible for ensuring that the trained laboratory personnel are appropriately qualified, experienced and competent to conduct their role in the work of the laboratory and that they participate in a scheduled continuous personal development programme.

The Head of Toxicology Service should be ultimately responsible for ensuring that the competency of laboratory personnel is monitored and maintained and skills verified. This training and competency assessment should be documented.

The Head of Toxicology Service should be ultimately responsible for ensuring the development of complete, up-to-date laboratory standard operating procedures (SOPs) that are available to and followed by all personnel carrying out tests.

The Head of Toxicology Service should be ultimately responsible for ensuring methods are fit for purpose and that procedures for validating new analytical methodologies and maintaining quality assurance programmes are in place to ensure the proper performance of methods and the reporting and interpretation (if required) of results.

Forensic toxicology laboratories handle controlled substances, generate results essential to the criminal justice system and have access to confidential information. The Head of Toxicology Service, to the extent practical or permitted by law, should exert reasonable efforts to ensure that all personnel meet high ethical and moral standards and that all personnel adhere to relevant legislation (e.g. Human Tissue Act and Misuse of Drugs Act) and other legal obligations.

4.2. Other laboratory staff

The range and type of duties of other laboratory personnel will vary according to the size and the scope of the laboratory but recommendations are detailed in the UKIAFT professional training & development document.

5. Standard operating procedures

The laboratory should have standard operating procedures (SOPs) that are complete, up-to-date, and available to all personnel who are carrying out tests.

SOPs should include detailed descriptions of procedures for sample receiving, accessioning, chain-of-custody, analysis, quality assurance and quality control (including validation of methods), review of data, reporting and sample disposal as well as IT and security protocols.

SOPs should be available for administrative procedures as well as analytical methods and be reviewed, signed, and dated whenever they are first placed into use or changed.

The SOP should include, for each analytical procedure if appropriate, the following: a) theory and principle of the method, b) instructions for preparation of reagents, c) details of the analytical procedure, d) instructions for preparation of calibrators and controls (including use of blanks), e) information about any special requirements for handling reagents or for ensuring safety, f) validation parameters (e.g. LOQ, linearity) or reference to the appropriate validation document, g) criteria for the acceptance or rejection of qualitative or quantitative results, h) references and i) instrumentation to be used.

Please refer to relevant sections of ISO 17025:2017, ISO 15189:2012 and ILAC G19:2014 for further guidance on the requirements for document control.

A SOP or protocol for the performance or outsourcing for infrequently requested assays is recommended.

The laboratory Quality System should contain a record of sample signatures and initials of all staff handling specimens and carrying out analytical work (i.e. a “signature page”). This should be updated as needed to reflect staffing changes.

All SOPs should be reviewed as outlined in the laboratory Quality System but should be at least once every two years and the laboratory should maintain out-dated copies of all SOPs and provide a means for their retrieval from archival storage.