



# **Codes of Practice and Conduct**

*for forensic science providers and practitioners  
in the Criminal Justice System*

**Issue 3**

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# Codes of Practice and Conduct

## Foreword

My aim is that all forensic science provided to the CJS is of the required level of quality; the quality standards are set out in detail in these Codes. Accreditation is simply the mechanism by which compliance is monitored, and whilst dates have been set by which accreditation is required, implementation of the quality standards must not be delayed.

In this third version of the Codes, additional detail on the requirement for accreditation is provided, particularly for digital forensics, firearms classification, drugs and toxicology. Having been first published in 2011, the time is approaching when accreditation to the Codes becomes a requirement; for most disciplines, this is in October 2017. The Statement of Accreditation Requirements has been substantially revised and therefore requires careful note. References to the 2015 Criminal Procedure Rules, 2015 Criminal Practice Directions and relevant standards and guidance documents have also been updated, with changes highlighted in grey.

The Codes are intended to assist organisations with understanding and interpreting the requirements of the standards, particularly BS/EN ISO/IEC 17025. Later this year, there will be a more in-depth review of the Codes, to ensure the requirements of BS/EN ISO/IEC 17020 and ILAC G19:08/2014 are fully reflected. Ahead of that review, I would value feedback on the clarity and utility of the Codes and any improvements that could be made.

I am aware that there is a great deal of work ongoing to achieve accreditation by the specified dates: significant quality improvements are already being made, and more are within reach. Organisations are reporting quality failures and putting in place measures to ensure that they do not recur – review and continuous improvement are at the centre of the quality standards framework.

I would encourage all forensic scientists to read the appendices to the Codes (FSR-C-series) and guidance documents (FSR-G-series) relevant to their areas of expertise, and also the general guidance document on cognitive bias effects (FSR-G-217). The forensic science quality framework does not operate in isolation, but as part of a legal system, so the legal obligations information document (FSR-I-400, which will shortly be updated to version 4.0) is core reading for all whose work may contribute at some point to expert evidence in a court in England or Wales.

When the provisions in the Codes are fully implemented by all forensic science providers and practitioners and are understood by all end users, the potential for a forensic science quality failure to cause a miscarriage of justice will be substantially reduced. This is of course why, despite the challenging financial environment, the requirement to comply is so crucially important.



**Dr Gillian Tully**

**The Forensic Science Regulator**

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### Preface - Statement of Accreditation Requirements for all providers of forensic science services

The Forensic Science Regulator expects that the following activities wherever performed to be conducted to the standards set out in Table 1, irrespective of whether the provider is public, police or commercial. The standard commencement dates for regulation of 6 April and 1 October apply.

**Table 1: Statement of accreditation requirements**

Standards/requirements for forensic science activity (1 of 5)	Accreditation to ISO/IEC 17025	Accreditation scope to include the Codes	Appendix/ Guidance	Notes
Crime scene examination (BS/EN ISO 17020)	Oct 2020	Oct 2020	UKAS RG201	Covers all aspects of crime scene investigations, including fire scene and collision investigations.
Visual screening, examination and/or sampling for biological material	Oct 2013	Oct 2017		It is assessed that screening of items to the standards expected in the Criminal Justice System includes competence in low power microscopy and a presumptive blood test as a minimum.
Processing recovered biological samples/material to obtain a DNA profile	April 2012	Oct 2017	Oct 2017	
Enhancement, development, imaging, recording and recovery of visible/latent finger marks	Oct 2015	Oct 2017		
Fingerprint comparison	Oct 2018	Oct 2018	Oct 2018	
Forensic Pathology	A separate code of practice and performance standards <sup>1</sup> applies - Oct 2012			
Blood pattern analysis	April 2012	Oct 2017	In draft	
Archaeology	A separate standard and guidance <sup>2</sup> applies - Dec 2015			
National DNA Database® (NDNAD)	ISO9001 TickIT ISO17043			

<sup>1</sup> Available from: <https://www.gov.uk/government/publications/standards-for-forensic-pathology-in-england-wales-and-northern-ireland>

<sup>2</sup> Available from: [http://www.archaeologists.net/sites/default/files/CIfAS&GForensics\\_2.pdf](http://www.archaeologists.net/sites/default/files/CIfAS&GForensics_2.pdf)

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Standards/requirements for forensic science activity (2 of 5)	Accreditation to ISO/IEC 17025	Accreditation scope to include the Codes	Appendix/ Guidance	Notes
Digital forensics				Digital forensics is the process by which information is extracted from data storage media (e.g. devices, remote storage and systems associated with computing, imaging, image comparison, video processing and enhancement [including CCTV], audio analysis, satellite navigation, communications), rendered into a useable form, processed and interpreted for the purpose of obtaining intelligence for use in investigations, or evidence for use in criminal proceedings. The definition is intentionally wide and any exclusions will be explicit. Automatic number plate recognition, manual classification of indecent images of children, crime scene photography, eFit, recovery from a working CCTV system, CCTV replay for viewing with no further analysis (acknowledging that there may be quality limitations to the material viewed) all should be conducted by competent staff using methods approved by the organisation, but are excluded from the ISO/IEC 17025 requirement.
- Imaging of hard drives and removable media	October 2017	October 2017	October 2017	The Regulator expects any method used for imaging 'conventional' hard drives to be validated as required in the Codes by Oct 2015.
- Screening or recovery of data from a device using an off the shelf tool for factual reporting	October 2017	October 2017	October 2017	The use of tools and methods by frontline non-practitioners is permitted but the organisation must hold accreditation for at least one deployment. Further deployments of the method under central control may be permitted outside the scope of accreditation provided that the method chosen can be demonstrated to have adequate configuration control (e.g. locked down data recovery methods and control) and that staff are competent.
- Extraction and analysis of data from digital media including remote storage	October 2017	October 2017	October 2017	
- Network capture and analysis	Under consideration for ISO 17025 by October 2018			
- Capture and analysis of social media and open source data	TBA			
- Cell site analysis & communications data	TBA			

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Standards/ requirements for forensic science activity (3 of 5)	Accreditation to BS EN ISO/IEC 17025	Accreditation scope to include the Codes	Appendix/ Guidance	Notes
Triage and simple classification of firearms	Either ISO 17025 accreditation by 2012 and accreditation to the Codes by 2017  or Alternative framework implemented by October 2016			This is for triage (deciding to take no further action or that an accredited examination is required) and for possession cases, <sup>3</sup> where simple classification <sup>4</sup> does not require a full evidential statement and includes, in the circumstances defined below, preparing an SFR1. An SFR1 can be produced in cases involving the following: the classification of firearms including all functioning centre-fire and rim-fire handguns, rifles, sub-machine guns and shotguns manufactured after 1939 where the dimensions of the weapon are more than 1" or 2.54cm above or below the legal limits contained in the Firearms Act 1968 (e.g. a sawn off shotgun with a barrel length of less than 23" or a handgun with a barrel of less than 27.46cm or overall length 57.46cm); and the classification of ammunition including all centre-fire and rim-fire ammunition, where there is sufficient quantity to warrant test firing of the ammunition, or where the ammunition can be dismantled to demonstrate that all the components of ammunition were present. <sup>5</sup>
Firearms classification, firing marks, ballistics etc.	April 2012	Oct 2017	In draft	Accreditation is required for classification where the SFR1 is contested, where the firearm has been discharged during any criminal act other than the possession offence in relation to which the firearm is being examined, for determining kinetic energy of air weapons, for all guns bearing deactivation stamps that appear to have been modified, all blank firing guns that appear to have been modified, any blank firing weapons that are suspected of being easily convertible within the terms of the Firearms Act 1982, all homemade weapons, all firearms that appear to have been modified (with the exception of sawn-off shotguns covered above under simple classification or triage), military ammunition suspected of being loaded with specialist projectiles (e.g. armour piercing, incendiary tracer etc.), all irritant spray devices, all electronic stun-gun devices, and all items presumed to be a firearm or component part that are suspected of having been used in a serious offence (e.g. homicide, sexual offences, robbery, aggravated burglary etc.) or attempting such an offence.
Firearm Discharge Residue	April 2012	Oct 2017		

<sup>3</sup> Possession means any case where the *actus reus* for the offence is possession of a firearm only. This shall include cases where a firearm is discharged as long as this does not lead to a charge other than a possession offence.

<sup>4</sup> Simple classification means any classification not falling within the description in the sections below.

<sup>5</sup> Adequate facilities for test firing and/or dismantling the ammunition must be available.

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Standards/requirements for forensic science activity (4 of 5)	Accreditation to BS EN ISO/IEC 17025	Accreditation scope to include the Codes	Appendix/ Guidance	Notes
Drug analysis to evidential standards	April 2012	Oct 2017		<p>Presumptive drug testing (for example under Evidential Drug Identification Testing [EDIT] guidance or HOC 15/2012) is currently permissible outside of the ISO17025 standards framework.</p> <p>For evidential purposes, all drugs for which the laboratory routinely tests (in relation to the Misuse of Drugs Act 1971) shall be within its scope of accreditation (either by being named in the scope or as a result of flexible scope) and new drugs, as they become more common, shall be brought within the scope in a timely fashion. The laboratory must have a procedure setting out how it analyses drugs that are new or rarely tested for and are not in scope of accreditation, covering how the laboratory assures the quality of such analyses.</p>
Toxicology	Oct 2017	Oct 2017		<p>Presumptive toxicology testing (using Home Office type approved equipment) is permissible outside of the ISO17025 standards framework. For evidential purposes, all compounds for which the laboratory routinely tests as part of a toxicology service shall be within its scope of accreditation (either by being named in the scope or as a result of flexible scope) and new compounds, as they become more common, will be brought within the scope in a timely fashion. The laboratory must have a procedure setting out how it analyses compounds that are new or rarely tested for and are not in scope of accreditation, covering how the laboratory assures the quality of such analyses.</p> <p>Analysis in relation to section 5A of Road Traffic Act 1988 is subject to specific requirements set out in FSR-C-133.</p> <p>Accreditation to BS/EN ISO 15189:2012 is a suitable alternative to ISO/IEC17025, provided that Forensic Testing/Analysis is clearly indicated in the scope of accreditation; this means that the laboratory has been assessed in accordance with ISO15189 taking into account ILAC G19:08/2014 Modules in a Forensic Science Process.</p>
Fingerprint comparison	Oct 2018	Oct 2018	Oct 2018	
Toolmark impression comparison	April 2012	Oct 2017		
Footwear impression screening	Oct 2017	Oct 2017		
Footwear impression comparison to evidential standards	April 2012	Oct 2017		

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Standards/requirements for forensic science activity (5 of 5)	Accreditation to BS EN ISO/IEC 17025	Accreditation scope to include the Codes	Appendix/ Guidance	Notes
Footwear impression comparison to evidential standards	April 2012	Oct 2017		
Sexual Assault Referral Centres	Standard to be agreed			The Regulator is developing an appendix based upon BS/EN ISO 15189:2012 and working towards development of a compliance mechanism alongside the Care Quality Commission.
Anthropology	A standalone code of practice is being developed			
Podiatry	A standalone code of practice is being developed			
Laboratory activity including, but not limited to, handling, developing, analysing and/or interpreting scientific evidence not listed separately here	Oct 2013	Oct 2017		Assessment of standards for specialist photography and vehicle examination for crime scene is included in the 2020 date for BS EN ISO/IEC 17020.

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### Code of Conduct for forensic science practitioners

The Forensic Science Regulator sets out for all practitioners, whether **instructed** by the prosecution or defence, the values and ideals the profession stands for.<sup>6</sup> This Code of Conduct provides a clear indication to customers and the public of what they have a right to expect.

As a practitioner:

1. Your overriding duty is to the court and to the administration of justice.
2. Act with honesty, integrity, objectivity and impartiality, and declare at the earliest opportunity any personal, business and/or financial interest that could be perceived as a conflict of interest.
3. Provide expert advice and evidence only within the limits of your professional competence.
4. Take all reasonable steps to maintain and develop your professional competence, taking account of material research and developments within the relevant field.
5. Establish the integrity and continuity of items as they come into your possession and ensure these are maintained whilst in your possession.
6. Seek access to exhibits/productions<sup>7</sup>/information that may have a significant impact on your findings.
7. Conduct casework using methods of demonstrable validity.
8. Be prepared to review any casework if any new information or developments are identified that would significantly impact on your findings.
9. Inform a suitable person within your organisation if you have good grounds for believing there is a situation that may result in a miscarriage of justice.
10. Preserve confidentiality unless the law obliges, a court/tribunal orders, or a customer explicitly authorises disclosure.

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<sup>6</sup> Developed from former work by the Council for the Registration of Forensic Practitioners.

<sup>7</sup> A production is a document or article produced as evidence in Scottish courts.

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## Code of Practice for providers of forensic science services

### 1. Introduction

- 1.1. The Code of Practice aligns with BS EN ISO/IEC 17025:2005 (for testing and calibration laboratories<sup>8</sup> as interpreted by ILAC G19:08/2014 ) and specifies the requirements for a management system for providers of laboratory-based forensic science services to demonstrate their ability to deliver consistently products and services that meet the requirements of their customers in the Criminal Justice System (CJS).
- 1.2. This is the **third** edition of the Code of Practice, significant changes from the first edition are highlighted in grey, significant deletions are marked with dots thus "...".
- 1.3. The United Kingdom Accreditation Service (UKAS<sup>®</sup>)<sup>9</sup> will assess laboratory-based providers of forensic science services against BS EN ISO/IEC 17025:2005 utilising any of the relevant UKAS<sup>®</sup> laboratory publications<sup>10</sup> and the supplementary requirements of this Code of Practice, and include compliance with this Code of Practice in the Schedule of Accreditation.<sup>11</sup> UKAS<sup>®</sup> can assess providers of forensic science services at scenes of crime<sup>12</sup> against BS EN ISO/IEC 17020:2012, **ILAC G19:08/2014** and the inspection recommendation and guidance publication UKAS-RG 201:**2015**.
- 1.4. The main headings in this Code of Practice are cross-referenced to relevant sections of the international standard BS EN ISO/IEC 17025:2005 and the interpretative document **ILAC G19:08/2014** for ease of use e.g. **9. Document control (ISO 17025:2005 ref. 4.3)**. However, this Code of Practice is not intended to be a substitute for the complete version of the international standards.
- 1.5. Appendices complementary to the Code will be produced and when they come into effect are to be read as part of the Code, expanding and interpreting it, where necessary, for specific activities, processes or evidence types.
- 1.6. The Code of Practice also incorporates, where applicable, any specific requirements determined by the CJS in England and Wales.<sup>13</sup>

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<sup>8</sup> This Code of Practice does not specifically address the requirements of calibration laboratories. Laboratories providing calibration services should comply with the requirements of BS EN ISO/IEC 17025 for this aspect of their work.

<sup>9</sup> UKAS<sup>®</sup> is a registered trademark of the United Kingdom Accreditation Service.

<sup>10</sup> A list of UKAS<sup>®</sup> *Publications for Laboratory Accreditation to ISO/IEC 17025* is available from: <http://www.ukas.com/technical-information/publications-and-tech-articles/publications.asp> [Accessed 1/8/14].

<sup>11</sup> The Regulator has a Memorandum of Understanding with the national accreditation body UKAS<sup>®</sup>, agreements with other national accreditation bodies may be entered into if required.

<sup>12</sup> Taken to be incidents with a scene where a crime is believed may have occurred, including but not limited to crime related incidents.

<sup>13</sup> The Codes can be extended or adopted by other jurisdictions with approval of the appropriate Ministers, governing bodies and prosecuting authorities.

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- 1.7. Compliance with this Code of Practice is intended to provide the CJS and the public with confidence in the reliability of forensic science and to enhance customer satisfaction through the effective application of the management system.
- 1.8. The Code and any subsequent appendices will be updated to reflect relevant changes in the requirements of BS EN ISO/IEC 17025:2005, BS EN ISO/IEC 17020:2012, ILAC G19:08/2014, ILAC-P15:06/2014 and the CJS. The updated version will be made available to all interested parties.
- 1.9. Other standards used for certification...of organisations that provide scientific services – e.g. Good Laboratory Practice (GLP) regulations, good manufacturing practice (GMP)... – are not alternatives to BS EN ISO/IEC 17025:2005, although they do overlap to some extent and provide compatible guidance on good practice.
- 1.10. Accreditation to BS EN ISO 15189:2012 is a suitable alternative to BS EN ISO/IEC17025, provided that Forensic Testing/Analysis is clearly indicated in the scope of accreditation; this means that the laboratory has been assessed in accordance with ISO15189 taking into account ILAC G19:08/2014 *Modules in a Forensic Science Process*.
- 1.11. All practitioners should comply with the principles contained in the Code of Conduct at the beginning of this document. Taken together with the Code of Practice these are referred to collectively from this point forward as the Codes.

## 2. Scope

- 2.1. The Codes are for providers of forensic science services to the CJS. Forensic science is taken to include the sciences performed by the police service, the public and private sector forensic science providers and, to a lesser extent, academia. They are intended to be able to cover sciences with scene and/or laboratory-based elements and therefore are not intended for disciplines such as forensic accountancy or psychiatry. Although the Codes could be extended to forensic medicine, they have not been drafted with that in mind. However, the accreditation process requires formal demonstration of competence to a third party so further work on development of a compliance mechanism alongside the Care Quality Commission is required to bring certain suspect and victim sampling in scope. The Codes cover the forensic science provider's work as required or applicable to the scope of accreditation:
  - a. initial forensic science activity at the scene;
  - b. the scene examination strategy;
  - c. the recovery, preservation, transport and storage of exhibits;
  - d. screening tests for use in the field;
  - e. the assessment, selection, examination, sampling, testing and/or analysis of exhibits;
  - f. testing activities using laboratory-based methods;
  - g. the recording of actions taken;

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- h. assessment/review of examination and test results; and
  - i. the reporting and presentation of results
  - j. interpretations and opinions.<sup>14</sup>
- 2.2. The Codes initially specify the general requirements for competence for laboratory activities including sampling, laboratory examinations and tests and the provision of expert testimony. Where relevant, appropriate legal, regulatory and information security is included.
- 2.3. All practitioners and providers offering forensic science services to the CJS are to be bound by these Codes; however it is accepted that experts from other professions will be called to give evidence from time to time and the customer should make such providers aware of, and require that they are bound by, the Code of Conduct as a minimum.
- 3. Normative references**
- 3.1. The following normative references are included in **26. Bibliography**:
- a. BS EN ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*;
  - b. ILAC G19:08/2014, *Modules in a Forensic Science Process*;
  - c. BS EN ISO/IEC 17020:2012, *General criteria for the operation of various types of bodies performing inspection*;
  - d. ILAC-P15:06/2014, *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*;
  - e. UKAS-RG 201:2015, *Accreditation of Bodies Carrying Out Scene of Crime Examination (Edition 2)*.
- 4. Terms and definitions**
- 4.1. For the purposes of these Codes, the definitions of terms are given in the **28. Glossary**.
- 4.2. The meanings of abbreviations are given in **27. Abbreviations**.
- 5. Management requirements**
- 5.1. The provider shall have a Schedule of Accreditation covering compliance with BS EN ISO/IEC 17025:2005 and where required by BS EN ISO/IEC 17020:2012 and the supplementary requirements of these Codes for the methods, products and services it is routinely providing.
- 5.2. Where top management is referred to in the standard, this would usually be at Chief Officer or Board level.

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<sup>14</sup> Where this it to be included in a provider's schedule of accreditation, they will need to ensure that they are in compliance with the UKAS publication LAB 13.

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### 6. **Business continuity**<sup>15,16</sup>

- 6.1. The provider shall develop procedures to be implemented following interruption to, or failure of, business critical processes, to maintain or restore operations and ensure continuous availability, confidentiality and integrity of information.
- 6.2. Providers should ensure that their business continuity plans include provision to preserve and or recover any material transferred to a subcontractor's facility should it go out of business with no legal successor (e.g. through stipulation in a contract).
- 6.3. Business continuity plans shall be tested on an annual basis and the results documented.<sup>17</sup> Any identified need for action to modify the plans shall be implemented and the plans re-tested.

### 7. **Independence, impartiality and integrity**

- 7.1. The provider shall ensure that all of its practitioners adhere to the Code of Conduct in respect of their independence, impartiality and integrity, and that the organisational structure, policies and procedures support this rather than hinder it.
- 7.2. Conflicts of interest, perceived or otherwise, and threats to impartiality may include a practitioner:
  - a. having the perception of being coerced, or is being coerced, openly or secretly;
  - b. being asked to disregard critical findings that support/undermine either the prosecution's or the defence's position;
  - c. being the sole reviewer of their critical findings;
  - d. being involved with activities that could be perceived as witness coaching or being coached, rather than training or familiarisation;
  - e. being over-familiar with or trusting another person instead of relying on objective evidence;
  - f. having organisational and management structures that could be perceived to reward, encourage or support bias;
  - g. having a close/significant personal or financial relationship with a party likely to be affected by the outcome;

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<sup>15</sup> Further guidance if required can be obtained from ISO 22313:2012, *Societal security -- Business continuity management systems -- Guidance*.

<sup>16</sup> Customers should ensure that their own business continuity plans have addressed the risk that a provider goes out of business with no legal successor, to ensure retained material, case files and associated paperwork is available (e.g. continuity and access records, validation records, competency records, calibration and maintenance records). Ideally this should be through stipulation in a contract, clarifying that copies of certain information needs to be supplied with the case files.

<sup>17</sup> This should be scaled based upon risk, in some circumstances a desk-top exercise will usually be deemed sufficient.

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- h. having a close/significant personal or financial relationship with any person acting as an expert witness in the case; or
  - i. acting in self-interest.
- 7.3. Where applicable it is expected that the expert, in assessing the results obtained, would consider the relevant hypotheses that could explain their findings prior to presenting relevant hypotheses as propositions to the case.
- 7.4. The required policies and procedures shall not only prevent internal and external influence on the results of their examinations and tests, but also cover the corrective action (such as formal disclosure) to be taken if there is a possibility of a practitioner's judgement having been, or perceived to have been, compromised.
- 8. Confidentiality**
- 8.1. The provider shall ensure that the documented policies and procedures for confidentiality requirements, including any disclosure requirements, are applied to any subcontractors.
- 9. Document control (ISO 17025:2005 ref. 4.3)**
- 9.1. The provider must ensure that document control procedures are applied to the following where they are integral to the forensic process, including:
  - a. both hard copy and electronic copies;
  - b. procedures – technical and quality;
  - c. software;
  - d. technical methods;
  - e. forms;
  - f. key external documents; and
  - g. statutory documents.
- 9.2. The retention period for obsolete/superseded documents should be defined and should take into account customer, regulatory and legal requirements.
- 10. Review of requests, tenders and contracts (ISO 17025:2005 ref. 4.4)**
- 10.1. The processes surrounding the review of requests, tenders and contracts may occur at several different levels and at several key stages through the processing of forensic work. These may include, but not be limited to:
  - a. the processes leading to the documentation of an overarching Service Level Agreement (SLA)/contract between the customer and the provider;
  - b. the management of the adherence to the agreed SLA/contract;
  - c. the documentation and review of more detailed case-specific requirements through the use of submission forms, etc;
  - d. outcomes from case conferences; and
  - e. significant discussions with the Officer In Charge (OIC), solicitors, etc.



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- 10.2. The aspects discussed and agreed as part of the review of requests, tenders and contracts may include, but not be limited to:
- a. turnaround times;
  - b. report format;
  - c. items to be examined;
  - d. case assessment and strategy;
  - e. sequence of examination;
  - f. precautions to be taken to preserve additional evidence;
  - g. methods to be used;
  - h. products to be delivered;
  - i. costs;
  - j. collection/transfer of items; and
  - k. retention, destruction or return of items (see **23.4. Exhibit return and disposal**).
- 10.3. The documented procedure and associated records must describe all relevant instances when work requirements are discussed and reviewed such that a demonstrable audit trail, including appropriate justifications and authorisations, is available for each piece of work undertaken.
- 11. Subcontracting (ISO 17025:2005 ref. 4.5)**
- 11.1. A provider may need to subcontract work and in all cases the customer shall be informed in writing and approval is required.
- 11.2. Where applicable, the provider shall include in their continuity plans the arrangements that have been made to preserve retained material<sup>18</sup> should their subcontractor provider or its contracted storage facility cease business and have no legal successor.
- 11.3. If other necessary approvals are required by rules or convention, such as work connected to firearms examination, drug analysis or for inclusion on the National DNA Database<sup>®19</sup>, the subcontracted provider must also be appropriately approved or licensed.
- 12. Packaging and general chemicals and materials (ISO 17025:2005 ref. 4.6)**
- 12.1. Customers and providers shall ensure that any sample, packaging and/or collection kits they use are fit for purpose.<sup>20</sup>

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<sup>18</sup> Including relevant data, reports and records.

<sup>19</sup> The National DNA Database<sup>®</sup> is a registered trademark of the Secretary of State for the Home Department.

<sup>20</sup> This can be demonstrated by consumable manufacturers and kit assemblers meeting the requirements set out in the Publically Available Specification (PAS) 377:2012 "Specification for consumables used in the collection, preservation and processing of material for forensic analysis - Requirements for product, manufacturing and forensic kit assembly".

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### 13. Complaints (ISO 17025:2005 ref. 4.8)

- 13.1. The provider shall have policies and procedures for dealing with complaints. These procedures shall define what constitutes a complaint<sup>21</sup> in relation to the work undertaken by the provider, and shall ensure that appropriately thorough investigations are instigated on receipt of any complaints.
- 13.2. The Forensic Science Regulator shall be informed at the earliest opportunity about any complaint if it has significantly disaffected the customer such that it could attract adverse public interest or lead to a miscarriage of justice. The policies and procedures relating to complaints shall also indicate the escalation criteria and the individual responsible for notifying the Regulator.
- 13.3. Complaint investigations shall include examination of the potential impact on any work that has already been undertaken by the provider. In the event that it is shown that there could have been an impact on any work this should be dealt with through the non-conforming work process (see **14. Control of non-conforming testing**).
- 13.4. Records shall be retained of all complaints and of the subsequent investigations and outcomes.
- 13.5. Complaints may be received from many sources including customers, victims of crime, police forces, and other departments within the same provider (e.g. laboratory, scene of crime unit, investigation unit) and the judicial system (including adverse court decisions pertinent to the work).

### 14. Control of non-conforming testing (ISO 17025:2005 ref. 4.9)

- 14.1. Examples of non-conforming testing that after investigation could require escalation to the Forensic Science Regulator could include, but are not limited to, significant instances of:
  - a. unexpected performance in proficiency testing/inter-laboratory comparison;
  - b. unauthorised access to restricted areas or information;
  - c. missing or compromised items/case files;
  - d. equipment failing to receive timely calibration or maintenance;
  - e. failure of staff to follow procedures;
  - f. contamination incidents;
  - g. technical method found to be producing erroneous results; or
  - h. any standards/reference materials, equipment or reagents found to have defects or deficiencies.
- 14.2. The Forensic Science Regulator shall be informed about any non-conforming test if it has potential to significantly disaffect the customer such that it could attract adverse public interest or lead to a miscarriage of justice.

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<sup>21</sup> A commonly accepted definition is any expression of negative feedback.

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14.3. The provider shall maintain a record of the nature of non-conformities capable of being used to identify trends, any concessions obtained to use non-conforming work, and any corrective and/or preventive actions taken.

### 15. Control of records (ISO 17025:2005 ref. 4.13)

#### 15.1. General

15.1.1. The provider shall establish retention times that satisfy the requirements of legislation, its accrediting body and its customers, as appropriate.

15.1.2. Records should be stored and subsequently disposed of in a manner appropriate to their sensitivity and/or protective marking (e.g. incinerated or shredded).

15.1.3. If information is lawfully required under the disclosure rules,<sup>22</sup> protective marking does not provide an exclusion.

#### 15.2. Technical records (ISO 17025:2005 ref. 4.13.2)

15.2.1. As a minimum, the technical records shall contain all relevant information relating to the following.

- a. The collection and movement of material (physical exhibits and information), including:
  - i. the date on which the material was taken or received;
  - ii. the date of subsequent movement of the material to another party;
  - iii. from whom or where and to whom or where the material was moved; and
  - iv. the means by which the material was received or passed from/to another party (see **5.8 Handling of test items**).
- b. Sufficient relevant detail to be able to trace any analytical output to:
  - i. a specific instrument;
  - ii. instrument configuration, e.g. software version or, if relevant, firmware;
  - iii. the operator; and
  - iv. the date of the analysis.
- c. The examination of exhibits, and materials recovered from exhibits, whether made by the practitioner or an assistant.
- d. Verbal and other communications, including reports and statements.
- e. Meetings attended and telephone conversations, including points of agreement or disagreement, and agreed actions.
- f. E-mails and other electronic transmissions (e.g. images) sent or received.

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<sup>22</sup> See ACPO/CPS *Guidance Booklet for Experts, Disclosure: Experts' Evidence, Case Management and Unused Material*, May 2010. Accessed from the internet 07/03/2014:  
[https://www.cps.gov.uk/legal/assets/uploads/files/Guidance\\_for\\_Experts\\_-\\_2010\\_edition.pdf](https://www.cps.gov.uk/legal/assets/uploads/files/Guidance_for_Experts_-_2010_edition.pdf)

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- 15.2.2. The records, in whatever form, shall be clear and comprehensive, and expressed in such a manner and in sufficient detail that another practitioner in the same field, and in the absence of the original practitioner, can follow the nature of the work undertaken, any interpretations/opinions made, and the inferences drawn from the work. This is particularly important in situations where an insufficient quantity of the exhibit remains for independent re-examination or testing, or the form of the exhibit is altered.
- 15.2.3. Whenever practicable, technical records shall be produced contemporaneously. The practitioner shall normally begin making records from the time instructions are received and shall continue making records throughout their involvement in the case, although, in some circumstances, it may be appropriate to start making records prior to any formal instructions from the customer.
- 15.2.4. When an examination, test result or observation is rejected, the reasons shall be recorded.
- 15.2.5. For the period of record retention, traceability should be maintained for all names, initials and/or identifiers, and for these to be legible.
- 15.2.6. It shall be possible to associate all changes to data with the person having made those changes (e.g. timed and dated electronic-signatures). Reasons for the changes shall be given.
- 15.2.7. The practitioner's examination records shall be paginated using a page numbering system, which indicates the total number of pages.<sup>23</sup> Each page of every document in the case record shall be traceable to the analyst or examiner responsible for the sampling and/or performance of each examination or test, to a uniquely identified case and uniquely identified exhibit<sup>24</sup>. It shall be clear from the case record who has performed all stages of the analysis or examination and when each stage of the analysis or examination was performed. Alterations or comments in the records shall be clear and be signed, or otherwise be attributable to the individual who made them, and dated.

### 15.3. Checking and review

- 15.3.1. The provider shall ensure that methods that require calculations (including those embedded in spreadsheets) and/or critical data transfers that do not form part of a validated electronic process include within the procedure that checks are carried out, preferably by a second person.
- 15.3.2. The provider shall have a procedure for carrying out checks on critical findings<sup>25</sup> and designated staff authorised to carry out such checks. Where checks on critical findings are carried out by authorised staff, the records shall indicate that

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<sup>23</sup> Alternative arrangements for demonstrating that all pages are present and the sequence of these pages are possible, but must be agreed with UKAS®.

<sup>24</sup> Items should be identified with a number which is unique within the organisation rather than simply within the case. A date and initials is not considered unique and although would not devalue or invalidate the exhibit if properly handled, it does add a risk which should be avoided.

<sup>25</sup> Critical findings are observations or results that: have a significant impact on the conclusion reached, the interpretation, or an opinion provided; cannot be repeated or checked in the absence of the exhibit or sample; and/or could be interpreted differently.

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each critical finding has been checked and agreed, and by whom and when the checks were performed. The procedure should include a process for resolving any non-conforming results or findings.

- 15.3.3. Where the organisation has deemed<sup>26</sup> the procedure requires an independent check, the organisation should define this level of independence and records should be kept to demonstrate this.
- 15.3.4. The provider shall have documented policies and procedures and authorised staff for the review of case records, including reports and statements. The review shall establish from the case notes and discussion with the practitioner that the work carried out is:
- a. appropriate to the requirements of the case;
  - b. fully documented in the case notes, with appropriate checks on critical findings, calculations and data transfers;
  - c. in compliance with the provider's documented policies and procedures; and
  - d. consistent with the contents of the report or statement.
- 15.3.5. In all reviews, the case record shall indicate that the review has been carried out, by whom and when.
- 15.3.6. The checks and reviews shall be recorded as entries against each finding or on a summary of findings or on a report, as appropriate. If the checker/reviewer disagrees on any point and the matter cannot be resolved, the reason(s) for the disagreement and any action taken as a result shall be recorded.
- 16. Internal audits (BS EN ISO/IEC 17025:2005 ref. 4.14)**
- 16.1. The annual audit programme shall cover all aspects of the management system, including but not be limited to:
- a. implementation of the management system;
  - b. records of individual files; and
  - c. information security.
- 16.2. A risk assessment-based approach is taken to determine the frequency of the audit schedule, but methods shall be audited at least once every four-year cycle.<sup>27</sup>
- 16.3. Where the provider undertakes to make statements of opinions and interpretations, the audits shall include a review of the process by which these are made and of the competence requirements of the individuals authorised to make such statements.

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<sup>26</sup> For instance, this determination may be at the identification of end-user requirements in the validation study.

<sup>27</sup> The frequency of audits should take account of the size of the organisation, the complexity of the work being audited, the frequency of use of specific technical methods or procedures, and the potential consequences of noncompliance with the requirements of the Standard. The value of occasional unannounced audits should also be considered.

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- 16.4. Where examination and testing activities are delivered from a number of different operational sites, the internal audits shall cover all sites and all aspects of the management system.
- 16.5. When the results of the audit cast doubt on the effectiveness of examinations, or the correctness or validity of the provider's test results to the extent that misleading information may have been reported, the provider shall treat this as a non-conforming test.
- 17. Technical requirements (ISO 17025:2005 ref. 5.2)**
- 17.1. Personnel**
- 17.1.1. The provider shall carry out appropriate background verification checks (e.g. security checks) on all candidates for employment and contractors in accordance with relevant laws, regulations and ethics. These checks shall be proportional to the business requirements, the classification of the information to be accessed and the perceived risks.
- 17.1.2. The contracts for all staff, permanent and temporary, shall contain confidentiality agreements,<sup>28</sup> their own and the provider's responsibility for information security, and details of their expected conduct.
- 17.2. Code of Conduct**
- 17.2.1. The provider shall have a Code of Conduct compatible with the Forensic Science Regulator's; staff should be made aware of it and how it relates to the objectives of the management system.
- 17.3. Training**
- 17.3.1. The provider and/or individual members of staff, including contracted staff, shall maintain and keep readily available appropriate records of education, training, skills and experience in sufficient detail to provide evidence of proper training and formal assessment.<sup>29</sup> These records shall include, but not be limited to:
- a. academic and/or professional qualifications;
  - b. internal/external courses attended;
  - c. relevant training/retraining received whilst employed by the provider;
  - d. any subsequent remedial action from any substantive complaints, errors or adverse judicial comments;
  - e. any substantive accolades, commendations, etc. pertinent to skills and experience;
  - f. the tasks for which the individual has been assessed as competent and authorised to carry out; and
  - g. the date(s) on which competence and authorisation were confirmed.

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<sup>28</sup> The confidentiality agreements should cover the intellectual property of the provider and all information relating to casework, and shall not conflict with any disclosure requirements.

<sup>29</sup> This may include records of Continuous Professional Development.

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17.3.2. The training system shall be fully documented and the provider shall have a policy for retention for training manuals and training records in line with that of case files.

### **18. Competence**

18.1.1. The competence of staff shall be routinely reassessed at intervals to ensure that it has been maintained and is up to date.

18.1.2. Policies and procedures for on-going competency should consider any adverse judicial comments and complaints that may undermine an individual's credibility.

18.1.3. The provider shall have policies and procedures for taking remedial action when competence is found to have lapsed.

18.1.4. The provider shall determine the appropriate competence framework for technical roles.<sup>30</sup>

### **19. Accommodation and environmental conditions (ISO 17025:2005 ref. 5.3)**

#### **19.1 Laboratory facilities**

19.1.1. The laboratory facilities shall include, as appropriate:

- a. suitable laboratory accommodation and appliances (e.g. laboratory benches, safety cabinets, refrigerators, freezers) and space (per employee) to carry out the work to the required standard, safely, and without cross-contamination;
- b. provision of appropriate environmental conditions (e.g. lighting, temperature, humidity, ventilation/air flow) required to facilitate correct performance of examinations or tests, and not adversely affect the required quality of any measurement or invalidate results;
- c. proportionate protection against likely risks, such as arson, theft or interference with exhibits;
- d. archive/storage facilities with adequate storage conditions to prevent loss, deterioration and contamination, and to maintain the integrity and identity of documents/records/exhibits both before, during and after examinations or tests have been performed; and
- e. facilities for the secure disposal of confidential waste and the safe disposal of hazardous materials.

19.1.2. The access and use of exhibit storage areas and server rooms should be controlled in addition to laboratory areas where work is carried out. The provider shall hold on record a list of all staff who are authorised to enter these areas. This shall be reviewed and updated regularly.

19.1.3. Delivery and loading areas, and other points where unauthorised persons may enter the building, shall be isolated from casework and information processing areas and access shall also be controlled. Unauthorised persons needing to

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<sup>30</sup> Recommended frameworks include the National Occupational Standards, such as produced by Skills for Justice<sup>®</sup> (a registered trade mark of the Justice Sector Skills Council).

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enter controlled areas shall be escorted at all times by authorised staff and a record of these entries shall be maintained.

### **19.2. Contamination avoidance, monitoring and detection**

- 19.2.1. The provider shall have policies and procedures relevant to the nature of the casework for the prevention, monitoring and detection of contamination that could interfere with the analyte of interest.
- 19.2.2. The steps in establishing procedures relevant to contamination control in new methods<sup>31</sup> shall include, but are not restricted to:
  - a. conducting a hazard or risk-based analysis of the entire method with respect to contamination (e.g. process mapping);
  - b. identifying points in the process where contamination events could occur (e.g. consumable selection, transfers, etc.);
  - c. establishing acceptable control limits at each point or stage of the method;
  - d. establishing monitoring requirements (e.g. frequency);
  - e. establishing preventative and corrective actions (e.g. when acceptable or control limits are found to be exceeded);
  - f. establishing effective methods for both routine and deep cleaning/decontamination of facilities and surfaces;
  - g. establishing requirements for record keeping; and
  - h. establishing procedures for verifying that the contamination control system remains fit for purpose.
- 19.2.3. The processes and procedures for the management of contamination shall also include consideration of, but not be restricted to, the following:
  - a. Limiting and recording access by internal and external visitors, taking into account any recent activities relevant to casework including, but not limited to:
    - i. crime scene attendance;
    - ii. prisoner handling; and
    - iii. firearm and drug handling.
  - b. Effective separation of incompatible activities to prevent cross-contamination. This includes, but is not limited to:
    - i. un-amplified and amplified DNA;
    - ii. high and low-level drugs work;
    - iii. examination of firearms and firearm discharge residues;
    - iv. examination of accelerant and fire scene debris; and

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<sup>31</sup> This is taken to be methods introduced or put forward for accreditation since the publication of the first edition of these Codes, December 2011.



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- v. examination of exhibits from suspects, victims and scenes.
  - c. Use of disposable equipment e.g. gloves, face masks and mob caps.
  - d. Testing and record keeping of batches of consumables and reagents in all areas of the examination/analytical processes and, where appropriate, for contaminants that could interfere with the success or interpretation of the examination or test.
  - e. Good working practices, such as:
    - i. protecting exhibits/samples in wrapping/containers when not being worked on or used;
    - ii. not introducing contaminated spatulas/pipettes into stock bottles of solvent, standard or reagent;
    - iii. not pouring unused portions of solvent, standard or reagent back into bulk supplies;
    - iv. frequent changing of solvent used for rinsing equipment.
  - f. Good housekeeping practices.
  - g. Analysis of blank controls.
  - h. Environmental sampling/monitoring with particular reference to acceptable levels of relevant potential contaminants should be carried out to include equipment, work areas, consumables and clothing to ensure that any contamination of accommodation and/or equipment that does occur is recognised and controlled.
  - i. Methods for both routine and deep cleaning/decontamination including:
    - i. the nature of contaminants significant to the operation of the laboratory;
    - ii. work surfaces, walls, doors, flooring, ceiling, ducting, other fixtures and fittings and the likely vectors of contaminant transmission;
    - iii. the materials/chemicals appropriate for use in contamination control;
    - iv. appropriate training and competence of staff deployed in cleaning/decontamination processes; and
    - v. the governance and oversight by senior management.
- 19.2.4. The policies and procedures shall ensure access to laboratory areas is restricted to authorised individuals. Where appropriate these individuals shall be covered by relevant elimination databases and any results found in casework screened against them as detailed in policies and procedures. These databases may be locally or remotely maintained.
- 19.2.5. Policies and procedures for elimination databases of laboratory staff, internal/external visitors and equipment suppliers should include, but are not limited to:
- a. reporting policies;

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- b. data formats;
- c. searching policies;
- d. validation of searching procedures;
- e. security and access;
- f. retention periods;
- g. sharing agreements (i.e. between laboratories/providers);
- h. agreements/consents; and
- i. release forms.

### **20. Test methods and method validation (ISO 17025:2005 ref. 5.4)**

#### **20.1. Selection of methods (ISO 17025:2005 ref. 5.4.2)**

- 20.1.1. The general requirement is that all technical methods and procedures used by a provider shall be validated. This section details the principles of the requirement for validated methods, the next section, **20.2. Validation of methods**, details the required processes.
- 20.1.2. Providers with methods already<sup>32</sup> within the schedule of accreditation will normally only be required to compile the existing validation paperwork to form as comparable validation library as possible, and produce the short statement of accreditation as detailed in section 20.15.<sup>33</sup>
- 20.1.3. Even where a method is considered standard and is in widespread use, validation will still need to be demonstrated. The topic of verification of the validation of adopted methods is discussed below although many of the other validation steps are likely also to apply. If a method is being newly included in the provider's scope of accreditation and validation has not been conducted at the laboratory site where it is to be implemented, the provider will have to follow the adopted methods procedure, which ends in the production of a validation library and statement of completion as well as demonstrating the method works in their hands.
- 20.1.4. If a method is required to use portable equipment for any reason, the validation study shall include any additional aspects that may impact on the tests (e.g. temperature, humidity, surfaces, cross reactivity, lighting). For ISO 17020:2012 applications, see Process Requirements 7.1.1 in UKAS-RG 201:**2015**.
- 20.1.5. For novel techniques or non-routine activities the provider should have validated the method, product or service in accordance with the requirements of these Codes and/or should ensure that the status of the validation, product, method or service is clearly understood by the customer prior to commissioning any such

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<sup>32</sup> This is taken to be methods introduced or put forward for accreditation since the publication of the first edition of these Codes, December 2011.

<sup>33</sup> Subsequent releases of these Codes may extend the requirement to existing methods. However, updates in technology, reviews of existing methods and the need for continuous improvement are expected to prompt validation studies.

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work. If these activities are to become part of the routine activities of the provider, accreditation should always be sought.

### **20.2. Validation of methods (ISO 17025:2005 ref. 5.4.5)**

- 20.2.1. Validation should be conducted prior to implementation of the method. This may be performed by the provider, manufacturer or another provider.
- 20.2.2. Where the validation has not been conducted at the laboratory site that will be using the method, the provider must still verify the scope of the validation with the required steps, scaled according to the adequacy and relevance of the available existing validation study. The provider's own competent staff shall demonstrate such adopted methods perform reliably at the given location following the validation process.
- 20.2.3. The validation policy or procedure shall set out roles and responsibilities of staff involved in conducting validation, authorisation of key stages and reviewing outcomes.
- 20.2.4. To ensure validation studies are conducted on the final method, there should a clear boundary between development and validation. This should include consideration of how to prevent inadvertent re-entering of the development process once validation has started.
- 20.2.5. The validation procedure shall include where relevant, but is not limited to:
  - a. determining the end-user's requirements and specification;
  - b. risk assessment of the method;
  - c. a review of the end-user's requirements and specification;
  - d. the acceptance criteria;
  - e. the validation plan;
  - f. the outcomes of the validation exercise;
  - g. assessment of acceptance criteria compliance;
  - h. validation report;
  - i. statement of validation completion; and
  - j. implementation plan.
- 20.2.6. In certain circumstances implemented methods will require revalidation, e.g. when:
  - a. quality control indicates that an established method, is changing with time;
  - b. equipment that was not validated to be mobile or portable is moved to a new location;
  - c. deficiencies have become apparent after the method has been implemented; or
  - d. the end-user identifies a change in requirement.

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### 20.3. Determining the end-user's requirements and specification

- 20.3.1. The process of innovation ending in the implementation of a validated method is more likely to be instigated by the provider than the end-user. However to meet the needs of the CJS, which is the end-user, the range of end-user's requirements needs to be determined.
- 20.3.2. The amount of direct input from the CJS end-user should be determined by the provider, based on the type of innovation; certain requirements may be generic and form a set of core requirements to the casework type.
- 20.3.3. The Criminal Practice Directions<sup>34</sup> (e.g. 19A.5) that supplement part 19 of the Criminal Procedure Rules<sup>35</sup> should be considered as providing an insight as to the expectations of the CJS end-user.
- 20.3.4. The end-user's requirement shall take account of, as appropriate:
- who will operate or use the new method, product or service post-delivery, and in what environment;
  - what the new method or product is intended to deliver for the end-user;
  - what statutory and regulatory requirements related to development and use of the method or product apply;
  - whether there are any compatibility issues to be considered, e.g. data output formats;
  - what level of quality performance is expected; and
  - by what date the new method, product or service is required for implementation.
- 20.3.5. End-user requirements should conform to the following rules:
- each requirement is a single statement;
  - each requirement is testable;
  - each requirement specifies something that the solution will do, not how it will do it;
  - each requirement specifies in its wording whether it is mandatory or desirable; and
  - each requirement is written in a language that can be understood by the non-technical stakeholders.
- 20.3.6. Where the method is part of a service to be provided to a specified customer, the provider shall also ensure their formal agreement.

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<sup>34</sup> The Criminal Practice Directions 2015 are available from:  
<https://www.judiciary.gov.uk/publications/criminal-practice-directions-2015/> [Accessed 17/11/15]

<sup>35</sup> The Criminal Procedure Rules 2015 are available from:  
<http://www.legislation.gov.uk/ukSI/2015/1490/contents/made> [Accessed 17/11/15]

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20.3.7. The end-user's requirements shall then be written as a detailed specification for the method, product or service, and shall include the technical quality standards.

### **20.4. Risk assessment of the method**

20.4.1. Once the method has been designed or determined, there shall be an assessment to identify any risks, or potential risks, to the CJS related to the use of the method or amendment to the method, including ad hoc methods. The process shall include, but not be limited to:

- a. identifying, on the basis of the use to which the results may be put, the possible impact on the CJS of any errors in the results, associated materials or procedures; and
- b. identifying areas where the operation of the method, or interpretation of the results, requires specialist skills or knowledge to prevent ambiguous or misleading outputs or outcomes.

20.4.2. Where the method relies on a scientific model or theory the risk assessment should address the following in a forensic science context:

- a. the validity of the theory/model;
- b. any assumptions incorporated within the theory/model; and
- c. limits on the application of the theory/model.

20.4.3. In light of the assessment there shall be recommendations for modification of the specification, specific studies to be included in the validation exercise or additional procedures and/or safeguards that should be implemented. Examples would include, but probably not be limited to:

- a. caveats about the use of the method;
- b. circumstances in which the use of the method would be inadvisable; and
- c. additional work that should be undertaken in combination with the method.

20.4.4. Where exhibits provided by end-users, or data derived from these, are required for the development work or validation, the provider shall obtain prior permission for their use and include their use in the risk assessment.

20.4.5. The risk assessment shall be subject to version control and should feed into the statement of validation completion.

### **20.5. Review of the end-user's requirements and specification**

20.5.1. The provider shall review the end-user's requirement to ensure that it has been translated correctly into the specification and is fit for purpose. Where appropriate the intended end-user may be involved in this review process.

20.5.2. When a review identifies that there are risks, compatibility, legality or ethical issues, the provider shall produce a revised end-user's requirements and/or specification.

20.5.3. Any subsequent changes to the specification shall then be made formally and only following further review and acceptance of the impact of the changes by the intended end-user.

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20.5.4. The provider shall ensure that all staff involved in the development and validation/verification of the method are informed of any agreed changes to the end-user's requirements or specification.

### 20.6. The acceptance criteria

20.6.1. The acceptance criteria should be clearly stated, based upon the specification, the risk analysis and any control strategies put in place to control identified risks.

20.6.2. The acceptance criteria shall be used to demonstrate the effectiveness of the method and control strategy within measurable and set tolerances.

### 20.7. The validation plan

20.7.1. The validation shall be carried out according to a documented validation plan. The validation plan shall identify and define the functional and performance requirements, the relevant parameters and characteristics to be studied and the acceptance criteria for the results obtained to confirm that the specified requirements for the method, product or service have been met.

20.7.2. Where appropriate, the validation plan shall also include a requirement to check the relevant parameters and characteristics of the procedures for sampling, handling and transportation. The same level of confidence in the results obtained shall be required whether the method is to be used routinely or infrequently.

20.7.3. The validation shall be carried out using simulated casework material in the first instance and subsequently, where possible, permitted and appropriate, with actual casework material to confirm its robustness.<sup>36</sup>

20.7.4. The validation plan will need to be tailored depending on whether it is intended for:

- a. validation of measurement-based methods;
- b. validation of interpretive methods;
- c. verification of the validation of adopted methods; and/or
- d. verification of the impact of minor changes to methods.

20.7.5. The validation plan should be signed off by an individual with sufficient knowledge of the relevant field under study.

20.7.6. Particularly where this is a plan for the validation of a new method rather than an adopted method (see section 20.10), it is accepted additional individuals may be needed to provide the breadth of technical knowledge to evaluate the plan.<sup>37</sup> In such cases these individuals should be listed and their role in supporting the person responsible for sign-off detailed.

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<sup>36</sup> Legal advice may be required for the use of casework material where the exemption in relevant legislation 'for law enforcement purposes' may not apply, further guidance may be issued.

<sup>37</sup> Good experimental design ensures the study tests the features required and can reduce the overall reduce experimental effort.

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### 20.8. Validation of measurement-based methods

- 20.8.1. The validation plan should ensure the required parameters and characteristics are studied:
- a. using an analyst or examiner competent in the field of work under study, who has sufficient knowledge of the work to be able to make appropriate decisions from the observations made as the study progresses; and
  - b. using equipment that is within specification, working correctly and, where appropriate, calibrated.
- 20.8.2. The functional and performance requirements, and the relevant parameters and characteristics for measurement-based methods that shall be considered include the:
- a. the competence requirements of the analyst/user;
  - b. environmental constraints;
  - c. the exhibit/sample size;
  - d. the exhibit/sample handling;
  - e. exhibit/sample homogeneity;
  - f. the ability of the sampling process to provide a representative sample of the exhibit;
  - g. the efficiency of recovery of the substance(s) to be identified/measured (i.e. analyte) during sample preparation for analysis;
  - h. the presence or absence of the analyte(s) of interest in the sample analysed;
  - i. the minimum quantity of each analyte that can be reliably detected;
  - j. the minimum amount of each analyte that can be accurately quantified;
  - k. the identification/measurement relates to the analyte(s) alone, and is not compromised by the presence of some matrix or substrate effect or interfering substance;
  - l. the results are consistent, reliable, accurate, robust and with an uncertainty measurement;
  - m. compatibility of results obtained by other analysts using different equipment and different methods; and
  - n. the limitations of applicability.

### 20.9. Validation of interpretive methods<sup>38</sup>

- 20.9.1. The functional and performance requirements for interpretive methods are less prescriptive than for measurement-based methods. They concentrate on the competence requirements for the staff involved and how the staff shall

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<sup>38</sup> Examples of interpretive methods may include the comparison of marks, handwriting or microscopic comparisons.

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demonstrate that they can provide consistent, reproducible, valid and reliable results that are compatible with the results of other competent staff. This may be achieved by a combination of:

- a. independent confirmation of results/opinions by another competent examiner (i.e. without prior knowledge of the first result/opinion provided);
- b. participating in inter-laboratory comparisons (collaborative exercises or proficiency tests);
- c. external recognition with a recognised and relevant professional body; and
- d. designing frequent in-house assessment into the process using positive and negative competence tests.

20.9.2. An interpretive method shall require only the relevant subset of the parameters and characteristics for measurement-based methods to be determined.

### **20.10. Verification of the validation of adopted methods**

20.10.1. Where the validation has not been conducted at the laboratory site that will be using the method, the provider must still verify the scope of the validation with the required activity scaled according to the adequacy and relevance of the available existing validation study.

20.10.2. Verification is defined as confirmation, through the assessment of existing objective evidence or through experiment that a method, process or device is fit (or remains fit) for the specific purpose intended.

20.10.3. The amount of work required to be carried out in verification exercises when introducing methods developed and validated elsewhere, shall take account of the adequacy of the available existing validation data and the familiarity and experience of the provider's staff with the techniques, equipment and facilities involved.

20.10.4. The provider shall check its performance against the specification for the method it is required to produce rather than simply against existing published data, as the requirements may differ.

20.10.5. The assessment to identify any risks, or potential risks, to the CJS related to the use of the method or amendment to the method should not be overlooked.

20.10.6. The 'validation' report shall have as a minimum a summary of the experimental work/review, results, staff training/competence requirement and assessment plans. The required validation library and statement of validation completion shall be produced.

### **20.11. Minor changes in methods**

20.11.1. Replacing like-for-like equipment<sup>39</sup> or minor changes to methods used by the provider may not always require a full revalidation exercise. The impact of the

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<sup>39</sup> Replacing the same make and model may still need some assessment as minor modifications, including software and firmware, might affect the operation.



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change shall be risk assessed, verified against the original validation and authorised in line with other validation studies.

- 20.11.2. A revalidation exercise should be carried out when changes are assessed to have the potential to influence the results obtained.

### 20.12. Validation outcomes

20.12.1. A summary of the outcome of the validation exercise shall be included in the validation report, which shall normally be retained for 30 years after the last use of the method. A full record of the validation exercise will normally be retained by the provider for a similar period, but as a minimum shall be maintained for the functional life of the method and shall include:

- a. the authorised validation plan and any subsequent changes to the plan, with justifications and authorisations for the changes;
- b. all experimental results from the validation exercise;
- c. a detailed comparison of the experimental results with the specified requirements;
- d. independent evaluation of the extent to which the results obtained conform or otherwise to the specified requirements;
- e. any corrective actions identified; and
- f. independent approval of the validation.<sup>40</sup>

### 20.13. Assessment of acceptance criteria compliance

20.13.1. The independent evaluation of compliance of the experimental results with specified requirements shall be carried out by a person (or persons) not involved in the development of the method or conducting the validation process.

20.13.2. The person(s) shall have demonstrated they have sufficient knowledge of the issues involved to be able to identify and assess the significance of any deficiencies.<sup>41</sup>

20.13.3. The independent authorisation shall typically establish whether:

- a. the validation work is adequate and has fully demonstrated compliance of the method with the acceptance criteria for the agreed specification; and
- b. the method is fit for its intended use.

20.13.4. Should the provider plan to implement methods rated as high risk and/or likely to attract challenge once implemented, the Forensic Science Regulator ought to be consulted as to the need for any wider review and/or publication prior to implementation.

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<sup>40</sup> The same person may carry out both the independent evaluation and the independent authorisation, if competent to do so.

<sup>41</sup> The person(s) may be employed by the provider, contracted by the provider to carry out the evaluation, or be wholly independent of the provider. If employed by the provider, the evaluator/authoriser would need to be able to demonstrate the appropriate level of independence.

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### 20.14. Validation report <sup>42</sup>

- 20.14.1. The provider shall produce a validation report in sufficient detail to allow independent assessment of the adequacy of the work carried out in demonstrating that the method, product or service conforms to the specification and is fit for purpose. It need not contain all the experimental data, but a summary of this data shall be provided and the raw data shall be available for inspection if required.
- 20.14.2. The content of the validation report shall depend on the type and extent of validation carried out, but as a general guide it should include, as applicable:
  - a. a title and unique identifier;
  - b. a description of the purpose of the method, product or service;
  - c. the specification;
  - d. the name, version number and manufacturer of any equipment used;
  - e. the name(s) and signature(s) of the person(s) accountable for the development and validation processes;
  - f. the validation plan;
  - g. risk assessment;
  - h. any authorised changes to the validation plan and justifications for the changes;
  - i. a summary of the experimental work and outcomes in sufficient detail to ensure that the tests could be independently replicated by a competent person;
  - j. details of any review reports produced;
  - k. conformity with the specification and acceptance criteria (expected compared with actual results and any pass/fail criteria);
  - l. any limitations/constraints applicable;
  - m. any related published papers and similar methods in use by the provider;
  - n. any recommendations relating to the implementation of the method, product or service; and
  - o. the date of the report.
- 20.14.3. The provider shall submit the validation report for review by persons suitably qualified and independent of the validation process; any issues arising should be dealt with expeditiously.
- 20.14.4. All the required records relating to the development and validation of the method, product or service shall be archived, together with the means of accessing the

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<sup>42</sup> Providers with methods already within the schedule of accreditation will normally only be required additionally to compile the validation library, which contains a validation report in its original format and specification.

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records, which will normally be kept for 30 years following its last use in casework.<sup>43</sup>

### 20.15. A statement of validation completion

- 20.15.1. The aim of this statement is to provide those making decisions on the use of the results a short executive summary of the validation steps performed, and key issues surrounding the validation. The intention is that the statement will be no more than two sides of A4 paper in plain language.<sup>44</sup>
- 20.15.2. The approval by the provider on the scope of the validation must be clear.
- 20.15.3. The provider should provide any further information that would be useful to the CJS. Examples would include, but probably not be limited to:
  - a. caveats about the use of the method;
  - b. the approved uses of the method, which could be by case type or exhibit type;
  - c. circumstances in which the use of the method would be inadvisable; and
  - d. additional work that should be undertaken in combination with the result.

### 20.16. Validation library

- 20.16.1. The provider shall have available a *library* of documents relevant to the authorisation of the new method through validation or verification. Where the following are not already distinct sections in the validation report, the content of this library shall include, but need not be limited to:
  - a. the specification for the method approved (**20.3 Determining the end-user's requirements and specification**);
  - b. any associated supporting material, such as academic papers or technical reports that were used to support or provide evidence on the applicability of the method<sup>45</sup>;
  - c. the risk assessment for the method approved;
  - d. the validation plan for the method approved;
  - e. the validation report;
  - f. the record of approval; and

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<sup>43</sup> The blanket retention period is an alternative to tracking a method's use in casework and applying the correct retention period in accordance with the Criminal Procedure and Investigations Act 1996, as amended.

<sup>44</sup> See also the CPS Key Requirements for Forensic Science Providers available from [http://www.cps.gov.uk/legal/s\\_to\\_u/scientific\\_evidence/core\\_foundation\\_principles\\_for\\_forensic\\_science\\_providers/](http://www.cps.gov.uk/legal/s_to_u/scientific_evidence/core_foundation_principles_for_forensic_science_providers/) [Accessed 17/11/15] and the list of questions in direction 19A.5 contained in the Criminal Practice Directions 2015 available from <https://www.judiciary.gov.uk/publications/criminal-practice-directions-2015/> [Accessed 17/11/15].

<sup>45</sup> The literature review also ensures the body of knowledge requirement as outlined in R v. Bonython [1984] 38 SASR 45 can be demonstrated as well as supporting the application of direction 19A.5d of the Criminal Practice Directions 2015.

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- g. the statement of validation completion.
- 20.16.2. Where the method implements a scientific theory/model or an interpretation or evaluation model, the library should include a record of information supporting the use of the theory/model.
- 20.16.3. Where the method relies on reference collections or databases, the nature, access and their availability should be described.
- 20.16.4. The information in the library shall be disclosable<sup>46</sup> and should be prepared with that requirement in mind.

### **20.17. Implementation plan and any constraints**

- 20.17.1. The provider shall have a plan for implementation of methods, products or services new to the provider. This plan shall address, where relevant:
  - a. if revisiting old cases should be explored, where the revised or new method offers new analytical opportunities and, if relevant, the benefits or risks communicated to the customer;
  - b. the standard operating procedure (including the process for assessment/interpretation/reporting of results) or instructions for use;
  - c. requirements for staff training, competence assessment and on-going monitoring of staff competence;
  - d. integration of the method with what is already in place;
  - e. if the method is intended to be included in the scope of accreditation and what steps are required;
  - f. the monitoring mechanisms to be used to demonstrate that the method remains under satisfactory control during its use;
  - g. the protocols for calibration, monitoring and maintenance of any equipment;
  - h. the supply and traceability of any standards/reference materials;
  - i. the supply and quality control of key materials, consumables and reagents;
  - j. the exhibit handling and any anti-contamination protocols;
  - k. the accommodation plan;
  - l. any special health and safety, environmental protection, data protection and information security arrangements;
  - m. the communication plan; and
  - n. the schedule for post-implementation review.

### **20.18. Estimation of uncertainty of measurement (5.4.6)**

- 20.18.1. Guidance on the estimation of uncertainty of measurement is contained in Appendix N of the UKAS<sup>®</sup> M 3003 publication *The Expression of Uncertainty and Confidence in Measurement*.

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<sup>46</sup> Commercial-in-confidence does not override the disclosure requirements of the Criminal Procedure and Investigations Act 1996 as amended and may prevent methods, products or services being used.

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- 20.18.2. When a procedure is modified, in addition to any validation or verification, providers should also review the uncertainty of measurement.
- 20.18.3. The Criminal Practice Directions (19A.5c) that supplements part 19 of the Criminal Procedure Rules include several factors with ought to be considered, however the following direction the court may take into account in accessing admissibility is particularly relevant:

*19A.5c if the expert's opinion relies on the results of the use of any method (for instance, a test, measurement or survey), whether the opinion takes proper account of matters, such as the degree of precision or margin of uncertainty, affecting the accuracy or reliability of those results.*

### **20.19. Control of data (ISO 17025:2005 ref. 5.4.7)**

#### **20.19.1. General**

- 20.19.1.1. The provider shall have procedures within its management system to ensure that all necessary information is recorded accurately, maintained so that its authenticity and integrity is not compromised, and is retained and destroyed in accordance with the provider's retention and destruction policy.

#### **20.19.2. Electronic information capture, storage, transfer, retrieval and disposal<sup>47</sup>**

- 20.19.2.1. The provider shall establish procedures for the capture and retrieval of electronic information appropriate for the process or method to ensure that all the necessary information is captured without change, and that any information lost as a result of the capture process is at an acceptable level.
- 20.19.2.2. Where scanning technology is used, the provider shall establish procedures and quality control for the scanning of documents in paper form, microforms and other forms of information, as appropriate, to ensure that any potential information loss as a result of the scanning is within acceptable limits.<sup>48</sup>
- 20.19.2.3. Appropriate to the associated method or process, the procedure and policies should ensure that where key information is extracted from image files the original images are retained and linked with the captured information, including metadata.
- 20.19.2.4. Where information in the form of a compound document is stored (e.g. embedded files, hyperlinks), the linkage of all elements of the compound document shall be stored in line with the provider's retention policy along with their content.
- 20.19.2.5. Critical information should be accessible throughout its period of retention.

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<sup>47</sup> Further information and guidance can be found in BS 10008:2014, *Evidential weight and legal admissibility of electronic information – Specification*.

<sup>48</sup> Further information and guidance can be found in ISO 12653-1:2000, *Electronic imaging - Test target for the black-and-white scanning of office documents - Part 1: Characteristics*.

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- 20.19.2.6. When information is migrated to alternative storage media, the provider shall establish procedures to ensure that all digital objects<sup>49</sup> have been successfully migrated and the digital object and file format of the migrated digital objects have not changed, or that the changes are known, have been audited, and meet requirements.
- 20.19.2.7. If replacement software (e.g. an operating system or application software) is implemented, the provider shall ensure that procedures are established to retain access to the relevant information.
- 20.19.2.8. Where information is compressed during the storage and transfer processes (e.g. in order to reduce stored file size), the compression method used shall not affect the authenticity and integrity.
- 20.19.2.9. Information shall be retained in audit trails, or using other appropriate processes, which record the disposal of information as specified by the retention and disposal policy.
- 20.19.3. Electronic information security**<sup>50</sup>
- 20.19.3.1. The provider shall establish and document a policy and procedure for the management of electronic information based on business and security requirements and include this in the schedule of regular audit and review.
- 20.19.3.2. The policy and procedure should include a formal method of granting and removing access rights, privileges and password control.
- 20.19.3.3. The policy and procedure should include:
- a. the selection and use of passwords;
  - b. that unattended equipment has appropriate protection;
  - c. a clear desk and screen policy;
  - d. management of removable storage media; and
  - e. segregation of developmental and operational IT environments.
- 20.19.3.4. The provider shall have procedures to protect or back-up electronic records, to prevent loss, corruption (actual or suspected) and unauthorised access to and/or amendment of the records, and for maintaining an audit trail. The back-up data shall be stored for as long as necessary to meet the requirements of the CJS at a separate and secure location. The back-up and restore/recovery procedures shall be tested at regular specified intervals to ensure that information can be retrieved in the event of an

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<sup>49</sup> A digital object is a discrete digital structure that contains meaningful data (e.g. a text file, call record or image), metadata (e.g. details of the data format, ownership or relationship to other data) and a unique identifier.

<sup>50</sup> Should it be required and relevant, more detailed good practice guidance can be obtained from BS ISO/IEC 27001:2013 *Information technology – Security techniques – Information security management systems – Requirements* and BS ISO/IEC 27002:2013, *Information technology – Security techniques – Code of practice for information security management*.

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information loss. Details of all recovery operations shall be retained for as long as the information to which they relate.

### **20.19.4. Reference collections and databases**

- 20.19.4.1. Providers shall maintain a list of all reference collections and databases used to make inferences and interpretation; this includes, but is not limited to, those internally developed, commercially developed or remotely accessed.
- 20.19.4.2. Providers shall have a process for determining the requirements of the CJS for internally developed reference collections and databases used to make inferences and interpretations, e.g. through reference to case law.
- 20.19.4.3. Information included in all reference collections and databases used to make inferences and interpretations shall be capable of authentication through documentation to its original source, meet a minimum quality standard specified by the owner of the database, be validated for accuracy of transcription on entry to the database, and be auditable for corruption.
- 20.19.4.4. Any programs or script for data manipulation employed within databases to make inferences and interpretations shall be validated, either separately or as part of the process or method they are used in as laid out in these Codes, e.g. with reference to the impact of any uncertainty of measurement and the risk of false positives/negatives.
- 20.19.4.5. All reference collections and databases used to make inferences and interpretations shall be covered by documentation specifying, as a minimum:
- a. their purpose;
  - b. their location and identification;
  - c. their scope and content;
  - d. the origin of the data;
  - e. any known significant limitations or restrictions;
  - f. the person responsible for management of the database;
  - g. the authorisation and competence requirements of organisations/practitioners contributing to the database;
  - h. the arrangements and format for data collection and submission;
  - i. the process for authentication or validation of the data;
  - j. the arrangements and format for data storage;
  - k. the process for making updates and amendments, and maintaining audit trails;
  - l. the protocols for access to the database and its interrogation and use;
  - m. the quality assurance requirements, including those for data integrity, transfer, inconsistency and error checking;

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- n. the confidentiality and security requirements;
  - o. the format and content of results and reports from interrogation of the database, including the provision of any caveats relating to any limitations with the results provided;
  - p. the projected shelf life of the data;
  - q. the arrangements for review of relevance, use and effectiveness; and
  - r. all relevant legal, commercial and ethical requirements covering their registration, data content, retention, accessibility or use.
- 20.19.4.6. Providers should collate the above information on existing as well as new reference collections and databases (used to make inferences and interpretations) and assess if any persisting gaps will affect critical findings and/or admissibility.

### **21. Equipment (ISO 17025:2005 ref. 5.5)**

#### **21.1. Computers and automated equipment**

- 21.1.1. The provider shall ensure that any software used on computers or automated equipment is assessed for its impact on results and is documented in sufficient detail based on that assessment. This includes any software, developed, configured or modified by the provider or by other outside agencies working on the provider's equipment.
- 21.1.2. Commercial off-the-shelf software and software tools whose operation has an impact in obtaining results will require validation, or any existing validation to be verified, as laid out in **5.4.5 Validation of methods**.
- 21.1.3. User acceptance testing shall be performed prior to software and/or related equipment being placed in service, e.g. when returning from calibration/maintenance or following a move.
- 21.1.4. Other commercial off-the-shelf software (e.g. Microsoft® Word and Excel) that does not directly contribute to results obtained shall be considered suitably validated for general use. However, calculations embedded in spreadsheets that do not form part of a validated electronic process should be included in the required systematic checks.
- 21.1.5. The provider shall maintain records of software products installed on computer systems critical to the production of analytical results, and shall ensure configuration control so that only specified versions of software, settings and firmware, if applicable, are used.<sup>51</sup> The provider shall have documented procedures for configuration management to ensure that all changes to software/hardware are controlled, and that all individual software installations are known and are periodically checked that the correct version is installed and no unauthorised modifications have occurred, e.g. by service engineers.

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<sup>51</sup> Older versions of software may be needed for compatibility with work being undertaken related to older products, or to maintain the validated systems' configuration.



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- 21.1.6. The provider shall have a policy for all items of equipment containing sensitive data to ensure the data:
- are secure during any maintenance visit;
  - remain secure while off-site (e.g. for servicing); or
  - have been removed or securely overwritten prior to removal from site or disposal.
- 22. Measurement traceability (ISO 17025:2005 ref. 5.6)**
- 22.1. Reference standards and reference materials (ISO 17025:2005 ref. 5.6.3)**
- 22.1.1. Intermediate checks (ISO 17025:2005 ref. 5.6.3.3)**
- 22.1.1.1. Reference standards/materials and reagents shall not be used beyond the expiry date, where provided, unless it is verified that they remain fit for purpose beyond that date.
- 23. Handling of test items (ISO 17025:2005 ref. 5.8)**
- 23.1. Receipt of cases and exhibits at the laboratory**
- 23.1.1. There shall be a documented risk-based case acceptance procedure for the handling of recoverable irregularities or rejection of an item for examination arising from, but not limited to:
- a missing exhibit label;
  - an unacceptably low level of agreement between the details on an exhibit label and those on the accompanying submission documentation;
  - inconsistency between the details on an exhibit label and/or accompanying submission documentation and what the exhibit actually is;
  - illegibility in the name, identification number or any other information on an exhibit label;
  - there being more than one label on an exhibit;
  - appropriate control samples not submitted;
  - repeat of the same identification details on different exhibit labels;
  - inadequate or untimely packaging or sealing of an exhibit that could prejudice its integrity;
  - previous handling, storage or evidence of tampering with an exhibit that could prejudice its integrity; and
  - insufficient material being available for meaningful examination or analysis.
- 23.1.2. If the provider is unable to accept the submission the reasons for rejection shall be recorded.
- 23.1.3. Any apparent evidence of tampering with an exhibit shall be investigated. If the outcome of the investigation indicates a deliberate attempt has been made to influence the results of the laboratory examination, the provider's top

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management should be informed to decide the appropriate escalation, which shall include notifying the Forensic Science Regulator.

- 23.1.4. The case acceptance procedure shall also specifically address the handling and receipt or rejection of potentially hazardous exhibits that might pose a risk to the health or safety of staff,<sup>52</sup> potentially compromise other work carried out at the laboratory,<sup>53</sup> or which may not be lawfully retained or handled if accepted by the laboratory.<sup>54</sup>

### **23.2. Case assessment and prioritisation**

- 23.2.1. Prior to commencing work the provider shall, in consultation with the customer, identify the issue(s) in the case, develop an appropriate examination strategy and agree the timescale for the delivery of the results. This may be in an overarching SLA/contract for more routine casework.
- 23.2.2. In developing the examination strategy,<sup>55</sup> as appropriate and as far as is practicable the practitioner shall:
- a. ensure the relevant requirements of the police investigation and/or the instructing solicitor and associated forensic strategy are understood;
  - b. ensure that either all the necessary information (including on any previous examinations), and exhibits required for an effective examination strategy are provided or that any resultant limitations to the scope of the examination are discussed with the customer and made clear to the CJS;
  - c. establish all relevant details of the incident, what exhibits have been recovered for examination, the circumstances relating to the location and recovery of the exhibits, and any examinations of the exhibits or potential for contamination or loss of integrity of the exhibits prior to their coming into their possession; or
  - d. select and prioritise the examinations according to the needs of the investigation, the instructing solicitor, and finally the CJS, with consideration to the exhibits available.

### **23.3. Exhibit handling, protection and storage**

- 23.3.1. The provider shall ensure that exhibit handling policies and procedures address continuity requirements including, but not limited to:
- a. the exhibit or sub-sample can, at all times when in the possession or control of the provider, be uniquely identified;

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<sup>52</sup> For example, when handling hypodermic syringe needles or blood samples.

<sup>53</sup> For example, firearms, bulk drugs seizures or explosives, where the laboratory also carries out gunshot residue analysis or trace drugs or explosives analysis, unless separate reception arrangements and accommodation are provided for these.

<sup>54</sup> For example, cases involving human tissues, drugs, firearms or explosives, for which there may be specific health and safety legislation requirements or specific licensing required.

<sup>55</sup> For further guidance, see Skills for Justice CN702 *Determine the forensic examinations to be undertaken*.

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- b. the exhibit can be conclusively shown to be the exhibit submitted to the provider;
  - c. any material recovered from or derived from an exhibit or sub-sample of an exhibit can be conclusively linked to the exhibit or sub-sample from which it came;
  - d. any results can be conclusively linked back to the exhibit or sub-sample from which it came, or the key equipment used;
  - e. the provider can show whether the exhibit was retained, returned to the organisation that submitted it, or destroyed; and
  - f. the measures to secure exhibits/derived material that have to be left unattended, to ensure that they cannot be tampered with or otherwise compromised.
- 23.3.2. The provider shall, as far as possible, preserve the exhibit, or part of the exhibit, in its original form to allow for independent re-examination or testing. If an insufficient quantity of the exhibit remains for independent re-examination or testing, or the form of the exhibit is altered, the provider shall ensure that details of the exhibit in its original form are recorded in sufficient detail for an independent examiner to be able to check that correct procedures and techniques have been used and that the results obtained are valid.

### **23.4. Exhibit return and disposal**

- 23.4.1. The provider shall have an agreement with its customers for the return or disposal of exhibits, and evidential material recovered from exhibits, once the laboratory examination has been completed.
- 23.4.2. The nature of forensic science is such that providers will deal with material that is subject to legal control or prohibition on possession, production or use. Policies covering such exhibits should reflect any legal control or prohibition covering retention, the return to the organisation that submitted it, or destruction. Examples of such exhibits include, but are not limited to:
- a. human tissue;<sup>56</sup>
  - b. drugs;
  - c. firearms; and
  - d. indecent images of children.
- 23.4.3. If exhibits are to be returned to the customer, or provided for use in court, the provider shall ensure that the customer or court is made aware of any potential health or safety issues relating to the exhibit or its handling, and take appropriate steps to minimise the risk to the customer or court.
- 23.4.4. Biohazardous exhibits shall be destroyed by the provider in accordance with health and safety legislation, regulations and Home Office guidelines.<sup>57</sup>

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<sup>56</sup> Where relevant in England and Wales and Northern Ireland, also see the Human Tissue Act 2004 or in Scotland the Human Tissue (Scotland) Act 2006.

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### 24. Assuring the quality of test results (ISO 17025:2005 ref. 5.9)

#### 24.1. Inter-laboratory comparisons (proficiency tests and collaborative exercises)

- 24.1.1. The provider shall investigate the availability and appropriateness of schemes for inter-laboratory comparisons that are relevant to their scope of accreditation.<sup>58,59,60</sup>
- 24.1.2. The provider shall participate in appropriate schemes, in order to monitor the validity of its examinations or tests, and its performance, both against its own requirements and against the performance of peer providers.<sup>61</sup>
- 24.1.3. When participating in inter-laboratory comparison schemes, the provider's own documented methods and procedures shall be used.
- 24.1.4. Unexpected performance in inter-laboratory comparisons shall be handled as non-conforming testing (**14. Control of non-conforming testing**).

### 25. Reporting the results (ISO 17025:2005 ref. 5.10)

#### 25.1. General

- 25.1.1. The provider shall detail lines of communication in a procedure that assigns roles and responsibilities to ensure the appropriate exchange of information and authorisations where relevant. This should cover communication of reports and evaluative statements with the police and prosecuting authorities, both nationally and locally, or with the instructing solicitor, as appropriate, within agreed

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<sup>57</sup> See HOC 40/73: *Handling and disposal of blood samples in criminal cases (other than those brought under the Road Traffic Act 1972)* this recommends to Chief Police Officers that on completion of examination the sample should be retained at the laboratory and the defence notified that it will be destroyed after 21 days unless they request otherwise. However, if the sample is exhibited, it should not be destroyed without the permission of the committing court. HOC 41/73 provides similar recommendations to HOC 40/73[as above and bibliography], but to the courts. HOC 125/76 extends the arrangements of HOC 40/73 and 41/73 to the handling and disposal of saliva samples. HOC74/82: *Disposal of blood samples, saliva samples and swabs stained with body fluid: handling of exhibits*: extends the arrangements of HOCs 40/73, 41/73 and 125/76 to the disposal of swabs stained with body fluid. HOC25/87 extends the provisions of HOC 74/82 to cover the disposal of urine and any other body samples not previously covered.

<sup>58</sup> Laboratories may refer to the European Proficiency Testing Information System (EPTIS) (<http://www.eptis.bam.de/en/index.htm>) or the European Network of Forensic Science Institutes (ENFSI) websites (<http://www.enfsi.eu/>) for the availability of proficiency testing (PT) schemes.

<sup>59</sup> BS EN ISO/IEC 17025:2005 requires laboratories to evaluate suppliers, this includes PT providers. ISO/IEC 17043:2010, Part 1 and ILAC G13:08/2007 contain recommendations and guidance on the requirements for the operation of PT schemes. These documents should be used as a basis for such an evaluation.

<sup>60</sup> UKAS® accredits PT providers to ISO/IEC 17043:2010; a list of accredited schemes/providers is available on [www.ukas.com](http://www.ukas.com). UKAS® recommends the use of an accredited scheme where one exists.

<sup>61</sup> See TPS 47 *UKAS Policy on Participation in Proficiency Testing*.

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timescales in accordance with the requirements and needs of each specific case and the known key dates in the criminal justice process.<sup>62</sup>

- 25.1.2. The provider shall provide early warning of any operational or scientific issues that could unavoidably affect the timeliness of service delivery to the customer.<sup>63</sup>
- 25.1.3. The reporting scientist shall be appropriately competent and have sufficient involvement in the work carried out in the case. Under exceptional circumstances another reporting scientist may attend court if required, as long as they have appropriate competence.
- 25.1.4. Full records shall be kept of work done and the results obtained in line with other retention policies, even if the customer does not require a detailed report or statement.<sup>64</sup>
- 25.2. Reports and statements to the CJS<sup>65</sup> (ISO 17025:2005 ref. 5.10.2/5.10.3)**
- 25.2.1. Providers shall ensure that all staff who provide factual evidence based on scientific methodology are additionally able to demonstrate, if required:
- whether there is a body of specialised literature relating to the field;
  - that the principles, techniques and assumptions they have relied on are valid; and
  - the impact that the uncertainty of measurement associated with the application of a given method could have on any conclusion.
- 25.2.2. Providers shall ensure that all staff who provide expert evidence have a sufficient level of experience, knowledge, standing in the peer group and, where appropriate, qualifications, relevant to the type of evidence being adduced, to give credibility to the reliability of the work undertaken and the conclusions drawn. They shall also ensure that they are able to explain their methodology and reasoning, both in writing and orally, concisely in a way that is comprehensible to a lay person and not misleading.
- 25.2.3. Providers shall ensure that all staff who provide expert evidence based on their practical experience and/or their professional knowledge are additionally able to provide:<sup>66</sup>
- an explanation of their methodology and reasoning;

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<sup>62</sup> See Protocol for the Supply of Forensic Science Services to the Police and the Crown Prosecution Service, 2006, available at <https://www.cps.gov.uk/publications/docs/forensic.pdf> [Accessed 2014].

<sup>63</sup> See Criminal Procedure Rules 19.2 – (1)(b)(ii) where warning the court of any significant failure to act as required by a direction includes warning of any substantial delay in the preparation of a report.

<sup>64</sup> Documentation of work underpinning reports and statements may be kept separate where it is traceable to the correct reports and statements.

<sup>65</sup> For England and Wales see also see part 19 of the Criminal Procedure Rules 2015, available at: <http://www.legislation.gov.uk/ukxi/2014/1610/contents/made> [Accessed 17/11/15].

<sup>66</sup> Also see the list included in the Criminal Practice Directions 2015 (19A.5c) available from: <http://www.judiciary.gov.uk/publications/criminal-practice-directions-amendment-no-2/> [Accessed 17/11/15]

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- b. reference to a body of specialised literature relating to the field of expertise and the extent to which this supports or undermines their methodology and reasoning;
- c. that any database they have relied on is sufficient in size and quality to justify the nature and breadth of inferences drawn from it, that the inferences are logically sound and that alternative hypotheses in the investigative mode and alternative propositions in the evaluative mode have been properly considered;
- d. their methodology, assumptions and reasoning have been considered by other scientists and are regarded as sound, or where challenged, the concerns have been satisfactorily addressed;
- e. an assessment of the extent to which their methodology and reasoning are now accepted by their peers, together with details of any outstanding concerns;
- f. relevant information to support claims of expertise, as well as anything that may adversely affects credibility or competence (e.g. adverse judicial findings),<sup>67,68</sup> and
- g. in England and Wales, that they have complied with part 19 of the Criminal Procedure Rules.

### 25.3. Report types

25.3.1. Providers can be required to supply both expert advice to support the investigative process and expert evidence to support the judicial process.

25.3.2. This can involve the provision of:

- a. interim progress reports to support investigations, which are the initial forensic investigation report used for an assessment of the forensic exhibits that may help an enquiry, interview or strategy. This report is non-evidential but can be used for disclosure;
- b. streamlined forensic reports introduced for certain evidence types for use in the case management process to establish the level of agreement between the defence and the prosecution. Further work, additional analysis, statements and/or reports are only then requested in areas where agreement was not achieved; or
- c. full evaluative statements for use in court proceedings.

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<sup>67</sup> For further information, refer to the CPS Disclosure Manual, including the requirements detailed here: [http://www.cps.gov.uk/legal/d\\_to\\_g/disclosure\\_manual/disclosure\\_manual\\_chapter\\_36/](http://www.cps.gov.uk/legal/d_to_g/disclosure_manual/disclosure_manual_chapter_36/) [Accessed 10/08/14]

<sup>68</sup> Note the Criminal Procedure Rules 2015 19.3-(3c) requires experts to provide “notice of anything of which the party serving it is aware which might reasonably be thought capable of detracting substantially from the credibility of that expert.” This provision applies to experts providing reports for either the defence or prosecution team.

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### 25.4. Retention, recording, revelation and prosecution disclosure

- 25.4.1. If a practitioner has carried out a test at the request of the police or prosecution, or if such a test has been carried out at their laboratory and is known to the practitioner, which casts doubt on the practitioner's opinion, they shall also reveal this to the police and prosecuting authorities.
- 25.4.2. The aim of disclosure is to ensure that there is a fair system for informing the defence of relevant unused material, which may assist the defence in timely preparation of its case. The term 'material' comprises the primary records contained on the case file, any pertinent materials recovered or generated during the testing or examination, and any secondary records such as batch records, standardisation and calibration records, audio and video tapes, computer records and survey information. 'Unused material' is that which is not identified within the expert's report(s) or statements(s).
- 25.4.3. Providers must support the disclosure process and provide access to the defence. Further guidance is set out in the *ACPO/CPS Guidance Booklet for Experts, Disclosure: Experts' Evidence Case Management and Unused Material*.
- 25.4.4. All documents, exhibits and evidential material recovered from exhibits that are retained by providers shall be archived in secure storage, in conditions to prevent damage or deterioration, and indexed so as to facilitate orderly storage and retrieval.<sup>69</sup>
- 25.4.5. Only personnel authorised by management shall have access to the archives. Movement of material in and out of the archives shall be properly recorded.

### 25.5. Defence examinations

- 25.5.1. The provider for the defence shall ensure that any tests or examinations they conduct, or are conducted on their behalf by someone other than the original provider, are carried out in accordance with the requirements set out in these Codes, and that they also comply with any conditions attached by the prosecutor to the release of the exhibits, or parts of exhibits, or evidential material recovered from them.
- 25.5.2. The provider appointed by the prosecution must have defined policies and procedures to facilitate access by defence examiners to carry out a review of the work already completed by the provider in the relevant case.
- 25.5.3. The policies and procedures shall be based on appropriate guidance.<sup>70</sup>
- 25.5.4. The policies and procedures must ensure the security and integrity of the exhibits and records requested for review, but must also ensure the confidentiality of other work in progress or previously undertaken by the provider to which access has not been granted.

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<sup>69</sup> The cost of archiving documents relating to the provider's testing and examinations is a business cost to be borne by the provider. Reimbursement of the costs for archiving exhibits and evidential material recovered from exhibits is a business matter to be agreed between the provider and the police.

<sup>70</sup> Such as, in England and Wales, the *ACPO/CPS Guidance Booklet for Experts, Disclosure: Experts' Evidence, Case Management and Unused Material*, May 2010.

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- 25.5.5. A provider appointed by the defence seeking pre-trial access to any case material shall first obtain approval for access to these from the prosecutor (or coroner if the prosecuting authority is not involved at that stage).
- 25.5.6. The provider shall make available to the defence's provider only what has been deemed by the prosecutor or court to be relevant. Copies of such case file records, documents and supporting information, etc. that have been reasonably requested by the defence and been deemed relevant may then be provided in hard copy or secure electronic form<sup>71</sup> and be taken into their possession for examination away from the provider's premises. The provider shall require that all such supporting material is returned by the defence's provider or that the supplied copies are destroyed, as appropriate, once it has served the specific purpose for which it was provided. Supporting information may be covered by a confidentiality agreement, if appropriate, provided it does not interfere with the disclosure requirements.
- 25.5.7. The provider shall only release exhibits (or evidential material recovered from them) to the defence for examination or testing away from the provider's premises on receipt of written instructions from the prosecutor and/or the court. Where the examinations or testing might affect their condition, the provider shall ensure that the prosecutor and/or the court is made aware of this before they are released and that this is recorded.
- 25.5.8. The provider shall ensure that all examinations and tests carried out on the provider's premises by the defence are adequately supervised, to ensure that they are carried out in accordance with the instructions given by the prosecutor and that nothing is altered, damaged or destroyed without the prior permission of the prosecutor.
- 25.5.9. The provider shall ensure that all exhibits (or parts of exhibits, or evidential material recovered from them) that are to be released to the defence are securely packaged and labelled. The provider shall also retain a signed record of the transfers for continuity purposes.
- 25.5.10. The provider shall check the integrity and continuity records of the returned exhibits, or parts of exhibits, or evidential material for compliance with any conditions of release. Any deficiency in these respects shall be communicated immediately to the prosecutor and the customer, e.g. the police.
- 25.6. Opinions and interpretations (ISO 17025:2005 ref. 5.10.5)**
- 25.6.1. Where this it to be included in a provider's schedule of accreditation, the provider will need to ensure that they are in compliance with the UKAS<sup>®</sup> publication LAB 13.

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<sup>71</sup> It would be reasonable to charge ... for any use of facilities or equipment, or for the provision of copies of documents in hard copy or electronic form under the disclosure regime. The Legal Aid Agency's position on charges levied upon the defence by prosecution forensic science laboratories is available from: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/346406/forensic-expert-lab-charges-guidance.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/346406/forensic-expert-lab-charges-guidance.pdf) [Accessed 29/08/14]



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HOC 55/80: *Risk of infection from stained exhibits.*

HOC 74/82: *Disposal of blood samples, saliva samples and swabs stained with body fluid: handling of exhibits.*

HOC 25/87: I *Agreement for the use of the Police National Computer*  
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<sup>72</sup> Home Office circulars are available, or can be requested, from:  
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### 27. Abbreviations

<b>ACPO</b>	Association of Chief Police Officers of England, Wales and Northern Ireland
<b>BS</b>	British Standard
<b>CJS</b>	Criminal Justice System
<b>CPIA</b>	Criminal Procedure and Investigations Act 1996
<b>CPS</b>	Crown Prosecution Service
<b>DNA</b>	Deoxyribonucleic acid
<b>EDIT</b>	Evidential Drug Identification Testing in police stations
<b>EN</b>	European Norm
<b>ENFSI</b>	European Network of Forensic Science Institutes
<b>EPTIS</b>	European Proficiency Testing Information System
<b>GLP</b>	Good Laboratory Practice Regulations 1999
<b>GMP</b>	Good manufacturing practice: Medicine and Healthcare Products Regulatory Agency, Inspection and Standards Division, Rules and Guidance for Pharmaceutical Manufacturers and Distributors, 2007, Section II: Guidance on Good Manufacturing Practice
<b>HOC</b>	Home Office Circular
<b>IAF</b>	International Accreditation Forum
<b>IEC</b>	International Electrotechnical Commission: an organisation that prepares and publishes International Standards for all electrical, electronic and related technologies.
<b>ILAC</b>	International Laboratory Accreditation Cooperation
<b>ISO</b>	International Organisation for Standardisation: a network of the national standards institutes of 157 countries
<b>MoPI</b>	Management of Police Information
<b>NPIA</b>	National Policing Improvement Agency (critical functions now transferred to various successor bodies which include the National Crime Agency, College of Policing Ltd and the Home Office).
<b>OIC</b>	Officer In Charge
<b>PT</b>	Proficiency testing
<b>SLA</b>	Service Level Agreement
<b>UKAS<sup>®</sup></b>	United Kingdom Accreditation Service:.

## 28. Glossary

### Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. In the UK the sole national accreditation body recognised by the Government to assess UK organisations that provide certification, testing, inspection and calibration services is UKAS®.

### Accuracy

The closeness of agreement between the mean of a set of results or an individual result and the value that is accepted as the true or correct value for the quantity measured.

### Analyte

Substance to be identified or measured.

### Audit

A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

**Internal audit:** sometimes called a first-party audit, conducted by, or on behalf of, the organisation itself for internal purposes.

**External audit:** includes what are generally termed a 'second-' or 'third-party' audit. Second-party audits are conducted by parties having an interest in the organisation, such as customers, or by other persons on their behalf. Third-party audits are conducted by external independent organisations. Such organisations provide certification or registration of conformity with requirements such as those of BS EN ISO 9001:2008.

### Blank

A sample containing none of the analyte of interest, used in analysis for detecting the background level of the analyte in the matrix or contamination.

### Calibration

The set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

### Collaborative exercise

An inter-laboratory exercise to determine the performance characteristics of a method or procedure, to establish the effectiveness and comparability of new tests or measurement methods, or to assign values to reference materials and assess their suitability for use in specific test or measurement procedures. Collaborative exercises do not require known expected outcomes.

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### Competence

The skills, knowledge and understanding required to carry out a role, evidenced consistently over time through performance in the workplace.

### Contamination

The undesirable introduction of substances or trace materials.

### Control sample

A matrix-matched standard used to determine the linearity and stability of a quantitative test or determination over time, prepared from a reference material (weighed or measured separately from the calibrators), purchased or obtained from a pool of previously analysed samples.

A **positive control** contains the analyte at a concentration above a specified limit.

A **negative control** contains the analyte at a concentration below a specified limit.

The term is used in the forensic science context to refer to a sample obtained from a known source against which material from an unknown source (recovered sample) is to be compared to consider the strength of the evidence in support of a common origin.

### Critical findings

Typically observations or results that meet one or more of the following criteria:

- a. have a significant impact on the conclusion reached and the interpretation and opinion provided;
- b. cannot be repeated or checked in the absence of the exhibit or sample;
- c. could be interpreted differently.

### Customer

Whether internal or external, it is the organisation or a person that receives a product or service (e.g. the consumer, end-user, retailer, beneficiary or purchaser).

### Databases

Collections of information designed to provide information rather than for archive, which are stored systematically in hard copy or electronic format and are, e.g. used for:

- a. providing information on the possible origin of objects or substances found in casework; and/or
- b. providing statistical information.

Also see the **Reference collection** entry.

### End user

The end-user of forensic science is the Criminal Justice System, essentially the courts. A method or tool may not be directly used by the courts, but it is assumed the results will need to be.

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### **Expert (witness)**

An appropriately qualified and/or experienced person familiar with the testing, evaluation and interpretation of test or examination results and recognised by the court to provide live testimony to the court in the form of admissible hearsay evidence.

### **Firmware**

A term sometimes used to denote the mainly fixed, usually rather small, programs that internally control various electronic devices (e.g. mobile phones, digital cameras, calculators, hard disks, keyboards, memory cards). There are no strict, or well defined, boundaries between firmware and software, but firmware is typically involved with very basic low-level operations in a device, without which the device would be completely non-functional.

### **Investigating body**

A relevant law-enforcement body as defined in s63A(1A) and (1B) of the Police and Criminal Evidence Act 1984, as amended

### **Measurand**

A physical quantity, property, or condition quantity that is being determined by measurement.

### **Method**

A logical sequence of operations, described generically for analysis (e.g. for the identification and/or quantification of drugs or explosives, or the determination of a DNA profile) or for comparison of items to establish their origin or authenticity (e.g. fingerprint/shoemark/toolmark examination; microscopic identifications).

### **Nonconformity**

The non-fulfilment of a requirement, either within the organisation's policies, procedures or in the specification of the customer.

### **Organisation**

A group of people and facilities with an arrangement of responsibilities, authorities and relationships (e.g. a company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof).

### **Practitioner**

An individual providing a forensic science service at any level or stage in the criminal investigation and trial process.

### **Product**

A product is a discrete manufactured item used in the application of a method (e.g. a sampling kit or a piece of software). Its contents and performance will have defined characteristics, normally provided as a product specification.

### **Proficiency tests**

Tests to evaluate the competence of analysts and the quality performance of a laboratory.

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**Open or declared proficiency test:** a test in which the analysts are aware that they are being tested.

**Blind or undeclared proficiency test:** a test in which the analysts are not aware that they are being tested.

**External proficiency test:** a test conducted by an agency independent of the analysts or laboratory being tested.

### Precision

Precision is synonymous with reproducibility or repeatability, whereas accuracy is about obtaining the true or correct value for the quantity measured. An incorrectly calibrated device may be capable of giving reproducibly precise readings even though data generated are not accurate.

### Provider

The term is used to include all providers of forensic science, whether commercial, public sector or internal to the police service (e.g. scenes of crime, fingerprint bureau).

### Quality

The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.

### Quality manual

A document specifying the management system of an organisation.

### Recovered sample

A term used in the forensic science context to refer to a sample obtained from an unknown source against which material from a known source (control sample) is to be compared to consider the strength of the evidence in support of a common origin.

### Reference collection

A collection maintained for the purpose of study and authentication, also see database.

### Reference material

A quality control material or substance, traceable to its source, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, the correct functioning of reagents, or for assigning values to materials.

### Reference standard

A standard, generally of the highest quality available at a given location, from which measurements made at that location are derived.

### Requirement

The need or expectation that is stated, generally implied or obligatory.

### Risk

The probability that something might happen and its effect(s) on the achievement of objectives.

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### **Robustness**

The capacity of an analytical procedure to remain unaffected by small, but deliberate, variations in method parameters.

### **Ruggedness**

The capacity of an analytical procedure to withstand small uncontrolled or unintentional changes in its operating conditions.

### **Sample**

A representative portion of the whole material to be tested.

### **Scene**

A person, vehicle or location associated with an incident, on or at which may be found evidence to indicate what has happened, when and how, who was involved, and whether a criminal offence may have been committed.

### **Schedule of accreditation**

A document issued by the national accreditation organisation specifying the examinations or tests the organisation has been accredited for, and for which it could issue certificates or reports bearing the testing mark.

### **Scope of accreditation**

The range of examinations or tests for which the organisation has been accredited by the national accreditation organisation.

### **Selectivity (or specificity)**

The ability of a method to determine accurately and specifically the analyte of interest in the presence of other components in a sample matrix under the stated conditions of the test.

### **Standard operating procedure**

A written procedure that describes how to perform certain examination or test activities.

### **Subcontractor**

A person or organisation contracted to do work for the provider within the subcontractor's own legal entity and under the subcontractor's own quality system.

### **Supplier**

An organisation or person that provides a product (e.g. a producer, distributor, retailer or vendor of a product, or provider of a service or information).

### **Uncertainty of measurement**

The estimation of the uncertainty of measurement is a BS EN ISO/IEC 17025:2005 requirement and is based upon the principle that all measurements are subject to uncertainty and that a value is incomplete without a statement of accuracy. Sources of uncertainty can include unrepresentative samples, rounding errors, approximations and inadequate knowledge of the effect of external factors.



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### **Validation**

The process of providing objective evidence that a method, process or device is fit for the specific purpose intended.

### **Verification**

Confirmation, through the assessment of existing objective evidence or through experiment that a method, process or device is fit (or remains fit) for the specific purpose intended. The provider must demonstrate the reliability of the procedure in-house against any documented performance characteristics of that procedure.

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