Forensic Science Regulator
Overseeing Quality

Guidance: Validation
Consultation draft

August 2013

This is a consultation draft and therefore should not be regarded or used as a standard. This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. Comments should be sent to FSRConsultation5@homeoffice.gsi.gov.uk and should be submitted by 27 September 2013. This mailbox is not for general correspondence and is not routinely monitored so no acknowledgement will normally be sent.

THIS DRAFT IS NOT CURRENT BEYOND 27 SEPTEMBER 2013.

Contents

1. EXECUTIVE SUMMARY

1.1.1 Forensic science is science applied to matters of the law. It is an applied discipline meaning scientific principles and practices are employed to obtain results which that the courts have a very reasonable expectation can be shown to be reliable.

1.1.2 Validation involves demonstrating that a method is fit for the specific purpose intended, i.e. the results can be relied on. It is the expectation of the Forensic Science Regulator (the Regulator) that all methods routinely employed within the criminal justice system (CJS), whether for intelligence or evidential use, will be validated prior to their use on live casework material.

1.1.3 Responsibility for validation lies with the organisation using the method and cannot be transferred to manufacturers or central agencies, although both can have a part to play in producing the objective evidence required to show that the method can be relied on. This guidance gives advice to assist with assessing the reliability of the source of this evidence as well as describing what the Regulator sees as needing validating in-house.

1.1.4 Validation should be conducted prior to implementation of the method. If the validation has not been conducted at the organisation's site that will be using the method, then objective evidence for features of a method that are deemed likely to be influenced by any local variation in implementation must be produced at that site by their staff.

1.1.5 This is sometimes summed up as 'demonstrating it works in your hands'. In such cases, an organisation is expected to provide adequate objective evidence to show that the method works, to the required standards, at each site where it is employed and in each configuration employed.

1.1.6 The risk assessment element of this framework is an important way of ensuring the validation study is scaled appropriately to the needs of the end-user, which for the most part is assumed to be the CJS rather than any particular analyst or intermediate user.

1.1.7 The *Codes of Practice and Conduct* (the Codes) require that the completed validation paperwork contains similar comparable features irrespective of the approach taken in the validation study, i.e. whether the whole of the validation

study was conducted in-house or if some, or in rare cases the majority, was conducted by the wider scientific community.

1.1.8 Part of that completed paperwork is a short statement of validation completion (i.e. two sides of A4) signed off on behalf of the organisation to provide those making decisions on the use of the results with an executive summary of the validation, and key issues or caveats about the method.

1.1.9 Producing a short document illustrating what a method can and cannot do is a key requirement in the Criminal Prosecution Service's *Core Foundation Principles for Forensic Science Providers*.[1]

2. INTRODUCTION

2.1 Background

2.1.1 Forensic science is science applied to matters of the law coming as it does from the Latin for 'of or before the forum', the place where the Romans would present a criminal case. It is an applied discipline, scientific principles and practices are employed to obtain results that the courts have an absolutely reasonable expectation can be shown to be reliable.

2.1.2 In the case of *R. v. Sean Hoey* (Neutral Citation No. [2007] NICC 49), Justice Weir quoted from the House of Commons Science and Technology Committee's report[2] *Forensic Science on Trial* that the:

"absence of an agreed protocol for the validation of scientific techniques prior to their being admitted in court is entirely unsatisfactory. Judges are not well placed to determine scientific validity without input from scientists."

2.1.3 Justice Weir went on to quote the UK Government's response[3] that:

"establishment of a regulator is one of the options to be considered, as is how the courts can be supported in appropriately weighing scientific evidence."

2.1.4 The Forensic Science Regulator (the Regulator) took up post in 2008 and has subsequently published a protocol for method validation in the *Codes of Practice*

1 Accessed from the internet 12/06/2013: http://www.cps.gov.uk/legal/s_to_u/scientific_evidence/core_foundation_principles_for_forensic_science_providers/

2 Accessed from the internet 12/06/2013: http://www.publications.parliament.uk/pa/cm200506/cmselect/cmsctech/427/42702.htm

3 Accessed from the internet 12/06/2013: http://www.publications.parliament.uk/pa/cm200506/cmselect/cmsctech/427/42704.htm

and Conduct (the Codes).[4] This guidance document is produced to support the use of the Codes.

2.2 Nature of Validation

2.2.1 There are a number of definitions of validation of scientific methods, but they all essentially agree that it is:

"the process of providing objective evidence that a method, process or device is fit for the specific purpose intended."[5]

2.2.2 Validation is to ensure that a method produces results that can be relied on. The importance of ensuring that methods are validated before they are used in casework should, therefore, be self-evident.[6]

2.2.3 If a provider says that they have not, or cannot, validate the method then are they saying that they cannot provide evidence that their method is reliable? It would be wise for a provider to look to how they can demonstrate reliability before it is questioned.

2.2.4 The Court of Appeal (Criminal Division) (*R. v. Harris & Ors.* [2005] EWCA Crim. 1980) made it clear that the courts are free to consider the admissibility of developments in scientific thinking, techniques or methods where formal validation studies are outstanding or incomplete. The courts remain free to consider all possible sources of evidence no matter how novel, but may rule scientific results inadmissible in cases when the reliability of the method was not demonstrated.

2.2.5 With that in mind, the Codes require that the provider ensures that the status of the validation for a product, method or service is clearly communicated to the customer and that is, in turn, made clear to the courts.

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4 Accessed from the internet 12/06/2013: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/118949/codes-practice-conduct.pdf

5 This and other definitions in the Codes tend to reflect those set out in ISO documents such as in BS EN ISO9000:2005 *Quality Management Systems – Fundamentals and Vocabulary*.

6 There are notable cases where reliability and/or admissibility of evidence arise including *R. v. Hoey* [2007] NICC 49 (20 December 2007), *R. v. Reed & Anor* [2009] EWCA Crim. 2698 (21 December 2009) and *R. v. Broughton* [2010] EWCA Crim. 549 (24 March 2010).

2.3 How to Use this Guidance

2.3.1 The Regulator has outlined the requirements for method validation in the Codes. This guidance has been produced to provide background information to the Codes and to assist the implementation of its requirements.

2.3.2 This guidance adopts a descriptive rather than a prescriptive style, although it does contain some lists of things that it might be wise to consider when formulating plans. It is accepted that there may be other ways of achieving the same goals so it is implicit that a departure from the guidance may be entirely acceptable or even advisable if better methods apply.

2.3.3 This is a guidance document and does not modify the requirements laid down in ISO/IEC17025:2005, ISO/IEC17020:2012, the International Laboratory Accreditation Cooperation's report ILAC-G19:2002 (see below) and the Codes, etc. In the event of any inadvertent conflict between the standards and this guidance then the standards prevail.

2.4 Further Reading

2.4.1 Although this guide covers general issues, readers unfamiliar with the topic may wish to consult other material, including one or more of the following.

a. **CITAC/Eurachem** (2002) *Guide to Quality in Analytical Chemistry An Aid to Accreditation*. Available from: http://www.eurachem.org/index.php/publications/guides/qa

b. **Eurachem (**1998) *The fitness for purpose of analytical methods – A laboratory guide to method validation and related topics*. Available from: http://www.eurachem.org/index.php/publications/guides/mv

c. **European Network of Forensic Science Institutes** (2006) *Validation and Implementation of (New) Methods*. Available on request from: http://www.enfsi.eu/contact

d. **International Laboratory Accreditation Cooperation** (2002) *Guidelines for Forensic Laboratories.* ILAC-G19:2002. Available from: http://www.ilac.org/documents/g19_2002.pdf.

e. **LGC** (2003) *In-House Method Validation: a Guide for Chemical Laboratories*, ISBN: 978-0948926181.

f. **United Nations** (2009) *Guidance for the Validation of Analytical Methodology and Calibration of Equipment used for Testing of Illicit Drugs in Seized Materials and Biological Specimens*. New York: UN, ISBN 978-92-1-148243-0. Available from: http://www.unodc.org/unodc/en/scientists/guidance-for-the-validation-of-analytical-methodology.html.

3. WHAT REQUIRES VALIDATION?

3.1 Scope

3.1.1 The International Laboratory Accreditation Cooperation (ILAC) organisation has the aim of harmonising laboratory and inspection accreditation practices internationally. The publication *Guidelines for Forensic Science Laboratories*[7] (ILAC-G19:2002) defines the scope of forensic science to include:

a. the examination of scenes of crime;

b. recovery of evidence;

c. laboratory analysis and interpretation of scientific findings; and

d. the presentation of findings and conclusions for intelligence purposes or for use in court.

It says that all:

"technical procedures used by a forensic science laboratory should be fully validated before being used on casework." (ILAC-G19, 5.4.2a)

3.1.2 This should not be taken to mean that validation is only required in areas that look like traditional laboratories. The term 'laboratory' here means the organisation that conducts the work, not simply the area where white coats are worn. Therefore, it might be more appropriate to widen the definition to all:

"technical procedures used in the production of a scientific result should be fully validated before being used on casework."

3.1.3 This definition encompasses the idea that even if it is not carried out in a traditional laboratory, the courts expect that all evidence can be demonstrated to be reliable.

3.1.4 In the definition in paragraph 3.1.2 above, 'fully validated' is a term that is hotly debated, sometimes generating more heat than light. Firstly, it would be impractical to demonstrate that a method operates in the expected manner in all possible circumstances. In fact the method may utilise instrumentation and software that have many features and functions that are not used in the method at all, or may only be used on a defined type of samples/items. Therefore, the validation study can be tailored, on a risk basis, to how the method is actually

[7] Accessed from the internet 05/3/2013: www.ilac.org/documents/g19_2002.pdf

going to be used – the 'fit for purpose' requirement. This approach may yield, in some simple cases, a short study and report of only a couple of pages.

3.1.5 The validation study should not attempt to compensate for areas of operation that have less developed methods of demonstrating effectiveness (such as those dealing with qualitative output) by merely producing extra data on the aspects that are well understood. When assessing the impact of such issues, consider what part professional judgement and technical ability can play to offset any remaining limitations in the testing.

3.1.6 The Codes require that the completed validation paperwork contains similar comparable features irrespective of the approach taken in the study, i.e. whether the whole of the validation study was conducted in-house or if some, or in rare cases the majority, was conducted by the wider scientific community. It is difficult to demonstrate, for instance, that the original user requirement has been reviewed if this review cannot be provided to the accreditation body or to the court.

3.1.7 It is not acceptable to say that a method, technique, tool or device is validated simply because someone else, including the manufacturer, says that it is. The process discussed in Section 5 shows the stages that apply whether it is a new validation study, verification of an existing validation study or part of an internal validation.

3.1.8 There is an assumption in the Codes that there is little to be gained for retrospectively creating documents when the validated method is already within the schedule of a provider's accreditation. In such cases the Codes require that a comparable 'library' of documents is, or at least can be, compiled. The existing validation will have something comparable for many of the sections, but do not neglect compiling the scientific papers, or other materials, that underpin the method. It is expected that there will be a natural convergence towards completing the library as methods are updated, reviewed and modified, or new ones introduced.

3.2 Standard Versus Non-Standard Methods

3.2.1 ISO/IEC17025:2005 requires that the *"laboratory shall validate non-standard methods"* so it is worth discussing here the difference between standard and non-standard methods.

3.2.2 A note in ISO/IEC17025:2005 under Section 5.4.1 indicates that only certain organisations can publish international, regional or national standards. It is not enough that everyone's method is similar, it can only be considered a 'standard method' if the published method comes from such an organisation and it:

a. contains concise information on how to perform the tests;

b. does not need to be supplemented or rewritten as internal procedures; and

c. can be used as published by the operating staff in a laboratory.

3.2.3 Based on the full definition, at the time of writing (2013) there appears to be no standard methods in the traditional forensic sciences in the UK *per se*, although there are some methods that might be amenable to that approach should an appropriate body choose to set or specify one. However, it is for others to set a standard method, not the Regulator.

3.2.4 Even if a method is officially recognised as 'standard', the items discussed in Section 4.3 on organisational competence will all need to be demonstrated. Ownership of the manual does not demonstrate expertise. The same requirement discussed under internal validation and verification to demonstrate precision, accuracy and usually the limit of detection will apply.

3.3 Method Validation

3.3.1 The validation definition provided was for any method, process or device. For ease of reading, this guidance will tend to refer only to the method in the text, even if it could also mean process, procedure, software tool, expert system, etc. It is generally the method, the use that something is put to, that can truly be validated rather than any sub-processes, component parts, devices or tools. For instance, a pipette could be validated to show that it is fit for the purpose of moving a measured volume of liquid, but such a validation says little about the wider process it is being put to, say DNA profiling. In reality it is calibration that is carried out on such instruments, not validation. This is a useful distinction, as an instrument or software may be employed as part of the method but it is only those features that have an impact on the result that are likely to be required to be included in the validation, i.e. showing that it is fit for the purpose it is being used for.

3.3.2 The focus for accreditation in the first edition of the Codes is on the laboratory,[8] but subsequent editions will include the crime scene. The requirement to demonstrate the reliability of scientific findings clearly extends to any methodology when the operation has an impact in the results obtained, wherever it is used. Therefore validation ought to be the norm.

3.4 Evidential Versus Intelligence

3.4.1 Neither the Codes nor ILAC-G19 differentiate between methods for evidential, intelligence or screening use. All methods should be validated for a particular purpose prior to implementation. Results provided as intelligence are likely to be acted on; the officer in the case will need to be able to support their actions and there will often an expectation that the intelligence can converted into evidence.

3.4.2 An aspect of a validation is to show what a method (or the output of a method) should be used for and any caveats that might apply, e.g. error rates. This does not mean that a test designed to be a presumptive test has to be tested as if it was an evidential method. The specification derived from the end-user requirement defines the purpose, validation provides objective evidence that it is fit for that purpose.

3.4.3 Provided any caveats that apply (e.g. an x% error rate) are clear when investigators are weighing up the other intelligence they have to support a decision, then that risk is minimised or at least controlled.

3.4.4 The National Intelligence Model (NIM) provides a systematic approach with standard intelligence products and consistent methods of working. If the end-user requirement is for an intelligence product then the way that intelligence analysts package and present the scientific results ought to reflect this, and reports should be designed accordingly. The central reporting method of the NIM is the 5 by 5 by 5 (or 5x5x5) system for grading the usefulness of a piece of intelligence/information in UK policing.[9]

3.4.5 Each of the 5s refers to a grade A–E or 1–5 for an assessment of the intelligence in 3 areas:

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8 Defined in the Codes as an area set aside for handling, developing, analysing or interpreting scientific evidence.

9 **National Policing Improvement Agency** (2008) *Practice Advice on Analysis*. Accessed from the internet 15/07/2013: http://www.acpo.police.uk/documents/crime/2008/200804CRIPAA01.pdf

a. source evaluation;
b. information/intelligence evaluation;
c. handling code.

3.4.6 Source evaluation: Rated A–E, with an A rating meaning that the source is "*always reliable*" with E being an "*untested source*". The guidance produced on behalf of the Association of Chief Police Officers (ACPO) gives the example of information received from technical products such as DNA and fingerprints as warranting an A rating. Therefore, it is not unreasonable to assume that the police may rate most forensic science providers as A, including their own.

3.4.7 Information/intelligence evaluation: Rated 1–5 with the following definitions or descriptions to the ratings.

1. Known to be true without reservation.
2. Known personally to source but not to officer.
3. Not personally known to source but corroborated.
4. Cannot be judged.
5. Suspected to be false or malicious.

3.4.8 The highest rating of be *"known to be true without reservation"* leaves little room for the caveats even evidential level results require, let alone presumptive test results. The model is not designed specifically for forensic science results, so the next level down from the top rating that the overworked intelligence analyst has to consider is "*known personally by the source but not to not to officer*". This definition may be helpful for evaluating information from informants (or rather covert human intelligence sources), but is not worded to steer an analyst towards it and there are examples that the Regulator has been made aware of where a default grading of 1 has been used for a presumptive method.

3.4.9 If a method is considered to be an intelligence-only method, it does not, nor will it, reach evidential standards (e.g. a presumptive test, high error rate). In this case marking the method as A1 (the handling code is not particularly relevant to validation) could be misconstrued as it leaves no room for doubt or caveats and limitations. Forensic science providers would be wise to consider the highest rating that a positive analytical result ought ever to receive for a particular method, and

any other wording that ought to be included to assist investigators and intelligence analysts to evaluate the information/intelligence correctly.

4. INTERNAL VALIDATION

4.1 Rationale

4.1.1 The requirements laid out in the Codes are for each of the steps of the validation process to be completed, whether the user is producing the objective evidence themselves or objectively reviewing data produced by others, for relevance, reliability and completeness. The expert presenting the evidence will be the one who will have to convince the court that it is admissible. Unfamiliarity with the objective evidence that shows the method to be reliable is a doubt that could grow to undermine the court's view as to reliability.

4.2 Verification

4.2.1 The term 'verification' is often used in conjunction with or as an alternative term for 'validation', which causes confusion. The Codes define verification as the:

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

4.2.2 This definition encompasses the idea that validation is the requirement but that existing objective evidence may exist, which may mean that less experimentation is required. The definition this guidance has used for verification is essentially the same as one might use to define 'internal validation'. Internal validation is probably a better term, as it is less likely to be misconstrued. However, as the term verification it is in common usage it cannot be dropped entirely.

4.2.3 There is an overriding requirement that there is evidence that the provider's own competent staff can perform the method at the given location. This is the requirement whether a developmental validation has been done by the organisation's own research department or if it is an adopted method. This topic is explored further in the Section 4.3.

4.2.4 Therefore verification can be thought of as demonstrating that the:

a. existing objective evidence produced externally is relevant, available and adequate for the intended specific purpose, and that the method performs reliably at the given location with the provider's own staff; or

b. the method remains fit for the specific purpose following a minor change in the process, and if the change does not require re-validation of the method.

4.2.5 If existing objective evidence is assessed as relevant, reliable and available to support the specific purpose that the method is being used for then, of course, this can be used. However, there are likely to be many features influenced by any local variations in implementation, instrumentation and staff skills/competence, which mean that existing objective evidence will be unlikely to be sufficient.

4.2.6 Objective evidence produced by another party to support method implementation used in a different manner, even for a similar yet different use, might not be adequate. Identical implementation will require an assessment of the scope, reliability and rigour of the existing validation study and even if instrumentation variation is controlled by external calibration, there will always remain local variation in staff skills/competence. It is unlikely that the accreditation body will be satisfied with anything less than objective evidence produced:

a. by the provider's competent staff;
b. at the given location;
c. showing the level of precision, accuracy, and probably the limit of detection that they can achieve.

4.3 Organisational Competence

4.3.1 Technical competence is essential for delivering quality forensic science to the criminal justice system (CJS). The aim of accreditation to ISO17025:2005 is to provide independent verification that an organisation has demonstrated the technical competence to produce valid and accurate data/results.

4.3.2 Therefore the organisation using the method must produce objective evidence of fitness for purpose for features of a method that are likely to be influenced by any local variation in implementation. This is sometimes summed up as 'demonstrating it works in your hands'.

4.3.3 The International Laboratory Accreditation Cooperation (ILAC) report ILAC-G19:2002, 5.4.2 b (see Section 2.4) requires that an organisation demonstrates that it can make the method work to the same standard as any other organisation based on published performance parameters. Therefore, the objective evidence required should show how well this has been achieved, a process termed 'performance verification'. However, the Codes require this check to be against the

required specification for the specific use that the method is being employed for, rather than simply against existing published data. This allows for differences in the requirements; e.g. if the National Physical Laboratory published data using their sensitive equipment on a method, is the local requirement really the same level of precision or accuracy?

4.3.4 Having an effective validation study to show adequate objective evidence for any given operational parameter is reliant on understanding the performance parameters. There may be advice in the literature to assist setting sample sizes, or supporting the decision arrived at internally, but there may be a need to seek the advice of statisticians should there be nothing already available. This may allow far less testing in the long run to achieve the same level of confidence in a range of operational parameters.

4.3.5 If the original acceptance criteria are shown to be unachievable, a good validation study design should be able to show what levels of precision, accuracy, and possibly the limit of detection can be achieved. If, following root-cause analysis, the differences between stated and actual performance parameters cannot be, or are too costly to be, addressed (i.e. different instrumentation), the impact and associated risks of this on the originally stated end-user requirement can then be assessed.

4.3.6 Modifying the end-user requirement, specification and method to have a different operational range may be acceptable. However, see Section 5.1.4, which discusses the separation of method development and validation.

4.4 Reliability of External Objective Evidence

Publications

4.4.1 Assessing the relevance and completeness of objective evidence produced by others in collaborative or developmental validation studies should be relatively straightforward if the requirements laid out in the Codes for each of the steps of the validation process have been completed. Assessing the reliability of the work of others is something that is sometimes a little less clear.

4.4.2 In considering the scientific model/theory in terms of its validity and the limits of applicability, the provider may usually rely on information available in a respected

and relevant scientific journal. Publication is a beneficial route to transparency with the various degrees of peer review of the science and/or the method it offers.

4.4.3 It is not expected that most validation studies would be considered novel enough to be published in the main journals. Even if it was considered for publication there is typically a considerable delay between the completion of a validation study, acceptance for publication and actual publication. It is therefore not a requirement that a validation study is published, but it is certainly easier for the provider wishing to rely on it if it is.

4.4.4 Much of the underlying science that a method relies on is, however, likely to have been published. Some of the possible sources, and issues related to these sources, are set out below.

a. Publications in books published by:

   i. respected organisations (e.g. large publishing houses, academic bodies, professional bodies) can normally be relied on with confidence;

   ii. authors respected in the field can normally be relied on with confidence;

   iii. vanity publishing houses should be treated with caution; and

   iv. organisations that advocate a particular viewpoint should be treated with appropriate caution.

b. Publications in journals:

   i. the points made in relation to books above refer equally to journals;

   ii. journals that regularly publish papers in the area of interest can normally be relied on;

   iii. journals where the articles are peer reviewed prior to publication are often considered to be more reliable than journals where they are not. Whilst there is some sense in this approach it must be noted that peer review does not establish the accuracy of the content of the paper;

   iv. journals that have a history of withdrawing papers due to fraud, plagiarism, error, etc., should be treated with great caution; and

v. publications in journals that do not regularly publish in the area should be treated with caution as they may not have been read by a significant proportion of the relevant scientific community.

c. Publications by professional or regulatory bodies can be relied on.

d. Publications by respected organisations can be relied on.

4.4.5 Regardless of the nature of the publication it would be inadvisable to rely on any publication by an author whose scientific reputation has been undermined.

4.4.6 Providers often have a significant amount of 'in-house' information relating to the techniques they employ. This information may be relied on in a validation exercise if it is relevant and robust. However, it needs to be added to the validation library, which may be required to be disclosed.

Science

4.4.7 There is an expectation that where the method implements any scientific model or theory (or provides for the interpretation or evaluation of results of one) the specification should address the following matters.

a. The nature of the scientific model/theory, including any required evaluation/interpretation implemented in the method, process or software. This would include considering the following:

i. the validity of the theory/model;

ii. the validity of the application of the theory/model in the method;

iii. any assumptions incorporated within the theory/model;

iv. the validity of the assumptions and any limits on the application of the assumptions;

v. limits on the application of the theory/model; and

vi. the robustness of the model on the basis of the information supporting the model.

b. In light of the consideration of the theory/model the specification should set out any limits to the use of the method or any additional procedures and/or safeguards that should be implemented.

4.4.8 The extent of this consideration may vary considerably. Methods that involve the application of commonly accepted scientific theories/principles in an area where it is relatively routine will require far less assessment than methods that apply a new scientific theory/model or apply an existing theory/model in a novel area. However, it is important that an assessment is performed – even with well-established techniques, it is useful to consider any issues or limitations.

5. VALIDATION PROCESS IN THE CODES

5.1 Overview

5.1.1 The framework published in the Codes is intended to ensure that completed validation studies contain comparable features irrespective of the approach taken in the study. An outline of this process is set out in Figure 1.

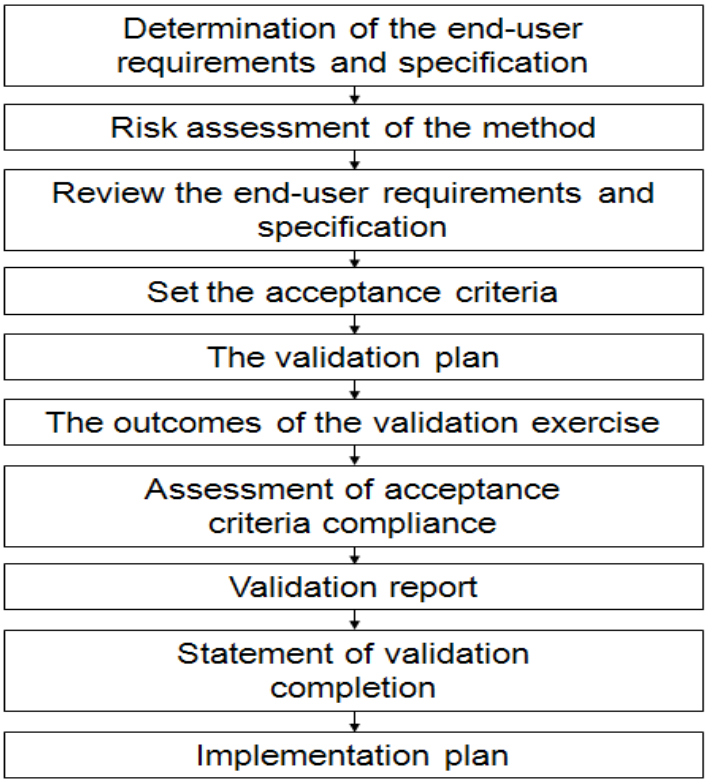

Figure 1: Framework published in the Codes

5.1.2 Following this process and compiling the paperwork is required by the Codes whether conducting a validation study or verifying that validation studies conducted elsewhere are applicable.

5.1.3 The approach taken in the validation study will vary depending on the nature of the method, the manner in which it is to be used, and the risks assessed to the criminal justice system (CJS). Further, it may be affected by the nature of the organisation performing the validation and external requirements imposed on it (e.g. legal or through accreditation).

5.1.4 There ought to be a clear separation between development and validation to ensure that the final version of the method is the subject of the validation study.

Figure 2 shows a shortened development cycle intended to show how the different stages can work together.

5.1.5 The correct operation of a method is the sum-of-its-parts, so modifying any aspect of it may influence several seemingly unconnected performance parameters. Once a performance parameter has been characterised, modifying the method/instrument to fix underachievement for subsequent performance characteristics may nullify all the previous testing.

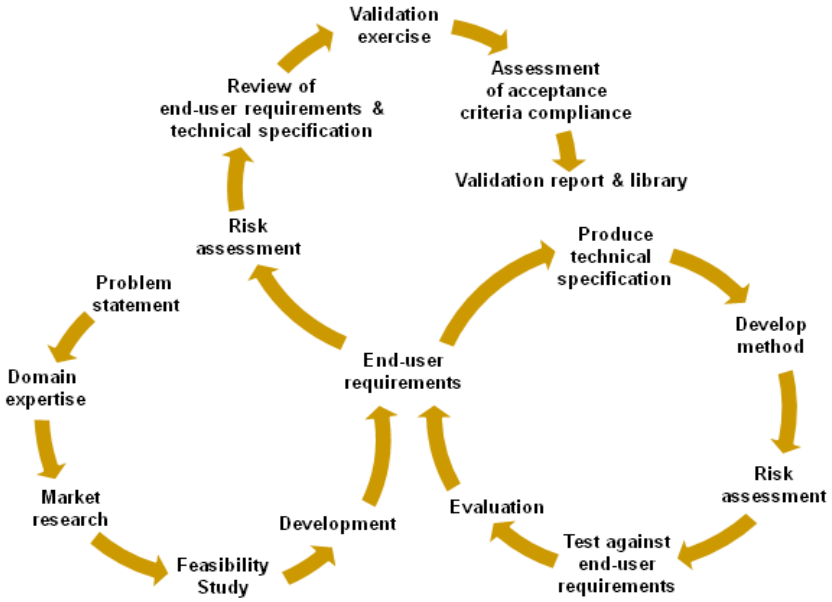

Figure 2: Shortened stylised innovation, method development and validation

Performance characteristics could mean quantitative type characteristics or qualitative features, such as error reporting or the operation of certain safeguards, e.g. write-blockers in digital forensics.

5.1.6 To assist in ensuring that the validation study refers to the final method there ought to be a unique identification of the final version of the method from the onset of the validation work. It might also be wise to consider applying this to any external methods, components or systems that feed into the method and ensure that proper configuration management applies.

5.1.7 The remainder of this section discusses each of stages in the framework listed in Figure 1.

5.2 The End-User Requirements

5.2.1 Any method providing information to the CJS ought to meet the requirements of the end-users. In considering these requirements it is important to note that the end-users are not only the person/organisation that may be directly provided with

the output from the method but the CJS as a whole. This includes, but is not limited to:

a. the investigative agencies (e.g. the police);[10]
b. the prosecution authorities (e.g. the Crown Prosecution Service, Public Prosecution Service or Crown Office and Procurator Fiscal Service);[11]
c. the defence;
d. the judiciary;
e. the reviewing authorities (e.g. the Criminal Cases Review Commission);
f. the public (including those serving as jurors).

5.2.2 It is not envisaged that many validations will require actual direct consultation with the wide range of CJS stakeholder and end-users. However, considering what such groups might expect from the operation and output of the method will assist in ensuring that it is fit for purpose.

5.2.3 Understanding the expectations of others might seem daunting. However, expert witnesses routinely are expected to satisfy the courts and understand the obligations they have to assist the courts. So as a starting point, it is worth considering the following.

a. What would the expert witness be expected to be able to say when they take the stand to report the results?
b. What caveats would they have to give and what counter claims could a defence expert legitimately make based on the extent of testing that has been conducted?
c. Have the appellate courts made observations or stipulations for the presentation of this type of evidence, and have these been thought through in the end-user requirement so they can be tested if required?

The Regulator has published information on the legal obligations related to expert evidence in England and Wales that covers a number of these areas.[12]

10 While the police are, perhaps, the most common investigative agency that providers will deal with, it may be necessary to consider the needs of more specialist agencies (e.g. HM Revenue and Customs, the Serious Fraud Office, the Financial Services Authority).

11 Whilst those listed are the most frequently encountered by providers, there may be a need to consider specialist prosecution agencies.

12 The Regulator's legal guidance document accessed from the internet 12/06/2013: https://www.gov.uk/government/publications/forensic-science-regulator-legal-obligations

5.2.4 Major breakthroughs, novel uses of existing science, or significant changes might warrant wider stakeholder consultations. In these cases it would be useful to inform the Regulator who may advise on the most expedient method of ensuring that the CJS requirements are understood.

5.2.5 In considering the end-user requirements providers ought to give consideration to possible sources of obligations on witnesses in the CJS. These include, but are not limited to, the following:

a. provisions in primary legislation;
b. provisions in secondary legislation (e.g. the Criminal Procedure Rules);
c. practice directions or equivalents;
d. disclosure;
e. judgments of the courts;
f. requirements established by prosecution authorities.

5.2.6 In this regard it ought to be borne in mind that there are different legal systems in operation within the UK.[13] It may, therefore, not be possible to produce one specification that sets out the requirements for the method in all jurisdictions. Where the specification is limited in territorial scope this ought to be stated in the specification.

5.2.7 The end-user requirements can be determined by consideration of the context in which the method is to be used, including the following.

a. The use to which the information generated by the method will be put.
b. Any legal or regulatory provisions that will apply to the operation of the method or to the use of the information it produces.
c. The persons within the CJS who will directly use the output.
d. The manner in which the output will be provided to the CJS.

5.3 Specification

5.3.1 The end-user requirement should contain the requirement from the perspective of the CJS including, of course, the intermediate users of the method all the way through to the expectations of the court (e.g. relevant case law). The specification adds the detail of what the requirement actually means and ultimately what is to be

[13] There are three commonly recognised legal jurisdictions in the UK – (a) Scotland, (b) Northern Ireland and (c) England and Wales. However, as a result of devolution of powers to the Welsh Assembly there is a possibility that relevant legal provisions differ between England and Wales.

tested, encapsulating what this method is to do, the configuration, and even what the method can and cannot be used for. As Section 5.3.5 shows, even if the end-user has not detailed all the technical requirements, some general scientific requirements need to be added somewhere.

5.3.2 Although one could also be thinking about the acceptance criteria at this stage, it is important to check that the specification has been translated correctly; many terms may be understood differently depending on background and discipline. For instance, the end-user might have said that they want a new method or device to be robust or rugged. Does this mean that it needs to be able to be knock about a bit or was it more the capacity of an analytical procedure to remain unaffected by small variations in method parameters that they had in mind?

5.3.3 So some normal usage terms may mean something more specific and subtly different in different contexts. Some scientific terms have several recognised definitions. For instance, the end-user requirement for a new test method may be that it must be as sensitive as the method it is likely to replace. Sensitivity in diagnostic testing can be defined as the proportion of known positive reference samples that are correctly identified by a screening test. However, in analytical testing it might be more the limit of detection/quantitation that is meant. Both definitions may apply if the test method is capable of both screening and producing an analytical result.

5.3.4 The Codes put special emphasis on ensuring that the end-user requirement is captured in the specification, as this was seen to be an area that had been overlooked. Of course, the interim and technical users' requirements should continue to be captured and included in the specification.

5.3.5 At this stage it is wise to ensure that the list contained in the International Laboratory Accreditation Cooperation's (ILAC's) report (ILAC-G19, see Section 2.4) is considered, even if the points listed were not explicitly raised in the end-user requirement capture exercise. These are:

a. matrix effects;
b. interferences;
c. sample homogeneity;
d. concentration ranges;
e. specificity;

f. stability of measured compounds;
g. linearity range;
h. population distribution;
i. precision;
j. measurement uncertainty.

5.3.6 This consideration ought to lead to a specification set of end-user requirements that may include the following.

a. The information to be determined by the method (e.g. the analytical results) or the opinion to be provided.
b. The nature of the results to be determined:
    i. the values to be determined (e.g. mass or concentration);
    ii. the units to be employed (e.g. mg per 100ml);
    iii. the required accuracy of the results (e.g. against a reference sample);
    iv. the required precision of the results (e.g. value ± 3 standard deviations or appropriate verbal scale).
c. Information that is required in the output:
    i. case-related information (e.g. case number and exhibit number);
    ii. relevant statutory declarations (e.g. the concentration exceeded a legal limit);
    iii. operator information;
    iv. instrument information (e.g. traceability to a specific piece of equipment and/or software version);
    v. results;
    vi. conclusions;
    vii. caveats (e.g. if the test is a presumptive test only).
d. Uses for which the output ought to be suitable:
    i. comparison with existing results;
    ii. inclusion in, or comparison with, existing databases.
e. Information that must not be in the output (e.g. likelihood ratios in footwear cases).
f. The format of the output.
g. Methods for delivery of the output.

h. Security requirements (e.g. security of electronic transmission).

5.4 Risk Assessment

5.4.1 The risk assessment element of this framework is an important method of ensuring that the validation study is scaled appropriately to the needs of the end-user, which for the most part is assumed to be the CJS. Adherence to general legal obligations (e.g. health and safety and environmental protection laws) is taken as a given requirement but is not seen as part of a scientific study to validate a method.

5.4.2 The risk assessment process during validation is not about managing out and/or mitigating all the risks inherent in the method, as the method development stage should have largely dealt with this. It is about understanding the risks to ensure that the validation study correctly assesses whether the risk mitigation put in place works. There may be risks that cannot be managed out of the analytical stage, but many of these can be dealt with by the more human aspects of secondary checks, use of controls or even through the expert's professional judgement.

5.4.3 Risk assessment in the CJS often concentrates on the risk of a wrongful conviction, but a more complete list includes the following:

a. the risk of wrongful conviction(s);
b. the risk of wrongful acquittal(s);
c. the risk of obstructing or delaying investigation(s).[14]

5.4.4 The risk assessment ought to inform the forensic provider of:

a. the possible impact on the CJS of any errors in the method, associated materials or procedures, on the basis of the use to which the information generated by the method may be put; and
b. areas where, although the output is accurate/correct or the method operates in the expected manner, the output is ambiguous or may be misleading – especially to a non-scientist or person who does not understand the full operation of the method.

5.4.5 The assessment ought to address the possible impact of the risks. In performing this assessment it will be relevant to consider the significance that may be

[14] The obstruction could be caused by the failure to provide information that would assist the prosecution or defence positions.

assigned to the output of the method or the information derived from it, and the resultant impact that any error may have:

a. where the evidential weight is likely to be high (e.g. DNA evidence) the impact of the risk is likely to be more significant;
b. where the evidential weight is likely to be low (e.g. glass evidence) the impact of the risk is likely to be far lower.

5.4.6 The approach to risk assessment will vary depending on what the method is and how it interacts with the CJS. Issues that it may be appropriate to consider include the following.

a. Information accuracy
    i. Are there circumstances where the output from the method, or the information derived from it, could be inaccurate?
    ii. Is the output from the method, or information derived from it, misleading or could it be misinterpreted?
    iii. Is the output from the method, or information derived from it, such that it cannot be easily, or reliably, understood by persons without specialist knowledge or experience?
b. Information context
    i. Are there circumstances where the output, or information derived from it, could be misleading if not properly addressed in the context of the case?
c. No information
    i. Are there circumstances in which the method will find no information when the information is there?
    ii. Where the method produces no result (e.g. no DNA profile) is the meaning of that properly understood and communicated to the CJS?
d. Delayed Information
    i. Are there circumstances where the provision of the information derived from the method to the CJS could be delayed as a result of the operation of the method, i.e. it requires confirmation prior to being actionable?

ii. If there are such circumstances, what are the possible impacts and can any adverse impacts be avoided/minimised?

5.4.7 As part of the risk assessment there may be recommendations for the modification of the specification, or additional procedures and/or safeguards that ought to be implemented and carried through to the statement of validation. These may include, but need not be limited to, the following.

a. Restrictions on the circumstances in which the method will be used. These may include the following:

i. circumstances in which it will not be used;
ii. circumstances in which it will not be used without some additional work;
iii. input types on which it will not be used;
iv. input material ranges for which it will not be used;
v. output types, or results, which will not be provided to the CJS.

b. Restrictions on the members of staff who can employ the method.
c. Warnings/caveats to be applied to the information provided to the CJS.

5.4.8 If the method can be augmented in this way then a new version of the specification and/or risk assessment ought to be produced, numbered and this version of the method clearly identified.

5.4.9 The risk analysis is intended to assist in identifying the critical aspects of the method that need to be tested. Method development should have included risk analysis and mitigation (see Section 5.1.4) and the validation is to ensure that the method does indeed manage these risks. During method development a failure modes and effects analysis (FMEA)[15] is an effective way of analysing the consequences of technical specification failure, as is the Japanese method of mistake proofing known as Poka-Yoke.[16]

5.4.10 A method is more than the analytical test or instrument; it includes the human element in the procedure, which may include any error-trapping, e.g. peer review,

[15] e.g. Accessed from the internet 12/06/2013: http://asq.org/learn-about-quality/process-analysis-tools/overview/fmea.html

[16] e.g. Accessed from the internet 16/07/2013: http://webarchive.nationalarchives.gov.uk/20050302214821/http://www3.dti.gov.uk/quality/pdfs/sections/Gurus.pdf

second checks. A good validation study and acceptance criteria would cover the management of the risks identified.

5.5 Review and Setting the Acceptance Criteria

5.5.1 The specification ought to be reviewed to ensure that all the recommendations made following the risk assessment are addressed. This process ought to lead to an agreed specification against which the validation is performed against specific and measurable, testable or observable acceptance criteria.

5.5.2 Unlike the initial end-user requirement, the acceptance criteria are expected to be technical in nature on most of the stated quantitative and qualitative requirements. Some of the features may be mandatory, with certain performance criteria, whereas others may be only desirable.

5.5.3 The experimental design needs to be properly thought through to ensure that the results used for the acceptance testing are significant, and therefore valid. If several replicate measurements are required to obtain a significant result to meet the acceptance criteria, these need to be planned for.

5.6 Validation Plan

5.6.1 There ought to be a validation plan, based on the agreed specification and risk assessment, which sets out the programme of tests to be performed and the acceptable results that ought to be achieved. The plan ought to ensure that all of the following requirements will be met by the validation exercise.

a. The validation plan ought to test the proper operation of the method over the range for which the provider considers it appropriate to employ the method.

b. For all acceptable permutations of input material and method operations the validation plan can establish, for mandatory requirements, that:

   i. the method performs as set out in the specification; and

   ii. the output complies with the specification.

c. Where the order in which work is undertaken may have an impact on the operation of the method then, for each order in which the work may be undertaken, the plan ought to establish, for mandatory requirements, that:

   i. the method performs as set out in the specification; and

   ii. the output complies with the specification.

d. For all acceptable permutations of input material and method operations the plan ought to establish, for desirable requirements, whether:

   i. the method performs as set out in the specification; and
   ii. the output complies with the specification.

e. All safeguards in the method operate as expected.
f. All safeguards established in relation to the use of the method (but not contained within the method) operate as expected.
g. All risks identified in the risk assessment have been considered and addressed.

5.6.2 It is important to note that the robustness of a validation exercise is determined by the proper consideration of the permutation of factors that may impact on the operation of the method. The use of a large number of samples without proper consideration of permutations is not likely to provide robust validation. It may in fact give a false sense of completeness.

5.6.3 Where the method is a component of a larger system or service (e.g. analytical equipment) the validation plan for the method may be incorporated in the plan for the system/service. In this case, it still ought to address the issues raised in the Codes and this guidance.

5.6.4 The validation plan can take account of validation undertaken by other, reputable, organisations where the results of that work are:

a. appropriate and relevant, e.g. the method, matrices and processes are comparable with those used by the laboratory; and
b. in the public domain.

5.6.5 The use of such work does not eliminate the need to demonstrate that the method works correctly when employed by the provider at the given location. This normally would include the level of precision, accuracy and probably the limit of detection they can achieve.

5.6.6 The quality of information provided to the CJS is not solely dependent on the method. It may also be affected by other materials associated with the use of the method. These include, but are not limited to, the following:

a. the instruction manuals/media for the method;

b. the training material for users of the method;

c. the quality management procedures implemented in relation to the use of the method;

d. the information provided to those within the CJS.

5.6.7 Either within the validation exercise, or as a separate exercise, there ought to be a consideration of whether the associated materials that have been generated are of sufficient scope and quality to ensure that the information provided to the CJS is fit for purpose.

5.6.8 Either within the validation or as a separate exercise there ought to be a consideration of all legal issues related to the development, testing and implementation of the method. The aim is to determine whether there are any issues that may be used to undermine the use of the method within the CJS.

5.6.9 In particular, consideration ought to be given to the following issues:

a. the legal rights and obligations related to casework material (see the discussion above);[17]

b. the appropriate use of personal information;[18]

c. observance of human rights;[19]

d. the appropriate handling of human tissue;[20]

e. restrictions on DNA profiling.[21]

5.6.10 This assessment ought to consider not only the method in isolation but also its use with any product/service of which it forms a part.

5.7 Validation Exercise

5.7.1 This guidance is provided to assist in developing the validation study. Readers are reminded that the *Guidelines for Forensic Science Laboratories* (ILAC-G19:2002) still apply, and these specify a number of parameters that may need to determined.

17 In England and Wales reference ought to be made to the Police and Criminal Evidence Act 1984 and the Criminal Procedure and Investigations Act 1996.

18 See the Data Protection Act 1998 and the Protection of Freedoms Act 2012.

19 See the Human Rights Act 1998.

20 In England, Wales and Northern Ireland the relevant provisions can be found in the Human Tissue Act 2004. In Scotland the relevant provisions are in the Human Tissue (Scotland) Act 2006.

21 See s45, Human Tissue Act 2004.

5.7.2 A robustness/sensitivity assessment may be required to show that the method operates in an acceptable manner throughout the range of conditions in which the provider states that it ought to be used. The end-user requirement and subsequent specification ought to have identified if this was required. It is often a sensible step as it assists troubleshooting.

5.7.3 The validation exercise ought to be performed to standards that ensure that the results are of a sufficient quality to be relied on to establish the reliability of the method, if necessary, in court.

5.8 Assessment of Acceptance Criteria

5.8.1 The assessment of acceptance criteria is intended to inform whether the method ought to be implemented in its existing form, modified with additional procedures and/or safeguards and revalidated, or even not implemented at all.

5.8.2 If certain criteria were considered mandatory and prove to be unachievable, this assessment offers the opportunity to review the stated criteria with the sponsor, or with the customer, to see what the next steps ought to be before finalising and writing up the report. As with all records, this review should be maintained for traceability.

5.8.3 If the method needs be modified with additional procedures and/or safeguards the effectiveness of these may also need validating. Where this is the case the following steps would be wise.

a. A new specification ought to be prepared. This should be subject to version control.
b. A new risk assessment ought to be undertaken and a report prepared. Again, this should be subject to version control.
c. There ought to be an assessment of whether, in light of the new specification and risk assessment:
    i. the validation exercise that has been performed to date is sufficient;
    ii additional work is required; or
    iii. the validation study needs to start afresh.
d. The results of this work ought to be set out in the validation report.

5.9 Validation Report

5.9.1 The completed report would be expected to supply the following information.

a. Identify the organisations or persons who produced and/or were involved in producing and/or authorising the:

   i. end-user requirement;[22]
   ii. specification;
   iii. risk assessment; and
   iv. validation exercise.

b. Identify, where relevant, the work of other organisations that are relied on within the validation.
c. Identify the method that is the subject of the validation exercise. The version of the method also ought to be identified.
d. State the date of the report.
e. Identify the specification against which the validation plan has been developed and the validation exercise performed. This may be included as an annex.
f. Identify the risk assessment against which the validation plan has been developed and the validation exercise performed. This may be included as an annex.
g. Identify the validation plan against which the validation exercise was performed. This may be incorporated in the report either as an annex or within the relevant sections of the report.
h. Provide the results of the validation exercise. This ought to include a full description of the following:

   i. the investigations/experiments performed;
   ii. the results of the investigations/experiments;[23]
   iii. whether the method operated as expected for each requirement set out in the specification;
   iv. if the method has not operated as expected there ought to be an analysis of whether that failure (either individually or in conjunction with any other failures) is sufficient to prevent the method being

[22] It may often be quite acceptable for common methods to have generic or centrally produced requirements, specifications and to a lesser extent risk assessments, provided they are verified as fit for the purpose that the organisation is actually using the method for.

[23] The report need not contain all of the data generated in the validation exercise. It may contain summaries of the data. The information provided must properly reflect the results obtained and be sufficient to support any conclusions drawn in the report.

employed in the CJS or whether (a) the output is still fit for purpose without any further intervention or (b) the output is still fit for purpose if additional procedures/safeguards are implemented.

i. Make recommendations as to what steps need to be taken to determine that the method is operating as expected when implemented. These recommendations ought to be sufficient to ensure the proper operation of the method at each site at which it is implemented, and for all staff using the method.

j. State the extent to which the method meets the specification and the issues raised in the risk assessment have been addressed appropriately.

k. Make a recommendation as to whether the method ought to:

   i. be implemented in the existing form;
   ii. be implemented in the existing form with additional procedures and/or safeguards (see also Section 5.8.3);
   iii. be implemented in a modified form (see also section 5.8.3); or
   iv. not be implemented.

5.10 Validation Library

5.10.1 The provider ought to have available a 'library' of documents relevant to the validation of the method. The Codes require the content of this library to include, but need not be limited to, the following:

a. the agreed specification for the method and evidence of the agreement;
b. the agreed risk assessment for the method and evidence of the agreement;
c. the agreed validation plan for the method and evidence of the agreement;
d. the validation report;
e. where the consideration of associated material is not undertaken as part of the validation exercise but conducted by a third party, the library ought to include that report;
f. where the consideration of legal issues is not undertaken as part of the validation exercise the library ought to record that decision.

5.10.2 Where the validation relies on material published by others the provider ought to keep a copy as part of the library to ensure that the information is readily

accessible. This is even more important if the source of the material is not permanent, e.g. published on the internet (beware of the dead hyperlink).

5.10.3 Where the method implements a scientific theory and/or model or an interpretation or evaluation model the library ought to include a record of information supporting the use of the model/theory. The amount of material required will depend on the novelty and application of the technique.

5.10.4 The validation library ought to be maintained by the provider to cover the period for which:

a. the method is in use; and
b. legal challenges to the output from the method may arise.

5.10.5 The production of a validation library may be viewed as a burden. It is, however, a sensible and effective business practice. The creation of the library at the time of validation ought to be a relatively simple task. Attempting to collate this information in response to a legal challenge, perhaps many years after the introduction of the method, is likely to be a far more difficult challenge. This is likely to be particularly true if the staff involved have left the organisation.

5.11 Statement of Validation Completion

5.11.1 The aim of this statement is to provide those making decisions on the use of the results with an executive summary of the validation and key issues about the method. It is intended to be a short (i.e. two sides of A4) summary that includes the following:

a. that the method has been approved, by whom, and the nature of that approval;
b. the scope of the validation performed;
c. any reservations or restrictions on the use of the method;
d. any caveats about the use of the method or the information derived from it;
e. whether the method is within the scope, or being brought within the scope, of any accreditation held by the provider;
f. key applications for the method;
g. the circumstances in which the use of the method is inadvisable.

5.11.2 The manager responsible for validation ought to ensure that the following have been established.

a. The validation exercise has shown that the information provided to the CJS is fit for purpose.
b. All recommendations in the validation report have been addressed or will be addressed prior to the implementation of the method.
c. There are no risks to the CJS that have not been properly addressed.
d. The associated material is sufficient to ensure that the information provided to the CJS is fit for purpose.
e. There are no legal issues that would:
    i. prevent, or undermine, the use of the method, or its output, as evidence;
    ii. mean that the use of the method, or output from it, would pose an unacceptable risk to the CJS; or
f. There is no information available that would raise significant doubts about whether the information generated/modified by the method is fit for purpose.

5.11.3 The provider ought to ensure that where approval is given it specifies the circumstances in which the method may be used, any limits/conditions related to the use, and information that must be supplied to the CJS in relation to the method.

5.11.4 The date, name, signature and role of the person authorising the use of the technique in casework should also be included.

5.11.5 Since the inclusion of a statement of validation as a requirement, the Crown Prosecution Service has added another requirement for a Q&A style document[24] illustrating the strengths and weaknesses of the scientific procedures offered. It would seem wise to produce this at this stage, although it is accepted that if the method is not going to be immediately adopted, this could fall under the implementation stage.

[24] Further details, accessed from the internet 12/06/2013: http://www.cps.gov.uk/legal/s_to_u/scientific_evidence/core_foundation_principles_for_forensic_science_providers/index.html

5.12 Implementation Plan

5.12.1 The development and introduction of a new method may require an incremental approach that sees it deployed in a number of increasingly demanding roles. These may include, but need not be limited to, the following:

a. use in a controlled (e.g. laboratory) environment on test data/information;
b. use in a controlled environment on casework data/information;
c. use in a pilot exercise or other controlled use on casework data/information;
d. inclusion on schedule of accreditation;
e. use in casework.

5.12.2 The implementation of a new method is often part of a process of improving the service provided to customers. Equally the validation may have been triggered by a method modification as a result of a corrective action. The Codes outline that there ought to be some assessment of the impact that the implementation of a new method(s) could have on old cases.

5.12.3 The validation exercise is likely to have been undertaken in a controlled environment and, perhaps, employing staff who have a particular skill in the area. When deployed in routine use the method is likely to be used in a less controlled environment. The Codes list a number of issues that might affect the approval for implementation of a new or modified method.

5.12.4 The validation exercise ought to assess the nature of any improvements to the output of the provider as a result of the new method, and whether the improved capability generates opportunities and/or raises questions over the nature of output generated under the old capability.

5.12.5 Issues that may be relevant to this consideration include, but are not limited to, the following.

a. Is the new method more discriminating than the previous approach?
b. Will the new method obtain results in circumstances where the previous approach would not?
c. Does the new method address problems with the previous approach?

5.12.6 The first two of the above, and in some cases the third, do not suggest that the existing method is flawed or not fit for purpose. It is the nature of scientific development that knowledge increases and techniques improve with time.

5.12.7 The manager responsible for authorising the use of the method ought to be responsible for determining whether there are any serious issues related to information previously supplied to the CJS. The provider ought to have effective procedures for raising these issues with senior management as a matter of urgency.

5.12.8 The provider ought to consider how to inform stakeholders of the identified issues. These ought to, where relevant, include the following:

a. customers who have been provided with information affected by these issues, e.g. casework results;
b. the relevant police leads, e.g. forensic science;
c. the Association of Chief Police Officers (ACPO) in England Wales and Northern Ireland, and the Association of Chief Police Officers in Scotland (ACPOS), etc.;
d. prosecuting authorities that may have used such information;
e. the Forensic Science Regulator.

6. USE OF CASEWORK MATERIAL

6.1.1 The validation plan may include the testing of the method in a series of more demanding ways using casework material. This may include, but not need be limited to, the following:

a. use of test materials within the laboratory;
b. use of fabricated 'casework' samples;
c. re-analysis of casework samples from closed cases;
d. analysis of casework samples (from current and/or closed cases) using the new method in parallel with the existing approach;
e. analysis of current casework material as part of a pilot exercise or within a controlled environment.

6.1.2 The use of casework material is valuable in many areas because it may be difficult to generate a set of test data that adequately reflect the range, quality and complexity of the material submitted in casework.[25]

6.1.3 The use of casework material gives rise to a number of issues. These include:

[25] In some areas (e.g. electronic and digital evidence types) generation of suitable test material is more practical.

a. whether the use complies with all legal requirements (see below);
b. whether the use complies with all contractual, and similar, obligations;
c. whether the results obtained in the validation could differ from, and raise questions in relation to, those obtained in casework (see below).

6.1.4 In England and Wales the applicable legal requirements include:

a. Police and Criminal Evidence Act 1984;
b. Criminal Procedure and Investigations Act 1996;
c. Regulation of Investigatory Powers Act 2000;
d. Human Tissue Act 2004;
e. Data Protection Act 1998;
f. Human Rights Act 1998.

6.1.5 The risk that different results may be obtained in the validation study gives rise to the following possibilities.

a. That the results obtained in the validation exercise suggest the results obtained in casework were:
    i. incorrect; or
    ii. incorrect and that this was the result of a systematic problem rather than an individual error.
b. That the results obtained in the validation exercise provide more information than was obtained in the casework analysis and that this information was:
    i. favourable to the defendant, i.e. exculpatory; or
    ii. favourable to the prosecution case, i.e. inculpatory.

6.1.6 In this area the use of material from closed cases is likely to be less problematic, but not without consequences.

6.1.7 The use of casework material in a validation exercise must be approved by those with authority over the material (e.g. the police) and the prosecuting authority responsible for the case.

UNCERTAINTY OF MEASUREMENT

6.1.8 If the art of flat pack assembly has taught us anything it is that even if all the parts are indeed present, not all the holes will align perfectly and brute force or a little judicious re-drilling might be appropriate. Each measurement may be close to the true figure, give or take a bit. Figure 3 illustrates the problem; two errors in opposing directions conspire against construction.

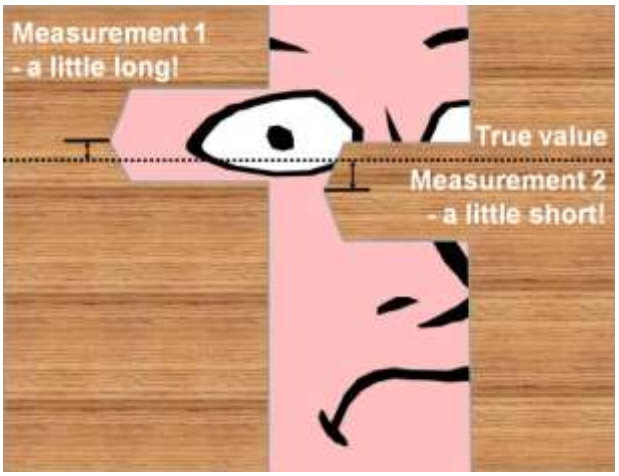

Figure 3: Measure twice, cut once – small errors add up

6.1.9 No measurement is perfect, it depends on many factors including differences in skill, equipment, method and even environmental factors. This section intends to introduce the topic, and some of the terms, with some suggested further reading at the end.

6.1.10 The terms ‘accuracy’ and ‘precision’ are often used when discussing measurements. Accuracy is a specific term referring to obtaining the true value for the quantity measured. It implies that a true value is known, perhaps using certified reference material. Precision is synonymous with reproducibility or repeatability, which can mean it is possible for a measurement to be precise but not accurate (Figure 4).

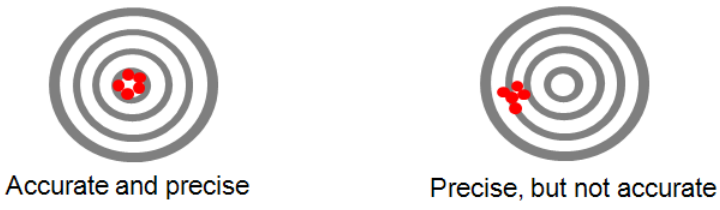

Figure 4: Dartboard analogy for describing accuracy and precision

6.1.11 If digital kitchen scales are used to determine the mass of an item, how close to the true value is this? For domestic purposes it is almost certainly fit for purpose, but would the user be happy to swear in a court of law that the 0.45kg weight obtained was accurate? Several weighings later, the figure comes out the same,

but all this has shown is the ability to get a precise, reproducible value; it has not demonstrated accuracy.

6.1.12 ISO17025:2005 requires that *"testing laboratories shall have and apply procedures for estimating uncertainty of measurement"*. The UKAS publication M3003[26] recognises *"the present state of development and application of uncertainties in testing activities is not as comprehensive as in the calibration fields"*. However, it states the *"laboratory should use documented procedures for the evaluation, treatment and reporting of the uncertainty"*.

6.1.13 One common method of describing uncertainty of measurement for quantitative tests is through standard deviations. A standard deviation describes the spread of data about the average, or more specifically the arithmetic mean. It is a measurement of precision and is denoted by the symbol sigma (σ) or sometimes simply the abbreviation sd. Figure 5 shows a normally distributed bell curve of data.

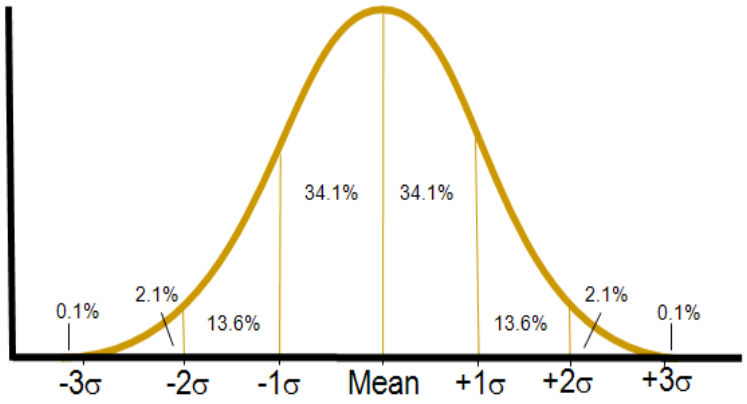

Figure 5: The bell curve of showing data distribution around the average or arithmetic mean

6.1.14 In Figure 5, the area under the curve 1 sigma either side of the mean contains about 68.3 per cent[27] of the data, 2 sigmas contain about 95.4 per cent and 3 sigmas contain about 99.7 per cent of the data. A height calculation with 2 sigmas either side does not therefore exclude a figure outside that range, if about 95.4 per

26 **UKAS** (2012) *The Expression of Uncertainty and Confidence in Measurement* M3003, 3rd edition, November 2012. Accessed from the internet 15/07/2013: http://www.ukas.com/library/Technical-Information/Pubs-Technical-Articles/Pubs-List/M3003_Ed3_final.pdf

27 'About' is a very loose term; in the example one decimal place is being used, for three the figure would read 68.269 per cent, for five it would be 68.26895 per cent, etc.

cent of the observations fall within that range, then about 4.6 per cent observations should be expected to be outside. This would predict that 46 in every 1,000 observations would be outside this range. This means that if the height calculation was to see if a person of interest in a video could be a specific suspect, and the true value of the suspect was outside that range, although unlikely, an outright exclusion of such an outlier would probably be incorrect. The well-known management consultancy tool Six Sigma, refers to six standard deviations either side of the mean alluding to the ability to make a manufacturing process 99.99966 per cent defect free (3.4 defects per 1 million).[28] The more precise the method, the smaller the spread of data and therefore the smaller the standard deviation. Specifying too large a multiple when the method is less precise could result in the range being so large that the result it is not particularly informative. However, if the method is that imprecise then perhaps it is not fit for purpose.

6.1.15 The point of forensic science is to assist the courts, so understanding how to express and use the estimate of uncertainty in reports is important. Calculating the figure in a validation study, or in a report and not ever referring to it again is incorrect. Case law sometimes points to how data should be expressed, other times it is up to the scientist to decide how to present data without oversimplifying the result to imply that there is no uncertainty.

6.1.16 For example, with measurements of alcohol in liquid blood, readings from the breathalyser tends to have three standard deviations deducted so the expert can report a single figure with confidence that the true value is unlikely to be below that figure. The provider's report shows the detail, but the message is simplified to assist the layperson to understand what the result means.

6.1.17 So the sigma value, or standard deviation, is describing precision of measurement. What about accuracy? There are methods that might be appropriate. These include calibration to a reference material or, where acceptable, comparison of the results of the proposed analytical procedure with those of a second method with known accuracy. What should not be done is to mistake a precise looking figure (one with many decimal places) for accuracy, as the layperson may not realise that no measurement is without an element of uncertainty.

[28] Example accessed from the internet 12/06/2013: http://asq.org/quality-progress/2009/08/34-per-million/perusing-process-performance-metrics.html

6.1.18 This is only a brief introduction to the topic, and has focused on the quantitative or measurement based estimation of uncertainty. Uncertainty in qualitative techniques is normally expressed in terms of false positives and negatives, which have been covered at some length in the Section 5.4 on risk assessment. Further guidance on the whole topic can be obtained from:

a. **National Physical Laboratory** (2001) *Good Practice Guide No. 11: A Beginner's Guide to Uncertainty of Measurement by the National Physical Laboratory*;[29]

b. **UKAS** (2012) *The Expression of Uncertainty and Confidence in Measurement* M3003, 3rd edition, November 2012.[30]

7. REGULATOR'S INVOLVEMENT

7.1.1 It is not part of the role of the Regulator to become directly involved in the validation of new methods within the field of forensic science. The responsibility for validation rests with the provider and ought to be overseen by accreditation bodies. There are particular provisions with regard to services linked to the National DNA Database®.[31]

7.1.2 In certain circumstances the Regulator should be informed of the intention to implement a new method:

a. where a new method involves the introduction of a scientific method not previously employed within forensic science in the UK;

b. where a new method involves the use of a previously employed scientific method in a new field; or

c. where the analysis of the impact to the criminal justice system suggests a significant change in capabilities.

[29] Accessed from the internet 12/06/2013: http://www.npl.co.uk/publications/a-beginners-guide-to-uncertainty-in-measurement

[30] Accessed from the internet 15/07/2013: http://www.ukas.com/library/Technical-Information/Pubs-Technical-Articles/Pubs-List/M3003_Ed3_final.pdf

[31] The National DNA Database is a registered trademark owned by the Secretary of State for the Home Department.

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9. GLOSSARY

Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

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 (see **precision**).

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.

Codes

The Codes of Practice and Conduct, published by the Forensic Science Regulator in 2011. Available from: https://www.gov.uk/government/publications/forensic-science-providers-codes-of-practice-and-conduct.

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.

Criminal justice system

The criminal justice system (CJS) is the collective term used in England and Wales for the police, the Crown Prosecution Service, the courts, prisons and probation, which work together to deliver criminal justice.

Customer

Whether internal or external, it is the organisation or a person who 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.

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 that the results will be.

Evidence

Anything that may prove or disprove an assumption to be true, e.g. an exhibit or the lack of expected findings.

Evidential

The Crown Prosecution Service applies an evidential test to decide whether there is enough **evidence** to prosecute and importantly whether the evidence can be used in court and whether it is reliable.

Exculpatory

Exculpatory **evidence** is broadly favourable to the defendant.

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**.

Five by five by five (5x5x5)

The five by five by five refers to an intelligence report/product, and is part of the **National Intelligence Model**. Each five refers to a grading of the evaluation of the source, **intelligence** and a handling code.

Fully validated

The International Laboratory Accreditation Cooperation's (ILAC's) report (ILAC-G19:2002, 5.4.2a, see Section 2.4) says *"technical procedures used by a forensic science laboratory should be fully validated before being used on casework"*. Fully validated in this context means that the study is completed and the objective **evidence** available is 'fit for purpose', rather than a **method** that operates in the expected manner for all possible circumstances.

Inculpatory

Inculpatory **evidence** is broadly favourable to the prosecution case.

Intelligence

Intelligence is information transformed through an analytical process.

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).

Method validation

The process of verifying that a **method** is fit for purpose (i.e. for use for solving a particular problem).

National Intelligence Model

The National Intelligence Model (NIM) is an **intelligence**-led business model, utilised by police forces in the UK to ensure that information is fully researched, developed and analysed to provide intelligence.

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).

Organisational competence

The ability of an **organisation** to deliver its mission, in this case providing the test results to the standard the **customer** expects.

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.

Accurate and precise

Precise, but not accurate

Presumptive test

The first test carried out on a specimen for the purpose of determining a presumption of a positive or negative identification or assay. Such tests include the Kastle-Meyer test for blood; it can show that a sample is unlikely to be blood (i.e. a low false negative) or that the sample is probably blood (a high false positive) but other substances are known to cross-react and give a false positive result. Usually positives are followed by a confirmatory test.

Provider

The term ‘provider’ 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.

Quantitative

A measurement or requirement based on some quantity or number.

Qualitative

Results or requires based on some quality rather than on some quantity i.e. the identity of the compound rather than concentration.

Risk

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

Robustness

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

Root-cause analysis

Is a problem solving process for investigating an identified incident, error, problem, unexpected result or non-conformity.

Standard methods

A 'standard method' is published by certain prescribed organisation and has the following characteristics:

a. contains concise information on how to perform the tests;
b. does not need to be supplemented or rewritten as internal procedures; and
c. can be used as published by the operating staff in a laboratory.

Based on the full definition ISO/IEC17025:2005 under Section 5.4.1, at the time of writing (2013) there appears to be no 'standard methods' in the traditional forensic sciences in the UK.

Uncertainty of measurement

The estimation of the uncertainty of measurement is a BS EN ISO/IEC17025:2005 requirement and is based on 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.

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 specific purpose intended. This is an overriding requirement that there is evidence that the **provider's** own competent staff can perform the method at the given location.