Forensic Science Regulator Statutory Code of Practice ('the Code') Validation Gap Analysis

June 2023

Introduction – This Validation Gap Analysis has been produced by combining and reviewing information provided by the Forensic Science Regulator (FSR), UKAS and Policing. It serves as an informative guide to support forensic units to transition from compliance with Issue 7 of the FSR non-statutory code to Issue 1 of the FSR Statutory Code. Whilst care has been taken to provide a full Validation gap analysis, organisations using this gap analysis are recommended to review the FSR Statutory Code to determine their own compliance.

Summary – The majority of the FSR Code requirements remain largely unchanged from the previous non-statutory version. However, there are some major changes as highlighted throughout this document. A key change that will impact all forensic units is the addition of the Senior Accountable Individual role.

Acknowledgements – Thank you to Durham and Staffordshire Police for providing the FCN with their gap analysis documents.

Category	Definition
Minor	Minor update or slight change of emphasis to an existing requirement with minimal additional work anticipated to comply
Major	Major update or significant change of emphasis to an existing requirement with considerable additional work anticipated to comply

CoP v7 Clause	Requirement	Statutory Codes Clause	New Requirement	Comment	Emphasis of change	Required for UKAS transition	Included in FCN Gap analysis
21.1 Selection of Methods							
		30.1.1	Methods and Method Validation, General: All technical methods used by a forensic unit shall be fit for purpose; this is demonstrated by method validation against the end-user requirements.	Expansion and clarification on end user requirements.	Minor	No	No
		30.1.2	This involves establishing that the method operates in a manner that fulfils the acceptance criteria derived from the end-user requirements, that the limitations of the method are properly understood, that the planned use of the method is appropriate, and that the approach to reporting is logical.	Expansion and clarification on end user requirements and acceptance criteria, limitations and reporting.	Minor	No	No

		30.1.3	Validation allows a proper understanding of the risks involved in the use of a method (section 30.6).	Expansion on risk management including the use of process maps and critical control points.	Minor	No	No
		30.1.4	Section 14.1.3 of this Code requires roles involved in development, validation and verification to be defined and competencies specified. Personnel will often be practitioners (i.e. perform the FSA) but may be other personnel who are deemed competent.	Requirement to have defined roles and competencies for method development and validation.	Minor	No	Yes
21.1.1	Selection of Methods: The general requirement is that all technical methods and procedures used by a forensic unit shall be validated. This section details the principles of the requirement for validated methods, the next section, 21.2 Validation of Methods, details the required processes.	30.2.1	Selection of Methods: This section details the principles of the requirement for validated methods; section 30.3 details the required processes.		Minor	No	No

21.1.2	Forensic units with methods already 60 within the schedule of accreditation will normally only be required to collate the existing validation paperwork to form as comparable a validation library as possible, and produce the short statement of validation completion as detailed in 21.2.57. 61			The validation library is covered elsewhere in the Code	Minor	No	No
21.1.3	Even where a method is considered standard and is in widespread use, scientific validity 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 forensic unit's scope of accreditation and validation has not been conducted at the laboratory site where it is to be implemented, the forensic unit 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.	30.2.2	Even where a method is considered standard and is in widespread use, scientific validity still needs 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 validation has not been conducted by the forensic unit, and validation data is available, the forensic unit should follow the adopted methods procedure. This includes demonstrating the method works in its hands.	Reorganisation of the section with validation library and statement of completion discussed elsewhere in the Code.	Minor	No	No

21.1.4	If a method is required to use portable equipment for any reason, the validation study shall include testing any additional controls as well as assessing any additional aspects that may impact on the tests. For ISO 17020 applications, see UKAS-RG 201:2015 section Process Requirements 7.1.1 (including but not limited to temperature, humidity, surfaces, cross reactivity, lighting, cross contamination control, handling controls).	30.2.3	If a method requires the use of portable equipment (i.e. equipment intended to be used at different locations) for any reason, the validation study shall include testing any additional controls as well as assessing any additional aspects that may impact on the tests. For ISO/IEC 17020 applications see, for example, UKAS-RG 201 (7.1.1) [40] which includes factors such as temperature, humidity, surfaces, cross reactivity, lighting, cross contamination control, handling controls etc.	Example given (i.e., equipment intended to be used at different locations).	Minor	No	No
21.1.5	For novel 62 techniques, non-routine or infrequently used activities the forensic unit 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 work. If these activities are to become part of the routine activities of the forensic unit, accreditation should always be sought.	30.2.4	The forensic unit should have validated the method (including the equipment) prior to use in casework in accordance with the requirements of this Code. If the implementation plan requires pilot testing of the method in a live environment after the validation study but prior to routine use in casework (e.g. for novel methods), any use by the forensic unit prior to this piloting being completed shall be declared to the commissioning party, i.e. the status of the validation or implementation, and the forensic unit shall disclose this status in any reports. Some restrictions may apply (e.g. see [17]).	Novel infrequently used techniques are discussed in depth elsewhere in the Code. Emphasis on disclosing the use of novel/new techniques in live environments. Customer removed.	Minor	No	No

		30.2.5	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.	Previously a footnote but now part of Code.	Minor	No	No
21.2 Validation of Methods							
		30.3.1	Validation of Methods: The forensic unit shall use methods of demonstrable validity (section 12).	Section 12 relates to standards of conduct including practitioner responsibilities, particularly referencing 12.1.2 j	Minor	No	No

21.2.1	Validation of Methods: Validation should be conducted prior to implementation of the method. This may be performed by the forensic unit, manufacturer or another forensic unit, but the forensic unit implementing the method will need to review the validation data to determine if the validation is adequate, reliable and relevant to the purpose it intends for the method.	30.3.2	Validation should be conducted prior to implementation of the method. This may be performed in its entirety by the forensic unit, or the studies to produce the data may be performed by the manufacturer or another forensic unit; in which case the forensic unit implementing the method shall review the data to determine if it is adequate, reliable and relevant to the purpose it intends for the method against the end-user requirements (section 30.4.1).	Includes studies performed by the manufacturer or another forensic unit and checking against end user requirements.	Minor	No	No

21.2.2	Except where the method has been validated for incident scene use (see UKAS-RG 201:2015), if the validation has not been conducted at the site that will be using the method the forensic unit must still verify the scope of the validation with the required steps in 21.2.5. This may be scaled up or down according to the adequacy and relevance of the available existing validation study. In such cases, following review of validation data to determine if the validation is adequate, the forensic unit's own competent staff shall demonstrate such adopted methods perform reliably at the given location following the validation process. 63 [29] [39] [40]	30.3.3	If the validation has been completed but this was not conducted at the site that will be using the method (or validated for incident scene use by the forensic unit [40] or as part of an agreed deployment, i.e. sections 108.3.13–108.3.15), the forensic unit shall verify the scope of the validation with the required steps in 30.3.10. This may be scaled up or down according to the adequacy and relevance of the available existing validation study. In such cases, following review of validation data to determine if the validation is adequate, the forensic unit's practitioners trained and signed off as competent in the method shall demonstrate that such adopted methods perform reliably at the given location by following the validation process [4] [41] [42].	Clarification for practitioners to be trained and signed off as competent in the method.	Minor	No	No

		30.3.4	See ILAC-G19 (3.10): "When a method has been validated in another organization the forensic unit shall review validation records to ensure that the validation performed was fit for purpose. It is then possible for the forensic unit to only undertake verification for the method to demonstrate that the unit is competent to perform the test/examination." This Code expects the review to be against the end-user requirements, with the production of a statement of validation completion (section 30.18).	Formerly a footnote, now part of the Code. Clarification on how validation and verification should work with external organisations with emphasis on end user requirements and statement of completion.	Minor	No	No
21.2.3	The validation policy or procedure shall set out roles and responsibilities of staff involved in conducting validation, authorisation of key stages and reviewing outcomes.	30.3.5	The validation policy or procedure shall set out roles and responsibilities of practitioners involved in conducting validation, authorisation of key stages, and reviewing outcomes.	Replaced "staff" with "practitioner."	Minor	No	No
21.2.4	To ensure validation studies are conducted on the final method, there should be 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.	30.3.6a	To ensure validation studies are conducted on the final method, there should be a clear boundary between development and validation. It is important that any significant unexpected outcomes are not corrected during validation, but that the method is declared to have failed validation. Following such a failure either: a. The method shall be abandoned; or	Expansion on method development and validation	Minor	Yes	Yes

		30.3.6b	The method shall be amended (if that is possible while maintaining the required standards), and the validation study evaluated and repeated.	Expansion on method development and validation	Minor	Yes	Yes
		30.3.7	Evaluation of the change may mean the entire validation study needs to be repeated, or that elements of the original study remain suitable to provide objective evidence depending on the nature or, more importantly, the stage of the method that is changed.	Expansion on method development and validation	Minor	Yes	Yes
		30.3.8	If validation needs to be repeated, it should be considered whether using the same dataset or item would risk optimising the method to the validation sample set itself.	Expansion on method development and validation	Minor	Yes	Yes
		30.3.9	If a method is amended during validation, then the validation is invalid. The procedure should include consideration of how to prevent inadvertent re entering of the development process once validation has started.	Expansion on method development and validation	Minor	Yes	Yes

21.2.5a	The validation procedure shall include where relevant, but is not limited to: a. Determining the end-user's requirements;	30.3.10	The validation procedure shall include where relevant, but is not limited to: a. Determining the end-user's requirements;	Unchanged		No	No
21.2.5b	Determining the specification;	30.3.10b	Determining the specification;	Unchanged		No	No
21.2.5c	Risk assessment of the method;	30.3.10c	Risk assessment of the method;	Unchanged		No	No
21.2.5d	A review of the end-user's requirements and specification;	30.3.10d	A review of the end-user's requirements and specification;	Unchanged		No	No
21.2.5e	Setting the acceptance criteria;	30.3.10e	Setting the acceptance criteria;	Unchanged		No	No
21.2.5f	The validation plan;	30.3.10f	The validation plan;	Unchanged		No	No
21.2.5g	The outcomes of the validation exercise;	30.3.10g	The outcomes of the validation exercise;	Unchanged		No	No
21.2.5h	Assessment of acceptance criteria compliance;	30.3.10h	Assessment of acceptance criteria compliance;	Unchanged		No	No
21.2.5i	Validation report;	30.3.10i	Validation report;	Unchanged		No	No
21.2.5j	Statement of validation completion; and	30.3.10j	Statement of validation completion; and	Unchanged		No	No
21.2.5k	Implementation plan.	30.3.10k	Implementation plan.	Unchanged		No	No

21.2.6a	In certain circumstances implemented methods will require revalidation, e.g. when:	30.3.11a	In certain circumstances an implemented validated method will require revalidation or replacement, such as when:	addition of the word "replacement."	Minor	No	No
	a. Quality control indicates that an established method is changing with time;		a. Quality control indicates that an established method is changing with time;				
21.2.6b	Equipment that was not validated to be mobile or portable is moved to a new location;	30.3.11b	Equipment that was not validated to be mobile or portable is moved to a new location;	Unchanged		No	No
21.2.6c	Deficiencies have become apparent after the method has been implemented; or	30.3.11c	Deficiencies have become apparent after the method has been implemented; or	Unchanged		No	No
21.2.6d	The end-user identifies a change in requirement.	30.3.11d	The end-user identifies a change in requirement.	Unchanged		No	No

21.2.7	Determining the End-Users' Requirement: The process of innovation ending in the implementation of a validated method is more likely to be instigated by the forensic unit than the end-user. However, to meet the needs of the CJS, which is the end-user, the requirements of all intermediate users of a method through to the expectations of the court (e.g. Criminal Practice Directions V 19A.5, relevant case law) need to be determined.	30.4.1	Determining the end-user requirements: The process of innovation ending in the implementation of a validated method is more likely to be instigated by the forensic unit than the end-user. If the forensic unit developed the method in-house or adopted a method against formal requirements then it may have assembled requirements already to consider. The likely requirements of all end-users (e.g. other practitioners, investigators, prosecutors and the CJS) should be considered. To meet the needs of the CJS and the expectations of the court (e.g. Criminal Practice Directions V [34]19A.5), relevant case law [20] need to be determined.	Additional examples of end users highlighted.	Minor	No	No
21.2.8	The amount of direct input from the CJS end-user should be determined by the forensic unit, based on the type of innovation; certain requirements may be generic and form a set of core requirements to the casework type.	30.4.2	The amount of direct input from the CJS end-user should be determined by the forensic unit, based on the type of innovation; certain requirements may be generic and form a set of core requirements to the casework type.	Unchanged		No	No

21.2.9	The Criminal Practice Directions V (e.g. 19A.5) that supplement Part 19 of the Criminal Procedure Rules should be considered as providing an insight as to the expectations of the CJS end-user. [27]	30.4.3	The Criminal Practice Directions V (i.e. 19A.5) [34] that supplement Part 19 of the Criminal Procedure Rules [35] should be considered as providing an insight as to the expectations of the CJS end-user. These expectations apply regardless of whether the result is evidence of fact or opinion.	Clarification, inclusion of fact and opinion.	Minor	No	No
21.2.10a	The end-user's requirement shall take account of, as appropriate: a. Who will operate or use the new method, product or service post-delivery, and in what environment;	30.4.4a	The end-user requirements shall take account of, as appropriate, the following: a. Who will operate or use the new method post-delivery, and in what environment.	Removal of the word's "product" and "service."	Minor	No	No
21.2.10b	What the new method or product is intended to deliver for the end-user;	30.4.4b	What the new method is intended to deliver to the end-user.	Removal of the word "product."	Minor	No	No
21.2.10c	What statutory and regulatory requirements related to development and use of the method or product apply;	30.4.4c	What statutory and regulatory requirements related to development and use of the method apply.	Removal of the word "product."	Minor	No	No

21.2.10d	Whether there are any compatibility issues to be considered, e.g. data output formats;	30.4.4d	Whether there are any compatibility issues to be considered, e.g. data output formats.	Unchanged		No	No
21.2.10e	What level of quality performance is expected; and	30.4.4e	What level of quality performance is expected.	removal of word "and"	Minor	No	No
21.2.10f	By what date the new method, product or service is required for implementation.	30.4.4f	By what date the new method is required for implementation.	Removal of the word's "product" and "service."	Minor	No	No
21.2.11a	End-user requirements should conform to the following rules:	30.4.5a	End-user requirements should conform to the following rules:	Unchanged		No	No
	a. Each requirement is a single statement;		a. Each requirement is a single statement;				
21.2.11b	Each requirement is testable;	30.4.5b	Each requirement is testable;	Unchanged		No	No
21.2.11c	Each requirement specifies something that the solution will do, not how it will do it;	30.4.5c	Each requirement specifies something that the solution will do, not how it will do it;	Unchanged		No	No
21.2.11d	Each requirement specifies in its wording whether it is mandatory or desirable; and	30.4.5d	Each requirement specifies in its wording whether it is essential, or desirable and therefore not essential; and	Replacement of word "mandatory" to "essential."	Minor	No	No

21.2.11e	Each requirement is written in a language that can be understood by the non-technical stakeholders.	30.4.5e	Each requirement is written in a language that can be understood by the non-technical stakeholders.	Unchanged		No	No
21.2.12	Where the method is part of a service to be provided to a specified customer, the forensic unit shall also ensure their formal agreement of the method selection.	30.4.6	Where the method is part of a service to be provided to a specified commissioning party, the forensic unit shall also ensure formal agreement of the method selection with the commissioning party.	"Customer" is changed to "commissioning party."	Minor	No	No
21.2.13	Determining the Specification: A detailed specification shall be written for the method, product or service, and shall include the technical quality standards. It may be an extension of the end-user requirement document or a separate document.	30.5.1	Determining the Specification: A detailed specification shall be written for the method and shall include the technical quality standards. It may be an extension of the end-user requirements document or a separate document.	Removal of the word's "product" and "service."	Minor	No	No

21.2.14	The specification adds detail to the requirements captured in end-user requirement from the range of users (e.g. analysts, reporting officers) as well as drawing in other technical requirements and is ultimately what is to be tested, encapsulating what this method is to do, the configuration, and what the method can and cannot be used for.	30.5.2	The specification translates the end-user requirement from the range of users, drawing in other technical requirements, into what is to be tested in the validation study. It encapsulates what this method is to do, the configuration, and what the method can and cannot be used for.	Inclusion of the word "translates" and removed examples of end users.	Minor	No	No
21.2.15	At this stage the list contained in the ILAC-G19:08/2014 (3.10) should be considered, even if the points listed were not explicitly raised in the end-user requirement capture exercise. The specification may also draw on technical details from a review of the scientific literature.	30.5.3	At this stage in the validation, the list contained in ILAC-G19 (3.10) should be considered, even if the points listed were not explicitly raised in the end-user requirement capture exercise. The specification may also draw on technical details from a review of the scientific literature.	Includes the word validation and removing the version reference to ILAC G19.	Minor	No	No
21.2.16a	Risk Assessment of the Method: 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:	30.6.1a	Risk assessment of the method: 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:	Removal of the word "results" and replaced by "method."	Minor	No	No

	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		a. Identifying, on the basis of the use to which the method maybe put, the possible impact on the CJS of any errors in the method, associated materials or procedures; and				
21.2.16b	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.	30.6.1b	Identifying areas where the operation of the method, or interpretation of the findings, requires specialist skills or knowledge to prevent ambiguous or misleading outputs or outcomes.	Change of word from "results" to "findings"	Minor	No	No
		30.6.2	The forensic unit should define the risk assessment method it will use. This Code requires risk assessment in various sections, including in contamination (section 29.3.2) and control of data (section 32.1.3). The methodology recommended in both is based upon process mapping and identifying the critical control points for the risks or failure modes [41] at those stages. One process map may be used to cover the whole method against different risks, and may be used to evaluate, or at least identify, potential contributions to uncertainty.	Expansion on FMEA and process mapping and critical control points to support risk management and uncertainty.	Minor	No	Yes

21.2.17a	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;	30.6.3a	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;	Unchanged		No	No
21.2.17b	Any assumptions incorporated within the theory/model; and	30.6.3b	Any assumptions incorporated within the theory/model; and	Unchanged	No	No	No
21.2.17c	Limits on the application of the theory/model.	30.6.3c	Limits on the application of the theory/model.	Unchanged	No	No	No
21.2.18a	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 not be limited to: a. Caveats about the use of the method;	30.6.4a	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 not be limited to: a. Caveats about the use of the method;	Unchanged	No	No	No
21.2.18b	Circumstances in which the use of the method would be inadvisable; and	30.6.4b	Circumstances in which the use of the method would be inadvisable; and	Unchanged	No	No	No

21.2.18c	Additional work that should be undertaken in combination with the method.	30.6.4c	Additional work that should be undertaken in combination with the method.	Unchanged		No	No
21.2.19	Where exhibits provided by an end-user, or data derived from these, are required for the development work or validation, the forensic unit shall obtain prior permission for their use and include their use in the risk assessment. [41]	30.6.5	Where items/exhibits provided by an end-user, or data derived from these, are required for the development work or validation, the forensic unit shall obtain prior permission, from those with responsibility for the items/exhibits and/or data (e.g. the commissioning party or prosecuting authority) for their use and include their use in the risk assessment [43]. Given the risks involved in the use of casework items/exhibits and/or data, the SAI for the forensic unit shall be informed of the proposed use and of the information contained in the Regulator's publication on the use of casework material [43].	Inclusion of the word "Items." Expansion and clarification on using data for validation and method development and role of SAI	Minor	Yes	Yes
21.2.20	The risk assessment shall be subject to version control and should feed into the statement of validation completion.	30.6.6	The risk assessment shall be subject to version control and should feed into the statement of validation completion.	Unchanged		No	No

21.2.21	Review of the End-Users' Requirement: The forensic unit shall review the end-user's requirement to ensure that requirements considered essential/mandatory have been translated correctly into the specification and the specification is fit for purpose. Where appropriate, the end-user specifying the requirement (e.g. analysts, reporting officers) may be involved in this review process.	30.7.1	Review of the end- user requirements: The forensic unit shall review the requirements collated to ensure that requirements considered essential/mandatory have been translated correctly into the specification. Where appropriate, the original contributor of a specific end-user requirement may be involved in this review process.	Removal of "specification is fit for purpose." Essential/mandatory is still referred to in this section although it may be better to use the word essential to tie in with clause 30.4.5d.	Minor	No	No
21.2.22	When a review identifies that there are risks, compatibility, legality or ethical issues, the forensic unit shall produce a revised end-user's requirements and/or specification.	30.7.2	When a review identifies that there are risks, or that there are compatibility, legality, or ethical issues, the forensic unit shall produce a revised end-user requirement and/or specification.	Rephrased	Minor	No	No

21.2.23	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.	30.7.3	The specification shall be subject to change control policies and procedures. Any proposed changes affecting end user requirements shall be subject to review, acceptance and change control of the end user requirements' documentation. Any proposed changes affecting the specification shall be reviewed and accepted before amendment of the specification.	Changes to specification to follow process with review of end user requirements	Minor	No	No
21.2.24	The forensic unit 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.	30.7.4	The forensic unit shall ensure that all personnel involved in the development and validation/verification of the method are informed of any agreed changes to the end-user requirements or specification so the correct version proceeds to the next stage.	Emphasis on end user requirements and/or specification is kept up to date throughout the process ad communicated to end users before work commences. Staff replaced by personnel.	Minor	No	No
21.2.25	Acceptance Criteria: 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.	30.8.1a	Acceptance Criteria: The acceptance criteria shall be established in advance of the experimental part of the validation study being commenced, and should be: a. Clearly stated; and	Acceptance criteria to be established in advanced not during validation process.	Minor	No	No

		30.8.1b	Based upon the specification, the risk analysis and any control strategies put in place to control identified risks.	Reorganisation of previous section 21.2.25.	Minor	No	No
21.2.26	The acceptance criteria shall be used to demonstrate the effectiveness of the method and control strategy within measurable and set tolerances.	30.8.2	The acceptance criteria shall be used to demonstrate the meeting of the formally accepted specification based on the end-user requirements, within measurable and set tolerances, and including any control strategy.	Emphasis has changed from demonstrating the effectiveness of the method to the meeting of the formally accepted specification and end user requirements.	Minor	No	No
21.2.27	The Validation Plan: 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.	30.9.1a	Validation Plan: The validation shall be carried out according to a documented validation plan. The validation plan shall be based on the formally accepted specification based on the end-user requirements. It shall identify and define: a. The functional and performance requirements; the relevant parameters and characteristics to be studied; and	Removal of product and service. Reorganisation of previous section 21.2.27. Further expansion points for the validation plan linking back to end user requirements and specification.	Minor	No	No

		30.9.1b	The acceptance criteria for the results obtained to confirm that the specified requirements for the method or service have been met.	Reorganisation of previous section 21.2.27. Removal of word product.	Minor	No	No
21.2.28	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.	30.9.2	Where indicated by the specification, 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 (section 30.14).	Rephrased, led by specification.	Minor	No	No
21.2.29	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.64	30.9.3	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 (see [43] for more detail). Legal advice may be required for the use of casework material where the exemption in relevant legislation 'for law enforcement purposes' may not apply.	May require legal advice for use of casework in validation	Minor	No	Yes

21.2.30a	The validation plan should be tailored depending on whether it is intended for the: a. Validation of measurement-based methods;	30.9.4a	The validation plan should be tailored depending on whether, for example, it is intended for the: a. Validation of measurement-based methods;	Addition of "for example"		No	No
21.2.30b	Validation of interpretive methods;	30.9.4b	Validation of interpretive methods;	Unchanged		No	No
21.2.30c	Verification of the validation of adopted methods; and/or	30.9.4c	Verification of the validation of adopted methods; and/or	Unchanged		No	No
21.2.30d	Verification of the impact of minor changes to methods.	30.9.4d	Verification of the impact of minor changes to methods	Unchanged		No	No
21.2.31	The validation plan should be signed off by a suitably competent individual who was independent from the development of the method and has sufficient knowledge of the relevant field under study.	30.9.5	A member of personnel with sufficient knowledge of the relevant field under study, and independence from the development of the method, should be responsible for the sign off of the validation plan.	Emphasis on plan being signed off by knowledgeable personnel within relevant field of study and being independent from development work.	Minor	No	No

21.2.32	Particularly where this is a plan for the validation of a new method rather than an adopted method (see 21.2.7), it is accepted additional individuals may be needed to provide the breadth of technical knowledge to evaluate the plan. 65 In such cases these individuals shall be listed and their role in supporting the person responsible for sign-off should be recorded.	30.9.6	Where this is a plan for the validation of a new method rather than an adopted method (section 30.4.1), it is accepted that additional personnel may be needed to provide the required breadth of technical knowledge to evaluate the plan. In such cases these personnel shall be listed in the validation report and their role in supporting the decision for sign-off should be recorded.	"Individuals" changed to "personnel." Personnel should be listed in validation report.	Minor	No	No
21.2.33a	Validation of Measurement-Based Methods: 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	30.10.1a	Validation of measurement-based methods: The validation plan should ensure the required parameters and characteristics are studied: a. By a practitioner 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	Removal of the role description "analyst" and "examiner" to "practitioner."	Minor	No	No
21.2.33b	Using equipment that is within specification, working correctly and, where appropriate, calibrated.	30.10.1b	Using equipment that is within specification, working correctly and, where appropriate, calibrated.	Unchanged		No	No

21.2.34a	The functional and performance requirements, and the relevant parameters and characteristics for measurement-based methods 66 that shall be considered include the: a. Competence requirements of the analyst/user;	30.10.2a	The functional and performance requirements, and the relevant parameters and characteristics for measurement-based methods that shall be considered, include the following: a. Competence requirements of the practitioner.	Removal of the role description "analyst/user" to "practitioner."	Minor	No	No
21.2.34b	Environmental constraints;	30.10.2b	Environmental constraints.	Unchanged		No	No
21.2.34c	Exhibit/sample size;	30.10.2c	Item/exhibit and/or sample size.	Includes "Item."	Minor	No	No
21.2.34d	Exhibit/sample handling;	30.10.2d	Item/exhibit and/or sample handling.	Includes "Item."	Minor	No	No
		30.10.2e	Consistent, reliable, accurate and robust results, with an uncertainty measurement.	Moved from section 21.2.34 l	Minor	No	No
		30.10.2f	Compatibility with results obtained by other practitioners using different equipment and different methods.	Moved from section 21.2.34 m	Minor	No	No
21.2.34e	Exhibit/sample homogeneity;	30.10.2g	Item/exhibit and/or sample homogeneity.	Includes "Item."	Minor	No	No
21.2.34f	Ability of the sampling process to provide a representative sample of the exhibit;	30.10.2h	Ability of the sampling process to provide a representative sample of the item/exhibit.	Includes "Item."	Minor	No	No

21.2.34g	Efficiency of recovery of the substance(s) to be identified/measured (i.e. Analyte) during sample preparation for analysis;	30.10.2i	Efficiency of recovery of the substance(s) to be identified/measured (i.e. analyte) during sample preparation for analysis.	Unchanged		No	No
21.2.34h	Presence or absence of the analyte(s) of interest in the sample analysed;	30.10.2j	Presence or absence of the analyte(s) of interest in the sample analysed	Unchanged		No	No
21.2.34i	Minimum quantity of each analyte that can be reliably detected;	30.10.2k	Minimum quantity of each analyte that can be reliably detected.	Unchanged		No	No
21.2.34j	Minimum amount of each analyte that can be accurately quantified;	30.10.2l	Minimum amount of each analyte that can be accurately quantified (if the method is not a qualitative test).	Includes "(if the method is not a qualitative test)."	Minor	No	No
21.2.34k	Identification/measurement relates to the analyte(s) alone, and is not compromised by the presence of some matrix or substrate effect or interfering substance;	30.10.2m	Identification/measurement relates to the analyte(s) alone, and is not compromised by the presence of some matrix or substrate effect or interfering substance.	Unchanged		No	No
21.2.34l	Results are consistent, reliable, accurate, robust and with an uncertainty measurement;			Moved to 30.10.2. e	Minor	No	No
21.2.34m	Compatibility of results obtained by other analysts using different equipment and different methods; and			Moved to 30.10.2. f	Minor	No	No
21.2.34n	Limitations of applicability.			Removed	Minor	No	No

21.2.35a	Validation of Interpretative Methods: The functional and performance requirements for interpretive methods are less prescriptive than for measurement-based methods although should include testing against representative ground truth data. 68 They concentrate on the competence requirements for the staff involved and how the staff shall 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:	30.11.1a	Validation of Interpretative methods: Though the functional and performance requirements for interpretive methods (such as comparison of marks, handwriting, microscopic comparisons) are less prescriptive than for measurement-based methods, the methods should include testing against representative ground truth data. They concentrate on the competence requirements for the practitioners involved and how the practitioners shall demonstrate that they can provide consistent, reproducible, valid and reliable results that are compatible with the results of other practitioners. This may be achieved by a combination of:	Added functional requirements for interpretative method examples (such as comparison of marks, handwriting, microscopic comparisons). Staff changed to practitioners and replacement of examiner with practitioner.	Minor	No	Yes
	Independent confirmation of results/opinions by another competent examiner (i.e. without prior knowledge of the first result/opinion provided);		a. Independent confirmation of results/opinions by another practitioner (i.e. without prior knowledge of the first result/opinion provided);				
21.2.35b	Participating in inter-laboratory comparisons (collaborative exercises or proficiency tests);	30.11.1b	Participating in inter-laboratory comparisons (collaborative exercises or proficiency tests); and	inclusion of "and"	Minor	No	Yes
21.2.35c	External recognition with a recognised and relevant professional body; and			Removed	Minor	No	No

21.2.35d	Designing frequent in-house assessment into the process using positive and negative competence tests.	30.11.1c	Designing frequent in-house assessment into the process using positive and negative competence tests.	Unchanged		No	No
21.2.36	An interpretive method shall require only the relevant subset of the parameters and characteristics for measurement-based methods to be determined.	30.11.2	An interpretive method shall require the relevant subset of the parameters and characteristics for measurement-based methods to be determined.	removal of the word "only"	Minor	No	No
21.2.37	Verification of the Validation of Adopted Methods: 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.	30.12.1	Verification of the validation of adopted methods: Verification is defined here as confirmation, through the assessment of existing objective evidence or through experiment, that a method is fit (or remains fit) for the specific purpose intended (i.e. the end-user requirements).	Added word "here" and removal of "process" and "device". Adds end user requirements as a specific purpose.	Minor	No	No

		30.12.2	Each of the steps of the validation process are to be completed (i.e. as detailed in 30.3.10), whether personnel are producing the objective evidence for relevance, reliability and completeness themselves or objectively reviewing data produced by others. External developers of methods or tools are encouraged to conduct their developmental validation exercises in a comparable manner to the requirements set out in this Code, as well as making the data available, which the forensic unit may use as part of this process.	Emphasis on manufacturers and vendors to conduct validation exercises in line with the Code and make data available to forensic units.	Major	No	No
21.2.38	Where the validation has not been conducted at the site 69 that will be using the method, the forensic unit must verify the scope of the validation with the study scaled up or down according to the adequacy and relevance of the available existing validation study.			Removed. Moved to Validation of methods 30.3.3.	Minor	No	No

21.2.39	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 forensic unit's staff with the techniques, equipment and facilities involved.	30.12.3	The end-user requirements and specification define the fitness of purpose the verification is intended to be against. If a specification is being adopted from elsewhere, this should be assessed for suitability against the end-user requirements and adapted if needed.	Emphasis is focused on end user requirements and specification rather than adequacy of existing validation data.	Minor	No	No
21.2.40	The forensic unit 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.			Removed. Points discussed in section 30.12.	Minor	No	No
21.2.41	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.	30.12.4	The assessment to identify likely risks, or potential risks, to the CJS related to the use of the method or amendment to the method should be included. 'If the method is to be deployed in a different manner than the study that provided the data, and the forensic unit intends to review the specification against that study, the differences require to be risk-assessed and may prompt a fuller validation study	Emphasis is focused on reviewing specification against the study and potentially further validation.	Minor	No	Yes

21.2.42	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.			Moved to section 30.12.7a-g	Minor	No	No
		30.12.5	Methods intended for incident scene use require validation (see UKAS RG 201 [40] and UKAS LAB 201 [44]), and where validation study was not conducted by the implementing forensic unit, the forensic unit shall verify the scope of the validation with the forensic unit's planned study, scaled up or down according to the adequacy and relevance of the available existing validation study for methods.	Previously section 21.2.2.	Minor	No	No
		30.12.6	For methods not validated for incident scene use as portable, or validated to be part of an agreed deployment (i.e. sections 108.3.13–108.3.15), validation with the new site or deployment is required. This is the case even if the validation study was performed by the same forensic unit but the validation was not conducted at the site that will be using the method.	Previously section 21.2.2.	Minor	No	Yes

		30.12.7a	The validation library (section 30.19) shall have, as a minimum, a summary of: a. the experimental work/review;	Expanded section from previous 21.2.42.	Minor	No	No
		30.12.7b	Results;		Minor	No	No
		30.12.7c	End-user requirements and specification used in the review;		Minor	No	No
		30.12.7d	The risk assessment;		Minor	No	No
		30.12.7e	Practitioner training/competence requirement;		Minor	No	No
		30.12.7f	Assessment plans; and		Minor	No	No
		30.12.7g	Statement of validation completion.		Minor	No	No

21.2.43	Minor Changes in Methods: Replacing like-for-like equipment 70 or minor changes to methods used by the forensic unit may not always require a full revalidation exercise. The impact of the change shall be risk assessed, verified against the original validation and authorised in line with other validation studies.	30.13.1	Minor changes in methods: Replacing like-for-like equipment or minor changes to a validated method in use by the forensic unit may not always require a full revalidation exercise. However, the impact of the change shall be risk assessed, verified against the original validation and authorised in line with other validation studies. Replacing the same make and model may still need some assessment, as minor modifications, including software and firmware, might affect the operation.	Further clarification on minor changes such as software and hardware updates.	Minor	No	No
21.2.44	A revalidation exercise should be carried out when changes are assessed to have the potential to influence the results obtained.	30.13.2	A revalidation exercise shall be carried out when changes are assessed to have the potential to influence the results obtained.	Unchanged		No	No
		30.14.1	Infrequently used methods: Infrequently used methods pose a challenge in maintaining competence and capability for any FSA. While the use of such methods is acceptable, there needs to be appropriate safeguards.	Expansion, highlights to the reader that infrequently used methods need to have appropriate safeguards.	Minor	Yes	Yes

		30.14.2	Methods used less than once in every three-month period across a forensic unit in separate cases are considered to be infrequently used.	New Change highlights the time period of an infrequently used technique. Once every three months.	Major	Yes	Yes
21.2.45	Infrequently Used Methods: Infrequently used methods may be maintained on the forensic unit's schedule of accreditation through regular use of mock casework, competence assessments and any other measures agreed with the accreditation body, or if not included on the schedule of accreditation re-verified in accordance with the requirements of these Codes prior to each use in casework. [42] If these activities are to become part of the routine activities of the forensic unit, accreditation should always be sought.			Moved to section 30.14.6	Minor	No	No
21.2.46	All methods the forensic unit intends using, including infrequently used methods, shall have been validated in line with these Codes and the forensic unit shall demonstrate competence to perform the method. The validation, verification or re-verification shall include the steps in	30.14.3	All methods used by the forensic unit, including infrequently used methods, shall have been validated in line with this Code and the forensic unit shall demonstrate competence to perform the method prior to implementation or use. The validation, verification, or re-verification shall include the steps in 30.3.10	Addition of "prior to implementation or use."	Minor	No	No

	21.2.5, and as with all methods, a validation library is required. 71		and, as with all methods, a validation library (section 30.19) is required.				
21.2.47a	Forensic units shall have a procedure to identify infrequently performed examinations/tests and their maintenance or use including:	30.14.4a	Forensic units shall have a procedure to identify infrequently performed methods and their maintenance or use, including the following:	Removal of "examination/tests" to "methods." Rewording and reorganisation of paragraph.	Minor	No	No
	a. How staff competence will be maintained or is demonstrated;		a. The definition of an infrequently performed method.				
21.2.47b	The definition of infrequently performed examinations/test;	30.14.4b	Responsibility for confirming the validation or verification remains appropriate.	Reorganisation of section and changed to wording with expansion on competency.	Minor	No	No
21.2.47c	Responsibility for the validation or verification;	30.14.4c	How competence will be maintained or is demonstrated, e.g.:	Reorganisation of section and changed to wording with expansion on competency.	Minor	No	No
			i. regular use of control samples even when casework samples are not being analysed; or				

			ii. re-verification before the examination/analysis in question is performed on a casework sample involving at least the use of an appropriate reference material, followed by replicate examination/testing of the real sample [4].				
21.2.47d	The sign-off procedure for use in the case including justification of method choice; and	30.14.4d	The sign-off procedure for use in casework including justification of method choice; and	added "work."	Minor	No	No
21.2.47e	How the status of the method will be reported in statements or reports.	30.14.4e	How the status of the method will be described in reports.	added "statement." Removal of "reported."	Minor	No	No
		30.14.5	The manner in which infrequently used methods are dealt with in relation to accreditation is considered in section 39.2.	Reference to another section	Minor	No	No

		30.14.6	If accredited, maintenance of infrequently used methods on a forensic unit's schedule of accreditation should include regular use of mock casework, competence assessments and any other measures agreed with the accreditation body. Forensic units should discuss with the accreditation body any specific requirements. For example, UKAS requires each aspect of the FSA included in the schedule of accreditation to be assessed at least once within the four-year accreditation cycle. UKAS detail their requirements in its policy on accreditation of infrequently performed conformity assessment activities [45].	Previously section 21.2.45. Expansion on having discussions with accreditation bodies regarding infrequently used techniques.	Minor	No	No

		30.14.7	If not included on the schedule of accreditation, then the methods shall be re-verified in accordance with the requirements of this Code prior to each use in casework (section 30.14.4 as well as ILAC-G19), unless the analyte and/or item/exhibit under test cannot be reproduced (e.g. a destructive chip-off procedure in digital forensics). In these rare events, the risks shall be assessed, documented and disclosed in the report. If these activities are to become part of the routine activities of the forensic unit (i.e. used more frequently than once every three months), and the FSA requires it, accreditation shall be sought.	Previously section 21.2.45. Infrequently used methods to be verified prior to each use unless a destructive technique. If used more than once in three months, accreditation is required.	Minor	No	No

21.2.48a	Validation Outcomes: 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 forensic unit for a similar period, but as a minimum shall be maintained for the functional life of the method and shall include:	30.15.1a	Validation outcomes: A summary of the outcome of the validation exercise shall be included in the validation report, which shall be retained for 30 years after the last use of the method (see section 11.2 of the National Police Chiefs' Council's (NPCC's) Guidance on Retention, Storage and Destruction of Materials and Records relating to Forensic Examination [29]). A full record of the validation exercise will usually be retained by the forensic unit for a similar period, but as a minimum shall be maintained for the functional life of the method and shall include:	Inclusion of NPCC National Police Chiefs' Council's (NPCC's) Guidance on Retention, Storage and Destruction of Materials and Records relating to Forensic Examination.	Minor	No	No
	The authorised validation plan and any subsequent changes to the plan, with justifications and authorisations for the changes;		a. The authorised validation plan and any subsequent changes to the plan, with justifications and authorisations for the changes;				
21.2.48b	All experimental results from the validation exercise;	30.15.1b	All critical experimental results from the validation exercise;	Inclusion of the word "critical."	Minor	No	No
21.2.48c	A detailed comparison of the experimental results with the specified requirements;	30.15.1c	Detailed comparison of the experimental results with the specified end user requirements and specification;	Inclusion of "end user requirements."	Minor	No	No

21.2.48d	Independent evaluation of the extent to which the results obtained conform or otherwise to the specified requirements;	30.15.1d	Independent evaluation of the extent to which the results obtained conform or otherwise to the specified requirements; and	Unchanged		No	No
21.2.48e	Any corrective actions identified; and			Removed	Minor	No	No
21.2.48f	Independent approval of the validation. 72	30.15.1e	Independent approval and sign off of the method as validated (independent evaluation (point d above), approval and sign off can be carried out by the same member of personnel if competent to do so).	Inclusion of sign off responsibilities.	Minor	No	No
21.2.49	Assessment of Acceptance Criteria Compliance: 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.	30.16.1	Assessment of acceptance criteria compliance: The independent evaluation of compliance of the experimental results with specified requirements shall be carried out by personnel not involved in the development of the method or conducting the validation process.	"Persons" changed to "personnel."	Minor	No	No

21.2.50	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. 73	30.16.2	The personnel shall have demonstrated they have sufficient knowledge of the issues involved to be able to identify and assess the significance of any deficiencies. The personnel may be employed by the forensic unit, contracted by the forensic unit to carry out the evaluation, or be wholly independent of the forensic unit. If employed by the forensic unit, the evaluator/authoriser would need to be able to demonstrate the appropriate level of independence.	Expansion of who can be an evaluator/authoriser. "Persons" changed to "personnel."	Minor	No	Yes
21.2.51a	The independent authorisation shall typically establish whether: The validation work is adequate and has fully demonstrated compliance of the method with the acceptance criteria for the agreed specification; and	30.16.3	The independent authorisation shall typically establish whether the validation work is adequate and has fully demonstrated compliance of the method with the acceptance criteria for the agreed specification and end-user requirements.	Inclusion of end user requirements.	Minor	No	No
21.2.51b	The method is fit for its intended use.			Removed from this section.	Minor	No	No
21.2.52	Should the forensic unit plan to implement methods rated as high risk and/or likely to attract challenge once implemented, the Regulator should be consulted as to the need for any wider review and/or publication prior to implementation.	30.16.4	For any major breakthroughs or novel uses of existing science, it would be useful to inform the Regulator, who may advise on the most expedient method of ensuring that the CJS requirements are understood.	Previously footnote 62. Encouragement to contact the Regulator pre validation rather than post validation	Minor	No	No

21.2.53	Validation Report: The forensic unit 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.	30.17.1	Validation report: The forensic unit 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 conforms to the specification and is fit for the purpose stated in the end-user requirements. The report 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.	Inclusion of end user requirements and removal of the words "product or service."	Minor	No	No
21.2.54a	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:	30.17.2a	The content of the validation report will depend on the type of validation carried out, but as a general guide it should include or reference to, as appropriate:	Changed to "shall" to "will."	Major	No	No
	A title and unique identifier;		a. a title and unique identifier;				
21.2.54b	A description of the purpose of the method, product or service;			Removed	Minor	No	No
21.2.54c	The specification;	30.17.2b	The end-user requirements and the specification;	Includes "end user requirements."	Minor	No	No
21.2.54d	The name, version number and manufacturer of any equipment used;	30.17.2c	The name, version number and manufacturer of any equipment used;	Unchanged		No	No
21.2.54e	The name(s) and signature(s) of the person(s) accountable for the development of the validation processes;	30.17.2d	The name(s) and signature(s) of personnel appointed by the SAI for the development of the validation processes;	"Person(s)" changed to "personnel." SAI to appoint personnel for validation	Minor	No	No

21.2.54f	The validation plan;	30.17.2e	The final validation plan;	Includes "final."		No	No
21.2.54g	The risk assessment;	30.17.2f	The risk assessment;	Unchanged		No	No
21.2.54h	Any authorised changes to the validation plan and justifications for the changes;			Removed see 30.17.2 e	Minor	No	No
21.2.54i	A summary of the experimental work and outcomes in sufficient detail to ensure that the tests could be independently replicated by a competent person;	30.17.2g	A summary of the experimental work and outcomes in sufficient detail to ensure that the tests could be independently replicated by competent personnel;	Competent "person" changed to "competent personnel."	Minor	No	No
21.2.54j	Details of any review reports produced;	30.17.2h	Details of any review reports produced;	Unchanged		No	No
21.2.54k	Conformity with the acceptance criteria (expected compared with actual results and any pass/fail criteria);	30.17.2i	Conformity with the acceptance criteria (expected compared with actual results and any pass/fail criteria);	Unchanged		No	No
21.2.54l	Any limitations/constraints applicable;	30.17.2j	Any limitations/constraints applicable;	Unchanged		No	No
21.2.54m	Any related published papers and similar methods in use by the forensic unit;	30.17.2k	Any related published papers and similar methods in use by the forensic unit;	Unchanged		No	No
21.2.54n	Any recommendations relating to the implementation of the method, product or service; and	30.17.2l	Any recommendations relating to the implementation of the method, product or service; and	Unchanged		No	No
21.2.54o	The date of the report.	30.17.2m	The date of the report.	Unchanged		No	No

21.2.55	The forensic unit 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.	30.17.3	The forensic unit shall submit the validation report for review by personnel who are suitably qualified and independent of the validation process; any issues arising should be dealt with expeditiously.	"Persons" changed to "personnel."	Minor	No	No
21.2.56	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 records, which will normally be kept for 30 years following its last use in casework. 75	30.17.4	All the required records relating to the development and validation of the method shall be archived, together with the means of accessing the records, and will be kept for a period in line with the forensic unit's retention policy for such documents. The period of retention is to comply, or assist the commissioning party to comply, with the Criminal Procedure and Investigations Act 1996 [24]. Guidance on retention periods is issued by the National Police Chiefs' Council [24] [29]	Removal of 30 year retention from the Code but redirects reader to consult CPIA and NPCC guidelines.	Major	No	Yes

21.2.57	A statement of Validation Completion: 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. 76	30.18.1	Statement of validation completion: The forensic unit shall prepare a 'statement of validation completion' on the successful completion of a validation exercise. The aim of the statement of validation completion is to provide a short executive summary of the validation steps performed and key issues identified in the validation, including strengths, weaknesses, and limitations. The intention is that the statement will be no more than two sides of A4 paper in plain language.	Further clarity on what needs to be included in the statement of validation completion, including strengths, weaknesses, and limitations.	Minor	No	No
21.2.58	The approval by the forensic unit on the scope of the validation must be clear.	30.18.2	The SAI may delegate authority for approving and signing off the method as validated or perform the function themselves. Either way, the scope of the validation being signed off as approved must be clear.	New details on the role of SAI and sign off options.	Minor	No	Yes
21.2.59a	The forensic unit should provide any further information that would be useful to the CJS. Examples would include, but not be limited to:	30.18.3a	The forensic unit should provide any further information that would be useful to the CJS. Examples would include, but not be limited to:	Unchanged		No	No
	Caveats about the use of the method;		a. caveats about the use of the method;				
21.2.59b	The approved uses of the method, which could be by case type or exhibit type;	30.18.3b	The approved uses of the method, which could be by case type or item/exhibit type;	Includes the word "item."	Minor	No	No

21.2.59c	Circumstances in which the use of the method would be inadvisable; and	30.18.3c	Circumstances in which the use of the method would be inadvisable; and	Unchanged		No	No
21.2.59d	Additional work that should be undertaken in combination with the result.	30.18.3d	Additional work that should be undertaken in combination with the result.	Unchanged		No	No
21.2.60a	Validation Library: The forensic unit 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 not be limited to:	30.19.1a	Validation library: The forensic unit 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 not be limited to:	Rephrased, pointed to section 30.5.1.	Minor	No	No
	The specification for the method approved (see earlier sub-section Determining the specification);		a. The specification for the method approved (section 30.5.1);				

21.2.60b	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; 77	30.19.1b	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 [46]. (The literature review also ensures the body of knowledge requirement as outlined in R v Bonython [1984] can be demonstrated as well as supporting the application of direction 19A.5d of the Criminal Practice Directions V [34]);	Previously footnote number 77, now part of body of the Code. Inclusion of literature review of relevant material.	Minor	No	No
21.2.60c	The risk assessment for the method approved;	30.19.1c	The risk assessment for the method approved;	Unchanged		No	No
21.2.60d	The validation plan for the method approved;	30.19.1d	The validation plan for the method approved;	Unchanged		No	No
21.2.60e	The validation report;	30.19.1e	The validation report;	Unchanged		No	No
21.2.60f	The record of approval; and	30.19.1f	The record of approval; and	Unchanged		No	No
21.2.60g	The statement of validation completion.	30.19.1g	The statement of validation completion.	Unchanged		No	No
21.2.61	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.	30.19.2	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.	Unchanged		No	No

21.2.62	Where the method relies on reference collections or databases, the nature, access and their availability should be described.	30.19.3	Where the method relies on reference collections or databases, the nature, access, and their availability should be described.	Unchanged		No	No
21.2.63	The information in the library shall be disclosable 78 and should be prepared with that requirement in mind.	30.19.4	The information in the library may be disclosable in criminal proceedings and should be prepared with that possibility in mind. 'Commercial-in-confidence' does not override disclosure requirements, including those of the Criminal Procedure and Investigations Act 1996 [24], and a refusal to disclose may prevent methods being used.	Previously footnote 78 in Codes. Validation library could be disclosed in "criminal proceedings" and should be prepare with that possibility in mind.	Minor	No	No
21.2.64a	Implementation Plan and Any Constraints: The forensic unit shall have a plan for implementation of methods, products or services new to the forensic unit. This plan shall address, where relevant: Whether 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;	30.20.1a	Implementation plan and any constraints: The forensic unit shall have a plan for implementation of methods new to the forensic unit. Where relevant, this plan shall address: a. whether the new method can provide new analytical opportunities relevant to revisiting old cases. If so, the forensic unit should determine if any action is warranted, such as communicating the benefits and risks to previous commissioning parties (this may be a general communication on the new capability);	Paragraph rephrased, replacement of the term "customer" to "commissioning parties," removal of "product or services."	Minor	No	No

21.2.64b	The standard operating procedure (including the process for assessment/interpretation/reporting of results) or instructions for use;	30.20.1b	The standard operating procedure (including the process for assessment/interpretation/reporting of results) or instructions for use;	Unchanged		No	No
21.2.64c	Requirements for staff training, competence assessment and on-going monitoring of staff competence;	30.20.1c	Requirements for practitioner training, competence assessment, and ongoing monitoring of practitioner competence;	Removed term "staff" and replaced with "practitioner."	Minor	No	No
21.2.64d	Integration of the method with what is already in place;	30.20.1d	Integration of the method with what is already in place;	Unchanged		No	No
21.2.64e	If the method is intended to be included in the scope of accreditation and what steps are required;	30.20.1e	The steps required to include the method in the scope of accreditation (if needed);	Rephased	Minor	No	No
21.2.64f	The monitoring mechanisms to be used to demonstrate that the method remains under satisfactory control during its use;	30.20.1f	The monitoring mechanisms to be used to demonstrate that the method remains under satisfactory control during its use. The forensic unit will also assist with any post-implementation review, including: i. managing planned increases in volume (i.e. any ramp up from validation studies levels), whether through a phased approach or piloting of the validated method using casework; ii. controlling changes in workflow.	Additional clarification on how to manage validation post implementation and changes.	Major	No	No

21.2.64g	The protocols for calibration, monitoring and maintenance of any equipment;	30.20.1g	The protocols for calibration, monitoring, and maintenance of any equipment;	Unchanged		No	No
21.2.64h	The supply and traceability of any standards/reference materials;	30.20.1h	The supply and traceability of any standards/reference materials;	Unchanged		No	No
21.2.64i	The supply and quality control of key materials, consumables and reagents;	30.20.1i	The supply and quality control of key materials, consumables, and reagents;	Unchanged		No	No
21.2.64j	The exhibit handling and any anti-contamination protocols;	30.20.1j	The item/exhibit handling and any anti-contamination protocols;	Addition of the word "item."	Minor	No	No
21.2.64k	The accommodation plan;	30.20.1k	The accommodation plan;	Unchanged		No	No
21.2.64l	Any special health and safety, environmental protection, data protection and information security arrangements;	30.20.1l	Any specific health and safety, environmental protection, data protection, and information security arrangements;	Unchanged		No	No
21.2.64m	The communication plan; and	30.20.1m	The communication plan; and	Unchanged		No	No
21.2.64n	The schedule for post-implementation review.	30.20.1n	The schedule for post-implementation review.	Unchanged		No	No
22. Estimation of Uncertainty							
		31.1.1	A forensic unit performing testing is required to evaluate measurement uncertainty.	Clarification on section relevance	Minor	No	No

22.1.1	Guidance on the estimation of uncertainty of measurement is contained in Appendix N of the UKAS M 3003 publication 'The Expression of Uncertainty and Confidence in Measurement'.			Moved to section 31.1.6	Minor	No	No
22.1.2	A forensic unit performing testing 79 is required to evaluate measurement uncertainty, even where the test method precludes rigorous evaluation of measurement such as a test that is qualitative in nature. UKAS M 3003 states "there will be uncertainties associated with the underlying test conditions and these should be subject to the same type of evaluation as is required for quantitative test results". [43]	31.1.2	The forensic unit may undertake testing as part of incident scene investigation. ILAC G19 includes, but does not limit such testing to, quantitative measurements and presumptive or screening tests [4]. FSAs that involve testing are expected to meet the relevant requirements of ISO/IEC 17025; this includes, but is not limited to, estimation of uncertainty of measurement (see also ILAC G27 [47]).	Expansion for scene examination considerations, screening and presumptive tests. References to ILAC G19 and G27.	Minor	No	No

		31.1.3	Qualitative testing may be for the presence or absence of a defined analyte but there will be uncertainty associated with the underlying test conditions. Where the test method precludes rigorous evaluation of measurement, such as a test that is qualitative in nature, UKAS M3003 [48] states, "there will be uncertainties associated with the underlying test conditions and these should be subject to the same type of evaluation as is required for quantitative test results". ILAC G17 [49] indicates that with qualitative testing or examinations, an estimation of the probability for false positive or false negative test results may be relevant. A method of evaluating contributions to uncertainty may include the method used for risk assessment during the validation of the method (section 30.6.2).	Expansion. Content previously covered by a footnote 66.	Minor	No	No
22.1.3	The impact uncertainty may have on the findings shall be included in both factual and evaluative reports to the CJS where it is relevant.	31.1.4	The impact that uncertainty may have on the findings shall be included in both factual and evaluative reports to the commissioning party where it is relevant.	Unchanged		No	No

22.1.4	When a procedure is modified, in addition to any validation or verification, forensic units should also review the measurement uncertainty.	31.1.5	When a procedure is modified, in addition to any validation or verification, forensic units should also review the measurement uncertainty.	Unchanged		No	No
		31.1.6	Guidance on the estimation of uncertainty of measurement is contained in Appendix N of the UKAS M3003 publication The Expression of Uncertainty and Confidence in Measurement [48] and EURACHEM's guide Quantifying Uncertainty in Analytical Measurement [50].	Previously section 22.1.1. Now includes EURACHEM's guide.	Minor	No	No
22.1.5	The Criminal Practice Directions V (19A.5c) that supplements Part 19 of the Criminal Procedure Rules include several factors which ought to be considered. However, the following direction that the court may take into account in accessing admissibility is particularly relevant:	31.1.7	The Criminal Practice Directions V (19A.5) [34], which supplements Part 19 of the Criminal Procedure Rules [35], include several factors which should be considered in determining the reliability of expert opinion, and especially of expert scientific opinion. However, the following factor that the court may take into account in determining admissibility is particularly	Expansion on the reliability of experts' opinion especially when they are referring to results from a method.	Minor	No	No

	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."		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."				