

Document Number ASB STD 040

Document Title: Standard for Forensic DNA Interpretation and Comparison Protocols

Note: a specific Proposed Resolution must accompany each comment or it cannot be considered.

#	Section	Type of Comment (E-)	Comments	Proposed Resolution	Final Resolution
85	Question		E.why do we use the term 'DNA data' rather than 'DNA profile(s)' Is this term used to encompass STR and Mt DNA?	No proposed resolution provided.	Yes - the term "DNA data" is meant to be a term that captures all types of DNA data generated (and not have this document be specific only to autosomal STRs).
1	general	E	In ASB 18 and 20, the ASB committee members responsible for drafting the standard were listed. Additionally, members of the OSAC that reviewed the standard were also listed. We understand that ASB is a completely separate entity independent of the OSAC and is not subject to any of its rules. However, it would be beneficial to know that members of ASB and OSAC are working together to make standards that can be accepted by ASB, ANSI, and the OSAC. In the interests of following a standard process and transparency, can the individuals involved in drafting the standard and reviewing the standard be added to the draft documents?	Add the names of member of the ASB and OSAC working groups responsible for drafting and reviewing the standard. If the names cannot be revealed, provide a statement that informs the reader that ASB and OSAC committee members were involved in drafting and reviewing the standard.	Reject. The acknowledgements section is no longer included per the ASB Manual for Standards, Best Practice Recommendations and Technical Reports, updated 2018. The list of current OSAC committee members is available on the OSAC website.
10	1	E	In the sentence beginning "The protocol should encompass all variables...", use of the word "should" makes the statement a recommendation, whereas the intent of the document is to establish a set of standards.	replace "should" with "shall"	Reject. This statement is in the Scope. The specific "shall" requirements are in section 4.
2	1	E	The way that this standard is titled and written it seems that there is a limited view of the various types of interpretations and comparisons and that can be made in a forensic DNA laboratory as well its needs for protocols. Various laboratories throughout the country perform Y-STR, mitochondrial DNA, and paternity testing analyses that require interpretation and comparison protocols. However, SWGDAM guidelines on Y-STR and mitochondrial DNA analysis and references on paternity testing are omitted from section 4.1 of Annex B as well as the bibliography of the document. The requirements for interpreting and comparing Y-STRs and mitochondrial DNA are vastly different than that of standard autosomal STRs. The types of interpretations and comparison covered by the standard need to be clearly conveyed.	The specific types of DNA interpretations and comparisons that are covered by the standard need to be stated in the scope of the document. References for Y-STR and mitochondrial DNA testing should be added to Annex B and the bibliography. If these types of testing are not covered by this standard, there should be a notation that there are standards that will cover these other testing methods. The title of the standard could be changed to "Standard for Forensic Evidentiary DNA Interpretation and Comparison Protocols" if paternity testing is not covered by the standard.	Accept in part. This document applies to any type of DNA testing technology and methodology used, including but not limited to, STR testing, DNA sequencing, SNP testing, haplotype testing, traditional and rapid protocols, etc., where mixtures of DNA may be encountered, analyzed interpreted and compared. The Bibliography was edited to include a link to all publications on the SWGDAM website. A paragraph has also been added to Annex A to clarify this. Nothing precludes this standard from being used for biological relationship testing in a forensic (or other) laboratory, where appropriate.
72	3	E	I think that all headings in the entire document should start with a capital letter	I think that all headings in the entire document should start with a capital letter	Reject. The header formatting is in accordance with the ASB Manual for Standards, Best Practice Recommendations and Technical Reports, updated 2018.

3	3	E	<p>ASB 40 is the first ASB standard where the term case record is mentioned. The term case record should be defined in the standard.</p>	<p>Provide a definition for a case record and detail what should be included in the case record. The National Commission on Forensic Science made recommendations to the Attorney General on the documentation, case records, and report contents (See Recommendation on Documentation, Case Record and Report Contents, Adopted at NCFS Meeting #11 - September 13, 2016). These recommendations note the need to include standard operating procedures and definitions in a report, case record, or through an easily accessible source. Additional recommendations pertaining to the record included:</p> <ul style="list-style-type: none"> • "Records should be created contemporaneously with the examination of evidence and undergo a technical review which, along with the FSSPs' quality management system documents relating to the forensic work performed, would allow another analyst or scientist, with proper training and experience, to understand and evaluate all the work performed and independently analyze and interpret the data and draw conclusions." <p>and</p> <ul style="list-style-type: none"> • "The case record should be organized and made available in a manner consistent with the National Commission on Forensic Science discovery recommendations." <p>The full recommendation document (Recommendation on Documentation, Case Record and Report Contents) can be found at https://www.justice.gov/archives/ncfs/work-products-adopted-commission</p>	<p>Reject. This standard addresses specific requirements for the laboratory interpretation and comparison protocol. For this document, the laboratory's definition of the case record applies.</p>
74	3.1	E	<p>Should <i>'The process of examining two or more DNA data sets to assess the degree of similarity or difference.'</i> have the term <i>'between them'</i> after <i>'difference'</i>?</p>	<p>Consider the following change in this section: <i>The process of examining two or more DNA data sets to assess the degree of similarity or difference.</i> ' have the term <i>'between them'</i> after <i>'difference'</i>?</p>	<p>Reject. "Between them" seems to be implied in the definition. Furthermore, the word "between" may suggest the limitation to only two data sets when more than two may be compared in some situations.</p>

4	3.3	E	<p>Can the authors provide clarity as to why the definition of internal validation in ASB 40 is different than those given in ASB 18 and ASB 20? Below are the three definitions of internal validation in ASB 18, 20, and 40 with the differences in noted in red.</p> <p>ASB 40 definition of internal validation: "In general, the accumulation of test data within the laboratory for developing the laboratory standard operating procedures and demonstrating that the established protocols for the technical steps of the test and for data interpretation perform as expected in the laboratory. 2) In the context of probabilistic genotyping, the accumulation of test data within the laboratory to demonstrate that established parameters, software settings, formulae, algorithms and mathematical functions perform as expected; and that the information/results/data obtained is correct and consistent with expected values."</p> <p>ASB 18 definition of internal validation: "The accumulation and evaluation of test data within the laboratory for developing the laboratory standard operating procedures and demonstrating that the established protocols for the technical steps of the test and for data interpretation perform as expected in the laboratory. The parameters (e.g., any variable that impacts interpretation) included in a test protocol used by the laboratory should be supported by validation studies conducted with samples of known origin similar to the types of samples routinely accepted and tested by the laboratory."</p> <p>ASB 20 definition of internal validation: "The acquisition of test data to verify the functionality of the system, the accuracy of statistical parameters, the appropriateness of analytical and statistical parameters, and the determination of limitations of the system."</p> <p>The lack of uniformity of terminology is a known problem across forensic science disciplines that the community has tried to address. A term should have a single definition unless there is contextual information or a difference in the application that supports having a second definition, as seen with the differences in ASB 18 and 20. ASB should also consider, as part of its mission, the importance</p>	<p>The definition of internal validation in ASB 40 should include the missing red sections from ASB 18 and ASB 20 unless the definitions in ASB 18 and 20 are going to be changed. Another option is to not define internal validation in the ASB 40 standard since the term is defined in two other locations that are supposed to be used in conjunction with this standard.</p>	<p>Reject. The definition in this standard is the current definition in the OSAC lexicon.</p>
75	3.5	E	<p>after individual, should we also have or individuals'?</p>	<p>consider the addition of adding 'Or individuals' after individual?</p>	<p>Reject. The term "reference data" as used in this document is referring to the DNA data obtained from a single individual (e.g., being used in a comparison to evidentiary data)</p>
76	3.7	E	<p>Change title to 'Un-interpretable DNA profiles (or data)'</p>	<p>Consider changing to 'Un-interpretable DNA profiles (or data)'</p>	<p>Reject. The word "uninterpretable" was removed.</p>
11	4	E	<p>Section 4 is a poorly organized assemblage of policy requirements, protocol requirements, and documentation requirements. The section does not make use of subsection headings as described in ASB Guide 001, which would improve the clarity of the section.</p>	<p>Subdivide Section 4 into the following subsections: 4.1 General Requirements, 4.2 Data Interpretation Requirements, and 4.3 Profile Comparison Requirements. Group the individual standards appropriately.</p>	<p>Reject. Headers are not required to comply with the ASB Style Guide.</p>
77	4.1	E	<p>Section 4.1Is is a bit wordy and a may cause some confusion' g</p>	<p>Consider changing the current wording to '4.1 Laboratory interpretation shall be based on internal validation studies which may be supplemented with peer reviewed, published scientific literature or other appropriate scientific resources.' be more appropriate?</p>	<p>Reject. The additional wording in the requirement as stated provides some critical specificity that may be lost if deleted.</p>

6	4.1	E	The use of the word "may" in the sentence "...supported by internal validation studies and may be supplemented with published scientific literature or other appropriate scientific resources, where available," can be rephrased to avoid any possibility for misinterpretation.	We suggest the following change to the paragraph: "The laboratory interpretation protocols and comparison protocols, including criteria for drawing conclusions from comparisons between evidentiary data and reference (or other evidentiary) data, shall be based on, developed from, and supported by internal validation studies. Published scientific literature or other appropriate scientific resources, where available, may supplement internal validation studies but cannot be used as a replacement for conducting such studies."	Accept in part. Broke into two sentences with the second being a note reading "Published scientific literature or other appropriate scientific resources, where available, may supplement internal validation studies. "
54	4.1	E	I think that this is a bit wordy and a bit confusing; would saying '4.1 Laboratory interpretation shall be based on internal validation studies which may be supplemented with peer reviewed, published scientific literature or other appropriate scientific resources.' be more appropriate?		No proposed resolution provided, but other comments on section 4.1 did result in clarification.
12	4.2	E	The statement should end with a colon.	End the statement with a colon.	Reject. The punctuation is in accordance with the ASB Manual for Standards, Best Practice Recommendations and Technical Reports, updated 2018.
78	4.2.1	E	I would replace 'Establish criteria upon which DNA data should be reported as originating from a sources' (sic). And delete 'single source versus multiple'	Consider replacing the current wording to 'Establish criteria upon which DNA data should be reported as originating from a sources (sic). delete "a" before 'sources' B4single source versus multiple'	Accept in part. Sentence changed to "Criteria for assessing the DNA data should be interpreted as originating from a single source or multiple sources."
79	4.2.1	E	Why not say ' Establish criteria upon which DNA data should be interpreted as originating from single or multiple sources'.? instead of the current section	change to ' Establish criteria upon which DNA data should be interpreted as originating from single or multiple sources'.? which, to me, reads more clearly	Accept in part. Sentence changed to "Criteria for assessing the DNA data should be interpreted as originating from a single source or multiple sources."
13	4.2.1	E	The structure of the statement is unnecessarily complex, and does not follow the structure of other statements in the list.	Replace with: "The interpretation of DNA data as having originated from a single individual versus multiple individuals."	Reject. Modifications made to Section 4.2.1 based on comment #79
80	4.2.2	E	This is a confusing statement.'When attempting to decide the number of possible contributors to a DNA profile, all alleles that above threshold levels are assumed to be contributors to th'e DNA extracted from a particular sample.	Could we simply say 'Establish criteria upon which DNA profiles are assessed as originating from single or multiple sources'?	Reject. Modifications made based to Sectionn 4.2.2 on comment #14
14	4.2.2	E	The structure of the statement is unnecessarily complex, and does not follow the structure of other statements in the list.	Replace with: "The assumptions that may be used in data interpretation, including..."	Accepted in part. Sentence changed to "Criteria upon which assumptions may be made and the types of assumptions that may be used in data interpretation, including but not limited to the number of contributors and the presence of assumed contributors."
63	4.2.4	E	for consistency, list examples in the same manner as they are listed in the prior section, 4.2.3	Delete parentheses and e.g., replace with ", such as..."	Accept.
81	4.2.4	E	We need to preface this statement with something like Establish the limitations ...and the presence of stutter. ' As it stands it doesn't have any 'action' word, it is simple a statment without any meaning	We need to preface this statement with something like Establish the limitations ...and the presence of stutter. ' As it stands it doesn't have any 'action' word, it is simple a statment without any meaning	Reject. Modifications made based on comment #63.
82	4.2.5	E	same comment as above I think we need 'Establish' (or some other related term) at the start of the section for it make sense.	same comment as above I think we need 'Establish' (or some other related term) at the start of the section for it make sense.	Accept in part. Wording was modified to match changes made to 4.2.1, 4.2.2, and 4.2.3.
15	4.2.5	E	The structure of the statement is unnecessarily complex, and does not follow the structure of other statements in the list. Also, this statement blends two distinct processes - the interpretation of electropherogram data, and the comparison of DNA profiles. These requirements are handled separately in the standard, and need to be handled separately here.	Split into two statements. Statement 1: "The requirements for instrumental data to be considered suitable/unsuitable for interpretation." Statement 2: "The requirements for sample profiles to be considered suitable/unsuitable for comparison purposes."	Accept in part. Section 4.2.5 was split into two and a new section 4.2.6 was added.

7	4.3	E	The standard as written, offers only one protection (standard 4.3) against cognitive bias in the evaluation of DNA evidence and readers may infer that knowing reference data information prior to interpretation is the sole source of bias that can influence an interpretation.	Section 4.3 should state that lab protocols be written to protect against cognitive bias. These protocols should include when and what information should and should not be used during interpretation of evidentiary data.	Reject. No proposed resolution to text provided. Requirement 4.2.2 specifies that the laboratory defines what assumptions can be made.
16	4.3	E	4.3 creates a policy requirement. It is inappropriately grouped with technical requirements.	Put 4.3 at the top of Section 4, in a subsection related to general policy requirements.	Reject. As stated in Annex B, the requirements are listed in order reflecting the routine, linear steps of data interpretation and comparison. Section 4.3 states a specific policy requirement that occurs during interpretation and prior to comparison. The policy may be defined in the laboratory protocol but may also be addressed by another appropriate mechanism (e.g., documentation of the interpretation of the evidence data in the case record prior to any comparison to reference data).
17	4.3.2	E	4.3.2 creates a policy requirement. It is inappropriately grouped with technical requirements.	Put 4.3.2 at the top of Section 4, in a subsection related to general policy requirements.	Reject. The policy may be defined in the laboratory protocol but may also be addressed by another appropriate mechanism (e.g., documentation of the interpretation of the evidence data in the case record prior to any comparison to reference data).
83	4.3.3	E	I think that 'along' is colloquial and a comma is needed in this section	I think that 'along' should be replaced with 'together with', also need a comma after the '...case record'	Accept in part. Section 4.3 was edited to include the documentation of all assumptions use.
84	4.4	E	I think that this section o has colloquialisms	I think that the term 'follow' should be replaced with the term "adhere to" and the term 'drawing' should be replaced by 'together with...contributor. The current terms used in 4.3.3 and 4.4 are colloquialisms	Reject. "Follow" and "adhere to" have the same meaning in forensic DNA testing. The second suggestion is unclear. There is no prohibition to using colloquialisms in standards from the OSAC or ASB.
41	4.4.2	E	Suggest add commas	All re-evaluations of, and changes to, the original evidentiary data interpretation shall be thoroughly documented within the case record.	Accept
8	4.4.2	E	Can the authors provide clarity on what is meant by a "re-evaluation of evidentiary data,"? Is this language meant to cover the technical review of data, or is this meant to address possible changes to evidentiary data in response to an incomplete or improper interpretation?	If the standard is meant to include the technical review of data, protocols should state that the re-evaluation of data should be conducted as blindly as possible. Any manual calculations or notes taken during the interpretation and comparison phase shall be kept in the case record. Lastly, there should be a protocol in place in the event of discrepant interpretations by multiple analysts which documents how the discrepancies are resolved.	Accept in part. In section 4.4.2, the second sentence was moved to the beginning to clarify. Annex B Section 4.4.2, the last sentence was edited to clarify
32	Annex B	E	This annex has additional information for Section 4.4.1.2, which does not exist in the document. I believe it should point to Section 4.4.1		Accept. The typographical error has been corrected.
47	Annex B	E	Suggest add commas	The analysis and interpretation of the new evidentiary data shall occur prior to, and be independent of, comparison to the previously generated reference data.	Reject. No longer necessary because this sentence was previously revised.
48	Annex B	E	"Section 4.4.1.2 – The ambiguity of whether reference data ..." Section 4.4.1.2 does not exist within the document. Maybe this is meant to reference Section 4.4.1?	Fix Annex B to properly reference the correct Section in the body of the document.	Accept.
64	Annex B	E	The next to last paragraph refers to section 4.4.1.2, which does not exist.	I think the correct reference should be 4.4.1	Accept.
65	Annex B	E	In the last paragraph, there should be no hyphen between sperm and fraction, just as there is no hyphen between non-sperm and fraction. Both of these terms are in the parentheses in the first sentence.	delete hyphen	Accept.

19	Annex B, Section 4.1	E	This section refers to documents that are not listed in the bibliography.	Make sure the bibliography is complete.	Accept. The two standards have been added to the Bibliography. The standards were under review at the time this document was submitted and were not included in the Bibliography initially for that reason.
20	Annex B, Section 4.3.2	E	The opening sentence beginning "When making this determination, the ..." is simply a restatement of the standard using different words, and is unnecessary.	Delete the sentence beginning "When making this determination, the ..."	Reject. This seems to be for 4.3.1.2. The statement has been retained to provide clarity and completeness to the paragraph.
21	Annex B, Section 4.3.2	E	The sentence beginning "The analysis and interpretation of ..." is an inexact restatement of the standard using different words. It is unnecessary.	Delete the sentence beginning "The analysis and interpretation of ..."	Reject. The statement has been retained to provide clarity and completeness to the paragraph.
22	Annex B, Section 4.3.2	E	Section 4.3.2 uses the phrase "shall occur independently of comparison to the previously generated reference data." A discussion of "independence" in this context would be helpful, both to provide guidance to laboratories, and to provide guidance to auditors. Complete, perfect independence would require that the supplemental testing be done by a second analyst who has no knowledge of the original work. This would be a difficult threshold for many casework laboratories to meet. Short of perfect independence, what would qualify as an acceptable degree of independence?	Provide guidance regarding what approaches would satisfy the standard of independence.	Accept in part. The word "independent" was removed from the standard 4.3.2 and the corresponding change was made to Annex B Section 4.3.2
23	Annex B, Section 4.4.1.2	E	There is no section 4.4.1.2 in the standard. This section of Annex B appears to refer to 4.4.1	Correct "4.4.1.2" to "4.4.1"	Accept. The typographical error has been corrected.
24	Annex B, Section 4.4.1.2	E	The sentence beginning "When making this determination, the ..." is an inexact restatement of the standard using different words. It is unnecessary.	Omit the sentence beginning "When making this determination, the ..."	Reject. The statement has been retained to provide clarity and completeness to the paragraph.
25	Annex B, Section 4.4.2	E	The sentence beginning "Any re-interpretation of evidentiary data..." is an inexact restatement of the standard using different words. It is unnecessary	Omit the sentence beginning "Any re-interpretation of evidentiary data..."	Reject. The statement has been retained to provide clarity and completeness to the paragraph.
50	3.1	E/t	To clarify does 'data sets' refer to profiles and MT dna; if so should data sets be replaced with 'DNA profiles'?		No proposed resolution provided. But comment 73 was the same comment with the following resolution: Reject. "Data sets" was purposefully used rather than "DNA profiles" to encompass all types of DNA data resulting from testing in a forensic laboratory.
73	3.1	E/t	To clarify does 'data sets' refer to STR profiles and MT dna; if so should data sets be replaced with 'DNA profiles'? rather than data sets???	Clarification required	Reject. "Data sets" was purposefully used rather than "DNA profiles" to encompass all types of DNA data resulting from testing in a forensic laboratory.

5	3.3	T/E	Can the authors provide clarity on what is meant by "perform as expected in the laboratory"? The purpose of an internal validation is to determine the appropriate parameters and limitations of a system or technical steps of a test. The definition as it stands can be interpreted as the hypothesis of how a procedure should work will determine how a procedure is done, rather than the data determining what the optimal conditions are in order for the procedure to work irrespective of the original hypothesis.	The definition of internal validation should be similar in all documents where it is defined. The ideas of appropriateness and the determination of limitations are themes that should be found in any and all definitions of the term.	Reject. The definition in this standard is the current definition in the OSAC lexicon.
33	1	T	" The protocol should encompass all variables permitted in the technical protocols ..." While an admirable goal, and the use of 'should' is not to the level of 'must', this is a virtual impossibility. There are simply too many variables to include all possibilities into a protocol. There remains a certain amount of 'professional judgement', whether we like it or not, that comes into play during interpretations. SWGDM's statement: "Due to the multiplicity of forensic sample types and the potential complexity of DNA typing results, it is impractical and infeasible to cover every aspect of DNA interpretation by a preset rule. However, the laboratory should utilize written procedures for interpretation of analytical results with the understanding that specificity in the standard operating protocols will enable greater consistency and accuracy among analysts within a laboratory."	The protocol should encompass sufficient variables permitted in the technical protocols that may have an impact on the data generated and the variety and range of test data anticipated in casework based on the types of samples routinely accepted and tested in the laboratory to minimize differences in interpretations between analysts. OR The protocol should encompass sufficient variables permitted in the technical protocols that may have an impact on the data generated and the variety and range of test data anticipated in casework based on the types of samples routinely accepted and tested in the laboratory to enable greater consistency and accuracy among analysts within a laboratory.	Reject. This statement is in the Scope which is not part of the audit process. The intent of the statement is to ensure that all variables and testing parameters permitted in the laboratory practices and internally validated are also addressed in the interpretation protocol. Please see Standard 20, Standard for Validation Studies of DNA Mixtures and the Development and Verification of a Laboratory's Mixture Interpretation Protocol.
34	3.6	T	Does "elevated stutter peaks" need to be explained? "Allele drop out", "locus drop out", and "allele drop in" all have nice short explanations.	4) elevated stutter peaks (a non-allelic peak in the stutter position exceeding the laboratory's stutter expectation for a given locus).	Accept in part. Added (a non-allelic peak in the stutter position exceeding the stutter expectation of the laboratory).
35	3.7	T	"uninterpretable" is not the same as "unsuitable for comparison". As per this document, "interpretation" is defined as: The process of evaluating DNA data for purposes including, but not limited to, defining assumptions related to mixtures and single source profiles, distinguishing between alleles and artifacts, assessing the possibility of degradation, inhibition, and stochastic effects, and determining whether the data are suitable for comparison. Using this definition, a DNA result can only be determined to be 'unsuitable for comparison' <i>after</i> it has been interpreted since the last stage of interpretation is to determine whether the data are suitable for comparison. The interpretation may be that the data is too poor quality and/or quantity for comparison (therefore is 'unsuitable for comparison'), but an interpretation was performed. Also, see 4.3.1 in this document: "Interpretation of evidentiary data shall include documentation of the suitability of the ... data for comparison." So - in order to make the determination that a DNA result is not suitable for comparison, it must be interpreted and such interpretation must be documented.	Remove "(uninterpretable)" from the phrase being defined.	Accept.
26	4.1	T	A critical component of any validated interpretation protocol is the check of the protocol (performance check) against a data set that is different from the data set used to develop and validate the protocol. It is only through a robust performance check process on new data that the predicted limitations of the interpretation procedure can be properly assessed.	Revise 4.1 to establish a requirement for performance checking of interpretation and comparison protocols using data not used in the internal validation studies.	Reject. This requirement is present in section 4.4 of the companion standard, Standard 20, entitled "Standards for Validation Studies of DNA Mixtures and Development and Verification of a Laboratory's Mixture Interpretation Protocol" and, thus, will not be duplicated here.

66	4.1	T	Scientific literature and studies must support the protocols; the language here is not mandatory.	Change "may be" supplemented to "shall be"	Reject. There may be situations where the laboratory's validation studies are sufficiently complete that support from the literature may not be applicable, thus, "may" was used instead of "shall."
27	4.2.2	T	Too vague to achieve goal of consistency among/between labs and analysts. Lab protocol re: number of contributors should be expressly linked to validation studies in a quantitative fashion. Lab protocol re assumed contributors should be required to be precise and detailed. E.g. I've seen labs interpret "intimate sample" differently in different cases and vague protocol allowed for that.	The lab interpretation protocol should be required to expressly link assumptions re: number of contributors to data from validation studies (e.g. When X alleles are detected across entire profile, then...)	Reject. No proposed resolution to text provided. The intended goal of this document and the companion standard, Standard 20, entitled "Standards for Validation Studies of DNA Mixtures and Development and Verification of a Laboratory's Mixture Interpretation Protocol" is that all steps in the laboratory protocol are directly linked to and supported by specific validation study data or relevant other documentation as stated in section 4.1.
28	4.2.3	T	Generally allows for too much subjectivity. E.g. A protocol that states "when one contributor deposits significantly more DNA than others in a mixture, a major contributor can be deduced" may be permissible under this standard. Should require specificity	Require labs to define precise criteria required that are linked to validation data, and where appropriate different sets of criteria for different potential numbers of contributors. E.g. for a mixture of three or fewer contributors, major contributor must make up X% of total mixture; for mixture of more than three contributors, major must make up Y%. Must say more than, e.g., "take allele sharing into consideration".	Accepted in part. Sentence changed to "Criteria for evaluating other considerations..." The intended goal of this document and the companion standard, Standard 20, entitled "Standards for Validation Studies of DNA Mixtures and Development and Verification of a Laboratory's Mixture Interpretation Protocol" is that all steps in the laboratory protocol are directly linked to and supported by specific validation study data or relevant other documentation as stated in section 4.1. It was not the intent of this document to define specific mandatory criteria to be used by all laboratories for all types of DNA testing. As stated in Annex B, it is likely that different laboratories will develop different criteria based on their validation studies.
67	4.2.4	T	Defining limitations is a critical requirement, but 4.2.4 lacks specificity. For instance, "Issues associated with low-level data" is too vague.	Make more specific instead of an "eg" list.	Rejected in part. The limitations will vary depending on the application of the DNA testing method used in each laboratory as well as for the type of DNA testing performed. It is not possible to define here all limitations that a laboratory may encounter during validation studies nor predict which will be stated in the protocol. The key is that limitations shall be stated and those limitations shall be directly linked to validation studies. Annex B (informative) was edited to clarify that protocols, including limitations, are derived from validation data sets.
36	4.2.5	T	Following up on my comment for 3.7: do not conflate "unsuitable for comparison" with "uninterpretable"	4.2.5 What constitutes data that is suitable for comparison from data that is unsuitable for comparison.	Accept in part. The sentence was reworded to "4.2.5.Criteria for defining data that can be interpreted versus data that cannot be interpreted"
29	4.3	T	Good, but should also require that the interpretation be documented prior to comparing to reference data	Add "and documentation of any interpretation" before "prior to the comparison to any reference data"	Accept.
37	4.3	T	I had a lengthy phone conversation with Charlotte Word regarding this... I don't believe that it should be a requirement to interpret all evidence data prior to comparison to ANY reference data. There are many instances where it makes perfect sense to utilize an assumed contributor's profile in the interpretation. Making the analyst do an interpretation blind to the profile of the assumed contributor and then reworking their interpretation using the profile of the assumed contributor is adding extraneous work to the process. SWGAM's statement regarding this concept: "The laboratory must establish guidelines to ensure that, to the extent possible, DNA typing results from evidentiary samples are interpreted before comparison with any known samples, other than those of assumed contributors."	4.3 The laboratory shall have a documented policy requiring the interpretation of evidentiary data prior to the comparison to any reference data, other than those of assumed contributors.	Reject. Using the definition for "interpretation" as provided in this document, the interpretation needs to be conducted independently of any comparisons (even assumed knowns).

38	4.3.1.1	T	<p>"... the loci eligible for use ... in a subsequent statistical calculation(s) shall be documented in the case record." While I understand the intent and don't <i>totally</i> disagree, I can see some issue with this statement.</p> <p>If a lab currently only performs CPI, they may not be able to properly document the loci eligible for use in a subsequent Likelihood Ratio that they may perform on the evidence profile next year after they become proficient in LR's, add them to their protocol, and maybe only after such time do they get a CODIS hit to the evidence for which a stat is required. So, since today they could not document in the case record which loci would be suitable for LR, why would this prevent them from doing an LR in the future once they gain the proper knowledge? Similarly, if a lab is currently doing binary LR, they may document certain loci as unsuitable for (binary) LR because the possibility of complete genotype dropout would render the locus neutral for (binary) LR. But, after they get Prob Gen online, all loci are used. In this example it may not be possible for the lab to prevent the Prob Gen software from using certain loci, and it may not be conservative to the defense to prevent the Prob Gen software from using loci that were neutral for binary LR but may be favoring the denominator in Prob Gen.</p> <p>Also... since the flow of this document is that the use of an assumed contributor has not been introduced yet, the reader is being directed to document loci eligible for stats prior to comparison of the assumed contributor. Since LR stats are dependent upon the profile of any assumed contributor, which loci are suitable for LR stats can change depending on the profile of the assumed contributor.</p> <p>SWGAM's statement regarding this: "The genetic loci and assumptions used for statistical calculations must be documented, at a minimum, in the case notes."</p>	4.3.1.1 If the data or a subset of the data [e.g., major contributor(s)] are deemed suitable for comparison using currently available procedures, the loci eligible for use in the comparison and in a subsequent statistical calculation(s), using currently available procedures, shall be documented in the case record.	Reject. All profiles can only be interpreted with the available procedures. Modifications using other or newer procedures must be documented in accordance with 4.4.2.
39	4.3.1.2	T	Similar to comment about 4.3.1.1. Given the advances that are occurring, something that is "unsuitable for comparison" today may become "suitable" in the future.	4.3.1.2 If the data or a subset of the data [e.g., minor contributor(s)] are deemed unsuitable for comparison using currently available procedures, the qualitative reason(s) shall be documented in the case record.	Reject. All profiles can only be interpreted with the available procedures. Modifications using other or newer procedures must be documented in accordance with 4.4.2.
40	4.3.2	T	Similar to comment about 4.3: There are many instances where the immediate use of an assumed contributor in the interpretation is suitable.	4.3.2 The subsequent interpretation of new evidentiary data shall occur independently of comparison to the previously generated reference data, other than those of assumed contributors.	Reject. Using the definition for "interpretation" as provided in this document, the interpretation needs to be conducted independently of any comparisons (even assumed knowns).
68	4.3.2	T	Independently is not defined. For instance, does it have to go to a different analyst?	Specify that any reinterpretation be performed by an analyst with no knowledge of the comparison to the previously generated reference data (nb: and perhaps of the other evidentiary profile).	Accept in part. The sentence was reworded to clarified that interpretation and documentation must be completed and documented prior to comparison.
69	4.3.3	T	Documentation of the assumption of the number of contributors in the case record should be required.	Add "The use of the assumption of the number of contributors to the mixture shall be documented in the case record."	Accept in part. Section 4.3 was edited to include the documentation of all assumptions use.
31	4.3.3	T	Other assumptions should be expressly required to be documented as well	Any assumption used in data interpretation must be documented.	Accept in part. Section 4.3 was edited to include the documentation of all assumptions use.

71	4.42	T	Changes in interpretation to evidentiary data should be documented in the case record even if they occur before comparison with a reference or other evidentiary profile (e.g., deducing a major profile). The second sentence in 4.4.2 appears to capture that requirement but there is a danger that it will be read to apply only after comparison with a reference sample.	Add another requirement "All re-evaluations of and changes to evidentiary data interpretation shall be thoroughly documented within the case record regardless of when the change occurs" or add phrase "either before or after comparison with a reference or other evidentiary data."	Accept in part. The second sentence was moved to the beginning to clarify.
9	5	T	Per ASB Guide 001, Section 5 is to state the conformity assessment specifications for the standard. As written here, Section 5 provides no specifications for how conformance shall be documented by the laboratory either in its policy and test method documents, or in the individual case record.	Section 5 should be re-written to provide clear guidance to laboratories regarding the documentation that will be expected in policy and test method documents, and in the case record.	Reject. This section is no longer required and was deleted.
42	Annex B	T	Following up on my comment for 3.7: do not conflate "unsuitable for comparison" with "uninterpretable". Document states "In casework analyses, the DNA data from evidentiary samples will be assessed to determine whether the data (either in part or as a whole) are interpretable, or unsuitable for comparison (Section 4.2)." However, part of the interpretation is to determine if the evidence profile is suitable for comparison. So... interpretation happens the moment an analyst looks at a DNA profile - they start the process: Is this single source, is it a mixture? Is there obvious degradation or inhibition? Are there obvious stochastic issues? Is the data suitable for comparisons? Isn't the statement that "the DNA data from evidentiary samples will be assessed" equate to an interpretation? What is the difference between an 'assessment' and an 'interpretation'?	In casework analyses, the DNA data from evidentiary samples will be interpreted to determine whether the data (either in part or as a whole) are suitable or unsuitable for comparison (Section 4.2).	Accept in part. The word "interpretable" was changed to "suitable"
43	Annex B	T	"This assessment shall be performed independently of any comparisons to reference data (Section 4.3)." Following up on my comment for 4.3: I think requiring two separate interpretations (one prior to looking at any reference samples, and then revising the interpretation based upon the assumption of an assumed contributor) is overly inefficient and inconvenient to the laboratory.	This assessment shall be performed independently of any comparisons to reference data, other than those of assumed contributors (Section 4.3).	Accept in part. "independent of" was changed to "prior to".
44	Annex B	T	"Once DNA data (or a portion thereof) have been deemed suitable for comparison, comparisons may be performed to reference or other evidentiary data (Section 4.4)." The document then gives three examples of conclusions that can be drawn when comparing the evidence data to reference data... but does not give any guidance as to conclusions that could be drawn when comparing evidence data to other evidence data.	Add text about what conclusions can be made when comparing the evidence data to other evidence data.	Accept in part. The sentence was reworded. See revised paragraph 3 of Annex B.
45	Annex B	T	" Additional guidance is available in the SWGDAM "Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories" (see Bibliography). " Directing the reader to the SWGDAM document may cause some confusion due to differences in the timing of when to introduce the assumed contributor into the interpretation, etc.	May want to clarify that the intent of this statement is not for the SWGDAM document to be elevated to the level of these Standards, and that these Standards supersede the SWGDAM Guidelines document.	Accept in part. The relevant sentence has been modified to state that guidance may be available at the SWGDAM website without reference to any particular document.
46	Annex B	T	"Section 4.2.5 - Samples in their entirety or an unresolvable subset of the data (e.g., multiple minor contributors to a mixture with a single major contributor) may be determined to be uninterpretable and therefore not suitable for comparison." Following up on my comment for 3.7: do not conflate "unsuitable for comparison" with "uninterpretable". Here, the analyst has interpreted the mixture to have an unresolvable subset (they have interpreted that there is a mixture of minor contributors - this is an interpretation).	"Section 4.2.5 - Samples in their entirety or an unresolvable subset of the data (e.g., multiple minor contributors to a mixture with a single major contributor) may be determined to not be suitable for comparison."	Accept in part. This section was revised to remove reference to "uninterpretable" . See revised paragraph 5 of Annex B.

49	Annex B	T	"Section 4.4.2 – After completion of the initial evaluation and interpretation of evidentiary data, ..." What is the difference between an 'evaluation' and an 'interpretation' (and an 'assessment', used elsewhere in the document)?	"Section 4.4.2 – After completion of the initial interpretation of evidentiary data, ..."	Accept in part. Changes were made to Section 4.4.2 of Annex B.
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