Deadline of Submission of Comments: 9-Sep-24
Document Number: ANSI/ASB Std 136
Document Title: Forensic Laboratory Standard for Prevention, Monitoring, and Mitigation of Human DNA Contamination

Comment #	Text Line # (s)	Document Section		Type of Comment E-Editorial T-Technical	Current Document Wording	Proposed Revision	Revision Justification	*For Working Group and Consensus Body use only, not to be completed by commenter.* Final Resolution
1		General		T	Thoughout the document, there are calls for documentation of processes, procedures, and decisions. However, it does not identify when the documentation should occur. Retrospective justifications of decisions are generally unreliable and will not reflect what a person was thinking at the time of the decision accurately. A preference should be indicated here for using and creating documentation that occurred relatively contemporaneous with the decision processes.	We have suggested a specific change for 4.3.12 that is a redlined section, but it might be better to provide a general statement or instruction about a preference to contemporaneous documentation rather than attempting to retrospectively figure out what was experienced, thought, or decided, and why, later on.		Reject- Comment is not specific enough. Investigations take time and cannot be contemporaneous
2				Ballot Comment	I continue to object to the language time or space.			Reject with modification-Small labs do not have adequate space. Notes have been added 4.3.3 e) and 4.3.3 f) to suggest separation in time and space when feasible.
3		new		E	none	add definition from BPR 171 for elimination profile	to maintain consistency between closely related documents from ANSI/ASB; this retains the information suggested to be deleted from "DNA elimination database" in comment above.	Accept
4	General	Foreword & some individual requiremen ts		E		Should additional language be added in relevant places (where not already included) to assist with understanding which issue of *limiting, detecting, assessing & mitigating* is addressed by the requirement? [e.g., 4.2.8 - add at the end something like "to ensure human DNA-free materials are being used during testing"]	While it is likely clear to most lab personnel which of these standards assists with limiting, detecting, assessing and mitigating contamination, it may not be clear to non-lab personnel and some quality assurance personnal, and the organization of the requirements does not aid in providing clarity.	Reject- Not necessary because the overall goal of the document is to prevent, monitor and mitigate contamination
5	1st sentence	Foreword, Scope		E	PCR-based	polymerase chain reaction (PCR)-	does PCR need to be defined (per ASB)? It's obviously a well-known abbreviation in DNA. (perhaps this was addressed with the NWP initially)	Accept with modification- PCR defined in its first use in the Foreword and the Scope.
6	2nd paragraph 2nd sentence	Foreword		E	Contamination can occur…	Contamination can occur from items or from individuals external to the DNA testing laboratory, including first responders, crime scene technicians and laboratory personnel from other sections. Contamination may also occur within the biology/DNA testing laboratory from individuals, supplies and reagents used in the testing, and/or from cross-contamination from other items, DNA extracts or amplified products being processed or tested at the same or later time.	There seems to be some confusion re: the definition of contamination in different standards. Making it clear that this document pertains to the detection of contamination that arises outside of the DNA lab at the crime scene or within other sections of the lab (both from reagents/supplies and personnel), as well as contamination that occurs within the DNA testing laboratory may be helpful. The second paragraph seems to only address people contamination and not contamination that comes into the testing lab via reagents and supplies. Tried to add some clarifying information.	Accept with modification- and/or changed to or
7	N/A	Forward (2nd paragraph)		T	It can never be known with certainty that a casework or database sample is contamination-free, but detection and tracing efforts facilitated through the use of elimination databases which contain the DNA profiles of laboratory personnel, first responders, law enforcement, and medical personnel can assist in the identification of contamination.	It can never be known with certainty that a casework or database sample is contamination-free, but detection and tracing efforts facilitated through the use of elimination databases which may contain the DNA profiles of laboratory personnel, first responders, law enforcement, and medical personnel can assist in the identification of contamination.	Beyond laboratory personnel it will be laboratory-dependent whether the other individuals will be included and we don't want to give the impression that having DNA profiles from all of those individuals in the elimination database is a forgone conclusion.	Reject with modification- the paragraph was expanded for clarification based on other comments.

8	N/A	Forward (2nd paragraph)		T	It can never be known with certainty that a casework or database sample is contamination-free, but detection and tracing efforts facilitated through the use of elimination databases which contain the DNA profiles of laboratory personnel, first responders, law enforcement, and medical personnel can assist in the identification of contamination.	It can never be known with certainty that a casework or database sample is contamination-free, but detection and tracing efforts facilitated through the use of elimination databases which contain the DNA profiles of laboratory personnel, first responders, law enforcement, and medical personnel can assist in the identification of contamination. There are additional considerations and concerns when applying these standards to post-conviction cases and the additional complications of obtaining appropriate elimination samples.	Laboratories should also critically think through how this standard applies to post-conviction cases.	Accept with modification- the paragraph was expanded for clarification. Additional information was added to 4.3.8.1 in regards to post-conviction cases.
9	2nd paragraph 3rd sentence	Foreword		E	It can never be known with certainty…	that a casework or database sample, or DNA extract and other test products, is contamination-free	insert "or DNA extract or other test products," to be more inclusive of what does get contaminated within the lab and for which a contaminant may be detected	Reject- Sample is expansive to include extract and other test products
10	2nd paragarph 3rd sentence	Foreword		E	, but detection and tracing efforts facilitated	through the use of appropriate controls and quality assurance measures, including the use of elimination databases, which contain the DNA profiles…(and add comma after medical personnel)	the use of controls is a requirement in this document but they are not mentioned in the foreword; makes clear these are critical QA measures	Accept
11	N/A	Foreward (3rd paragraph)		T	Certain probabilistic genotyping software capabilities may be useful to detect contamination events…	Certain probabilistic genotyping software and analysis software capabilities may be useful to detect contamination events	Incorporation of analysis software (e.g. GeneMapper IDX) since it also has capabilities that may be useful to detect contamination events.	Accept with modification- Paragraph was reworded for clarification
12	3rd paragraph, 2nd sentence	Foreword		E	…and performing comparisons between unknown mixtures to assess	…between mixed DNA profiles from unidentified contributors to assess the likelihood of a common donor.	clarify language used	Accept with modification- "unknown" removed from sentence.
13	4th paragraph	Foreword		E	4th paragraph	Since first implemented in the 1980s, all PCR testing has involved risks of contamination; this risk increases as the sensitivity of the testing and the ability to detect contaminating DNA increases. As the sensitivity of assays to continue to increase in forensic DNA testing laboratories, it is increasingly important to continue limiting, detecting, assessing and mitigating contamination to better ensure reliable interpretation and comparison of DNA data.	reword sentences to make it clear that this risk is for all types of PCR testing, not just unique or new to forensic testing. The last sentence can also be more accurately stated. Don't think there is any reason to mention drop-in since it is unknown if that has happened in a particular profile except when testing known samples with known profiles. As it regards to this standard, the methods used to prevent, limit and detect contamination is basically the same for overt contamination & drop-in.	Reject with modification- A sentence was added to the end of the paragraph for clarification
14	4th paragraph	Foreword		E	add to end	Increased vigilance throughout all phases of evidence collection, storage, preservation, handling and testing, and the monitoring for and detection of contamination in the DNA test results, is critical.	Perhaps add, at the end of this paragraph, a statement of caution and reinforce the importance of care throughout ALL phases of evidence handling.	Accept
15		Scope		E		add from Foreword 1st paragraph, 2nd sentence (and shorten it as the last part is probably not necessary): "This standard includes provisions for Rapid DNA analysis performed in accredited forensic DNA laboratorys."	the Foreword (1st paragraph) mentions this standard also pertains to Rapid DNA conducted in accredited labs only. Don't we usually include that clarifying and limiting information in the Scope? (or was it deleted in a previous version)	Accept with modification- Rapid DNA was added to the scope.
16		Scope		T	This standard provides requirements for limiting, detecting, assessing the source of, and mitigating the effect of DNA contamination as applied to PCR-based human DNA analysis conducted within a forensic laboratory (i.e., casework and DNA database).	N/A	There are places where this standard doesn't seem to account for all types of PCR testing (e.g., mtDNA, Y-STRs, X-STRs) and additional considerations may be necessary. Suggestions to consider revising the scope and specifically include all PCR-based testing that was intended to fall under this standard.	Reject-By not listing all the techniques, the standard is all encompassing.
17				Ballot Comment	Formatting Edit: I believe you lost the "3.6" in the terms and definition section			Accept

18	17-21	3.2		T	Exogenous DNA or other biological material in a DNA sample, PCR reaction, or item of evidence, which may be present before the sample is collected or introduced during collection or testing of the sample	Contamination can be defined as DNA that is introduced into a forensic biology sample during and/or after its collection by responsible personnel. This is distinguished from DNA or biological material that might be present on an item or in a sample, but not connected to the crime event.	Definition is incorrect. Several published sources provide the correct definition: Van Oorschot, R.A.H. et al., Forensic Sci. Int. Genetics, DNA transfer in forensic science: A review, 2019 ; Forensic Science Regulator, Guidance: Contamination controls – Scene of crime, 2023 ; Inman, K. and Rudin, N. Principles and Practice of Criminalistics: The Profession of Forensic Science, CRC Press Inc., Boca Raton, FL, 2000	Reject. This definition is used also in Standard 171 so it has had editorial modifications for consistency.
19		3.2		E	…in a DNA sample,	in a DNA extract,	extract is the more appropriate term and used in other ANSI/ASB standards definitions	Reject. This definition is used also in Standard 171 so it has had editorial modifications for consistency.
20		3.3		E	positive and negative control definitions as written	change the format (and minimally the definitions) to those used in the recently published Standard 175	for consistency in wording and format between published ANSI/ASB standards when the definitions have essentially the same meaning in both documents	Accept
21	22-31	3.3		T	**3.3** **controls** Samples of known type, run in parallel with experimental, reference, or evidence samples that are used to evaluate whether a procedure is working correctly. A **positive control** is a sample that is used to determine if a test performed as expected. This control consists of the test reagents and a known DNA sample that will provide a known DNA profile as a result of the test. A **negative contro**l (e.g., extraction blanks, reagent blanks and amplification blanks) consists of the reagents used in various stages of testing without the introduction of sample; no results are expected from a negative control.	**negative control** An analytical control that consists of the reagents used in various stages of testing without the introduction of sample; no results are expected from a negative control. **NOTE** For DNA testing, negative controls include extraction blanks/reagent blanks and amplification blanks. A negative control in DNA testing is used to detect contamination introduced into the assay during the testing process via reagents, disposables, or handling errors (which may impact the results observed from samples tested at the same time).	Revise for consistency with ASB Standard 175	Accept
22	22-31	3.3		T	**3.3** **controls** Samples of known type, run in parallel with experimental, reference, or evidence samples that are used to evaluate whether a procedure is working correctly. A **positive control** is a sample that is used to determine if a test performed as expected. This control consists of the test reagents and a known DNA sample that will provide a known DNA profile as a result of the test. A **negative contro**l (e.g., extraction blanks, reagent blanks and amplification blanks) consists of the reagents used in various stages of testing without the introduction of sample; no results are expected from a negative control.	**positive control** An analytical control sample that is used to determine if a test performed properly; this control consists of the test reagents and a known sample that will provide an expected positive response with the test. **NOTE** For DNA testing, positive controls include positive amplification controls and may include extraction positive controls.	Revise for consistency with ASB Standard 175	Accept
23		3.4		E	entire definition as written	Change to: Searchable collection of elimination profiles.	Recommend changing definition to that in published BPR 171 for consistency. And add the extra information under a new definition as in BPR 171 for "elimination profile."	Accept
24	34-36	3.4		T	**DNA elimination database** Collection of DNA profiles, held in a searchable format, from individuals whose access, role, or activities present a potential DNA contamination risk including possible contamination DNA profiles recognized by the laboratory.	**elimination database** Searchable collection of elimination profiles **elimination profile** DNA profile from an individual whose access, role, or activities might result in DNA contamination; includes profiles associated with consumables and positive controls; but not case-specific known DNA reference standards or exemplars	Revise for consistency with ASB BPR 171	Accept
25	41	3.5		E	DNA laboratory monitoring	DNA laboratory contamination monitoring	Revise for consistency with standard 4.2.7	Accept with modification- term revised to "DNA contamination monitoring program" section 4.2.8 also revised for consisency.

26	46-48	3.6		T	Presence of a low number of nonreproducible alleles (as determined by validation) in DNA data where each allele may be interpreted as coming from different individuals whereas contamination consists of multiple alleles from one or more individuals.	A drop-in allele is generally defined as the observation of a single low-level peak detected at a given locus that is not considered part of the profile in question (e.g. it most often attributed to random DNA found either in the laboratory environment, consumables or reagents used testing).	Unclear what "where each allele may be interpreted as coming from different individuals whereas contamination consists of multiple alleles from one or more individuals" means	Accept with modification- term removed from definitions and the document.
27		3.6 drop-in		T	entire definition as written	peak(s) in an electropherogram that are not reproducible across multiple independent amplification events	Recommend changing to definition in draft 078 for consistency, simplicity and for accuracy. This definition as written does not aid in the understanding of how to use this standard. Parts of this definition are unhelpful and incorrect (e.g., "as determined by validation" provides NO information regarding drop-in events in a particular profile of unknown origin and has no meaning or use in terms of an elimination database). It would be impossible to know if there are truly 2 3 extra peaks and if that is due to one or more person's DNA being present in an actual case work sample that shouldn't be there due to drop-in or contamination. The drop-in rate determined during validation may not be consistent over the history of testing in the laboratory and provides no direct meaningful information during the interpretation of a particular profile.	Accept with modification- term removed from definitions and the document.
28		3.6 and requirements		T		Consider whether all mention of drop-in could just be deleted from the entire document. Is it helpful, meaningful or necessary anywhere in this document?	It is unclear if the term "drop-in" is necessary in this document and whether any mention of it in this standard is critical to meeting the requirements of this document. It should only be discussed and left in where it is: 1) *critical* (and possible) for the laboratory to distinguish between contamination vs. drop-in (totally unclear how that can ever be done for a profile of unknown origin in casework!) and 2) for the lab to do anything differently for limiting, detecting, assessing the source of and mitigating contamination while meeting the specific requirements of this standard.	Accept with modification- term removed from definitions and the document.
29		3.7 interpretation		E		retain "but not limited to"	The definition as originally in this document is consistent with the definition published in previous ANSI/ASB standards (040, 123, 175). Consistency seems important unless the change is meaningful and necessary.	Reject. This was removed in the previous round, and agreed to by the CB due to the comment: 'but not limited to' is not needed because 'including' encompasses this concept that the list following is not exhaustive.
30	N/A	3.7		T	Include the definition of first responders (from ASB BPR 171)	**first responders** Any individual responding to a crime scene, including but not limited to: law enforcement, investigative, medical, fire/paramedic, and laboratory personnel	Include the definition of first responders (from ASB BPR 171) since the term is utilized in ASB Standard 136	Reject- First Responders is not used in any of the requirements. It is only used in the Foreword.
31	48-49	3.8		E	**interpretation (interpretable DNA profile)** should be 3.8 assuming you opted to include the definition for first responders	interpretation (interpretable DNA profile) should be 3.8 assuming you opted to include the definition for first responders	Formatting issue	Reject- didn't include first reponders defintion Formatting issue of "interpretation" to be fixed by ASB staff.
32	48-49	3.8		E	The process of evaluating DNA data for purposes including 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.	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.	Added "but not limited to" to be consistent with ASB Standard 175	Reject- Not limiting to is implied by the word including
33		3.8 Rapid		E	developing a DNA profile from samples	either 1) developing DNA profiles from samples OR 2) developing a DNA profile from a sample	grammatical correction	Accept
34	54	3.9		E	**3.7** **Rapid DNA analysis**	**3.9** **Rapid DNA analysis**	Rapid DNA analysis should be 3.9 assuming you opted to include the definition of first responders	Reject- didn't include first reponders defintion Formatting issue of to be fixed by ASB staff.

35		4 Requirements General & Bibliography					recommendation for the working group to review more recent publications regarding contamination to see if any requirements should be modified, added, deleted, and additional documents be added to the Bibliography. (e.g., several Forensic Science Regulator publications; NIST Foundational Review draft; SWGDAM Guidelines/QAS; relevant new publications)	Accept. Additional documents added to the bibliography.
36	66	4.2.1	now 4.2.2	T	Access to laboratory areas shall be restricted to authorized individuals to reduce the risk of introducing extraneous DNA into work areas and samples.	Access to laboratory areas shall be limited to specific individuals to reduce the risk of introducing extraneous DNA into work areas and samples.	"authorized" is a quality management term referring to someone who is authorized to perform particular laboratory activity and the revision is meant to prevent conflation of this term with the layman's understanding of the term	Reject- The layman's definition of authorize is used which means to get approval or permission.
37	77	4.2.2	now 4.2.3	E	Evidence shall be stored…	Evidence items shall be stored…	to be consistent with 4.2.3 (and also consider including derivatives and/or work products to be consistent)	Accept with modificatin- The word items was removied from 4.2.3 (now 4.2.4)
38	81	4.2.3	now 4.2.4	E	https://www.nist.gov/system/files/documents/forensics/NIST-IR-7928.pdf	The Biological Evidence Preservation Handbook: Best Practices for Evidence Handlers (https://www.nist.gov/system/files/documents/forensics/NIST-IR-7928.pdf)	Suggestion to include the document's name in case the link becomes defunct	Accept
39	89	4.2.5	now 4.2.6	T	The laboratory shall arrange the working environment to mitigate potential contamination.	omit	How will a laboratory be assessed for compliance to this standard? It is too broad to be able to demonstrate objective evidence of compliance.	Reject- There needs to be a catch all for when an assessor observes poor laboratory environment.
40	91	4.2.6	now 4.2.7	E	The laboratory shall have and follow a written, regularly scheduled decontamination procedure to include laboratory areas, items to bedecontaminated, and decontamination frequency.	The laboratory shall have and follow a written, regularly scheduled decontamination procedure to include laboratory areas, items to be decontaminated, and decontamination frequency.	missing space in "be decontaminated"	Accept
41	91	4.2.6	now 4.2.7	E	items to bedecontaminated	items to be decontaminated	add space between words	Accept
42	93-95	4.2.7	now 4.2.8	T	The laboratory shall have and follow a written, regularly scheduled laboratory DNA contamination monitoring program. The results from the program shall be documented and made available for inspection upon request.	N/A	After much discussion our group was unclear what this means. Would the reviewing of reagent blanks as a routine part of laboratory operations qualify for standard 4.2.7 or would there need to be a standalone event in order to comply?	Reject with modification- The policy is at laboratory discretion because there are many different laboratory environments. The important point is that there needs to be a policy and it must be followed. "laboratory" was removed for sentence structure.
43	97	4.2.8	now 4.2.9	T	ISO18385:2016	most current version of ISO 18385	To prevent ASB Standard 136 from needing revision upon revision of ISO 18385	Accept
44	105-106	4.3.1		T	The laboratory shall define and use appropriate decontamination and/or cleaning agents, or procedures for each method, technology, tool and instrument, and laboratory area. Decontamination agents or procedures known to destroy DNA shall be used as appropriate on the items and surfaces being cleaned.	Appropriate decontamination agents and/or procedures known to destroy DNA shall be used on applicable objects and surfaces being cleaned.	Entire first sentence is not needed. Second sentence was revised to be all inclusive.	Reject- Different surfaces need different decontamination procedures and they must be defined.
45	114-116	4.3.3		E	The laboratory shall have procedures and policies defined to reduce potential contamination events during evidence and evidence derivative/work product processing to include the following requirements:	The laboratory shall have procedures and policies designed to reduce potential contamination events during evidence and evidence derivative/work product processing to include the following requirements:	consistency with the verb structure	Accept with modification- the word "defined" was deleted.
46	117-128	4.3.3		E	a) the use of b) the decontamination of c) handle d) limit e) separate f) examine g) have	a) using b) decontaminaing c) handling d) limiting e) separating f) examining g) having	Revised for consistency with the verb structure	Reject- This is the grammatical preference of the Working Group
47	114-115	4.3.3 and 4.3.3 c)		E	during evidence and evidence derivative/work product processing to include	be consistent with 4.2.2 & 4.2.3	make consistent with 4.2.2 & 4.2.3	Accept with modification- 4.2.3 changed to be consistent with 4.3.3
48	118-119	4.3.3.b		T	the decontamination of work surfaces and examination tools that are not single use with DNA destroying reagents or processes before new evidentiary items are examined;	the decontamination of work surfaces and examination tools that are not single use with decontamination and/or cleaning agents or processes before new evidentiary items are examined;	Revised for consistency with standard 4.3.1	Accept

49	117-128	4.3.3 c-g		E	c) handle and package… d) limit the opening… e) separate in time or space… f) examine potential… g) have validated procedures…	c) the handling and packaging of… d) limiting the opening… e) separating in time and space… OR the separation in time and space… f) examining potential… OR the examination of…. g) having validated procedures… OR validating procedures…	sections a and b use a different verb tense(?) than c through g	Reject- This is the grammatical preference of the Working Group
50	124-128	4.3.3 f) and g)		T		delete g) - Is there a good reason these cannot be separated to ensure high quality work? If delete g), also delete "when possible" from f)	these seem contradictory to each other - either the lab does the extraction separately or they don't; it seems impossible to audit for both of these statements	Reject with modification-Small labs do not have adequate space. Notes have been added 4.3.3 e) and 4.3.3 f) to suggest separation in time and space when feasible.
51	131-132	4.3.4		T	The laboratory shall document in the case record when items of evidence are received packaged together and how they were packaged.	Omit	This statement (albeit important) seems to fall outside the scope of this document in that although this information is relevant a laboratory will not be able to determine whether a contamination event occurred based solely on this infomation. In addition this information should be included on reports as part of ISO/IEC 17025:2017 7.8.2.1.g.	Reject- Assessing the source of contamnation which is in the scope, should include when items are packaged together.
52	137	4.3.6	Now 4.3.7.1	E	step of processing the contamination likely occurred	step of processing in which the contamination likely occurred	grammatical correction	Accept
53	141-143	4.3.7	now 4.3.8	T	These searches shall occur for every interpretable/comparable DNA profile obtained, and all results shall be documented in the case record.	These searches shall occur for every interpretable/comparable DNA profile obtained, and all results shall be documented in the case record. Exceptions can be made if a profile is associated with a known reference sample in the case.	The provided rephrasing may not be ideal but hopefully it's enough to explain the concern around needing to search profiles if they are conistent with a known reference from a complainant	Accept
54	148-152	4.3.7.1	now 4.3.8.1	T	Where possible, the laboratory shall include profiles from any DNA laboratory visitors and individuals who are involved in the collection and handling of evidence, work samples, reagents, equipment, or consumables (e.g., staff, agency personnel and other associated workers such as medical examiners, law enforcement, sexual assault nurses, service personnel, and laboratory vendors).	Where possible, the laboratory shall include profiles from any DNA laboratory visitors and individuals who are involved in the collection and handling of evidence, work samples, reagents, equipment, or consumables (e.g., staff, agency personnel and other associated workers such as medical examiners, law enforcement, sexual assault nurses, service personnel, laboratory vendors, and employees involved in any criminal proceedings who may have handled evidence in post-conviction cases).	Suggestion to include considerations around post-conviction cases as well.	Accept
55	144	4.3.7.1	now 4.3.8.1	T	biology staff	expand to include all individuals having access to evidence, laboratory working areas, and equipment and consider making this consistent with BPR 171 especially where the BPR has more stringent recommendations than requirements here	this seems too limited (e.g., may not include janitorial staff, QA staff, etc. with access to the laboratory), plus the term "biology" may not have the same meaning in different laboratories	Accept with modificatin- Biology changed to biology/DNA. Janitorial staff added.
56	153-154	4.3.7.2	now 4.3.8.2	T	Confidentiality of DNA profiles within the elimination database shall follow applicable laws and regulations.	Collection and confidentiality of DNA profiles within the elimination database shall follow applicable state and federal laws and regulations.	The collection event also needs to follow applicable state and federal laws and regulations.	Accept with modification- Collection added but federal and state not necessary. Applicable refers to federal, state and local.
57	155	4.3.7.3	now 4.3.8.3	T	DNA elimination database profiles shall be added in a defined timeframe.	DNA elimination database profiles shall be added in a defined timeframe in order to maximize the potential of detecting a contamination event.	Suggestion to provide context as to why the standard is requiring a defined timeframe.	Accept
58	162-163	4.3.9.1	now 4.3.10.1	T	The laboratory shall include the contamination assessment and underlying data in the validation documentation.	The laboratory shall include the contamination assessment and underlying data in the validation documentation for applicable validations.	Not all validations require a contamination assessment.	Reject- Assessment may be as simple as documenting contamination is not applicable for a validation. Assessment is not a contamination study.
59	164-165	4.3.9.2	now 4.3.10.2	T	The laboratory shall conduct a contamination assessment when a laboratory method/technology is modified.	The laboratory shall conduct a contamination assessment when an applicable laboratory method/technology is modified.	Not all method/technology modifications require a contamination assessment.	Reject- Assessment may be as simple as documenting contamination is not applicable for a validation. Assessment is not a contamination study.
60	166-168	4.3.10	now 4.3.11	T	If the laboratory uses probabilistic genotyping software (or other software),	If the laboratory uses probabilistic genotyping software or other software (e.g.,……),	Suggestion to include examples of "other software". Would this apply to semi-continuous probabalistic genotyping software (ArmedExprt), databasing software (SmallPond), CODIS?	Reject- Specific examples of other software change over time. Other software includes whatever the laboratory uses

61	174-175	4.3.10.e	now 4.3.11 e	T	each laboratory should determine a likelihood ratio threshold value to report for comparisons to an elimination database. This should be documented in the case record and in the report.	N/A	Clarity is needed as to if this threshold is the same as a laboratory's validated uniformative threshold or if this is the same. And are the LR values (assuming they exceed the threshold) expected to be reported?	Accept with modification- It is up to the laboratory to define and validate the threshold being used. Reporting the thresholod has been clarified to be if applicable in the report.
62	175	4.3.10.e	now 4.3.11 e	T	This should be documented in the case record and in the report.	N/A	Suugestion to further clarify what "this" is specifically.	Accept- This is spelled out.
63	174-175	4.3.10.e	now 4.3.11 e	T	ach laboratory should determine a likelihood ratio threshold value to report for comparisons to an elimination database. This should be documented in the case record and in the report.	N/A	Is there a corollary for non-PG labs?	Accept- A corollary for non-PG labs was added
64	176-177	4.3.11	now 4.3.12	T	Potential contamination events shall be investigated and referenced or documented within the case record or sample record.	Confirmed contamination events shall be investigated and referenced or documented within the case record or sample record.	The current language is so broad that it is onerous.	Accept with modification- "Potential" changed to "suspected". A contamination event is not confirmed until after the investigation.
65		4.3.12	4.3.13	T	"When contamination is identified, a root cause analysis shall be conducted and, documented, and included referenced within a case file, the case record or sample record." - this does not identify when the documentation should occur. Retrospective justifications of decisions are generally unreliable and will not reflect what a person was thinking at the time of the decision accurately. A preference should be indicated here for using and creating documentation that occurred relatively contemporaneous with the decision processes.	"When contamination is identified, a root cause analysis shall be conducted and, documented, and included referenced within a case file, the case record or sample record. The root cause analysis should favor documentation of processes and procedures during the analysis that were created at the time the evidence was processed or analyzed, rather than obtained retrospectively from memory. The persons conducting the root cause analysis should also document their judgments and considerations as they arise during the root cause analysis, as more information is gathered."		Reject- How to conduct a root cause analysis is out of scope and under the purview of the accreditation body.
66	180-181	4.3.13	4.3.14	T	Records of contamination events shall be maintained indefinitely in a centralized manner that allows such events to be tracked across cases/batches and over time.	Records of contamination events shall be maintained in accordance with the laboratory's documented retention schedule in a centralized manner that allows such events to be tracked across cases/batches and over time.	If a laboratory's retention schedule allows for the destruction of records (in accordance with applicable regulations), the laboratory should adhere to those.	Accept
67	186-191	4.3.15	4.3.6	E		move higher up in the requirements, perhaps as 4.3.6	seems illogical to have it tacked on at the end; perhaps fits better before requirements for elimination database	Accept
68	193-194	4.4.1		T		add "and shall be documented in the case record and along with the records required under 4.3.12."	seems this action should be documented and retained	Reject- See 4.3.12 for the standard requiring root cause analysis documentation
69	195-196	4.4.2		T		add "and how and where that information shall be documented, to include as appropriate: "	seems this action should be documented and retained. And a lead in into the subsections a), etc. is needed.	Accept with modification- "and documented" was added. The suggested language was simplified.
70	205	4.5.2		T		add at the end "training regarding:"	add training for clarity as without it, it seems duplicative of requirements above	Reject- The training requirement is in 4.5.1
71	207	4.5.2 b)		E	evidence and evidence derivatives handling and packaging;	handling and packaging of evidence and evidence derivatives	grammatical consistency with other items in the list	Accept
72	210	4.5.2 e)		T	documentation, investigation, and reporting	documentation, investigation (including root cause analysis), and reporting	needs to be added since included in the requirements above for process and documentation	Reject- It is not necessary. RCA is part of investigation.
73	214-215	4.6.2		E	rooms outside of evidence examination areas	rooms outside of evidence storage and examination areas	insert "storage and"	Accept with modification- Storage was added and reworded slightly not to have too many "and" in a row.
74	216-217	4.6.3		E	the use of a positive and negative controls	the use of appropriate positive and negative controls	delete "a" for grammatical correctness and insert "appropriate"	Accept with modification- The ''a' was deleted but appropriate was not included.
75				Ballot Comment	While the standard contains an important requirement to maintain a log of exogenous DNA--both drop in and contamination--events (4.3.6), there isn't sufficient guidance on the need to periodically analyze it for trends in the laboratory to mitigate the risk of contamination (see SWGDAM contamination document at 4.5; see ENFSI contamination document at section 5.10-https://enfsi.eu/wp-content/uploads/2023/10/ENFSI-GUIDELINE-FOR-DNA-CONTAMINATION-MINIMIZATION-IN-DNA-LABORATORIES.pdf). Should we update the bibliography to			Accept
76				Ballot Comment	In the citations for this standard, it may be useful for the reader to include some research publications by Dr. Roland van Oorschot's group if not cited in the other references. Here are a few to consider:Goray, M., Taylor, D., Bibbo, E., Patel, D., Fantinato, C., FonnelÃ¸p, A. E., ... & van Oorschot, R. A. (2024). Up in the air: Presence and collection of DNA from air and air conditioner units. Electrophoresis, 45(9-10), 933-947.			Reject. The documents show problems and not mitigations or prevention.

77	261	reference 16		E	Taylor D., Bright, McGovern J., C.,	Taylor D., Bright J.A., McGovern C.	correct names of co-authors	Accept