ASB Std 136, Forensic Laboratory Standards for Prevention, Monitoring, and Mitigation of DNA Contamination
Public Comment Period: August 13, 2021 - September 27, 2021

#	Section	Updated Section	Type of Comment	Comments	Proposed Resolution	Final Resolution
95	Foreword		E	"While contamination has always been an issue in forensic laboratories, the sensitivity of testing instrumentation and methods in use in human forensic DNA laboratories has steadily increased and has resulted in a greater chance of detecting low-level contamination and drop-in events"	While contamination has always been an issue in forensic laboratories, the sensitivity of testing instrumentation and methods in human forensic DNA laboratories has steadily increased and has resulted in a greater chance of detecting low-level contamination and drop-in events	Accept
93	Forward		E	"to limit, to detect, to assess the source of, and to mitigate contamination events"	"to limit, detect, assess the source of, and mitigate contamination events"	Accept
94	Forward		E	"This standard includes provisions for Rapid DNA analysis performed in a laboratory and does not cover the use of Rapid DNA instrumentation outside of a laboratory environment." This is unclear, there are many types of laboratories, not all are held to the same type of standards an accredited forensic DNA laboratory are held to	This standard includes provisions for Rapid DNA analysis performed in **an accredited forensic DNA laboratory** and does not cover the use of Rapid DNA instrumentation outside of **an accredited forensic DNA laboratory** environment.	Accept
1	3.1		T	this definition of background DNA isn't clear	better definitions exist: e.g., see "Background DNA on Flooring…", Reither et al FSIG 2019. https://www.sciencedirect.com/science/article/pii/S1875176819300757#bib0005	Accept with modification- Definition deleted because "background DNA" is not referred to in the standard.
43	3.1		E	This definition does not clearly describe the presence of DNA which may be present on an item prior to and unrelated to a crime event.	DNA present on an item which is unrelated to a crime being investigated. The origin and source of this DNA is unknown.	Accept with modification- Definition deleted because "background DNA" is not referred to in the standard.
44	3.1		T	"foreign" usually refers to DNA foreign to a known contributor i.e. DNA foreign to the female from which a vaginal swab is collected. The use of the term "foreign" does not make sense in this context.	Delete the sentence including the term "foreign".	Accept with modification- Definition deleted because "background DNA" is not referred to in the standard.
78	3.1		T	the use of "unknown" in the definition of background DNA is not accurate. The source of background DNA on an item is often known (for example, the background DNA on my steering wheel is mine, it is known who it belongs to and how it got there).	Reword to remove the word "unknown"	Accept with modification- Definition deleted because "background DNA" is not referred to in the standard.
96	3.1		T	"DNA that is present from unknown sources and unknown activities. It can be described as 'foreign' (non-self). It is unknown how or why it is there"	May want to include language stating background DNA can be deposited prior to the crime to differentiate between background and contaminant DNA.	Accept with modification- Definition deleted because "background DNA" is not referred to in the standard.
112	3.1		E	This definition is not used in the requirements	delete the definition for background DNA	Accept
42	3.2	3.1	T	The definition of "contamination" doesn't take into account that evidence can be contaminated before responders arrive.	Revise 3.2 to state: Introduction of DNA onto the evidence **[by contact with people or objects not related to the crime.]**	Accept with modification- Definition was modified.
45	3.2	3.1	E	Since contamination can occur following a crime and prior to the arrival of a first responder, for instance by a witness or individual who discovers the crime scene, this definition is too narrow. Also, evidence can be tested outside of the laboratory by crime scene personnel which can introduce contamination.	The inadvertent introduction of DNA onto the evidence due to improper handling, storage, or testing procedures.	Accept with modification- Definition was modified.
79	3.2	3.1	T	Definition of contamination - who are the "responders" who are arriving, and why is contamination limited to occurring after their arrival	Reword to be more encompassing of the way that contamination can occur. The original definition seems to be more appropriate.	Accept with modification- Definition was modified.
97	3.2	3.1	T	The introduction of DNA onto the evidence after the crime occurred. Contamination can occur through handling and storage of the evidence and laboratory work products. Drop-in is distinguished from contamination. (See 3.7. Drop-in.)	Parts of this definition have been crossed out, which we believe is in error. It should be stated that contamination is deposited after the crime or during handling by forensic personnel.	Accept with modification- Definition was modified.

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113	3.2	3.1	T	this definition is too limited in scope. Contamination may be introduced into the evidence by anyone on the scene after commission of the crime and prior to first responders arrival. It may also be introduced at any step during laboratory testing to the evidence item or into any of the DNA containing tubes (e.g., the DNA extract or PCR amplification or CE set up) from contaminated solutions or other direct or indirect mechanisms. It needs to encompass any DNA introduced by any means that is not directly related to what was on an evidence item at the time of the crime and any subsequent introduction to any evidence derivatives or subitems, such as extracts, etc. in the laboratory.	Substitute modification of OSAC glossary "Exogenous DNA present in a DNA sample, PCR reaction, or item of evidence; the exogenous DNA or biological material could be present before the sample is collected, or introduced during collection or testing of the sample."	Accept with modification- Definition was modified.
98	3.3	3.2	E	A positive control is a sample that is used to determine if a test performed properly. This control consists of the test reagents and a known DNA sample that will provide a known DNA profile in the test	A positive control is a sample that is used to determine if a test performed properly. 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.**	Accept
99	3.3	3.2	T/E	The use of negative controls helps assess the overall health of the testing process but cannot be used to determine whether a particular sample is free from contamination.	This language has been removed but we feel strongly this caveat should be stated in this document, we see it in the Foreword but it should also be included here as this is the area most analysts and lawyers will point to as an indication there is no contamination.	Reject - information is not essential for this defintion.
12	3.4	3.3	T	Remove explanation from the definition.	Delete, "A DNA elimination database cannot detect all forms of contamination, but with DNA profiles of first responders including law enforcement and medical personnel, and with the production of likelihood ratio distributions for elimination database profiles, more contamination can be detected."	Reject with modification: The CB feels that the content is important to the definition and it has been converted to a note.
46	3.4	3.3	E	the change from recognized to identified seems to exclude the inclusion of consumable profiles provided to a laboratory by a vendor since the laboratory would not be the party who identified the profile.	revert to recognized by the laboratory	Accept
47	3.4	3.3	E	The entire last sentence should be deleted since it is not a definition but rather an opinion.	delete the last sentence "A DNA elimination database cannot detect all forms of contamination……"	Reject with modification: The CB feels that the content is important to the definition and it has been converted to a note.
70	3.4	3.3	T	While having the DNA profiles of first responders/investigators/etc. is a wise idea, that is a policy decision set outside the crime labs. I would argue it's not appropriate to use a document intended to be useful during the analysis process to try and effect large policy changes that are the responsibility of government appointed persons or elected officials.	Soften language throughout, as it is a true statement to say that having a large elimination database is useful, but that ultimately it is recognized the crime lab has no control over compelling elimination samples from stakeholders.	Reject- The suggestion is ambiguous and does not provide a concrete change for evaluation.
114	3.4	3.3	T	evaluate for consistency with other documents in circulation regarding elimination database	Recommend having a consistent definition across various documents using this term, if feasible. If, however, the term is used differently in different documents, the definition should clearly reflect what the difference is as it relates to each specific document.	Reject- The suggestion is ambiguous and does not provide a concrete change for evaluation.
60	3.5	3.4	Technical	"such activities" implies that one has options and this is an example. We are unaware of documentation showing that swabbing areas of the laboratory has provided useful information that helps discover potential sources of contamination. Additionally, it is unclear how to perform testing in the post-amplification area because swabbings would have to be brought back into pre-amplification areas for processing.	Change to "such activities **may** include" or consider moving it to section 4.4 as one option to help with corrective measures when issues arise.	Accept with modification- Definition was modified.

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13	3.6	3.5	T	The definition for "drop-in" is excessively complex and brings educational aspects (e.g., "The occurrence of drop-in alleles may be minimized, but cannot be avoided completely. If drop-in occurs then approximately 1 to 3 alleles are expected in addition to the main profile(s). The number of alleles which can reasonably be assumed to be drop- in as opposed to 'contamination' can be estimated by plotting a Poisson distribution. The data are taken from negative controls. These data can be used to inform probabilistic genotyping models that take account of the phenomenon.") that may be better in an Annex. I recommend using the definition from the SWGDAM Enhanced Detection Guidelines - Final 10/6/2014, page 17.	Replace existing wording to SWGDAM ED Guidelines definition, "Drop-in: Non-reproducible allele(s) that show up in the profile or control that does not originate from the principal DNA donor(s). Typically, drop-in events are not detected using Standard Methods." And add appropriate reference.	Accept with modification- Definition was modified.
34	3.6	3.5	T	It isn't clear what the basis is for the statement that "If drop-in occurs then approximately 1 to 3 alleles are expected in addition to the main profile(s)."	Include a citation for this assertion.	Reject- Citations are inappropriate for a definition.
100	3.6	3.5	T	The definition is not clear, and appears inconsistent with ISFG	The drop-in phenomenon is the presence of 1 or 2 alleles in a sample that are assumed to come from different individuals. We differentiate between drop-in and contamination in that the latter describes more than two alleles that come from a single individual. The distinction is important because the assumption of independence enables the use of the product rule to multiply drop-in probabilities, whereas this is not valid if the events are dependent. (P. Gill et al. / Forensic Science International: Genetics 6 (2012) p. 682)	Accept with modification- Definition was modified.
115	3.6	3.5	T	some critical language seems to be missing from the definition that is present in the OSAC terminology document. It is not possible to know what is a "spurious" allele without knowing the true contributor(s) to a DNA extract. The meaning of the second sentence is unclear. We cannot know if 3 alleles are due to contamination or drop-in. Not sure that part of the definition is helpful and seems wordy.	Recommend substituting: (1) Allelic peak(s) in an electropherogram that are not reproducible across multiple independent amplification events. (2) A hypothesis/postulate for the observation of one or more allelic peaks in an electropherogram that are inconsistent with the assumed/known contributor(s) to a sample not likely to be due to the presence of DNA from an additional contributor. The number of alleles that can reasonably be assumed to be drop-in as opposed to contamination in a DNA profile can be evaluated using negative control data, which may also be used to inform probabilistic genotyping models that take this phenomenon into account.	Accept with modification- Definition was modified.
101	3.7	3.6	T	What makes this process rapid is not the hands free process, it's the truncated testing time to develop a profile.	The time to develop the profile using "rapid" DNA seems relevant here, consider adding language about what time is defined as "rapid"	Reject with modification: Definition was modified for clarification, though defining what "rapid" is, is outside the scope of this document.
48	4.1		E	A DNA technical leader can ensure that the laboratory protocols and procedures address these standards, but they are not necessarily the individuals responsible for ensuring compliance.	The laboratory shall have and follow standard operating procedures addressing the requirements of this standard which are approved by the technical leader.	Reject with modification: alternate roles to the technical leader added for clarification, refer to section 4.3 of this document for the procedural requirements.
116	4.1		T	1) Some laboratories may not have a person designated as a "technical leader," but have personnel with other titles appropriate to fulfill the role. The roles of the technical leader are specified in the QAS document for use in the US. 2) Not sure how one would audit to this requirement as written.	Recommend: The laboratory shall develop and follow appropriate documented laboratory procedures and policies to address each of the requirements in this standard.	Accept with modification-Sentence was modified.
107	4.1.7	4.2.7	E	4.1.7 Laboratory work area surfaces and furnishings shall be able to withstand frequent cleaning and/or decontamination (e.g., bleaching).	This is a good example of considerations that should be made under 4.2.6	Reject- Cleaning is not the same as the physical arrangement and work flow of a DNA laboratory.

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50	4.2.1		T	The laboratory areas cannot be restricted to only individuals involved with the laboratory procedures. This is not a practical expectation in an operational forensic laboratory. For instance, laboratory supervisory staff and/or janitorial staff may have legitimate access to these spaces. The laboratory employs precautions to mitigate potential contamination risks from anyone with authorized access to laboratory work areas.	Access to laboratory areas shall be restricted to individuals authorized by the laboratory to reduce the risk of introducing extraneous DNA into work areas and samples.	Accept
71	4.2.1		T	What about custodial staff, repair personnel, etc.? This is not practical as written.	"…restricted to appropriate personnel to reduce the risk…"	Accept with modification- Sentence was modified.
102	4.2.1		T	"Access to laboratory areas shall be restricted to individuals actively involved with laboratory procedures to reduce the risk of the introducing extraneous DNA into work areas and samples." Building maintenance personnel, HVAC technicals, emergency medical/fire personnel, field service technicians, etc. may all have to access the laboratory at some time or another performing functions not described by any laboratory procedure or sample test. This language is overly specific, I suspect for a reason. There are accredited laboratories whose justice systems require testing observation by defense experts. This standard should not be an attempt to exclude them.	"Access to laboratory areas shall be restricted to reduce the risk of introducing extraneous DNA into work areas and samples." Ambiguous words like "actively involved" and "laboratory procedures" should be removed.	Accept with modification- Sentence was modified.
103	4.2.1		T/E	May be beneficial to include language describing best practices recommended to restrict access (logs, key fobs, biometrics, sign in/out).	Add language further describing what is being required/recommended.	Reject- This is at laboratory discretion and is audited by the accreditation body.
117	4.2.2		E	word seems to be missing	add "the" before "PCR"; "Post-PCR includes the PCR…"	Reject- It does not appear any words are missing.
14	4.2.2.1	appears to be a comment on 4.2.1 or 4.2.1.1	E	Typographical	Add a space between "pre-" and "and"	Accept
80	4.2.2.2	appears to be a comment on 4.2.1.2	E	Why cleaned *and* decontaminated? Isn't decontamination a form of cleaning? The use of the word and imply that they are two separate steps.	remove "cleaned and" so the sentence reads "...without first being decontaminated."	Accept
118	4.2.2.2	appears to be a comment on 4.2.1.2	T	the deleted sentence seem to suggest a requirement to use a method appropriate to the item being moved. That requirement seems to be lost now.	Suggest adding a qualifying phrase to maintain the requirement such as: "…cleaned and decontaminated using appropriate methods"	Reject- It is up to the laboratory to decide what are appropriate methods.
104	4.2.3		T	Evidence packaging is an important aspect of mitigating contamination. More language should be included to describe what is being required by this standard with regard to proper evidence packaging	Add language further describing what is being required/recommended for best practice for storing evidence (lockers, separate packaging requirements etc.)	Reject- It is up to the laboratory to decide what are appropriate storage conditions.
119	4.2.4 (& 4.3.3, 4.3.3 b, 4.5.2)	appears to also be a comment on 4.2.3, 4.5.2 b), 4.3.3 c)	T	Unclear what the difference is between "evidence" and "samples" and how that relates to the requirement to be "packaged and handled."	Clarify what is evidence vs. samples so the laboratory personnel and an auditor can correctly differentiate what is needed for each separately to meet this requirement (and the others listed).	Accept with modification: "sample" was removed and replaced with "evidence derivative"
15	4.2.5	4.2.4	E	Although it is not part of the red-line, suggested revision. The sentence can be misconstrued to not realize that reagents and consumables are separate from extracts and PCR products.	Change to, "Separate storage areas shall exist for reagents/consumables, DNA extracts, and PCR products.	Accept with modification- A "," was added instead of a"/"

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16	4.2.5.1	4.2.4.1	E	Although it is not part of the red-line, suggested revision. Since reagents and consumables are combined in 4.2.5, add consumables here.	Change to, "Applicable reagents/consumables and DNA extracts shall be stored separately in pre-PCR areas."	Accept with modification- A "," was added instead of a"/"
17	4.2.5.2	4.2.4.2	E	Although it is not part of the red-line, suggested revision. Since reagents and consumables are combined in 4.2.5, add consumables here.	Change to, "Applicable reagents/consumables and PCR product shall be stored in post-PCR areas."	Accept with modification- A "," was added instead of a"/"
2	4.2.6	4.2.5	T	this requirement is vague and does not give clear direction to accomplish it; it is redundant to the rest of the standard	remove 4.2.6	Reject-The topic is important for consideration and it is up to the laboratory to apply based upon local workspace conditions.
49	4.2.6	4.2.5	E	word *The* needed at start of standard to make sentence read smoothly.	Add *The* to the start of the sentence	Accept
105	4.2.6	4.2.5	T	"Laboratory shall arrange the working environment to mitigate potential contamination."	Please explain **how** these standards recommend this be accomplished? What are the best practices recognized by this body that a lab should implement to do this?	Reject-The topic is important for consideration and it is up to the laboratory to apply based upon local workspace conditions.
120	4.2.6	4.2.5	E	Add "The"	The laboratory shall…	Accept
81	4.2.7	4.2.6	E	"… frequency of The cleaning."	make "The" lowercase.	Accept with modification- section was modified.
122	4.2.7	4.2.6	E	suggestion of word with more clarity perhaps	Substitute "defined" or "established" or other appropriate word in place of "determined"; "The cleaning schedule shall be defined/established by the…"	Accept with modification- section was modified.
121	4.2.7	4.2.6	E	words missing and extra commas that may be confusing	May have better clarity in the meaning by changing to: "…a written and regularly scheduled cleaning procedure to include the laboratory areas and items to be cleaned, and the frequency of cleaning."	Accept with modification- section was modified.
31	4.2.8	4.2.7	T	The laboratory shall have and follow a written, regularly scheduled DNA laboratory monitoring program and the results from the program shall be documented and made available for inspection.	This seems vague, does it mean a regularly scheduled contamination monitoring program? That can take many forms (i.e.. random substrate controls, staff comparison databases, searching batch profiles against each other).	Reject- See definition 3.5.4 for a clearer description.
35	4.2.8	4.2.7	T	It is important that the monitoring program and results be made available for external stakeholders. As written ("made available for inspection") is not clear as to who may review these materials.	Revise 4.2.8 to state: The laboratory shall have and follow a written, regularly scheduled DNA laboratory monitoring program and the results from the program shall be documented and made available for inspection [and shall be posted online or made available upon request].	Accept with modification- "upon request" was added to 4.2.7 (old 4.2.8).
106	4.2.8	4.2.7	T	"The laboratory shall have and follow a written, regularly scheduled DNA laboratory monitoring program and the results from the program shall be documented and made available for inspection."	Please add language to whom these documents should be "made available for inspection." I believe these should be publicly available as a best transparent practice, as should all quality documents in the spirit of the NCFS recommendations.	Accept with modification- "upon request" was added to 4.2.7 (old 4.2.8).
123	4.2.8	4.2.7	E	minor editorial edits for ease of flow and aid for auditing	…follow a written and regularly scheduled DNA laboratory monitoring program. The results from the program shall be documented….	Accept
18	4.2.9	4.2.8	T	Making this a "shall" now may be excessive, especially if the laboratory has implemented processes to decontaminate consumables into their procedures. If you leave this as a "shall", ISO 18385:2016 is now a Normative Reference.	Change "shall" to "should". You may want to add a caveat that if they don't purchase ISO 18385 items, they "shall" implement a decontamination process similar to 4.2.10.	Reject- Flexibility is already provided with the words "when possible".
82	4.2.9	4.2.8	T	It may be possible for a laboratory to purchase ISO 18385 consumables but it may not be practical for them to do so. They may not have validated the consumable, the consumable may be cost prohibitive, etc.	Change "possible" to "practicable"	Reject- When possible is stronger than when practicable.
19	4.2.10	4.2.9	T	If a laboratory does buy ISO 18385 consumables, do they still also have to use a decontamination process to those consumables?	If you add the proposed caveat to 4.2.9, remove consumables from this list.	Reject- Purchasing items from ISO 18385 minimizes the contamination risk. It does not eliminate it or eliminate the risk after a laboratory receives an item.

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124	4.2.10	4.2.9	E	should "for" be "from"?	…contamination from laboratory equipment...	Accept
51	4.2.11	4.2.10	T	Not all consumables have lot numbers, the addition of this statement would restrict the tracking to only items with lot numbers and not necessarily all reagents/consumables used during a process.	Suggest elimination of the added text "the lot numbers of".	Accept with modification- "lot numbers" was moved after reagent.
61	4.2.11	4.2.10	Technical	Unsure of what consumables are in this context (scalpels, Kimwipes, tips, plates, etc.)	Define consumables and/or add qualifier critical consumables	Reject-Consumable is a generic term left to laboratory discretion.
108	4.3.3		T	"The handling and packaging of evidence and samples to limit the possibility of contamination"	Please explain **how** these standards recommend this be accomplished? What are the best practices recognized by this body that a lab should implement to do this?	Reject- It is up to the laboratory to decide what are appropriate procedures.
109	4.3.3	4.3.3 d	E	The laboratory shall limit the opening and examining of no more than one item of evidence at a time.	The laboratory shall limit the opening and **examination to** one item of evidence at a time.	Accept
110	4.3.3	4.3.3 b	E	The cleaning of work surfaces and examination tools with DNA destroying reagents or processes before new evidentiary items are examined.	**The laboratory shall require** the cleaning of work surfaces and examination tools with DNA destroying reagents or processes before new evidentiary items are examined.	Accept
6	4.3.3.a-f		E	these sections are worded in different styles: a, b, and f are sentence fragments that go with the 4.3.3 sentence (which should end in a ":" if this style is kept), but c, d, and e start with "The laboratory shall"	adjust for style	Accept
135	4.3.3 - C	4.3.3 e		4.3.3 (c) should include separation for evidence collected from a crime scene or victim and evidence collected from a suspect to avoid cross contamination. 		Reject- See 4.3.3e. Only 1 item is open and examined at a time.
137	4.3.3 - C	4.3.3 g		Laboratories with automated pathways may not be able to guarantee that 4.3.3 c or d are met nor should they be required to if the automated pathway is validated.		Accept with modification. Section 4.3.3 d was modified to delete "during the entirety of processing....". For 4.3.3 c, was changed to require validated procedures to mitigate.
32	4.3.3 c	4.3.3 f	T	The laboratory shall examine and extract high template evidence (e.g., blood, semen, saliva) separately in time or space and independently from low-template evidence (e.g., epithelial cells/touch DNA).	Not all labs can do this and many items have both types of evidence, robotics help at extraction. Remove?	Accept with modification- The standard was modified and the word potential was added.
72	4.3.3 c	4.3.3 f	T	How does the lab know what is high and what is low?	"Efforts should be made to examine and extract high/low separately...."	Accept with modification- The standard was modified and the word potential was added.
83	4.3.3 c	4.3.3 f	T	This is not practical for a working forensic laboratory. Many labs employ robotics that are validated and capable of manipulating high and low template samples simultaneously or in sequence without contamination. It may not be apparent until after quantitation whether the evidence was high or low template; therefore, a lab could unintentionally violate the standard as written.	Remove 4.3.3 c entirely	Accept with modification- Section 4.3.3 c, was changed to require validated procedures to mitigate any risk of concurrent extraction.
4	4.3.3.c	4.3.3 f	T	this requirement is unneeded. Labs with high throughput systems/robots/ procedures have validated them to handle high and low template samples together on an extraction robot. If validation shows that no contamination occurs, there is no reason to implement a second stream of evidence	remove 4.3.3.c	Accept with modification- Section 4.3.3 c, was changed to require validated procedures to mitigate any risk of concurrent extraction.
53	4.3.3c	4.3.3 f	T	It is not always possible to recognize high template vs low template samples and is unreasonably restrictive.	Delete requirement	Accept with modification- The standard was modified and the word potential was added.
62	4.3.3c	4.3.3 f	Technical	Very little screening (especially with sexual assault kits that may contain semen or saliva) is still done prior to extraction and therefore we are unable to estimate the amount of DNA present. This is also not conducive with automation.	Remove the words "The laboratory shall examine high template separately in time in space" or delete high template and low template from the discussion.	Accept with modification- The standard was modified and the word potential was added.
69	4.3.3 c + d	4.3.3 e & f	T	I know this has been raised in the meeting, but this should read time *and* space.	time and space (in both c) and d))	Reject-The DNA CB already decided this point at a meeting.

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125	4.3.3 c), d) and e)		E	"The laboratory shall" is duplicated since it is included in 4.3.3	Delete "the laboratory shall" and modify the first word(s) appropriately for the context of 4.3.3 (e.g., The examination and extraction of…)	Reject- All sections were modified to include "the laboratory shall".
5	4.3.3.d	4.3.3 g	T	same comment as above	remove 4.3.3.d	Accept with modification- Section 4.3.3 c, was changed to require validated procedures to mitigate any risk of concurrent extraction.
20	4.3.3 d	4.3.3 e	T	Currently this reads as if you cannot load reference samples and evidence on the same CE plate for genetic analysis.	Change to, "The laboratory shall separate in time or space the processing of reference samples from evidentiary items during the entirety of laboratory processing from screening through PCR amplification."	Accept with modification- requirement deleted "during the entirety of processing…"
136	4.3.3 -D	4.3.3 e		4.3.3 (d) should include a requirement for separation in time and space for reference and evidence items. There have been documented contamination events between reference and evidence samples even when handled at different times within a laboratory. To allow the same space to be used for both types of samples is inviting contamination.		Reject-The DNA CB already decided this point at a meeting.
52	4.3.3d	4.3.3 e	T	It is not practical or possible for a laboratory to separate in time/space the processing of known and unknown samples during the entirety of the testing process. For instance, MPS combines samples into a single tube for analysis and automated platforms are specifically designed to run large numbers of batched samples. Laboratory validation should identify the steps in the process where the separation of K/Q samples is essential and when batching is allowed.	Delete requirement	Accept with modification- requirement deleted "during the entirety of processing…"
84	4.3.3d	4.3.3 e	T	As mentioned in the previous comment, many labs use robotics that can co-process evidence and reference samples simultaneously without contamination. This substandard is not necessary for a lab that has validated robotic tools.	Remove 4.3.3 d entirely or add exceptions for laboratories using validated robotic workflows.	Accept with modification- Section 4.3.3 c, was changed to require validated procedures to mitigate any risk of concurrent extraction.
133	4.3.3-D	4.3.3 e		4.3.3 (d) should be separate in time AND space for reference and evidence items. Should also be separate in time and space when examining items from suspects, items from victims, and items from crime scene in the one case . It is unacceptable to examine items from different suspects/victims on the one bench one after another, or worse at the same time, as this does not mitigate contamination.		Reject-The DNA CB already decided this point at a meeting.
21	4.3.3 e	4.3.3 d	E	Sentence reads awkwardly	Change "examining" to "examination"	Accept
73	4.3.3 e	4.3.3 d	T	Any though given to what happens in other lab disciplines before it ever gets to DNA in the first place? What's the point of DNA examiner having only 1 item open at a time when latent print branch fumed them all at the same time?	Address this at the laboratory level.	Reject- Outside the scope of the document.
126	4.3.3 e)	4.3.3 d	T	should this include the opening of only one tube containing DNA at a time? Limiting cross contamination of DNA on plates?	Expand this language to include steps during the DNA testing process, and not just limit to the initial handling of evidence	Reject- Plates which are used for most of the processing have all wells open.
54	4.3.3e	4.3.3 d	T	This standard seems to restrict laboratories to the examination of only one item even if the laboratory is composed of multiple examiners that could be working on separate cases simultaneously in separate work areas.	Delete requirement	Accept with modification- "at each workstation" was added to the requirement.
55	4.3.3f		E	The note addressing the SWGDAM Contamination document should be moved to the bibliography	move reference to the bibliography	Reject- The note was added to highlight specific procedures. It is also in the bibliography.
22	4.3.4		E	As it reads the lab has to document "when" item of evidence is packaged together, but timing is not something the lab might know. Further expand the description of what is to be documented.	Change to, "The laboratory shall document in the casefile when items of evidence are packaged together and how they were packaged."	Accept

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111	4.3.4		E	"The laboratory shall document when and how items of evidence are packaged together and include such information in the casefile." Unclear language	The laboratory shall document when and how items of evidence are packaged together by laboratory personnel and include such information in the casefile, as well as what steps shall be taken when items of evidence are received by the laboratory packaged together.	Accept with modification- The requirement was clarified.
127	4.3.4		T	It seems the intent of this is to document when evidence is received packaged together and to document how it was packaged, but the current wording seems to suggest that the laboratory needs a policy for packaging evidence together - not something typically needed by a laboratory.	Suggested edit: If evidence items are received packaged together, the laboratory casefile documentation shall include what items were packaged together and specify how they were packaged. (or detail how they were packaged)	Accept with modification- The requirement was clarified.
23	4.3.5		E	Provide more specific information concerning what you mean by use.	Add "evidentiary items" after "testing"	Accept with modification- Requirement was clarified.
24	4.3.6		T	Allelic drop-in is a analytical by-product (stochastic amplification artifact) and not exogenous DNA.	Remove the "(contamination and drop-in)"	Reject- See definitions for contamination and drop-in. Drop-in is exogenous DNA.
36	4.3.6		T	The laboratory should include in the log the source of the contamination (lab personnel, law enforcement, etc.) and document other information that would inform procedures to prevent future contamination events.	Revise 4.3.6 to state: The laboratory shall document, maintain, and periodically evaluate a log containing exogenous DNA (contamination and drop-in) found in any sample or control. [This log shall include the source of the contamination (if known), stage of contamination, individuals involved, and other information that would inform procedures to prevent future contamination events.]	Accept with modification- Part of the proposed change was accepted.
56	4.3.6		E	The added sentence requiring the availability of the log for audit purposes seems unnecessary since all documentation retained by a laboratory should be available for review	Delete added sentence	Reject- The log is crucial for audit review.
7	4.3.7		T	The addition is too far reaching, and many labs don't have the ability to do this type of search and will not be able to meet this requirement. Nor is it needed in many cases where there are no unknown profiles. DNA analysts should be able to select appropriate samples to compare to the database.	Remove "These searches shall occur for every comparable DNA profile obtained and"	Reject-Searching comparable profiles is essential to the Quality System.
37	4.3.7		T	The laboratory should search the DNA elimination database before comparing the evidence results to a suspect.	Revise 4.3.7 to state: The laboratory shall…These searches shall occur for every comparable DNA profile obtained **[before comparing the evidence results to suspects]** and all results shall be documented in the case file.	Reject- Overly prescriptive when the search is done is not as important as the fact that it is done.
63	4.3.7	4.3.6	Technical	Unclear on what OSAC means by the word "comparable." Unclear if this would include when there is no probative value to a sample (e.g. an assumed donor is the only contributor to the sample). We have determined what DNA profiles are comparable in our lab and require STRmix.	This is a broad term. Please define or provide additional information.	Accept with modification- "comparable" changed to "interpretable/comparable".
67	4.3.7		T	In 4.3.7, it seems that "These searches shall occur for every comparable DNA profile obtained and all results shall be documented in the case file." appears to contradict 4.3.10a "Comparing all mixtures, SS profiles, or deduced profiles to profiles contained within the DNA elimination database." For 4.3.7, does comparable mean interpretable (not inconclusive)? Does this mean one needs to search known DNA standards or an single source F1 (female fraction) from a vaginal swab differential extraction that matches the victim?	These statements should be consistent and the types of samples needs to be reasonable so as to not do unnecessary searches.	Accept with modification- "comparable" changed to "interpretable/comparable".

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74	4.3.7		T	So every profile suitable for comparison must be checked against the elimination database? Even those that match/include/accounted for by the references submitted in the case? That is not needed nor practical. Turing's rule says that we absolutely know we will get "results" for elimination databases randomly. As databases grow, there will be more "hits". This is expected, and offers nothing of value to the case file. Furthermore, if this required for every sample (seems to be current language) there will be numerous "hits" to the elimination database over time in the lab, even in samples where all DNA is accounted for by the references in the case.	Re-word this to address when it matters: "Unaccounted for profiles, no-suspect cases, alleles/genotypes/profiles not found in references" or similar. The only time something needs to be documented is when a contamination event was determined to have occurred and some corrective action was taken. Remove the part about checking every "comparable" profile. Remove the part about "all results shall be documented" as this is not realistic and only confuses things.	Reject- This documents supports comparing every interpretable DNA profile is searched and all elimination database search results should be documented.
25	4.3.7.1		T	During Round 1 of comment adjudication #110 proposed resolution states "delete laboratory visitors or move to a different list" and the comment is "Accept". But the red-line version appears to have "DNA laboratory visitors and" added. Including visitors is excessive and may cause privacy concerns outside the scope of the lab's control. It might be included as an option, but currently it's under a "shall" requirement. The "Where possible" starting the sentence doesn't address this because it is possible to get samples from all visitors, it may not be realistic.	Remove "DNA laboratory visitors and". You may consider a separate sentence to state, "When visitors are present in the DNA laboratory during analysis of evidence, elimination samples shall/should be collected and included in the database." Your choose between "shall" and "should".	Reject- It is important to collect DNA from anyone who is in the lab. The word "where possible" gives the laboratory some flexibility.
85	4.3.7.1		T	It is not feasible to include every partial low-level consumable contamination profile detected in a laboratory within an elimination database without generating a large volume of spurious matches. Reword this section to either remove that example or add a clarifying note.	At a minimum, this database shall include biology staff and positive control samples from donors and kits. A laboratory may also include contamination elimination profiles, such as unknown DNA profiles obtained from controls or profiles that have been putatively assigned as possible contamination profiles (e.g., from consumables), when these profiles have been determined to the extent that warrants inclusion in a searchable database.	Reject- Section 4.3.7.1 states profiles and not alleles from a variety of sources shall me included in the elimination database.
38	4.3.8		T	If a contamination result occurs in a intra-batch comparison, the results of these comparisons should be made available in every case file impacted.	Add to 4.3.8: If a contamination event occurs, it should be documented in every case file for the samples that were run in that batch.	Reject-Assessing the source of the contamination, and subsequently documenting the contamination event should at a minimum be in the affected casefiles.
64	4.3.8		Technical	Unclear how "Batch" is defined. When does this guideline attach in the process? How is this to be completed? This is too vague. We currently have many controls in place to detect contamination and have a process to document.	Further clarification on what is needed and the process to complete this task or remove the guideline all together.	Reject- Batch is defined in the parenthesis.
86	4.3.8		T	Many labs have workflows that involve samples coming together for a single quantitation plate that are then subsequently distributed to multiple (combined with other samples) amplification plates. With respect to "samples processed concurrently," is the intent to apply to all of those different analytical steps? That is not feasible in most high volume forensic laboratories.	Narrow the definition of "concurrently" or reword to "Intra-batch comparisons to detect contamination shall be conducted as practicable to the laboratory's established workflow"	Reject- Batch is defined in the parenthesis.
39	4.3.9.1		T	Transparency is critical and thus, the contamination assessment and underlying data should be available to the public.	Revise 4.3.9.1 to state: The laboratory shall include the contamination assessment and underlying data in the validation documentation **[and shall be posted online or made available upon request]**.	Reject- This is more appropriate for inclusion in a validation standard. This is a bigger issue than just contamination.
87	4.3.9.2		T	Not every procedural modification will require a contamination assessment. Adding an extra 15 minutes onto a PCR adenylation step, or doing a performance check of a new subversion of genotyping software (where no threshold changes are made) would not warrant a new contamination assessment.	Edit to be more focused on when a contamination assessment is warranted.	Reject- An assessment may mean that nothing needs to be done but it at least needs to be thought about.

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88	4.3.10		T	Not all labs are going to validate all aspects of a software program, so although a software tool may have the capability to do something, the lab may find, in validation, that is a feature that is not appropriate to use.	"… shall use such software within its validated capabilities to detect contamination…"	Accept
89	4.3.10 a		T	4.3.7 requires the that "comparable DNA profile[s]" be compared to the elimination database, 4.3.10 a requires ALL profiles.	Edit 4.3.10 a to cover interpretable samples, not all samples	Accept with modification- "comparable" changed to "interpretable/comparable".
8	4.3.10.a		T	not all profiles need to be checked - there is no need to check every profile against the elimination database	remove "all" and "single source profiles"	Accept with modification- "comparable" changed to "interpretable/comparable".
90	4.3.10 b		T	Mixture to mixture comparisons are not always feasible and detection of common sources does not necessarily support the investigation of contamination.	Remove this substandard.	Accept with modification- "comparable" changed to "interpretable/comparable".
66	4.3.10 b.c.d		Technical	Unclear on what OSAC means by these three.	Provide additional clarification on what this means and how to perform.	Reject- This is a laboratory dependent decision.
75	4.3.10 e		T	Remove e	There can be numerous random person LRs > 1 if enough profiles are compared to any samples. This is a fundamental tenant of DNA, and is described as Turing's rule. A small lab with only a 10-20 persons in an elimination database may only rarely see LRs >1. If a large lab system successfully gets profiles of first responders, investigators and so on (I know a lab with >1000 elimination profiles) they will get LRs >1 one in many, many mixtures. Often this has no meaning in the case whatsoever, as the submitted references account for the number of contributors to the mixture, and each reference has an LR >>>> than elimination database LRs.	Accept with modification- The LR threshold was changed to be determined by each laboratory.
91	4.3.10 e		T	This is not practical. A 4 person mixture may generate many likelihood ratios >1 that are simply spurious and not contamination. Laboratory thresholds MUST be used in order to filter out these matches so that a laboratory is not chasing down non-contamination incidents.	Remove this substandard.	Accept with modification- The LR threshold was changed to be determined by each laboratory
30	4.3.10 e		T	This requirement seems overly burdensome and potentially misleading to the customer and the courts. Some laboratory's have several hundred samples in their staff databases to monitor for contamination. The calculation of a LR >1 in a 4 person mixture does not indicate that the person is necessarily a source of contamination.	Change to "relevant" staff, individuals that actually had contact with the item. Additionally, an LR greater than 1,000 may provide more support for contamination than an incidental inclusion.	Accept with modification- The LR threshold was changed to be determined by each laboratory
9	4.3.10.e		T	this started out as a great way for labs to use their elimination database to detect contamination and improve their lab environment. These additional requirements have added an impossible burden on labs. A complex mixture has value in the calculated LR. If my elimination database is large, I can also expect to get additional fortuitous hits (if there is a low level contributor that would produce a low LR if compared). This does not implicate my lab in 10s or 100s of contamination events, it simply reflects the limited nature of the results. There is no benefit to the lab to detect and report these results. To suggest that a lab is "hiding" behind an LR threshold is absurd. Those labs are trying to focus on true contamination events and protect the resources required to track down true, damaging contamination. Tabulating these meaningless results in a report is also worthless, as it just adds confusion to an already complex report.	remove 4.3.10 e	Accept with modification- The LR threshold was changed to be determined by each laboratory

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57	4.3.10e		T	This requirement to report an LR>1 is arbitrary, discounts laboratory validation, and does not allow for troubleshooting or re-working samples. Adventitious LR>1 are known to occur with low level data and are not necessarily indicative of contamination. Requirement for tabulating in case report is inconsistent with 4.3.11 which requires documentation in the case record.	Amend requirement to: establishing a likelihood ratio threshold via internal validation studies for determining possible contamination events based on searching the elimination database.	Accept with modification- The LR threshold was changed to be determined by each laboratory
65	4.3.10e		Technical	"(greater than 1)" We have a higher number that we have established through a rigorous internal validation. This should supersede any arbitrary number established by these guidelines. Published data indicates that a low likelihood ratio value can produce adventitious inclusions. The larger the database, the more likely an adventitious inclusion can occur. Providing potentially adventitious inclusions in the report would be misleading.	Each lab should determine a likelihood ratio threshold value to report for comparisons to an elimination database. This should be documented in the casefile.	Accept with modification.- The last sentence of the suggestion was expanded
68	4.3.10e		T	Why do any LRs greater than 1 need to be tabulated in a report? Does report mean the report sent to the submitting agency with the DNA results? This is impractical because the more complex a mixture is, the more known non-contributors will have LRs >1. This does not mean they are actually contributors. A better check would be to see what the LRs are of true known non-contributors and compare the LRs >1 from the elimination database. An LR that is greater than the LRs from the known non-contributors would need to be investigated as possible contamination.	Remove "and tabulate them in the report".	Reject- A summary sentence is all that is required in the report as long as the data is maintained in the casefile.
76	4.3.10 f		T	Remove f or narrowly define this	It seems like the criteria for "potential" contamination is any LR>1 from an elimination data base. This would be a misuse of the elimination database and a misunderstanding of the LR and adventitious inclusions. When an actual contamination even is deemed to have occurred, then the case file needs to reflect it. But putting all LR>1 into a case file from an elimination database, and calling those "potential" contamination is incorrect. However, I may be misunderstanding this entire section.	Accept
92	4.3.10 f		T	Is a non-contributor test a check for contamination? How does this play into the detection of contamination?	Remove this substandard.	Accept
128	4.3.10 f)		T	possible word missing at the end - unclear what "non-contributor" is being referred to. Many individuals in a case may be non-contributors to a DNA profile, but that has nothing to do with elimination databases.	add appropriate missing word(s)	Accept with modification- the subsection was deleted.
10	4.3.10.f		T	this requirement is conflating an elimination database with a non-contributor database search. It doesn't belong here, and it should be recognized that using a non-contributor database as another/separate metric for the value of the evidence is not a universally accepted approach. The value of the evidence is best represented by the LR.	remove 4.3.10 e	Accept
58	4.3.10f		T	redundant with subpoint f	delete requirement	Accept
40	4.3.11		T	Transparency is critical and thus, the results of the root cause analysis should be available to the public.	Revise 4.3.11 to state: Potential contamination events shall be investigated and referenced or documented within the case record. When contamination is identified, a root cause analysis shall be conducted and documented [and shall be posted online or made available upon request].	Accept with modification- The language was partially modified.

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77	4.3.11		T	If any elimination LR>1 is a "potential" contamination, and requires an investigation, this will be a massive task for labs.	Find a different criteria than LR>1 from the elimination database for "potential" contamination. If that is NOT what the document is using as the main criterion, the document needs to be re-written to make the actual criteria more clear to the reader.	Accept- 4.3.10 e was modified to remove the requirement for an LR>1.
26	4.3.12		E	You don't need the word "also"	Remove "also"	Accept
11	4.3.13		T	there is not always a legal party assigned/available at the time of the testing and reporting. The customer of the laboratory is the investigator, and the laboratory should not be accountable to report contamination to the legal parties. These records are maintained in the case file and available during discovery.	change back to customer	Accept with modification- Customers were added and legal parties modified if known.
59	4.3.13		E	Laboratories should determine the parties authorized to receive the results of testing performed.	Suggest deleting all text following communicating contamination events.	Accept with modification- Customers were added and legal parties modified if known.
129	4.3.13		T	also add "clients" or other designation for individuals who submitted the evidence and are the receivers/users of the reports initially (e.g., other crime labs, law enforcement, private individuals, court); on another note, isn't this requirement outside the scope of this document since this is not preventing, monitoring or mitigating contamination	expand the list of individuals who need to be notified of any contamination event beyond attorneys or delete the requirement all together since it is outside the scope of this document	Accept with modification- Customers were added and legal parties modified if known.
27	4.3.14		E	The use of the word "health" is strange here and doesn't match the definition of the word.	Replace "health" with "suitability", "robustness", or "appropriateness".	Accept
3	4.3.2.2		E	i.e. should be e.g. - this is an example, not the only way it can be accomplished	change to e.g.	Accept
130	4.4.2		T	suspension for the whole laboratory or for an individual?	clarify what suspension is being referred to	Reject- The laboratory has to define when suspension refers to an individual or the whole laboratory.
28	4.4.2 c		T	Using just "review of casework" does not indicate that the review may require additional cases.	Change to, "the extent of review of other casework"	Reject- The laboratory's policy would include the extent of the review of casework.
131	4.4.2 f)		T	unclear what "post-contamination review" means and what is being reviewed	Provide more information or definition for this	Accept with modification- The term was removed.
41	4.5.1		T	There should be a timeframe for when trainings will occur.	Add that trainings should occur yearly or at the beginning of employment.	Reject- It is laboratory discretion for the training.
29	4.5.2		E	Can this be made into a list because when contained in this sentence the individual requirements get lost in the "ands" within each clause.	Reorganize list	Accept
132	4.5.2		E	flow is awkward	maybe add a ":" after "include" to prevent associating "the use of" with the later items in the list	Accept with modification- Was reorganized as a list.
33	Bibliography		E	link for footnote c does not work	update link	Accept with modification - link and reference was updated to Version 2 instead of keeping the link for Version 1
134	Bibliography			Reference 12 should not have "NIST" as the author. This is a National Commission on Forensic Science document, so NCFS should be the listed author. The footnote URL is correct.		Accept with modification - reference was updated to remove NIST as the author. Link listed in footnote h was verified to work.