**Deadline of Submission** 3-Oct-22
**Document Title:** ASB Standard 175, Standard for Interpreting, Comparing and Reporting DNA Test Results Associated with Failed Controls and Contamination Events

| # | Section | Type of Comment | Comments | Proposed Resolution | Final Resolution |
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| 40 | General | T | This standard does not provide a list of scenarios that should and should not require retesting. | Include a list of scenarios that should require retesting. (e.g., reagent contamination, possible masking of low level sample by contaminant, possible sample switch-up, etc.). | Reject. This standard applies only where re-testing is not performed. If re-testing is performed for any reason and the new data are used instead, then the laboratory's standard procedures apply to the interpretation, comparison and reporting of the DNA data; this document would not be applicable. Additional information has been added as a note in 4.2.1. Also see Annexes A & B. |
| 15 | General | T | This standard does not provide a list of scenarios that should and should not require retesting. | Include a list of scenarios that should require retesting. (e.g., reagent contamination, possible masking of low level sample by contaminant, possible sample switch-up, etc.). | Reject. This standard applies only where re-testing is not performed. If re-testing is performed for any reason and the new data are used instead, then the laboratory's standard procedures apply to the interpretation, comparison and reporting of the DNA data; this document would not be applicable. Additional information has been added as a note in 4.2.1. Also see Annexes A & B. |
| 44 | General | | I voted "Yes" for this standard, but it needs more clarification on when this should and should not be used based on previous comments. | | No proposed resolution was provided. If re-testing is performed for any reason and the new data are used instead, then the laboratory's standard procedures apply to the interpretation, comparison and reporting of the DNA data; this document would not be applicable. Additional information has been added as a note in 4.2.1. Also see Annexes A & B. |
| 45 | General | | The examples in Annex A were helpful in understanding the intent of this standard and where it may be useful in specific situations. | ASB NOTE: CB Comment, Resolution may be in the comment. | This is a positive statement. No issue was provided and no resolution was proposed therefore no action was taken. |
| 46 | General | | Retesting the samples would seem the most appropriate action to take when controls fail. While this document addresses instances where retesting is not undertaken, it does not appear to address what conditions would preclude retesting<br>(Such as when the entire evidence sample was consumed) | ASB NOTE: CB Comment, Resolution may be in the comment. | Accept. Additional information has been added as a note in 4.2.1. |
| 47 | General | | Although I can understand why it may be informative to use data associated with failed controls in extenuating circumstances, it carries a lot of risk and the procedure should include more requirements for analysis of this risk. I would like to see more stress made in this procedure that it is to be used only when samples have been consumed or are otherwise unavailable for retesting. The reporting requirement in 4.3 should also include a stronger statement regarding the failed controls and the associated risks in using this data. | ASB NOTE: CB Comment, Resolution may be in the comment. Comment provided via email for modifying 4.3: When reporting interpretations and comparisons associated with a failed control or contamination event, the report shall identify the DNA test results associated with the failed controls, the rationale for using the results, the limitations of and any identified risks with the use of the data. | Accept with modification: The performance and documentation of the assessment of the integrtity of the data is required under 4.2. A note was added to 4.2 "It is intended that this is performed and documented in conjunction with the laboratory's documented quality assurance program." Risk assessment associated with moving forward with data interpretation vs. with re-testing is required under 4.2.1 with documentation in the case record required under 4.5.4. The risk assessment would be case and sample dependent and would require the use of the laboratory's documented quality assurance program, validation studies and procedures manuals. 4.3 requires the reporting of the event and the impacted results. |
| 48 | General | | There needs to be more clarification on when and how to use data with failed controls and how to describe the risk associated. | ASB NOTE: CB Comment, Resolution may be in the comment. | Accept. Additional information has been added as notes in 4.2 and 4.2.1. |
| 49 | General | | This standard will be used by labs to circumvent controls. The standard will essentially eliminate controls which are needed to ensure quality. | ASB NOTE: CB Comment, Resolution may be in the comment. | Reject. No resolution was proposed. Controls are mandatory in labs for PCR testing due to the known risks associated with the testing. |
| 50 | General | | If this standard is intended to provide guidance on the types of items that should be included in the assessment and what constitutes "risk", then it is not adequate. It seems that if there are nearly as many examples as there are standard elements, then the standard does not completely clarify its requirements. | ASB NOTE: CB Comment, Resolution may be in the comment. | Accept with modification. Additional guidance is provided in notes under 4.2and 4.2.1 to assist the lab in the processes that may be followed and issues to address. |
| 51 | General | | Having been involved with the standard at OSAC, I know the reason this was written was to address cases where there was exculpatory or probative information in a sample associated with contamination or a failed control but there was no sample left to re-test. But I don't see that in here and feel that without that being stated, the standard could be misused and labs could skip re-running samples that could easily be re-run. | ASB NOTE: CB Comment, Resolution may be in the comment. | Reject. While this document is critical for the evaluation of data where re-testing is not possible, especially where an exclusion can be reported, it may also be used according to the laboratory's QA/QC program, validation studies and protocols for inclusionary data. Re-testing may not always be the prudent decision. |

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| 52 | General | | If the laboratory is permitted to report information gathered during a run with a failed control, this organization should be giving specific and clearly defined guidance as to what the boundaries of what can be reported after such an incident. This standard will be used to support low-quality and potentially misleading evidence that will likely be misunderstood and given an inappropriate weight by the legal audience of the report. | ASB NOTE: CB Comment, Resolution may be in the comment. | Accept with modification. Additional information has been added as notes in 4.2 and 4.2.1. Laboratories must rely on their documented quality assurance programs (e.g., under ISO 17025) to research the event, document the process, etc. and their validation studies and protocols for the interpretation and comparison of the data (e.g., Standard 40) to assess if the data are suitable for interpretation. |
| 53 | General | | Comments submitted to ASB. "Handling error" is mentioned in the forward as a reason for this standard, yet, it is not included in the title nor throughout the document. | ASB NOTE: CB Comment, Resolution may be in the comment. | Reject. The focus of this standard is not on handling errors, although handling errors may be one possible cause of contamination. |
| 54 | General | | There should be more clarity in what types of extenuating circumstances (consumption of samples) allow for interpretation with failed controls. Without extenuating circumstances, some type of retesting should be performed when controls fail. | ASB NOTE: CB Comment, Resolution may be in the comment. | Reject. While this document is critical for the evaluation of data where re-testing is not possible, especially where an exclusion can be reported, it may also be used according to the laboratory's QA/QC program, validation studies and protocols for inclusionary data. Re-testing may not always be the prudent decision. |
| 55 | General | | The standard is too susceptible to being used to justify unreliable results and could erode the importance of controls and contamination prevention and mitigation protocols. More specificity is needed in section concerning the weighing of the risk associated with data interpretation vs. the risk of retesting (4.2.1) | ASB NOTE: CB Comment, Resolution may be in the comment. | Accept with modification. Additional information has been added as notes in 4.2 and 4.2.1. |
| 1 | Foreword | T | The first paragraph needs some qualifiers to properly orient the reader to the point of the Standard | Add: "or a contamination event may NONETHELESS provide critical" and "it may STILL be possible to interpret" | Accept with modification. The first paragraph of the Foreword has been reorganized and modified slightly in response to this comment. |
| 21 | Forward paragraph 2 | | Missing handling error | | Reject. The focus of this standard is not on handling errors, although handling errors may be one possible cause of contamination. |
| 41 | Forward, Para 1 | E | This language is inappropriate for a scientific standard. The only quesiton relevant to an examiner in this regard is whether data is scientifically valid, not whether it might be "critical" as a piece of evidence in a criminal case. | Evaluation and reporting of data possibly compromised by failed controls or a contamination event<br>may provide valid information under some circumstances. | Accept with modification. "to support the investigation of" was deleted. |
| 16 | 1 Scope | T | In the forward it lists three reasons these requirements would need to be applied 1- control failed, 2- handling error, 3 - contaminating event. The scope only includes control failure and contamination | Include handling error into the scope | Reject. The focus of this standard is not on handling errors, although handling errors may be one possible cause of contamination. |
| 2 | 3.4 | E | Needs a period instead of a semicolon at the end | Replace semicolon with period | Accept. |
| 22 | 3.4 | E | end sentence with period | delete ";" and insert "." | Accept. |
| 23 | 3.4 | T | other docs (ASB 139) use the term "evidentiary sample" and it has an almost identical definition; the definition of reference sample at 3.8 uses "evidentiary sample". | change to "evidentiary sample: Biological sample recovered from a crime scene or collected from persons or objects associated with a crime." Also replace "forensic sample" with "evidentiary sample" throughout. | Accept with modifcation. Forensic sample embraces any type of sample including evidentiary samples, but is not exclusive. The definition was replaced with the suggested definition. |
| 17 | 3.6 Note | | negative controls include extraction blanks | negative controls **may** include extraction…. (this would mimic the wording of the positive control) | Accept with modification. The positive control definition was re-written to mimic the negative control. |
| 24 | 3.10 | T | the definition in ASB 139 stops after "…qualtiy assurance requirements…"; since the this is addressed multiple times in the standard, it isn't needed here | remove the phrase "this decision is based…" | Accept with modification. Definitions 3.9 & 3.10 were slightly edited to have the same wording. |
| 25 | 3.10 | E | defined word should be on the line following the number | add hard return | Accept. |
| 18 | 4.1 | | Again, contamination is here and failed controls, but not handling error | g) a handling error | Reject. The focus of this standard is not on handling errors, although handling errors may be one possible cause of contamination. |
| 3 | 4.1(d) | E | There is an extra space between "in" and "reference" | Remove the extra space | Accept. |
| 26 | 4.1.d | E | extra space between "in" and "reference" | remove extra space | Accept. |
| 11 | 4.2 | T | A failed positive control (non-contamination or artifact event) is not applicable to this standard. Failed positive controls should result in automatic retesting. The positive control is used to assess if the reagents are active, instruments are working properly (Thermocycler and CE system), any human error was made, etc. If a positive control fails, there is a high probability that the other samples in that batch was affected. Hence, the whole batch should be retested | Remove language about failed positive controls. All failed positive controls (no peaks, spectral shift, or wrong profile) should result in retesting. | Reject. When review, assessment and/or with some limited retesting demonstrates that the only reason the positive control failed was due to analyst error of not adding the DNA, and supports that the reagents used worked correctly, then it may be appropriate to interpret and compare the profiles obtained for some samples. |
| 13 | 4.2 | T | If artifacts are present in the negative or positive controls, the lab should used the appropriae protocol to determine and record if those artifacts are presented in other samples. | Include a section under 4.2, to detail the action of the analyst if artifacts are observed in the positive andnegative controls. | Reject. Artifact determination should be in the laboratory's interpretation and comparison protocol. This comment is outside the scope of this document. |
| 27 | 4.2 | E | rephrase | shall assess and document the integrity | Reject. The word "perform" is retained to refer to the action of performing the assessment per the QA protocols. |

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| 36 | 4.2 | T | A failed positive control (non-contamination or artifact event) is not applicable to this standard. Failed positive controls should result in automatic retesting. The positive control is used to assess if the reagents are active, instruments are working properly (Thermocycler and CE system), any human error was made, etc. If a positive control fails, there is a high probability that the other samples in that batch was affected. Hence, the whole batch should be retested. | Remove language about failed positive controls. All failed positive controls (no peaks, spectral shift, or wrong profile) should result in retesting. | Reject. When review, assessment and/or with some limited retesting demonstrates that the only reason the positive control failed was due to analyst error of not adding the DNA, and supports that the reagents used worked correctly, then it may be appropriate to interpret and compare the profiles obtained for some samples. |
| 38 | 4.2 | T | If artifacts are present in the negative or positive controls, the lab should used the appropriae protocol to determine and record if those artifacts are presented in other samples. | Include a section under 4.2, to detail the action of the analyst if artifacts are observed in the positive andnegative controls. | Reject. Artifact determination should be in the laboratory's interpretation and comparison protocol. This comment is outside the scope of this document. |
| 42 | 4.2 | E | Despite ostensibly being a standard for interpreting, comparing, and reporting DNA test results associated with failed controls and contamination, the standard gives almost no guidance to how labs should actually undertake to do this. Almost all of what might give this standard real depth (i.e., how to determine whether "the impact of the failed control or contamination" has affected the integrity of the results) is offput to laboratory policy. While Annex A is useful, without actual guidance within the standard about how lab protocols should address this situation, the standard will not be helpful to FSSPs. | Give evidence-based guidance to FSSPs about how the impact of contamination and failed controls should be assessed vis-a-vis the integrity of any results and what lab policies and protocols should direct in this regard. | Accept with modification. Additional information has been added to notes in 4.2 and 4.2.1. Laboratories must rely on their documented quality assurance programs (e.g., under ISO 17025) to research the event, document the process, etc. and their validation studies and protocols for the interpretation and comparison of the data (e.g., Standard 40) to assess if the data are suitable for interpretation. |
| 28 | 4.2.1 | E | first sentence: why list the protocols? Second sentence: should be a separate number (4.2.2) and could be shortened for simplicity | end first sentence after 'validation studies and protocols.' put second sentence in 4.2.2 and rephrase: This assessment shall determine: (1) the possible cause and effect of the failed control and contamination and (2) the risks of interpreting the data rather than retesting. | Reject. The suggested phrase recommended for deletion is critical clarifying information. The second sentence is part of the point of this requirement and should stay with the first sentence. |
| 32 | 4.2.1 | Clarification | The assessment shall be based on the laboratory's validation studies and protocols, including but not limited to interpretation and comparison protocol(s) and quality assurance protocols. This assessment shall include a determination of the possible cause and effect of the failed control or contamination, and an assessment of the risks associated with moving forward with data interpretation vs. those associated with re-testing. | Is the intent of the portion in red to include all of this documentation in the report just in the entire discovery? I read it as an assessment must occur and therefore must be documented somehow. | Reject. Requirement 4.2 has "document the assessment." Requirement 4.3 covers reporting, and Requirement 4.5 includes information regarding documentation in the case record. |
| 29 | 4.2.2 | E | redundant to list validation and SOPs | remove "for interpretation / comparison within the constraints of the laboratory's internal validation studies and documented interpretation and comparison protocols" | Reject. This is a separate requirement under 4.2 and not a subsection of 4.2.1, and therefore is not redundant. |
| 4 | 4.2.3 NOTE | T | This should be more than a NOTE | Move it from a NOTE to 4.2.4 | Reject. This is a note that addresses samples that are retested and is outside the scope of this document. This is simply a reminder that if some samples are re-tested, that it may need to be reported according to the existing laboratory protocols. |
| 5 | 4.2.3 NOTE | T | If retesting is done, reporting of results should be mandatory | Replace "it may be necessary" with "it shall be necessary" | Reject. This is a note that addresses samples that are retested and is outside the scope of this document. This is simply a reminder that if some samples are re-tested, that it may need to be reported according to the existing laboratory protocols. |
| 30 | 4.2.3, also in the NOTE | E | brevity | remove "compromised to the extent of being". Should "interpretation" in the last sentence be "interpretation / comparison"? | Accepted. |
| 14 | 4.3 | T | The report should also have a summary of the root cause analysis and the integrity assessment. | "...the report shall identify the associated DNA test results, describe the nature of the event, hav a summary of the root cause analysis, and state how the failed control or contaminant impacted the integrity of the sample." | Reject. This documentation is required under 4.2 and 4.5. |
| 31 | 4.3 | T | It is not clear if this means both if the sample is not retested and if it is retested. | "When reporting interpretations and comparisons associated with a failed control or contamination event whether retested or not, the report shall identify the associated DNA test results and describe the nature of the event." | Reject. This document applies to situations where a sample is not re-tested; thus reporting is required per 4.3. If re-testing is performed, then the laboratory procedures for reporting in that scenario would apply. Some of the examples in Annex B are provided for additional information regarding re-testing. |
| 39 | 4.3 | T | The report should also have a summary of the root cause analysis and the integrity assessment. | "...the report shall identify the associated DNA test results, describe the nature of the event, hav a summary of the root cause analysis, and state how the failed control or contaminant impacted the integrity of the sample." | Reject. This documentation is required under 4.2 and 4.5. |
| 10 | 4.4 | T | Agency counsel (and potentially external oversight entities) would need to approve release of identifying information, especially when it relates to agency staf | Make a suggestion, not a "shall" | Reject. The protocol should provide what information is permissible for release per agency and legal requirements. Also see Note to 4.5.2. |

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| 33 | 4.4/4.5.2 Note | Clarification | 4.4 The laboratory shall have a written protocol for the release of identifying information for the source of the contamination. 4.5.2 The likely or known source of contamination. NOTE If an individual is determined to be the source, that individual may be identified by name, employment position or other descriptor as permitted by law and agency policies. | What if lab counsel does not approve of this? What if the union has issue with the identify or release of a staff associated profile? | Reject. The standard requires a protocol for addressing and reporting any identifying information according to legal and agency policies. It does not require the release of a specific name, for example. |
| 19 | 4.5 | | Missing handling error | with a failed control, handling error, or contamination event; add a 4.5.6 for language when it is a handling error | Reject. The focus of this standard is not on handling errors, although handling errors may be one possible cause of contamination. |
| 12 | 4.5.1 | T | Case records should also include actions taken to investigate or resolve the issue. | Include a section that requires lab to record their investigation tactics and resolutions. | Reject. The documentation is required under 4.2 in conjunction with 4.5. The statement "the required assessment detailed in 4.2" has been added to 4.5 for clarity. |
| 37 | 4.5.1 | T | Case records should also include actions taken to investigate or resolve the issue. | Include a section that requires lab to record their investigation tactics and resolutions. | Reject. The documentation is required under 4.2 in conjunction with 4.5. The statement "the required assessment detailed in 4.2" has been added to 4.5 for clarity. |
| 6 | 4.5.2 NOTE | T | The "may" doesn't do enough work, and it should be mandatory as permitted by law | Replace "may be identified" with "shall be identified" | Reject. The actual requirements of 4.4, 4.5 and 4.5.2 specify identifying the source of contamination. The note simply clarifies that the identification may take several different forms as permitted by law and/or policy. |
| 7 | 4.5.5 | T | Should also provide an explanation for why the determination was suitable or unsuitable | At the end, add ", and why that determination was made." | Reject. This recommendation is covered under requirements 4.2, 4.3, the FBI Quality Assurance Standards, and ANSI/ASB Standard 40. ADD 139?? |
| 34 | Annex | Clarification | Realizing these are examples, which are quite lengthy, wondering if labs choose to re-amp immediately samples that have failed controls, is this entire portion needed? It seems this is a lot of additional work and notification if extract is available. | | No proposed resolution was provided. If re-testing is performed on all samples, then this document is not applicable. Root cause, corrective action and other quality assurance procedures in the laboratory would apply. |
| 20 | Annex A | | Missing handling error | | Reject. The focus of this standard is not on handling errors, although handling errors may be one possible cause of contamination. |
| 43 | Annex A | E | These examples provide scenarios where logic suggests results may be useable, but no examples that demonstrate a laboratory making an assessment "based on the laboratory's validation studies and protocols." This is particularly problematic because the standard requires that FSSPs assess the integrity of results on these bases, but provides no guidance on how to do it. | Provide detailed examples that demonstrate a laboratory making an integrity assessment "based on the laboratory's validation studies and protocols." | Reject. Every evaluation of DNA data in all laboratories must be based on the laboratory's detailed protocols (and not just loose guidelines), which must be based significantly on the laboratory's internal validation studies. This is not unique to the evaluation for the limited use in this standard. See also ANSI/ASB standards 18, 20 and 40. |
| 8 | Annex A (1) | T | The reference to "expected" results is problematic in this example, because it allows for backward logic to justify using the results | Remove "and, where predictable, the expected results" and the accompanying parenthetical. | Reject. Based on the type of sample tested (e.g., fresh vs. old blood stain, small vs. large number of sperm, handled item, known reference standard) and the quantitation results (e.g., amount and ratio of DNA from male-to-female, degradation index), it is often possible to predict the general quality and minimum number of contributors to the DNA profile prior to looking at the data in the electropherogram. |
| 9 | Annex A (5) | T | The reference to "was consistent with" is problematic in this example, because it allows for backward logic to justify using the results | Remove this example | Reject. The complainant's own profile is typically observed in the epithelial/non-sperm fraction of DNA recovered from body swabs. It is reasonable to expect the individual's profile to be present. In fact, the absence of the profile may suggest a possible problem. |
| 35 | Bibliography | Editorial | Link to FBI QAS | The link goes to a generic FBI webpage that is cumbersome to search. Suggest instead linking to the SWGDAM page for the QAS directly | Accepted. |