Deadline For Public Comments: October 3, 2022

ASB Std 123, Standard for Routine Internal Evaluation of a Laboratory's DNA Interpretation and Comparison Protocol

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
8		T	This standard should include a list of tasks that may be required to complete the interpretation/comparison.	E.g., electropherogram editing, peak height and mixure ratio calcuations, using a PGS, generating input data for PGS, calculating RMP, etc.	Reject. No resolution addressing modifications to the document was provided. In addition, the goal of this standard is to assess the continued application of the interpretation and comparison protocol by the analysts in the laboratory per requirement 4.1. The range of the assessment is at the discretion of the administrator to decide what sections of the protocol are to be evaluated using various types of relevant DNA mixtures.
17	Foreward Foreword	T	Going along with my comments about who should be taking the evaluation ("analyst" or anyone doing PTs): "Compliance with this standard allows the laboratory to demonstrate reliable and reproducible DNA interpretation, comparison and reporting by the analysts of profiles that range in complexity and are representative of those encountered in casework." Should there be any comment about technical reviewers (who are not "analysts")?	IF it will actually only be "analysts" who undergo this evaluation, leave statement as current. IF the intention is to have any individual who is in any way involved in mixture proficiency testing do this evaluation: "The responses from the participants shall include..."	Accept. "the analysts" was changed to "each participant in the evaluation"
1	3.5	E	Stochastic effects are random variations or differences and not necessarily "changes".	"Random variations in a DNA profile that generally occur when suboptimal or limiting quantities of DNA are tested."	Reject. This definition had no redline changes, therefore the Working Group and Consensus Body are not required to address this comment.
9	4.1	Clarification	Would like to verify the TL must complete this evaluation only if currently taking PTs. Does this standard assume all TL take PT and are current with proficiencies?		No resolution was proposed. Only a clarification question was asked. 4.1 clearly states "All proficiency-tested individuals…who are performing mixed DNA data interpretation and/or comparisons including analysts, technical reviewers and the technical leader…"
12	4.1	E	The "NOTE" has first formula as "(n-1)/2" and second formula as "(n+1)/2". However, the example of 7 analysts has been updated in this version to have 4 examiners on the year one test [4 being consistent with "(n+1)/2"] and having 3 examiners on the year two test [3 being consistent with "(n-1)/2"]. It is odd that the order of the number of examiners has been updated to be counterintuitive to the order of the formulas.	If keeping the formulas in the current order: "e.g., if there are 7 examiners, then 3 examiners will be tested in year one, and 4 will be tested in year two (or vice versa)]." OR, if keeping 4 examiners on year one and 3 examiners on year two, then: "If the number of examiners (n) is odd, then (n + 1) / 2 and (n - 1) / 2 will be tested in alternate years"	Accept. The equations have been rearranged for consistency.
13	4.1	T	"All proficiency-tested individuals in the laboratory who are performing mixed DNA data interpretation and/or comparisons including analysts, technical reviewers, and the technical leader, shall fulfill the requirements of this standard a minimum of once every two years." I do not agree that someone acting solely in the role of a technical reviewer is "perfoming mixed DNA data interpretation and/or comparisons". Nor is someone acting solely in the role as a technical leader (a TL who is not being casework proficiency tested).	If the intention is to evaluate all staff who have any level of proficiency testing that includes mixtures: "All proficiency-tested individuals in the laboratory who are performing, or reviewing, mixed DNA data interpretation and/or comparisons, shall fulfill the requirements of this standard a minimum of once every two years." If the intention is to evaluate all staff who actually perform (not just review) proficiency testing that includes mixtures: "All proficiency-tested individuals in the laboratory who are performing mixed DNA data interpretation and/or comparisons, shall fulfill the requirements of this standard a minimum of once every two years."	Reject. "All proficiency-tested individuals" refers to all individuals in the laboratory who participate in proficiency tests. If they perform mixed DNA data interpretation and/or comparisons, they are required to participate in this internal evaluation per this requirement.
22	4.1	T	Is there a standard or assumption that the technical leader be proficiency tested and therefore required to fulfill the evaluation every two years, and be able to administer the evaluation?	Define technical leader requirement for proficiency and/or clarify if technical leader needs to participate in evaluation.	Reject. "All proficiency-tested individuals" refers to all individuals in the laboratory who participate in proficiency tests. Anyone who performs mixed DNA data interpretation and/or comparisons, is required to participate in this internal evaluation per this requirement regardless of job title.
2	4.1.1	E	Change "frequency with" to "level at"	"... the level at which each technology, kit, and protocol used within the laboratory will be evaluated using this standard."	Reject. This requirement had no redline changes, therefore the Working Group and Consensus Body are not required to address this comment.

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3	4.1.2	E	This sentence "When the technical leader (or equivalent) is participating in the internal evaluation, the technical leader shall assign another person to take on the administrator role. " seems out of place	Make it subsection 4.1.3 or add to the definition of adminstrator.	1) Reject making the statement 4.1.3; it was left as is. 2) Accept with modification - the definition of administrator was modified to state: "The indivdiual who oversees, but does not participate in, the evaluation"
10	4.1.2	Clarification	When the technical leader (or equivalent) is participating in the internal evaluation, the technical leader shall assign another person shall to take on the administrator role.	Not sure if this is written to allow the TL to not participate due to time or due to not being current in PTs (especially since 4.4 and 4.4.1 have removed TL language and refer to adminstrator only)	No resolution was proposed. Only a clarification question was asked. The technical leader cannot both coordinate and participate in the evaluation. This provides guidance for someone else to take on the admininstrator role when the TL is required to participate in the evaluation.
11	4.1.2	E	Current wording: "When the technical leader (or equivalent) is participating in the internal evaluation, the technical leader shall assign another person to take on the administrator role." This does NOT state that the other person taking on the admin role cannot be taking the evaluation. As such, why would it be necessary for the TL to not be the administrator of an evaluation they are taking, but any other random analyst could be the administrator of an evaluation they are taking?	Since 3.1 states that the administrator is not restricted to being the TL: "The administrator shall not be a participant in the evaluation." IF going with the assumption that that TL will routinely be the administrator: "When the technical leader (or equivalent) is participating in the internal evaluation, the technical leader shall assign another person (who themselves is not a participant) to take on the administrator role."	Accept with modification. The definition was modified to state: "The indivdiual who oversees, but does not participate in, the evaluation."
18	4.2	T	Going along with my comments about who should be taking the evaluation ("analyst" or anyone doing PTs): "Mixed DNA data under evaluation shall be provided to each analyst participating in the evaluation, and shall meet the following criteria."	IF it will actually only be "analysts" who undergo this evaluation, leave statement as current. IF the intention is to have any individual who is in any way involved in mixture proficiency testing do this evaluation: "Mixed DNA data under evaluation shall be provided to each individual participating in the evaluation, and shall meet the following criteria."	Accept. Changed "analyst" to "individual"
19	4.2.c	T	Going along with my comments about who should be taking the evaluation ("analyst" or anyone doing PTs): "... the data used shall not have been previously interpreted by the analyst(s) participating in this evaluation."	IF it will actually only be "analysts" who undergo this evaluation, leave statement as current. IF the intention is to have any individual who is in any way involved in mixture proficiency testing do this evaluation: "... the data used shall not have been previously interpreted or reviewed by the individuals participating in this evaluation."	Accept. Changed "analyst" to "individual"
4	4.2 (c)	E	"Shall not have been" is awkward	"...the data used shall not be any that was previously interpreted by the analyst(s) participating in this evaluation. "	Reject. This requirement had no redline changes, therefore the Working Group and Consensus Body are not required to address this comment.
5	4.2 (f)	T	Alllele overlapping also affects mixture complexity.	"...mixture complexity shall include variations in template amount, contributor ratio, number of contributors, and allele overlapping."	Reject. This requirement had no redline changes, therefore the Working Group and Consensus Body are not required to address this comment.
6	4.2 (f, seventh bullet)	E	For the statement "that are mixtures requiring subjective decisions and/or analyst discretion, if any exist in the protocol;" change subjective decisions to deductive reasoning to emphasis that the decisions, even if it's subjective, should be logical.	"that are mixtures requiring deductive reasoning and/or analyst discretion, if any exist in the protocol;"	Reject. This requirement had no redline changes, therefore the Working Group and Consensus Body are not required to address this comment.
7	4.2 (f, eight bullet)	E	"That exceed the parameters and limitations of the laboratory protocol" is redundant because all DNA profiles that exceeds the parameters and limitations of the lab should be deemed as "uninterpretable or unsuitable for comparison"	Remove "that exceed the parameters and limitations of the laboratory protocol. "	Reject. This requirement had no redline changes, therefore the Working Group and Consensus Body are not required to address this comment.
20	4.2.f	T	Going along with my comments about who should be taking the evaluation ("analyst" or anyone doing PTs): "-- that are mixtures requiring subjective decisions and/or analyst discretion, if any exist in the protocol;"	IF it will actually only be "analysts" who undergo this evaluation, leave statement as current. IF the intention is to have any individual who is in any way involved in mixture proficiency testing do this evaluation: "-- that are mixtures requiring subjective decisions and/or individual discretion, if any exist in the protocol;"	Accept. Change to "analyst/individual"

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21	4.4.1	T	Going along with my comments about who should be taking the evaluation ("analyst" or anyone doing PTs): "...and that the assumptions and propositions made by the analysts are consistent with the laboratory's protocol."	IF it will actually only be "analysts" who undergo this evaluation, leave statement as current. IF the intention is to have any individual who is in any way involved in mixture proficiency testing do this evaluation: "… and that the assumptions and propositions made by the participants are consistent with the laboratory's protocol."	Accept. Changed "analysts" to "participants"
16	4.4.2	T	Going along with my comments for 4.1, 5.1.e, and 5.2 (who should be evaluated), it is noted that 4.4.2 states "The responses from the analysts shall include...". An individual who is only a technical reviewer or only a TL (neither actually performing casework analysis, nor perfoming proficiency test interpretations) is not "an analyst".	IF it will actually only be "analysts" who undergo this evaluation, leave statement as current. IF the intention is to have any individual who is in any way involved in mixture proficiency testing do this evaluation: "The responses from the participants shall include..."	Accept. Changed "analysts" to "participants"
14	5.1.e	T	Going along with my comment for 4.1 (who should be evaluated), it is noted that 5.1.e states that "the orginal documentation from each analyst...". An individual who is only a technical reviewer or only a TL (neither actually performing casework analysis, nor perfoming proficiency test interpretations) is not "an analyst".	IF it will actually only be "analysts" who undergo this evaluation, leave statement as current. IF the intention is to have any individual who is in any way involved in mixture proficiency testing do this evaluation: "the original documentation from each individual who performed the annual evaluation;"	Accept. Changed "analysts" to "participants"
15	5.2	T	Going along with my comments for 4.1 and 5.1.e (who should be evaluated), it is noted that 5.2 states "such as re-training of analyst(s);...". An individual who is only a technical reviewer or only a TL (neither actually performing casework analysis, nor perfoming proficiency test interpretations) is not "an analyst", but may require re-training as technical reviewers.	IF it will actually only be "analysts" who undergo this evaluation, leave statement as current. IF the intention is to have any individual who is in any way involved in mixture proficiency testing do this evaluation: "such as re-training of analyst(s) or technical reviewer(s);..."	Accept. Changed "analyst(s)" to "the individual(s)"