

Deadline for publi comments submission: 12/20/2021

ASB Std 153, Standard Practices for Proficiency Testing for Forensic Toxicology Laboratories and Breath Alcohol Programs

#	Section	Type of Comment	Comments	Proposed Resolution	For Work Group use only, not to be completed by commenter.
		(E-Editorial, T-Technical)			Final Resolution
1	4.2	E	Presumably, the purpose of participating in an interlab comparison when no "appropriate proficiency tests" are available is to evaluate performance at the participating lab. But that makes it a proficiency test under the definition in § 3.7 (defining "proficiency testing" as "Evaluation of participant performance against pre-established criteria by means of interlaboratory comparison." (Source: ISO/IEC 17043:2010).". The purpose of § 4.2 and the difference between a proficiency test and an interlab comparison contemplated in § 4.2 should be stated more clearly.	Rewrite to make clear whether an interlab comparison is intended to count as a 'proficiency test' (as it seems to be under 3.7) or not (as seems to be the gist of the current redlined 4.2, which says such comparison should only be used when an appropriate proficiency test isn't available).	Accept: The first sentence in the second paragraph of 4.2 was rewritten as follows: "When externally prepared proficiency tests from accredited providers are not available, a laboratory shall participate in intralaboratory or interlaboratory comparisons. While intra-/interlaboratory comparisons may not meet the definition of proficiency tests, they are valuable for laboratories to assess the reliability of test results."
2	4.2	E	Proficiency testing should ideally be blind, at least in the sense that the examiner does not know it's a test.	Add the following 4.2.1: "Proficiency testing should be blind (meaning that the test subject does not know it is a test rather than casework) wherever possible. If testing is not blind, the laboratory shall document this fact and offer a written explanation for why such a test was not available or appropriate."	Reject: Although the Consensus Body agrees that blind proficiency testing is a useful tool, blind proficiency testing is not practical for most forensic toxicology laboratories. The normative reference (ISO/IEC 17043) states the following in A.3.1 General: "One special application of proficiency testing, often called "blind" proficiency testing, is where the proficiency test item is indistinguishable from normal customer items or samples received by the laboratory. This type of proficiency testing can be difficult, since it requires coordination with a normal laboratory customer. In addition, because of unique packaging and shipping needs, bulk processing is usually not feasible and homogeneity testing is difficult."
3	4.6	E	Proficiency testing should involve samples that are not only "routine" but also samples that are more difficult and complex to interpret, where the most errors in casework likely occur.	Change to "specimens shall be subjected to the same tests or testing scheme as the full range of casework that is analyzed in the laboratory."	Reject: The Consensus Body reviewed the wording in Section 4.6. For a minimum standard, the language is appropriate as written. A laboratory can choose to exceed the minimum standard.
4	4.8.3.1, 4.8.3.2	E	Is a measured alcohol concentration x that is, say four standard deviations ($4s$) from m (the consensus result for many analysts) but 9.5% above or below m acceptable? In this instance, "whichever is greater" (as between $\pm 10\%$ and $\pm 2s$) is $\pm 2s$. The analyst's measurement x exceeds the $\pm 2s$ window, but it is within the greater $\pm 10\%$ window. Thus, the acceptance region is "no less stringent" than what is given in § 4.8.3.2(a). If this is what is intended, then § 4.8.3.2.1 could be shorter and clearer if it were to read like the suggested language in the next column. More radically, why not use proficiency tests to investigate interval estimates of BAC rather than point estimates? Would that eliminate the perceived need for dual criteria for accuracy?	The laboratory's predefined acceptability range for the accuracy of an analyst's breath or blood alcohol measurement (as compared to the consensus value for the test) shall be no greater than $\pm 10\%$ or ± 2 standard deviations, whichever is larger (and hence, less stringent).	Reject: The Consensus Body reviewed the wording in Sections 4.8.3.1 and 4.8.3.2, and the language is appropriate as written.
5	4.9.2	E	Under definition 3.7, an intralab comparison is never a proficiency test, and under this section (4.9.2), neither is a "supplemental" interlaboratory comparison. But if these tests are being used to gauge proficiency, the section should require the same kind of documentation of these exercises as it does for proficiency tests.	Either change 4.9.2 to require documentation both for proficiency testing <i>and</i> intralab comparisons (and supplemental comparisons), or change the definition of proficiency test to exclude such comparisons.	Accept: The language in 4.10 was changed to clarify the requirement to document inter-/intralaboratory comparisons.
6	4.9.2	E	If seven years is a desirable minimum retention period, then that should be the recommended period. If local (or other) law on document retention departs from this recommendation, then it goes without saying that the laboratory will have to follow the law. But this constraint does not mean that the standard should be less exacting. It means that local rules fall short of what the standard requires. In that situation, laboratories in the jurisdiction will have to adopt their own, modified version of the standard, and everyone should understand that this jurisdiction has chosen not to comply with the entirety of the ASB standard.	Delete (a) because scientific standards from SDOs should not say that whatever the law happens to be is satisfactory. However, if this view were to be rejected, the draft still should be revised to be more readable and complete—by rephrasing the second paragraph to read as follows: "Unless otherwise required by federal, state, or local law, proficiency testing documentation shall include the laboratory's supporting data, test results, provider reports, and any record of follow-up, and these documents shall be kept for at least seven years."	Accept: Removed reference to local statutes. While the reference to local statutes was added to the document after the first round of public comments, the position stated in this comment convinced the CB to reconsider the addition.