Deadline for submission of comments **4/19/2021**

ASB Std 153, Standard Practices for Proficiency Testing for Forensic Toxicology Laboratories

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
50	Foreward	T	Reword first two sentences to shorten and to allow a wider range of methods for reference value determination. Use of a consensus result as the accepted reference value for a proficiency test cannot guarantee accuracy of laboratory results, which is recognized in the standard as one of the primary reasons for proficiency testing in forensic science.	Change the existing first sentence to read, "Proficiency testing in forensic toxicology evaluates the overall performance, accuracy and reliability of a laboratory through the testing of case-like specimens whose composition is unknown to the participant(s). Performance is assessed by comparing laboratory results to an accepted reference result using preestablished criteria."	Accept with modification: The first sentence was broken into two sentences. However, the wording "case-like" specimens was not included since it doesn't accurately reflect proficiency test samples.
51	Foreward	E	Change the sentence that gives examples of the types of improvements that a proficiency test may reveal to emphasize that changes to the laboratory's SOPs will be needed to in order to effect the identified improvements. The last example in the list does not seem to fit with the first two, so it possibly should be moved later in that paragraph, as suggested in the next comment.	Change sentence to read, "Examples of the types of improvements that may be identified include the need to refine an assay to increase its precision or the need to update an assay's characteristics or operation to lower its detection limit."	Reject: Adding analytes to the scope of testing is considered an improvement and appropriately placed in the sentence.
52	Foreward	T	Add some text to the sentence giving examples of the postive things proficiency testing can do to indicate that determination of accuracy from a proficiency test requires traceability of reference values to known standards. The final example from the previous list of examples is included here as well.	Change existing final sentence of Foreward to read, "Proficiency testing also can give a laboratory, and those who rely on their work, confidence that it is producing accurate and reproducible casework results when related proficiency test performance is successful and the accepted reference value for the test is traceable to known a standard or reference material. In addition to ongoing confidence, successful proficiency tests also can provide the evidence needed for a laboratory to add analytes to its scope to cover the inevitable changes or expansions in its casework over time."	Reject: The final sentence is acceptable as written.
9	Foreword	E	Comma needed between words 'laboratory' and 'through'	insert necessary comma	Reject: A comma is not necessary.
10	Keywords	E	none listed	add appropriate keywords	Accept:
29	Scope	T	What is meant by "breath alcohol"? Does the document intend to cover breath instrument calibration programs? Or breath alcohol testing? Is the standard only applicable to breath alcohol within a "laboratory"? Or does it also apply to testing or calibration work performed at a police dept or instrument manufacturer?	Clarify if breath alcohol testing and/or calibration work in included. Clarify if non-lab based breath alcohol work is in or out of scope.	Accept: The title was changed, and further clarifications were made in the document to define a breath alcohol program.
20	1	T	There are certain requirements denoted within this document that would be more appropriately geared to PT providers since the laboratory does not have the direct control as to the drug classes, sensitivity, matrices, and sources used by them. They only have control over these if they create samples for inter-intralab comparisons.	To make this document more comprehensive, the scope should be expanded to include proficiency test providers that offer PTs in the required sub-disciplines.	Reject: The inclusion of proficiency test providers is not appropriate.
53	1	T	Add "requirements" to the first sentence of Section 1, along with scope and frequency, since this standard does specify some characteristics for a proficiency test to be acceptable.	Change the first sentence of Section 1 to read, "This document defines the minimum scope, requirements, and frequency for proficiency testing for laboratories engaged in the following sub-disciplines:"	Accept:
54	2	T	Add ISO 13528 Statistical Methods for Use in Proficiency Testing by Interlaboratory Comparison as a normative standard for ASB 153. ISO 13528 contains many well-vetted strategies for establishing acceptance criteria for proficiency tests that account for the different goals a proficiency test may have, the different types of reference values that may be used, and the uncertainty in the testing results.	Add the suggested reference to the list in Section 2.	Reject: ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers.
55	3	T	Add a definition for the term "assigned value" from ISO 13528. This term will be used in comments on Section 4.8.3 of ASB 153.	assigned value- value attributed to a particular property of a proficiency test item	Reject: The term "assigned value" is not used in this document. The term "nominal quantity value" was added.

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56	3	T	Add a definition for the term "standard deviation for proficiency assessment" from ISO 13528. This term will be used in comments on Section 4.8.3 of ASB 153.	standard deviation for proficiency assessment - measure of dispersion used in the evaluation of results of proficiency testing Note 1 to entry: This can be interpreted as the population standard deviation of results from a hypothetical population of laboratories performing exactly in accordance with requirements. Note 2 to entry: The standard deviation for proficiency assessment applies only to ratio and interval scale results. Note 3 to entry: Not all proficiency testing schemes evaluate performance based on the dispersion of results. [SOURCE: ISO/IEC 17043:2010, modified — In the definition “, based on the available information” has been deleted. Note 1 to the entry has been added, and Notes 2 and 3 have been slightly edited.]	Reject: ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers. ISO 13528 is not referenced in this document.
5	3.2	T	Use of a 'consensus result'	Defer to proficiency provider's assigned value	Reject: In forensic toxicology, a proficiency test provider's assigned value is typically obtained from a consensus-based approach. Therefore, the use of "consensus result" is appropriate based on the scope of the document. It is noted that some breath alcohol proficiency tests consist of known, traceable reference material (see 4.7.3.1 b)).
38	3.2	T	How many results are needed to constitute a "consensus result"? This would be important for labs that may need to rely on inter or intra lab comparisons to meet some of the requirements that are not met by 17043 providers.	Establish the requirements to consider something a "consensus result" since that is required to be used in in 4.8.3.	Reject: Determining the number of results that constitute a consensus result is outside the scope of this document.
57	3.2	T	Change the term "consensus result" and its definition to "consensus value" to match ISO 13528.	consensus value - value derived from a collection of results in an interlaboratory comparison Note 1 to entry: The phrase ‘consensus value’ is typically used to describe estimates of location and dispersion derived from participant results in a proficiency test round, but may also be used to refer to values derived from results of a specified subset of such results or, for example, from a number of expert laboratories.	Reject: The definition is appropriate as written.
11	3.6	E	change wording for clarity from 'proficiency test items, and the evaluation' to 'proficiency test items, inlcuding the evaluation…'	make necessary changes	Reject: The definition was taken directly from ISO/IEC 17043.
19	4.1	E	need comma between 'up' and 'shall'	insert necessary comma	Accept: A comma was inserted in 4.10 between "up" and "shall".
1	4.2	T	HFSC participates in a intralaboratroy blind quality control program as a supplement to declared PT samples, not because external PT is not available. This clause reads as if we can only participate in such program if external PT is not available. Also, it is not clear whether the subsequent requirements can be met through participating different PT and intralaboratory programs or if they have to be met strictly via external PT samples if external PT is available.	Clarify how a laboratory can meet the requirements if it participates in different types of PT related programs.	Reject: The clarification is explained in 4.9.2.
21	4.2	T	The following sentence in 4.2 "A laboratory may participate in intralaboratory or interlaboratory comparison when appropriate proficiency tests are not available." seems contradictory of clause 4.9.1	Either 4.2 should provide more clarification or it should reference 4.9.1. There may be instances where there could be PT providers but they dont meet all of the required criteria a lab needs to take into consideration for their PT program per this document.	Accept: Commentary added to Section 4.2.
30	4.2	E	all other references to 17043 include IEC	update to ISO/IEC 17043	Accept:

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58	4.2	T	Change wording to indicate a preference for proficiency test providers who also use methods in ISO 13528. Also change the text regarding the alternate use of interlaboratory studies to indicate that they should be carried out in a manner consistent with ISO 17043 and ISO 13528.	Change the text of Section 4.2 to read, "Forensic toxicology laboratories shall use externally prepared proficiency tests from proficiency test providers accredited to ISO 17043 when available and appropriate. Laboratories should prefer proficiency tests from test providers also accredited to ISO 13528 when available and appropriate. A laboratory may participate in an interlaboratory comparison that follows methods consistent with ISO 17043 and ISO 13528 when appropriate proficiency tests are not available."	Reject: ISO 13528 is written for proficiency test providers and is outside the scope of this document. As a minimum standard, Section 4.2 is appropriate as written. Laboratories can do more than the minimum requirements.
2	4.3	T	Regarding the minimum number of eight PT samples, do they have to be different samples; in other words, samples containing different concentrations or can a laboratory purchase two tests containing the same set of samples but distribute to different people?	Clarify what the minimum number of samples entails.	Reject: Section 4.3 d) and the language describing alternative testing paradigms clearly indicate that eight distinct specimens in at least two separate rounds are minimally required for blood alcohol.
59	4.3 a)	T	The specifcation that proficiency testing need only cover the most common matrix a laboratory sees for blood alcohol may not be adequate, even as a minimum requirement. For example, suppose a laboratory typically receives 35% of its samples for testing in a whole blood matrix, 35% of the samples in plasma, and 30% of the samples in another matrix. Would it be acceptable for the laboratory to have the majority of its output not covered by associated proficiency tests?	Change the requirement so that proficiency testing must cover matrices that comprise a specified proportion, say 80%, of a laboratory's typical test result output for blood alcohol.	Reject: As a minimum standard, Section 4.3 a) is appropriate as written for blood alcohol.
31	4.3.a	T	Section 4.5.a specifies that synthetic or animal based matrices may be used for drug PTs, is this not accetpable for alcohol PTs?	for consistency, clarify if human sources are the only acceptable option	Accept:
26	4.3.c	T	While I do think that the intent is correct and appropriate in 4.3.c.; I do not think these accreditation scopes as currently written support the provision.	Consider future expectation of these volatiles being included on scopes and impact on the community as a whole vs. a smaller population.	Accept: Future expectations were considered, and the language in 4.3 c) is appropriate as written. Proficiency tests that include acetone, isopropanol and methanol are readily available and must be included if a laboratory has these volatiles in their scope of testing.
43	4.3.c	T	The availability of the acetone, isopropanol, and methanol from PT manufacturers is not up to the customer. Rarely have these been included in the past therefore it should not be required. This should be a recommendation.	"…analytical scope of testing, if available."	Reject: Proficiency tests that include acetone, isopropanol and methanol are readily available.
44	4.3.d, 4.4.d, 4.5.e	E	The number of annual PT Tests is in excess of that required by ISO/IEC 17025 accreditaion and why the difference between blood and breath.	one time per calendar year for 4.3, 4.4 and 4.5	Reject: 17025 covers a large range of disciplines including non-forensic science disciplines. For forensic toxicology, the frequency of PT tests in Table 1 are appropriate considering the risk involved in forensic testing.
6	4.3 Table 1	T	3 specimens for each PT round	1 specimen or increase frequency to 2 rounds annually	Reject: The suggested change is unclear. For forensic toxicology, the frequency of PT tests in Table 1 are appropriate considering the risk involved in forensic testing.
15	4.3.e	T	Language is vague when specifying the interval of several months between tests, then using the example of of 4 rounds of 2 specimens. 'Several' implies 3 or more months between tests.	The interval between rounds of tests should be spaced approximately evenly throughout year, with at least 1 month, not to exceed 8 months between rounds.	Reject: Although the word "several" is vague, the wording provides flexibility to laboratories and proficiency test providers.
65	4.3.8.1 (new section)	T	Add a new section to discuss how the assigned value for the proficiency test, and its associated uncertainty, will be determined.	The assigned value(s) for the proficiency test, for their associated standard uncertainties, and the standard deviation for proficiency assessment shall be based on methods from Sections 7 of ISO 13528 that are fit for purpose given the characteristics of the proficiency test in use. Note that limitations on the uncertainty of the assigned value may need to be prespecified for the proficiency test as discussed in Sections 9.2 of ISO 13528.	Reject: The CB believes this comment was intended for Section 4.8.3. ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers.
66	4.3.8.2 (new section)	T	Move the text on the acceptability criterion that is not included in the new version of 4.8.3 to this new section and change as noted to better cover the various different acceptability criteria from ISO 13528 that might be useful.	The acceptablity criterion used shall be based on a method for performance evaluation from Sections 8 and 9 in ISO 13528 that is fit for purpose given the characteristics of the proficiency test in use. The acceptability criterion shall account for uncertainty in the assigned value, if significant, and for uncertainty in laboratory results, if reported in casework. Some typical quantitative acceptability criteria for each type of testing follow.	Reject: The CB believes this comment was intended for Section 4.8.3. ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers.

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12	4.4	T	Is this section referring to the calibration of breath alcohol testing instruments?	change wording to 'breath alcohol testing and/or calibration'	Accept with modification: The wording was changed to "breath alcohol program". "Breath alcohol program" was added to the terms and definitions.
23	4.4	E	Is this section referring to PT for breath testing or breath calibration? The opening statement implies breath *testing* , but a) refers to matrices used to calibrate the instrument.	We were recently accredited for breath alcohol calibration, so I'm wondering if there will be any recommendations for that.	Reject: No proposed resolution was provided. Note that the wording was changed to "breath alcohol program". "Breath alcohol program" was added to the terms and definitions.
32	4.4	T	Refers to breath alcohol testing, and the lab's testing services. Is this supposed to be breath alcohol instrument calibration programs? If so, then is it limited to only those programs within laboratories? If it is about breath alcohol testing, then is it only for testing within a lab and not testing at a police station?	Clarify the actual type of breath alcohol work requiring PTs and the type of orgnaziations subject to the PT standard.	Accept: The wording was changed to "breath alcohol program". "Breath alcohol program" was added to the terms and definitions.
45	4.4	T	There is not currently accrediation in breath alcohol testing	When breath alcohol calibration is included in a laboratory's analytical scope of accreditation, …	Reject: The wording was changed to "breath alcohol program". "Breath alcohol program" was added to the terms and definitions and includes breath alcohol calibration or the management of calibrated breath alcohol instrumentation.
7	4.4 c)	T	Evidential breath alcohol instruments will not provide quantitative results when interferents are detected	Eliminate inclusion of acetone, methanol, and isopropanol in proficiency testing scheme.	Accept:
4	4.4 c.	T	The standard indicates, in addition to ethanol, acetone, methanol, and isopropanol shall be included in the proficiency test scheme. Breath alcohol equipment is designed to monitor for the presence of volatile chemicals that could possibly be in the breath of humans. However, these instruments are not capable of characterizing and identifying the specific interfering substance(s). Should one or more of the interferents be present in a sample the instrument will simply indicate an interferent is present but it will not identify the specific compound. Clarification is needed regarding the expectations of simply identifying an interferent is present as opposed to naming the interfering compound(s).	In addition to ethanol, the ability to identify the presence of potential interferents acetone, methanol, and isopropanol or any combination thereof shall be included in the proficiency testing scheme.	Reject: The language regarding acetone, methanol and isopropanol was removed from the document.
13	4.4.c	T	After a quick search, I couldn't find any accredited breath alcohol PT providers that list interferents as part of their PT programs.	insert 'when available'	Reject: The language regarding acetone, methanol and isopropanol was removed from the document.
27	4.4.c	T	The inclusion of acetone, methanol and isopropanol as interferents are valuable to Proficiency Testing. However, including all in every PT scheme may be extreme.	Loosen wording to allow for more flexibility in the inclusion of these interferents in the PT scheme.	Reject: The language regarding acetone, methanol and isopropanol was removed from the document.
46	4.4.c	T	Acetone does not "interfere" with EC based instruments, therefore it's presence would not be detected as an interferent.	Add an exception for the reporting as it relates to the other ASB Breath Alcohol documents (i.e. allow for elevation or reporting as interferent).	Reject: The language regarding acetone, methanol and isopropanol was removed from the document.
47	4.4.c	E	These are not currently available therefore requiring something that is not available is improper and setting labs up for excessive critique from outside enitities for not meeting a requirement that cannot be met.	"…as interferents, if available."	Reject: The language regarding acetone, methanol and isopropanol was removed from the document.
14	4.4.d	T	a commonly used provider for simulator solution PT's only provides 2 items. It could be cost-prohibitive for some agencies to add in a second round of PT's just to test the 3rd item. It would be more in line with the intended of rigor of testing 1 round of breath testing per year to lower the minimum sample size to 2 items per year.	Change 3 items per year to 2 items per year.	Reject: Note that all of the requirements in Table 1 were harmonized. The updated number of rounds/specimens is intended to cover a wide range of concentrations.
33	4.4.d	E	"administering the breath alcohol program" is a very broad term that probably goes beyond the scope of the document.	The suggested resolution depends on what type of work this section is targeting. Clarify that the PT testing shall be performed the agency performing the calibration services. (or "lab only" or testing services?)	Accept: "Breath alcohol program" was added to the terms and definitions. The requirements of PT testing for breath alcohol programs were clarified in Section 4.4.
60	4.5 a)	T	Same as comment 10, only for drugs. Since there is a wider array of matrices for drug testing, an example analogous to that in comment 10 likely would have even more extreme results with regard to the proportion of matrices covered if proficiency testing is only required for the single most common matrix.	Same as comment 10, only for drugs. The specified proportion of tests covered does not necessarily need to be the same as for blood alcohol.	Reject: As a minimum standard, Section 4.5 a) is appropriate as written for drugs. As the percentage of analyzed matrices will vary from one lab to the next, to implement the suggested revision would be impractical for proficiency test providers.

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34	4.5.b	T	4.5.a requires the most common matrix be tested, but 4.5.b suggests including alternate matrices. It seems unnecessary to make that a separate criteria. Just include OF and hair as examples in 4.5.a	Edit 4.5.a to require (shall) the most common and suggest (should) that other matrices be included.	Reject: The most common matrix is already required to be PT tested. The CB prefers the original language.
22	4.5 d)	T	I'm in agreement that these components need to be taken into consideration to assure a laboratory has a robust PT scheme program. Because the criteria listed in the sub-clause is written as a requirement, it will be easier for laboratories to show conformance to this by moving this sub-clause to the PT program annual review section.	This sub-clause would be better suited in clause 4.9.2. The components listed within this sub-clause shall be taken into consideration when evaluating a PT provider and/or their PT program. That way the laboratories can provide documentation and conformance to this requirement. In addition, if the required components are not being met with the current PT samples, this will help labotories determine if they need to make samples in-house (intra-laboratory comparisons) to complement their PT scheme and meet the required criteria.	Reject: The contents of Section 4.5 d) are already part of the recommended review items listed in 4.9.2 (note this section is currently numbered 4.9.1).
35	4.5.d	T	This is very vague for a requirement within a standard. If it is a "shall", then more information is needed so a lab can assess if they are in compliance.	Provide details on what are considered to be "general drug classes", what compounds are considered to be sufficiently "representative" to challenge the scope. Specify what is considered to challenge the lab's sensitivity? Within a certain percentage of the lab's LOD? Section 4.9.2 seems to be attempting to provide some guidance, but that is not sufficient for a lab to determine if they are in complaince with 4.5.d.	Accept with modification: Language was added to specify conformance with ASB Standards 119, 120 and 121.
16	4.5.e	T	Language is vague when specifying the interval of several months between tests, then using the example of of 4 rounds of 2 specimens. 'Several' implies 3 or more months between tests.	The interval between rounds of tests should be spaced approximately evenly throughout year, with at least 1 month, not to exceed 8 months between rounds.	Reject: Although the word "several" is vague, the wording provides flexibility to laboratories and proficiency test providers.
24	4.5e	T	Our current PT provider for Tox is CTS and they provide 3 specimens per drug testing set. Is there a significance to making this 4 specimens? It would be easiest for most labs if this clause aligned with the minimum number that is provided by CTS. Then, 4.9.2 goes beyond the minimum and addresses additional tests that may need to be prepared after an annual review.	Work with PT providers that meet 17043 so they prepare 4 specimens per test or change this to 3 specimens.	Reject: While the standard is intended for laboratories, the Consensus Body anticipates that proficiency test providers will review the published document. Section 4.2 addresses availability of proficiency test schemes.
36	4.6	E	The second parapgraph does not seem to have any relevance to a PT standard. The personnel standards would reference the PT standard as a monitoring tool, but the opposite does not seem relevant.	remove the second paragraph.	Accept:
61	4.7	T	Add a brief explanation of blind proficiency testing and its advantages to this section to encourage their development and to start preparing laboratories for eventual requirements for blind proficiency testing.	Change the text of Section 4.7 to read, "The proficiency test specimens shall be subjected to the same tests/testing scheme as routine casework that is analyzed in the laboratory. The use of blind proficiency testing, where the proficiency test samples cannot be distinguished from requlr casework, is the best method to ensure that proficiency test results are representative of casework results. The use of blind proficiency testing reduces implicit changes to testing procedures that inevitably arise to some degree whenever an analyst is aware that s/he is being tested."	Reject: Although the Censensus 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."
37	4.8	E	sentence should be more specific that this section is about evaluating testing results in comparison to the PT provider results, or the inter/intra lab results.	clarify that the lab results are being evaluated against the consensus results.	Reject: This concept is mentioned in Subsection 4.8.3.
62	4.8.1	T/E	Change the text of this section to remove the intent of the proficiency test provider from consideration and to focus instead on the actual content of the sample. For example, if it is found that a proficiency test provider sent out a sample that was contaminated with a controlled substance and a laboratory correctly reports the presence of that substance, the result should not be deemed a false positive even though it didn't match the test provider's intent.	Change the text of Section 4.8.1 to read, "The laboratory will investigate and document through a corrective action program the cause(s) of any instance in which a positive result is reported for an analyte not present in the test specimen (a false positive result)."	Accept with modification: The wording "through a corrective action program" was removed.

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63	4.8.2	T/E	Change the text of this section to remove the intent of the proficiency test provider from consideration and to focus instead on the actual content of the sample, as above.	Change the text of Section 4.8.2 to read, "The laboratory will investigate and document through a corrective action program the cause(s) of any instance in which a negative result is reported for an analyte present in the test specimen and within the scope and sensitivity of the laboratory's routine testing (a false negative result)."	Accept with modification: The wording "through a corrective action program" was removed.
64	4.8.3	T	Change the text of 4.8.3 to make use of the variety of methods given in ISO 13528 for determination of acceptability criteria.	Change the first parapraph of this section to read, "A laboratory shall have predefined criteria for acceptability of quantitative results in proficiency tests. Acceptability criteria may be defined either by the proficiency test provider and adopted by the laboratory or defined directly by the laboratory. In either case, acceptability criterion shall be based on methods from ISO 13528 that are fit for purpose given the characteristics of the proficiency test in use, as outlined below.	Accept with modification: ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers.
67	4.8.3 a)	T	Move this section to 4.3.8.2 a) and change text to expand the types of accepted reference or assigned values that can be used for a measurment-error based criterion or the standard deviation used for a dispersion-based criterion. Note: Use of ±2 standard deviations of the consensus result will not work well as an acceptability criterion. The standard deviation of the consensus result will depend on the number of labs participating in the proficiency test and it leaves out the uncertainty in the result of the individual lab that is assessing its results. It will be essentially impossible for most well-performing labs to pass the test using this criterion and the fraction that will pass will decrease with the size of the proficiency test. This situation is analogous to the percentage of data points that will fall into a confidence interval for the mean, which approaches zero as the sample size goes to infinity.	Change text of Section 4.8.3 a) to read: a) Blood alcohol - acceptable laboratory results should fall within ±10% of the assigned value for an acceptability criterion based on measurement error alone (see sections 8.1, 8.6, and 9.3 of ISO 13528 for more information) - acceptable laboratory results should fall within the interval defined by the assigned value ±2 standard deviations for proficiency assessment for an acceptability criterion based on measurement error and dispersion of results (see sections 8.1, 8.6 and 9.4 from ISO 13528 for more information)	Reject: The majority of toxicology proficiency tests are prepared in a variety of matrices. There are many variables that impact the result including analyte stability. Moreover, synthetic proficiency matrices are not equivalent to actual laboratory matrices. Therefore, forensic toxicology proficiency test providers obtain a consensus result based on data from the participants. Acceptable criteria for blood alcohol are assigned based on +/- 10% of the mean consensus result or +/- 2 standard deviations of the mean consensus result, whichever is greater. This acceptability criteria for blood alcohol are achievable. Note that ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers.
8	4.8.3 b)	T	It is unclear why a laboratory would establish acceptance criteria that relies on consensus results instead of NIST-traceable assigned values.	Defer to comparison of study summary statistics for individual performance and any subsequent corrective action OR defer to laboratory's quality system.	Reject: (1) For breath alcohol consensus-based proficiency tests: The majority of toxicology proficiency tests are prepared in a variety of matrices. There are many variables that impact the result including analyte stability. Moreover, synthetic proficiency matrices are not equivalent to actual laboratory matrices. Therefore, forensic toxicology proficiency test providers obtain a consensus result based on data from the participants. Acceptable criteria for breath alcohol are assigned based on +/- 10% of the mean consensus result or +/- 2 standard deviations of the mean consensus result, whichever is greater. This acceptability criteria for breath alcohol are achievable. Note that ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers. (2) For breath alcohol proficiency tests consisting of known, traceable reference material: Acceptable criteria are assigned based on +/- 10% of the nominal quantity value or +/- 0.005 g/210L, whichever is greater. This acceptability criteria for breath alcohol are achievable. Note that ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers.

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
68	4.8.3 b)	T	Move this section to 4.3.8.2 b) and change text to expand the types of accepted reference or assigned values that can be used for a measurment-error based criterion or the standard deviation used for a dispersion-based criterion, as described in the comment on section 4.3.8.2 a).	Change text of Section 4.8.3 b) to read: b) Breath alcohol - acceptable laboratory results should fall within ±5% of the assigned value for an acceptability criterion based on measurement error alone (see sections 8.1, 8.6, and 9.3 of ISO 13528 for more information) - acceptable laboratory results should fall within the interval defined by the assigned value ±2 standard deviations for proficiency assessment for an acceptability criterion based on measurement error and dispersion of results (see sections 8.1, 8.6 and 9.4 from ISO 13528 for more information)	Reject: (1) For breath alcohol consensus-based proficiency tests: The majority of toxicology proficiency tests are prepared in a variety of matrices. There are many variables that impact the result including analyte stability. Moreover, synthetic proficiency matrices are not equivalent to actual laboratory matrices. Therefore, forensic toxicology proficiency test providers obtain a consensus result based on data from the participants. Acceptable criteria for breath alcohol are assigned based on +/- 10% of the mean consensus result or +/- 2 standard deviations of the mean consensus result, whichever is greater. This acceptability criteria for breath alcohol are achievable. Note that ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers. (2) For breath alcohol proficiency tests consisting of known, traceable reference material: Acceptable criteria are assigned based on +/- 10% of the nominal quantity value or +/- 0.005 g/210L, whichever is greater. This acceptability criteria for breath alcohol are achievable. Note that ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers.
69	4.8.3 c)	T	Move this section to 4.3.8.2 c) and change text to expand the types of accepted reference or assigned values that can be used for a measurment-error based criterion or the standard deviation used for a dispersion-based criterion, as described in the comment on section 4.3.8.2 a).	Change text of Section 4.8.3 c) to read: c) Drugs, drug metabolites and other chemicals - acceptable laboratory results should fall within ±20% of the assigned value for an acceptability criterion based on measurement error alone (see sections 8.1, 8.6, and 9.3 of ISO 13528 for more information) - acceptable laboratory results should fall within the interval defined by the assigned value ±2 standard deviations for proficiency assessment for an acceptability criterion based on measurement error and dispersion of results (see sections 8.1, 8.6 and 9.4 from ISO 13528 for more information)	Reject: The majority of toxicology proficiency tests are prepared in a variety of matrices. There are many variables that impact the result including analyte stability and absorption to glass. Moreover, synthetic proficiency matrices are not equivalent to actual laboratory matrices. In addition, traceable reference materials are not available for many substances. Therefore, forensic toxicology proficiency test providers obtain a consensus result based on data from the participants. Acceptable criteria for drugs, drug metabolites and other chemicals are assigned based on +/- 20% of the mean consensus result or +/- 2 standard deviations of the mean consensus result, whichever is greater. This acceptability criteria for drugs, drug metabolites and other chemicals are achievable. Note that ISO 13528 does not align with the scope of this document. It is more appropriate for proficiency test providers.
48	4.8.4	E	This should be worded more generically as not every lab defines an inquiry into quality issues as a corrective action.	Remove "…through a corrective action program."	Accept:
70	4.8.4	T	add "any" to the description of the unacceptable quantative results to be investigated for consistency with sections 4.8.1 and 4.8.2.	Change the text of section 4.8.4 to read, "The laboratory will investigate and document the cause(s) of any unacceptable quantitative results through a corrective action program."	Accept with modification: The word "any" was included. The wording "through a corrective aciton program" was removed.
39	4.8.5	T	why is this specific only to drug testing?	edit to "…reported inaccurate results to the customer."	Accept:
71	4.8.5	E	Change will to shall since will is not the preferred verb to indicate a requirement in ASB standards.	Change the text of Section 4.8.5 to read, "The corrective action program shall include evaluating and documenting the risk of having reported inaccurate results on casework specimens for the drug or drug class in question, as appropriate."	Accept with modification: "Will" was changed to a "shall". Additional modifications were made to the sentence.
17	4.9	E	Remove comma between 'need' and 'and'	delete unnecessary comma	Accept with modification: The sentence was rewritten.
40	4.9	T	This is extremely vague for a standard and does not allow for a lab to actually assess themselves for conformance to the standard. (similar problem as 4.5.d)	4.9.2 attempts to provide some guidance but there is still no defined criteria for a lab to meet. Either define what needs to be met for scope and sensitivity of the PT program, or change the requirement to a "should".	Reject: The recommendations for what should be included in the annual review are included in 4.9.1.
41	4.9	T	the section ignores breath alcohol	Specify what the program evaluation requirements are for breath instrument calibration programs (if that is in the scope of the standard).	Reject: 4.9 and 4.9.1 a) are relevant to breath alcohol.
72	4.9	E	Change will to shall since will is not the preferred verb to indicate a requirement in ASB standards. Also change need to needs.	Change the text of Section 4.9 to read, "The laboratory shall document evaluation of their proficiency test program on an annual basis to determine if it meets their needs, and appropriately covers their scope of testing."	Accept with modification: "Will" was changed to a "shall". Additional modifications were made to the sentence.

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
18	4.9.1	E	Remove comma between 'tests' and 'when'	delete unnecessary comma	Accept with modification: The sentence was rewritten.
73	4.9.1	T	Change may to shall since consideration of alternatives really must be carried out if a proficiency test program is not meeting a laboratory's needs. In some SDO's the verb may connotes permission as well, which doesn't seem like the appropriate sense of the word here. Given that convention, however, it is somewhat likely to be read that way by those familiar with standards.	Change the text of Section 4.9.1 to read, "The laboratory shall consider supplementing their proficiency testing program with intralaboratory comparison testing, interlaboratory comparison testing, or new proficiency tests, when review of the program determines that testing does not met the needs of the laboratory."	Reject: The sentence was re-written, but the suggested language was not implemented.
3	4.9.2	T	The number and type of drugs in the PT samples will be dicated by the PT providers and this is not something controlled by the lab. How can a lab adjust the number and type based on its needs?	Provide information regarding what a lab should do if its PT samples do not cover the sufficient number of drugs or the type of drugs prevalent in its cases or challenge its scope and sensitivity.	Accept: Language was added in section 4.9.2.
49	4.9.2	E	Customers have no control over the number of drugs/targets available in each specimen provided by the PT manufacturer. This should also be based off of the scope of each lab's testing as some labs may have a larger scope of testing to include all or some of the targets provided by the PT.	Without final published version of these documents, not sure how to agree with that.	Reject: No proposed resolution was provided.
74	4.9.2	T	Change may to should since these are all very reasonable questions that really ought to be considered when reviewing the proficiency test program. In some SDO's the verb may connotes permission as well, which doesn't seem like the appropriate sense of the word here. Given that convention, however, it is somewhat likely to be read that way by those familiar with standards.	Change the text of Section 4.9.2 to read, "The laboratory should include the following questions in their annual review of their proficiency testing program. These questions and any others that are considered should be documented for future use or review."	Accept with modification: The "may" was changed to "should". No further modifications were made to the text. The suggested additional language is covered in Section 4.9.
28	4.9.2.b	T	When considering the minimum amount of drugs per year that may be considered appropriate for each of the testing types (10 -impaired driving, 10 - drug-facilitated crimes, and 20- medicolegal death investigation) and abiding by the yearly minimum specimen requirements in section 4.5e, 8 specimens yearly, these factors combined would necessitate one of two paths for compliance: 1) The proficiency testing provider would need to include a vast number of drugs in each sample. With consideration always given to the metabolites that may be found with a primary analyte and multiple drug interactions, creation of tests that meet these requirements proves problematic. In addition, doing so may sacrifice the ability to produce proficiency tests that are as close to case-like samples as possible. 2)The laboratory would have to take significantly more tests than the minimum requirement.	Review wording on minimum number of drugs to analyze per year, per testing type, and how it relates to minimum number of tests taken yearly. Perhaps change focus to breadth of drugs evaluated, and not a specific number which could drive unreasonable expectations.	Reject: The Consensus Body reviewed the wording in Section 4.9.2.b) (4.9.1.b) in the current version), and the language is appropriate as written. The number of drugs evaluated is reasonable based on each testing category.
25	4.10	T	As required (and limited) by our state records retention laws, we only keep these for six years and would not be permitted to maintain them longer than that.	Revise to mention limitations based on state records retention rules.	Accept:
42	Annex A	E	#4 and #5 are irrelevant to the PT program	remove #4 and #5	Accept: