Deadline of Submission of Comments: 16-Feb-24

Document Number: ANSI/ASB Std 056

Document Title: Standard for Evaluation of Measurement Uncertainty in Forensic Toxicology

Comment #	Text Line # (s)	Document Section	Type of Comment E-Editorial T-Technical	Current Document Wording	Proposed Revision	Revision Justification	*For Working Group and Consensus Body use only, not to be completed by commenter.* Final Resolution
4		Scope	E	It does not address evaluating measurement uncertainty for breath alcohol testing.	It does not address evaluating measurement uncertainty for breath alcohol **subject** testing.	Subject testing is the terminology used to clearly differentiate between breath alcohol instrument calibration work and obtaining breath test results from a subject.	ACCEPT:
30		2	T	ANSI/ASB Standard 054	remove	I was not able to find any reference to Std 054 in the document	REJECT: ANSI/ASB Standard 054 was added to section 5.1.4
35		3.13	E		"same conditions"	How does this differ from the "same operating conditions"? Perhaps provide an example?	REJECT: "same conditions" was removed
36		5.1.4	E		Calibration Methods	Capoital letters not needed	ACCEPT:
37		5.4.1.2	E	No less than three	No fewer than three		ACCEPT:
38		5.4.1.2	E		Differences in font in this subsection	Make consistent	ACCEPT:
31		5.4.1.3 NOTE 2	T	Double-counting of a component will result in an overestimation of the measurement uncertainty.	Add some context of whether this is ok or not. Or just remove the note.	The note is not very helpful without indications if this is ACCEPT:able or not. The first draft indicated this "should be avoided".	REJECT: As written, this statement alerts the reader to the potential for overestimation.
39		5.4.2.2.1.3	T		Proficiency tests data may also be used for a Type A uncertainty component;	Proficiency "test" data? Does this refer to data that has been measured previously or re-testing of proficiency samples? If the latter, need to consider stability	ACCEPT:
24		5.4.2.2.1.3	E	NOTE is incorrect font	reduce font size for the NOTE	consistency	ACCEPT:
2		5.4.2.2.2.2	T	Testing laboratories shall evaluate variance of control data (e.g., perform a statistical F-test).	provide example of F-test calculation and evaluation in Annex A & B	change in 5.4.2.2.2.2 does not seem to be reflected in examples.	REJECT: The F-Test is offered as an example and not a requirement.
32		5.4.2.3.1.4.a	E	be representative of the measurand that will be tested or calibrated	be representative of the measurand that will be calibrated	Remove "tested" since this is a subsection of 5.4.2.3 which is specific to calibration	ACCEPT:
33		5.4.2.3.1.4 c and d	E	order is reversed from 5.4.2.2.1.4	switch c and d	recommend consistency between 5.4.2.2.1.4 and 5.4.2.3.1.4	ACCEPT:
25		5.4.2.3.2.2	T	shall evaluate variance of measurement standard data for an individual breath alcohol measuring instrument or across a population of breath alcohol measuring instruments	Unsure of the proposed revision due to confusion about this section. Possibly update this section to refer to multiple calibration levels and instruments?	The beginning only refers to combining data across multiple instruments, but all the sub sections are about combining data from multiple concentrations. Recommend clarifying if this is about combining mutliple concentrations AND multiple instruments. This is written in a much clearer manner for testing labs.	REJECT: Section was revised for clarity
40		5.4.2.2.2.3	E		Differences in font in this subsection	Make consistent	ACCEPT:
41		5.4.3.2 b)	E		ensure components are handled evaluated according	Remove the word "handled"	ACCEPT:
26		5.4.3.2.b	E	ensure components are handled evaluated according to	"ensure components are evaluated according to" OR "ensure components are handled according to"	sentence should have either "handled" or "evaluated", not both	ACCEPT:
1		5.4.3.2b)	E	ensure components are handled evaluated according to the assumed distribution of the quantity value; and	delete "handled"	added "evaluated" and assuming it was meant to replace "handled"	ACCEPT:
34		5.5.1 and 5.5.1.1	E	"General" section has no info and only one subsection	eliminate the subsection designation of 5.5.1.1 (but keep content)	This document is extremely sub-numbered, anywhere that can be reduced would be beneficial. This would also be consistent with the way 5.4.2.1 is formatted.	ACCEPT:
7		5.6.1.2	E	NOTE ...deemed significant if when it impacts...	...deemed significant if it impacts...	grammar	REJECT: NOTE was removed.
21		5.6.1.2	T	The note is not clear - what does it mean by the least significant digit in the reported value for MU? If MU is 18%, a component is deemed significant if its contribution is >1%?	Suggest adding an example.		REJECT: Changed to a requirement to document justification of exclusion of uncertainty components from combined standard uncertainty calculation.
27		5.6.1.2 note	E	is deemed significant if when it impacts	"is deemed significant if it impacts" OR "is deemed significant when it impacts"	sentence should have either "if" or "when", not both	REJECT: This note was removed from the document.

#		Section	Type	Comment / Original	Proposed Revision	Rationale	Disposition
42		5.6.2.3 and 5.9.3.8	E		Reference missing	Fix missing reference link	ACCEPT:
22		5.6.2.3, c), 2)	E		There are errors regarding reference sources	I am not sure what references should have been cited here but it will be helpful to know what actions a lab can take to address significant bias.	ACCEPT:
28		5.6.2.3.c.2, 5.9.3.8, p38	E		Error! Reference source not found.	correct section references	NA	ACCEPT:
5		5.8.2 d)	E	EXAMPLE: control limits of ± 20 % for a method with expanded MU of 10 %. For any single analytical batch, this limit would allow a variation of up to 20 % which exceeds the stated expanded MU for the method, which would prompt the testing laboratory or breath alcohol program to reevaluate the control limits to ensure the MU statement will always be correct.	EXAMPLE: control limits of ± 20 % for a method with expanded MU of 10 %. For any single analytical batch, this limit would allow a variation of up to 20 % which exceeds the stated expanded MU for the method, which would prompt the testing laboratory or breath alcohol program to reevaluate the control limits.	Remove "...to ensure the MU statement will always be correct." The MU would be correct, assuming calculations were accurate. Not sure to what "MU statement" is referring. What would not be reasonable would be having control limits larger than the MU (but this is not the MU or "MU statement"). Would it be ACCEPT:able to have a control limit of 20 % if the expanded MU was 18 % or 19%? Or, must the MU be equal to or greater than the control limits? Removing "...to ensure the MU statement will always be correct." directs the lab or program to look at the control limits in light of the MU so they can make any necessary changes to those limits.	ACCEPT:
8		5.8.2 EXAMPLE	T	...for a method with expanded MU of 10%.	...for a method with expanded MU of 10% (95.45% coverage probability)	Adding the coverage probability (and/or the k-value) will provide better insight regarding how different 20% as a threshold is when compared to the method MU. (without the coverage probability or a k-value, the MU is an unknown quantity)	ACCEPT:
43		5.9.1	E		coverage factor k not given in italics	Make italics for consistency with when it is defined	ACCEPT:
6		5.9.2	E	For calibration laboratories, the MU shall be reported.	For calibration laboratories, the MU shall be reported with calibration results.	This seems redundant with 5.9.3.2. Could remove 5.9.2 or add to the sentence (suggestion in proposed revision).	REJECT: 5.9.2 specifies when MU shall be reported, while 5.9.3 (and its subsections) explains how to report it.
23		5.9.3.8	E	The same error regarding reference source	The link should be fixed.		ACCEPT:
44		6.2a)	E		change	changes	ACCEPT:
3		Annex A	E	The laboratory has set internal criteria for combined aliquots from both each syringe:	Decide on using either "both" or "each" in sentence	both and each are redundant	ACCEPT:
9		Annex A, Homogenization	T	Rectangular distribution presented	A triangular distribution would be a better model for 2 reasons. As such, the equation to use would be [a / (6^0.5)] #1- homogenization is partially captured in the historical QC blood sample, and this has demonstrated a normal distribution over 101 measurements. #2- When the 5% threshold is not met, the analysis is repeated. In combination, these 2 concepts suggest that values are more likely to be closer to the middle vs. the boundaries, rather than a uniform distribution that provides equal probability across the range of values. NOTE- if change is made, later calculations would need appropriate revision.	Triangular distribution would be a more appropriate model, and provides more diversity in the examples	REJECT: The annexes contain examples of different options. For this example, the laboratory chose a rectangular distribution, which is more conservative.
11		Annex A, Table A.1, Analysis header	E	Row 5 under "Analysis" sub-header- "...through the procedure administrative requirement for agreement of replicates."	"...through the procedure administrative requirement for agreement of replicates (Type B Evaluation)."	Consistency w/ rest of Table	ACCEPT:
10		Annex A, Step 6	T/E	"The data from the measurement process is assumed to follow a normal distribution."	"The data from the Blood Matrix QC Sample has demonstrated that the measurement results follow an approximately normal distribution."	Rather than 'assume', use the collected data	ACCEPT:
12		Annex A, Step 6	E	"...from the Student's t-distribution table will be used."	"...from the Student's t-distribution table with 100 degrees of freedom will be used."	Not all readers will recognize that Student's t-distribution is a function of degrees of freedom. Worth repeating here to solidify why DOF was discussed immediately above.	ACCEPT:
13		Annex A, Step 8	E	"The laboratory has established a procedure for rounding the expanded uncertainty." Consider changing the numbers in the example such that the final MU calculated in Step 6 is 9.3404%, for example. Then in Step 8, the rounding will still result in a value of 9.4% as values always need to be ROUNDED UP to maintain the chosen coverage probability (or greater).	"The expanded uncertainty value must be rounded up to maintain the established coverage probability. Following that procedure, the expanded uncertainty was rounded up to two significant figures: U = 9.4% "	Provides an example where 'traditional rounding' is not the correct approach for statistics probability reasons, which is a good lesson to communicate.	REJECT: The standard allows laboratories to establish and support their rounding rules. Annex A is an example of one laboratory's decision.
14		Annex B, 2nd paragraph	E	"calibrators at 6concentrations..."	"calibrators at 6 concentrations..."	Space needed after "6"	ACCEPT:
15		Annex B, 2nd paragraph	E	"...across the concentration range...was observed across the concentration range."	"Lack of consistent variance (heteroscedasticity) was observed across the concentration range."	remove redundancy	ACCEPT:
16		Annex B, Meas Traceability, paragraph 3	T	"...volumetric flasks have been and are routinely calibrated."	"The volumetric flasks have been calibrated and the pipettes have been and are routinely calibrated."	Volumetric flasks are typically calibrated one time and provided with a lengthy calibration lifetime (eg, 10 years) and thus are not 'routinely calibrated'	REJECT: Language has been clarified.

17		Annex B, multiple instances	T	One example- "The largest uncertainty was 0.74 uL for a 100uL pipette"	"The largest relative uncertainty was 0.74 uL for a 100uL pipette."	This distinction is important as the largest uncertainty observed might very well NOT be the largest RELATIVE standard uncertainty, which would be the value that should be carried forward. This occurs multiple times in Annex B.	REJECT: The statement is accurate.
18		Annex B, multiple instances	T	One example- "...a coverage factor of k = 2.87, and a coverage probability of approximately 95%."	Change k to a smaller value and fix calculations	A calibration certificate at a 95% level with a k = 2.87 is not realistic. It is too large of a k-value for such a scenario	REJECT: This coverage factor for a calibration certificate is not unrealistic. It is only an example to demonstrate the calculations to be performed.
19		Annex B, Step 6	E	"Refer to the Student's t-distribution table to determine the k factor."	"Refer to the Student's t-distribution table to determine the k factor for 14 degrees of freedom."	Not all readers will recognize that Student's t-distribution is a function of degrees of freedom. Worth repeating here to solidify why DOF was discussed immediately above.	ACCEPT:
20		Annex B, Step 8	T	"...expanded uncertainty rounded to two significant figures: For Amphetamine: U = 8.7%...Methamphetamine: U = 8.2%"	"...expanded uncertainty rounded to two significant figures: For Amphetamine: U = 8.8%...Methamphetamine: U = 8.3%"	Uncertainty values must be rounded UP to maintain the probabilities that were used in the calculations (ie, must stay on the conservative side of the probability calculation to ensure the stated coverage probability is met)	REJECT: The standard allows laboratories to establish and support their rounding rules. Annex A is an example of one laboratory's decision.
29		Annex C Step 6 (p47)	T	A laboratory can choose to increase the coverage probability.	remove	This sentence seems out of place in the breath calibration program example.	ACCEPT: