Deadline of Submission of Comments: 21-Aug-23
Document Number: ANSI/ASB Std 055
Document Title: Standard for Breath Alcohol Measuring Instrument Calibration

#	Section	Comments	Proposed Resolution	Final Resolution
5	4.5	Using the LLOQ as the lower and ULOQ as the upper calibrators is problematic. Alcohol values as low as 0.01 can be valuable to agencies in their evaluation of the DUI. However, using a 0.01 as a calibrator makes very little sense. On the upper end you run into a similar problem. It is well established that the uncertainty increases with increasing dry gas tank values. Using the highest BrAC possible (~0.40) means the uncertainty for the tank would exceed legal requirements in some areas.	Remove the requirement to make the LLOQ and ULOQ the lowest and highest calibrator values.	REJECT: The practice of using the LOQs as the criteria for reporting is present in other applicable ASB Toxicology documents (ANSI/ASB Standard 054, *Standard for a Quality Control Program in Forensic Toxicology Laboratories,* Clause 7.3 (d) and example). The Breath Alcohol Program can administratively set limits that are bracketed by the calibration curve (ULOQ/LLOQ) (see 4.5.1 in this document). The Consensus Body does not support reporting results outside of a successful calibration (objective proof of bias and precision within a defined range).
1	4.5	Reference to (see also 5.e) is a circular reference that points back to itself.	Remove unnecessary reference	ACCEPT: Reference removed within the sentence.
16	4.5	extra paranthesis at end of sentence "…(see also 5.e)).	delete extra paranthesis after "e"	ACCEPT: Editorial error fixed; however the Consensus Body ultimately chose to remove the reference.
2	4.6.9	The wording refers to: "The measurement technology (detector)…" which implies a reference to the hardware technology, rather than the calibration method.	We suggest updated wording: "The calibration model shall be considered linear if all bias results are < 0.005 g/210L or 5% (whichever is greater) and the r2 value is > 0.990."	REJECT: The phrase 'calibration model' is incorrect in this instance. It is used in other ASB Toxicology documents to refer to the process of adjusting and verifying a calibration curve. For Breath Alcohol instrumentation, the adjustment calculations are proprietary and not controlled by the user (i.e., Breath Alcohol Program). Linearity is a function of the detector and computer system. Therefore, the linearity study written in this document provides objective evidence that the detector and computer system in tandem are providing accurate results encompassing the entire calibration range. However, the Consensus Body did add "computer system" to the sentence to provide greater clarity.
17	4.7	While not part of the redline changes, there is a missing period after (i.e,)	change "(i.e, not…" to "i.e., not…"	ACCEPT: Editorial error fixed.
3	5D.3	The wording refers to: "...if measurement technology is linear…"	We suggest updated wording: "a minimum of four non-zero calibrators if calibration model is linear or six non-zero concentrations shall be used as calibrators if non-linear (see section 4.6);	REJECT: The phrase 'calibration model' is incorrect in this instance. It is used in other ASB Toxicology documents to refer to the process of adjusting and verifying a calibration curve. For Breath Alcohol instrumentation, the adjustment calculations are proprietary and not controlled by the user (i.e., Breath Alcohol Program). Linearity is a function of the detector and computer system.
4	5 d) 5	Number of replicates per concentration shall be a minimum of 5.	replicates must be minimum of three. Software are designed for three replicate.	REJECT: While this requirement was not changed (and therefore not open for public commenting), the Consensus Body reviewed the request. The number of replicates and concentrations was chosen based on statistics and the Consensus Body does not support changing the parameters.
18	5.d.6	"Shall" should be lower case for consistency	change "S" in shall from capital to lowercase	ACCEPT: Editorial error fixed.
12	6.3.2.1	"(i.e., the computer program will calculate the normalized value and present it to the user)." The words "computer program"--is this referring to instrument software?	If referring to software, suggest using "software" to be in line with 9.5	ACCEPT: Language revised.
13	6.3.2.1	"If the computer program normalizes the results, the calculations shall be validated." Because this is often done by the software, how does one verify the calculations?	Provide guidance to validating calculations	REJECT: This document is a minimum requirement/standard. There is an expectation for users to have some level of technical understanding in order to use the standard. Requirements were added when the CB felt a standardized approach was necessary.

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6	6.3.2.1	The second paragraph (Low concentrations shall be no more than 3 times the lowest calibrator….and high shall be within 80% of the highest calibrator) contradicts what is said in 4.5.	Keep this standard. It is much more practical and gives flexibility for agencies to follow local rules and regulations.	ACCEPT: This section was retained as requested. For further clarification--- Section 4.5 is for the Calibration Method. Section 6 deals with validation of the calibration method. Clause 6.3.2.1 outlines validation experiments (i.e., the calibration has already been performed and now you should use different concentrations or different sources to provide objective evidence that the calibration method works as intended).
7	6.3.2.1	The second paragraph (Low concentrations shall be no more than 3 times the lowest calibrator….and high shall be within 80% of the highest calibrator) does not make sense grammatically. If two different version (3 times vs 80%, then they need to be in seperate sentences. Use of middle is non-sensical.	Low concentrations shall be no more than 3 times the lowest calibrator (LLOQ) utilized in the calibration method. High concentrations (ULOQ shall be within 80% of the highest calibrator used in the calibration method. Mid-level concetrations shall be near the midpoint between the low and high concentrations.	REJECT: This language was harmonized with the current version of ANSI/ASB Standard 036, *Standard Practices for Method Validation in Forensic Toxicology* .
19	6.3.2.1	Should the requirement to validate the computer program's gas pressure normalization calculations should occur during method development? Section 4.6.4 requires normalization of gas pressure, so shouldn't the validation of the instrument calculations be performed prior to any calculations performed on gas results?	Add requirement to validate gas pressure normalization calculations to section 4.3 prior to performing % difference and % CV calculations during development. Also, add an example of how to validate the instrument software calculations that normalize gas pressure.	REJECT: This document is a minimum requirement/standard. There is an expectation for users to have some level of technical understanding in order to use the standard. Requirements were added when and where the CB felt a standardized approach was necessary.
8	6.3.2.4	It is not clear what "within run" means. This is a breath document not blood. Each sample is independent.	Clarify what is meant here.	ACCEPT: The Consensus Body added a definition in Section 3 for "run". Additionally, 6.3.2.4 was revised to provide greater clarity. Annex C provides an example of both calculations.
9	6.3.2.5	It is not clear what "between run" means. This is a breath document not blood. Each sample is independent.	Clarify what is meant here.	ACCEPT: The Consensus Body added a definition in Section 3 for "run". Additionally, 6.3.2.5 was revised to provide greater clarity. Annex C provides an example of both calculations.
20	6.3.5.2	While not part of the redline changes, consider changing the "." after "following" to ":"	Make necessary corrections.	ACCEPT: Editorial error fixed.
21	6.3.5.2.c	While not part of the redline changes, consider changing to "." after "choices" to ":"	Make necessary corrections.	ACCEPT: Editorial error fixed.
10	9.4	Low concentrations shall be no more than 3 times the lowest calibrator….and high shall be within 80% of the highest is combining two forms (3 times vs 80%). Medium concentrations is an inappropriate term.	Low concentrations shall be no more than 3 times the lowest calibrator (LLOQ) utilized in the calibration method. High concentrations (ULOQ shall be within 80% of the highest calibrator used in the calibration method. Mid-level concetrations shall be near the midpoint between the low and high concentrations.	REJECT: This language was harmonized with the current version of ANSI/ASB Standard 036, *Standard Practices for Method Validation in Forensic Toxicology* . This requirement is focused on calibration, therefore the terms LLOQ and ULOQ are unnecessary.
14	9.5	"See Annex C for example calculations used when the software does not automatically normalize results." The word, "software"	harmonize with using either the word "software" or "computer program"	ACCEPT: The wording in the requirement was revised.
11	Annex B2	Requirement of 5 instruments assumed all agencies will have at least 5. Smaller agencies may have less than 5.	a total of 5 insturments will…..experiments. If an agency does not have at least 5 instruments, they shall demonstrate all instruments can successfully complete all validation experiments.	REJECT: The Annexes are all examples (Annex B is an example of a mock Method Validation Plan, for illustrative purposes only). The applicable requirement is located in clause 6.2.1 which specifies a minimum of 1 instrument for validation.
22	C.1.4.b	While not part of the redline changes, the last line of the between-run % CV is written as "Within-Run % CV"	Change "With-Run % CV" to "Between-Run % CV"	ACCEPT: Editorial error fixed.
15	C.2	While not part of the redline changes, this section needs correction: 2.1 should be the conversion factor from g/210L to mg/100mL (not 210) and the target concentration should be 99 mg/100mL (not 0.99) in this example. The conversion factor needs to take into account converting from g to mg and L to 100 mL (or dL).	Make necessary corrections.	ACCEPT: Conversion factor updated and appropriate units revised.