Deadline of Submission of Comments: 6-Feb-23
Document Number: ANSI/ASB Std 055
Document Title: Standard for Breath Alcohol Measuring Instrument Calibration

Master Number	#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Editor or Working Group Review
1	29	3.17	T	In the "reporting range" section, it sounds like the total range of the method is being confused with the correct test result plus the corresponding range due to MU. The range that can be measured (e.g. The method range of 0-0.500%) is not specified on the subject report. The MU is printed on the subject report. Do you mean Calibration Report?	remove "(e.g., what appears on a Subject Test Result Cerificate)".	ACCEPT: Working Group removed example to lessen confusion.
2	8	3.5	T	This definition is different than what is used for a calibration lab under ISO 17025	The ASB Standard should use consistent language so that labs who are already accreditated are not forced to use the langauage of a lower standard (ASB). Calibration refers to the checking of the adjustment. Adjustment should be used here to match that wording.	REJECT: The definition for calibration and several other terms used in this document originate from the VIM (International Metrology Vocabulary). In Breath Alcohol standards, the VIM is cited when applicable and is available for free. ISO/IEC 17025:2017 does not contain a definition for Calibration or Adjustment. The terms defined in the Breath Alcohol standards by Standards Developing Organizations (SDO) and used by accrediting bodies typically come from the VIM. These terms were repeated within Breath Alcohol standards for ease of reference.
3	61	3.5	T	This defintion is a run on sentence. The meaning of calibration is not easily udnerstood from this description.	An instrument operation that determines the concentration of a set of known standards. The standards have associated measurement uncertainties. This operation is performed under specified condtions.	REJECT: The definition for calibration and several other terms used in this document originate from the VIM (International Metrology Vocabulary). In Breath Alcohol standards, the VIM is cited when applicable and is available for free. ISO/IEC 17025:2017 does not contain a definition for Calibration or Adjustment. The terms defined in the Breath Alcohol standards by Standards Developing Organizations (SDO) and used by accrediting bodies typically come from the VIM. These terms were repeated within Breath Alcohol standards for ease of reference.
4	9	3.7	T	The term carryover is typically applied to a GCMS run. This term does not seem appropriate for breath testing.	Perhaps contamination is the word you are looking for.	REJECT: Carryover is a component that needs to be addressed by Breath Alcohol. While Breath Alcohol instrumentation has advanced mitigation strategies (e.g., air blanks), the use of a shared pathway necesitates the evaluation of carryover.
5	11	4.1	E	This sentence is very difficult to read. I do not understand the meaning completely.	Re-word to make clearer. All the words should be the same format in a list. For example you wouldn't say I enjoy running, to read, and walks. The correct way to phrase that would be I enjoy running, reading and walking. The words (legal, prorgammatic, legal precedent and or accreditation requirements) do not follow the same format.	ACCEPT: Working Group revised sentence to address commenter concerns.
6	10	4.4	T	What does "with-in run and between run %CV" mean? This is normally a term used for GCMS analysis	The wording should be changed to "The largest calculated CV for each concentration shall be used to determine precision acceptability."	REJECT: The concepts of within-run and between-run are not limited to a particular instrument (e.g., GC/MS). All instrumental based methods are subject to variation. While the exact term used may vary, the Consensus Body is using the same language found in ANSI/ASB 036 to provide a common terminology across ASB standards.
7	51	4.5	E	the reference to section 5 at the end of the paragrpah is incorrect	correct 5.1.d).2 to 5.d).2 (remove the 1)	ACCEPT WITH MODIFICATION: Pointer revised to 5.e).

8	12	4.5.1	T	You are requiring standards with traceability to be used to bracket the upper limits. Then suggest to move down in increments to achieve the desired precision. Standards for breath are not cheap. Using simulator solutions can be problematic. Using dry gas canisters at such tight intervals requires that they be mixed for the client. These often take months to recieve and have a minimum order.	Remove the requirement that the standards have traceability. If the program has an adjacent blood program, determining the values through GCMS with traceable standards should be sufficient.	REJECT: Metrological traceability is fundamental for calibration. Sections 4.5.1 and 4.5.2 are provided as examples of determining ULOQ and LLOQ. Additionally, this is the Method Development section and the Consensus Body does not anticipate a Program performing these steps frequently. The exact requirements for establishing metrological traceability are defined in ANSI/ASB 017 and is outside the scope of this standard.
9	4	4.5.1.a and 4.5.2.a	T	Limiting the number of ethanol concentrations to 3 seems restrictive. What if you want to do more than 3?	Change wording to "3 or more ethanol concentrations"	REJECT: This document outlines minimum requirements. This is also stated in the Scope to alert the reader that a Program can always do more.
10	13	4.5.2	T	The same issue as above exists for the lower standards. Traceable standards are very expensive and impratical.	Remove the requirement that the standards have traceability. If the program has an adjacent blood program, determining the values through GCMS with traceable standards should be sufficient.	REJECT: Metrological traceability is fundamental for calibration. Sections 4.5.1 and 4.5.2 are provided as examples of determining ULOQ and LLOQ. Additionally, this is the Method Development section and the Consensus Body does not anticipate a Program performing these steps frequently. The exact requirements for establishing metrological traceability are defined in ANSI/ASB 017 (insert title here) and is outside the scope of this standard.
11	64	4.5.2 C	T	If you are trying to determine a LLOQ of 0.01 g/210L and that concentration is supposed to be bracketed, the lower value is likely to be 0.005 g/210L. With the uncertainties I have reviewed for alcohol standards, the concentration is likely to be 0.005 +/- 0.002 which would be greater than the allowable bias.	A series of test showing the bias and precision at the administrative cutoff concentration should be enough to set the LLOQ at the administrative cutoff and not require bracketing.	ACCEPT: While no specific resolution was provided, the Consensus Body believes the current wording supports the commenter's position. Sections 4.5.1 and 4.5.2 are provided as examples of determining ULOQ and LLOQ. Both sections allow for an administratively set LOQ. Furthermore, Section 6.3.3 allows for both experimentally determined LOQs and administratively set LOQs.
12	16	4.6	T	It is unclear if the intent is to perform linarity one time on one instrument, one time for each instrument or each time that the instrument is adjusted. If the linearity is a narrower range than the instrument provides, this would require the manufacturer to re-program the instrument. This is not practical. This will also be used in court in an inappropriate way. Breath testing is not static. The "bias" would change depending on when you tested the instrument. Even the pressure of the tank could change the value. This will be used in court to substract off a value from the test. This requirement kills breath testing.	Linearity should be established for a techology but this standard is far too specific to actually be applied in the real world. This should be removed or modified heavily.	REJECT: Linearity is a fundamental concept of calibration. Reporting forensically defensible numerical values (subject test results) requires the Program to know and control the linearity of the Breath Alcohol Instrument responses. Determination of linearity resides in the Method Development section. Programs should determine the number of instruments to be used based upon their risk and no attempt to provide specifics has been made due to the variability of Programs (i.e., there are Programs with 3 instruments, and Programs with 300+ instruments). The Consensus Body does not anticipate a Program performing these steps frequently; and the number of instruments will be captured in the validation plan (6.2.7).
13	14	4.6.1	T	You are now using the word adjust instead of calibration.	Use standard wording to avoid confusion.	REJECT: The term "adjust" is the correct term for this requirement. The rationale for this choice is outlined in the second sentence of the requirement. Please note, this document uses the international definitions for adjustment and calibration.
14	33	4.6.1	T	Adjust the instrument using the number and concentration levels documented chosen...	remove the word chosen	ACCEPT: The language in this section was revised for clarity.
15	38	4.6.1	E	"Adjust the instrument using the number and concentration levels documented chosen to produce a linear response. "	Correct grammar? Does this refer to the levels specified by the manufacturer that would produce a linear response?	ACCEPT: The language in this section was revised for clarity.
16	52	4.6.1	E	Sentence does not read properly "Adjust the instrument using the number and concentration levels **documented chosen** to produce a linear response.	I believe the "levels chosen" is the intent, so delete the word documented. (But it could be intended the opposite way and "chosen" should be deleted instead?)	ACCEPT: The language in this section was revised for clarity.

17	39	4.6.2	T	"established traceability"--Traceability is not defined in terms/definitions.	Define what satisfies having extablished traceability earlier (currently this is defined on pg 12)	REJECT: The mechanism to establish metrological traceability is captured in ANSI/ASB 017. Therefore, 017 is a normative document and referenced in Section 2 and Requirement 5.d) 6. Requirements in Adjustment Section 9 (page 13) of 055 take ANSI/ASB 017 a step further and should be considered in addition to ANSI/ASB 017.
18	65	4.6.3	T	Running 10 tests at 5 concentrations could begin to show fuel cell fatigue, depending on age of fuel cell and concentrations being tested. This would increase the bias and uncertainty and does not reflect how the instrument would actually be used in the field.	Reduce the number of replicates, or the number of concentrations would help prevent fuel cell fatigue.	REJECT: The number of replicates and concentrations was chosen based on statistics and the working group does not support changing the parameters. There is however no mention of timing in the requirement - a Program could choose to expand the timing between concentrations to mitigate impact on the fuel cell. Additionally, this is required during the method development phase. The Consensus Body does not anticipate a Program performing these steps frequently.
19	40	4.6.4	E	normalized to standard pressure	add link to Annex C here--the reader is first directed to Annex C in Section 6.3.2.1, but if reading from the beginning, it would be helpful to have the link earlier in the document	ACCEPT: A reference to Annex C was added to 4.6.4 and to 9.5 for consistency. It was also retained in 6.3.2.1.
20	15	4.6.5	T	This requires 50 data points every time an instrument is adjusted. We recently did a study on this and found it did not improve the reliabitliy of the instrument at all. This is excessive amount of work for no gain. It will also greatly increase the cost and time of performing a calibration check. THis would require additional staff to manage the extra work flow. In our lab we have over a hundred pieces of equipment. This is not practical for all labs.	Reduce the data points. Three levels is more than sufficient. 5 data point per level is also sufficient to see if there are precision issues. We require both accruacy and precision be within our criteria currently.	REJECT: The number of replicates and concentrations was chosen based on statistics and the working group does not support changing the parameters. Additionally, this is required during the method development phase. The Consensus Body does not anticipate a Program performing these steps frequently.
21	17	4.7	T	This requires manufacturers to reprogram individual instruments. This is highly impratical.	Remove.	REJECT: This clause does not contain a requirement to reprogram. It directs the user to 'consider' the impact.
22	5	4.9	T	Adjustment is a maintenance function and therefore should be seperated from the calibration method development section.	Move to section 9 or make a separate section/document for adjustment method development.	REJECT: The consensus body intentionally placed the requirement to validate the adjustment and calibration methods at the very end of the development step because validation is the next step in the process.
23	34	4.6.10	T	…bias and precision criteria "is"…	Is should be are	ACCEPT: Wording updated as requested.
24	18	5.d.3	T	6 non-zero calibrators is excessive. There is little to gain by testing so many areas. The precision and accuarcy can easily be demonstrated by 3 values. Three points is enough to determine linearity. Doing any more is just a waste of resources.	3 non-zero calibrators.	REJECT: The number of calibrators was chosen to align with ANSI/ASB 036. The requirement allows for four non-zero calibrators when the Program has demonstrated the calibration model is linear. The process to determine linearity is outlined in Section 4.6.
25	19	5l	T	Precision of 10% is fairly large. If an instrument cannot maintain a tighter precision, it likely needs a fuel cell replacement (not sure about IR instruments).	Change this to a lower value (recommend 5%).	REJECT: This is a minimum standard (i.e., Programs may lower the %CV). This value was chosen to harmonize with the ANSI/ASB 036 standard.
26	1	5.2	T	Having the reporting range to be within in the calibration could require a state code change as underage cannot have any measurable alcohol, which can be outside the power of the program. Also, the standards available are limited.	Allow the reporting range to be outside the calibration range if validation proves the instruments accurancy and precision within established ULOQ and LLOQ	REJECT: This standard does not specify the quantitative range that Programs are to use in evidential testing. The requirements are intended to ensure that any reported subject quantitative test result is based upon a validated method.
27	20	6.3.2.1	T	In the second paragaph it says that the concentrations should be no more than 3 times the lowest calibrator. I think you are mixing terms again which is making it confusing. For ISO purpose calibrator is used to test adjustment and this makes sense. However in the glossary you define a calibrator as something used to adjust the way the instrument reads. In that regard, there is only one calibrator.	Use consistent wording throughout the document. Define words like "run." That is not a word typically used for breath analysis. I suggest using ISO wording throughout, so in this case calibrator would remain the same.	REJECT: The definition of calibrator indicates it is a reference standard to be used in calibration (not adjustment). The definition of calibration originates in the VIM (ISO documents reference the VIM) and does not include adjustment as this is a separate analytical process. The term “run” was self defined in paragraph one of 6.3.2.1. {run(accuracy experiment)}.

28	35	6.3.2.1	E	Throughout section: "approximately" does not meet the definition of "shall"	Remove the word approximately or shall throughout section	ACCEPT: The word "approximately" was removed in this section.
29	41	6.3.2.1	T	ULOQ is within while LLOQ is no more than 3x lowest cal point. Is the intent that the upper cal point could not be used as the upper bias test?	Allow the inclusion of the highest calibrator as a test for bias	ACCEPT: The Consensus Body removed the phrase "approximately" from this section. The phrase of 'within 80%' would allow a Program to use the highest calibrator for this test. However, Programs should consider the ramifications of this choice. Each time the reference material is run, there is variabiity and using the highest calibrator may result in a message vs. a quantitative result. Determining bias and precision (i.e., acceptance criteria) requires a quantitative result.
30	53	6.3.2.1	T	"no less than 80% of the highest calibrator" was changed to "within approximately 80% of the highest calibrator". Can the concentration be between 80-100% of the highest calibrator (and the “approximately” allows a little wiggle room)? Or does the high level need to be ~80% of the highest calibrator, and something equal to the ULOQ is not ok?	Clarify the concentration requirements for the high. Potentially mirror language from Std 036 "high concentrations shall be within approximately 80% (or more) of the highest end of the working range of the method"	ACCEPT: The Consensus Body removed the phrase "approximately" from this section. The phrase of 'within 80%' would allow a Program to use the highest calibrator for this test. The experimental concentrations can be equal to or within the highest and lowest calibrators (ULOQ and LLOQ). Programs have the flexibility in both instances to select the experimental concentrations.
31	2	6.3.2.1, 9.5	T	Instruments may be programmed to adjust the response based on the barometric pressure.	Note normalization may not be necessary if instrument is programmed to compensate for the barometric pressure	ACCEPT: Additional requirements were added related to instruments performing the normalization calculation automatically. The wording in Requirement 9.5 language does not need revision, as either manual calculations or computer programming is acceptable.
32	21	6.3.2.2	T	I do not believe you are using "bias" correctly. It looks like you are trying to discuss uncertainty of measurement which is different from bias.	Suggest using uncertainty of measurement here instead and defining better in the the glossary.	REJECT: The definition of bias (3.3) originates from ANSI/ASB 036. Bias is determining how far from the 'true' value your experimental values read (i.e., the result on the instrument vs the certified reference material value). Uncertainty of Measurement is a different concept than bias. Uncertainty of Measurement evaluates the overall variability in the measurement process. Precision data (typically standard deviation) is a major contributor to the evaluation of uncertainty.
33	54	6.3.2.3	E	Should the 2 different types of precision calcs be sub sections of the Precision number? (This section is not part of the revision, just a formatting suggestion for consideration.)	Change 6.3.2.4 to 6.3.2.3.1; change 6.3.2.5 to 6.3.2.3.2	REJECT: The numbering scheme follows the Manual and Style guide for ASB Standards, Guidelines, Best Practice Recommendations, and Technical Reports. The Consensus Body agrees with the numbers currently in the document.
34	22	6.3.2.4	T	The term "within run" is unprofesional and inappropriate.	Come up with a better term to desribe the batch of testing you wish to compare.	REJECT: While the commenter did not provide a recommended resolution, this term is commonly understood in Toxicology.
35	42	6.3.2.4	E	suggestion in 6.3.2.1 is minimum of triplicate but directions for calculations specify triplicate	change word "triplicate" to "replicate"	ACCEPT: The language in this section was revised to meet the recommendation.
36	6	6.3.3	E	In the last sentence, the ULOQ and LLOQ are reversed.		ACCEPT: The language was revised (corrected).
37	36	6.3.3	T	ULOQ associated with lowest calibrator and LLOQ associated with highest calibrator	ULOQ should be associated with highest calibrator and LLOQ should be associated with lowest calibrator	ACCEPT: The language was revised (corrected).
38	55	6.3.3	E	the added text for lowest and highest calibrators appears to be reversed	edit to be: ULOQ (highest calibrator) and LLOQ (lowest calibrator)	ACCEPT: The language was revised (corrected).
39	23	6.3.4	T	carryover is not the appropriate term. Carryover is used in GCMS or GCMSLC testing. I think you mean contamination from a previous sample.	Use appropriate terms for breath testing such as contamination from a previous sample.	REJECT: The definition of carryover (3.7) originates from ANSI/ASB 036. Carryover occurs when the expected analytes from one test item (e.g., CRM, subject test sample) continue to appear in the next test item(s) result . While Breath Alcohol instrumentation has advanced mitigation strategies (e.g., air blanks), the use of a shared pathway necesitates the evaluation of carryover.

40	7	8.2	T	This may be in conflict with some state's record retention policies.	Go back to the previous language which allowed for following the program policy OR 10 years after calibration method is no longer used.	REJECT: The removal of the reference to retention policies was based on Consensus Body conversations and published ASB/Toxicology documents.
41	24	8.2	T	This standard is unclear that is applies to the validation only.	Change statement to "Records for the validation shall be retained…."	REJECT: This requirement is within the Validation Documentation Requirements section.
46	25	9.4	T	You are requiring that the instrument do 3 levels to determine an adjustment is needed. This is excessive. It is generally fairly obvious when an insturment needs an adjustment. Either the value is way off or it fails a previous calibration. To require this excessive work prior to adjusting and testing it all again is a waste of resources.	To evaluate instrument performance a calibration check can be utilized. Other reasons for an adjustment can include, but are not limited to a fuel cell replacement, or a previously failed calibration.	REJECT: A single concentration is insufficient to determine the performance (e.g., calibration status) prior to adjusting the instrument. The purpose of this performance verification is not only to determine if you should adjust, but also to document the condition of the instrument prior to changing the instrument's response. This is commonly referred to as the "as found" condition. While apparent failures (e.g., the instrument won't power on) would make it impossible to conduct this verification, that is covered in Requirement 9.10.
47	37	9.4		Throughout section: "approximately" does not meet the definition of "shall"	Remove the word approximately or shall throughout section	ACCEPT: Wording revised, removed "approximately".
48	43	9.4	T	"within 80%" Is the intent that the upper cal point could not be used as the upper performance test?	Allow the inclusion of the highest calibrator as a test for instrument performance	ACCEPT: The phrase of 'within 80%' would allow a Program to use the highest calibrator for this test. The experimental concentrations can be equal to or within the highest and lowest calibrators (ULOQ and LLOQ). Programs have the flexibility in both instances to select the experimental concentrations.
49	56	9.4	T	"no less than 80% of the highest calibrator" was changed to "within approximately 80% of the highest calibrator". Can the concentration be between 80-100% of the highest calibrator (and the “approximately” allows a little wiggle room)? Or does the high level need to be ~80% of the highest calibrator, and something equal to the ULOQ is not ok?	Clarify the concentration requirements for the high. Potentially mirror language from Std 036 "high concentrations shall be within approximately 80% (or more) of the highest end of the working range of the method"	ACCEPT: The phrase of 'within 80%' would allow a Program to use the highest calibrator for this test. The experimental concentrations can be equal to or within the highest and lowest calibrators (ULOQ and LLOQ). Programs have the flexibility in both instances to select the experimental concentrations.
50	67	9.4	E	Should be a bullet point for 9.3	Change 9.4 to be 9.3.1	REJECT: The numbering scheme follows the Manual and Style guide for ASB Standards, Guidelines, Best Practice Recommendations, and Technical Reports. The Consensus Body agrees with the numbers currently in the document.
51	26	9.6	T	Our criteria are far in excess of our state statues for accuracy. To require us to evaluate if results were affected when we are adjusting prior to it going outside the state limits is excessive.	Determine a criteria under which the insturment results should be evaluated in the event that the perfomance evaluation results do not meet acceptable criteria.	REJECT: This clause is not a requirement (intentional choice of the word "should"). The intent of the clause is to identify the relationship between calibration & subject testing. Any requirements related to subject testing results would be more appropriately covered in a different OSAC/ASB document.
52	31	9.8	T	See above	9.8 change to "If the laboratory maintains a calibration program, an adjustment shall be followed by a calibration before the instrument is used for evidential Breath Alcohol testing Change".	REJECT: This standard does not specify who (personnel or Program) will conduct any of the steps. Regardless of who performs the adjustment, a calibration is to be performed prior to evidential use.

53	3	10.1	T	A 12 month calibration period is not feasible for programs with limited staffing. ASB 017 uses the term annually- annually is not defined as a 12 month period and could be interpreted as a calendar year. Intermediate checks	Calibration performed each calendar year with performance checks performed monthly during that interval	REJECT: The 12 month calibration interval has not changed with any of the public releases. As stated in previous Public Comment Adjudication documents --Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology. This document builds upon that work. Many Breath Alcohol programs have been involved during the standards development process at OSAC and ASB. Based upon the goal of standardization, a defined calibration interval was determined to be necessary. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
54	27	10.1	T	Requiring a calibration every year will cripple some breath labs. For example we have 140+ instruments. If we use the extended guidelines of this document it will take 1-2 days to calibrate each instrument. We also have to have a second analyst to review this work. This would require 2 additional staff members just to handle the calibrations. Add on to that the instruments that need to be calibrated earlier than that. It will create a serious problem, potentially leading to insturments falling outside the requirement when analysts have to go to court or are out sick.	Change the criteria. Requiring a calibration relating to the expected life of the detector makes more sense. A year is completely arbitrary.	REJECT: The 12 month calibration interval has not changed with any of the public releases. As stated in previous Public Comment Adjudication documents --Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology. This document builds upon that work. Many Breath Alcohol programs have been involved during the standards development process at OSAC and ASB. Based upon the goal of standardization, a defined calibration interval was determined to be necessary. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
55	59	10.1	T	While I agree that specifiying a timeline for calibration would be best practice for consistency, there is no reason to impose a strict 12 month interval. We are a small program and have set our calibration interval as once per calendar year. Many agencies would experience a significant burden, if they had to adhere to a 12 month interval. In previous responses to this concern, ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology was referenced as the source for the guidance in determining the 12 month interval. However that document states in 4.1.3 f, that calibrations must be repeated at established and appropriate intervals. It seems that *appropriate* intervals could only be determined by individual programs, based on their resources, robustness of their particular instrumentation, and any requirements their state (or governing body) may impose. Most programs (including mine) already have measures/checks in place that occur between calibration intervals.	Make the required calibration interval longer if you must place a firm timeline on it, and require additional accuracy checks, or the equivalent, to be performed between calibrations.	REJECT: The 12 month calibration interval has not changed with any of the public releases. As stated in previous Public Comment Adjudication documents --Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology. This document builds upon that work. Many Breath Alcohol programs have been involved during the standards development process at OSAC and ASB. Based upon the goal of standardization, a defined calibration interval was determined to be necessary. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
56	62	10.1	T	A required calibration interval based on a number of months when the instrument is still performing at described criteria seems uncessary.	An instrumenst used for evidential purposes shall be calibrated under the following circumstances: a) after a change to the computer system that impacts the analytical results; b) after any system component that impacts an analytical result is replaced or repaired; c) after an adjustment (see Section 9); d) when acceptance criteria are not successfully met (e.g., failed calibration); and e) prior to being used the first time for evidential testing.	REJECT: The 12 month calibration interval has not changed with any of the public releases. As stated in previous Public Comment Adjudication documents --Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology. This document builds upon that work. Many Breath Alcohol programs have been involved during the standards development process at OSAC and ASB. Based upon the goal of standardization, a defined calibration interval was determined to be necessary. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.

57	66	10.1	T	In the state of California we have a check of accuracy every 10 days or 150 tests which ever comes first.	The results of the accuracy checks should be able to be used to extend the calibration interval and not be held to a 12 month interval	REJECT: The 12 month calibration interval has not changed with any of the public releases. As stated in previous Public Comment Adjudication documents --Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology. This document builds upon that work. Many Breath Alcohol programs have been involved during the standards development process at OSAC and ASB. Based upon the goal of standardization, a defined calibration interval was determined to be necessary. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
58	30	10.1, 10.1.c	T	Our agency, with over 1200 PEBTs in the field, performs adjustments, performance verifications and linearlity checks. The lab is not an accredited calibration lab, therefore calibration verifications serve to verify the correct measurement of a PEBT. It is unreasonable to require calibrations and certification, as outlined in this standard, especially annually. The manufacturer provides a calibration uncertainty and title 17 (CA) requires verification within 0.01%. The subject's breath component of the measurement is by far the largest component of the variablility of a test, making uncertainty of calibration irrelevant in the result (though trending may be a slight factor). It would be more useful for the committee to recommend testimony strategy around uncertainty of a breath test, rather than trying to obviate the question by requiring calibrations.	10.1 "The calibration method shall have a specified interval not to exceed 12 months from the date of calibration" to "The calibration method shall have a specified interval".	REJECT: The 12 month calibration interval has not changed with any of the public releases. As stated in previous Public Comment Adjudication documents --Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology. This document builds upon that work. Many Breath Alcohol programs have been involved during the standards development process at OSAC and ASB. Based upon the goal of standardization, a defined calibration interval was determined to be necessary. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
59	45	Figure A.1	E	X and Y axes are flipped	Make Nominal as x-axis and Experimental as y-axis	ACCEPT: Numbers were correct, axis labels reversed. The axis labels were corrected.
60	44	Table A.3	E	"acceptable bias and precision"	should read "acceptable bias and correlation"	ACCEPT with Modification: The example record was updated to include correlation.
61	57	Annex B	T	6.2.7 requires the plan to specify the number of instruments used for validation experiments, the sample plan only specifies the number of instruments used for the bias experiment	Specify the number of instruments used for all validation experiments. E.g. Add a statement that the validation experiments will be conducted on 5 instruments. Or specify that all experiments, other than bias, will be conducted on ## instruments.	ACCEPT: Additional information was added to the example to meet the criteria from 6.2.7.
62	58	Annex B	T	6.2.9 states the plan shall require successful completion of all validation experiments...	add a statement to the sample validation plan that addresses the requirement	ACCEPT: Additional information was added to the example to meet the criteria from 6.2.9.
63	46	Annex C.1.1	E	Certified Reference Material possess	make plural-- Materials (CRMs)	REJECT: The term "Certified Reference Material" can be both singular and plural. The Consensus Body has chosen to retain the current abbreviation.
64	47	Annex C.1.1	E	Certified Reference Material should…	make plural-- Materials or write as "A Certified Reference Material should…"	REJECT: The term "Certified Reference Material" can be both singular and plural. The Consensus Body has chosen to retain the current abbreviation.
65	48	Annex C.1.3b	E	#4 located in Section **6.3.2.3**	#4 located in Section **6.3.2.4**	ACCEPT with Modification: The reference to a 'section' was removed and numbering updated.
66	49	Annex C.1.4b	E	#5 located in Section **6.3.2.5**	#5 located in Section **6.3.2.5**	ACCEPT with Modification: The reference to a 'section' was removed and numbering updated.
67	50	Annex H	E	numbers don't match footnote #s	Correct numbering	REJECT: The footnotes are numbered sequentially throughout the entire document. This follows the *Manual and Style Guide for ASB Standards, Guidelines, Best Practice Recommendations, and Technical Reports.*