Deadline of Submission of Comments: **21-Feb-22**

Document Title: **ASB Standrd 055, Standard for Breath Alcohol Measuring Instrument Calibration**

Comment #	Section	Type of Comment	Comments	Proposed Resolution	Final Resolution
39	General	E	Document is significantly improved and much easier to follow.	NA	REJECT: Thank you for this comment. Commenter did not provide proposed resolution or issue.
126			I like the ideas for standards that have been posted; especially requiring a unique uncertainty declaration for each sample as well as a report of the understanding of the limitations of the breath estimate obtained in any given case.		REJECT: Thank you for this comment. Commenter did not provide proposed resolution or issue.
127			1. There is no standard as to whether a validation method must require a certain number of validation points. My state uses only two points for breath test calibration and frequently reports results above or below the .10 and .20 points. There should be specific standards on this. To show linearity, at least three points ought to be required, if not more.		REJECT: Thank you for this comment. Section 6.3 outlines validation criteria, which does specify a minimum of three concentrations.
128			2. The proposed standard does require results reported as either below the lower limit of quantification or above the higher limit of quantification. It appears to me that has always been there, which is a revelation to me.		REJECT: Thank you for this comment. Commenter did not provide proposed resolution.
129			3. The mere act that this standard presumes that states are validating their calibration method is a surprise. I bet many states do not validate their calibration method.		REJECT: Thank you for this comment. Commenter did not provide proposed resolution.
144	All	E	From one individual: THIS DOCUMENT IS VERY HARD TO READ AND UNDERSTAND, ALTHOUGH MY COMMENTS ARE FROM SOMEONE WHO HAS NO EXPERTISE IN THIS AREA. LEGAL PRACTITIONERS, WHO MAY BE END USERS OF THIS STANDARD, WILL NEED THIS TRANSLATED MORE INTO PLAIN ENGLISH. BUT THIS IS AN AREA THAT MAY NOT BE CONDUCIVE TO THAT, GIVEN THE TECHNICAL NATURE OF THE STANDARD.	Consider possible legal audiences for this document and make sure it is not too technical for end users in the legal system.	REJECT: The Toxicology Consensus Body is made up of individuals who represent different stakeholders (including the legal community). The ASB has established education programs and resources to raise awareness of the importance of standards and conformity assessment to students, academia, and the public, and provide engagement opportunities for the next generation of standardization participants. The development of forensic standards and those techniques or methods herein is by their nature technical. While every effort is made to draft standards in a clear concise manner, the use of technical terms are necessary to carry out the intent of the standard under development.
1	Foreword	E	End of 1st paragraph describes the document as providing a "model program" for developing and validating a cal method. But the document is a minimum standard of practice for development, validation, evaluation, and monitoring. Model program implies something aspirational, rather the minimum that must be done.	Remove sentence or reword to be consistent with Scope.	REJECT: The sentence does not say 'model program', instead it says "This document provides a model for…." which to the Consensus Body does not imply method exclusivity.
2	Foreword	E	2nd parargraph, last sentence "By following these standards…"	By following this standard	ACCEPT: Sentence updated.
145	Foreword/p.3	E	The term 'Breath Alcohol Program" is used before it is defined on page 5	Either insert definition here or refer to page where term is defined	REJECT: This phrase (Breath Alcohol Program) uses common words. The term was placed in Section 3 to alert non technical readers (e.g., fiscal personnel, criminal justice system personnel) of the myriad of tasks that are frequently included in a Breath Alcohol Program (i.e., it doesn't define the term but offers clarification).
108	Table of Contents	E	Table of contents does not align numerically, contextually, or to proper page numbers	Update table of contents to align with document	REJECT: Unfortunately the default entry (The TOC will be updated prior to publication) did not make it into the draft standard. It will be fixed prior to publication.
116	TOC	E	Section headings and page numbers are incorrect	Update table of contents	REJECT: Unfortunately the default entry (The TOC will be updated prior to publication) did not make it into the draft standard. It will be fixed prior to publication.
3	1 Scope	E	"These minimum requirements are included…"	Remove "these" from sentence	REJECT: The addition/deletion of "these" does not alter the intent of the sentence and will be retained.

42	3.2	E	update definition to be consistent with the OSAC Preferred Term	Edit Bias definition to: A systematic tendency for estimates or measurements to be above or below their true values. Note 1: Statistical bias arises from systematic as opposed to random error. Note 2: Statistical bias can occur in the absence of prejudice, partiality, or discriminatory intent.	REJECT: The definition mirrors ANSI/ASB 036 which is a National published standard. Additionally, the preferred term provided is for statistical bias which is used for trending purposes (systematic evaluations).
117	3.2	E	Unnecessary comma between 'identical conditions' and 'to'	delete comma	ACCEPT: Comma was removed.
130	3.2	T	Bias is defined as "[a]n estimate of systematic measurement error, calculated as the difference between the mean of several measurements under identical conditions, to a known "true" value. It is often reported as a percent difference." There are four problems with this definition: (1) Bias is systematic measurement. It is not an estimate of that error. (2) Precisely identical conditions cannot be achieved. (3) If bias is calculated as a percentage difference, ther sentence describing how the estimate is calculated is wrong. (4) The definition departs from the "preferred" definition.adopted by OSAC's Forensic Science Standard Board to achieve greater consistency in forensic science	Consider the following definition: "Statistical bias is a systematic tendency for estimates or measurements to be above or below their true values. When the true value of the quantity being measured is known, the bias of the measuring device can be estimated as the mean of a set of repeated measurements (made under essentially the same conditions) minus the true value. This mean difference also can be expressed as a percentage of the true value.	REJECT: The definition mirrors ANSI/ASB 036 which is a National published standard. Additionally, the preferred term provided is for statistical bias which is used for trending purposes (systematic evaluations).
158	3.2	E	Unnecessary comma	Remove comma between 'conditions' and 'to'	ACCEPT: Comma was removed.
159	3.2	E	to a known' should be 'and a known' in order to correspond with the earlier 'between'	Change 'to' to 'and'	REJECT: This definition mirrors ANSI/ASB 036 which is an American National Standard.
146	3.3.	E	unclear term: breath alcohol activities	Possibly replace the word activities with testing/measurement or documentation	ACCEPT WITH MODIFICATION: Revised the 2nd sentence to provide clarity.
160	3.3	E	Comma needed between words 'responsibilities' and 'and'	insert necessary comma	ACCEPT: Sentence updated to support the Oxford comma.
4	3.4 Calibration	E	references ANSI/ASB 036 - calibration is not defined in that document, only Calibration Model	update citation	ACCEPT: Corrections made to footnotes.
147	3.4.	T	As written, the paragraph on calibration is difficult to follow	Possibly divide into 2 or 3 sentences	REJECT: This definition is the standard definition used in the international community.
40	3.4	E	Be consistent with when footnotes are added.	Add footnote and reference to VIM: Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.[1, c] Footnote: [c] Joint Committee for Guides in Metrology (JCGM), International vocabulary of metrology-Basic and general concepts and associated terms (VIM) (Sèvres, France: International Bureau of Weights and Measures [BIPM]- JCGM 200) available from: https://www.bipm.org/en/publications/guides.	ACCEPT: Corrections made to footnotes.
41	3.4	E	Add notes from the VIM for clarification especially if the VIM is not footnoted for this term.	Add: NOTE 1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty. NOTE 2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called "self-calibration", nor with verification of calibration.	ACCEPT: Corrections made to footnotes.

95	3.4	T	The appropriate footnote (VIM) is not on this page. Also reference is "1" and footnotes are letters. Inconsistent use of markers directing to bottom of page or Bibliography (Annex H).	Add appropriate reference to bottom of page 2 (VIM). The document would be more clear if you referenced only footnotes or the bibliography.	ACCEPT: Corrections made to footnotes.
96	3.5	E	"...standardize or calibrate an instrument or laboratory procedure". A laboratory procedure cannot be calibrated.	Delete "or laboratory procedure."	ACCEPT WITH MODIFICATION: The definition was revised to mirror that used in both ANSI/ASB 017 and ANSI/ASB 054
131	3.7	E	"Computer system" is defined as "A system containing one or more components and elements such as computers (hardware),associated software, and data (e.g., software, firmware, hardware, configuration files)." Is a definition really necessary?	Consider deleting this term from the definitions section and defining "computer system parameter" instead.	REJECT: The chosen definition is the best choice for this document. However, the Consensus Body did subsequently go through the document and review when "parameters" was inluded.
5	3 Terms & Def	E	Numerous inconsistencies. Examples include 3.7 and 3.13 reference the same document but one uses a footnote, the other the bibliogrpahy. Page 3 footnotes e and f are the same thing.	Edit to use either footnotes or bibliography (whichever is consistent with ASB Manual) and not repeat citations.	ACCEPT: Corrections made to footnotes.
97	Page 3 Footnotes	E	List VIM as both e and f	Reference both 3.11 and 3.15 to the same footnote and delete the duplicate footnote.	ACCEPT: Corrections made to footnotes.
132	3.7	E	The definition of "computer system" does not clarify what a computer system is. That a computer system is "a system containing one or more components and elements such as computers" provide little information. The examples of "software and data" are puzzling or awkward. Software is an example of software? Firmware is an example of data?	Inasmuch as readers and users of the standard should know what a computer system is without this definition, consider removing this term with "computer system parameter"--a phrase that has no commonly known meaning and is used later in the standard.	REJECT: The chosen definition is the best choice for this document. However, the Consensus Body did subsequently go through the document and review when "parameters" was included.
133	3.8	E	Section 3.8 defines data as "[a] quantitative or qualitative representation that is observed, measured, collected, or gathered that	Replace with definition, adapted from the OECD: "information, either qualitative or quantitative, that are typically collected through observation"	REJECT: The chosen definition is the best choice for this document.
134	3.9 & 3.18	T E	characterizes some static or dynamic attribute of the physical world or the use of it by individuals or groups of people and that is suitable for communication, interpretation, or processing by humans or machines."	Define LLOQ as "the lowest concentration of an analyte in a sample that is deemed to permit the concentration to be measured with acceptable bias and precision." Define ULOQ as "the highest concentration of an analyte in a sample that is deemed to permit the concentration to be measured with acceptable bias and precision." Relatedly, it seems as though 6.2.13 provides some additional guidance for what a reliable measure is with respect to precision (not to exceed +/- 10%) and bias (not to exceed +/- 5%). If this is what 'reliably measured' is referring too, or if it provides some lower floor on what the lab-criteria for reliable measurement should consist in, it may be helpful to reference in the relevant subsections of 3, or perhaps to define separately.	REJECT: These definitions mirror ANSI/ASB 036 which is an American National Standard.
149	p.7 3.11	E	term unclear :a quantity value representing a measurement result	replace the term quantity with quantitative	REJECT: Due to the far reaching impact of this standard the Consensus Body has chosen to use internationally published definitions.
150	p.7 3.13	T	term: nominal quantity value is unclear for any non-expert	possibly define the term nominal quantity value	REJECT: Due to the far reaching impact of this standard the Consensus Body has chosen to use internationally published definitions.
43	3.13	E	Be consistent with when footnotes are added.	Add footnote reference to VIM: A rounded or approximate value of a characterizing quantity of a measuring instrument or measuring system that provides guidance for its appropriate use.[5, e]	ACCEPT: Corrections made to footnotes.
6	3.16 reporting range	T	definition should address that the reporting range may be narrower than the range of concentrations that can be reliably measured	update definition	ACCEPT WITH MODIFICATION: The term "reporting range" was revised to provide greater clarity. The language in 5.1.f) was revised to clarify that the reporting range shall be within the calibration range.
77	3.16	T	The definition of reporting range does not indicate that the reporting range may be smaller than the analytical range of the instrument.	Reword to the statement from 5.1 f)	ACCEPT WITH MODIFICATION: The term "reporting range" was revised to provide greater clarity. The language in 5.1.f was revised to clarify that the reporting range may be within the calibration range.
151	p.8 3.18	E	ULOQ: What is acceptable bias?	Either delete the term, specify what is considered acceptable bias or refer to sections 4.5.1e) and 4.5.2. d) if those are in fact equal to the definition of acceptable bias	REJECT: Definitions do not contain requirements.
67	4	T	How often is it intended for this procedure to be utilized?	Provide definition of a calibration method to clarify when this section would be utilized	REJECT: Section 4.1 defines the reason for developing a method.

135	4.1	E	Is it the representation or object being represented that must be observed, measured, collected, or gathered?	Consider this alternative text: " Consequently, the Program may need to perform various experiments to develop and optimize a method that meets Program requirements. Regardless of legal, programmatic,or accreditation requirements.this standard.requires experimentation to develop a suitable calibration method."	REJECT: The suggested language adds a requirement that the Consensus Body does not agree with - development and optimization needs to occur as specified by the program.
152	p.8 4.3	E	How is accuracy related to bias and precision?	Either specificy how they are related or integral to	ACCEPT: Consensus Body added a definition for accuracy.
7	4.4	E	acceptability criteria guidance should be in the validation section	move to section 6	REJECT: The document was formatted in an order to assist Programs in considering validation elements while developing the method. Validating the method can't occur until there is a method, and the method can't be written unless you know the behavior of the instrument. Performing development experiments provides the data to determine the behavior of the instrument.
136	4.4	T	Section 4.4 reads: "The largest calculated within-run and between-run % CV for each concentration shall be used to determine precision acceptability." Is using a single value as opposed to a statistic that attendees to all the data desirable?	Use a more robust statistic?	REJECT: %CV is not based on a single number but considers all experimental data. This is a well understood, validated, and widely used statistical approach.
68	4.5	T	Do the LLOQ and ULOQ have to be determined experimentally if the instrument firmware already sets the quantitative limits?	Specify if the limits are not predetermined by the instrument, then perform this section.	REJECT: Programs do need to perform method development experiments to help establish or support the limits of quantitation (see Section 6.3.3).
109	4.5	E	Formatting differences between 4.5.1 and 4.5.2	Move the first line of 4.5.1 to 4.5, renumber 4.5.1 a) to 4.5.1 (to be consistent with 4.5.2) and reletter 4.5.1 b) through 4.5.1 f) accordingly	ACCEPT: Formatting was updated.
137	4.5	E	Section 4.5 reads: "During method development, the LLOQ and ULOQ shall be determined. The range of ethanol concentrations of interest (e.g., statutory concentrations, administrative concentrations) shall be considered when determining the appropriate proposed limits." The wording is somewhat awkward.	Consider this alternative text: "4.5 The LLOQ and ULOQ shall be determined during method development. Ethanol concentrations of particular interest (e.g., those that trigger legal consequences) shall be considered in determining these values."	ACCEPT WITH MODIFICATION: The second sentence was revised to the recommended language.
161	4.5.1	E	Should spell out numbers less than 10 and be consistence in what is spelled out versus written numerically	In part f, change the '3's to 'three' to correspond with parts b and c	ACCEPT: All 3's are now known as three.
73	4.5.1	Technical	Based on the text in this section it seems to me that the bias and precision limits could be met for the data taken at some of the three concentrations but not all and the test could still be passed even though the data would actually suggest it should not be passed. For example, the bias and precision limits could be met for 0.420 but not for 0.040 or 0.038. In that case the ULOQ would be declared to be 0.420, since it is the highest data point where acceptable bias and precision criteria are met, yet the data indicating that this result has not been consistently met at the other concentrations suggests a ULOQ of 0.42 would be too high. Part of the problem is that it is not clear to me exactly what the text in 4.5.1 f) means.	Update or better explain the criterion use to determine the ULOQ, preferably with a method that takes into account the uncertainty in the measurements used to evaluate the ULOQ. If I have misunderstood the criterion and it just needs to be better explained, consider illustrating a case where the first ULOQ test fails and then is passed for a lower set of values. This would be somewhat similar to the current ULOQ example, except there only the highest values failed so the result is not as problematic as it would be if a there were a pass for a higher concentration and a fail for a lower concentration.	ACCEPT: ULOQ/LLOQ sections revised to provide better clarification on expectations of the written example.
138	4.5.1 & 4.5.2	E	Sections 4.5.1 and 4.5.2 enumerate steps in "one of multiple paths that can be used to determine these values." How does one know the statistical properties of the outcome for a small number of data points that are required in these paths? What other procedures are permissible?	Present a procedure for determining minimally acceptable values that has specified statistical properties.	REJECT: A prescriptive approach is not specified. A possible approach is provided. In all instances, this can only be experimentally determined. The Program can choose to perform however many replicates they choose in order to provide greater confidence in the developed method. Ultimately, the method has to successfully complete validation parameters, which do have prescribed acceptance criteria and statistically calculated results.
78	4.5.1 b)	E	Extra space between "limit" and "."	Remove space	ACCEPT: Space removed.
79	4.5.1 d)	E	The number of decimals should be consistent in the "(e.g,..." section.	Change "0.38" to "0.380"	ACCEPT: Number changed.

80	4.5.1 e)	T	This statement is suggesting that the criteria are established and where the criteria are met is the ULOQ but in 4.5 this states that the section is method development and is how you determine what the acceptable limits are.	This need to be reworded to indicate some sort of preliminary acceptance criteria or reference to state that the acceptance criteria is listed in section 6.3.2.2	ACCEPT: ULOQ/LLOQ sections revised to provide clarity.
81	4.5.1 f)	T	This statement is suggesting that the criteria are established and where the criteria are met is the ULOQ but in 4.5 this states that the section is method development and is how you determine what the acceptable limits are.	This need to be reworded to indicate some sort of preliminary acceptance criteria or reference to state that the acceptance criteria is listed in section 6.3.2.2	ACCEPT: ULOQ/LLOQ sections revised to provide clarity.
74	4.5.2	Technical	Analogous comment to comment 1 for the method used to evaluate the LLOQ.	Same proposed resolution as for comment 1.	ACCEPT: ULOQ/LLOQ sections revised to provide clarity.
162	4.5.2	E	Should spell out numbers less than 10 and be consistence in what is spelled out versus written numerically	In part e, change the '3's to 'three' to correspond with parts a and b	ACCEPT: All 3's are now written as three.
82	4.5.2 a)	E	Extra space between "limit" and "."	Remove space	ACCEPT: Space removed.
83	4.5.2 d)	T	This statement is suggesting that the criteria are established and where the criteria are met is the LLOQ but in 4.5 this states that the section is method development and is how you determine what the acceptable limits are.	This need to be reworded to indicate some sort of preliminary acceptance criteria or reference to state that the acceptance criteria is listed in section 6.3.2.2	ACCEPT: ULOQ/LLOQ sections revised to provide clarity.
84	4.5.2 e)	T	This statement is suggesting that the criteria are established and where the criteria are met is the LLOQ but in 4.5 this states that the section is method development and is how you determine what the acceptable limits are.	This need to be reworded to indicate some sort of preliminary acceptance criteria or reference to state that the acceptance criteria is listed in section 6.3.2.2	ACCEPT: ULOQ/LLOQ sections revised to provide clarity.
44	4.6	T	Change shall to should in the first sentence. Someone who needs to validate their current firmware, the development of a calibration method has some limitations as the firmware is already set. For instance, in our current firmware, removing the masking is not possible and would require purchasing a new firmware to make this possible. While I agree that this would be great to do (if your firmware allows for this), if your mask is for 0.005 and below, then showing the masking works properly at that concentration should be what is required.	If masking is to be utilized during testing, this function should be removed during performance of the calibration method, if possible. The specific concentrations at which point masking occurs shall be determined during the method development and optimization phase.	ACCEPT WITH MODIFICATION: The sentence structure was completely revised for clarity. (this is now 4.7)
98	4.6	E	Our instrument does not have the capability for us to turn off masking during calibration. This is a function of the instrument and not the calibration method.	Phrase as a strong recommendation rather than a requirement.	ACCEPT WITH MODIFICATION: The sentence structure was completely revised for clarity. (this is now 4.7)
104	4.6	T	Turning off masking is not currently an option on instrumentation	Make it optional. "If masking is able to be removed, it shall be removed during performance..."	ACCEPT WITH MODIFICATION: The sentence structure was completely revised for clarity. (this is now 4.7)
199	4.6	T	Possible misinterpretation regarding when masking must be turned off; confusion regarding whether or not requirement is stating that masking cannot be used during calibration activities.	Suggest clarifying masking requirements for method development only; not method once in use.	ACCEPT WITH MODIFICATION: The sentence structure was completely revised for clarity. (this is now 4.7)
8	4.7	T	I don't understand what this is referring to, nor what modifications would be appropriate or inappropriate	Add some additional guidance or examples. Provide info on the impact of those modifications on traceability.	ACCEPT: Section modified to provide a reference to the section within the document that addresses the expectations.
139	4.7	E	Section 4.7 reads: “The usage, storage, and transportation requirements for reference material may need to be modified to eliminate limitations. In cases when it is not possible to modify, limitations shall be documented in the calibration method.” This observation provides no guidance on when and how to make changes “to eliminate limitations.” What kind of limitations does it refer to?	Describe the limitations and what modifications are permissible.	ACCEPT: Section modified to provide a reference to the section within the document that addresses the expectations.
105	5.1 d 3) and 5.1 f	T	Instrumentation does not have an ability to report within a user determined range. (might be able to be set by a manufacturer, but that's not something we can set at the lab/agency level)	Remove requirement until instrumentation/software has the capability to do this.	REJECT: The Program has the ability/responsibility to specify the requirements with their vendor(s). This will likely require a computer system change (e.g., software, firmware) in order to manage calibration and subject testing results.
200	5.1.d)3); 5.1.f)	T	Requirements in 5.1.d)3) seem to conflict with 5.1.f). It is unclear the intent or requirement meaning when discussing "reporting range" under the calibration method.	Suggest clarifying "reporting range" requirements.	ACCEPT WITH MODIFICATION: The Consensus Body did not see conflict between the two requirements. However, the definition of 'reporting range' was revised to provide greater clarity.
118	5.1.d.3	T	Criteria forces programs to calibrate with wet bath at upper reporting range of instruments since dry gas concentations are not available at these high BrACs.	Assess linearity during method development and optimization and select the highest BrAC standard available.	ACCEPT WITH MODIFICATION: A new section was added to address linearity. However, the practice of reporting above the calibration range is not supported by this standard.

9	5.1.d.3 high limit	T	This requirement would preclude a FSSP from performing calibrations only with dry gas, unless they had a very low upper reporting limit.	Validate the full reporting range with dry and wet ref materials. But in routine calibrations, provide for dry gas calibrations with a QC check at the upper repoting limit. E.g. Cal with gas as high as 0.25, but run a sim solution at 0.40 to check the upper reporting limit.	REJECT: The standard does not preclude the use of both aqueous and compressed gas certified reference material within a single calibration method. Alternatively, the Program could narrow their calibration range to reflect the outer limits of their selected CRM matrix.
69	5.1.d.3.	T	Does the reporting range have to be determined experimentally if the instrument firmware already sets the quantitative limits?	Specify if the limits are not predetermined by the instrument, then perform this section.	REJECT: This section defines non experimental criteria (the Program determines what concentrations are prepared/purchased). Confirmation of the chosen reporting range is experimentally determined through validation (see the validation section).
70	5.1.d.4.	T	Why 6? If the goal is to determine/confirm linearity and/or accuracy and precision, can fewer concentrations be used?	Minimum of 3	REJECT: language mirrors ANSI/ASB 036 which specifies number of calibrators dependent on the status of linearity. The calibration method is confirming the calibration item (Breath Alcohol Instrument) conforms to all specifications.
106	5.1 d 4)	T	6 non zero concentrations seems excessive. Especially considering the limited range/availablity of gas standards (and the fact nothing on the NHTSA CPL is over a 0.120 g/210L)	reduce the concentrations to 4.	ACCEPT WITH MODIFICATION: The original ASB 055 language (public comment 1) was re-inserted into the document. This language mirrors ANSI/ASB 036 which specifies number of calibrators dependent on the status of linearity. (4 for linear systems). Additional requirements for a linearity study was added to clarify the phrasing of "if linear"
201	5.1.d)4)	T	6 non-zero calibrators may be difficult to address depending on the applicable measurement range including instrumental LOD/LOQ. Increase in the number of non-zero calibrators would impose a significant cost increase and resource drain depending on the laboratories' source of calibrators.	Decrease minimum requirement or allow for laboratories to determine number based on appropriate method validation and testing need.	ACCEPT WITH MODIFICATION: The original ASB 055 language (public comment 1) was re-inserted into the document. This language mirrors ANSI/ASB 036 which specifies number of calibrators dependent on the status of linearity. (4 for linear systems). Additional requirements for a linearity study was added to clarify the phrasing of "if linear"
63	5.1.d (4-6)	T	In Standard 036, when developing a Calibration Model, 5 reps of 6 different calibrator concentrations are required to establish a calibration model. After the validation is complete, as stated in 036, Calibration Model (8.3) paragraph 7 "If a linear calibration model has been established, fewer calibration samples (i.e. fewer levels or single/fewer replicates) may be used for routine analysis". With regards to breath alcohol instruments, if linearity has been established during the Development of a Calibration Method, 5 replicates of 6 calibrators should not be required for every subsequent calibration. In addition, many breath alcohol instruments are calibrated in the field, hauling and analyzing additional wet bath simulators or dry gas tanks to meet the 6 calibrator requirement may prove difficult and time consuming.	Add section in the Validation of a Calibration Method (Section 6) for Establishing a Calibration Model, requiring i.e. a minimum of 6 calibrators over the reporting range, 5 replicates each, over 5 different days. *Note in Bias and Precision (6.3.2) section, if linear and reducing to 4 calibrators, a 4 calibrator calibration must be used for bias and precision (see ASB 036 Calibration Model (8.3) para. 7 wording) In the Elements of a Calibration Model section (5), include wording similar to previous version, "if a linear model was established (from section 4), 5 replicates of a minimum of 4 calibrators are required, if a non-linear model was established (from section 4), 5 replicates of a minimum of 6 calibrators are required.	ACCEPT WITH MODIFICATION: The original ASB 055 language (public comment 1) was re-inserted into the document. This language mirrors ANSI/ASB 036 which specifies number of calibrators dependent on the status of linearity. (4 for linear systems). Validation for the calibration method was not changed to address this comment. However, additional requirements for a linearity study were added to clarify the phrasing of "if linear"
10	5.1.d.5	E	may be more consistent to refer to reporting range	replace calibration range with reporting range	REJECT: The choice of wording is intentional. Programs may choose to report more narrowly than the calibration range.
11	5.1.d.6	T	5 replicates of each calibration level is excessive. This sets a higher requirement for daily method operation than was required to validate (3 replicates for bias/precision).	reduce to 3 replicates	REJECT: The chosen number meets the needs of Programs utilizing aqueous as well as compressed gas reference material.
119	5.1.e	E	Incorrect references to section 4.4	Update to 4.5	ACCEPT: Reference updated.
12	5.1.f	E	requires reporting range to be within the validated reporting range	reword to "The reporting range may be administratively set but shall be within the validated measurement (or calibration) range."	ACCEPT WITH MODIFICATION: Language revised to differentiate between calibration and reporting ranges.
13	5.1.g	T	this is more of a definition than a requirement	require that the calibration method define the calibration sequence	REJECT: The opening portion of this section states that all elements listed are required. The actual sequence is to be defined by the Program.
85	5.1 j)	T	Section 6.3.2.2 establishes acceptance criteria for certain aspects of the validation. This should be referenced.	Add a statement referencing section 6.3.2.2 for acceptance criteria.	ACCEPT: Acceptance criteria for method validation and calibration may be different. Additional language was added to provide clarity, and accuracy/precision validation sections were moved up to the calibration method section..
14	5.1.j	T	As a min standard of practice the document should provide minimal acceptance criteria for a calibration.	Define min acceptance criteria for the calibrators for accuracy and precision. Include if it is appropriate to base acceptance on the average of replicates or if all results must be within the criteria.	ACCEPT: Acceptance criteria for method validation and calibration may be different. Additional language was added to provide clarity, and accuracy/precision validation sections were moved up to the calibration method section..

153	p.11 5.1.j	E	"Criteria shall be defined for a successful calibration" - is this left up to the individual programs?	Clarify whether there are inter-program standards or whether this is determined by each program	ACCEPT: Additional language was added to provide clarity, and accuracy/precision validation sections were moved up to the calibration method section..
163	6.1.1	E	Repetitive; 'currently' and 'current'	Remove 'current'	ACCEPT: Removed "currently". We appreciate the catch!
15	6.1.1.a	E	"…that does not curently meet the current requirements…"	reword to "…that does not curently meet the requirements…	ACCEPT: Removed "currently". We appreciate the catch!
86	6.1.1 e)	T	Acceptance testing is not defined.	Add a definition for acceptance testing that gives a general statement about what is to be tested, unless there is another document planned that addresses this. If there is another document, that should be referenced.	ACCEPT: Clause (e) deleted. Concept adequately covered in Section 7.1. and note added for even more clarity.
16	6.1.1.e	T	The current wording requires acceptance testing to determine the impact. There could be modifications that have nothing to do with the measurement system(s) and should not require testing to prove that.	Allow for options other than testing to prove no impact. E.g. Labs should assess if the modification could impact the measurement system, and if so shall conduct testing.	REJECT: Clause (e) deleted. Concept of 'analytical' is covered in Section 7.1. The intent is not for additional work to be performed if the change is not impacting calibration.
56	6.2.2 Note	E	add an apostrophe after Program	6.2.2 A validation plan shall be in place prior to starting any validation experiments. NOTE The validation plan is typically separate from a Program's standard operating procedure (SOP) for method validation. It provides direction for the specific experiments that will be performed and acceptance criteria for each parameter.	ACCEPT: We agree and added an apostrophe.
17	6.2.3	E	It is important that nothing changes during validation, however this does not need to be stated in the validation plan. (ANSI/ASB Std 036 does not require this be stated in the plan.)	Move this to 6.3.1 to state that the method cannot change. If validation experiments demonstrate that a change is needed, then go back to Dev and then repeat impacted validation studies.	REJECT: The Consensus Body felt that this was a necessary requirement for the validation plan.
87	6.2.6	T	This statement should be clarified. It appears that the intent is such that if a Program says there calibration will be performed in temperatures ranging from -5C to 40C, then they need to test all of the validation experiments at those temperatures.	Reword or expand on the example scenario: "For example, a Program may require the calibration method to appropriately perform at a specific temperature range of -5C to 40C (in a non-controlled environment). The plan may state that five replicates of the calibration will be performed across this range of temperatures in increments of 15C (e.g., -5C, 10C, 25C, 40C)." It may also be worthwhile to provide a separate example such as: "The plan may state that calibrations will only be performed in controlled laboratory or office environments therefore no testing at a range of temperatures is required."	ACCEPT WITH MODIFICATION: The clause was revised for clarity. Intent is to perform the calibration and validation under the same conditions (See Section 6.3.1).
120	6.2.7	T	Validating on 1 instrument is insufficient to demonstrate robustness of method across multiple instruments.	Change requirement to a minimum of 2 instruments.	REJECT: This section defines method validation and not instrument validation (different document). Programs are free to do more than the minimum requirements.
18	6.2.7 note	T	This Note is setting a requirement. Will perfomance verification requirements be outlined in a different document?	Suggest removing note. Or state that individual instrument requirements for evidential use will be established in other standards.	REJECT: Language revised to remove a potential requirement. Future document is planned that will address this subject; however ASB rules prohibit mentioning that in the document since it is unpublished.
19	6.2.8 and 6.2.9	E	duplicative of each other and 6.2.3	consolidate the requirement and move to 6.3.1	REJECT: Each of the three clauses contains separate thoughts/requirements. The word "calibration" was added to 6.2.3 to clarify the intent of "calibration method" vs a validation experiment.
140	6.2 10	T	"6.2.10 Programs should consider uncertainty estimation in developing the validation plan". This should be changed to "shall consider". Uncertainty estimation is essential both to validation and to providing accurate and transparent results.	Delete "should" and replace it with "shall".	ACCEPT: The Consensus Body accepts this requested revision.
141	6.2.13.1	E	Accuracy (bias and precision) shall be measured … ." Accuracy is a property of measurements, but it is not a measurement. The quantities being estimated are bias and precision.	Replace with "Bias and precision shall be estimated … ."	REJECT: This is actually related to 6.3.2.1. The term accuracy is understood by the general public (those who may use this document). A definition of accuracy has been added to the document to assist the reader in understanding the relationship between the terms of accuracy, bias, and precision.

154	p.13 6.2.13.1	E	Unclear here how often per month/year accuracy (bias & precision) should be measured	Possibly refer here to section 10.1	REJECT: The Consensus Body believes this is referencing clause 6.3.2.1 which is a method validation subsection. Subsection 6.1 details 'when' a method is to be validated. The act of calibrating an instrument verifies accuracy each time it is performed.
75	6.2.13.2	Technical	The text in this section offers two options for computing the bias and gives a choice as to which can be used. What if the bias limit would be met when using one way but not the other though? Even if it were specified in advance it seems that evidence of potential bias would be being ignored in that case.	If possible, specify which method is preferred. Professional providers of reference materials, like NIST, provide a single reference value for their materials and use of a nominal value would not be acceptable. If laboratories are making up their own reference materials I would think a single best choice of the reference value could also be determined.	REJECT: It is up to the individual laboratory to determine which value to use and they will be expected to defend their choice. One value is not necessarily preferred over another - experimental results gathered during method development should provide guidance.
142	6.2.13.4	T	Section 16.2.13.4 contemplates “”within-run precisions … calculated for each concentration separately for each of the six runs … using the data from each run’s triplicate analyses at each concentration.” Are three measurements sufficient to computing a useful standard deviation?	Specify a reasonable number of measurements for computing a standard deviation.	REJECT: The Consensus Body believes this is referring to 6.3.2.1. The minimum number generated from this approach is eighteen (n=18). This exceeds requirements specified in ANSI ASB 036 Standard Practices for Method Validation in Forensic Toxicology (Section 8.2.2.3.3).
38	6.3	E	Interferences are an important part of any method validation. Is that being considered unnecessary for the calibration method since those interferences would likely only come from human samples? Will there be a method validation standard for the evidential test method?	Suggest a comment about why interferences are not addressed in this standard and if they will be addressed elsewhere.	REJECT: The use of metrologically traceable reference material precludes interferences for the calibration method. This section will be addressed in a future document (breath test subject method).
164	6.3.1	E	Awkward wording	Add in 'to those' in front of 'in which as calibration…'	ACCEPT: Consensus Body revised language.
20	6.3.2.1	T	What is the basis for 6 days? Why can't independent runs be conducted on the same day? Potential environmental impacts are already addressed in 6.3.6.	Suggest consistency with ANSI/ASB Std 036 which requires 5 independent runs.	REJECT: The Consensus Body supports 6 days since testing is always performed on a historical calibration (i.e., the calibration must be accurate over a longer period of time).
45	6.3.2.1	T	Replace calibration for adjustment in the following sentence "Accuracy (bias and precision) shall be measured using reference material with established traceability that is different than that used for the calibration." If there has to be 6 concentrations for the calibration (checks on the instrument and not what is used to create the calibration curve (adjustment), then to have 3 separate reference materials for accuracy does not make sense to me.) The calibration or checks performed on the instrument as a part of the calibration method	"Accuracy (bias and precision) shall be measured using reference material with established traceability that is different than that used for adjusting the instrument."	REJECT: This section is for method validation (validation would be performed infrequently). Method validation's purpose is to ensure that the method performs as expected, so using different material (as specified in ANSI ASB 017) is necessary.
46	6.3.2.1	T	Why have 3 replicates for 3 concentrations over 6 days (total number of replicates per concentration is 18). In ASB 036, section 8.2.2.3.1 the requirement is 3 replicates for 3 different concentrations over 5 runs (total number of replicates per concentration is 15). It also says a run on the same day with different calibration curves is acceptable. With a breath test instrument, most are single point calibrators (not all) and the calibration curves is not updated (adjusted) each time the instrument runs so I understand the difference in saying days instead of runs. I would suggest making it consistent with ASB 036 in the total number of replicates per concentration as 15.	A minimum of three concentrations (low, medium, high) shall be evaluated over five different days, with a minimum of three replicates of each concentration per day.	REJECT: The Consensus Body supports 6 days, which would cover a minimum of 2 work weeks. This is based on the risk associated with Breath Alcohol vs. General Toxicology. In Breath Alcohol, the subject tests are always performed on a historical calibration (i.e., the calibration must be accurate over a longer period of time)
64	6.3.2.1	T	"high concentrations shall be no less than 80% of the highest calibrator". We understand this is to coincide with ASB Standard 036, however, obtaining certified, commercially available standards from an ISO 17034 accredited producer at 80% is difficult. For example, with aqueous standards, if the ULOQ is 0.400 g/210 L, 80% of that is minimum 0.320 g/210L, the next available concentration is 0.300 g/210L.	Remove the "80%" requirement, or replace with "75% due to available standards", or "the next highest available standard" or similar wording. *This would also pertain to 9.4 in the Adjustment section.*	REJECT: The Program has the ability/responsibility to specify the chosen ULOQ. This decision may be based upon various factors, including availability of reference material (see ANSI ASB 017).
88	6.3.2.1	T/E	This requirement states that the accuracy shall be measured "over six different days" which is in contrast to the other validation document which states "five different runs". Also, the high concentration is listed as "no less than 80%" and the other validation document uses "approximately".	Reword: Change "days" to "runs" and "no less than" to "approximately".	ACCEPT WITH MODIFICATION: Revisions to the document include both "days" and "runs". The use of "no less than" was replaced with "approximately" to match the language in ANSI ASB 036.

121	6.3.2.1	T	Concentration selection for accuracy as stated contradicts 4.3 requirement to use bias and precision data to determine acceptability criteria for method and 6.3.3.2.	Include LLOQ and ULOQ in accuracy determination.	REJECT: While Limits of quantitation are captured in the process of evaluating bias and precision during the validation process, they are not part of the definition of accuracy. The lowest calibrator is the LLOQ, and the highest calibrator is the ULOQ. The evaluation of LOQ's occurs during method development and again each time the instrument is calibrated. Validation experiments typically 'test' different concentrations than the calibration in an effort to ensure more points in the reporting range are evaluated.
89	6.3.2.2	T	Inconsistent with 5.1 j) that lets the Program set acceptance criteria.	Reference this section in section 5.1 j)	ACCEPT: Acceptance criteria for performance of the calibration method and validation of that method may be different. Language added to 5.1.j) to provide clarity.
21	6.3.2.3	E	Last sentence "…for each concentation SHALL not exceed…"	insert shall	ACCEPT: Consensus Body revised language.
90	6.3.2.3	E	Extra space between ± and 10	Remove space	REJECT: There is one space present.
110	6.3.2.3	E/T	Last sentence is missing should/shall: "The largest calculated within-run and between-run % CV for each concentration [should/shall] not exceed +/- 10%."	Insert intended word	ACCEPT: Consensus Body revised language.
122	6.3.2.3	E	Insert the word 'shall' between 'concentration' and 'not'	insert 'shall'	ACCEPT: Consensus Body revised language.
22	6.3.2.4	E	"…MAY be calculated using…". Are there alternative ways to calculate it?	change may to shall	ACCEPT: "Shall" was added.
47	6.3.2.4	E	Update run to day since that is what is set forth in 6.3.2.1	Within-run precisions are calculated for each concentration separately for each of the six days.	REJECT: The Consensus Body kept 'run' and 'day' in the document but revised Section 6.3.2.1 to provide further clarification on the relationship between the two terms.
49	6.3.2.4	E	Update number of runs from 6 to 5 if you make change in 6.3.2.1	Within-run precisions are calculated for each concentration separately for each of the five runs.	REJECT: The Consensus Body retained 6 runs, carried out over 6 days.
91	6.3.2.4	E	Inconsistent terminology - six days changed to six runs.	Change section 6.3.2.1 to runs.	REJECT: The Consensus Body kept 'run' and 'day' in the document but revised Section 6.3.2.1 to provide further clarification on the relationship between the two terms.
23	6.3.2.5	E	"…MAY be done by using…". Are there alternative ways to calculate it?	change may to shall	ACCEPT: "Shall" was added.
48	6.3.2.5	E	Update run to day since that is what is set forth in 6.3.2.2	Within-run precisions are calculated for each concentration separately for each of the six days.	REJECT: The Consensus Body kept 'run' and 'day' in the document but revised Section 6.3.2.1 to provide further clarification on the relationship between the two terms.
50	6.3.2.5	E	Update number of runs from 6 to 5 if you make change in 6.3.2.2	Within-run precisions are calculated for each concentration separately for each of the five runs.	REJECT: The Consensus Body retained 6 runs, carried out over 6 days.
92	6.3.3.1	T	There is no criteria established for what is acceptable in method development.	The method development section should clearly delineate or reference another section for acceptable performance of the ULOQ and LLOQ.	REJECT: The commenter is asking for revisions to Section 4.6 (Method Development). While clarification language has been added to 4.6.1.d), final acceptance criteria is specified in the Method Validation and Calibration Method sections- therefore development should aim to produce a method that will meet those requirements.
165	6.3.3.2	E	Unnecessary comma	Remove comma between 'chosen' and 'meet'	ACCEPT: Sentence updated.
24	6.3.4	T	LLOD - abbreviation not defined and there is nothing in the standard about determining the method's LLOD.	change to LLOQ, or add information about LLOD	ACCEPT: Language revised to reflect LLOQ vs LOD.
25	6.3.4	E	3rd paragraph - this seems more appropriate to be evaluated during dev	discuss carryover checks in section 4	REJECT: We agree with the commenters concept and anticipate Programs will evaluate all the method validation parameters during the development stage. However, the Method Validation portion is the appropriate place to add the requirement to verify lack of carryover.
65	6.3.4	E	Last sentence in second paragraph "… at which no carryover exists shall be confirmed by repeating the determiniation twice (i.e., a total of 3 repeated tests). These number are confusing.	To better coincide with ASB 036, use similar wording for Carryover replicate analysis requirements (from 8.4).	REJECT: The Consensus Body believes this language is appropriate and less likely to cause confusion.
107	6.3.4	T	Instrumentation automatically does an ambient air blank after every analyzes concentration. There is no way to turn this off.	Remove requirement until instrumentation/software has the capability to do this. - OR clarify if the airblank is required between the concentration and the analysis of the "ethanol negative sample"	ACCEPT WITH MODIFICATION: Language clarified.

26	6.3.5.2	E	should be : at end of 1st paragraph	replace period with colon	ACCEPT: Language clarified.
99	6.3.5.2	T	"Characteristics that shall be evaluated include." should end with a colon rather than a period.	Change period to colon.	ACCEPT: Language clarified.
111	6.3.5.2	E	Period should be colon: "Characteristics that shall be evaluated include:"	Change period to colon	ACCEPT: Language clarified.
166	6.3.5.2	E	Period should be a colon	Replace the period after 'include' with a colon	ACCEPT: Language clarified.
112	6.3.5.2 c)	E	Period should be colon: "Examples of possible calibration method or Program choices:"	Change period to colon	ACCEPT: Language clarified.
27	6.3.5.2.c	E	missing : at end of paragraph	insert a colon	ACCEPT: Language clarified.
167	6.3.6.1	E	Awkward wording	Change 'that are' to 'to those'	ACCEPT WITH MODIFICATION: Language clarified.
148	p.6 3.8	T	As written, the paragraph on data is difficult to follow	Possibly divide into 2 or 3 sentences	REJECT: Consensus Body believes this comment is in relation to 3.8, definition of data. This definition is sourced from an ISO standard and therefore won't be modified.
100	7.2	E	The first sentence appears to be a continuation of 7.1. A paragraph should not begin with "For example…"	Delete the first sentence and add to 7.1.a) analytical changes to the computer system (e.g. affecting linearity, precision, or bias);	ACCEPT WITH MODIFICATION: Language clarified between Sections 7.1 and 7.2.
28	8.1	E	missing apostrophe	"…part of a Program's operating…"	ACCEPT: Sentence updated.
29	8.1	E	"organized" is a very subjective term	edit to "…records shall be retained and available for review:"	REJECT: the term 'organization' if fairly well understood in the general community. Specifics requirements surrounding organization were intentionally not included.
55	8.1	E	add an apostrophe after Program	8.1 Record keeping is an essential part of a Program's operating procedures and is a key component of method validation	ACCEPT: Sentence updated.
113	8.1	E	Apostrophe needed in word "Programs"	Change to "Program's"	ACCEPT: Sentence updated.
123	8.1	E	insert apostrophe in 'Programs'	insert necessary apostrophe	ACCEPT: Sentence updated.
168	8.1	E	Should have an apostrophe	Change 'Programs' to 'Program's'	ACCEPT: Sentence updated.
176	8.2	T	Document retention policy should be based on consensus best practices. A State/Laboratory can adjust their retention policy (if necessary) if they choose to meet the standard.	Remove the wording "according to the Program's record retention policy".	ACCEPT: Sentence updated.
202	9.2	T	Some instrumental adjustments can be done electronically rather than with liquid/gas standards therefore traceability of adjustment solutions would not have an effect in all adjustment situations. Traceability of adjustment solutions add little value since it is followed by a calibration with traceable solutions.	Allow for the use of adjustment solution preparations which are non-traceable as long as they are different from the solutions used in the calibration method.	ACCEPT: Sentence updated and clarified.
203	9.2 (Continued)	T	In some laboratories, instrument adjustments are considered a separate function (e.g., instrumental maintenance) than as part of the calibration method. Adjustment solutions may be created for single or limited use based on determination by the calibration analyst. Use of non-traceable adjustment solutions can help minimize downstream risk to evidential testing due to limited use (e.g., minimum number of instruments affected) as opposed to traceable adjustment solutions which would be placed into bulk use and potentially affect hundreds of instruments.		ACCEPT: While no resolution is provided for this 'row', the Consensus Body believes this is a continuation of comment number 139 which has been adjudicated.

204	9.3 (related to 9.4-9.6)	T	Performance evaluation before adjustment seems overly redundant and does not add value to the integrity of the calibration method end product which contains multiple controls and QA procedures to address risk to results integrity. If an instrument is broken or determined to be non-functional, pre-adjustment evaluation may not be possible (unclear where necessary repairs may fit in to this requirement). Performance evaluations should be done continuously via safeguards in the instrument and testing method.	Allow laboratory discretion regarding "as found" evaluations to be based on their methodology and testing needs.	REJECT: It is important to know if the instrument was performing as expected. This document does not require ongoing QC or delve into subject testing requirements as those are outside of the scope of this calibration document. As found data is expected among all metrological measurements (calibrations).
71	9.4	T	If the instrument accuracy values are drifting away from the target, this would be an indicator to perform an adjustment. Why continue running accuracy checks to satisfy the minimum of 3 concentration requirement, when an adjustment Is going to be performed anyway?	Do not specify a minimum of 3 concentrations. Allow for within program discretion.	REJECT: This is a standardized approach to collecting data that shows instrument status. This data may prove valuable to a Program if one of the points is out (e.g., if the other 2 points are in, there may be support for historical subject test results)
93	9.4	E	Terminology used is "no less than" 80% but should be consistent with other documents using "approximately".	Change "no less than" to "approximately".	REJECT: This section meets the intent of ANSI ASB 036 …. Which states approximately 80% (or more). The intent is that it not be lower than 80%.
205	9.4	T	Refer to 9.3 comments. The specific requirements provided in 9.4 are extremely impactful to laboratory costs and resources. As written, this seems to force laboratories to perform a pre-calibration, calibration event. Additional recourses would need to be added to the requirement to cover situations in which it is not possible or feasible to comply with the requirements as stated.	Refer to 9.3	REJECT: It is important to know if the instrument was performing as expected. This document does not require ongoing QC or delve into subject testing requirements as those are outside of the scope of this calibration document. As found data is expected among all metrological measurements (calibrations).
156	9.6.	E	"Prior instruments results should be evaluated" Up to what point? For example up to the last/most recent calibration or adjustment?	Possibly specify the time frame within which prior instruments should be evaluated	REJECT: Additional specificity is more appropriate for a different document (a document surrounding subject test method and acceptance criteria is planned in the future). However, the Consensus Body did feel it important to raise this as a thought (hence the 'should' vs. a shall).
62	10.1	T	A calendar timed calibration interval is defined in this document without any justification for such a practice. No consideration is given to the instrument design, type, robustness of calibration, manufacturer recommendations, or rigors of a quality assurance system while the device is in use. A review of ILAC-G24:2007 / OIML D 10:2007 (E) may be in order before mandating a single automatic or "staircase" (calendar-time) approach to instrument calibration inervals. There are numerous ways to determine appropriate cailbration intervals and the laboratory should have the flexibility to make such a determination in order to maiximize efficiencies, manage down time, and controls costs. Additionally, ASB 098 (Draft) currently states in section 4.1, "Further, documented regular instrument calibration and maintenance shall follow recommendations of the manufacturer and shall be described in the appropriate laboratory procedures." Consistency across documents is important to the CB yet ASB 055 is in direct conflict with ASB 098.	Replace first two sentences with: Documented regular instrument calibration and maintenance shall follow recommendations of the manufacturer and shall be described in the appropriate laboratory procedures.	REJECT: This argument was discussed at length among this group during both comment adjudication periods and our decision remains consistent with previous adjudication. Calibration intervals for equipment are specified ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology. While the instrument is a calibration item (rather than a piece of equipment) this document builds upon that work. 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.
66	10.1	T	"The calibration method shall have a specified interval not to exceed 12 months from the date of calibration." We have 164 instruments to recertify every year with 1.5 (one part time) analysts. The issue with this wording is the recertifications get pushed earlier and earlier every year to meet this requirement. For example, if an instrument is recertified 3/12/22, it must be recertified earlier than that the next year. With court, other lab duties, vacations, or sick time, this schedule can be difficult to maintain.	Strike the words "from the date of calibration". We understand its important to have an interval requirement. We believe this is a resonable compromise. This way, if an instrument is calibrated 3/12/22, we can recalibrate the instrument any time in March of 2023 to meet the 12 month requirement.	REJECT: This argument was discussed at length among this group during both comment adjudication periods and our decision remains consistent with previous adjudication. The date of calibration was chosen as it provides a clearly understood reference point vs the date the certificate (however named) was issued.

143	10.1	T	10.1 When to Calibrate The calibration method shall have a specified interval not to exceed 12 months from the date of calibration." Is there a cite to any authority for the choice of 1 year as a minimum.	Please provide a basis for the minimum of one year.	REJECT: This argument was discussed at length among this group during both comment adjudication periods and our decision remains consistent with previous adjudication. Calibration intervals for equipment are specified ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology this document builds upon that work. 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.
170	10.1	T	Requiring the calibration of breath testing instruments every 12 months places an undue burden upon certain agencies.	Change the required calibration interval	REJECT: This argument was discussed at length among this group during both comment adjudication periods and our decision remains consistent with previous adjudication. Calibration intervals for equipment are specified ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology this document builds upon that work. 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.
206	10.1	T	The proposed interval could have an extremely high cost and resource impact on laboratories/programs. Any interval that is established should balance the increased costs/resources and the requirements for accuracy of testing analysis. Calibration and testing methodologies should have robust procedures to effectively determine the need for re-calibration events. Modern instrumentation uses features like electronic gain control and internal standard references to offset component aging and other issues that may deteriorate calibration accuracy over time.	Each program should establish a calibration interval which is determined based on historical data, internal validation on calibration stability, and robustness of their particular brand/type of instrument. Any specific interval requirement should be based in real world data pertaining to instrument and calibration reliability and longevity. Additional performance check measures conducted in periods between calibration events should be considered as effective alternatives to a specific calibration interval.	REJECT: This argument was discussed at length among this group during both comment adjudication periods and our decision remains consistent with previous adjudication. Calibration intervals for equipment are specified ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology this document builds upon that work. 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	10.4	E	add an apostrophe after Program	Programs shall retain all records related to calibration, adjustment, and instrument maintenance according to the Program's retention schedule.	ACCEPT: apostrophe added.
114	10.4	E	Apostrophe needed in word "Programs"	Change to "Program's"	ACCEPT: apostrophe added.
169	10.4	E	Should have an apostrophe	Change 'Programs' to 'Program's'	ACCEPT: apostrophe added.
30	11	T	suggest consistency with ISO/IEC 17025 requirements	e.g. require page numbering and indication of total pages or end of report, not specifically require the final page count. Not require name of SOP.	ACCEPT: Language clarified, which mirrors the language in ISO/IEC 17025:2017.
58	11	T	Add exception to meet statutory requirements or simplified certificate when the additional information can be found in calibration records.	Each certificate shall be written clearly and shall include at least the following information, unless the laboratory has a valid reason for not doing so, thereby minimizing any possibility of misunderstanding or misuse: Add sentence: If the laboratory has a valid reason for not including information on the certificate (however named), the information shall appear in the calibration records or cite the regulatory statute that applies (conformance statement).	REJECT: Standardization is the goal, as Certificates may be used in court cases in many jurisdictions (including multiple states). This is a reasonable requirement to allow the end users to compare information.
155	p.20 11	E	Is the calibration certificate author the same person who conducted and documented the calibration?	Consider whether this could be a conflict of interest and/or clarify	REJECT: A prescriptive approach is not specified. Programs may choose the author based upon needs such as legal, programmatic, personnel, accreditation requirements, etc. For instance, there are Programs where law enforcement performs the calibration, a scientist authorizes (ISO/IEC 17025:2017 langauge) and testifies to the results. This task group did not feel it necessary to require the authorization of results.

60	11 d)	T	The date the certificate is issued can cause confusion as to when the instrument was certified. The important date is the date of the calibration. Certificates are not issued in our state until after 2 reviews, so the instrument is used in the field while these reviews are being conducted. An issuance date on the certificate that is 2 week later would cause confusion and legal issues as to whether the instrument was certified during those two weeks.	Remove requirement or make optional.	REJECT: The inclusion of both dates (calibration and issue) stem from ISO/IEC 17025:17025 7.8.2.1.
59	11 e)	T	This requirement is in opposition to ISO 17025 7.8.4.3	Remove requirement.	REJECT: ISO/IEC 17025:2017 7.8.4.3 references recommendations, typically aimed at calibration laboratories providing the service to an external laboratory. This language ensures the end user is aware of the interval in use for this Instrument. This document contains requirements and not recommendations.
207	11 E)	T	Refer to 10.1 comments.	Refer to 10.1.	REJECT: The argument of calibration intervals was discussed at length among this group during both comment adjudication periods and our decision remains consistent with previous adjudication. Reference to the interval on the certificate (however named) provides transparency to the end user.
115	11 k)	T	The requirement to list the total number of pages on each page of the certificate is more specific than is found in similar standards. While an indication of the total number of pages is appropriate, it should not be required on each page of the document.	Change criteria to allow (minimally) for noting total number pages on first page of the document	REJECT: The language was clarified. Inclusion of total page numbers was not intended as a requirement for every page.
72	11.e.	T	Is this needed on the certificate if stated elsewhere, e.g. in statutory requirements?	Remove calibration interval from certificate.	REJECT: Standardization is the goal, as Certificates may be used in court cases in many jurisdictions (including multiple states). This is a reasonable requirement to allow the end users to compare information.
177	Annexes	E	Include both Bias (%) and Bias (g/210L) in all tables similar to Table A.3 for clarity.	Include both Bias (%) and Bias (g/210L) in all relevant tables in the Annexes.	ACCEPT: Edits made to Annexes.
178	Annexes	E	The number of signigicant figures for instrumental data is inconsistent in the tables. For example, Table A.1 lists replicates #1, #2 and #3 to three decimal places for the 0.015 and the 0.025 concentrations, but the 0.02 concentration is listed with only 2 decimal places for replicates #1 and #2. If the instrument reports to 3 decimal places, all three decimal places need to be included.	All Instrumental data listed in the annexes need to include the proper number of significant figures (e.g., report all instrumental data to three decimal places).	REJECT: Different styles and approaches to experiments and data tables were intentionally included.
182	Annexes	E	When calculating the +/- 5% acceptable bias ranges in tables, most entries use standard rules of rounding; one entry is truncated (truncated example: see Table A.3, (+/- 5% or 0.005) acceptable bias range for 0.15 is truncated to "0.142-0.157").	Handle numberical rounding/truncating consistently within the same table and throughout the entire document. If rounding, update these values to "0.143-0.158".	ACCEPT: The values were all calculated using Microsoft Excel. Table was modified to allow more digits to be visible.
94	Annex A	E	Uses "+/-" instead of ±	Change to ±	REJECT: Annexes are informative. Different styles and approaches to experiments and data tables were intentionally included.
61	A.1.2	E	Fix alignment of the text in parentheses		ACCEPT: Formatting was updated.
179	Annex A	E	Incorrect numbers in Table A.2.	In Table A.2, last column (0.430 concentration): the minimum acceptable bias for the last column needs to be corrected to "0.409", and the maximum accept bias needs to be corrected to "0.452".	ACCEPT: Rounding had occurred, original, nonrounded number returned to the table (e.g., 0.425 g/210L)
180	Annex A	E	Information in wrong location. Section A.3, a) and b) are out of order and appear to belong in Annex C on the top of page 24.	Section A.3, move a) and b) to Annex C on the top of page 24.	ACCEPT: Tables modified to fit the page in the correct order.
181	Annex A	E	Table order and Table numbering. Table A.3 needs to be placed prior to the next table (currently labeled as Table A.5). Table A.5 and the reference to it in A.3.2 need to be changed to Table A.4 (there are only 4 tables in Annex A).	Update the naming convention of Table A.5 and the reference to it in A.3.2 to "Table A.4". Move the location of Table A.3 before Table A.4.	ACCEPT: Tables modified to fit the page in the correct order.
196	Annex A	E	Table A.3, left most column: remove extra space in "Bias (g/ 210 L)".	In Table A.3, remove the extra space after the slash in "Bias (g/ 210 L)".	ACCEPT: Sentence updated.

31	Table A.1	E	The example is showing an administratively set LLOQ that is higher than the lowest level demonstrating acceptable bias/precision. The last line should not refer to 0.02 as the Final "determined" LLOQ - it was determined to be at least 0.015, but selected at 0.02.	reword last row to something like "Method LLOQ", or "Selected LLOQ".	ACCEPT: Sentence updated.
76	Table A.2	Technical	It doesn't seem right to use the label "Minimum acceptable bias" since that seems to imply a bias of zero would be unacceptable.	Change the labels for the bias limits to read "Maximum acceptable low bias" and "Maximum acceptable high bias".	ACCEPT WITH MODIFICATION: suggested language was utilized, except for "maximum" for the low value.
193	Annex A,D	E	When calculating Bias as a percentage, the result should be rounded to 1 decimal place.	On page 18 (2 entries), on page 31 (1 entry) and on page 32 (7 entries), the results for Bias (%) should be rounded to 1 decimal place.	REJECT: The values were all calculated using Microsoft Excel. Language was added to assist the reader in understanding calculations (one should always let the numbers run out until the final result (do not truncate or round until the final result)).
183	Annex B	E	Information is missing/incorrect in Table B.1 under Bias, Validation paramenters.	Add information to Table B.1 under Bias, Validation Parameters. At a minimum, the 0.08 g/210L (statutory limit) is missing; there may be additional data points missing (e.g., 0.04 g/210L); in addition, 0.30 g/210L is incorrectly labeled as a "mid-range concentration" and requires correction.	ACCEPT: We replaced the missing .0.08. Revision to move the calibration method parameters occurred, which enabled us to revise the validation concentrations that would be used. The mid-range concentration is now correct.
103	Annex B Table B.1	T	Validation Parameters Column appears to be missing information.	The 0.02 should be spaced down a line. The next line should be 0.08 g/210L ("0.08 g per 2" is absent")	ACCEPT: We replaced the missing .0.08. Revision to move the calibration method parameters occurred, which enabled us to revise the validation concentrations that would be used. The mid-range concentration is now correct.
32	Table B.1	E	typo 1st statutory limit	not sure what was intended?	ACCEPT: Uncertain what the solution was but significant revision occurred (which we hope fixed the concern).
51	Table B.1	E	Update run to day in the Validation Parameters column for Bias since that is what is set forth in 6.3.2.2	10 replicates, 6 separate days, 5 different instruments at the following concentrations: 0.02 g/210L (i.e. statutory limit & LLOQ)	REJECT: The Consensus Body kept 'run' and 'day' in the document but revised Section 6.3.2.1 to provide further clarification on the relationship between the two terms.
171	Table B.1	E	Words left out in the Validation Parameters section	Add in "0.08g/2" in front of the "10L (statutory limit)" below the 0.02 concentration	ACCEPT: We replaced the missing .0.08. Revision to move the calibration method parameters occurred.
124	Table B.1 Note	E	Insert period at conclustion of Note	insert necessary period	ACCEPT: Periods addedd as applicable.
52	Table B.2	E	Update number of runs from 6 to 5 if you make change in 6.3.2.2	10 replicates, 5 separate runs, 5 different instruments at the following concentrations: 0.02 g/210L (i.e. statutory limit & LLOQ)	REJECT: the minimum days was kept at six.
157	B2	E	Is storage of reference material a concern?	Possibly specificy ideal temperature in the room and length of storage of calibration solution	REJECT: This is an example, which captures the minimum requirements.
33	Annex C	T	This new annex is very useful, but should not be buried with the Instrument Calibration standard. This applies to much more than just this standard and should be easily found and accessed by stakeholders	Remove Annex C from ASB Std 055 and make it an independent ASB Technical Note.	REJECT: We appreciate the comment. But this is within the scope of the document and will remain here.
34	Annex C	E	C.1.2 uses 0.08 example, C.1.3 uses example data from a 0.05.	suggest consistent level throughout	REJECT: Annexes are informative (examples) and multiple values were intentionally referenced to help promote diversity in numbers.
184	Annex C	E	Annex C.1.3 b) reference location needs to be corrected.	Correct the reference to the Within-Run Precision formula - it is located Section 6.3.2.4.	ACCEPT: Revised formats so tables appear in the correct order. Renumbering occurred when necessary.
185	Annex C	E	Annex C.1.4 b) reference location needs to be corrected.	Correct the reference to the Between-Run Precision formula - it is located Section 6.3.2.5.	ACCEPT: Revised formats so tables appear in the correct order. Renumbering occurred when necessary.
186	Annex C	E	Annex C.1.3 b) calculation for Within-Run % CV doesn't make sense. Although the Within - Run % CV result of 3.1% is correct based on Table C.3, the math does not add up when taken out of the context of the table (0.002/0.050 x 100 = 4.0, not "3.1").	Use additional significant figures in the calculation, or move the calculation into Table C.3.	ACCEPT: Both the table and language was updated to clarify the calculations that were performed (e.g., use of software).
188	Annex C	E	Annex C.1.4 b) calculation: the numberator is italicized.	Remove the italics font for "0.001".	ACCEPT: The italicized language was changed.
189	Annex C	E	C.2 needs a reference.	The A.W. Jones paper listed in the second paragraph needs a proper citation.	REJECT: The citation appears in the Bibliography.
190	Annex C	E	C.2: degrees C editorial change.	The "c" needs to be capitalized in "34 degrees c".	ACCEPT: the 'c' was capitalized.
191	Annex C	E	C.4: remove extra space.	In the heading, remove the extra space after the slash in "g/ 210 L".	ACCEPT: Space removed.
198	Annex C	E	Table C.6 and Table C.7, left most column: remove extra space in "Normalized results (g/ 210 L)".	In Table C.6 and Table C.7, remove the extra space after the slash in "Normalized results (g/ 210 L)".	ACCEPT: Space removed.

102	Annex C	T	PT is not defined	Define PT prior to using the acronym	ACCEPT: PT defined in Annex C
187	Annex C	E	Annex C.1.3 b) calculation: the numberator is italicized.	Remove the italics font for "0.002".	ACCEPT: The italicized language was changed.
53	Table C.1.4 a)	E	Update run to day in the Validation Parameters column for Bias since that is what is set forth in 6.3.2.2	a) Table C.4 provides validation data for a single concentration (6 separate days with 3 replicates per concentration) Rename Run 1-Run 6 to Day 1- Day 6 in table	REJECT: The Consensus Body kept 'run' and 'day' in the document but revised Section 6.3.2.1 to provide further clarification on the relationship between the two terms.
54	Table C.1.4 a)	E	Update number of runs from 6 to 5 if you make change in 6.3.2.2	a) Table C.4 provides validation data for a single concentration (5 separate runs with 3 replicates per concentration)	REJECT: The Consensus Body retained 6 runs, carried out over 6 days.
35	C.2	E	Jones publication reference missing bibliography citation	add #7 to refer to bibliography	REJECT: citations follow the ASB Manual and Style Guide for ASB Standards, Guidelines, Best Practice Recommendations, and Technical Reports
172	C.4	E	Should have an apostrophe	Chance 'providers' to 'provider's'	ACCEPT WITH MODIFICATION: Noun revised
192	Annex D	E	In the table on page 30, the Bias (g/210 L) result should be expressed as a negative number.	Change "0.001" to "-0.001" in the Bias (g/210 L) calculation.	REJECT: Example results are appropriately reported.
194	Annex E	T	The Bias (%) values are incorrectedly calculated in Table E.1. In addition, the conclusion needs to be updated to reflect a logical explanation of the actual data.	In Table E.1, the Bias (%) needs to be corrected from "0.2, -0.1, -0.6, -1.4" to "1.4, 1.1, 0.6, -0.1". The last sentence on page 34 also needs to be updated based on the true results (note that it appears that the % bias actually improves with each freeze/thaw cycle).	ACCEPT WITH MODIFICATION: The values were all recalculated. Last sentence was removed.
197	Annex E	E	% CV should be rounded to one decimal place in Table E.1.	In Table E.1, the % CV row (bottom most row) should be calculated to one decimal place (4 instances).	ACCEPT: The %CV was modified to just one significant figure.
173	Annex G Scope and Purpose	E	Awkward wording	Change 'that are' to 'to those'	ACCEPT WITH MODIFICATION: Revision to entire section for clarity.
36	Annex H	E	#1 incorrect citation	"ANSI/ASB"	ACCEPT: ANSI added.
37	Annex H	E	Are all the footnotes necessary? Why not include website in citation?	Check compliance with ASB Manual	REJECT: The format follows the process defined in the *Manual and Style Guide for ASB Standards, Guidelines,* *Best Practice Recommendations, and Technical Reports.*
195	Annex H	E	The reference link (www.nsc.org) provided for superscript "s" on the bottom of the page (National Safety Council History Document CAOD) is insufficient. The document is difficult to find on such an expansive website when provided a generic link.	Link the reference for superscript "s" on the bottom of the page directly to the actual document or to the CAOD site.	ACCEPT: Updated URL provided.
101	Annex H (p.39)	E	Page 39 states the Annex is informative. Because this is cited in the document, it is not merely informative.	Do not include the bibliography under the Annex heading.	REJECT: The format follows the process defined in the *Manual and Style Guide for ASB Standards, Guidelines,* *Best Practice Recommendations, and Technical Reports.*
174	Annex H 5]	E	Missing paranthesis	Add a paranthesis after 'quality' and in front of 'Geneva'	ACCEPT: Parentheses added
175	Annex H 8]	E	Capitalization not consistent	Change 'of' to 'OF'	REJECT: The references are listed exactly as they appear in their published form.
125	Annexes B-H	E	Update header to 2022	make necessary correction	ACCEPT: Formatting was updated.