30-Mar-20
ANSI/ASB Std 055
Standard for Breath Alcohol Measuring Intrument Calibration

Note: a specific Proposed Resolution must accompany each comment or it cannot be considered.

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
230	ASB Standard 055	E	The document is titled BrAC calibration but addresses method development, QC program approaches, personnel qualifications. The ASB 054 document addresses calibration in one section with four subsections covering two pages and applies to every conceivable piece of instrumentation in a forensic toxicology laboratory. Yet ASB 055 takes over 30 pages to address BrAC devices which are far less complex than most all instruments in a typical forensic tox laboratory. The thought occurs to me this document is using the consensus standard to develop a calibration document and in the process attempts to establish a sound evidential breath alcohol test program.	As the Foreword details, this document was prepared to provide minimum practices for the calibration of evidential BrAC devices. It should focus on calibration of instruments and not program management. Program administration has many elements including personnel, training, quality control programs, maintenance, calibration, reporting, methodology development, administrative rules, supporting the LE community, accreditation requirements, as well as legal mandates such as certification of individuals, equipment, testimony, and tests. Most of those areas are or will be addressed in other ASB documents related to forensic toxicology. If there is a need for a particular standard to address elements of a BrAC program administration those should be developed. For instance, ASB/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology (Method Development in Forensic Toxicology) explicitly excludes BrAC method development. Such a standard for BrAC methods would be beneficial to the community and it should address all methods in BrAC and not just calibration. Develop standards for each of the areas where there is a need and don't try to address those in ASB 055. Perhaps another document defining acceptable practices in BrAC, much like the NSC-ADID document referenced in the Foreword, would be beneficial to the community.	REJECT: No specific resolution was provided by the commenter. The Task Group does not support modification of the contents of this document.
8	Title	T	Include 'Evidential' in title	Standard for Evidential Breath Alcohol Measuring Instrument Calibration	REJECT: The Task Group does not support a change in the title. The Foreward and Scope outline the limitations (e.g., evidential) appropriately.
271	Forward	T	Instead of testing in first paragraph, shouldn't it say "calibration"	Replace with "calibration"	REJECT: The National Safety Council has not published any documents related to calibration; their documents are limited to subject testing, training, and quality control.
272	Forward	T	Guidance on what programs should do if they don't perform calibrations (e.g. Mfr does all calibrations and program verifies). Does program need to do anything? Does manufacturer need to meet this standard of calibration?	Write guidance for alternate situations (vendor calibrations)	REJECT: The document is a minimum standard for all Breath Alcohol Programs that calibrate breath alcohol measuring instruments for evidentiary purposes (e.g., state programs, local programs, manufacturers).
97	Table of Contents	E	Inconsistent use of periods, spacing, colons, and dashes between numbers and titles	Standardize use of periods, spacing, colons, and dashes between numbers and titles	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
171	Table of Contents	E	does not align with document	update to match document	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
9	TOC	E	Update section numbers to correspond to text	2 Normative Reference	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
10	TOC	E	Update section numbers to correspond to text	3 Terms and Definitions	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
11	TOC	E	Update Section numbers to correspond to text	4 The Calibration Method (Development and Optimization)	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
12	TOC	E	Update Section numbers to correspond to text	4.2 Validating the Calibration Method	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
13	TOC	E	Update Section numbers to correspond to text	4.2.1 When to Validate the Calibration Method	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
14	TOC	E	Add section to TOC	4.4.3 Limits of Quantitation	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
15	TOC	E	Update page numbers in TOC	Update page numbers throughout TOC to reflect correct page number in text	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
273	TOC	E	Multiple places where TOC doesn't match content	Finalize with final edits	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
98	1	E	"breath alcohol" capitalization is inconsistent	Capitalize or uncapitalize all instances of "breath alcohol"	ACCEPT: Breath Alcohol Program was capitalized, all other instances of the words breath and alcohol are sentence case.
172	1	T	the standrad actually defines what must be included in the calibration method - this should be stated in the scope	include requirements for a calibration method in the scope	REJECT: The document includes information on validating a calibration method but does not fully define the actual requirements of the calibration method that must be used. However, the Task Group added to this document a listing of elements of a calibration method.
274	3.12	E	use of word "reliably"	delete word	REJECT: The word "reliably" remains, as this document describes the minimum requirements to demonstate the "reliability" of the determined "reporting range". This definition aligns with ANSI/ASB Std 036.
176	3.12	T	what an instrument can reliabily measure may be broader than the reporting range	the reporting range may be adminsitratively set, but must be within the validated measurement range	ACCEPT WITH MODIFICATION: The suggested language is not applicable for a definition. However, the working group revised the language in Section 4.2.d.4.ii to require validation of the reporting range.
101	3.14	E	Parentheses not used for abbreviation	Upper Limit of Quantitation (ULOQ)	REJECT: This follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports
177	3.14	E	inconsistent with ASB Std 054	use the same wording	ACCEPT: Language revised to match DRAFT ASB Standard 054: Standard for a Quality Control Progam in Forensic Toxicology Laboratories
173	3.2	E	inconsistent with ASB Std /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology	use the same wording	ACCEPT: Language revised to match ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology
99	3.3, 4.1	E	"Program" abbreviation used in 3.3 is not defined until 4.1	Define "Program" abbreviation prior to first use in document	ACCEPT: Breath Alcohol Program definition revised to include "Breath Alcohol" prior to program.

174	3.4	E	inconsistent with ASB Std 054	use the same wording	REJECT: This definition aligns to the citation (The VIM)
100	3.7	E	Parentheses not used for abbreviation	Lower Limit of Quantitation (LLOQ)	REJECT: This follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports
175	3.7	E	inconsistent with ASB Std /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology	use the same wording	ACCEPT: Language revised to match ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology
144	3.10	E	3.10 refers to %CV then 4.4.2.3 Precision uses SD, but does NOT provide a connection between SD and %CV. The relationship between these calculations needs to be given.	Provide additional explanation, show relationship between SD and %CV plus numerical examples.	REJECT: The requirement language was revised to mirror the language in the definitions.
259	3.10; 4.4.2.3	T	Definition of "Precision" differs in terminology of the mathmatic expression	Use "SD of Replicates" or "%CV" in both sections.	ACCEPT: The requirement language was revised to mirror the language in the definitions.
178	4	E	The title states "Development and Optimization". The section includes the required parameters of the Calibration Method and the Validation requirements. The only mention of dev and optimization is a reference to Annex B.	Retitle Section 4 to Calibration Method Requirements. Make Method Validation it's own requirements section.	REJECT: This document does not define the specific parameters of a calibration method. The title of this section was reworded to help clarify the contents.
231	4	T	Method validation is not what this document is supposed to be addressing. It is addressed in ASB/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology. But BrAC was intentionally excluded from ASB/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology.	Delete this section. Develop an ASB standard for method development related to BrAC which will address not only calibrations, but evidential testing, adjustments etc.	REJECT: This document was drafted to address the requirements for validating a Breath Alcohol Calibration method. The concept of including evidential testing was previously discussed. Breath Alcohol Subject Testing methodology is planned for a separate document.
275	4	T	refers to development and optimization but only Annex B lays out an example. Annex B is lengthy and given the recent move of ISO to focus on development, more guidance here would be preferable	Consider moving parameters from Annex B to the body of the document, or put some minimum criteria that should be used in development	REJECT: Due to the many program specific implications (e.g., regulatory, instrumentation) a standardized document dictating how to develop a method is not feasible. Annex B provides an example that may be helpful for programs to consider when evaluating their specific situation.
179	4/Annex B	T	A six page annex is dedicated to method development and optimization, yet there are no requirements or guidance provided in the standard - just a simple reference to the Annex	add guidance (or requirements?) for method development that are then illustrated in the Annex	REJECT: Due to the many program specific implications (e.g., regulatory, instrumentation) a standardized document dictating how to develop a method is not feasible. Annex B provides example components that may be helpful for programs to evaluate their specific situation.
180	4.1	E	The actual requirements for what must be contained in a Calibration Method should not be listed under the heading of "General"; use standard numbering system	Provide a clear heading that alerts the reader this setion is outlining requirements, e.g. Calibration Method Requirements. Use the 1, 1.1, 1.1.1 standard outline format	Part 1- (titling of section) ACCEPT WITH MODIFICATION: This document does not define the specific parameters of a calibration method. The title of this section was reworded to help clarify the contents. Part 2 -(use of standard numbering scheme) REJECT: This follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports
181	4.1	E	does not require the Calibration Method to state the frequency	add requirement to have the Method specify the frequency (and reference 6.1)	REJECT: The frequency is not a required element of a method. The information required in Section 10.1 (When to Calibrate) may be specified elsewhere (regulation, administrative rules, quality manual).
102	4.1 a)-h)	E	Some descriptive text within the list is numbered; others are not	Number or remove numbers from all descriptive text in list	REJECT: Formatting follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports (2018 version)
182	4.1 b	E	last sentence missing a "."	add "."	ACCEPT: Editorial change made.
16	4.1.b	E	Add punctuation after the word 'method' in final sentence of section	Insert necessary period	ACCEPT: Editorial change made.
145	4.1.c.2	T	A difference between the analytical portion of software and the user interface needs to be made. 4.1.c.2 IMPLIES that no software changes can every be made to the measuring system (instrument). While all software changes should be validated to determine if the change affects calibration. A subsequent software change to the background color of the display THAT HAS BEEN VALIDATED NOT TO EFFECT THE ANALYTICAL PORTION OF THE SOFTWARE does NOT justify a new calibration.	The Program should define which portions of system software are critical to the analytical calculated result. ALL software updates and changes MUST be validated to determine the effect, if any, on analytical calculations. Any change that does NOT effect the analytical calculation will not mandate a calibration. The Program may choose to calibrate after any software change.	ACCEPT: The Task Group revised and added several sections (including Section 4, 5, 6) to clarify the intent of the document.
276	4.1 d 4	T	Often a manufacturer states linearity for all measurement systems, only for the customer to later find out that additional factors are required in the adjustment process to make it behave linearly (eg quadratic correction factors)	guidance for how to evaluate measurement systems for linearity	REJECT: Linearity is dependent on many factors and evaluating the instrument linearity is outside the scope of this document.
103	4.1 d) 4)	T	Number of different concentrations seems arbitrary and other method parameters are left to the authority of the program	Allow programs to establish acceptable number of different concentrations	REJECT: This document specifies requirements for the validation process. The number (at or above the minimum specified in this document) of calibrators used for the Program's specific Breath Alcohol Calibration Method are determined by the Program.
183	4.1 d) 4)	T	No informaton is provided as to how the user is supposed to determine if the detector is linear or not. Is this based on manufacturer's claims? Or does the user need to determine this experimentally?	Add information on how to assess the linearity of the measurement system	REJECT: Linearity is dependent on many factors and evaluating the instrument linearity is outside the scope of this document.
184	4.1 d) 4)	T	There is no guidance or requirement on the range of concentration required to be used in the calibration. Does it need to challenge the reporting range? In Annex B, the lowest calibrator is 4x the low end of the measurement range.	Add language as to what is required or suggested for the calibration levels.	ACCEPT: Revised to specify the range of calibrators.
104	4.1 d) 5)	T	Number of replicates seems arbitrary and other method parameters are left to the authority of the program	Allow programs to establish acceptable number of replicates	REJECT: The Breath Alcohol Program may determine the number of replicates. The requirement of a minimum of 5 replicates supports statistical analysis (e.g., bias, precision, uncertainty of measurement).
277	4.1 e	E	LOQ refers to 4.3.3	should be 4.4.3	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
105	4.1 e)	E	Incorrect section number for limits of quantitation, unnecessary capitalization of "see"	"Limits of quantitation (see Section 4.4.3)"	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
185	4.1 e)	E	incorrect section reference	correct section reference	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
232	4.1. e)	E	references a section that does not exist	should read (See section 4.4.3)	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
17	4.1.e	E	Update reference to correct section	Should read (See section 4.4.3).	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
146	4.1.e	E	No section 4.3.3 in document, should read 4.4.3	Editorial change.	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
106	4.1 e), Table C.1	E	"section" capitalization is inconsistent	Capitalize or uncapitalize all instances of "section"	ACCEPT: Capitalization harmonized throughout document.
278	4.1 f	T	Reporting range could be limited by manufacturer	Consider "Manufacturer specifications and/or legally mandated..."	REJECT: While the manufacturer may state a reporting range, the method must still define the reporting range that will be utilized for this specific method.

107	4.2.1	E	Incorrect section number for revalidation of methods	"See Section 4.5 for further guidance […]"	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
147	4.2.1	E	Most current Programs are accredited and already have a validated calibration in place. The Program just needs to insure that current methods meet this new standard. The addition of a note or reference will clarify the intent of this section for the casual reader.	Add Note or new section pointing to Section 4.5. Programs using calibration methods that were validated prior to the publication of this standard shall demonstrate and document that those previous calibration methods are acceptable for use under this standard.	ACCEPT WITH MODIFICATION: Language from ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology was added to address the concern.
186	4.2.1	E	incorrect reference to 4.4 for revalidation	Correct reference	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
279	4.2.1 d	E	Further guidance for previously validated methods refers to 4.4	Correct to 4.5	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
18	4.2.1.d	E	Update reference to correct section	Should reference section 4.5	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
108	4.3	E	Singular/plural disagreement between "role(s)", "responsibility(ties)", and "personnel"	"The plan shall also define the roles and responsibilities of all personnel involved in the validation."	REJECT: Personnel removed from this Section.
148	4.3	E	The example given -5 to 40 degrees C would only be applicable in a few locations where calibrations are performed in the USA. A casual reader of this section might assume this is the range that ALL calibrations must be performed. The current wording may be an attempt to address roadside testing and calibration when most breath measure systems are calibrated in forensic labortories in a controlled environment.	Recommend a more conservative range example (15 C to 25 C) such as the likely temp range in a forensic laboratory versus an roadside calibration in the Alaska outback.	REJECT: This is an example and is not a requirement. Programs calibrating within a controlled environment may not need a temperature range this large.
3	4.3	T	The validation plan should also address the response of the instrument to common interferences such as acetone, as the claim that the instrument picked up something other than ethanol is a common defense in court.	The validation plan should include assessing response to acetone or other potential interferences or a justification as to why this is not necessary.	REJECT: This recommendation is outside the scope of this document as it only covers calibration. Another document addressing the validation and SOP requirements for the subject test method will be drafted.
189	4.3 footnote 4	E	sentence is missing a "."	add "."	ACCEPT: Replaced footnote with NOTE in Section 6.2.6 with proper punctuation.
187	4.3/Annex C	E	"The plan shall also define the role(s) and responsibility(ies) of all personnel involved in the validation." This statement implies a level of specificity in the plan that is inconsistent with the example. Annex C states "…multiple analysts…" and "The name of the analyst …shall be recorded."	Remove sentence. Recording personnel involved is already covered in 4.6 Documentation. If the sentence remains, then the Annex should be updated to define the "roles and responsibilities" of all personnel involved.	ACCEPT: Removed the entire sentence as this is planned to be covered under another ANSI/ASB standard.
21	4.4	T	Validation parameters should include linearity since the minimum number of concentrations specified in this standard for a calibration method is dependent upon linearity.	4.4.X Determine the linearity of the measurement technology over the reporting range.	REJECT: This document does not require the Program to establish the calibration model (e.g., linear, non-linear). The calibration model is instrument dependent.
199	4.4	T	missing evaluation of interferences	add interference section to validation requirements (or delete it from Annex C and the definitions)	ACCEPT: Interference deleted from Annex C and Definitions.
110	4.4.1	E	Incorrect/unclear grammar	"[…] on different days and by different analysts (i.e., analysts other than whoever calibrated the instrument, if practicable)."	ACCEPT WITH MODIFICATION: Verbiage updated for better clarity.
88	4.4.1	T	It is confusing to have "shall be" and then "if practicable" as almost an aside.	Remove parenthesis and make the "if practicable" part of the sentence.	ACCEPT WITH MODIFICATION: Verbiage updated for better clarity.
109	4.4.1	T	Statement requires validation experiments to be performed by different analysts, then states that they should be performed by an analyst that did not perform the calibration on that instrument "if practicable"	Ideally, this requirement should become a guideline (change "shall" to "should"), as some programs may not have access to different analysts for a validation experiment. If the requirement must stay in place, then "if practicable" should be removed.	REJECT: Instrument calibrations may be performed infrequently, under many different conditions, and by different staff. The validation is designed to show the ruggedness and robustness of the method. Programs that employ a single analyst are not expected to involve additional personnel.
188	4.4.1	E	First 2 sentences contradict each other	Reword to state all applicable validation parameters shall be addressed either through validation experiments or other means (e.g. QA, references)	REJECT: Deleted the first 2 sentences for clarity.
89	4.4.2.1	T	5 consecutive times is too few	Suggest a higher standard of a minimum of 10 to allow for instrument conditioning	REJECT: Numbers are a minimum to ensure bias and precision are captured. Programs may choose to utilize greater replicates.
190	4.4.2.1	Technical	I feel the requirement unnecessarily exceeds the Toxicology method validation document without any reasoning for the increase. Whether the calibration is a simple linear model or a complex quadratic, a low, med, and high concentration sufficiently demonstrates accpetable bias/precision throughout the calibration range. In addition, no additional validation requirements apply to a historic calibration. What is expected to be different about the measurement system of a breath instrument that requires more points in the range be assessed for bias/precision to prove the method valid? The Calibration Method requirements already state you need to run 4 or 6 levels, so that will be done in routine operation.	Require a low, medium, and high concentration for validation. NOTE: if you require the bias/precision to be done at levels that are not the same as the LLOQ/ULOQ, then you have accomplished the same thing without creating more inconsistencies between the 2 standards.	ACCEPT: Section revised to mirror the ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology
280	4.4.2.1	T	Five points for bias/precision exceeds current rquirements of ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology and all mid points (3) would be clustered around the mid of the low and high; unsure how this lends more weight than just having three poinst that span a low, medium and high	Bias and Precision with Low, Med, High only (3 points minimum)	ACCEPT: Section revised to mirror the ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology
281	4.4.2.1	T	Unsure why you need bias/precision at concentrations that would be "masked" during normal operation, especially if you are running bias/precision at 3x lowest reporting range. Would this be better suited in 4.4.3 LOQ section when one has to determine LLOQ?	Remove language and consider moving to a relevant LLOQ section 4.4.3	REJECT: Masking is now mentioned in two instances in the standard. Masking is to be removed during calibration and validation to ensure bias and precision acceptance critera are met.
73	4.4.2.1	T	We run three replicates. We cant change that right now as it will need funds to update software with Intoximeter. Our instrument lower range is 0.005g/210L and higher is 0.500g/210L.We calibrate (adjustment) with 0.100g/210L We use four different dry gas stds for certification procedure(validation of calibration) from Airgas , 0.040, 0.082,0.0.200, 0.300g/210L. We use 0.150 g/210L from airgas only for measurement assurance check. All three replicates must be within 0.003 or 3% from dry gas target whichever is greater for accuracy and all three replicates must be within 0.003 form each other.	Why three replicates are not ok? Why 5 needed? I think in most of the calibration lab are running three replicates. Changing replicates means more money to update software. We just bought new instruments.	ACCEPT: Section revised to mirror the ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology
191	4.4.2.1 footnote 5	T	Provides additional requirements for a low and high, and that the "Medium concentrations shall be near the midpoint..." That could be interpreted to mean all 3 medium concentrations be clustered around the mid-point. If 5 levels are required, then guidance should address 5 levels, not only 3 levels. If the 2 additional levels are essential to providing confidence the calibration method is fit for purpose, then there needs to be instruction on what shall be tested to provide that necessary confidence.	If 5 levels are required then provide requirements that will ensure the user will adequately address the purpose of the 2 additonal levels.	REJECT: Section revised to mirror the ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology, utilizing three concentrations.

149	Page 5 Footnote 4	E	Add period to end of footnote 4 on page 5. - *4* Although a minimum of only 1 instrument is specified for method validation, all instruments shall undergo performance verification and calibration prior to evidential use.	*4* Although a minimum of only 1 instrument is specified for method validation, all instruments shall undergo performance verification and calibration prior to evidential use.	ACCEPT: Editorial change made.
151	4.4.2.2	E	Maximum acceptable bias. Important definition, needs more emphasis. New subsection or definition.The maximum acceptable bias is ±5% or 0.005 g/210 L, (whichever is greater) at each concentration.	New subsection or definition for Maximum acceptable bias. Better yet do both. (Add to definitions in section 3.)	REJECT: The statement appears clear as written. Additionally, it is a requirement, not a definition. A definition does exist for bias.
282	4.4.2.2	E	use of "target" instead of "known" in second example ("for calculating bias utilizing the target value…")	Correct to "known"	ACCEPT: revised language
150	4.4.2.2	T	Bias Calculations. Numerical examples would greatly benefit the understanding. Definition of Nominal, Known and Calculated need to be defined here and demonstrated by numerical examples. Refer to Table B.1 Page 15 - show steps to achieve data indicated in the table. One example should be sufficient.	Refer to Table B.1 Page 15 - show steps to achieve data indicated in the table. One example should be sufficient.	ACCEPT WITH MODIFICATION: Examples added in Annex A
152	4.4.2.3	E	Important definition, needs more emphasis. Add new section plus definition in section 3. The maximum acceptable standard deviation is less than or equal to 1/3 of the maximum acceptable bias for each concentration.	Important definition. Add new section plus definition in section 3.	REJECT: The section was revised for clarity. Additionally, a definition does exist for precision.
153	4.4.2.3	T	Better way to express the exact version of the SD math formula required.	On a practical note NIST could develop a Excel worksheet and Google Sheets page that demonstrates formatting for the SD formula required. That way someone doesn't select the wrong function in their spreadsheet program.	REJECT: The formula is provided for reference. The creation of NIST sponsored material is outside the scope of this document.
283	4.4.2.3	E	3.10 definition uses CV, not SD	Correct to CV, more in line with ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology	ACCEPT: Section revised to mirror the ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology
4	4.4.2.3	E	States that precision is expressed as the standard deviation of the replicates. Precision is more commonly expressed as a relative standard deviation (RSD) or coefficiency of variability: the Standard Deviation/Mean expressed as a percentage.	Precision should be expressed as %RSD with a maximum acceptable percentage specified.	REJECT: Section revised to mirror the ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology
192	4.4.2.3	T	3.10 definition for precision states it is expressed as %CV. Yet 4.4.2.3 is using SD to assess precision.	Use %CV for assessment of precision to be consistent with other forensic toxicology method validation practices. If there is something unique for breath instrument calibrations that make SD a better assessment, then update definition of precision.	ACCEPT: Section revised to mirror the ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology
62	4.4.3	T	Limits of Quantitation LLOQ/LLOD are not normally part of a calibration procedure, but rather an instrument validation. To validate the Cal procedure.	Remove 4.4.3	REJECT: Section renumbering performed to clarify requirements related to the calibration method vs those for the validation of the calibration method. This section lies within the validation requirements.
74	4.4.3	T	Limits of Quantitation LLOQ/LLOD are not normally part of a calibration procedure, but rather an instrument validation. To validate the Cal procedure, only processes to be included in a normal calibration should be validated.	Remove 4.4.3	REJECT: Section renumbering performed to clarify requirements related to the calibration method vs those for the validation of the calibration method. This section lies within the validation requirements.
195	4.4.3	T	Why is the ULOQ a required parameter for breath calibration, but not for blood alcohol or any other tox method validation? Assessing bias/precision at within 80% of the ULOQ is deemed sufficient for all other forensic tox methods.	Remove ULOQ requirement. Conversely, if deemed essential for a minimum standard, than the CB should include it in the next revision of Std /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology.	REJECT: The concept of upper limits is addressed differently for general toxicology due to the flexibility in performing methods (e.g., they can drop points).
260	4.4.3	T	LLOQ/ULOQ can be established in Instrument Validations without being required for calibrations. If not included in the calibration method, there is no need to use them in a validation of that method.	Remove 4.4.3	REJECT: Section renumbering performed to clarify requirements related to the calibration method vs those for the validation of the calibration method. This section lies within the validation requirements.
111	4.4.3.1	E	List format is inconsistent with similar lists throughout document - letter subsections should be used for items	Change "4.4.3.1.1" to "4.4.3.1 a)"; "4.4.3.1.2" to "4.4.3.1 b)"; and "4.4.3.1.3" to "4.4.3.1 c)"	REJECT: Formatting follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports (2018 version)
193	4.4.3.1.2	E	This comment applies to both experimentally determined and administratively set LLOQ/ULOQ, so it should not be a subset of 4.4.3.1	move to a subset of 4.4.3	REJECT: The Task Group feels it is appropriately placed as guidance for determining ULOQ/LLOQ.
284	4.4.3.1.2	T	consider adding manufacturer stated values	manufacturer stated quantitaive limits	REJECT: The manufacturers statements are a specification. Each Breath Alcohol Program must consider the environment in which their end results will be used (legal, administrative, etc).
194	4.4.3.1.3	E	"…achieving acceptable …criteria in ALL THREE SAMPLES…" This does not make sense. The 3 samples are of decreasing or increasing concentrations. Is this meant to apply to the 5 replicates? Or simply a copy/paste error?	clarify the requirement	ACCEPT: Separated and enhanced the expectations surrounding ULOQ/LLOQ to provide greater clarity.
19	4.4.3.1.3	T	Not clear, criteria references 3 samples meeting criteria, but 4.4.3.1 states to run 3 different concentrations 5 times.	The lowest/highest concentration capable of achieving acceptable bias and precision criteria in all 5 replicates is considered the estimated LLOQ/ULOQ.	ACCEPT: Separated and enhanced the expectations surrounding ULOQ/LLOQ to provide greater clarity.
20	4.4.3.2	E	Period needed after the word 'criteria' at conclusion of sentence.	Insert necessary period	ACCEPT: Editorial change made.
285	4.4.3.2	E	period missing	add period	ACCEPT: Editorial change made.
196	4.4.3.2	T	Clearly state the expected requirements	Add that the administratively set LLOQ and ULOQ must be analyzed 5 consecutive times and meet all bias/precision requirements.	ACCEPT With Modification: Revised section to point back to the bias and precision criteria.
112	4.4.3.2, Annex A, Annex G	E	"program" capitalization is inconsistent	Capitalize or uncapitalize all instances of "program"	ACCEPT: Capitalization harmonized throughout document.
154	4.4.4	T	I have never observed any carryover in a evidential breath analyzer (infrared or chemical analysis). However, in portable handheld devices (Roadside - Fuel cell type) some carryover MAY be possible. So if a portable device is being submitted for EVIDENTIAL testing this test MUST be performed. Because this is calibration method development the results could be used to determine if this testing needed to be done as part of calibration in that Program.		REJECT: No proposed resolution. Evaluating carryover during method validation is an important aspect of validation. This testing will provide objective evidence that your instrumentation and method have addressed carryover.
63	4.4.4	T	Same logic as above. Carryover is a function of instrument performance and not to be evaluated during a calibration other than through normal measurement uncertainty evaluations.	Remove 4.4.4	REJECT: Evaluating carryover during method validation is an important aspect of validation. This testing will provide objective evidence that your instrumentation and method have addressed carryover.
75	4.4.4	T	Same logic as above. Carryover is a function of instrument performance and not to be evaluated during a calibration other than through normal measurement uncertainty evaluations.	Remove 4.4.4	REJECT: Evaluating carryover during method validation is an important aspect of validation. This testing will provide objective evidence that your instrumentation and method have addressed carryover.
223	4.4.4	E	Second paragraph. This is not an issue for Infrared instruments. This is already accounted for through the software and in the validation process.	Remove the second paragraph or specify instrumentation affected.	REJECT: Evaluating carryover during method validation is an important aspect of validation. This testing will provide objective evidence that your instrumentation and method have addressed carryover.

233	4.4.4	T	Carryover should be evaluated for batch evaluations in analytical runs which contain unknowns. The very nature of a calibration is the idea there are no unknowns. That is we know what the result should be. In a BrAC calibration every analyte (reference material) run should be followed with an airblank. The only acceptable result is 0.000. This sufficiently demonstrates no carryover. Even it was somehow hidden, every run is a known reference material traceable to SI units. Any carryover would push the reference material result outside acceptable limits.	delete section. If carryover is an issue it should be addressed in the calibration method development and validation in a separate document.	REJECT: Evaluating carryover during method validation is an important aspect of validation. This testing will provide objective evidence that your instrumentation and method have addressed carryover.
261	4.4.4	T	Carryover is a function of instrument performance and should be reflected in the measurement uncertainty	Remove 4.4.4	REJECT: Evaluating carryover during method validation is an important aspect of validation. This testing will provide objective evidence that your instrumentation and method have addressed carryover.
286	4.4.4, 4.4.5 and 4.4.6	E	Suggest referring to these as Additional Validation Experiments since this is how they are presented in the Annexes	Add a heading	ACCEPT WITH MODIFICATION: Removed "Additional" from the Annex.
197	4.4.4-4.4.6	E	Thee are as applicable, but are not clearly labeled that way in the outline	Label these sections as "Additonal Validation Parameters"	ACCEPT WITH MODIFICATION: Removed "Additional" from the Annex.
198	4.4.5	E	2nd sentence "material" should be plural	change material to materials	REJECT: Use of "material" is grammatically correct.
5	4.4.5	T	The stability of reference solution concentration when repeatedly opened and/or decanted should also be determined as ethanol is volatile and can be lost over time when a solution is repeatedly used. Stability of number of uses is different from stability over a certain time frame.	Add that the stability of the solution over a given number of uses should be documented.	ACCEPT: Included language to address repeated usage.
64	4.4.5	T	Reference material should only be validated if not sourced from a Certified Reference Material provider. In the case of purchased materials, stability is determined by the CRM laboratory	Add the comment that this condideriation is only applicable to calbration materials that are made in house to 4.4.5	REJECT: The use of reference material must be validated to ensure fitness for purpose in the expected parameters (environment, usage, storage, etc.).
76	4.4.5	T	Reference material should only be validated if not sourced from a CRM laboratory. In the case of purchased materials, stability is determined by the CRM laboratory	Add the comment that this is only applicable to calbration materials that are made in house to 4.4.5	REJECT: The use of reference material must be validated to ensure fitness for purpose in the expected parameters (environment, usage, storage, etc.).
85	4.4.5	T	Certified Reference Materials provides have established these parameters.	A note should be added to address those that utilize an accredited CRM provider.	REJECT: The use of reference material must be validated to ensure fitness for purpose in the expected parameters (environment, usage, storage, etc.).
155	4.4.5	T	If the Program uses Certified Reference Material from an Accredited laboratory, then much of this testing has already be done and documented. There should be some method to reference those results (providing they meet all the criteria of this standard).	There should be some method to reference Accredited CRM results (providing they meet all the criteria of this standard).	REJECT: The use of reference material must be validated to ensure fitness for purpose in the expected parameters (environment, usage, storage, etc.).
262	4.4.5	T	If the calibration laboratory is purchasing Certified Reference Material from a CRM Provider, the provider should validate the stability. Only if the material were produced in-house, would validation of the stability of the material be needed.	Add language appropriate to cover only labs producing CRM's in-house.	REJECT: The use of reference material must be validated to ensure fitness for purpose in the expected parameters (environment, usage, storage, etc.).
65	4.4.6	T	Special environmental conditions are not critical to the performance of Breath Alcohol Instrumentation. These devices are designed to be used in jail facilities, and thus to provide accurate measurements as long as normal room temperatures are maintained. Any environmental problem encountered during calibration will cause a failure of the calibration measurements, and are thus accounted for by the analysis of the standards themselves.	The only factor that may be appropriate to include for 4.4.6 is that calibrations should be perfomed at normal room temperatures.	REJECT: Programs may choose to calibrate under a variety of conditions. The anticipated conditions are to be evaluated during validation to ensure fitness for purpose.
77	4.4.6	T	Any environmental problem encountered during calibration will cause a failure of the calibration measurements, and are thus accounted for by the analysis of the standards themselves.	The only factor that may be appropriate to include for 4.4.6 is that calibrations should be perfomed at normal room temperatures.	REJECT: Programs may choose to calibrate under a variety of conditions. The anticipated conditions are to be evaluated during validation to ensure fitness for purpose.
90	4.4.6	T	Is it really practicle to test for environmental conditions in programs that cover large state areas?	Suggest allowing for wording: "Documentation of conditions that fall within the manufacturer's recommended parameters is acceptable."	REJECT: Programs may choose to calibrate under a variety of conditions. The anticipated conditions are to be evaluated during validation to ensure fitness for purpose.
113	4.5	T	Phrasing of statement assumes the likelihood of validation experiments meeting criteria of this document prior to its publication	"This calibration method may have sufficient historical calibration and control data [...]"	REJECT: Choice of "may" vs. "will likely" does not alter the intent of the requirement. Language was revised to mirror ANSI/ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology...
22	4.5	T	Acquistion of the same model of instrument, if all instrument specifications are the same, should only require a performance verification, not a re-validation.	Acquisition of the same model may require limited validation, depending on what, if any, instrument specifications have changed.	REJECT: For clarity, the sentence in this comment was deleted.
156	4.5	E	Refer to comment regarding 4.1 above " ... validated prior ....". Question: Is a time period going to be set so previously validated methods can be phased out with no effect on evidentiary tests until after the time period expires? Perhaps 1 year or renewal of Accreditation, but not longer than a year. Texas cannot pull every evidential instrument out of service the day this document takes effect.	Establish a time period to phase out previously validated methods.	REJECT: Requirements for validation of the calibration method do not address every single instrument that is used by a Program. While calibration methods are expected to meet the requirements, an implementation period is expected and is not outlined in a standard document. It is understood that time will be needed for Program's to gather the data to support conformance with this standard once published.
157	4.5	T	"Acquisition of the same model may require limited validation." Who decides MAY? The Program? ASB?	The Program should be given the option to investigate, validate and document whether or not a new calibration method will be required to meet this standard.	REJECT: For clarity, the sentence in this comment was deleted. It is the Program's responsibility to evaluate performance characteristics.
200	4.5	T	"Acquisition of the same model may require limited validation." Validation only requires one instrument (at the minimum), but all instruments have performance verification and calibration (4.3 footnote 4). If you purchase another instrument that's the same model, and has the same firmware, etc installed, why would any validation be needed?	remove this example	ACCEPT: For clarity, the sentence in this comment was deleted.
114	4.6 a)	E	Unnecessary capitalization	"conclusion/summary"	ACCEPT: Editorial change made.
201	4.6a)	E	Summary is capitalized	use lower case to be consistent with rest of section	ACCEPT: Editorial change made.
66	4.6 d	E	What is raw data?	Define raw data or remove this term which is just a favorite harping point for attorneys. How about just the 'analytical results'.	REJECT: While the term "raw" was removed for clarity, the intent behind 'data" remains the same. A definition was added for 'data' to provide additional guidance.
78	4.6 d	E	Definbe raw data	Define raw data or remove this term	REJECT: While the term "raw" was removed for clarity, the intent behind 'data" remains the same. A definition was added for 'data' to provide additional guidance.
86	4.6. d	T	Raw data is very subjective and can be defined a number a different ways.	Better define the scope of raw data to better define the expectation.	REJECT: While the term "raw" was removed for clarity, the intent behind 'data" remains the same. A definition was added for 'data' to provide additional guidance.
202	4.6 d)	E	1-4 should not be subsets of "raw data"	update to make these their own required items, and not specific to raw data	REJECT: Wording modified for clarity; however same intent as original document.

67	4.6 d 4	E	LOQ should not be part of calibrations	Remove it.	ACCEPT WITH MODIFICATION: Section was revised for clarity and to harmonize with ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology. This section only addressed requirements for validation documentation (which included LLOQ and ULOQ).
79	4.6 d 4	T	LOQ should not be part of calibrations	Remove it.	ACCEPT WITH MODIFICATION: Section was revised for clarity and to harmonize with ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology. This section only addressed requirements for validation documentation (which included LLOQ and ULOQ).
263	4.6 d 4	E	LOQ should not be included in calibration.	Remove 4.6 d 4	ACCEPT WITH MODIFICATION: Section was revised for clarity and to harmonize with ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology. This section only addressed requirements for validation documentation (which included LLOQ and ULOQ).
203	4.6 d) 4)	E	Unnecessary to single out LOQ data. Item d) covers all data.	remove	ACCEPT: Section was revised for clarity and to harmonize with ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology.
204	5	T	Should this be part of the Program's overall Calibration process?	If yes, then suggest moving to 4.1.	REJECT: Requirements surrounding adjustment are independent of validation and calibration. The sections were revised to clearly delineate validation, calibration, and adjustment.
2	5	T	Procedurally, an as-found calibration seems unnecessary, particularly in situations where the calibration is verified as a part of every test. By conducting a calibration verification with subject tests, we are already establishing the as-found criteria without having to conduct a lengthy calibration procedure.	Remove the "as-found" requirement prior to an adjustment.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
83	5	T	Performing an as found calibration prior to an adjustment seems extraneous. In situations where calibration is verfied as a part of every subject test we are setting already the stage for an as-found criteria by monitoring that verification.	Remove "as-found" reqiurement before adjustment	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameter'.
91	5	T	Where possible, a calibration shall be performed before and after an adjustment to establish the as-found and as-left condition. This seems unnecessary if the analyst has already determined that an adjust is required.	Remove quoted statement.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
96	5	T	Procedurally, an as-found calibration seems unnecessary, particularly in situations where the calibration is verified as a part of every test. By conducting a calibration verification with subject tests, we are already establishing the as-found criteria without having to conduct a lengthy calibration procedure.	Remove the "as-found" requirement prior to an adjustment.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
158	5	T	Assume an instrument's display suddenly dims, but is still readable. The instrument needs to be removed for repairs but analytical functions are NOT affected. The best course of action would be to verify the reference standard currently in use as found (duplicate tests as part of every evidential test sequence). Possibly 4.4.3.1.1 could also be utilized to verify the limits of quantitation. NO adjustments or calibrations should be performed UNTIL the current as found performance can be established. The Limit of Quantitation verifies the previous Calibration in use at the "as found" time.	Further even the Limits of Quantitation approach would require the person inspecting the instrument (not the operator) to always have on hand Certified Reference Material, addition Reference Sample devices, or gas cylinders, Calibrated thermometers, Computer or Tablet to record information. Very difficult when the supervisor may oversee 20-25 instruments at 15 widely separated locations requiring hours of driving, Better ideal is to establish (if possible) limits of quantitation at the instrument's current location then remove the inst to the Calibration Lab location for further evaluation and possible adjustment and Calibration.	REJECT: Re: instrument display comment, see Section 10.1c. Re: The location of pre-adjustment performance evaluation is not specified in the standard. Re: Limits of Quantiation, see Section 6.3.3 for additional information
205	5	T	Adjustment is critical to the performance of the instrument, but this section provides little guidance. e.g. Does the adjustment process require validation? Do changes to the adjustment procedure require any revalidation of the calibration method? Are there different requirements for internal vs external adjustments?	Provide information on the expectations for the adjustment process. If this is going to be handled in a different standard, then suggest stating that and updating to the Scope to state that adjustment is outside the scope.	ACCEPT: The section was revised to specify pre-adjustment performance evaluation parameters.
224	5	T	Why does it state that "Where possisible, a calibration should be perfmed before and after an adjustment?" There is no reason to be required to perform a calibration before an adjustment.	Remove "before" in the first paragraph.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
234	5	T	Laboratories with an appropriate QC program do not rely upon calibration to establish as-found and as-left but rather rely upon their controls to document instrument performance. Calibration laboratories are routinely separated from the maintenance facility where adjustments may be made. This requirement will double the work load of such facilities and is unacceptable. The calibration certificate handles this when it documents "results are both as found and as left". Ultimately the needs of the customer should dictate this concept.	delete section or edit wording to include language such as 'laboratories without QC Programs which allow for a means to establish performance before the adjustment shall perform a calibration prior to any adjustment'	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters. Monitoring field performance through controls is essential, but outside the scope of this standard. A future standard is planned that will address subject testing requirements.
241	5	T	The calibration is verified with a NIST traceable solution two times during every test. Additionally, if possible, at least once a month and before the instrument is removed from service an inspection is performed. Part of the inspection consists of using fresh NIST traceable solution to verify the calibration two times.	Remove the "as-found" requirement prior to an adjustment.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.

244	5	T	An "as-found" calibration seems excessive, especially in situations where the calibration is verified as a part of the testing sequence (which would be following 6.3 "calibration verification using reference materials after a calibration has been performed"). The "as-found" condition is already established.	Remove the "as-found" requirement prior to an adjustment.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
248	5	E	Procedurally, an as-found calibration seems unnecessary, particularly in situations where the calibration is verified as a part of every test. By conducting a calibration verification with subject tests, we are already establishing the as-found criteria without having to conduct a lengthy calibration procedure.	Remove the "as-found" requirement prior to an adjustment.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
254	5	T	The calibration is verified with a NIST traceable solution two times during every test. Additionally, if possible, at least once a month and before the instrument is removed from service an inspection is performed. Part of the inspection consists of using fresh NIST traceable solution to verify the calibration two times.	Remove the "as-found" requirement prior to an adjustment.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
256	5	T	An as-found calibration is redundant. Calibratons verifications are done as a part of every subject test. This would establish an as-found basis before a required calibration interval. In the case of a repair that necessitates an adjustment it is useless to perform a calibration that more than likely would fail.	Remove the "as-found" requirement prior to an adjustment	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
264	5	T	Why is a paragraph about adjustment even necessary?	Remove 5	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
249	5	T	An 'As-found' should be included if it exists. It should not be required to create an 'as-found' in cases where an adjustment will likely be performed. This changes the calibration procedure into a maintenance function.	Remove the 'As-Found' calibration as a requirement. Inclusion into the certificate file could be required if it already exists.	REJECT: Calibration activities within the larger scientific community ensure instrument performance across a defined timeframe. Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The section was revised to specify pre-adjustment performance evaluation parameters.
299	5 & 6.1.b)	T	For States that are afforded the autonomy to calibrate at State specified intervals, the "As Found, As Left" condition can be determined using data collected from the calibration verification data of the instrument. Technical Supervisors are monitoring the accuracy and precision of evidential instruments and perform calibration verifications with a wet bath reference solution change once per calendar month. It is from these inspections that often the Technical Supervisor determines that a calibration is necessary, thus addressing the "As Found" condition upon removal.	6.1.b) before and after an adjustment (if applicable) For States not operating on the 12 month interval due to robust calibration verification procedures, "calibration data before an adjustment" may not be feasible.	REJECT: The section was revised to specify pre-adjustment performance evaluation parameters. Monitoring field performance through controls is essential, but outside the scope of this standard. A future standard is planned that will address subject testing requirements.
206	6	T	Would make more sense to have this section be the "Calibration Program" and include the Calbration Method requirements within it.	consider updating organization of the topics	REJECT: Adjustment is a separate topic from calibration and is therefore handled in a separate section.
213	6	E	Nothing addresses adjustments, calibrations, or repairs done externally (e.g. by the manufacturer)	Since there is such a variety in the way Breath Programs are run, it is suggested to add some guidance and/or requirements for Programs who rely heavily on the manufacturer. For example, what must be done following external work - most manufacturers calibrate the instrument after they adjust or repair - can a Program use the calibration or do they need to perform their own calibration? Some Programs rely on the manufacturer for the calibrations, should there be some guidance for the Program to state those calibrations should be conducted in accordance with this standard?	REJECT: Program management (e.g., expectations of manufacturer) is outside the scope of this standard. This standard outlines requirements, irrespective of who conducts the work (Breath Alcohol program, manufacturer, external service provider for example).
60	6; 6.1	T	Based on evidence and history of Oklahoma instrumentation attached is a "Random_Sample" performance and reliability of our instrumentation, the Board would request that the language cited as "**..a specified interval not to exceed 12 months."** be stricken. Historically Oklahoma has been a rural state and some instrumentation may only be used thirty (30) times before the gas canister control check expires. Currently, in Oklahoma, when the gas expires or depletes, routine maintenance is completed and a linearity test is completed prior to redeployment. The majority of our instruments have been in service for three or more years and still meet manufacturer standards and calibrations when compared against known BAC values during a linearity test. The language proposed creates a mandatory calibration adjustment when such adjustment may not be warranted.	We request striking lanaguage setting mandatory intervals of calibration or adjustments and moving forward with items (a) through (e). The reasons for calibrations pertaining to (a) through (e) appear appropriate for the industry and scientific community. We also request that the information cited be reviewed.	REJECT: 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. 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.
1	6.1	T	The one year calibration interval is unnecessarily restrictive, especially for areas in our state who have Technical Supervisors that may responsible for upwards of 20 instruments. Texas DPS has recently conducted a long-term calibration longevity study with instrument calibration ages as old as 5 years by the conclusion of the study. The results show that there was negligible "decay" over that time period for most instruments in the study population.	Change the calibration interval to "not exceed 36 months" and keep the "may be calibrated more frequently" caveat, along with 6.1 a-e	REJECT: Calibration intervals for equipment are specified in {ASB 017}, this document builds upon that work. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
68	6.1	T	A calibration interval of 12 months does not reflect the stability of most breath alcohol instruments. There are many different devices, and the calibration interval should be determined by stability studies and historical data. I know of no study showing that a breath alcohol device of any manufacture develops measurement problems in 12 months. In many programs, the instrument calibration is verified with a NIST traceable standard during each breath test.	Let the calibration lab and their customers determine the calibration interval.	REJECT: Calibration intervals for equipment are specified in ANSI/ASB 017 Standard, Standard Practices for Measurement Traceability in Forensic Toxicologythis 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.

71	6.1	T	The one year calibration interval is burdensome and has been found to be unnessary. Texas DPS has recently conducted a long-term calibration longevity study. The results show that there was negligible "decay" over that time period for most instruments in the study population. Most instruments only showed changes (positive or negative) in the 1/10000th decimal place with no impact across the entire sample population outside of the 1/1000th decimal place. Texas DPS believes this shows that policy of calibration "as necessary" is appropriate. The ISO standards does require an interval, and based on data we have received and reviewed, albeit from just one of the many makes and models used in breath testing, an interval longer than a year would be more appropriate.	Change the calibration interval to not exceed 24 or 36 months and keep the "may be calibrated more frequently"	REJECT: 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. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
80	6.1	T	A calibration interval of 12 months does not reflect the stability of most breath alcohol instruments. The calibration interval should be determined by stability studies and historical data. In many programs, the instrument calibration is verified with a NIST traceable standard during each breath test.	Let the calibration lab and their customers determine the calibration interval.It may be appropriate to have the calibration lab complete a calibration longevity study to determine the calibration interval that is appropriate.	REJECT: 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. 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.
84	6.1	T	The one year calibration interval is very restrictive. Some of our Technical Supervisors supervise more than 30 instruments in their area. Texas DPS has recently conducted a long-term calibration longevity study with several of the instruments still on their initial calibration which could be up to 5 years old. The study showed that there was not a significant change in how accurately the instruments read the 0.08 and 0.150 solutions run quarterly. This study showed us that the "as neccessary" clause outlined in our Standard Operating Procedures works well for our program's needs in regards to the frequency of calibrations. A longer interval with the option to calibrate more frequenty would as needed would be far less restrictive.	Change the calibration interval to "not exceed 36 months" and keep the "may be calibrated more frequently", along with 6.1 a-e	REJECT: Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicologythis document builds upon that work. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
87	6.1	T	The specified interval of 12 months seems arbitrary. Our program conducted a study of calibration stability on our instrumentation for the past 3 years. The data supports an interval much longer than 12 months. We have a large program with over 500 instruments and a team of 45 folks trying to calibrate those instruments (not including all of their other job duties) across a vast geographical area. A change like this would have a huge impact on the services that we currently provide our customers.	I suggest that the interval be set by the laboratory or the customer based on data that supports the interval.	REJECT: Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicologythis 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.
92	6.1	T	"The calibration method shall have a specified interval not to exceed 12 months. Instruments may be calibrated more frequently." The 12 month interval seems arbitrary and unnecessary. If an instrument is performing well, there is no need to remove it from use.	Remove the quoted statements and change section title to "Calibration" rather than "When to Calibrate"	REJECT: Calibration intervals for equipment are specified in {ASB 017}, 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. The section title was retained for clarity.
95	6.1	T	The one year calibration interval is unnecessarily restrictive, especially for areas in our state who have Technical Supervisors that may responsible for upwards of 20 instruments. Texas DPS has recently conducted a long-term calibration longevity study with instrument calibration ages as old as 5 years by the conclusion of the study. The results show that there was negligible "decay" over that time period for most instruments in the study population. Most instruments only showed changes (positive or negative) in the 1/10000th decimal place with no impact across the entire sample population outside of the 1/1000th decimal place. To us, that showed that the Dept. policy of calibration "as necessary" was appropriate. I understand that the ISO standards require an interval, but based on data we have received and reviewed, a longer interval, with the caveat that they may be calibrated more frequently would be appropriate.	Change the calibration interval to "not exceed 36 months" and keep the "may be calibrated more frequently" caveat, along with 6.1 a-e	REJECT: Calibration intervals for equipment are specified in ANSI/ASB 017 Standard Practices for Measurement Traceability in Forensic Toxicology, this document builds upon that work. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
115	6.1	T	We agree that some form of monitoring calibration status across the range of analysis over time should be required; however, longer calibration intervals should be permissible as long as the agency has the data to support an extended interval for that specific instrumentation	"The calibration method shall have a specified interval not to exceed 12 months, unless the agency has performed a stability study which supports a longer calibration interval."	REJECT: 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. 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. The section title was retained for clarity.
159	6.1	T	",,,not to exceed 12 months ...." What if a currently Accredited Program has verified, demonstrated and documented that calibration is stable for a period greater than 12 months? Will ASB Std 055 allow an Accredited Program a greater period of time?	Suurvey current Accredited Programs to determine their Calibration Stability policy, if any.	REJECT: 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 were 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.
225	6.1	T	A time period for how often a calibration is performed boxes a program into unnecessary restrictions. DPS conducted a calibration study which showed the stability of the calibration over a period of time. If it's working properly, why pull an instrument and calibrate? Some instruments will need calibration more often and some will need fewer calibrations. This should be up to the individual programs based on the needs of the area.	Don't demand a time period but rather change the wording to give more liberty with individual programs. Add phrases such as "when needed, as determined, etc."	REJECT: Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicologythis 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.
235	6.1	T	"When to calibrate" with a designated time frame is a backdoor way of trying to get a program to establish a proper QC program using controls as part of the evidential test procedure. This document is not the place to drive this practice. Instead a standard such as the proposed ASB 054 should be developed for BrAC. Most all BrAC devices on the CPL are incredibly robust with respect to calibration. Laboratories should be allowed to develop and validate calibration periods without arbitrary time frames. A proper QC program is sufficient to have confidence in the results. Additionally most jurisdictions have administrative rules that dictate such arbitrary time frames.	ASB Standard 054 7.4 addresses this much more pragmatically and is more conducive to a BrAC program. Use the ASB 054 approach to calibrations and use of controls during testing.	REJECT: Breath Alcohol is outside the Scope of ANSI/ASB 054. Calibration intervals for equipment are specified in ANSI/ASB 017 Standard, 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. The requirement for controls in subject testing is outside the scope of this document; but is planned to be addressed in a future ASB document.

242	6.1	T	The calibration is verified with a NIST traceable solution two times during every test. Additionally, at least once a month an inspection is performed. Part of the inspection consists of using fresh NIST traceable solution to verify the calibration two times.	Change the calibration interval to "not exceed 36 months" and keep the "may be calibrated more frequently" caveat, along with 6.1 a-e	REJECT: 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. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
243	6.1	T	The one year calibration interval is very restrictive as there are some areas of our State that have 15-20 instruments. Texas DPS has recently conducted a long-term calibration longevity study with instrument calibration ages as old as 5 years by the conclusion of the study. The results show that there was negligible "decay" over that time period for most instruments in the study population. Knowing that ISO standards require an interval, and based on the date we have, a longer interval would be more appropriate. With also leaving the allowance for calibrations occurring more frequently and additional circumstances.	The calibration method shall have a specified interval not to exceed 36 months.	REJECT: 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. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
247	6.1	T	The one year calibration interval is unnecessarily restrictive, especially for areas in our state who have Technical Supervisors that may responsible for upwards of 20 instruments. Texas DPS has recently conducted a long-term calibration longevity study with instrument calibration ages as old as 5 years by the conclusion of the study. The results show that there was negligible "decay" over that time period for most instruments in the study population. Most instruments only showed changes (positive or negative) in the 1/10000th decimal place with no impact across the entire sample population outside of the 1/1000th decimal place. To us, that showed that the Dept. policy of calibration "as necessary" was appropriate. I understand that the ISO standards require an interval, but based on data we have received and reviewed, a longer interval, with the caveat that they may be calibrated more frequently would be appropriate.	Change the calibration interval to "not exceed 36 months" and keep the "may be calibrated more frequently" caveat, along with 6.1 a-e	REJECT: 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. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
255	6.1	T	The calibration is verified with a NIST traceable solution two times during every test. Additionally, at least once a month an inspection is performed. Part of the inspection consists of using fresh NIST traceable solution to verify the calibration two times.	Change the calibration interval to "not exceed 36 months" and keep the "may be calibrated more frequently" caveat, along with 6.1 a-e	REJECT: 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. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
257	6.1	T	Calibration interval - The 12 month interval is very burdensome with the number of instruments most TX DPS Technical Supervisors administer. It would require a TS calibrate one insrtument every 2-3 weeks. A recent TX DPS calibration longevity study indicated that there was insignificant change to an instrument's calibration results. The DPS policy of as as necessary is appropriate but as a specific interval is required by the standards a longer one may be adopted.	Change the interval to "not to exceed 36 months." Keep the remaining requirements listed in 6.1 a, c, d, & e. 6.1 3) change to "after an adjustment."	REJECT: Calibration intervals for equipment are specified ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicology, this document builds upon that work. To account for the risk associated with Breath Alcohol testing and calibration, the interval of 12 months was retained.
265	6.1	T	Setting an arbitrary calibration interval for programs that use many different instruments and methods of analysis "casts a wide net", imposing logistical and economic problems that may be entirely unnecessary.	Remove arbitrary " 12 months " language and allow programs to set their own intervals based on calibration stability and longivity data pertinent to the instrumentation, analytical method, and field testing conditions.	REJECT: 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.
298	6.1	T	The State of Texas Breath Alcohol Testing Program's current SOPs require that an instrument be calibrated under three conditions. 1.) If an instrument is being placed into evidential service for the first time. 2.) If an instrument has been adjusted. Or 3.) As deemed necessary by the Technical Supervisor. The BAL Advisory Board conducted a 2 year study to look at the stability of the Intoxilyzer 9000 calibration over two of the calibration points (0.080 and 0.150) and determined that our current interval (as deemed necessary) is adequate to meet our program's needs. The 12 month interval proposed appears to be an arbitrary number with no scientific proof to justify this interval length.	Allow states to maintain autonomy and determine calibration intervals that best suit their needs. The State of Texas conducts calibration verification on each evidential instrument once per calendar month. "The calibration method shall have a specified interval not to exceed 12 months, unless calibration verifications are performed regularly to assess the accuracy of the instrujent."	REJECT: 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. 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.
250	6.1	T	A calibration interval of 12 months is an arbitrary interval. Most instruments sustain their ability to perform accurately and precisely beyond that interval. This is supported with the NIST traceable reference material used in every standard test.	Remove the 12 month interval calibration requirement.	REJECT: Calibration intervals for equipment are specified in ANSI/ASB Standard 017, Standard Practices for Measurement Traceability in Forensic Toxicologythis 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.
236	6.1 a)	T	"...that affects the measurment process" is ripe for misinterpretation. One could argue any change in the firmware/software is a change to the process. Instruments are designed with a clear separation between analytical firmware/software routines that affect measurement results and user interface firmware/software for this precise reason. So the a) section may not even be necessary.	change wording to "after a firmware/software change that may affect instrument response". Or borrow language from ASB 054 Section 7.4 "New calibrations shall be performed after instrument maintenance or repair that may affect the calibration..."	REJECT: Once a method is validated on a specific instrument (make/model), any decisions as to when and how to revalidate are left to the Programs discretion.
160	6.1.a	T	a) after a firmware/software change that AFFECTS the measurement process. Who decides? If the software change only affects the user interface AND the Program has validated and documented no effect on the analytical calculations to achieve a result, why should the instrument be calibrated?	Each Program must validate and document whether or not a software/firmware change affects the analytical calculations of the result. If change affects calculations a new metod of calibration will be established.	ACCEPT: Once a method is validated on a specific instrument (make/model), any decisions as to when and how to revalidate are left to the Program's discretion.
23	6.1.b	E	Reference made to a section that doesn't exist	see Section 5	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
69	6.1 b	T	Before an adjustment is unnessesary. 'As found' criteria can be satisfied by stating that the instrument was functioning normally when received into the calibration lab. Adjustments are only necessary if the calibration procedure fails, and thus the 'as found' information will be self evident.	Remove 6.1 b	REJECT: Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The adjustment section (Section 5) was revised to allow for a performance verification prior to performing the adjustment (if possible).
81	6.1 b	T	Before an adjustment is unnessesary. 'As found' criteria can be satisfied by stating that the instrument was functioning normally when received into the calibration lab. Adjustments are only necessary if the calibration procedure fails, and thus the 'as found' information will be self evident.	Remove 6.1 b	REJECT: Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The adjustment section (Section 5) was revised to allow for a performance verification prior to performing the adjustment (if possible).

266	6.1 b	T	Again, this is "casting a wide net". Due to varying methods of analysis and technological differences, there may be additional factors used to determine when an adjustment is necessary. While calibration is always appropriate after adjustment, it may be an inappropriate use of time and resources to require it before an adjustment. I cannot see a neccesity in establishing an "as found" condition of the instrument prior to an adjustment.	Remove "before and"	REJECT: Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The adjustment section (Section 5) was revised to allow for a performance verification prior to performing the adjustment (if possible).
207	6.1 b)	T	incorrect reference to Section 5.6	correct reference	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
237	6.1 b)	E	requiring calibrations both before and after every adjustment is unnecessary when a laboratory has a robust QC program. QC programs using controls as part of the testing of breath samples will be aware of instrument performance up to the last test. Likewise it is not a requirement in ISO 17025. ISO 17025 handles this issue in the reporting certificate. It is common practice in metrology laboratories to not make an adjustment during the calibration process if they include a statement that 'results are both as found and as left'. Such a requirement will at a minimum double the workload in calibration laboratory. I find it interesting this requiremnt is not necessary in any other forensic toxicology discipline.	delete and rely upon Section 6.6.1 f) of this document	REJECT: Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The adjustment section (Section 5) was revised to allow for a performance verification prior to performing the adjustment (if possible).
161	6.1.b	E	Should be (See Section 5), There is no Section 5.6.	Editorial change.	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
72	6.1b	T	no section 5.6	Change to read "(see Section 5)"	ACCEPT WITH MODIFICATION: Numbering changed within document, reference updated appropriately.
226	6.1b	E	As stated above in Section 5. A calibration before an adjustment shouldn't be "required."	Remove "before"	REJECT: Once an adjustment is performed, there is no mechanism to verify prior performance. Data (e.g., calibration, pre-adjustment performance evaluation, field tests) should be used to manage the calibration program. The adjustment section (Section 5) was revised to allow for a performance verification prior to performing the adjustment (if possible).
70	6.1 c	T	Analytical sampling components can be misinterpreted easily.	Change the term to 'component that can effect the accuracy of the instrument if replaced without recalibration'.	ACCEPT WITH MODIFICATION: Language modified to meet the intent of the commenters. "...after any system component that impacts an analytical result is replaced or repaired."
82	6.1 c	T	Analytical sampling components can be misinterpreted easily.	Change the term to 'component that can effect the accuracy of the instrument if replaced without recalibration'.	ACCEPT WITH MODIFICATION: Language modified to meet the intent of the commenters. "...after any system component that impacts an analytical result is replaced or repaired."
267	6.1 c	T	Again, there are a wide array of different instrument configurations. Would a breath hose qualify as an analytical component of a sampling system? If it were measuring breath temperature than the answer would probably be "yes". If not, then why calibrate an instrument after replacing a breath hose that does not affect the measuring process?	Add the wording "that affects the measurement process" after ".....component(s)".	ACCEPT WITH MODIFICATION: Language modified to meet the intent of the commenters. "...after any system component that impacts an analytical result is replaced or repaired."
238	6.1 c)	T	The wording is ripe for misinterpretation. Some would argue a mouth piece is critical to sampling and thus would be a sampling system component. More realistically, the breath tube and any breath plumbing is definitely a component of the sampling system yet they will rarely change the instrument response.	Edit wording to: 'after any analytical sampling system component that may affect instrument response is replaced or repaired'	ACCEPT WITH MODIFICATION: Language modified to meet the intent of the commenters. "...after any system component that impacts an analytical result is replaced or repaired."
162	6.1.c	T	Replacing the breath tube on the sample deliver system has no effect on the acalculated nalytical results. Will the Program be able to designate which items would be considered "...analytical sampling system component(s) ....". As currently written could be interpreted that the instrument MUST be calibrated every time a fresh mouthpiece is utilized!	Designate that the Program must determine which items would be considered "...analytical sampling system component(s) ...."	REJECT: Language revision should provide greater clarification. "...after any system component that impacts an analytical result is replaced or repaired." The responsible party is not specified in the standard.
227	6.1c	T	This sentence needs to be reworded. "Any analytical sampling system component" is too restrictive. If an analyst removes a breath hose, which is part of the analytical sampling system, why would you require them to recalibrate? Not all components will affect the calculated quantitation.	Change the wording to be something like "Any analytical sampling system component where the quantitation could be affected" or use wording that doesn't restrict every component in the sampling system.	ACCEPT WITH MODIFICATION: Language modified to meet the intent of the commenters. "...after any system component that impacts an analytical result is replaced or repaired."
268	6.1 e	T	Why calibrate if said requirements do not affect the measurement process?	Add the wording "that affects the measurement process"	REJECT: This clause was removed from the standard.
24	6.2	T	Degree requiremements for a Technician are too restrictive by limiting the Associates degree to natural or applied sciences.	Expand the degree requirements to include the technical disciplines needed to perform breath instrument maintaince and repair.	REJECT: The entire Section was removed. The OSAC has formed a task group to revise the SWGTOX Personnel documents. The OSAC document will go through the SDO process and will be released for several rounds of public comment.
25	6.2	T	Provide a clause to substitue experience in the field for personnel requirements.	Personnel requirements shall apply to newly-appointed or newly-promoted personnel within a specified category. A combination of documented education, experience and demonstation of proficiency for existing personnel shall saisfy the requirements of this standard.	REJECT: The entire Section was removed. The OSAC has formed a task group to revise the SWGTOX Personnel documents. The OSAC document will go through the SDO process and will be released for several rounds of public comment.
208	6.2	T	Forensic Toxicology is moving toward using ANS documents because they have been through an accredtied SDO process. SWGTOX documents do not meet that standard and therefore should not be requirements.	change the "shall" to "should"	REJECT: The entire Section was removed. The OSAC has formed a task group to revise the SWGTOX Personnel documents. The OSAC document will go through the SDO process and will be released for several rounds of public comment.
239	6.2	T	Unless, I'm missing something the SWGTOX document for BrAC Personnel has not gone through the consensus standard process. Qualified people should be repsonsible for the process, but personnel qualifications are not contained in any other ASB Tox document other than the ASB 037 and even that is a Best Practice **Recommendation** as opposed to a Standard. The accrediting bodies address this in their supplemental standards like ANAB AR 3125. Manufacturers may not have degreed individuals performing this metrological process but according to what is propsed the manufacturer would then not be qualified to calibrate the device they make and service.	remove "shall" and use "should"	REJECT: The entire Section was removed. The OSAC has formed a task group to revise the SWGTOX Personnel documents. The OSAC document will go through the SDO process and will be released for several rounds of public comment.
287	6.2	T	Use of word shall; suggest using should	change "shall" to "should"	REJECT: The entire Section was removed. The OSAC has formed a task group to revise the SWGTOX Personnel documents. The OSAC document will go through the SDO process and will be released for several rounds of public comment.
6	6.3	T	In addition to how, programs should also specify when performance verification will be performed (i.e. weekly, after the instrument is moved, etc.)	Add a statement to 6.3 that the process of calibration validation monitoring includes specifing how often and when such monitoring is to occur.	REJECT: The working group relies upon the common definition of schedule (e.g., procedural plan that indicates the time and sequence of each operation) to communicate the intent.
26	6.4	E	I believe the intent of this section is to address calibration results that do not meet acceptability criteria, not calling into question the validated method itself	Change wording: The Program shall define the action(s) to be taken when the calibration results do not meet the defined acceptance parameters.	ACCEPT: Language modified to use "result" vs "method".

209	6.4	T	duplicative of 4.1 h)	combine into one criteria	REJECT: Requirement removed from the Optimization/Development Section. The requirement now exists only in the Unacceptable Calibration Results Section.
288	6.4	T	Redundant--was already mentioned in 4.1 h	Delete Section 6.4	accept: Requirement removed from the Optimization/Development Section. The requirement now exists only in the Unacceptable Calibration Results Section.
246	6.4	E	Noting when calibration results have not met the acceptance criteria is important, i.e. a failed calibration. I would consider any additional actions maintenance and not calibration, therefore should not be required to be notated during a calibration.	The Program shall define the action(s) to be taken when the calibration method does not meet the defined acceptance parameters. The instrument may not be used for evidentiary purposes until a calibration with acceptable results has been met.	accept WITH MODIFICATION: Section 10.1 (When to Calibrate) was modified to include the requirement to calibrate when acceptance critera are not successfully met (e.g., failed calibration).
258	6.4	E	It would be impossible to define every possible way a calibration fails and the required action for each case. It seems any failure would be evaluated and the necessary steps taken, whether troubleshooting or repair, to achieve a successful calibration. TX DPS currently indicates a reason for the calibration on the calibration certificate.	Document on the calibration certificate the reason the calibration was performed; required interval, repair, adjustment, etc. as indicated in 6.1.	REJECT: The working group did not feel that this request is appropriate for a minimum standard document. Programs may choose to voluntarily provide the commenter's requested information for a variety of reasons (e.g., their management system, legal requirements, accreditation requirements).
251	6.4	T	The phrase 'calibration method' is used in this section, I believe in context, it means 'calibration result'	The word 'Method' should be removed or changed to a more suitable word	ACCEPT: Language modified to use "result" vs "method".
252	6.4	T	This section suggests that actions be defined in the event of a failed calibration. Those maintenance functions should be left up the individual forensic scientist. Listing specific actions to be taken could not be all-encompassing as it would require individual scientists to perform unnecessary actions in order to fulfill the defined actions.	The actions required in case of a failed calibration should remain general instead of specific.	REJECT: The use of the term 'may' indicates a permissability wth three different possible actions listed. The term 'define' may continue this thought of flexibility (e.g., based upon the forensic scientist's expert opinion, a single new calibration may be attempted. if this is unsuccessful, an adjustment is to be performed)
240	6.5	T	retention time 10 years'	State law typically defines retention schedules. Again the use of the word "should" is appropriate	ACCEPT WITH MODIFICATION: The requirement language was revised to allow flexibility for government retention schedules.
269	6.6	T	This document is currently worded to be more stringent than International Standards (ISO/IEC 17025:2017) in terms of what the required elements of a Calibration Certificate are. It does not allow for a simplified format if agreed upon with the customer. For example, breath instruments in my Program's oversight are not at the Program's address, and some locations can serve multiple customers. So instead of having several addresses on the Calibration Certificate, our customers agreed to a simplified format that has the Program's address and the Name of the location where the instrument is being used by our various customers.	Suggest adding wording such as in ISO/IEC 17025:2017, Section 7.8.1.3 to this section to allow for this, for example: "When agreed with the customer, the results of the calibration may be reported in a simplified way. Any element listed in 6.6.1 that is not reported to the customer shall be readily available."	REJECT: The Task Group feels that all elements are necessary and a simplified report does not meet the needs of the end user. The Task Group however did remove certain elements to ensure only minimum content is required.
7	6.6.	T	Is it mandatory for programs to offer calibration certificates? Some programs have a log of calibrations done by the servicing technician but do not print a separate calibration document for the agency housing the instrument.	State whether calibration certificates are mandatory or if other documentation such as service logs with the specified information are sufficient.	ACCEPT: Language revised to clarify the intent (i.e., a Certificate is required).
27	6.6.1	T	'calibration item instrument' is redundant, simplify terminology	Choose either 'calibration item' or 'calibration instrument'	ACCEPT: The word 'item' was removed from this element.
212	6.6.1	T	does not require any page numbering or clear indication of the end of the report	suggest requiring a means to recognize the full report (e.g. page numbering, end of report)	ACCEPT: The section was modified to require pagination (e.g., 1 of 3).
270	6.6.1	T	This document is currently worded to be more stringent than International Standards (ISO/IEC 17025:2017) in terms of what the required elements of a Calibration Certificate are. It does not allow the Program to have a valid reason for not including an element on the Calibration Certificate. The same example as given for 6.6 applies here with multiple customers using one instrument at a location that is NOT at the Program's address. Having several addresses on the Calibration Certificate would be confusing to our customers, so we opted NOT to include some addresses and agreed to a simplified format.	Suggest adding wording such as in ISO/IEC 17025:2017, Section 7.8.2.1 to allow for this, for example: Change "Calibration certificates (however named) shall be written clearly and shall include at the minimum the following:" to "Calibration certificates (however named) shall be written clearly and shall include at the minumum the following, unless the Program has valid reasons for not doing so:"	REJECT: The Task Group feels that all elements are necessary to meet the needs of the end user. The Task Group however did remove certain elements to ensure only minimum content is required.
289	6.6.1	E	date of calibration is present, but not date of report. This would be more consistent with ISO	Add report date	ACCEPT WITH MODIFICATION : Date certificate issued added to the requirement.
290	6.6.1	T	Is intent to harmonize with ISO? If so, calibration interval is a disconnect. ISO states that a cal interval shall not have a recommendation to an interval unless agreed upon with the customer	Remove or add "if required by the customer"	REJECT: The length of the interval is specified by the Breath Alcohol Program (in no instance longer than 12 months from the calibration date). The interval chosen by the Breath Alcohol Program is an important piece of information for end users (Law Enforcement, Attorneys, Judges) to determine the calibration status of an instrument (e.g., was the instrument calibrated when my subject's test was performed?).
253	6.6.1 F	T	Any results before the calibration should not be required for inclusion into the calibration certificate. It doesn't matter what the results before the calibration were. Each calibration certificate should only contain information pertinent to itself and the procedures done for that calibration.	Remove 6.6.1 F	ACCEPT: This requirement was removed. Section 9 addresses the data that must be collected before and after an adjustment is performed. As Breath Alcohol has a legal component, it is expected that Breath Alcohol Programs would provide all records requested through legal avenues (e.g., subpoena, open records request).
245	6.6.1.f	T	I do not see the merit of having before and after adjustment or repair calibration results on a calibration certificate. The adjustment is changing the “prescribed indications corresponding to given values of the quantity to be measured". Therefore, the previous calibration data is not pertinent to the current calibration being completed. If a repair was to be performed, a pre-repair calibration may not exist. All previous calibrations, complete and unacceptable (failed), would be maintained in a calibration file to be maintained for "no less than 10 years".	Deletion	ACCEPT: This requirement was removed. Section 9 addresses the data that must be collected before and after an adjustment is performed. As Breath Alcohol has a legal component, it is expected that Breath Alcohol Programs would provide all records requested through legal avenues (e.g., subpoena, open records request).
300	6.6.1.g)	T	Indicating that a calibration is only valid for 12 months from the date of calibration implies that any test conducted after that 12 months without calibration would become invalid.	Remove the example. (eg.) The interval has already been recommended in the document in section 6.1. For states who choose not to adopt the recommended 12 month calibration interval, this example could cause a negative impact in court due to the concrete wording regarding "validity".	REJECT: The calibration interval of no more than 12 months is a requirement, not a recommendation. The Task Group decided the example provided more guidance and therefore retained the wording.
210	6.6.1 g	T	This requirement conflicts with ISO/IEC 17025:2017 7.8.4.3 "A calibration certificate… shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer."	If the requirement is to remain, then add an additional requirement in 6.1 that the Program must have a written agreement with the customer as to the calibration interval.	REJECT: This document is not recommending a specific interval. Inclusion of a calibration interval is required in the calibration method (to be defined by the laboratory, but no longer than 12 months past the previous calibration).
93	6.6.1 g)	T	This reference the calibration interval which I believe is arbitrary and unnecessary.	Remove entirely to align with comment #5.	REJECT: Calibration intervals for equipment are specified in ANSI/ASB 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.
228	6.6.1g	T	The calibrated interval Again, giving a time restriction to the interval restricts programs.	Depending on if the interval/wording is changed, the statement here would need to reflect the wording in Section 6.1	REJECT: The language earlier in the document regarding the calibration interval (12 months) was not modified.

28	6.6.1.h	E	Change i.e. to e.g.	Make necessary correction	REJECT: The requirement was deleted.
29	6.6.1.l	T	Add version to method, if necessary	the name of the calibration method and version, if appropriate (e.g., title of standard operating procedure);	REJECT: This document is a minimum standard. Breath Alcohol Programs have the flexibility to make their own processes more stringent.
94	6.6.1 n)	T	Unless two calibrations are performed on the same day I don't believe it is necessary to incorporate a unique identifier. The calibration is inheritantly identified by the serial number of the instrument and the date calibration is performed without this being explicitly written.	Removed entirely.	ACCEPT: This requirement was deleted.
211	6.6.1 n)	T	I don't understand the purpose of this requirement? If all the info required in the other letters is included, then there is sufficient uniqueness to the calibration certificate	remove n	ACCEPT: This requirement was deleted.
30	6.6.1.m	E	Add comma between the words'signature' and 'or' and another between 'equivalent' and 'of'	Insert necessary commas	ACCEPT: Editorial change made.
163	8.1.2.records	T	Full Name and Initial cross reference should be included in the document. Possible that two persons could have the same initials. Cross reference would address this possibility. The Program may already have such documentation as part of Accrediation process.	The Program may already have such documentation as part of Accrediation process. If so supply suitable reference. Otherwise create document.	REJECT: Clause 8.1.2 was not present in the document released for public comment. The Task Group searched for "initial" in the document and it is only present in the Annexes as an example. No changes made by the Task Group.
214	Annex A	E	This is no longer an ASB requirement.	Suggest moving relevant portions to the Foreword.	ACCEPT: Task Group moved relevant information to the Foreword and deleted the Annex information.
291	Annex A	E	So much of this seems redundant to Forward	Move any relevant info to Forward that is missing	ACCEPT: Task Group included relevant information into the Foreward and deleted the Annex information.
31	Annex A, paragraph 2	E	Change i.e. to e.g.	Make necessary correction	REJECT: Task Group included relevant information into the Foreward and deleted the Annex information.
294	Annex B	E	Bias is 3% in example, but because it is an example, suggest going with actual requirement in standard	Change 3% to 5%	accept: Although this was only an example, it was changed to match minimum acceptance criteria.
164	Annex B Pages 15 -18	E	Pages 15-18. Each EXAMPLE page needs a reference printed on the page to Footnote 6, page 13. This document will be examined and questioned in a judicial setting. Single pages may be offered. Therefore every example page must be clearly marked.	Editorial change.	REJECT: Formatting follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports (2018 version)
32	B.1	E	Rearrange table to present columns in order of descending concentration	Switch the column reporting the 0.005 results with the column reporting the 0.008 results.	REJECT: Columns are sorted by the date of analysis not concentration.
116	B.1.1	E	List format is inconsistent with similar lists throughout document - semicolons should be used between items and a period used for last item	Semicolons following a), b), and c); period following d)	ACCEPT: Editorial change made.
117	B.1.2	E	Unnecessary capitalization	"Company XYZ simulators (temperature traceable to SI units)"	ACCEPT: Capitalization harmonized throughout document.
118	B.1.2	E	Unnecessary capitalization	"External barometer [...]"	ACCEPT: Capitalization harmonized throughout document.
119	B.1.2	E	Unnecessary capitalization	"For calibration: compressed gas [...]"	ACCEPT: Capitalization harmonized throughout document.
120	B.1.2	E	Unnecessary capitalization	"[...] aqueous reference material [...]"	ACCEPT: Capitalization harmonized throughout document.
122	B.1.2	T	Unnecessary capitalization	"Concentrations of interest"	ACCEPT: Capitalization harmonized throughout document.
123	B.1.2	E	Statement related to "Records -" should be only plural if consistent with requirement for different days/analysts	"The names and dates of those involved [...]"	ACCEPT: Parantheses removed. Method development would involve more than a singular person and date.
215	B.1.2	E	Max Bias/Precision - suggest keeping it consistent with the min requirement to avoid confusion or others using this example to suggest you should do better than the minimum	change to meet min requirement (5%, 0.005)	ACCEPT: Changed example to match acceptance criteria stated in 6.3.2.2.
124	B.1.2 a)	E	Margin of this subsection differs from all other subsections	Correct margin of this subsection	ACCEPT: Editorial change made.
217	B.1.2 b)	E	Only citing the 0.20 legal level does not seem appropriate for ULOQ evaluation	Reword to be more applicable to what you would evaluate for ULOQ. e.g. state that 0.20 is the highest level set in the law, however, a significant number of breath alcohol results are expected to exceed that level. Therefore ULOQ will be evaluated starting at 0.30 and increase from there.	REJECT: While this section does not explicitly state the concentrations to be used, Table C.2 provides example concentrations.
125	B.1.2 c)	E	Unnecessary capitalization	"The concentrations of interest must also be considered."	ACCEPT: Capitalization harmonized throughout document.
126	B.1.2 g)	E	Incorrect/unclear grammar and should be only plural if consistent with requirement for different days/analysts	"The names of analysts, dates of analysis, instrument parameters, and final data will be retained [...]"	Partial ACCEPT: Removed parantheses as more than one person and date will be relevant, but did not include "analyst" or "analysis" as there will be relevant personnel and dates that are not confined to analysis.
121	B.1.2 superscript 6	E	Inconsistent wording with Title of Annex B	"This is an example of a mock Method Development and Optimization Plan [...]"	REJECT: Superscript is consistent with and expands upon the title of this annex
33	B.1.2.a	T	LLOQ is determined by running a minimum of 3 concentrations each with 5 replicates, reword last sentence of the last paragraph for clarity	The lowest concentration that is capable of achieving acceptable bias and precision criteria in all five replicates is considered the LLOQ.	Partial ACCEPT: Removed "in all three samples" to clarify. It is also consistent with the definition in Section 3.9.
34	B.1.2.a	T	ULOQ is determined by running a minimum of 3 concentrations each with 5 replicates, reword last sentence of the last paragraph for clarity	The highest concentration that is capable of achieving acceptable bias and precision criteria in all five replicates is considered the ULOQ.	Partial ACCEPT: Removed "in all three samples" to clarify. It is also consistent with the definition in Section 3.18.
127	Table B.2	E	For Range and Standard Deviation of the rightmost column, "N/A" would be more appropriate than superscript "a"	Change Range and Standard Deviation in rightmost column from superscript "a" to "N/A"	ACCEPT: While examples are for illustrative purposes, this was revised for greater clarity.
35	Table B.3	E	'Higher Reporting Limit' should read 'Highest Reporting Limit'	Make necessary correction	ACCEPT: Revised for clarity.
128	Table B.3	E	Inconsistent use of capitalization throughout table	Standardize capitalization within table	ACCEPT: Capitalization harmonized throughout document.
292	Table B.3	E	Formatting of last column--year is wrapped to second line	Widen margin	ACCEPT: Editorial change made.
130	B.3.1	E	Comma should be semicolon	"No further optimization is necessary; both Method A and Method B meet the requirements."	ACCEPT: Editorial change made.
38	B.3.1	T	The lowest concentration used in this calibration example is 4x the lower limit of the reporting range. Was this intended?	Update the example to use a concentration that is within 3x the lower limit of the reporting range.	ACCEPT: Values were updated in the table.
39	B.3.1	T	The highest concentration used in this calibration example is ~75% of the highest limit of the reporting range. Was this intended?	Update the example to use a concentration that is within 80% the upper limit of the reporting range.	ACCEPT: Values were updated in the table.

218	B.3.1	T	I don't see anywhere that the Program has established that the detector is linear within their reporting range to support using only 4 calibrators.	State in the development example how the Program determined if the measurement system is linear or not within their reporting range. (e.g. epxerimental, scientific literature, manufacturer's claims)	REJECT: This document has been changed so that the requirements are the same whether the instrument is linear or not.
131	B.3.2	E	Unnecessary comma	"In August 2016, [...]"	ACCEPT: Editorial change made.
132	B.3.2	E	Inconsistent capitalization of "calibration method(s)"	Capitalize or decapitalize all instances of "calibration method(s)"	ACCEPT: Capitalization harmonized throughout document.
295	Annex B.3.2	E	Refers to calibratiosn performed in 2016, but all data in table is 2015	Fix paragraph or tables	ACCEPT: Changed paragraph to read August 2015
36	Table B.4	E	Example results report using an expired CRM for the Verification test	Update example to a non-expired CRM	ACCEPT: Changed year so that solution was unexpired at date of analysis.
129	Table B.4	E	Text in the Date/Initials, CRM Lot#, and CRM Exp. rows goes to a second line	Slightly extend margins for columns to give enough space for text	ACCEPT: Editorial change made.
37	Table B.5	E	Example results report using an expired CRM for the Verification test	Update example to a non-expired CRM	ACCEPT: Changed year so that solution was unexpired at date of analysis.
216	Annex B-G footnotes	E	seems unnecessary - An Annex is illustrative and says ("informative") and the Title starts with "Example"	remove footnote	REJECT: Working group believes the footnote will assist some readers in understanding that the informative annexes are examples and are not requirements.
293	Annexes B-F	E	Footnotes not needed--understood that Annexes are examples	Delete footnote	REJECT: Working group believes the footnote will assist some readers in understanding that the informative annexes are examples and are not requirements.
229	Annex B-H	T	These seem to be examples on how to validate but it's not clear why they are included in this document.	Put validations and such in a different document. Also, make sure that they are merely "examples" and not restrictions on how to validate.	REJECT: Document addresses validation of calibration method. Annexes are provided, and clearly stated, as examples of the requirements and practices set forth within this standard. The working group hopes that these examples will assist the reader in implementing the requirements.
170	Tables B.1 - F.1	T	All Tables B.1 - F.1. Verify all calculation results shown in these EXAMPLE tables. This reviewer was able to verify the SD calculations on some values indicated, but not on others. Calculations were conducted with software and hand calculations. Page 16 the 0.380 SD shown was verified, but the 0.400 SD calculation could not be verified.	Provide better documentation as to exactly how calculations performed. On a practical note NIST could develop a Excel worksheet and Google Sheets page that demonstrates formatting for the SD formula required. That way someone doesn't select the wrong function in their spreadsheet program.	REJECT: Calculations may be performed in a variety of ways. Specifying a prescriptive approach to calculations is outside the scope of this document.
40	Annex C-Title	E	Delete duplicate 'Method Validation Plan' in the title	Make necessary correction	ACCEPT: Editorial change made.
133	C.1	E	Portion of title is unnecessarily repeated	Remove "Method Validation Plan" after superscript 7	ACCEPT: Editorial change made.
41	C.1.1	T	Correct reference to 'Table 1' to 'Table C.1'	Make necessary correction	ACCEPT WITH MODIFICATION: Numbering changed within document, references updated appropriately.
219	C.1.1	E	refers to the Measurement Range, but the standard sets the validation requirements for bias/precision based on the REPORTING RANGE (4.4.2.1)	State in the Introduction what the Calibration Method Reporting Range will be. If not 0.02-0.60, then the 5 bias/precision concentrations may need to be modified.	ACCEPT: Verbiage changed from "Measurement" to "Reporting" range for clarity.
42	Table C.1	E	In the Bias row, Assessment Parameters column, delete 'i.e.'	Make necessary correction	REJECT: Task Group unable to locate an 'i.e.,' in this section.
43	Table C.1	E	Correct Main Text references listed in Column 1 (Parameter) to correspond to the correct location in the text	Bias (see section 4.4.2.2) Precision (see section 4.4.2.3) Endogenous and Physiological Influences Carryover (see section 4.4.4)	ACCEPT WITH MODIFICATION: Numbering changed within document, references updated appropriately.
44	Table C.1	E	In the note, correct reference from 'Table B.1' to 'Table C.1'	Make necessary correction	ACCEPT WITH MODIFICATION: Numbering changed within document, references updated appropriately.
136	Table C.1	E	"SIM SOL" is breath alcohol lingo and not defined earlier - could be written out for clarity	"[...] with a blank simulator solution or air blank [...]"	ACCEPT: Task group revised language for clarity.
220	Table C.1	E	section references are inaccurate	correct	ACCEPT WITH MODIFICATION: Numbering changed within document, references updated appropriately.
222	Table C.1	E	I believe the note intends to refer to Table C.1?	correct reference if interpretation is correct	ACCEPT WITH MODIFICATION: Numbering changed within document, references updated appropriately.
296	Table C.1	E	If intention is that "main text reference" is for ASB document, then numbers do not match	Haarmonize with ASB document	ACCEPT WITH MODIFICATION: Numbering changed within document, references updated appropriately.
297	Table C.1	E	there is no matching endogenous/physiological influences section	Add it back in to main document in section with Carryover, Ref Material Stability, Env Conditions (Additional Val Experiments)	ACCEPT WITH MODIFICATION: Language referencing endogenous/physiological influences in the Table was removed. While this is an important topic in Subject testing, it is not relevant to calibrators which use CRMs.
221	Table C.1	T	LLOQ and ULOQ have distinct requirements and should be listed separately in the Validation Plan. It is acceptable to have data serve multiple purposes, but the requirements and results should be documented independently for each of the Validation Requirements	Add to Parameters - LLOQ and ULOQ	REJECT: In this Annex (example), the ULOQ and LLOQ have previously been determined. These elements should be considered during the method development stage.
165	Table C1 Page 20	E	Page 20. This EXAMPLE page needs a reference printed on the page to Footnote 7, page 19. This document will be examined and questioned in a judicial setting. Single pages may be offered. Therefore every example page must be clearly marked.	Editorial change.	REJECT: Formatting follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports (2018 version)
45	C.1.2	E	Remove period after 'A1216.'	Make necessary correction	ACCEPT: Editorial change made.
46	C.1.2	E	Add period at the conclusion of 'The lot numbers of all reference materials and other reagents shall be recorded as well as the serial numbers of all equipment'	Make necessary correction	ACCEPT: Editorial change made.
134	C.1.2	E	Unnecessary capitalization	"[...] infrared technology [...]"	ACCEPT: Editorial change made.
135	C.1.2	E	Missing period	"[...] as well as the serial numbers of all equipment."	ACCEPT: Editorial change made.
47	Annex D	E	Correct date in header from 2019 to 2020	Make necessary correction	ACCEPT: Editorial change made.
48	Table D.1	E	Correct t 'METHOD 5' to 'METHOD A1216'	Make necessary correction	REJECT: Each Annex is a stand alone example. However, changes were made to entries.
49	Table D.1	E	Correct 'Model-X' to 'Model-123'	Make necessary correction	REJECT: Each Annex is a stand alone example. No changes were made to entries.

50	Annex E	E	Correct date in header from 2019 to 2020	Make necessary correction	ACCEPT: Editorial change made.
166	Annex E Page 22	E	This EXAMPLE page needs a reference printed on the page to Footnote 9 page 22. This document will be examined and questioned in a judicial setting. Single pages may be offered. Therefore every example page must be clearly marked.	Editorial change.	REJECT: Formatting follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports (2018 version)
137	E.2	E	Missing comma	"The mean of each analysis, as well as the combined mean for each event, are recorded in the following table."	ACCEPT: Editorial change made.
51	Annex F	E	Correct date in header from 2019 to 2020	Make necessary correction	ACCEPT: Editorial change made.
138	Annex F	E	"psi" can be difficult to understand within sentences	Replace "psi" with "pressure" when practical	ACCEPT: Changed "psi" to "pressure" where appropriate.
139	F.1	E	psi used in title before being defined in F.1.1	"Minimum Allowable Pressure of dry Gas Reference Standards"	ACCEPT: Changed "psi" to "pressure" where appropriate.
56	F.1.2.a	E	Insert an 's' after 'CRM'	Make necessary correction	ACCEPT: Editorial change made.
53	F.1.2.b	E	Insert period after 'CRM'	Make necessary correction	ACCEPT: Editorial change made.
52	F.1.2.b.1	E	Clarify wording.	'Perform a test to determine if the result is within acceptable parameters (0.005 or +/-5%).'	ACCEPT: Used suggested wording.
140	F.1.2 e)	E	Inconsistent/unclear list	"Record the route of deliver for each test (breath port or internal)"	ACCEPT WITH MODIFICATION: Clarified language to reflect the actual route of entry for reference material into the instrument.
54	F.1.2.e.1	E	Insert period after 'port'	Make necessary correction	ACCEPT: Editorial change made.
55	F.1.2.e.2	E	Insert period after 'gauge'	Make necessary correction	ACCEPT: Editorial change made.
167	F.13 and F14 Page 25	E	This EXAMPLE page needs a reference printed on the page to Footnote 10 page 24. This document will be examined and questioned in a judicial setting. Single pages may be offered. Therefore every example page must be clearly marked.	Editorial change.	REJECT: Formatting follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports (2018 version)
57	F.1.4	E	Correct section references from 'E.1.2 (Table E.1 - Summary of Minimum Allowable psi)' to 'F.1.3 (Table F.1-Summary of Minimum Allowable psi)'	Make necessary correction	REJECT: Numbering was correct in the original document.
58	Annex G	E	Correct date in header from 2019 to 2020	Make necessary correction	ACCEPT: Editorial change made.
141	Annex G	E	Format inconsistent with other validation summary examples	Use numbering/sections to make consistent with other annexes	REJECT: Formatting follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports (2018 version)
142	Annex G	E	Data tables were included with other validation summary examples, which helped express the data more clearly than descriptive writing	Include data tables similar to other validation summary examples	REJECT: The authors of the document intentionally used different examples and styles to illustrate different approaches that may be taken by Breath Alcohol Programs. The summary for validations may be in any format that meets the requirements of the Breath Alcohol Program.
143	Annex G RFI	E	"EMC" is lingo and not defined	"[…] internationally accepted electromagnetic compatibility standards."	ACCEPT: Added "electromagnetic compatibility" with the abbreviation.
168	Annex G RFI Page 27	E	This EXAMPLE page needs a reference printed on the page to Footnote 11 page 26. This document will be examined and questioned in a judicial setting. Single pages may be offered. Therefore every example page must be clearly marked.	Editorial change.	REJECT: Formatting follows the ASB Manual for Standards, Best Practice Recommendations, and Technical Reports (2018 version)
59	Annex H	E	Correct date in header from 2019 to 2020	Make necessary correction	ACCEPT: Editorial change made.
169	Annex H	T	Cannot determine the merit of an unpublished Reference (See 3).	Reference should be deleted, or ASB STD 055 should NOT be released until After ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology and been evaluated and published.	REJECT: ASB /ASB Standard 036, Standard Practices for Method Validation in Forensic Toxicology…. Is an ANSI/ASB published standard

61			As cited from https://blog.ansi.org/2020/03/calibration-verification-validation-labs/	Many laboratories have misinterpreted the term “verification” to avoid performing a calibration on a device used to support testing. The terms “calibration,” “verification,” and “validation” are quite different. They should not be confused with one another or used interchangeably. •Calibration: 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. (JCGM 200 International vocabulary of metrology – Basic and general concepts and associate terms, 2.39) •Verification: Provision of objective evidence that a given item fulfills specified requirements. (JCGM 200 International vocabulary of metrology – Basic and general concepts and associate terms, 2.44; ISO/IEC 17025 3.8) •Validation: Verification, where specified requirements are adequate for intended use. (JCGM 200 International vocabulary of metrology – Basic and general concepts and associate terms, 2.45; ISO/IEC 17025 3.9) Calibration Data Leads to Decisions Simply put, a calibration produces data, nothing more. Once the calibration data is available, there are decisions to be taken. A verification decision is typically taken each time an item is calibrated. Does the measurement data fall within specifications? Is the uncertainty sufficiently low to make this determination? A validation decision is normally taken with a first-time calibration or the first time an item is used for a task. A secondary validation decision should be taken when the item does not meet all the specified limits as it may still be fit for purpose for some, but not all operations. An item may be identified for several purposes (tests) in a laboratory; an out-of-tolerance data point for one measurement parameter may not affect some of those tests. In short, there are three steps: Calibration as a first step produces measurement results, verification as a second step confirms results are within defined limits, and validation as a third step confirms fitness for purpose.	REJECT: Task Group was unable to determine the commenter’s intent with the comment. Nor was a proposed solution provided.