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2020

**Standard for Breath Alcohol Measuring Instrument  
Calibration**

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## Standard for Breath Alcohol Measuring Instrument Calibration

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## Foreword

The field of Toxicology includes Breath Alcohol testing. Breath Alcohol testing is widely used to determine the alcohol (ethanol) content of an individual. Breath Alcohol Programs vary widely in their requirements (statutory, regulatory, programmatic), resources, and oversight/administration. Historically, the National Safety Council (Alcohol, Drugs and Impairment Division, previously known as Committee on Alcohol and Other Drugs) has outlined initial minimum guidelines for various components of Breath Alcohol testing<sup>1</sup>.

This document was prepared and finalized as a standard by the Toxicology Consensus Body of the ASB. The draft was developed by the Toxicology Subcommittee of the Organization of Scientific Area Committees for Forensic Science to provide minimum standards of practice for the calibration of evidentiary Breath Alcohol instruments. This document provides a model for Breath Alcohol programs to follow in developing and validating a calibration method. By following these standards, a Breath Alcohol program will be able to objectively show that a Breath Alcohol instrument is capable of successfully performing at its intended level of accuracy and precision using the validated calibration method.

All hyperlinks and web addresses shown in this document are current as of the publication date of this standard.

**Keywords:** *Breath Alcohol, calibration, methodology, validation.*

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<sup>1</sup> National Safety Council, *A HISTORY of THE COMMITTEE ON ALCOHOL AND OTHER DRUGS (CAOD)*, [http://www.nsc.org/NSCDocuments\\_Advocacy/NSChistoryofCAOD.pdf](http://www.nsc.org/NSCDocuments_Advocacy/NSChistoryofCAOD.pdf), accessed 4/21/2017.

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# Standard for Breath Alcohol Measuring Instrument Calibration

## 1 Scope

This standard is applicable to the calibration of breath alcohol measuring instruments for evidentiary purposes. These minimum requirements are included for (1) the development and validation of calibration methods on these instruments; (2) evaluation of performance following adjustments and calibrations; and (3) monitoring the validity of the calibrations performed. This standard is not intended to cover preliminary (non-evidentiary) testing, ignition interlock, or federally-regulated testing.

## 2 Normative References

There are no normative reference documents. Annex B, Bibliography, contains informative references.

## 3 Terms and Definitions

For purposes of this document, the following definitions apply.

### 3.1 adjustment

A set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of the quantity to be measured<sup>2</sup>.

### 3.2 bias

Difference between the mean of several measurements under identical conditions, to a known “true” value. It is often reported as a percent difference.

### 3.3 Breath Alcohol Program

An organizational structure including policies, procedures, responsibilities and resources necessary for implementing core Breath Alcohol activities. The Program includes, but may not be limited to, requirements or specifications for reference materials, training of operators, maintenance and calibration of instrumentation, the evidential Breath Alcohol test sequence, and record retention.

### 3.4 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<sup>2</sup>.

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<sup>2</sup> Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)* (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200).

**3.5  
carryover**

Appearance of unintended analyte signal in samples after the analysis of a positive sample.

**3.6  
interferences**

Non-targeted analytes (e.g., matrix components, other drugs and metabolites, impurities) which may impact the ability to detect, identify, or quantitate a targeted analyte.

**3.7  
Lower Limit of Quantitation  
LLOQ**

The lowest concentration of a measurand that can be reliably measured by an analytical procedure.

**3.8  
masking**

Automated function where results below a pre-specified threshold are reported as no analyte (e.g., ethanol not present, 0.000 g/210 L ethanol).

**3.9  
measurement assurance**

The process of monitoring the validity of the calibrations performed.

**3.10  
precision**

The measure of the closeness of agreement between a series of measurements obtained from multiple samplings of the same homogenous sample. It is expressed numerically as the coefficient of variation (%CV).

**3.11  
reference material**

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process<sup>3</sup>.

**3.12  
reporting range**

Range of concentrations that can be reliably measured by an analytical procedure.

**3.13  
stability**

An analyte's resistance to chemical change in a matrix under specific conditions for given time intervals.

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<sup>3</sup> Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)* (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200).

**3.14****Upper Limit of Quantitation****ULOQ**

The highest concentration of a measurand that can be reliably measured by an analytical procedure.

**4 The Calibration Method (Development and Optimization)****4.1 General**

The calibration method shall be a defined procedure with specified components and pre-defined acceptance criteria. Breath Alcohol Programs (hereafter called Program) providing calibration services for evidentiary Breath Alcohol instruments are often subject to legal, programmatic, legal precedent, and/or accreditation requirements. Consequently, the Program may need to perform various experiments to develop and optimize a method that meets Program requirements.

Prior to performing calibration method validation experiments all components of the calibration method shall be determined and defined. The final calibration method, however determined, shall be validated prior to use on instruments for evidential purposes. Annex B provides an example of a method development and optimization plan with example results.

The calibration method shall include, but may not be limited to, the following.

- a) Method name.
- b) Instrument make and model.

This document does not address instrument specifications; however, the instrument make and model shall be specified in the calibration method

- c) Computer system parameters.

Analysis and the subsequent information obtained (e.g., diagnostics, response curves), calculated (e.g., results), retained, and reported is controlled by a computer system.

- 1) Components of the computer system (e.g., software, firmware, hardware, configuration files) which shall be uniquely identified and versioned if applicable.
- 2) The Program may choose to revise computer system parameters during the method development phase to optimize components such as method, instrumentation, or user interface. However, the computer system parameters shall remain the same throughout validation and subsequent evidentiary testing.

- d) Reference material.

- 1) Matrix: aqueous and/or compressed dry gas;
- 2) source (traceability, uncertainty);
- 3) concentrations;

- 4) number of different concentrations;
  - i. minimum of 4 non-zero calibrators if the measurement technology (detector) is inherently linear;
  - ii. minimum of 6 non-zero calibrators if measurement technology is not linear;
- 5) number of replicates per concentration (minimum of 5).
- e) Limits of quantitation (See section 4.3.3).
- f) Reporting range.

The calibration method shall define the reporting range. The calibration method shall ensure acceptable results across the entire reporting range. Legally mandated ethanol concentrations should guide the decision regarding the reporting range.

- g) Calibration sequence.

The calibration sequence is comprised of the number of replicates, number of concentrations, and the order of operations performed during the calibration method. Programs may use an automated process for their calibration sequence.

- h) Acceptance criteria.

Criteria shall be defined for a successful calibration. The method shall also specify steps to be taken when the calibration does not meet the parameters for successful calibration.

## 4.2 Validating the Calibration Method

### 4.2.1 When to validate the calibration method.

Calibration methods shall be validated when it is necessary to verify a method's performance parameters are acceptable for use. Common examples requiring validation include:

- a) existing calibration methods that do not currently meet the current requirements outlined in this document;
- b) modifications of an established calibration method to improve performance or extend its use beyond that for which it was originally validated (e.g., expanded reporting range);
- c) new calibration method;
- d) to demonstrate equivalent uniformity between an established method/instrument and a new method/instrument.

The parameters to be evaluated for validation of calibration methods will depend upon the circumstances in which the method is to be used. Likewise, it is recognized that after validation has occurred, methods may be revised. The extent and frequency of revalidation of previously validated methods will depend upon the nature of the intended changes or Program policy. See Section 4.4 for further guidance on revalidation of previously validated methods.

### 4.3 Establishing a Validation Plan

The Program is responsible for ensuring the calibration method is satisfactorily validated. A validation plan shall be in place prior to starting any validation experiments. The validation plan is separate from a Program's standard operating procedure (SOP) for method validation and it provides direction for the experiments that will be performed and acceptance criteria for each parameter. The plan shall include the elements specified in Section 4.4. Further, it shall document the validation and method requirements that will allow it to be acceptable for use (e.g., the calibration shall be accurate in temperatures from -5° to 40°C). The plan shall also define the role(s) and responsibility(ies) of all personnel involved in the validation. Annexes C and D provide examples of a calibration method validation plan and selected results.

The Program shall determine the number of instruments used for validation experiments. The validation shall be conducted using the same calibration conditions and parameters as specified in the final method. A minimum of 1 instrument shall have all validation experiments performed in totality<sup>4</sup>.

Programs should consider uncertainty estimation in developing the validation plan. Validation experiment data may be used to calculate the initial estimation of measurement uncertainty.

### 4.4 Validation Parameters

#### 4.4.1 General

It is important to evaluate all applicable validation parameters and address them in the validation plan. Alternatively, parameters may be addressed through other means (e.g., quality assurance practices, published references) and documented within the validation plan.

All validation experiments outlined below shall be conducted in similar environments and conditions in which a calibration may take place. Validation experiments shall be conducted on different days and by different analysts (i.e., other than whomever calibrated the instrument, if practicable).

#### 4.4.2 Bias and Precision

##### 4.4.2.1 General

Bias and precision shall be calculated for each instrument (if performing validation experiments using more than one instrument) using reference material with established traceability at five separate concentrations across the reporting range<sup>5</sup>. Each concentration shall be run a minimum of five consecutive times (replicates).

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<sup>4</sup> Although a minimum of only 1 instrument is specified for method validation, all instruments shall undergo performance verification and calibration prior to evidential use

<sup>5</sup> For purposes of this document, low concentrations shall be no more than approximately 3 times the lowest end of the reporting range of the method and high concentrations shall be within approximately 80% (or more) of the highest end of the reporting range of the method. Medium concentrations shall be near the midpoint of the low and high concentrations.

Programs that utilize masking during testing may need to cancel masking during validation to determine bias and precision at lower concentrations.

#### 4.4.2.2 Bias Determination and Acceptance

The bias shall be calculated for each concentration. The Program may utilize the nominal value or known value of the reference material to calculate the bias, however, it shall be specified in the validation plan.

For calculating bias utilizing the nominal value, use the following formula:

$$\text{Bias (\% at Concentration}_x) = \left[ \frac{\text{Grand Mean of Calculated Concentration}_x - \text{Nominal Concentration}_x}{\text{Nominal Concentration}_x} \right] \times 100 \quad (1)$$

For calculating bias utilizing the target value, use the following formula:

$$\text{Bias (\% at Concentration}_x) = \left[ \frac{\text{Grand Mean of Calculated Concentration}_x - \text{Known Concentration}_x}{\text{Known Concentration}_x} \right] \times 100 \quad (2)$$

The maximum acceptable bias is  $\pm 5\%$  or 0.005 g/210 L, (whichever is greater) at each concentration.

#### 4.4.2.3 Precision

Precision is expressed as the standard deviation (SD) of the replicates. The following formula is used to calculate the standard deviation:

$$SD = \sqrt{\frac{\sum(x_i - m)^2}{n-1}} \quad (3)$$

where  $\sum$  means "sum of",  $x_i$  is a value in the data set,  $m$  is the mean of the data set, and  $n$  is the number of data points.

The maximum acceptable standard deviation is less than or equal to 1/3 of the maximum acceptable bias for each concentration.

#### 4.4.3 Limits of Quantitation

4.4.3.1 Determining the LLOQ/ULOQ using reference material with established traceability:

4.4.3.1.1 Minimum of three decreasing/increasing ethanol concentrations shall be analyzed five consecutive times (replicates);

4.4.3.1.2 The lowest/highest statutorily mandated ethanol level should be considered when determining the appropriate ethanol concentrations to use;

4.4.3.1.3 The lowest/highest concentration capable of achieving acceptable bias and precision criteria in all three samples is considered the estimated LLOQ/ULOQ.

4.4.3.2 Alternatively, programs may administratively set a LLOQ/ULOQ based upon results gained during development, regulatory, or statutory constraints; however, the Program shall demonstrate that the LLOQ/ULOQ levels chosen meet acceptable bias and precision criteria

#### 4.4.4 Carryover

Carryover shall be evaluated as part of method validation. Ethanol negative sample(s) (e.g., human breath, dry gas, and/or aqueous solution) shall be analyzed immediately after the highest concentration of the reporting range. This shall be tested using three replicate analyses.

If possible, the calibration method will eliminate any carryover. In cases when it is not possible to eliminate the carryover, the calibration method shall address how carryover will be managed.

#### 4.4.5 Reference Material Stability

Reference material used to calibrate the instrument(s) may be subject to variables including storage and transportation conditions and handling. The stability of reference material shall be evaluated as applicable. Stability experiments shall be designed and conducted to address situations typically encountered with reference material used to calibrate a Breath Alcohol instrument. Annex E and Annex F provide examples of validation plans related to reference material stability. Characteristics that may be evaluated include:

- a) shelf life of reference material;
- b) stability of reference material over time and/or usage;
- c) stability of reference material when stored/transported outside of room temperature;
- d) stability of compressed gas at lower pressure (i.e., amount of compressed gas introduced to instrument at lower cylinder pressure).

#### 4.4.6 Environmental Conditions

The performance of the calibration method shall be assessed under similar environmental conditions that are typically encountered in the laboratory and/or field (as applicable). If environmental conditions exist that potentially cause an effect on the instrument operation and calibration method, then those conditions shall be evaluated. The Program shall define these conditions in the validation plan. The Program shall calibrate the instrument(s) under the defined conditions and then assess the applicable validation parameters. Annex G provides examples for validation plans for environmental conditions. Environmental conditions may include, but are not limited to:

- a) atmospheric pressure;
- b) humidity;
- c) radiofrequency interference (RFI);
- d) temperature.

#### 4.5 Revalidation of Previously Validated Methods

Modifications to a validated method require evaluation to confirm that the changes do not have an adverse effect on the method's performance. The decision regarding which performance characteristics require additional validation is based on logical consideration of the specific

parameters likely to be affected by the change(s). These changes may include, but are not limited to:

- a) analytical changes to software/firmware;
- b) expanded reporting range;
- c) instrumentation (e.g., different model);
- d) location of calibration method performance (e.g., initiating field calibrations).

For example, an analytical change in software/firmware may affect linearity, physiological influences, precision, or bias. Consideration should be given to conducting parallel studies using a previously validated method and the modified method to evaluate the effects of the change(s). The goal is to demonstrate any impact the change(s) have on the performance of the previously validated procedure. New models/manufacturers of instrumentation shall require a complete validation study. Acquisition of the same model may require limited validation.

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. This calibration method will likely have sufficient historical calibration and control data that can be used to address a number of the required validation parameters. Without sufficient data to fulfill this minimum standard, appropriate studies shall be conducted to ensure compliance with this document.

#### **4.6 Documentation Requirements**

Record keeping is an essential part of a Program's operating procedures and is a key component of method validation. The following records shall be retained, organized, and available for review:

- a) conclusion/Summary;
- b) date of approval;
- c) name and title of person(s) approving the calibration method;
- d) raw data or reference to where the raw data are stored;
  - 1) personnel involved in the method validation;
  - 2) dates when each parameter was evaluated;
  - 3) source of reference material (e.g., lot number, manufacturer);
  - 4) limits of quantitation data (see Section 4.4.3).
- e) references;
- f) results and calculations;
- g) validation plan;

- 1) scope;
- 2) name of calibration method;
- 3) description of all the parameters evaluated. If any of the parameters were not evaluated, then the reason shall be stated or justified.

Records shall be retained according to the Program's record retention policy or for a minimum of 10 years after the calibration method is no longer used.

## 5 Adjustment

An evidential Breath Alcohol instrument may require adjustment for corrective or preventive reasons, or to comply with administratively established intervals. Where possible, a calibration shall be performed before and after an adjustment, to establish the as-found and as-left condition. An adjustment shall be followed by a calibration before the instrument is used for evidential Breath Alcohol testing. Examples of instances when the as-found calibration may not be possible:

- a) The instrument is unable to run tests until repairs are performed.
- b) The instrument software is preventing continued testing without first performing an adjustment.

## 6 Calibration (Logistics)

### 6.1 When to Calibrate

The calibration method shall have a specified interval not to exceed 12 months. Instruments may be calibrated more frequently. Additionally, instruments used for evidential purposes shall be calibrated under the following circumstances:

- a) after a firmware/software change that affects the measurement process;
- b) before and after an adjustment (see Section 5.6);
- c) after any *analytical* sampling system component(s) is replaced or repaired;
- d) prior to initial use for evidential testing;
- e) statutory, regulatory, programmatic requirement(s).

### 6.2 Personnel

Personnel performing calibration activities shall comply with the Scientific Working Group for Forensic Toxicology (SWGTOX) Standard for Breath Alcohol Personnel.

(<https://academic.oup.com/jat/article/39/3/231/2357610?searchresult=1>)

### 6.3 Measurement Assurance

Programs shall have a process for monitoring the validity of their calibration activities. Techniques to evaluate calibration results may include, but are not limited to, the following: participation in an

inter-laboratory proficiency program; routine calibration checks on evidential instruments; and calibration verification using reference materials after a calibration has been performed.

#### **6.4 Unacceptable Calibration Results**

The Program shall define the action(s) to be taken when the calibration method does not meet the defined acceptance parameters. This response may be a subsequent attempt at calibration, troubleshooting, and/or repair.

#### **6.5 Documentation**

All records that are produced during the calibration shall be retained according to the Program's retention schedule. However, the retention time can be no less than 10 years.

#### **6.6 Calibration Certificates**

##### **6.6.1 Elements of a Calibration Certificate**

Calibration certificates (however named) shall be written clearly and shall include at minimum the following:

- a) a description of the calibration item instrument (e.g., instrument make/model);
- b) an unambiguous identification of the calibration item instrument (e.g., serial number);
- c) date of calibration;
- d) evidence that the measurements are traceable;
- e) calibration results, with units of measurement;
- f) the results before and after any adjustment or repair, if available;
- g) the calibration interval (e.g., "The calibration of this instrument is valid for 12 months from the date of calibration");
- h) the condition of the calibration item instrument (i.e., "as found");
- i) the name and address of the Program;
- j) the name and address of the customer (if different than the Program);
- k) the name and address where the calibration was performed (if different than the Program's address);
- l) the name of the calibration method (e.g., title of standard operating procedure);
- m) the name, title, and signature or secure electronic equivalent of the calibration certificate author (e.g., the individual taking responsibility for the calibration certificate);

- n) the Program's unique identification for the calibration (e.g., serial number + date, certificate number);
- o) the uncertainty of measurement;
- p) title (e.g., Instrument Calibration Certificate, Certification Record).

### **6.6.2 Amended Certificates**

When modifications to the original calibration certificate are necessary, an amended certificate shall clearly indicate the amendment. If a new certificate is issued, the certificate shall reference the original certificate.

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## **Annex A** **(informative)**

### **Foundational Principles**

A scientifically valid program is required to ensure that instruments used for evidentiary Breath Alcohol testing produce accurate and reliable results. Program components include personnel, instrument specifications, calibration protocols, subject testing protocols, and quality assurance procedures. This document focuses on calibration; additional program components will be included in other documents. The calibration of Breath Alcohol instrumentation is the cornerstone of a scientifically valid program.

The term “calibration” is used in various ways in the scientific community. For Breath Alcohol instrumentation, the calibration involves the analysis of specific known standards to determine the relationship between the expected values and the reported values for a given analyte (i.e., ethanol). This should not be confused with an adjustment, where changes are made to the instrument’s response in order to match a known value. Anytime an adjustment is performed on an instrument, a calibration is performed to ensure that the instrument was adjusted as expected.

Calibration methods are validated to ensure methods are acceptable for their intended use. Validation is the process of performing a set of experiments that reliably estimate the efficacy and reliability of an analytical method. The goal of validation is to establish objective evidence that demonstrates a method is capable of successfully performing at the level of its intended use and to identify the method’s limitations under normal operating conditions.

## Annex B (informative)

### Example of a Method Development and Optimization Plan with Selected Results<sup>6</sup>

#### B.1 Method Development and Optimization Plan

##### B.1.1 Objective

Develop and optimize a calibration method for Instrument ABC that provides the:

- a) required minimum bias and precision
- b) necessary analytical capabilities
- c) determination of the lower and upper limits of quantitation
- d) determination of the reporting range

##### B.1.2 Development Protocol

Instrument –	Instrument ABC equipped with Anytown P.D. software/firmware
Equipment –	Company XYZ Simulators (Temperature traceable to SI units) External Barometer (traceable to SI units by an accredited ISO/IEC 17025 calibration laboratory)
Standards –	For Calibration: Compressed gas (EtOH in N <sub>2</sub> ) (traceable to SI units) For verification of the calibration method during method development: Aqueous reference material (EtOH in H <sub>2</sub> O) (traceable to SI units)
Location(s) –	Anytown P.D. Crime Laboratory 1234 Main Street, Anytown, USA
Maximum bias/precision –	Bias = 3% or 0.003 g/210 L (whichever is greater)  Precision = $\leq 1/3$ of the acceptable bias for each concentration

<sup>6</sup> This is an example of a mock Method Development/Optimization Plan and subsequent results, for illustrative purposes only.

- Concentrations of Interest – 0.02 g/210 L of breath = underage DUI
- 0.04 g/210 L of breath = mass transit operators
- 0.08 g/210 L of breath = rebuttable presumption of DUI
- 0.15 g/210 L of breath = enhanced penalty for DUI
- 0.20 g/210 L of breath = enhanced penalty for DUI
- Records – The name(s) and date(s) of those involved with executing this plan will be recorded with the resultant data.
- Analytical process – The following process will be repeated, as necessary, to achieve the stated objective.
- a) Determine the Lower Limit of Quantitation (LLOQ).
- A minimum of three samples of decreasing ethanol concentrations shall be analyzed five consecutive times (replicates). The lowest statutorily mandated ethanol level (0.02 g/210 L of breath) will be considered when determining the appropriate ethanol concentrations. The lowest concentration that is capable of achieving acceptable bias and precision criteria in all three samples is considered the estimated LLOQ.
- b) Determine the Upper Limit of Quantitation (ULOQ).
- A minimum of three samples of increasing ethanol concentrations shall be analyzed five consecutive times (replicates). The highest statutorily mandated ethanol level (0.20 g/210 L of breath) will be considered when determining the appropriate ethanol concentrations. The highest concentration that is capable of achieving acceptable bias and precision criteria in all three samples is considered the estimated ULOQ.
- c) Determine the reporting range.
- The reporting range will be determined using data developed from Step a) and Step b) above. The Concentrations of Interest must also be considered.
- d) Develop appropriate calibration method(s).
- Specify the instrument parameters, concentrations, acceptance parameters, and number of replicates used for each calibration method used during the method development phase.
- e) Evaluate the data obtained from Step d) above to determine if further optimization is desired.
- f) At the conclusion of Steps a) through e), identify the appropriate calibration method that will advance to the validation stage.
- g) The name(s), date(s), instrument parameters, and final data will be retained until the method validation is successfully concluded.

## B.2 Method Development Results and Summary

### B.2.1 Determination of the Lower Limit of Quantitation (LLOQ)

Five (5) different traceable aqueous standards of decreasing concentration were evaluated to determine the LLOQ. It was determined by experiment and manufacturer's literature that the instrument has a masking function at 0.005 g/210L. The LLOQ was determined to be at 0.010 g/210L.

**Table B.1—Determination of LLOQ**

<b>Date/initials:</b>	<b>8/1/14 TNW</b>	<b>8/1/14 TNW</b>	<b>8/1/14 TNW</b>	<b>8/1/14 TNW</b>	<b>8/2/14 TNW</b>
Instrument SN	090299	090299	090299	090299	090299
Simulator SN	XN1480	XN1425	XN1454	XN1493	XN1493
Sim Solution Lot#	140301A	140728A	140301B	140728B	140802A
Sim Solution Exp.	3/1/15	7/28/15	3/1/15	7/28/15	8/2/15
<b>Target conc (g/210L)</b>	<b>0.020</b>	<b>0.015</b>	<b>0.010</b>	<b>0.005</b>	<b>0.008</b>
Replicate #1	0.020	0.014	0.010	0.000	0.012
Replicate #2	0.020	0.014	0.010	0.000	0.010
Replicate #3	0.019	0.014	0.010	0.000	0.008
Replicate #4	0.019	0.013	0.010	0.000	0.007
Replicate #5	0.019	0.013	0.010	0.000	0.000
Mean:	0.019	0.013	0.010	0.000	0.007
Number of Analyses:	5	5	5	5	5
Range (Low-High):	0.019-0.020	0.013-0.014	0.010-0.010	0.000-0.000	0.000-0.012
± 0.003 acceptable bias range	0.017-0.023	0.012-0.018	0.007-0.013	0.002-0.008	0.005-0.011
Standard Deviation:	0.000	0.000	0.000	0.000	0.004
Acceptable bias and precision	Yes	Yes	Yes	No	No

### B.2.2 Determination of the Upper Limit of Quantitation (ULOQ)

Four (4) different traceable aqueous standards of increasing concentration were evaluated to determine the ULOQ. It was determined by experiment and manufacturer's literature that the instrument has an upper detection limit of 0.420 g/210L. The ULOQ was determined to be at 0.400 g/210L.

**Table B.2—Determination of ULOQ**

<b>Date/initials:</b>	<b>8/2/14 TNW</b>	<b>8/2/14 TNW</b>	<b>8/2/14 TNW</b>	<b>8/2/14 TNW</b>
Instrument SN	090299	090299	090299	090299
Simulator SN	XN1480	XN1425	XN1454	XN1430
Sim Solution Lot#	140301C	140728C	140301D	140728D
Sim Solution Exp.	3/1/15	7/28/15	3/1/15	7/28/15
Target conc (g/210L)	<b>0.380</b>	<b>0.400</b>	<b>0.420</b>	<b>0.425</b>
Replicate #1	0.375	0.401	0.410	Sample Over Range
Replicate #2	0.382	0.400	0.412	Sample Over Range
Replicate #3	0.381	0.399	0.415	Sample Over Range
Replicate #4	0.379	0.399	0.419	Sample Over Range
Replicate #5	0.380	0.403	Sample Over Range	Sample Over Range
Mean:	0.379	0.400	0.414	Sample Over Range
Number of Analyses:	5	5	5	5
Range (Low-High):	0.375-0.382	0.399-0.403	0.410-0.419 <sup>a</sup>	a
± 3% acceptable bias range	0.368-0.391	0.388-0.412	0.407-0.432	0.412-0.437
Standard Deviation:	0.002	0.001	0.003	a
Acceptable bias and precision	Yes	Yes	Yes	<b>No</b>
<sup>a</sup> Instrument message "Sample Over Range" at concentrations $\geq$ upper detection limit				

### B.2.3 Determination of the Reporting Range

The LLOQ, ULOQ and concentrations of interest were considered in determining the reporting range. The final reported result has 2 significant figures with units = g/210 L of breath. Therefore, the lowest concentration reported will be 0.01 g/210 L of breath. For results <0.01 g/210 L of breath, the instrument will report 0.00 g/210 L of breath. The highest concentration reported will be 0.40 g/210 L of breath. For results >0.40 g/210 L of breath, the instrument will report "Sample Over Range".

**Table B.3—Determination of the Reporting Range**

<b>Concentrations of Interest</b>	<b>Concentration (g/210 L)</b>
LLOQ	0.01
Lowest conc. of interest	0.02
Lower Reporting Limit	0.01
ULOQ	0.40
Highest conc. of interest	0.20
Higher Reporting Limit	0.40
Resulting Reporting Range	0.01-0.40

### B.3 Method Development

Tables B.4 and B.5 summarize the instrument parameters, concentrations, acceptance parameters, number of replicates and results for each calibration method (Method A and Method B) used during the method development phase.

**Table B.4—Summary of Results Using Method A**

<b>METHOD A</b>	<b>Calibration</b>						<b>Verify</b>
Date/initials	8/15/15 NLT	8/15/15 NLT	8/15/15 NLT	8/15/15 NLT	8/15/15 NLT	8/15/15 NLT	8/15/15 NLT
Instrument SN	090320	090320	090320	090320	090320	090320	090320
CRM matrix	gas	gas	gas	gas	gas	gas	aqueous
CRM Lot#	AL141202	AL141204	AL141208	AL141015	AL141220	AL141030	140728D
CRM Exp.	16-Dec	16-Dec	16-Dec	16-Oct	16-Dec	16-Oct	7/28/15
<b>Target conc. (g/210L)</b>	<b>0.020</b>	<b>0.040</b>	<b>0.080</b>	<b>0.150</b>	<b>0.200</b>	<b>0.300</b>	<b>0.100</b>
Replicate #1	0.019	0.039	0.079	0.148	0.201	0.302	0.099
Replicate #2	0.019	0.039	0.079	0.149	0.202	0.304	0.099
Replicate #3	0.020	0.039	0.079	0.150	0.202	0.303	0.099
Replicate #4	0.020	0.040	0.080	0.149	0.201	0.303	0.098
Replicate #5	0.020	0.040	0.080	0.150	0.203	0.303	0.100
Replicate #6	0.019	0.040	0.080	0.151	0.202	0.304	0.100
Replicate #7	0.020	0.040	0.081	0.150	0.202	0.303	0.100
Replicate #8	0.019	0.040	0.081	0.149	0.202	0.304	0.099
Replicate #9	0.020	0.039	0.080	0.150	0.203	0.304	0.099
Replicate #10	0.020	0.039	0.081	0.150	0.203	0.304	0.099
Mean:	0.020	0.040	0.080	0.150	0.202	0.303	0.099
Range (Low-High)	0.019-0.020	0.039-0.040	0.079-0.081	0.148-0.151	0.201-0.203	0.302-0.304	0.098-0.100
(± 3% or 0.003) acceptable bias range	0.017-0.023	0.037-0.043	0.077-0.083	0.145-0.154	0.194-0.206	0.291-0.309	0.097-0.103
Standard Deviation	0.001	0.001	0.001	0.001	0.001	0.001	0.001
Acceptable bias and precision	Yes	Yes	Yes	Yes	Yes	Yes	Yes

**Table B.5—Summary of Results Using Method B**

<b>METHOD B</b>	<b>Calibration</b>				<b>Verify</b>
Date/initials:	8/20/15 NLT	8/20/15 NLT	8/20/15 NLT	8/20/15 NLT	8/20/15 NLT
Instrument SN	090320	090320	090320	090320	090320
CRM matrix	gas	gas	gas	gas	aqueous
CRM Lot#	AL141204	AL141208	AL141015	AL141030	140728D
CRM Exp.	16-Dec	16-Dec	16-Oct	16-Oct	7/28/15
<b>Target conc. (g/210L)</b>	<b>0.040</b>	<b>0.080</b>	<b>0.150</b>	<b>0.300</b>	<b>0.100</b>
Replicate #1	0.039	0.079	0.148	0.302	0.101
Replicate #2	0.039	0.079	0.149	0.304	0.101
Replicate #3	0.039	0.079	0.150	0.303	0.101
Replicate #4	0.040	0.080	0.149	0.303	0.102
Replicate #5	0.040	0.080	0.150	0.303	0.102
Mean:	0.039	0.079	0.149	0.303	0.102
Range (Low-High):	0.039- 0.040	0.079- 0.081	0.148- 0.151	0.302- 0.304	0.101- 0.102
(± 3% or 0.003) acceptable bias range	0.037- 0.043	0.077- 0.083	0.145- 0.154	0.291- 0.309	0.097- 0.103
Standard Deviation:	0.001	0.001	0.001	0.001	0.001
Acceptable bias and precision	Yes	Yes	Yes	Yes	Yes

### B.3.1 Assessment and Comparison of Method A and Method B

No further optimization is necessary, both Method A and Method B meet the requirements.

Calibration Method B involves fewer concentrations and replicates to achieve equivalent accuracy and precision. Therefore, Method B will advance to the validation stage.

### B.3.2 Summary of Method Development

In August, 2016, Anytown PD performed method development for the ABC evidential Breath Alcohol instrument. The reporting range was determined to be 0.01-0.40 g/210L of breath. Two (2) Calibration Methods were developed and tested. Both Calibration methods met the requirements. Method Validation experiments will be performed using Calibration Method B to assess the suitability of the method for evidential calibration purposes.

## Annex C (informative)

### C.1 Example of a Method Validation Plan<sup>7</sup>Method Validation Plan

#### C.1.1 Introduction

During Method Development it was determined that the LOD for instrument “Model-123” was 0.01 g/210L, the LLOQ was 0.02 g/210L, the ULOQ was 0.60 g/210L, and the resulting Measurement Range was 0.02 to 0.60 g/210L.

Because this calibration method will serve as a quantitative procedure for evidential use, the method validation parameters will be assessed for the desired requirements as listed in Table 1. The assessments shall be performed by multiple analysts and in multiple locations, including field locations. The name of the analyst and the location shall be recorded each time.

#### C.1.2 Equipment, Method and Materials

Instrument –	“Model-123” evidential Breath Alcohol measuring instrument, Infrared technology calibrated with Method A1216.
Method –	Method Validation Procedure for Breath Alcohol Instruments (MVP_001), approved 1/1/2015
Simulator –	Model “XYZ” simulators from Company-A, with certified thermometers from Company-B
Reference material –	Aqueous, certified ethanol-water solutions from Company-C, multiple concentrations
Reference material –	Gas, certified dry gas-ethanol from Company-D, multiple concentrations
Water –	Laboratory grade deionized water, made in-house
Volatiles –	Laboratory grade acetone, methanol, isopropanol from Company-E

The lot numbers of all reference materials and other reagents shall be recorded as well as the serial numbers of all equipment

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<sup>7</sup> This is an example of a mock Method Validation Plan, for illustrative purposes only.

**Table C.1—Validation Plan for Instrument “Model-123” (Method A1216)**

Parameter (Main text reference)	Pre-Determined Acceptance Criteria	Assessment Parameters
Bias (see section 6.1)	Shall not exceed $\pm 5\%$ , or $\pm 0.005$ g/210L, whichever is greater	10 replicates, 5 separate runs, 5 different instruments at the following concentrations: 0.02 g/210L (i.e. statutory limit & LLOQ) 0.08 g/210L (statutory limit) 0.15 g/210L (statutory limit) 0.30 g/210L (mid-range concentration) 0.60 g/210L (ULOQ) Separately evaluate the bias for each instrument.
Precision (see section 6.1.3)	$\leq 1/3$ of the acceptable bias for each concentration	Use the same data obtained from the bias study. Separately evaluate the precision for each instrument, for each separate run, by combining the data from all 10 replicates at each concentration (N=10 data points for each concentration).
Endogenous and Physiological Influences (see section 6.3)	Endogenous - No interfering signal from matrix  Physiological - No interfering signal from common volatiles, either alone or in combination with an ethanol reference material solution	— Endogenous (human) — 10 different sources  — Part 1, Common Volatiles (5 replicates at low, <b>target</b> , high concentrations) — Acetone at 0.02 g/210 L, <b>0.06 g/210L</b> , 0.10 g/210L — Methanol at 0.005 g/210L, <b>0.01 g/210L</b> , 0.03 g/210L — Isopropanol at 0.005 g/210L, <b>0.01 g/210L</b> , 0.03 g/210L  — Part 2, Common Volatiles (5 replicates) — Repeat Part 1, but with each volatile level spiked in an ethanol solution at 0.10 g/210L
Carryover (see section 6.2)	Carryover at ULOQ does not exceed 0.01 g/210L	For each instrument, follow each 0.60 g/210L calibrator with a blank SIM SOL or air blank, perform in triplicate
NOTE Several of the parameters listed in Table B.1 can be assessed simultaneously; for example, the data used for bias assessment can also be used to assess precision		

## Annex D (informative)

### Example of Validation Results<sup>8</sup>

**Table D.1—Summary of Validation Results**

METHOD 5	Model-X Validation Data				
Location	Headquarters Laboratory				
Date/initials:	08/15/16 DBS	08/15/16 DBS	08/15/16 DBS	08/15/16 DBS	08/15/16 DBS
Instrument SN	90320	90320	90320	90320	90320
CRM matrix	gas	gas	gas	aqueous	aqueous
CRM Manufacturer	ACME	ACME	ACME	DURHAM	DURHAM
CRM Lot#	AL141202	AL141208	AL141015	NC1030	NC1060
CRM Exp.	16-Dec	16-Dec	16-Oct	16-Oct	16-Nov
Target conc (g/210L)	<b>0.02</b>	<b>0.08</b>	<b>0.15</b>	<b>0.30</b>	<b>0.60</b>
Replicate #1	0.019	0.079	0.148	0.302	0.601
Replicate #2	0.019	0.079	0.149	0.304	0.595
Replicate #3	0.020	0.079	0.150	0.303	0.599
Replicate #4	0.020	0.080	0.149	0.303	0.602
Replicate #5	0.020	0.080	0.150	0.303	0.605
Replicate #6	0.019	0.080	0.151	0.304	0.595
Replicate #7	0.020	0.081	0.150	0.303	0.598
Replicate #8	0.019	0.081	0.149	0.304	0.599
Replicate #9	0.020	0.080	0.150	0.304	0.601
Replicate #10	0.020	0.081	0.150	0.304	0.602
Mean:	0.020	0.080	0.150	0.303	0.600
Range (Low-High):	0.019-0.020	0.079-0.081	0.148-0.151	0.302-0.304	0.595-0.602
Calculated Bias %	-2.000	0.000	-0.267	1.133	-0.050
(± 5% or 0.005) acceptable bias range	0.015-0.025	0.075-0.085	0.1425-0.1575	0.285-0.315	0.570-0.630
Standard Deviation	0.001	0.001	0.001	0.001	0.003
Acceptable bias and precision	Yes	Yes	Yes	Yes	Yes

<sup>8</sup> This is an example of mock Validation Results, for illustrative purposes only.

## Annex E (informative)

### Example of Additional Validation Parameters and Results – Part 1<sup>9</sup>

#### E.1 Freeze/Thaw Validation Plan

##### E.1.1 Validation Plan:

To evaluate the effect of freezing and thawing on wet-bath calibration materials, the Program will examine the effect on 0.080 g/210L reference materials. A total of twenty bottles of reference materials will be used in this experiment. Five bottles (e.g., bottle 1-5) that have never been frozen will be analyzed initially five times (replicates). The bottles (e.g., bottle 6-20) will then be placed in a freezer at  $-10^{\circ}\text{C}$  for a minimum of forty-eight hours. After they are allowed to thaw unassisted at room temperature for forty-eight hours, five bottles (e.g., bottle 6-10) will be analyzed five times (replicates). The remaining bottles will undergo a second (e.g., bottle 11-15) and third (e.g., bottle 16-20) freeze/thaw cycle respectively, and be analyzed in the same fashion described previously.

This experiment will be performed on an “ABC-123” instrument with “XYZ” Simulators connected to the instrument’s calibration port. All reference materials shall be of the same lot for adequate comparison.

##### E.1.2 Acceptance Criteria:

The reference materials are considered stable if the combined mean of the analysis of the frozen/thawed samples is within 5% of the combined mean of the initial analysis.

#### E.2 Freeze/Thaw Validation Results and Summary

The validation experiment took place from 02/01/2016 to 02/27/2016 using 0.080 g/210L reference material lot 3456-8. The raw data and all documentation generated from this experiment have been retained in the validation file for this method. The mean of each analysis, as well as the combined mean for each event are recorded in the following table.

**Table E.1—Freeze/Thaw Experiment Data Means**

	Initial Analysis	After One Cycle	After Two Cycles	After Three Cycles
	Bottles 1-5	Bottles 6-10	Bottles 11-15	Bottles 16-20
Replicate Mean	0.0813	0.0809	0.0805	0.0798
Replicate Mean	0.0807	0.0805	0.0800	0.0795
Replicate Mean	0.0817	0.0815	0.0811	0.0804
Replicate Mean	0.0809	0.0806	0.0802	0.0797
Replicate Mean	0.0811	0.0809	0.0806	0.0801
Combined Mean:	0.0811	0.0808	0.0805	0.0799

<sup>9</sup> This is an example of additional mock Validation Parameters and subsequent results, for illustrative purposes only.

	<b>Initial Analysis</b>	<b>After One Cycle</b>	<b>After Two Cycles</b>	<b>After Three Cycles</b>
% Deviation		0.37%	0.74%	1.48%
<5% of combined mean?		Yes	Yes	Yes

The impact of freeze/thaw cycles was demonstrated to be at an acceptable level, with the greatest deviation from the initial analysis being 1.48%, which meets the requirement to be less than 5%. However, the lab noted that the deviation consistently increased slightly with each cycle; therefore, a decision was made to discard any reference material that goes through more than three freeze/thaw cycles.

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## **Annex F**

### (informative)

### **Example of Additional Validation Parameters and Results – Part 2<sup>10</sup>**

#### **F.1 Minimum Allowable psi of Dry Gas Reference Standards**

##### **F.1.1 General**

The purpose of this validation is to ensure that dry gas reference standards used for calibration of evidential Breath Alcohol instruments continue to provide acceptable results at minimum psi (pounds per square inch) (i.e., running low to empty). Anytown, USA calibrates 2 models of evidential instruments (Desktop A and Handheld B). The software used in Anytown, USA's evidential instruments will provide a "dry gas tank empty" test result when the pressure reaches 50 psi and will not allow a subject test or calibration to continue.

##### **F.1.2 Validation Plan**

Two instruments, installed with software version XXXXX will be used to assess Certified Reference Material (CRM) acceptability.

- a) Test a minimum of three different dry gas CRM of different known values with a pressure close to 50psi; e.g., 60psi.
- b) Record the initial psi for each CRM
  - 1) Perform a test to determine if it is within acceptable parameters (0.005 or +/-5%).
  - 2) Record the psi after this test.
- c) Continue to perform tests of each CRM until:
  - 1) The instrument's minimum psi level of acceptance is reached (tank empty message appears), or
  - 2) An insufficient sample warning is given, or
  - 3) A result outside of the acceptable parameters is produced.
- d) Perform a test on each CRM on different days and with different analysts, if possible.
- e) Record the route of delivery for each test.
  - 1) Breath port
  - 2) As an accuracy check with an internal pressure gauge

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<sup>10</sup> This is an example of additional mock Validation Parameters and subsequent results, for illustrative purposes only.

Evaluate the results to determine the acceptable lower psi levels. Acceptability shall be concluded if CRM results are within the acceptable parameters at all concentrations and all pressure readings unless an instrument message alerts the user of “dry gas tank empty”.

### F.1.3 Validation Results

**Table F.1—Summary of Minimum Allowable psi**

<b>Date/initials:</b>	<b>2/11/16 ESZ</b>	<b>2/12/16 RPM</b>	<b>3/7/16 RPM</b>	<b>3/8/16 ESZ</b>	<b>3/9/16 ESZ</b>	<b>3/10/16 RPM</b>
Instrument Model	Desktop A	Handheld B	Desktop A	Handheld B	Desktop A	Handheld B
Instrument SN	1234	9876	1236	9874	1238	9872
Delivery Route	Internal	Breath port	Internal	Breath port	Internal	Breath port
Dry Gas Std. Lot/Tank #	OP416120/5	OP416121/3	OP335123/8	OP335126/7	OP435127/16	OP435128/12
Dry Gas Std. Exp.	06/10/2016	6/10/2016	12/19/2016	12/19/2016	12/19/2016	12/19/2016
Target conc (g/210L)	<b>0.198</b>	<b>0.200</b>	<b>0.040</b>	<b>0.040</b>	<b>0.081</b>	<b>0.081</b>
Replicate #1	0.199	0.203	0.041	0.040	0.080	0.081
Replicate #1 psi	56	54	56	56	54	52
Replicate #2	0.199	0.204	0.041	0.040	0.080	0.081
Replicate #2 psi	51	54	54	55	54	52
Replicate #3	0.199	0.203	0.041	0.040	0.080	0.081
Replicate #3 psi	51	51	51	53	51	51
Replicate #4	0.199	0.198	0.041	0.040	0.080	0.081
Replicate #4 psi	51	46	51	46	51	46
Replicate #5	“Tank Empty”	*Sample Timeout	“Tank Empty”	*Sample Timeout	“Tank Empty”	*Sample Timeout
Replicate #5 psi	46	31	46	41	46	41
Acceptable Results (Y/N)	Yes	Yes	Yes	Yes	Yes	Yes

### F.1.4 Validation Summary

A total of 3 Desktop A and 3 Handheld B instruments installed with Anytown, USA software were evaluated at low psi levels with CRMs. The results presented in E.1.2 (Table E.1 – Summary of Minimum Allowable psi) indicate that all results at lower psi were either within the acceptable parameters or generated an instrument message. This demonstrates that no negative effects are to be expected while calibrating the instrument using dry gas cylinders at lower pressure. The instruments will either produce valid results or stop calibration activities. The results objectively support that the Certified Reference Material used to calibrate is acceptable at low psi levels.

## **Annex G** (informative)

### **Example of a Validation Summary for Environmental Impact<sup>11</sup>**

#### Scope and Purpose:

The performance of the calibration method (SOP 4.3) was assessed under similar environmental conditions that are typically encountered during calibration. The Town Everywhere Sheriff's Department calibrates evidential instruments in the laboratory and field (external facilities and roadside). The Town Everywhere experiences great fluctuation in temperatures and humidity throughout the year. Additionally, the instruments located in various facilities across Town Everywhere are subject to different barometric pressures due to differing altitudes. To assess the performance of the calibration method, Breath Alcohol program personnel shall calibrate the instrument(s) under these expected conditions and evaluate the resultant data to ensure the method's acceptability.

#### **Example experimental design (evaluation plan)**

##### Temperature:

The lowest and highest laboratory temperatures over three months were recorded with a NIST-traceable reference thermometer. An instrument was calibrated using SOP 4.3 during the temperature highs and lows. Post-calibration, the following parameters were assessed: bias, precision, and carryover. Results met the defined criteria for acceptance. Data are included in the main summary for the SOP 4.3 calibration method.

Annual temperature data from the National Weather Service- Everywhere Office was obtained to determine reasonable high and low temperature expectations for roadside conditions. The average high temperature was 110°F (43°C) and the average low temperature was -50°F (-45°C). An administrative decision was made to limit field calibration to the temperature range of 32°F to 100°F (0°C to 38°C). An instrument was calibrated three times each using SOP 4.3 at 32°F (0°C) and at 100°F (38°C). Post-calibration, the following parameters were assessed: bias, precision, and carryover. Results met the defined criteria for acceptance. Data are included in the main summary for the SOP 4.3 calibration method.

##### Barometric Pressure:

Altitude ranges from Town Everywhere were obtained. The altitude ranged from sea level (~10 meters) to 5,000 feet (~457 meters). An instrument was calibrated at the highest and lowest point in Town Everywhere. Post-calibration, the following parameters were assessed: bias, precision, and carryover. Results met the defined criteria for acceptance. Data are included in the main summary for the SOP 4.3 calibration method.

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<sup>11</sup> This is an example of a mock Validation Summary for illustrative purposes only.

RFI:

The manufacturer provided independent testing to internationally accepted EMC standards. In addition to this independent testing, Everywhere Sheriff's Office personnel activated their emergency communication devices (radios) during and after the SOP 4.3 calibration method was being performed. Personnel were in close proximity to the instruments during these experiments. Results met the defined criteria for acceptance. A passing result is one which either flags an RFI error, *or* provides a valid result whose value is not altered by more than the acceptable bias from the expected result. Data are included in the main summary for the SOP 4.3 calibration method.

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## Annex H (informative)

### Bibliography

This is not meant to be an all-inclusive list as the group recognizes other publications on this subject may exist. At the time this standard was drafted, these were the publications available for reference. Additionally, any mention of a particular software tool or vendor as part of this bibliography is purely incidental, and any inclusion does not imply endorsement.

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- 1] Joint Committee for Guides in Metrology (JCGM). *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)*. Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM, 2000.<sup>12</sup>
- 2] International Organization of Legal Metrology (OIML), R 126 - *International Recommendation for Evidential Breath Analyzers*, 2012.<sup>13</sup>
- 3] ASB Standard 036, *Standard Practices for Method Validation in Forensic Toxicology*, First Edition, 2019.<sup>14</sup>
- 4] International Organization for Standardization (ISO). ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories* (Geneva, Switzerland: ISO). American National Standards Institute (ANSI) Webstore.<sup>15</sup>

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<sup>12</sup> Available from <http://www.bipm.org/en/publications/guides/vim.html>.

<sup>13</sup> Available from [https://www.oiml.org/en/files/pdf\\_r/r126-e12.pdf/view](https://www.oiml.org/en/files/pdf_r/r126-e12.pdf/view).

<sup>14</sup> Available from <http://www.asbstandardsboard.org/published-documents/>

<sup>15</sup> Available from <https://webstore.ansi.org/Standards/ISO/ISOIEC170252017>

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