STANDARD OPERATING GUIDELINES: EVIDENTIAL BREATH ALCOHOL INSTRUMENT CALIBRATION

1 Scope

To describe the procedure for breath alcohol instrument calibration and the calculations used to establish the combined uncertainty.

Any changes which occur as a result of the implementation of these guidelines apply only to calibrations which are completed on or after the effective date of this document. Previous policies are not nullified and nothing herein should be construed as limiting or canceling the effect of old policies on calibrations performed under these previous policies.

2 Calibration Terms

2.1 Definitions

ACA – An instrument testing sequence which analyzes a series of air blanks and vapor samples.

Accuracy – A qualitative term describing the closeness of agreement between a measured quantity value and the true value of a particular quantity intended to be measured.

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.

Analyst – A Technical Supervisor, who in addition to performing tests and calibrations, interprets data, conducts technical and administrative reviews, reaches conclusions and authorizes the release of a calibration certificate, report or label.

Calibration – A procedure that establishes the accuracy, precision, uncertainty of measurement and linear response of a breath alcohol measuring instrument by the measurement of known standards. It is not defined as any other action to repair, adjust, clean, autocal or test an instrument. These actions are maintenance and are not part of the calibration procedure.

Certified Reference Material (CRM) – Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Combined uncertainty – The standard deviation of the result of a measurement when the result is obtained from the values of a number of other quantities. It is obtained by combining the individual standard uncertainties using the "root-sum-of-squares" method. Combined uncertainty shall be reported at approximately the 99.7% level (k = 3) to three digits (rounded) after the decimal point.

Confidence level – A number (e.g. 99.7%) expressing the degree of confidence in a result.

Mean – The average of a set of numbers that shall be reported to four digits (rounded) after the decimal point.

Nominal value – The rounded or approximate value, which is reported to three digits after the decimal point for a Solution Lot.

Office of the Scientific Director (OSD) – The entity created by the Texas Department of Public Safety to carry out the provisions of Texas Administrative Code Title 37 Chapter 19 Breath Alcohol Testing Regulations.

Precision –The degree to which replicate measurement results agree amongst themselves, most commonly quantified by a standard deviation.

Purified water – Water purified by any scientifically acceptable means

Pure ethanol – An ethanol reagent that is certified by the manufacturer to contain at least 99.5% ethanol.

Repeatability – Closeness of the agreement between repeated measurements of the same property with the same methods, on identical test items, in the same lab, by the same analyst using the same equipment, in a short time interval.

Reference material – A homogenous and stable material sufficiently characterized with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Simulator – A device designed to heat an aqueous solution to a specific temperature, used to deliver a vapor sample, usually ethanol, to a breath alcohol testing instrument.

Solution Lot – A large volume of a reference material that is mixed in a single container and considered to be uniform in concentration once the material is divided into smaller containers.

Solution Lot number – A unique designator to document the preparation, analysis and traceability of a reference material or standard.

Standard – A reference material accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Standard deviation – A measure of the spread of a set of results, describing how values typically differ from the average of the set.

Technical Supervisor (TS) – A forensic scientist certified by the Office of the Scientific Director pursuant to the provisions of Texas Administrative Code Title 37 Chapter 19.

Traceability – The property of a measurement result whereby it can be related to a national authoritative standard through an unbroken chain of comparisons with each level having estimated uncertainties.

True value – The value that would be obtained by a theoretical perfect measurement.

Uncertainty budget – Summary of the combined uncertainty calculations including a listing of all factors that contribute to the overall uncertainty measurement for a process.

Uncertainty of measurement – An estimate of the range of values most likely to contain the measured quantity.

Vapor concentration – The concentration in the vapor above a solution contained in the simulator (expressed in g/210 L).

2.2 Abbreviations

C	Concentration
COA	Certificate of Analysis
Comb	Combined
CRM	Certified Reference Material
CV	Coefficient of Variation
Intox	Intoxilyzer
NIST	United States National Institute of Standards and Technology
SD	Standard deviation
TXDPS	Texas Department of Public Safety
VC	Vapor concentration

3 Calibration Record File (uniquely identified by instrument)

A. Instrument Certificate issued by the Office of the Scientific Director

B. Calibration Documentation

1. Calibration Analyst Worksheets
2. Technical and Administrative Review Checklist
3. Instrument printouts
4. Calibration notes and observations

C. Administrative documentation, as applicable

D. Instrument specific Deviation Requests and Quality Action Plans, as applicable

E. Evidential Breath Alcohol Testing Instrument Calibration Certificate (i.e., Calibration Report)

4 Breath Alcohol Instrument Calibration Procedure

4.1 General

A. Instruments are to be calibrated only by certified Technical Supervisors in the Technical Supervisor's laboratory, which has limited access. Handling and storage of instruments while in the laboratory shall be exercised with care in order to preserve their scientific integrity.

B. The calibration procedure shall be performed under any of the following conditions:

1. Prior to an instrument being placed into evidential service for the first time.
2. The instrument has undergone a calibration adjustment.
3. As determined by the Technical Supervisor.

C. If the Technical Supervisor determines that an environmental or other condition might affect the quality of the calibration, the procedure shall be terminated and not resumed until the cause for concern has been eliminated.

D. There are no periodic maintenance requirements for calibration equipment, other than NIST thermometers.

E. Simulators are the only calibration equipment that may require repair.

F. Simulators do not require periodic calibration. The proper functionality of a simulator is confirmed as part of the breath alcohol instrument calibration procedure.

G. Instruments maintained in the Technical Supervisors laboratory should be labeled with the instrument status. At a minimum, the label shall indicate either "out of service" or "calibrated and ready for service" and contain the date of calibration and initials of the Technical Supervisor.

4.2 Receiving the Instrument into the Calibration Laboratory

A. When received into the calibration laboratory, in no particular order, the Calibration Analyst shall note the following on the Instrument Receipt and Condition Notes Label (OSD-CAL-02). The label is available from the TXDPS website.

1. The serial number of the instrument
2. The date the instrument was received into the calibration laboratory
3. The operating condition of the instrument.

B. When received into the calibration laboratory, the instrument should be in proper working order and suitable for calibration. To demonstrate this, the instrument must successfully complete the following:

1. Intoxilyzer 5000:
   a) *Turn on the instrument. If the instrument is already on, turn it off and then turn it on.*
   b) *The instrument must conduct an air blank.*
   c) *The instrument must then display NOT READY.*
   d) *The instrument must then conduct and pass the Diagnostic Test.*
   e) *The instrument must then display the scrolling message.*
2. Intoxilyzer 9000:
   a) *Turn on the instrument. If the instrument is already on, turn it off and then turn it on.*
   b) *The instrument must then display NOT READY.*
   c) *The instrument must conduct an air blank.*
   d) *The instrument must then conduct and pass the Operational System Check.*

C. The Calibration Analyst shall sign and date the Instrument Receipt and Condition Notes Label.

D. If any of the above cannot be successfully completed for the relevant instrument, the calibration procedure shall be stopped, the Instrument Receipt and Condition Notes Label affixed to an 8.5 x 11 inch sheet of paper and all deficiencies noted on the Calibration Analyst Worksheet (OSD-CAL-04).

E. An instrument received into the calibration laboratory that has any visual defects that would prevent the instrument from being calibrated and/or does not successfully complete all of the requirements above, shall not be calibrated. All deficiencies shall be noted on the Calibration Analyst Worksheet and the instrument should be repaired before it may be calibrated.

4.3 Reference Material and Certified Reference Material

A. The nominal values of the reference material, 0.000, 0.040, 0.080, 0.150, and 0.400, will be used to perform the calibration. The 0.000 reference material shall consist of purified water. Purified water and all ethanol reference materials used in the calibration will be provided by the OSD.

B. The solutions used to calibrate the instrument must be from a different source, manufacturer and/or lot number than the solutions used to adjust the instrument.

C. Each bottle of certified reference material and purified water may only be used once to provide 20 consecutive ACA measurements for the calibration of a single breath alcohol instrument.

D. The OSD shall provide the documents necessary to establish NIST traceability, vapor concentration, nominal value and combined uncertainty of the certified reference materials used to perform instrument calibrations. The OSD shall also provide information and documentation on the preparation of purified water used to perform instrument calibrations.

4.4 Conducting the Calibration Procedure

A. While conducting the calibration procedure, the Calibration Analyst shall document on the Calibration Notes Label (OSD-CAL-03), in no particular order, the following for each nominal value. Calibration notes should be filled out as each step is completed.

- The serial number of the NIST traceable thermometer.
- The calibration expiration date of the NIST traceable thermometer.
- The foil liner was sealed to the solution bottle.
- The Lot Number of the reference solution.
- The simulator model.
- The simulator serial number.
- The simulator is properly sealed.

- Ensure the stirring mechanism is turning.
- Before and after the analysis of each reference solution, ensure that a NIST traceable thermometer in the simulator is reading 34.0 ±0.2ºC.

B. Calibration Procedure

1. Place the purified water or CRM into the simulator.
2. Check the reference solution with a NIST traceable thermometer and ensure that the solution temperature is 34.0 ±0.2ºC. After removing the thermometer, ensure that the simulator is properly sealed.
3. Connect the simulator to the instrument.
4. Conduct twenty sequential ACAs.
5. At the conclusion of the ACA sequence, check the reference solution with a NIST traceable thermometer and ensure that the solution temperature is 34.0 ±0.2ºC.
6. Repeat this procedure for the remaining nominal values.
7. During the calibration procedure, the ACA sequence for each nominal value may only be attempted once.

C. The Calibration Analyst shall sign and date the Calibration Notes Label.

D. Affix the following labels to the appropriate ACA printout.

1. Affix the Instrument Receipt and Condition Notes Label to the 0.000 ACA printout.
2. Affix the appropriate Calibration Notes Label to each ACA printout.
3. Affix the label from the reference material bottle to the corresponding ACA printout.
4. Initial and/or sign the ACA printout.

E. If at any time it becomes necessary to terminate the calibration procedure due to unacceptable results, an operational message, instrument/equipment in need of adjustment/repair or for any other reason, all records generated to that point must be retained and the reason for the unsuccessful attempt will be documented on the Calibration Analyst Worksheet. All of the documents generated during the calibration attempt shall be combined electronically into a single pdf document and emailed to the OSD.

F. A new calibration procedure, as described in this section, must be successfully performed before a Calibration Certificate can be issued.

5 Instrument Calibration Certificate Workbook

5.1 General

A. To document the calibration, a Technical Supervisor shall complete OSD-CAL-04, OSD-CAL-05 and OSD-CAL-06 in the most current version of

the Instrument Calibration Certificate Workbook (OSD-WBK-01). The Instrument Calibration Certificate Workbook is composed of the following:

1. The Calibration Analyst Worksheet (OSD-CAL-04),
2. The Technical and Administrative Review Checklist (OSD-CAL-05)
3. The Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06) (also referred to as the Calibration Certificate)
4. The Amended Calibration Analyst Worksheet (OSD-CAL-08)
5. The Amended Technical and Administrative Review Checklist (OSD-CAL-09)
6. The Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10) (Also known as the Amended Calibration Certificate)

B. The Calibration Certificate Workbook and the Supplemental require the electronic signature of the Technical Supervisor. The electronic signature is secured within the workbook by a password at least eight characters in length.

C. All documents transmitted between the Calibration Analyst and the Reviewing Analyst may be done by any electronic means other than facsimile transmission.

D. The Workbook is available from the TXDPS website.

5.2 Calibration Analyst Worksheet

A. The Calibration Analyst Worksheet shall be completed by the Calibration Analyst.

B. Entries to the Calibration Analyst Worksheet may be made in any order by the Calibration Analyst and must be completed before forwarding the Workbook to the Reviewing Analyst.

C. In order to ensure ethanol vapor equilibration between the simulator and instrument, record only the final 15 ACA results for each nominal value in the Calibration Analyst Worksheet. Results are to be recorded to three digits after the decimal point.

D. Calibration test results

1. Each of the fifteen analyses of the purified water must be 0.000.
2. The mean of the fifteen analyses of each ethanol reference solution must be within ±0.0030 or 3% (whichever is greater) of the vapor concentration of the certified ethanol reference solution. Mean results shall be recorded to four digits (rounded) after the decimal.
3. The standard deviation of the nominal 0.040, 0.080 and 0.150 g/210 L certified reference solutions shall be recorded to five digits (rounded) after the decimal and must be less than 0.00100.
4. The standard deviation of the nominal 0.400 g/210 L certified reference solution shall be recorded to five digits (rounded) after the decimal and must be less than 0.00200.

E. When the information and the data entered in the Calibration Analyst Worksheet meet all of the required specifications, the Calibration Analyst shall enter their electronic signature and then save the Workbook.

F. The date on which the last ACA of the calibration procedure is performed is the date that should be entered as “Date Analysis Completed” on the worksheet

G. The Calibration Analyst shall submit the Calibration Workbook, all initialed/signed and scanned ACA printouts, and a copy of the relevant NIST Thermometer Calibration Certificate to another analyst for technical and administrative review.

H. When the Calibration Worksheet is sent to the reviewer, the worksheet is considered to be complete. Any changes made to the Calibration Worksheet during the review period must be documented on the Worksheet along with the date the changes were made. Changes made to the ACAs, Instrument Receipt and Condition Notes or the Calibration Notes Label must be dated and initialed by the Calibration Analyst.

5.3 Technical and Administrative Review

A. The Technical and Administrative Review Checklist shall be completed by the Reviewing Analyst.

B. The Reviewing Analyst shall not be the analyst who performed the calibration procedure.

C. The Reviewing Analyst shall ensure that the calibration was properly completed and that all of the information entered on the Calibration Analyst Worksheet, and all other documents submitted by the Calibration Analyst, are accurate.

D. Entries to the Technical and Administrative Review Checklist may be made in any order by the Reviewing Analyst.

E. Discrepancies shall be brought to the attention of the Calibration Analyst and resolution taken place prior to issuance of the certificate.

1. If the Calibration Analyst determines the discrepancy does not affect the quality of the work, the Calibration Analyst shall make the needed correction, document the correction being made and resubmit the Workbook to the Reviewing Analyst for technical and administrative review. Some examples of discrepancies that do not affect the quality of the work include, but are not limited to, typographical errors or failure to sign/initial an ACA printout.

2. If the Calibration Analyst determines the discrepancy affects the quality of the work, the Calibration Analyst shall terminate the calibration procedure and note the error on the Calibration Worksheet. Example: A data entry error that when corrected results in the instrument not meeting one or more requirements listed in this document.

F. When all of the documents submitted by the Calibration Analyst have been reviewed and the Technical and Administrative Review Checklist is

properly completed, the Reviewing Analyst will enter their electronic signature and the Calibration Certificate tab will open.

G. The Reviewing Analyst shall review the Calibration Certificate and if it is properly completed, affix their electronic signature to the Calibration Certificate and save the Workbook.

H. The Workbook must be returned to the Calibration Analyst, who will issue the Calibration Certificate.

5.4 Evidential Breath Alcohol Testing Instrument Calibration Certificate

A. The Calibration Analyst who issues the certificate shall be the Technical Supervisor who performed the calibration procedure.

B. The Calibration Analyst shall ensure that the calibration was properly completed and that all of the information entered on the calibration documents is correct. The Calibration Analyst shall then issue the certificate by affixing their electronic signature to the Calibration Certificate and then saving the Workbook. The date that the electronic signature is affixed to the Calibration Certificate is the date the certificate is issued.

C. After the Calibration Analyst issues the Calibration Certificate, the Workbook and all of the relevant documents generated during the calibration of the instrument shall be combined electronically into a single PDF document and emailed to the OSD.

D. An electronic file for each calibrated instrument shall be maintained by the OSD.

6 Discrepancies Identified After Certificate Issuance

6.1 General

A. After the certificate has been issued, any discrepancies identified which are related to the calibration procedure shall be brought to the attention of the Calibration Analyst, the OSD and all other affected parties.

B. Discrepancy(s) identified after an instrument has been placed into service will be evaluated by the OSD and the validity of the tests conducted on the instrument will be determined.

6.2 SUPPLEMENT TO THE CALIBRATION CERTIFICATE

A. A Supplement to the Calibration Certificate (OSD-CAL-07) is necessary when any discrepancies have been found after the certificate has been issued.

B. A supplement is required when a correction has been made to any of the following:

1. The Instrument Receipt, Condition, and Notes Label
2. The Calibration Notes Label
3. The ACA printouts
4. The Calibration Workbook and/or Calibration Certificate

5. Any document within the Calibration Workbook and/or corresponding data.

C. When corrections are made to the Instrument Receipt and Condition Notes, the Calibration Notes or the ACA printouts, all changes and/or additions shall be initialed and dated, noted and explained in the Supplement to the Calibration Certificate.

D. When the Supplement has been completed, the Calibration Analyst shall affix their electronic signature and then save the Supplement.

E. The Supplement and any relevant documents must be submitted to a Reviewing Analyst.

F. When all of the documents submitted by the Calibration Analyst have been reviewed and found to be accurate, the Supplement shall be signed by the Reviewing Analyst using their electronic signature.

G. The Supplement and all other relevant documents generated during the calibration of the instrument shall be reviewed by the Calibration Analyst, combined electronically into a single PDF and emailed to the OSD to be included into the instrument's electronic file.

H. When a calibration discrepancy occurs that cannot be corrected, such as when a value within the calibration is corrected but causes the statistical analysis to fall outside of the prescribed criteria, only a Supplement to the Calibration Certificate shall be completed noting and explaining the discrepancy(s). The instrument must undergo a new calibration in order to be certified.

6.3 Amended Calibration Workbook and Certificate

A. An Amended Calibration Workbook and Certificate must be completed when changes are necessary in order to correct discrepancies identified in the workbook or Calibration Certificate after the certificate has been issued. The original Workbook shall not be changed, altered or discarded.

B. When it is determined that an Amended Calibration Certificate must be issued, the Calibration Analyst shall first complete and electronically sign a Supplement, noting and explaining the discrepancy(s). They will then complete an Amended Calibration Analyst Worksheet

C. The corrected information and data shall be entered in the Amended Calibration Analyst Worksheet. When all corrections have been made, the Calibration Analyst shall enter their electronic signature and then save the Workbook.

D. If the results cannot meet the specifications set forth in Section 5.2 D once the corrected information and data have been entered into the Amended Calibration Analyst Worksheet, then a Supplement to the Calibration Certificate shall be completed noting and explaining the discrepancy(s). The instrument must undergo a new calibration in order to be certified.

E. The Calibration Analyst shall submit the Workbook, all initialed/signed and scanned ACA printouts and a copy of the relevant NIST Thermometer Calibration Certificate to the Reviewing Analyst for technical and administrative review.

F. The Reviewing Analyst shall ensure that the calibration was properly completed and that all of the information entered on the Amended Calibration Analyst Worksheet and all other documents submitted by the Calibration Analyst are accurate.

G. Discrepancies shall be brought to the attention of the Calibration Analyst and resolution shall take place prior to issuance of the certificate.

H. When all of the documents submitted by the Calibration Analyst have been reviewed, found to be accurate and the Amended Technical and Administrative Review Checklist is properly completed, the Reviewing Analyst shall enter their electronic signature and the Amended Calibration Certificate tab will open.

I. The Reviewing Analyst shall review the Amended Calibration Certificate and if it is properly completed, affix their electronic signature to the Amended Calibration Certificate and save the Workbook.

J. The Workbook containing the Amended Calibration Analyst Worksheet, the Amended Technical and Administrative Review Checklist and the Amended Calibration Certificate must be returned to the Calibration Analyst, who will issue the Amended Calibration Certificate.

K. After the Calibration Analyst issues the Amended Calibration Certificate, the Workbook and all of the relevant documents generated during the calibration of the instrument shall be combined electronically into a single PDF and emailed to the OSD to be included in the instrument's electronic file.

7 Thermometers Used in the Instrument Calibration Procedure

A. The purpose of this section is to establish quality assurance guidelines for NIST traceable thermometers used in the instrument calibration procedure.

B. NIST traceable thermometers are to be maintained in the Technical Supervisor's calibration laboratory, which has limited access. Reasonable care should be taken in the handling and storage of NIST thermometers in order to avoid extreme temperatures, shock or breakage.

C. NIST traceable thermometers shall be calibrated annually by an approved vendor.

1. NIST traceable thermometers shall be submitted to an ISO 17025 accredited laboratory capable of issuing a calibration certificate establishing traceability to a NIST reference standard.

2. The thermometer calibration must include an evaluation at 34^{o}C with a tolerance of +/-0.10^{o}C and uncertainty estimated at k=2, 95%.

3. When a thermometer is received back into the Technical Supervisor's laboratory, the following must be performed.

a) *A visual inspection to ensure no damage has occurred during shipping. Damaged thermometers shall be reported to the Quality Manager and will be considered out of service.*

b) *A review of the calibration certificate to ensure that it is acceptable and meets all required specifications. If the certificate is not acceptable or does not meet required specifications, contact the calibration vendor.*

4. When the review is complete and found to be acceptable, date and initial the calibration certificate and submit to the Quality Manager.

5. The calibration certificate generated by the calibration laboratory for each NIST traceable thermometer shall be kept in the **Thermometer File**.

D. A NIST traceable thermometer which has passed calibration and been issued a calibration certificate, shall be used to verify the proper operational temperatures of simulators used in the instrument calibration procedure.

E. When placed in a simulator, a NIST traceable thermometer that reads 34.0^{o}C ±0.2^{o}C verifies that the solution is at the proper operational temperature and is fit for instrument calibration.

8 Proficiency Testing

A. Once per calendar year, all certified Technical Supervisors will be proficiency tested on their ability to properly calibrate an evidential breath alcohol testing instrument.

B. The proficiency procedure will be provided to each Technical Supervisor being tested. The results will be recorded on a Microsoft® Excel 2003 or later spreadsheet that will be provided by the OSD.

C. The unknown proficiency solutions will be CRMs prepared using the method described in BAL-CRM-SOP and distributed in person, through common carrier or the equivalent.

D. Any Technical Supervisor who fails the first attempt will be sent another unknown proficiency solution and given a new deadline date for reporting the results. Any Technical Supervisor who fails the second attempt will be asked to come to the OSD to demonstrate their ability to calibrate an instrument and for remedial training, if necessary.

9 Receipt and Storage of CRM Solutions and Purified Water Used to Calibrate Evidential Breath Alcohol Testing Instruments

A. Certified reference material and purified water provided by the Office of the Scientific Director are sealed to prevent contamination and tampering. The analyst shall ensure that the seal is intact prior to use in the calibration procedure.

B. Upon receipt of the CRM solutions and purified water, the bottles shall be stored at room temperature in a secured, limited access location.

C. The CRM solutions and purified water are valid and approved for use as as defined on the Certificate of Analysis. CRM solutions and purified water that have expired shall be discarded or they may be retained for training or other non-calibration purposes. The label on all retained expired CRM solutions and purified water shall be crossed out. Expired solutions shall not be used for evidential breath alcohol instrument calibration and shall be stored separately from unexpired CRM solutions and purified water.

10 Uncertainty of Measurement

10.1 General

A. The uncertainty budget for breath alcohol instrument calibration describes those components that have been identified as contributing to the overall measurement uncertainty for the instrument calibration at a specific concentration. These components include contributions from, reference materials, measurement procedure, constants and repeatability. Multiple sources may contribute to a single uncertainty component.

10.2 Uncertainty Budget for Breath Alcohol Instrument Calibration

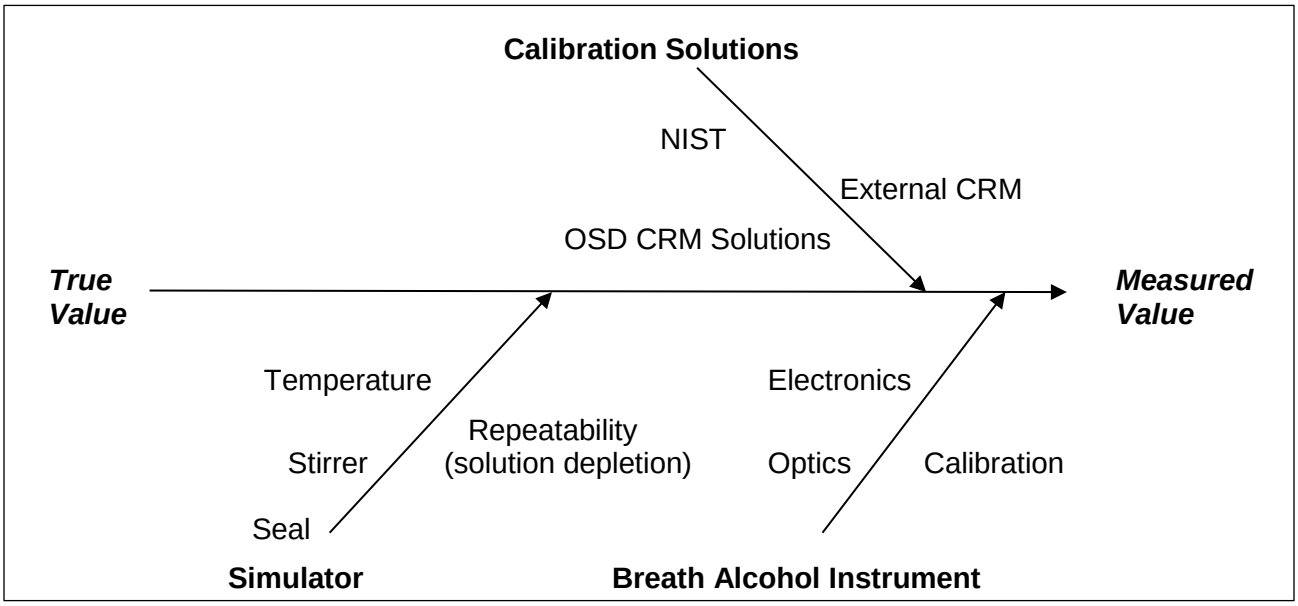

Figure 1: Cause and effect diagram for the calibration of the breath alcohol instrument

10.3 Measurement Uncertainty of Breath Alcohol Instrument Calibration CRMs

A. Uncertainty of Ethanol CRMs

1. Multiple ethanol CRM solutions, obtained from the OSD CRM Laboratory, are analyzed during the calibration of a breath alcohol instrument. The combined uncertainty of each solution, traceable to NIST, is obtained from the solution's Certificate of Analysis. The procedure for estimating the combined uncertainty of OSD CRMs is described in BAL-CRM-SOP.

B. Uncertainty from Repeatability Measurements

1. The repeatability of breath alcohol instrument measurements is dependent upon multiple factors. These factors can include the simulator temperature, stirrer, and seal; the instrument calibration, optics and electronics; equilibrium between the simulator and the breath alcohol instrument; and depletion of ethanol from the simulator solution from repeated testing and evaporation over time. To minimize solution depletion, the ethanol vapor produced by the simulator is recirculated back into the solution and each solution may only be used for one calibration run of 20 analyses. The 20 analyses, nor the time it takes to complete the run, is sufficient to deplete the ethanol in the solution by a significant amount. To ensure equilibrium between the simulator and the breath alcohol instrument, only the last 15 analyses are recorded in the Calibration Analyst Worksheet. Variations in each of these factors may affect repeatability and contribute to uncertainty.

2. This variability of the simulator solution measurements are represented through calculation of the coefficient of variation (CV), from repeated testing of the simulator solution on a breath alcohol instrument. First the average solution concentration ($\overline{X}$) is calculated using the following.

$$\overline{X} = \frac{1}{n}\sum_{i=1}^{n} X_i$$

Where:

$\overline{X}$ = the average simulator solution measurement result
n = the number of measurements (15)
X_i = each individual simulator solution measurement result
i = incremental measurement results, first through last

The standard deviation (SD) of the simulator solution measurements is calculated using the following:

$$SD = \sqrt{\frac{\sum_{i=1}^{n}\left(X_i - \overline{X}\right)^2}{n-1}}$$

3. The combined uncertainty of a CRM solution ($CV^2_{Lot\,COA}$) is traceable to NIST through an external standard obtained from an ISO 17025-accredited provider in a method described in BAL-CRM-SOP. When used to calibrate an Intoxilyzer, the combined uncertainty of the solution, obtained from the CRM Certificate of Analysis, is represented by the following:

$$CV^2_{Lot\,COA} = \left(\frac{SD}{\overline{X}}\right)^2$$

4. The uncertainty of a CRM as tested on an Intoxilyzer ($CV^2_{Lot\ Intox}$) is calculated using the following equation. The standard deviation of the mean of 15 measurements is used in this equation.

$$CV^2_{Lot\ Intox} = \left(\frac{SD}{\overline{X}}\right)^2$$

10.4 Calculations and Number Rounding Used in the Instrument Calibration Certificate Workbook

A. All calculations will be performed using Microsoft® Excel 2003 or later. Intoxilyzer results will be recorded to three digits. All values will be rounded to the appropriate number of digits at the completion of the calculation for each formula. Means and vapor concentrations will be rounded to four digits. Combined uncertainties will be rounded to three digits. Standard deviations and coefficients of variation will be rounded to five digits.

B. The formulas used to calculate the combined uncertainty of the Intoxilyzer for each of the four ethanol solutions used during a calibration are detailed below.

1. *Eq. 1* is used to calculate the combined Coefficient of Variation (CV_{Comb}) of the Intoxilyzer

$$CV_{Comb} = \sqrt{CV^2_{Lot\ COA} + CV^2_{Lot\ Intox}} \qquad \textit{Eq. 1}$$

Where:

CV_{Comb}= the combined *CV* for the ethanol concentration of the CRM solution lot as analyzed by the Intoxilyzer

$CV_{Lot\ COA}$= the combined *CV* for the CRM solution lot (SD_{Comb}÷ vapor concentration of the CRM solution lot) from the CRM solution lot Certificate of Analysis

$CV_{Lot\ Intox}$= the CV of the vapor concentration of the CRM solution lot as analyzed on the Intoxilyzer (SD of the CRM solution lot analyzed on the Intoxilyzer ÷ vapor concentration of the CRM solution lot)

2. *Eq.2* is used to calculate the combined standard deviation (SD_{Comb}) of the Intoxilyzer.

$$SD_{Comb} = (CV_{Comb})\ (VC_{Lot\ COA}) \qquad \textit{Eq. 2}$$

Where:

SD_{Comb} = the combined standard deviation of the Intoxilyzer. The combined standard deviation (SD_{Comb}) establishes the combined uncertainty of the Intoxilyzer at approximately the 68% confidence level.

$VC_{Lot\ COA}$= the vapor concentration of the CRM solution lot from its Certificate of Analysis.

3. *Eq. 3* is used to calculate the combined uncertainty which is to be reported at the k = 3 or approximately the 99.7% confidence level.

SD_{Comb} x 3 = the combined uncertainty for the Intoxilyzer at approximately the 99.7% confidence level *Eq. 3*

C. All of the calculations performed in the Instrument Calibration Certificate Workbook shall be verified and documented prior to the release of each revision of the Workbook.

Preparer

Scott Brown Date: 5/10/2016
Advisory Board Chair

Concurrence

J. Mack Cowan Date: 5/10/2016
Scientific Director

Version #	Effective Date	Brief Description of Change(s)
00	03/01/2013	Original Issue; Standard Operating Guidelines for Technical Supervisors (1/30/2012)
00a	03/01/2013	Minor Revision – Administrative
01	07/01/2013	Major Revision – Section 2.2, 9.2, 9.3
02	09/27/2013	Major Revision – Section 4.2, 5.5
03	09/19/2014	Major Revision – All Sections
04	03/31/2015	Major Revision – Sections 5.2, 6.3
05	08/24/2015	Minor Revision – Sections 1, 2.1, 4.1, 4.2, 4.3, 5.2, 5.3, 6.2, 7, 8, 9, and 10.3
06	06/01/2016	Minor Revision – Sections 2.1, 4.1, 5.1, 5.3, 5.4, 6.2, 6.9, 9 Major Revision – Sections 4.2, 4.3, 5.2