STANDARD OPERATING PROCEDURES: EVIDENTIAL BREATH ALCOHOL INSTRUMENT CALIBRATION

1 Scope

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

2 Related Documents

CLD Manual:

- Monitoring the Validity of Results
- Laboratory Equipment
- Validations and Performance Verifications
- Measurement Uncertainty
- Review of Laboratory Records

3 Calibration Terms

3.1 Definitions

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

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.

Calibration (Breath Alcohol) – 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.

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

Purified water – Water purified by any scientifically acceptable means.

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

3.2 Abbreviations

COA	Certificate of Analysis
COBRA	Computer Online BReath Archive
Comb	Combined
Conc	Concentration
CRM	Certified Reference Material
CV	Coefficient of Variation
Intox	Intoxilyzer
NIST	United States National Institute of Standards and Technology

OSD Office of the Scientific Director

RM Reference Material

SD Standard deviation

TXDPS Texas Department of Public Safety

VC Vapor concentration

4 Records

4.1 Instrument Calibration Record

A. Instrument calibration records are uniquely identified by instrument serial number.

B. The Technical Supervisor fulfills the role of custodian of records on behalf of the Department. Instrument calibration records shall be retained for 100 years as per the DPS Records Retention Schedule.

C. Records shall be kept in paper or electronic form separate from the COBRA database and a copy made available on the Texas DPS Public Website.

D. Calibration records include, but are not limited to the following:

1. Instrument Certificate issued by the Office of the Scientific Director
2. Instrument certification technical records
3. Calibration Certificate Workbook (OSD-WBK-01)
   - *a) Calibration Analyst Worksheet (OSD-CAL-04)*
   - *b) Technical and Administrative Review Checklist (OSD-CAL-05)*
   - *c) Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06)*
   - *d) Amended Calibration Analyst Worksheet (OSD-CAL-08), where applicable*
   - *e) Amended Technical and Administrative Review Checklist (OSD-CAL-09), where applicable*
   - *f) Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10), where applicable*
4. Calibration Technical Records
   - *a) Instrument ACA printouts*
   - *b) Calibration Notes Labels (OSD-CAL-03)*
5. Supplement to the Calibration Certificate, where applicable (OSD-CAL-07)
6. Administrative documentation, where applicable
7. Instrument specific deviation requests and/or Quality Incidents/Quality Action Plans, where applicable

5 Equipment

5.1 Significant Equipment

A. NIST Thermometer

1. A NIST traceable thermometer shall be used to verify proper operational temperatures of simulators used in the instrument calibration procedure.
2. 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.
3. NIST traceable thermometers shall be calibrated annually by an approved supplier.
    a) *The thermometer calibration shall include an evaluation at 34°C with a tolerance of +/- 0.10°C and uncertainty estimated at k=2, 95%.*
    b) *When a thermometer is received back into the laboratory, the following must be performed:*
        i. *A visual inspection to ensure no damage has occurred during shipping. Damaged thermometers shall be reported to the BAL Quality Manager and shall be removed from service and labeled or marked appropriately. DPS Technical Supervisors shall follow procedures outlined in the Texas DPS CLD Manual.*
        ii. *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.*
        iii. *When placed in a simulator, a NIST traceable thermometer that reads 34.0°C ±0.2°C verifies that the solution is at the proper operational temperature and is fit for instrument calibration. Verify the thermometer conforms to this specified requirement and document performance verification in accordance with laboratory procedures. If the thermometer cannot meet specifications, it shall be removed from service. DPS Technical Supervisors shall follow procedures outlined in the Texas DPS CLD Manual.*
4. If the thermometers meets specifications, the analyst shall date and initial/sign the calibration certificate and submit it to the BAL Quality Manager.
5. The calibration certificate provided by the approved supplier and any additional records for each NIST traceable thermometer shall be maintained in the **Thermometer Record** and a copy made available on the Texas DPS Public Website.
6. There is no scheduled maintenance for the NIST traceable thermometer.

5.2 Non-Significant Equipment

A. Simulator

1. Simulator devices are maintained and repaired as needed.
2. The proper functionality of a simulator is confirmed as part of the breath alcohol instrument calibration procedure.

6 Reference Material (RM) and Certified Reference Materials (CRMs)

6.1 Receipt and Storage

A. RM and CRMs 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 RM and CRMs, the bottles shall be stored at room temperature in a secured, limited access location.

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

6.2 Use in Calibration Procedure

A. The nominal values of the RM 0.000 and CRMs 0.040, 0.080, 0.150, and 0.400 (reported in g/210L), shall be used to perform the calibration.

1. The 0.000 RM shall consist of purified water.
2. The RM and all CRMs used in the calibration procedure shall be provided by the OSD.

B. The source of material(s) used to calibrate a measuring instrument are different from those used to adjust a measuring instrument and those used to verify calibration status. Preference is given to material(s) from different manufacturers, followed by different lot numbers of material from the same manufacturer.

C. Each bottle of RM and CRMs may only be used once to provide twenty consecutive ACA measurements for the calibration of a single breath alcohol instrument.

D. CRM Certificate of Analysis records necessary to establish NIST traceability, vapor concentration, nominal value and combined uncertainty of the CRMs used to perform instrument calibrations shall be made available on the Texas DPS Public Website.

7 Breath Alcohol Instrument Calibration Procedure

7.1 General

A. Instruments are calibrated by certified Technical Supervisors in a calibration laboratory which has limited access.

B. Handling and storage of instruments while in the laboratory shall be exercised with care in order to preserve their scientific integrity.

C. 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.

D. 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. Environmental conditions to be considered include, but are not limited to: extreme ambient temperature, known radio frequency interference, or known ambient air contaminants.

E. Instruments maintained in the Technical Supervisor's laboratory shall 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 the initials/signature of the Technical Supervisor.

7.2 Receiving the Instrument into the Calibration Laboratory

A. When an instrument is received into the calibration laboratory, in no particular order, the Calibration Analyst shall note the following on the Calibration Analyst Worksheet:

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 shall be in proper working order and suitable for calibration.

C. An instrument received into the calibration laboratory that has any visual defects that would prevent the instrument from being calibrated or does not successfully complete all of the requirements above, shall not be calibrated.

D. All deficiencies shall be noted on the Calibration Analyst Worksheet and the instrument is repaired before it may be calibrated.

7.3 Conducting the Calibration Procedure

A. When conducting the calibration procedure, the Calibration Analyst shall document on the Calibration Notes Label, in no particular order, the following for each nominal value. The Calibration Notes Label should be filled out as each step is completed.

1. The serial number of the NIST traceable thermometer.
2. The calibration expiration date of the NIST traceable thermometer.
3. Ensure the foil liner was sealed to the solution bottle.
4. The lot number of the reference solution.
5. The simulator model.
6. The simulator serial number.
7. Ensure the simulator is properly sealed.
8. Ensure the stirring mechanism is turning.
9. Before and after the analysis of each reference solution, ensure that a NIST traceable thermometer in the simulator is reading 34.0º ±0.2ºC.

B. Calibration Procedure

1. Place the RM or CRM into the simulator.
2. Check the RM or CRM with a NIST traceable thermometer and ensure that the solution temperature is 34.0ºC ±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 RM or CRM with a NIST traceable thermometer and ensure that the solution temperature is 34.0ºC ±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 appropriate Calibration Notes Label to each ACA printout.
2. Affix the label from the RM or CRM bottle to the corresponding ACA printout.
3. Initial/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/device in need of adjustment/repair, or for any other reason, all technical records generated to that point must be retained and the reason for the unsuccessful attempt shall be documented on the Calibration Analyst Worksheet. All of the technical records generated during the calibration attempt shall be combined electronically into a single PDF document and emailed to the BAL Quality Manager.

F. The calibration procedure must be successfully completed before a Calibration Certificate can be issued.

8 Calibration Certificate Workbook (OSD-WBK-01)

8.1 General

A. To document the calibration, a Technical Supervisor shall complete the most current version of the Calibration Certificate Workbook

B. The Calibration Certificate Workbook requires the electronic signature of the Calibration Analyst. The electronic signature is secured within the Calibration Certificate Workbook by a password at least eight characters in length.

C. The Calibration Certificate Workbook is available from the TXDPS Breath Alcohol Laboratory website.

8.2 Calibration Analyst Worksheet (OSD-CAL-04)

A. Entries to the Calibration Analyst Worksheet may be made in any order by the Calibration Analyst and must be completed before forwarding the Calibration Certificate Workbook for review.

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

C. Calibration Results

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

D. The date on which the last ACA of the calibration procedure is performed is the date that shall be entered as “Date Analysis Completed” on the Calibration Analyst Worksheet.

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 Calibration Certificate Workbook.

F. The Calibration Analyst shall submit the Calibration Certificate Workbook and all initialed/signed scanned ACA printouts to another analyst for technical and administrative review.

G. The Calibration Analyst Worksheet is considered complete when sent to the Reviewing Analyst.

8.3 Technical and Administrative Review

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

B. The Reviewing Analyst shall be a certified Technical Supervisor.

C. DPS Technical Supervisors shall select a Reviewing Analyst authorized by Texas DPS to perform technical reviews of calibration.

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

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

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

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

1. Any changes made to the Calibration Analyst Worksheet shall be documented on the Calibration Analyst Worksheet along with the date the changes were made. Changes made to the ACAs or the Calibration Notes Label shall be dated and initialed by the Calibration Analyst.

2. For administrative corrections that do not affect the reliability of the calibration, the Calibration Analyst shall make the needed correction(s) and resubmit 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.

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

H. When all of the records submitted by the Calibration Analyst have been reviewed and the Technical and Administrative Review Checklist is completed, the Reviewing Analyst shall affix their electronic signature and the Evidential Breath Alcohol Testing Instrument Calibration Certificate tab will open.

I. The Reviewing Analyst shall affix their electronic signature to the Evidential Breath Alcohol Testing Instrument Calibration Certificate and save the Calibration Certificate Workbook.

J. The Calibration Certificate Workbook shall be returned to the Calibration Analyst, who shall authorize and issue the Calibration Certificate.

8.4 Issuing the Calibration Certificate (OSD-CAL-06)

A. The Calibration Analyst who performed the calibration will authorize and issue the Calibration Certificate.

B. The Calibration Analyst shall complete a final review to ensure that the calibration was properly completed and that all of the information entered on the calibration records is correct. The Calibration Analyst shall then authorize the results and issue the certificate by entering the date and affixing their electronic signature to the Evidential Breath Alcohol Testing Instrument Calibration Certificate and then saving the Calibration Certificate Workbook. The date that the electronic signature is affixed to the Evidential Breath Alcohol Testing Instrument Calibration Certificate is the date the Calibration Certificate Workbook is authorized and issued.

C. The Calibration Certificate Workbook and all of the relevant records generated during the calibration of the instrument shall be combined electronically into a single PDF document and emailed to the BAL Quality Manager.

D. An electronic record for each calibrated instrument shall be made available on the Texas DPS Public Website.

9 Discrepancies Identified After the Certificate is Issued

9.1 General

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

B. Any discrepancies identified after an instrument has been placed into service shall be evaluated by the Scientific Director and the validity of the tests conducted on the instrument shall be determined.

9.2 Supplement to the Calibration Certificate (OSD-CAL-07)

A. A Supplement to the Calibration Certificate is necessary when any discrepancies have been found after the Calibration Certificate has been authorized and issued.

B. The Supplement to the Calibration Certificate is required when a correction has been made to any of the following:

1. The Calibration Notes Label
2. The ACA printouts
3. Any document within the Calibration Certificate Workbook

C. When corrections are made to the Calibration Notes Label or the ACA printouts, all changes and additions shall be initialed and dated on the label or printout. The corrections shall also be noted and explained in the Supplement to the Calibration Certificate.

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

E. The Supplement to the Calibration Certificate and any relevant records must be submitted to a Reviewing Analyst for technical and administrative review.

F. When all of the records submitted by the Calibration Analyst have been reviewed and found to be accurate, the Supplement to the Calibration Certificate shall be electronically signed by the Reviewing Analyst.

G. The Supplement to the Calibration Certificate and all other relevant records shall be combined electronically into a single PDF and emailed to the BAL Quality Manager 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 any discrepancies. The instrument must undergo a new calibration in order to be certified.

9.3 Amended Calibration Certificate Workbook (OSD-WBK-01)

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

B. When it is determined that an Amended Calibration Certificate Workbook must be issued, the Calibration Analyst shall also complete and electronically sign a Supplement to the Calibration Certificate, noting and explaining any discrepancies.

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 affix their electronic signature and then save the Amended Calibration Certificate Workbook.

D. If the results cannot meet the specifications set forth in Section 8.2.C 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 Amended Calibration Certificate Workbook and all initialed/signed and scanned ACA printouts 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 records 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 Amended Calibration Certificate Workbook.

H. When all of the records 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 affix their electronic signature and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate tab will open.

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

J. The Amended Calibration Certificate Workbook shall be returned to the Calibration Analyst, who will ensure that all of the information entered on the amended calibration records is correct.

K. The Calibration Analyst shall then authorize and issue the Amended Calibration Certificate Workbook by affixing their electronic signature to the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate and then saving the Amended Calibration Certificate Workbook. The date that the electronic signature is affixed to the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate is the date the Amended Calibration Certificate is authorized and issued.

L. The Amended Calibration Certificate Workbook and all of the relevant records generated during the calibration of the instrument shall be combined electronically into a single PDF and emailed to the BAL Quality Manager.

10 Assuring the Quality of Calibration Results

A. Quality control results for monitoring the reliability of calibrations undertaken shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results.

B. Quality control monitoring is planned and reviewed periodically by the BAL Quality Manager and shall be recorded annually.

C. Quality control procedures may include, but are not limited to, the following:

1. Regular use of certified reference materials and/or internal quality control using secondary reference materials.
2. Replicate calibrations using the same method.
3. Technical and administrative reviews.
4. A documented proficiency testing program.

11 Examiner Assessment

Once per calendar year, all certified Technical Supervisors shall complete a proficiency test, an intralaboratory comparison, or an interlaboratory comparison.

11.1 Proficiency Testing

A. For Technical Supervisors participating in proficiency testing, proficiency tests shall be provided by an ISO/IEC 17043 accredited supplier.

B. Proficiency tests shall be completed using a certified Intoxilyzer 9000 that was last calibrated by the analyst performing the test within the current calendar year.

C. Examiner Assessment Report Form (LAB-312), or electronic equivalent, shall be completed for participating DPS Technical Supervisors per the Texas DPS CLD Manual and submitted to the BAL Quality Manager.

D. Local Technical Supervisors participating in proficiency testing shall provide documentation of successful completion to the BAL Quality Manager to satisfy the annual requirement.

11.2 Intralaboratory and Interlaboratory Comparison

A. Intralaboratory and interlaboratory comparison tests shall be provided by the OSD upon request.

B. Comparison tests shall be performed using a certified Intoxilyzer 9000 that was last calibrated by the analyst performing the test within the current calendar year.

C. The comparison test procedure shall be provided to each Technical Supervisor being tested. The results shall be recorded on a Microsoft® Excel 2003 or later spreadsheet provided by the BAL Quality Manager.

D. The unknown comparison test solution shall be a CRM prepared using the method described in BAL-CRM-SOP and distributed in person, through common carrier, or the equivalent.

E. To pass the comparison test, the vapor concentration of the solution shall be within ±0.0030 or 3%, whichever is greater, of the prescribed concentration.

F. An Examiner Assessment Report (LAB-312) or electronic equivalent shall be issued to each Technical Supervisor to document the assessment and capture acknowledgement of participants of the outcome. Results are designated as "Satisfactory" on the assessment report if the expected results have been obtained.

G. For DPS Technical Supervisors, potential inconsistencies are evaluated in accordance with Texas DPS CLD Manual policy.

H. Local Technical Supervisors who are unsuccessful on their first attempt shall be sent another unknown comparison test solution and given a new deadline for reporting results. If the Technical Supervisor is unsuccessful on the second attempt, they shall be asked to come to the OSD to demonstrate their ability to calibrate an instrument and provided remedial training as necessary. Any unsuccessful attempt shall be documented as a Quality Incident.

12 Measurement Uncertainty

12.1 General

A. The measurement 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 ethanol concentration.

1. These components include contributions from certified reference materials, measurement procedure, constants, and repeatability. Multiple sources may contribute to a single uncertainty component.

2. For the purposes of measurement uncertainty, the measurand is defined as the concentration of ethanol expressed as g/210 L.

12.2 Measurement Uncertainty Budget for Breath Alcohol Instrument Calibration

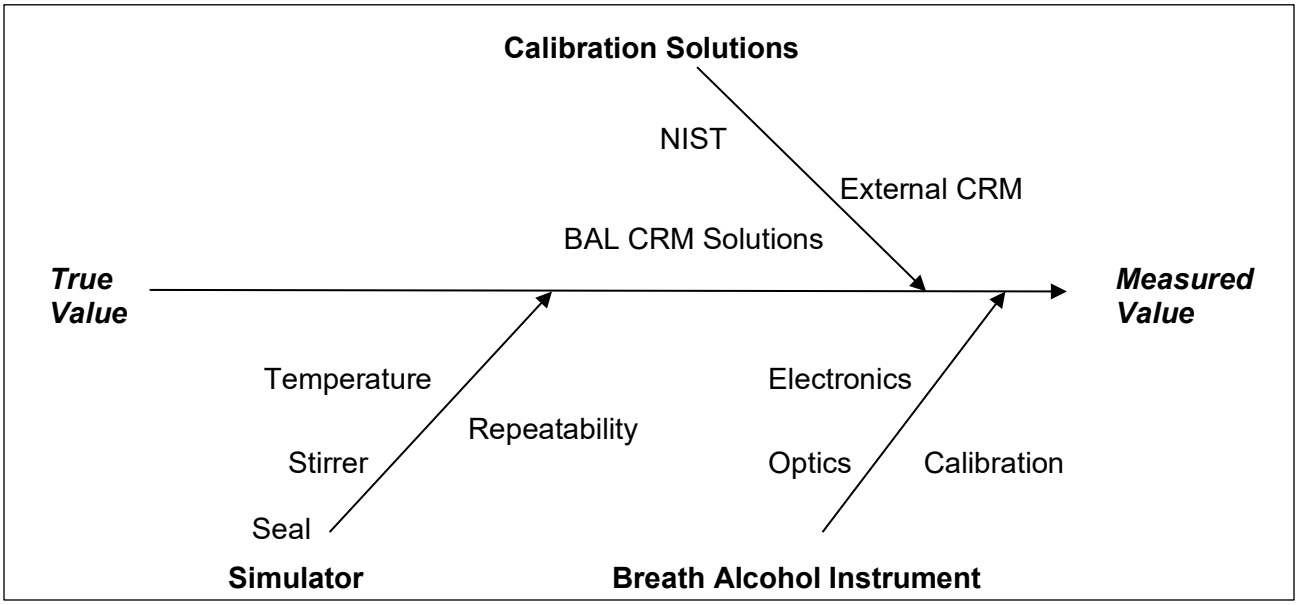

Figure 1: Cause and effect diagram for the calibration of the breath alcohol instrument

12.3 Measurement Uncertainty of Breath Alcohol Instrument Calibration CRMs

A. Ethanol CRMs

1. Multiple ethanol CRMs, obtained from the BAL CRM Laboratory, are analyzed during the calibration of a breath alcohol instrument.
2. The expanded uncertainty of each CRM, traceable to the SI through use of a NIST Standard Reference Material, is obtained from the solution's Certificate of Analysis.
3. The procedure for estimating the expanded uncertainty of BAL CRMs is described in BAL-CRM-SOP.

B. Repeatability

1. The repeatability of breath alcohol instrument measurements is dependent upon multiple factors, including;
   a) The simulator temperature, stirrer, and seal;
   b) The instrument calibration, optics, and electronics;
   c) Equilibrium between the simulator and the breath alcohol instrument;
   d) Depletion of ethanol from the CRM from repeated testing and evaporation over time.
2. To minimize CRM depletion, the ethanol vapor produced by the simulator is recirculated back into the simulator and each RM and CRM solution may only be used for one calibration run of twenty analyses. Neither the twenty analyses, nor the time it takes to complete the run, is sufficient to deplete the ethanol in the CRM by a significant amount.
3. To ensure equilibrium between the simulator and the breath alcohol instrument, the last fifteen analyses are recorded in the Calibration Analyst Worksheet. Variations in each of these factors may affect repeatability and contribute to uncertainty.
4. This variability of the ACA measurements is represented through calculation of the relative standard deviation (RSD) from repeated testing of the simulator solution on a breath alcohol instrument. First the mean solution concentration ($\overline{X}$) is calculated using the following.

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

Where:

$\overline{X}$	=	the mean ACA measurement result
n	=	the number of measurements (fifteen)
X_i	=	each individual ACA measurement result
i	=	incremental measurement results, first through last

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

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

5. The relative standard deviation of a CRM solution ($RSD_{Lot\ COA}$) is traceable to the SI through use of a NIST Standard Reference Material obtained from an approved accredited provider in a method described in BAL-CRM-SOP. When used to calibrate an Intoxilyzer, the relative standard deviation of the CRM, obtained from the CRM Certificate of Analysis, is represented by the following:

$$RSD_{Lot\ COA} = \left(\frac{SD}{\bar{X}}\right)$$

Where:

SD = combined standard deviation (SD_{Comb}) from the CRM Certificate of Analysis

$\bar{X}$ = vapor concentration (VC_{Lot}) from the CRM Certificate of Analysis

6. The relative standard deviation of a CRM as tested on an Intoxilyzer ($RSD_{Lot\ Intox}$)) is calculated using the following equation. The standard deviation of the mean of fifteen measurements is used in this equation.

$$RSD_{Lot\ Intox} = \left(\frac{SD}{\bar{X}}\right)$$

12.4 Calculations and Number Rounding Used in the Calibration Certificate Workbook

A. All calculations shall be performed using Microsoft® Excel 2003 or later. All values are rounded to the appropriate number of decimal places at the completion of the calculation for each formula:

1. Means are reported to four decimal places.
2. Standard deviations are reported to five decimal places.
3. Rounded means and combined standard uncertainties are reported to three decimal places.

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

1. *Eq. 1* is used to calculate the combined Relative Standard Deviation (RSD_{Comb}) of the Intoxilyzer

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

Where:

RSD_{Comb}= the combined relative standard deviation for the ethanol concentration of the CRM as analyzed by the Intoxilyzer

$RSD_{Lot\ COA}$= the combined relative standard deviation for the CRM from the CRM Certificate of Analysis

$RSD_{Lot\ Intox}$= the relative standard deviation of the vapor concentration of the CRM as analyzed on the Intoxilyzer

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

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

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 (k=1).

$VC_{Lot\ \ COA}$ = the vapor concentration (VC_{Lot}) of the CRM from the CRM Certificate of Analysis.

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

$$Combined\ Standard\ Uncertainty = SD_{Comb} \times 3 \qquad \textit{Eq. 3}$$

4. The measurement uncertainty of the Intoxilyzer for each of the four ethanol CRMs used during a calibration is expressed as the rounded mean of the ACA measurement results ± combined standard uncertainty at approximately 99.7% level (k=3).

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

Revision History

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
07	09/01/2017	Minor Revision – Sections 2.1, 2.2, 3, 4.1, 4.4, 5.2 and 7 Major Revision – Sections 4.2, 5.3, 8 and 9
08	05/15/2019	Revision – All sections
09	09/01/2020	Revision – All sections
10	07/01/2021	Revision – Section 12.1
11	10/01/2021	Revision – Sections 2, 5, 8, 11, and 12