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.

Any changes which occur as a result of the implementation of these procedures 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 Standard Uncertainty – The standard uncertainty of the result of a measurement when the result is obtained from the values of a number of other quantities, equal to the positive square root of the sum of the individual standard uncertainties. Combined standard 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.

Interlaboratory Comparison - Organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.
**Intralaboratory Comparison** - Organization, performance, and evaluation of measurements or tests on the same or similar items within the same laboratory, in accordance with predetermined conditions.

**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.

**Proficiency Testing** - Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

**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 (RM)** – 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 – Parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurement.

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

2.2 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
- RM: Reference Material
- SD: Standard deviation
- TXDPS: Texas Department of Public Safety
- VC: Vapor concentration

3 Instrument Calibration Record File (uniquely identified by instrument serial number)

The Technical Supervisor fulfills the role of custodian of records on behalf of the Department. Records in the Instrument Calibration File shall be retained for 100 years. Records shall be kept in paper or electronic form separate from the COBRA database. Calibration records include, but are not limited to the following:

A. Instrument Certificate issued by the Office of the Scientific Director
B. Instrument Certification Technical Records
C. Calibration Certificate Workbook (OSD-WBK-01)
   1. Calibration Analyst Worksheet (OSD-CAL-04)
   2. Technical and Administrative Review Checklist (OSD-CAL-05)
   3. Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06)
   4. Amended Calibration Analyst Worksheet (OSD-CAL-08), as applicable
5. Amended Technical and Administrative Review Checklist (OSD-CAL-09), as applicable

6. Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10), as applicable

D. Calibration Technical Records
   1. Instrument ACA printouts
   2. Instrument Receipt & Condition Notes Label (OSD-CAL-02)
   3. Calibration Notes Labels (OSD-CAL-03)

E. Supplement to the Calibration Certificate, as applicable (OSD-CAL-07)

F. Administrative documentation, as applicable

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

4. Laboratory Equipment, Reference Material/Certified Reference Materials, and Devices

4.1 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 vendor.
      a) 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.
      b) The thermometer calibration shall include an evaluation at 34°C with a tolerance of +/-0.10°C and uncertainty estimated at k=2, 95%.
      c) When a thermometer is received back into the Technical Supervisor's laboratory, the following must be performed:
         d) A visual inspection to ensure no damage has occurred during shipping. Damaged thermometers shall be reported to the OSD and shall be considered out of service and labeled or marked appropriately.
         e) 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.
         f) Verify thermometer conforms to specified requirements and document performance verification in accordance with laboratory procedures.
         g) The analyst shall date and initial/sign the calibration certificate and submit to the OSD.
4. The calibration certificate generated by the calibration laboratory and any additional records for each NIST traceable thermometer shall be kept in the Thermometer File.

5. Only a NIST traceable thermometer which has met the outlined requirements of this section shall be used to verify the proper operational temperatures of simulators used in the instrument calibration procedure.

6. A NIST traceable thermometer which has not been successfully calibrated shall be isolated and clearly marked or labeled as out of service.

7. 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.

4.2 Reference Material and Certified Reference Materials

A. The nominal values of the reference material 0.000 and certified reference materials 0.040, 0.080, 0.150, and 0.400 (reported in g/210L), shall be used to perform the calibration. The 0.000 reference material shall consist of purified water. The purified water reference material and all ethanol certified reference materials used in the calibration procedure shall be provided by the OSD.

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

C. Each bottle of RM and CRMs 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 records 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 the purified water reference material used to perform instrument calibrations.

4.3 Laboratory Devices

Simulator Devices

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

5 Breath Alcohol Instrument Calibration Procedure

5.1 General

A. Instruments are to be calibrated by certified Technical Supervisors in a Technical Supervisor 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. Environmental conditions to be considered include, but are not limited to: extreme ambient temperature, known radio frequency interference, or known ambient air contaminants.

D. 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.

5.2 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 & 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.

C. The Calibration Analyst shall sign and date the Instrument Receipt & 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 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.

5.3 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. 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. 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. 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 34.0 ±0.2°C.

B. Calibration Procedure
   1. Place the RM or CRM into the simulator.
   2. Check the RM or CRM solution with a NIST traceable thermometer and ensure that the solution temperature is 34.0 ±0.2°C. 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 ±0.2°C.
   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 & Condition Notes Label (OSD-CAL-02) to the 0.000 ACA printout.
   2. Affix the appropriate Calibration Notes Label (OSD-CAL-03) to each ACA printout.
   3. Affix the label from the RM or CRM bottle to the corresponding ACA printout.
   4. 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 (OSD-CAL-04). All of the technical records generated during the calibration attempt shall be combined electronically into a single pdf document and emailed to the OSD.

F. A calibration procedure, as described in this section, must be successfully performed before a Calibration Certificate Workbook (OSD-WBK-01) can be authorized and issued.

6 Calibration Certificate Workbook (OSD-WBK-01)

6.1 General
   A. To document the calibration, a Technical Supervisor shall complete the most current version of the Calibration Certificate Workbook (OSD-WBK-01). The Calibration Certificate Workbook is composed of the following:
      1. Calibration Analyst Worksheet (OSD-CAL-04)
2. Technical and Administrative Review Checklist (OSD-CAL-05)
3. Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06)
4. Amended Calibration Analyst Worksheet (OSD-CAL-08), as applicable
5. Amended Technical and Administrative Review Checklist (OSD-CAL-09), as applicable
6. Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10), as applicable

B. The Calibration Certificate Workbook requires the electronic signature of the Calibrating Analyst. The electronic signature is secured within the Calibration Certificate 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 Calibration Certificate Workbook is available from the TXDPS website.

6.2 Calibration Analyst Worksheet (OSD-CAL-04)
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 Calibration Certificate 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 reference material must be 0.0000.
   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 Calibration Certificate Workbook.
F. 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 worksheet.
G. The Calibration Analyst shall submit the Calibration Certificate Workbook and all initialed/signed scanned ACA printouts to another analyst for technical and administrative review.

H. The Calibration Analyst Worksheet is considered complete when sent to the Reviewing Analyst. Any changes made to the Calibration Analyst Worksheet during the review period must be documented on the Calibration Analyst Worksheet along with the date the changes were made. Changes made to the ACAs, Instrument Receipt & Condition Notes (OSD-CAL-02) or the Calibration Notes Label (OSD-CAL-03) must be dated and initialed by the Calibration Analyst.

6.3 Technical and Administrative Review Checklist (OSD-CAL-05)

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

B. The Reviewing Analyst shall be a current member of the Breath Alcohol Testing Program who is currently certified as a Technical Supervisor, or who has been authorized to review calibrations.

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

D. The Reviewing Analyst shall ensure that the calibration was properly completed and that all of the information entered on the Calibration Analyst Worksheet (OSD-CAL-04), and all other documents submitted by the Calibration Analyst, are accurate.

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

F. 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 must be documented on the Calibration Analyst Worksheet along with the date the changes were made. Changes made to the ACAs, Instrument Receipt & Condition Notes or the Calibration Notes Label must be dated and initialed by the Calibration Analyst.

2. If the Calibration Analyst determines the discrepancy does not affect the quality of the work, 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 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 Analyst Worksheet. Example: A data entry error that when corrected results in the instrument not meeting one or more requirements listed in this document.

G. When all of the records submitted by the Calibration Analyst have been reviewed and the Technical and Administrative Review Checklist is properly completed, the Reviewing Analyst shall affix their electronic signature and the Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06) tab will open.

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

6.4 Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06)

A. The Calibration Analyst who authorizes and issues the Calibration Certificate Workbook shall be the Technical Supervisor who performed the calibration procedure.

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 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 (OSD-WBK-01) is authorized and issued.

C. The Calibration Certificate Workbook (OSD-WBK-01) 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 OSD.

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

7 Discrepancies Identified After Certificate Issuance

7.1 General

A. After the Calibration Certificate Workbook 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 OSD and all other affected parties.

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

7.2 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 Workbook (OSD-WBK-01) has been authorized and issued.

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

C. The Supplement to the Calibration Certificate is required when a correction has been made to any of the following:
   1. The Instrument Receipt & Condition Notes Label (OSD-CAL-02)
   2. The Calibration Notes Label (OSD-CAL-03)
3. The ACA printouts

4. Any document within the Calibration Certificate Workbook

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

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

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

G. 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 signed by the Reviewing Analyst using their electronic signature.

H. The Supplement to the Calibration Certificate and all other relevant records 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.

I. 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.

7.3 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 (OSD-CAL-07), noting and explaining the discrepancy(s).

C. The corrected information and data shall be entered in the Amended Calibration Analyst Worksheet (OSD-CAL-08). 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 6.2 D once the corrected information and data have been entered into the Amended Calibration Analyst Worksheet, then a Supplement to the Calibration Certificate (OSD-CAL-07) 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 (OSD-CAL-09) is properly completed, the Reviewing Analyst shall affix their electronic signature and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10) 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 Calibration Certificate and save the Amended Calibration Certificate Workbook.

J. The Amended Calibration Certificate Workbook containing the Amended Calibration Analyst Worksheet, the Amended Technical and Administrative Review Checklist and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate must be returned to the Calibration Analyst, who shall authorize and issue the Amended Calibration Certificate Workbook.

K. 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 OSD to be included in the instrument’s electronic file.

8 Assuring the Quality of Calibration Results

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. Quality control monitoring is planned and reviewed periodically by the Quality Manager and shall be recorded annually. Quality control procedures may include, but are not limited to, the following:

A. Regular use of certified reference materials and/or internal quality control using secondary reference materials.

B. Replicate calibrations using the same method.

C. Technical and administrative reviews.

D. A documented proficiency testing program.

9 Competency Evaluation

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

9.1 Proficiency Testing

A. Proficiency tests must be provided by an ISO/IEC 17043 accredited vendor.

B. Proficiency 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. Examiner Assessment Report Form (LAB-312), or equivalent shall be submitted to the OSD.

9.2 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 OSD.

D. The unknown comparison tests 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. Any Technical Supervisor who is unsuccessful on the first attempt shall be sent another unknown comparison test solution and given a new deadline date for reporting the results. Any Technical Supervisor who is unsuccessful on the second attempt shall be asked to come to the OSD to demonstrate their ability to calibrate an instrument and for remedial training, if necessary. Any unsuccessful attempt shall be documented as a Quality Incident.

F. An Assessment Report shall be issued to each Technical Supervisor who completes an intralaboratory or interlaboratory comparison test. The Assessment Report shall be designated as “Satisfactory”, or “Unsatisfactory” and additional information shall be documented, as necessary.

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

A. Certified reference materials and purified water reference materials 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 and RM solutions, the bottles shall be stored at room temperature in a secured, limited access location.

C. The CRM and RM solutions are valid and approved for use as defined on the Certificate of Analysis. CRM and RM solutions 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 and RM solutions shall be crossed out. Expired solutions shall not be used for evidential breath alcohol instrument calibration and shall be stored separately from unexpired CRM and RM solutions.

11 Measurement Uncertainty

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

### 11.2 Measurement Uncertainty Budget for Breath Alcohol Instrument Calibration

![Figure 1: Cause and effect diagram for the calibration of the breath alcohol instrument](image)

**Calibration Solutions**
- NIST
- External CRM
- OSD CRM Solutions

**True Value**
- Temperature
- Stirrer
- Seal

**Measured Value**
- Electronics
- Optics
- Calibration

**Simulator**

**Breath Alcohol Instrument**

The diagram illustrates the flow of uncertainty from the calibration solutions through to the breath alcohol instrument measurement.

### 11.3 Measurement Uncertainty of Breath Alcohol Instrument Calibration CRMs

A. 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 standard 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. 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 simulator solution from repeated testing and evaporation over time.*

2. 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. Neither 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, the last 15 analyses are recorded in the Calibration...
Analyst Worksheet. Variations in each of these factors may affect repeatability and contribute to uncertainty.

3. This variability of the ACA measurements is 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 ACA measurement result
- $n$ = the number of measurements (15)
- $X_i$ = 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:

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

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

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

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

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

11.4 Calculations and Number Rounding Used in the Calibration Certificate Workbook (OSD-WBK-01)

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

\[
CV_{\text{Comb}} = \sqrt{CV_{\text{Lot COA}}^2 + CV_{\text{Lot Intox}}^2}
\]

\text{Eq. 1}

Where:

- \(CV_{\text{Comb}}\) = the combined Coefficient of Variation for the ethanol concentration of the CRM solution lot as analyzed by the Intoxilyzer
- \(CV_{\text{Lot COA}}\) = the combined Coefficient of Variation for the CRM solution lot (SD_comb \div \text{vapor concentration of the CRM solution lot}) from the CRM solution lot Certificate of Analysis
- \(CV_{\text{Lot Intox}}\) = the Coefficient of Variation of the vapor concentration of the CRM solution lot as analyzed on the Intoxilyzer (SD of the CRM solution lot analyzed on the Intoxilyzer \div \text{vapor concentration of the CRM solution lot})

2. Eq. 2 is used to calculate the combined standard deviation (SD_comb) of the Intoxilyzer.

\[
SD_{\text{Comb}} = (CV_{\text{Comb}}) (VC_{\text{Lot COA}})
\]

\text{Eq. 2}

Where:

- \(SD_{\text{Comb}}\) = 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).
- \(VC_{\text{Lot COA}}\) = the vapor concentration of the CRM solution lot from its 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.

\[
SD_{\text{Comb}} \times 3 = \text{the combined uncertainty for the Intoxilyzer at approximately the 99.7% confidence level}
\]

\text{Eq. 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

<table>
<thead>
<tr>
<th>Version #</th>
<th>Effective Date</th>
<th>Brief Description of Change(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>03/01/2013</td>
<td>Original Issue; Standard Operating Guidelines for Technical Supervisors (1/30/2012)</td>
</tr>
<tr>
<td>00a</td>
<td>03/01/2013</td>
<td>Minor Revision – Administrative</td>
</tr>
<tr>
<td>01</td>
<td>07/01/2013</td>
<td>Major Revision – Section 2.2, 9.2, 9.3</td>
</tr>
<tr>
<td>02</td>
<td>09/27/2013</td>
<td>Major Revision – Section 4.2, 5.5</td>
</tr>
<tr>
<td>03</td>
<td>09/19/2014</td>
<td>Major Revision – All Sections</td>
</tr>
<tr>
<td>04</td>
<td>03/31/2015</td>
<td>Major Revision – Sections 5.2, 6.3</td>
</tr>
<tr>
<td>05</td>
<td>08/24/2015</td>
<td>Minor Revision – Sections 1, 2.1, 4.1, 4.2, 4.3, 5.2, 5.3, 6.2, 7, 8, 9, and 10.3</td>
</tr>
<tr>
<td>06</td>
<td>06/01/2016</td>
<td>Minor Revision – Sections 2.1, 4.1, 5.1, 5.3, 5.4, 6.2, 6.9, 9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major Revision – Sections 4.2, 4.3, 5.2</td>
</tr>
<tr>
<td>07</td>
<td>09/01/2017</td>
<td>Minor Revision – Sections 2.1, 2.2, 3, 4.1, 4.4, 5.2 and 7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major Revision – Sections 4.2, 5.3, 8 and 9</td>
</tr>
<tr>
<td>08</td>
<td>05/15/2019</td>
<td>Revision – All sections</td>
</tr>
</tbody>
</table>