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REVISION HISTORY

Effective Date	Brief Description of Change(s)
10/17/2022	Original Issue Previous revision history for individual chapters included in archived documents

ACTIVE DEVIATIONS

This list reflects deviations that are active as of 10/18/2022.

Deviation	Related Chapter(s)	Deviation From



01 OVERVIEW

OSD-CAL-01 STANDARD OPERATING PROCEDURES: EVIDENTIAL BREATH ALCOHOL INSTRUMENT CALIBRATION

1 Scope

To describe evidential breath alcohol instrument calibration program policies and procedures for instrument calibration, instrument measurement uncertainty, record keeping, and technical supervisor examiner assessment.

2 Related Documents

CLD Manual:

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

Texas Breath Alcohol Program Testing Manual:

- Standard Operating Procedures: Evidential Breath Alcohol Testing (OSD-TST-01)

3 Terms

3.1 Definitions

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

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. This procedure does not include 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 reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. Note: In this document “CRM” refers to the certified reference materials produced by the Breath Alcohol CRM Laboratory.

Nominal value – The rounded or approximate value, which is reported to three decimal places for a solution lot.

Purified water – Water purified by any scientifically acceptable means including, but not limited to: filtration, deionization, distillation, UV sanitization, or reverse osmosis.

Quality incident/quality action plan (QI/QAP) – The documentation related to a nonconformance to required specifications in a standard, procedure, or policy.



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

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

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

3.2 Abbreviations

Admin	Administrative
BAL	Breath Alcohol Laboratory
CLD	Crime Laboratory Division
COA	Certificate of analysis
COBRA	Computer Online BReath Archive
Comb	Combined
Conc	Concentration
CV	Coefficient of variation
DPS	Texas Department of Public Safety
Eq	Equation
Exp	Expiration
Intox	Intoxilyzer
NIST	National Institute of Standards and Technology
OSD	Office of the Scientific Director
SD	Standard deviation
SI	Système International d’Unités (International System of Units)
SN	Serial number
SOLN	Solution
STD	Standard
Tech	Technical
Temp	Temperature
VC	Vapor concentration

4 Technical 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 DPS. Instrument calibration records are retained in accordance with the DPS Records Retention Schedule.



- C. Records are kept in paper and/or electronic form separate from the COBRA database and a copy is made available on the DPS Breath Alcohol Laboratory 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) records;
 - 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. Calibration Supplement (OSD-CAL-07), where applicable;
 - 6. Administrative documentation, where applicable; and
 - 7. Reference to instrument specific deviation requests and/or quality incidents/quality action plans, where applicable.

5 Equipment

5.1 Significant Equipment

- A. NIST Traceable Thermometer
 - 1. Use
 - a) *A NIST traceable thermometer is used to verify proper operational temperatures of simulators used in the instrument calibration procedure.*
 - b) *NIST traceable thermometer(s) are maintained in the technical supervisor's calibration laboratory, which has limited access.*
 - i. *In the event that a NIST traceable thermometer goes outside the control of the technical supervisor's calibration laboratory, a performance verification as specified in **Section 5.1 A.3.b.iii** is required prior to using the thermometer in calibration work.*
 - c) *Reasonable care is taken in the handling and storage of NIST thermometer(s) in order to avoid extreme temperatures, shock, or breakage.*
 - d) *Refer to the manufacturer's instructions for general operating information, if available.*
 - 2. Maintenance and Repair



- a) *Thermometers are kept clean at all times.*
- b) *For digital thermometers:*
 - i. *Replace the battery, as needed.*
 - ii. *In the event of a broken power supply cable, thermometers may be submitted to the DPS Breath Alcohol Electronics Laboratory for repair.*
- c) *Damaged thermometers are reported to the BAL quality manager, removed from service, and labeled or marked appropriately to prevent unintended use.*
 - i. *A performance verification as specified in **Section 5.1 A.3.b.iii** is required prior to using the thermometer in calibration work.*
 - ii. *DPS technical supervisors follow requirements specified in the DPS CLD Manual for significant equipment.*

3. Calibration and Performance Verification

- a) *NIST traceable thermometers are calibrated annually by an approved supplier and are considered to be suitable for use for a period of one year from the date of calibration.*
 - i. *The thermometer calibration certificate includes an evaluation at 34.000°C with a tolerance of +/- 0.100°C and uncertainty estimated at k=2, 95%.*
 - ii. *If the calibration certificate is not acceptable or does not meet required specifications, contact the calibration vendor.*
- b) *When a thermometer is received back into the laboratory post-calibration, the following activities are performed prior to using the thermometer in calibration work:*
 - i. *A visual inspection to ensure no damage has occurred during shipping;*
 - ii. *A review of the calibration certificate to ensure that it is acceptable and meets all required specifications; and*
 - iii. *A performance verification that, when placed in a simulator heated to 34.00°C, the thermometer reads 34.00°C ± 0.20°C.*
- c) *If the thermometer successfully meets the specifications as listed above, the analyst initials/signs the calibration certificate, includes the date the verification was completed, and submits it to the BAL quality manager.*
 - i. *DPS technical supervisors follow requirements specified in the DPS CLD Manual for performance verifications.*
 - ii. *Local technical supervisors document the performance verification in accordance with their laboratory procedures. Additional laboratory documentation is submitted to the BAL quality manager with the calibration certificate.*
- d) *Thermometers that do not meet specifications are reported to the BAL quality manager, removed from service, and labeled or marked appropriately to prevent unintended use.*
 - i. *DPS technical supervisors follow requirements specified in the DPS CLD Manual for significant equipment.*

4. Records

- a) *The calibration certificate provided by the approved supplier and any additional records for each NIST traceable thermometer are maintained in the Thermometer*



Record and a copy is made available on the DPS Breath Alcohol Laboratory website.

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.
3. Refer to the *Standard Operating Procedures: Evidential Breath Alcohol Testing* chapter (OSD-TST-01) of the OSD Testing Manual for information pertaining to simulator maintenance records.

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

6.1 Receipt and Storage

- A. RMs and CRMs provided by the DPS Breath Alcohol Laboratory are sealed to prevent contamination and tampering. The analyst ensures that the seal is intact prior to use in the calibration procedure.
- B. Upon receipt of the RMs and CRMs, the bottles are stored at room temperature in a secured, limited access location.
- C. The RMs and CRMs are valid and approved for use as defined in the associated RM product information sheet or CRM certificate of analysis.
- D. Expired RMs and CRMs are discarded unless retained for training or other non-calibration purposes.
 1. The label on all retained expired RMs and CRMs is crossed out and the bottles are stored separately from unexpired RMs and CRMs.
 2. Expired RMs and CRMs are not used for evidential breath alcohol instrument calibration.

6.2 Use in Calibration Procedure

- A. The nominal values of the 0.000 RMs and 0.040, 0.080, 0.150, and 0.400 CRMs (reported in g/210 L), are used to perform the calibration.
 1. The 0.000 RMs are purified water (0.000 ethanol concentration).
 2. The RMs and CRMs used in the calibration procedure are provided by the DPS Breath Alcohol Laboratory.
- 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 CRM may only be used once to provide 20 consecutive ACA measurements for the calibration of a single breath alcohol instrument.
- D. For CRMs used to perform instrument calibrations, the certificate of analysis records which establish NIST traceability, vapor concentration, nominal value, and combined uncertainty are available on the DPS Breath Alcohol Laboratory 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 is exercised with care in order to preserve their scientific integrity.
- C. The calibration procedure is 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; or
 - 3. As determined by the technical supervisor.
- D. The calibration procedure is performed using RMs and CRMs specified in **Section 6.2 A.** (may also be referred to as reference solutions).
- E. Assessment of Environmental or Other Conditions
 - 1. Prior to starting a calibration, if the technical supervisor determines that an environmental or other condition may affect the quality of the calibration, the procedure is not attempted until the cause for concern has been remediated or eliminated.
 - 2. During a calibration, if the technical supervisor determines that an environmental or other condition is affecting the quality of the calibration, the procedure is terminated. Subsequent calibration attempts may not occur until the cause for concern has been remediated or eliminated.
 - 3. Environmental conditions to be considered include, but are not limited to:
 - a) *Extreme ambient temperature;*
 - b) *Known radio frequency interference; and/or*
 - c) *Known ambient air contaminants.*
- F. Instruments maintained in the technical supervisor's laboratory are labeled with the instrument status. At a minimum, the label indicates either "out of service" or "calibrated and ready for service" and contains 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, the calibration analyst notes the following on the Calibration Analyst Worksheet (OSD-CAL-04), in no particular order:
 - 1. The serial number of the instrument;
 - 2. The date the instrument was received into the calibration laboratory; and
 - 3. The operating condition of the instrument (refer to **Section 7.2 B.**).
- B. A visual assessment is performed to determine the presence of any operational defects that would prevent the instrument from being successfully calibrated.



1. In the event of observed defects, the calibration procedure is terminated and all deficiencies are noted on the Calibration Analyst Worksheet. Subsequent calibration attempts may not occur until the defects have been remediated or eliminated.
 - a) *Refer to the Standard Operating Procedures: Evidential Breath Alcohol Testing chapter (OSD-TST-01) of the OSD Testing Manual for information pertaining to instrument maintenance records.*
2. If no defects are observed, the calibration procedure continues as specified in **Section 7.3**.

7.3 Conducting the Calibration Procedure

- A. When conducting the calibration procedure, the calibration analyst documents on the Calibration Notes label (OSD-CAL-03) the following for each reference solution, as each step is completed (steps may be completed in any order):
 1. Verification that the reference solution was sealed prior to use;
 2. Lot number of the reference solution;
 3. Simulator model;
 4. Simulator serial number;
 5. Verification that the simulator is properly sealed prior to analysis;
 6. Verification that the simulator stirring mechanism is turning prior to analysis;
 7. Serial number the NIST traceable thermometer;
 8. Calibration expiration date of the NIST traceable thermometer; and
 9. Verification that before and after the analysis of each reference solution, the NIST traceable thermometer in the simulator read $34.00^{\circ}\text{C} \pm 0.20^{\circ}\text{C}$ (refer to **Section 7.3 B**).
- B. Calibration Procedure
 1. Place the reference solution into the simulator.
 2. Check the reference solution with a NIST traceable thermometer and ensure that the solution temperature is $34.00^{\circ}\text{C} \pm 0.20^{\circ}\text{C}$.
 - a) *After removing the thermometer, ensure that the simulator is properly sealed.*
 3. Connect the simulator to the instrument.
 4. Conduct 20 consecutive ACAs.
 5. At the conclusion of the ACA sequence, check the reference solution with the NIST traceable thermometer and ensure that the solution temperature is $34.00^{\circ}\text{C} \pm 0.20^{\circ}\text{C}$.
 6. Repeat this procedure for the remaining reference solutions.
 7. During the calibration procedure, the ACA sequence for each reference solution may only be attempted once.
- C. The calibration analyst signs and dates the Calibration Notes label (OSD-CAL-03).
- D. The calibration analyst affixes the following labels to the appropriate ACA printout:
 1. The appropriate Calibration Notes label; and



2. The label from the reference solution bottle.
- E. The calibration analyst initial/signs the ACA printout.
- F. When corrections or amendments are made to the Calibration Notes label or the ACA printouts, the corrections or amendments are made in a manner which allows the altered or amended record to be tracked back to previous or original versions.
 1. Deletions are made by single line strikethrough(s) and initialed and dated by the calibration analyst.
 - a) *Erasures or obliterations are not permitted.*
 2. Additions (e.g., placing new information on the record) are initialed and dated by the calibration analyst.
 3. When corrections or amendments involve both an addition and a deletion, the correct information is added near the deletion, where possible.
- G. If at any time it becomes necessary to terminate the calibration procedure due to an environmental or other condition; unacceptable results; an operational message; instrument or equipment in need of adjustment or repair; or for any other reason, all technical records generated to that point are retained and the reason for the unsuccessful attempt are documented on the Calibration Analyst Worksheet (OSD-CAL-04).
 1. All of the technical records generated during the calibration attempt are combined electronically into a single PDF document and emailed to the BAL quality manager to be included in the Instrument Calibration Record.
- H. The calibration procedure is successfully completed before an Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06) is issued.

8 Calibration Certificate Workbook (OSD-WBK-01)

8.1 General

- A. To document the calibration, a technical supervisor completes the most current version of the Calibration Certificate Workbook. The Calibration Certificate Workbook also serves as the Amended Calibration Certificate Workbook (all documents are maintained within OSD-WBK-01).
- B. The Calibration Certificate Workbook requires the electronic signatures of the calibration analyst and reviewing analyst. The electronic signatures are secured within the Calibration Certificate Workbook by passwords of at least eight characters in length.
- C. Modifications to the Calibration Certificate Workbook follow requirements specified in the DPS CLD Manual for validations and performance verifications of software.
 1. Minor modifications include administrative changes that do not impact the analytical process, interpretation, or statistical calculation function of the workbook.
 2. Major modifications include algorithm modification, statistical or calculation equation modification, a major functionality addition or removal, and/or inclusion of a new module.
 3. Major modifications require a manual calculation and formula verification.
 4. Updated versions of the Calibration Certificate Workbook are sufficiently tested in order to demonstrate they do not adversely affect results.



- D. The Calibration Certificate Workbook is available on the DPS 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 are completed before forwarding the Calibration Certificate Workbook for review.
- B. In order to ensure ethanol vapor equilibration between the simulator and instrument, only the final 15 ACA results for each reference solution are recorded on the Calibration Analyst Worksheet. Results are recorded to three decimal places.
- C. Calibration Results Acceptance Criteria
 - 1. Each of the 15 analyses of the purified water reference material must be 0.000.
 - 2. The mean result of the 15 analyses of each CRM must be within ± 0.0030 or 3% (whichever is greater) of the vapor concentration of the CRM. Mean results are recorded to four decimal places (rounded).
 - 3. The standard deviation of the nominal 0.040, 0.080, and 0.150 g/210 L CRMs is 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 is recorded to five decimal places (rounded) and must be less than 0.00200.
- D. The "Date Analysis Completed" on the Calibration Analyst Worksheet is the date on which the last ACA of the calibration procedure is performed.
- E. When the information and the data entered on the Calibration Analyst Worksheet meets all of the required specifications, the calibration analyst affixes their electronic signature and then saves the Calibration Certificate Workbook.
- F. The calibration analyst submits the Calibration Certificate Workbook and all associated ACA printouts to a reviewing analyst for technical and administrative review.
 - 1. The Calibration Analyst Worksheet is considered complete when sent to the reviewing analyst.

8.3 Technical and Administrative Review

- A. The reviewing analyst:
 - 1. Is a certified technical supervisor; and
 - a) *DPS technical supervisors utilize a reviewing analyst authorized by DPS to perform technical reviews of instrument calibration.*
 - b) *DPS technical supervisors are prohibited from reviewing calibration work completed by a technical supervisor who is a family member.*
 - 2. Is not the analyst who performed the calibration procedure (i.e., the calibration analyst).
- B. The reviewing analyst ensures that the calibration was properly completed, all required information has been entered correctly on the Calibration Analyst Worksheet (OSD-CAL-04), and all other documents submitted by the calibration analyst are accurate.
- C. The reviewing analyst completes the Technical and Administrative Review Checklist (OSD-CAL-05).



1. Entries to the Technical and Administrative Review Checklist may be made in any order by the reviewing analyst.
- D. Discrepancies are brought to the attention of the calibration analyst and resolution takes place prior to completion of the review and issuance of the Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06).
1. Any changes made to the Calibration Analyst Worksheet are documented on the Calibration Analyst Worksheet along with the date the changes were made.
 2. Any changes made to the ACA printouts or the Calibration Notes labels follow the requirements specified in **Section 7.3 F**.
 3. For administrative or technical discrepancies that do not affect the integrity of the calibration, the calibration analyst makes the needed correction(s) and resubmits the documentation to the reviewing analyst for continuation of the technical and administrative review.
 - a) Refer to **Section 9.1 B** for examples of administrative and technical discrepancies.
 4. If a discrepancy is identified that affects the integrity of the calibration, the calibration analyst terminates the calibration procedure and notes the reason on the Calibration Analyst Worksheet.
 - a) Example: corresponding correction causes the statistical analysis requirements to fall outside of the prescribed criteria in **Section 8.2 C**.
- E. When all of the records submitted by the calibration analyst have been reviewed and the Technical and Administrative Review Checklist is complete, the reviewing analyst affixes their electronic signature and the Evidential Breath Alcohol Testing Instrument Calibration Certificate tab will open in the Calibration Certificate Workbook.
- F. The reviewing analyst affixes their electronic signature to the Evidential Breath Alcohol Testing Instrument Calibration Certificate and saves the Calibration Certificate Workbook.
- G. The Calibration Certificate Workbook is returned to the calibration analyst for authorization and issuance of the Evidential Breath Alcohol Testing Instrument Calibration Certificate.

8.4 Issuing the Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06)

- A. Upon completion of the technical and administrative review, the calibration analyst completes a final review to ensure that the calibration was properly completed and that all of the information contained on the associated calibration records is accurate.
- B. The calibration analyst authorizes the results and issues the certificate by entering the date and affixing their electronic signature to the Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06) and then saving the Calibration Certificate Workbook.
 1. 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 associated records generated during the calibration of the instrument are combined electronically into a single PDF document and emailed to the BAL quality manager to be included in the Instrument Calibration Record.



9 Discrepancies Identified After the Certificate is Issued

9.1 General

- A. After the Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06) has been authorized and issued, any discrepancies identified which are related to the calibration procedure are brought to the attention of the calibration analyst, the BAL quality manager, and all other affected parties.
- B. Discrepancies are evaluated to determine whether they are administrative or technical in nature.
 1. Administrative discrepancies
 - a) *Error(s) to the following information contained on the Calibration Analyst Worksheet (OSD-CAL-04) and/or Calibration Notes label (OSD-CAL-03):*
 - i. *Instrument calibrated and serial number;*
 - ii. *Date received in the calibration lab;*
 - iii. *Laboratory name and address;*
 - iv. *Customer name and address;*
 - v. *Simulator model and serial number;*
 - vi. *Date analysis completed;*
 - vii. *Reason for instrument calibration; and*
 - viii. *Description of the change(s) made to the worksheet during the tech/admin review and the date they were made (includes missing dates).*
 - b) *Error(s) to the ACA printout(s):*
 - i. *Incorrect location; and*
 - ii. *Missing calibration analyst signature/initials.*
 2. Technical discrepancies
 - a) *Usage of an outdated version of OSD-WBK-01 or OSD-CAL-03*
 - b) *Error(s) to the following information contained on the Calibration Analyst Worksheet (OSD-CAL-04) and/or Calibration Notes label (OSD-CAL-03):*
 - i. *Instrument condition;*
 - ii. *Solution lot number;*
 - iii. *ACA results;*
 - iv. *Repairs/adjustments; and*
 - v. *Laboratory environmental conditions.*
 - c) *Error(s) to the ACA printout(s):*
 - i. *Usage of an outdated firmware version; and*
 - ii. *Incorrect number of ACAs performed.*
 3. Discrepancies which may be either administrative or technical, depending on the nature and impact of the discrepancy:



- a) *Error(s) to the following information contained on the Calibration Analyst Worksheet (OSD-CAL-04) and/or Calibration Notes label (OSD-CAL-03):*
 - i. *Missing verification that the reference solution was sealed prior to use;*
 - ii. *Simulator operating condition (e.g., missing verification of proper seal and stirring mechanism turning);*
 - iii. *NIST traceable thermometer serial number;*
 - iv. *NIST traceable thermometer calibration expiration date; and*
 - v. *NIST traceable thermometer temperature verification before and after ACAs.*
- 4. Discrepancies are addressed in accordance with **Sections 9.2** and **9.3** below.
- C. Technical discrepancies identified after an instrument has been placed into evidentiary service are additionally evaluated by the scientific director and potential impacts to the validity of the tests conducted on the instrument are determined. A new calibration may be required in order to resume evidential testing use.
- D. When a technical discrepancy occurs that results in an amended calibration failure (e.g., correction causes the statistical analysis requirements to fall outside of the prescribed criteria in **Section 8.2 C**), a subsequent successful calibration is required in order to resume evidential testing use.

9.2 Calibration Supplement (OSD-CAL-07)

- A. A Calibration Supplement is required when any discrepancies to the following have been found after the Evidential Breath Alcohol Testing Instrument Calibration Certificate has been authorized and issued:
 - 1. The ACA printout(s);
 - 2. The Calibration Notes label(s) (OSD-CAL-03); and/or
 - 3. The originally issued calibration certificate (OSD-CAL-04, OSD-CAL-05, OSD-CAL-06).
- B. Applicable corrections or amendments are made to the ACA printouts, Calibration Notes labels, and/or through the use of the Amended Calibration Certificate Workbook (OSD-WBK-01) (refer to **Section 9.3**).
 - 1. Any changes made to the ACA printouts or the Calibration Notes labels follow the requirements specified in **Section 7.3 F**.
 - 2. All corrections or amendments are noted and explained in the Calibration Supplement.
- C. When the Calibration Supplement has been completed, the calibration analyst affixes their electronic signature and saves the Calibration Supplement.
- D. The Calibration Supplement and any relevant records are submitted to a reviewing analyst for technical and administrative review.
- E. When all of the records submitted by the calibration analyst have been reviewed and found to be accurate, the Calibration Supplement is electronically signed by the reviewing analyst.
- F. The Calibration Supplement and all other relevant records are combined electronically into a single PDF and emailed to the BAL quality manager to be included in the Instrument Calibration Record.



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

A. General

1. An Amended Calibration Certificate Workbook is completed when changes are necessary in order to correct discrepancies identified in the Calibration Certificate Workbook (OSD-WBK-01) after the Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06) has been issued.
 - a) *The original Calibration Certificate Workbook documentation (OSD-CAL-04, OSD-CAL-05, OSD-CAL-06) is not changed, altered, or discarded.*
2. When an Amended Calibration Certificate Workbook is required, the calibration analyst also completes a Calibration Supplement (OSD-CAL-07), noting and explaining any discrepancies.

B. Amended Calibration Analyst Worksheet (OSD-CAL-08)

1. The information and data from the original Calibration Certificate Worksheet (OSD-CAL-04) is entered in the Amended Calibration Analyst Worksheet, including any required corrections.
2. When the information and data entered on the Amended Calibration Analyst Worksheet meets all of the required specifications and all corrections have been made, the calibration analyst affixes their electronic signature and then saves the Amended Calibration Certificate Workbook.
3. The calibration analyst submits the Amended Calibration Certificate Workbook and the original ACA printouts to the reviewing analyst for technical and administrative review.
 - a) *The Amended Calibration Analyst Worksheet is considered complete when sent to the review analyst.*

C. Technical and Administrative Review

1. The reviewing analyst meets the requirements specified in **Section 8.3 A**.
2. The reviewing analyst ensures 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.
3. The reviewing analyst completes the Technical and Administrative Review Checklist (OSD-CAL-09).
 - a) *Entries to the Technical and Administrative Review Checklist may be made in any order by the reviewing analyst.*
4. Discrepancies are brought to the attention of the calibration analyst and resolution takes place prior to completion of the review and issuance of the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10).
 - a) *Any changes made to the Amended Calibration Analyst Worksheet are documented on the Amended Calibration Analyst Worksheet along with the date the changes were made.*
 - i. **Note:** *Documented changes pertain to discrepancies in the Amended Calibration Analyst Worksheet, not the discrepancies identified in the original Calibration Certificate Workbook.*



- b) *Any changes made to the ACA printouts or the Calibration Notes labels follow the requirements specified in **Section 7.3 F**.*
 - c) *For administrative or technical discrepancies that do not affect the integrity of the original calibration, the calibration analyst makes the needed correction(s) and resubmits the documentation to the reviewing analyst for continuation of the technical and administrative review.*
 - i. *Refer to **Section 9.1 B** for examples of administrative and technical discrepancies.*
 - d) *If a discrepancy is identified that affects the integrity of the original calibration, the calibration analyst indicates that the calibration procedure was not properly completed and notes the reason on the Amended Calibration Analyst Worksheet.*
 - i. *Example: corresponding correction causes the statistical analysis requirements to fall outside of the prescribed criteria in **Section 8.2 C**.*
5. When all of the records submitted by the calibration analyst have been reviewed and the Amended Technical and Administrative Review Checklist is complete, the reviewing analyst affixes their electronic signature and the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate tab will open in the Amended Calibration Certificate Workbook.
6. The reviewing analyst affixes their electronic signature to the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate, and saves the Amended Calibration Certificate Workbook.
7. The Amended Calibration Certificate Workbook is returned to the calibration analyst for authorization and issuance of the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate.
- D. Issuing the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-10)
- 1. Upon completion of the technical and administrative review, the calibration analyst completes a final review to ensure that the original calibration was properly completed and that all of the information contained on the associated amended calibration records is accurate.
 - 2. The calibration analyst authorizes and issues the Amended Calibration Certificate Workbook by entering the date and affixing their electronic signature to the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate and then saving the Amended Calibration Certificate Workbook.
 - a) *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.*
- E. The Amended Calibration Certificate Workbook and any associated records are combined electronically into a single PDF and emailed to the BAL quality manager to be included in the Instrument Calibration Record.
- F. Discrepancies Identified After the Amended Certificate is Issued
- 1. After the Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate has been authorized and issued, any discrepancies identified which are



related to the amended calibration procedure are brought to the attention of the calibration analyst(s), the BAL quality manager, and all other affected parties.

2. The DPS QI/QAP process is initiated to document the discrepancies and evaluate potential impacts to the validity of the tests conducted on the instrument.
 - a) *The Amended Calibration Certificate Workbook documentation (OSD-CAL-08, OSD-CAL-09, OSD-CAL-10) is not changed, altered, or discarded.*

10 Assuring the Quality of Calibration Results

- A. Quality control results for monitoring instrument calibrations undertaken are 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 is 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; and
 4. A documented examiner assessment program.

11 Examiner Assessment

11.1 General

- A. For the purposes of assessing technical supervisor competency and as a provision for maintaining technical supervisor certification, technical supervisors are required to participate in examiner assessments with results assessed by the OSD.
- B. Examiner assessments are comprised of proficiency test(s), intralaboratory comparisons, and/or interlaboratory comparisons.
 1. Once per calendar year, all certified technical supervisors complete a proficiency test.
 2. Intralaboratory comparisons or interlaboratory comparisons may be assigned at the discretion of the OSD.
- C. Examiner assessments are completed using a certified Intoxilyzer 9000 that was last calibrated by the technical supervisor within the current calendar year.
- D. DPS technical supervisors follow requirements specified in the DPS CLD Manual for monitoring the validity of results. The completion of the annual proficiency test additionally meets the proficiency testing requirement for DPS CLD accreditation purposes.
- E. Examiner assessment records are retained in accordance with the DPS Records Retention Schedule; a copy is made available on the DPS Breath Alcohol Laboratory website.

11.2 Proficiency Tests

- A. Proficiency tests are provided by an ISO/IEC 17043 accredited proficiency test supplier and approved for use by the OSD.



- B. Local technical supervisors provide documentation of completion to the BAL quality manager which includes, but is not limited to:
 - 1. Sample analysis results (i.e., ACA printouts);
 - 2. Proficiency provider data sheets (must include documentation of the participant code/webcode that identifies the participant submission); and
 - 3. Any additional documentation generated during the proficiency test, as applicable.
- C. DPS technical supervisors follow requirements specified in the DPS CLD Manual for proficiency testing.

11.3 Intralaboratory and Interlaboratory Comparisons

- A. The comparison test procedure, solution samples, and required documentation are provided to technical supervisors upon distribution of the test.
- B. Solution samples are comprised of CRMs (preferred practice) or solutions created and verified by the OSD.
 - 1. For CRMs, the solutions' certificates of analysis is retained by the OSD in an examiner assessment administrative record.
 - 2. For solutions created by the OSD, the solutions are analyzed on a calibrated instrument prior to distribution in order to determine the intended results. The analysis documentation is retained by the OSD in an examiner assessment administrative record.

11.4 Assessment of Results

- A. To pass the examiner assessment, the measured vapor concentration of the solution(s) must be within ± 0.0030 or 3%, whichever is greater, of the prescribed concentration(s).
 - 1. For proficiency test(s), the prescribed concentration is reported as the grand mean of the associated batch results.
 - 2. For intralaboratory and interlaboratory comparisons, the prescribed concentration is the certified vapor concentration of the CRM or the mean of the associated OSD analysis results.
- B. An Examiner Assessment Report (LAB-312), or electronic equivalent, is issued to each technical supervisor to document the assessment result and capture participant and management acknowledgement.
 - 1. Potential inconsistencies are evaluated in accordance with DPS CLD Manual policy.
 - 2. Results are designated as satisfactory on the assessment report if the results confirm the prescribed concentration (expected results have been obtained).
- C. Unsatisfactory results require the initiation of the DPS QI/QAP process that includes at least the following actions:
 - 1. The technical supervisor refrains from further calibration work until the examiner assessment resolution process has been completed;
 - 2. A review of a sampling of calibration work completed since the last demonstration of proficiency or competency;
 - 3. An entry on the Disclosure Form (LAB-302, or electronic equivalent), for DPS technical supervisors; and



4. The successful completion of an intralaboratory or interlaboratory comparison test provided by the OSD (i.e., second attempt).
 5. A final assessment of unsatisfactory remains for the proficiency despite correction or corrective action.
- D. In the event a technical supervisor is unable to obtain a satisfactory result on the subsequent intralaboratory or interlaboratory comparison test, the technical supervisor's certification is suspended by the scientific director.
1. For DPS technical supervisors, the suspension of work for cause process is also initiated.

11.5 Missed Examiner Assessments

- A. DPS technical supervisors follow the requirements for missed tests specified in the DPS CLD Manual for monitoring the validity of results.
- B. If a scheduled examiner assessment is not distributed to or completed by a local technical supervisor, an alternate examiner assessment may be considered by the OSD.
- C. Initiation of the DPS QI/QAP process occurs if the required annual proficiency test is missed, which may result in the suspension of the technical supervisor's certification by the scientific director.

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

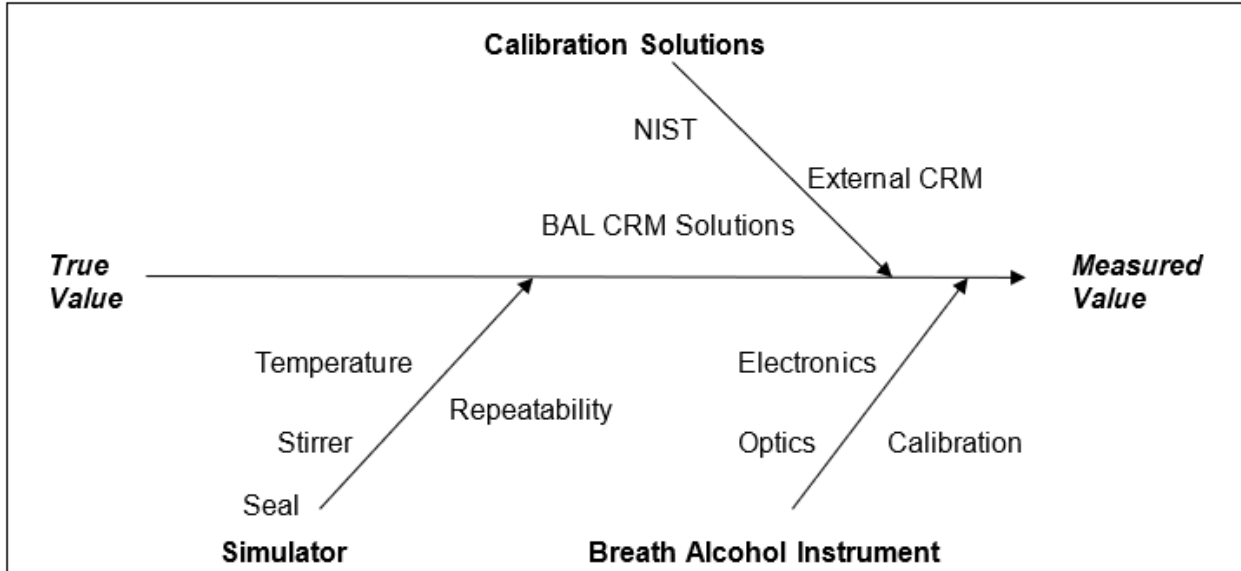


Figure 1: Cause and effect diagram for the calibration of the breath alcohol instrument

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 applicable 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; and*
 - 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 20 analyses (ACAs). Neither the 20 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 15 analyses are recorded in the Calibration Analyst Worksheet (OSD-CAL-04).



Variations in each of these factors may affect repeatability and contribute to uncertainty.

- 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 (\bar{X}) is calculated using the following.

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

Where:

\bar{X} = the mean of the ACA measurements

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:

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

- The relative standard deviation of a CRM ($RSD_{Lot\ COA}$) 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

- The relative standard deviation of a CRM as tested on an Intoxilyzer ($RSD_{Lot\ Intox}$) is calculated using the following equation.

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

Where:

SD = the standard deviation of the ACA measurements

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



12.4 Calculations and Number Rounding Used in the Calibration Certificate Workbook

- A. All calculations are performed using the approved and current version of the Calibration Certificate Workbook (OSD-WBK-01) (Microsoft® Excel). 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

$$RSD_{Comb} = \sqrt{RSD_{Lot\ COA}^2 + RSD_{Lot\ Intox}^2} \quad Eq. 1$$

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.

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

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.

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

- 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).



* Directory of Forms (1)

02 FORMS

DIRECTORY OF FORMS

	Document Name	FRN
1	Calibration Notes	OSD-CAL-03
2	Calibration Analyst Worksheet ¹	OSD-CAL-04
3	Technical and Administrative Review Checklist ¹	OSD-CAL-05
4	Evidential Breath Alcohol Testing Instrument Calibration Certificate ¹	OSD-CAL-06
5	Amended Calibration Analyst Worksheet ¹	OSD-CAL-08
6	Amended Technical and Administrative Review Checklist ¹	OSD-CAL-09
7	Amended Evidential Breath Alcohol Testing Instrument Calibration Certificate ¹	OSD-CAL-10

¹ Within OSD-WBK-01

DIRECTORY OF WORKBOOKS

	Document Name	FRN
1	Calibration Supplement	OSD-CAL-07
2	Calibration Certificate Workbook / Amended Calibration Certificate Workbook	OSD-WBK-01