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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
10/02/2023	**Revision:** Sections 3-4, 6-9, 11-12 **New:** Section 13
10/01/2024	**Revision:** Sections 2-3, 5, 7-9, 11-13

ACTIVE DEVIATIONS

This list reflects deviations that are active as of 10/1/2024.

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

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. Also referred to as a calibration adjust, calibration adjustment, or auto cal.

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, 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 DPS 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 reference sample 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
Dev	Deviation
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
Rel	Relative
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 calibration analyst's handwritten initials, signature, or electronic equivalent are on all page(s) which represent their work.

C. 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.

D. 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.

E. 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.

5 Equipment

5.1 Significant Equipment

A. NIST-Traceable Thermometer

1. A NIST-traceable thermometer is used to verify proper operational temperatures of simulators used in the instrument calibration procedure.
2. NIST-traceable thermometer(s) are maintained in the technical supervisor's calibration laboratory, which has limited access.
   a) *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.6.b.iii** is required prior to using the thermometer in calibration work.*

3. Reasonable care is taken in the handling and storage of NIST-traceable thermometer(s) in order to avoid extreme temperatures, shock, or breakage.
4. Refer to the manufacturer's instructions for general operating information, as applicable.
5. Maintenance and Repair
   a) *Thermometers are kept clean at all times.*
   b) *Replace the battery, as needed.*
   c) *In the event of a broken power supply cable, thermometers may be submitted to the BAL electronics technician for repair.*
   d) *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.6.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.*
6. Calibration and Performance Verification
   a) *NIST-traceable thermometers are calibrated by an approved supplier and are suitable for use for a period of one year from the date of calibration (i.e., one year calibration interval).*
      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. *Non-DPS 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.

7. 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 *OSD-TST-01 – Standard Operating Procedures: Evidential Breath Alcohol Testing* chapter of the OSD Testing Manual for information pertaining to simulator maintenance records.
4. Refer to the manufacturer's instructions for general operating information, as applicable.

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

6.1 Receipt and Storage

A. RMs and CRMs provided by the DPS CRM Laboratory are:

1. Uniquely identified by lot number;
2. Sealed to prevent contamination and tampering; and
3. Valid and approved for use as defined in the associated RM product information sheet or CRM certificate of analysis.

B. Upon receipt of the RMs and CRMs, the bottles are stored at room temperature in a secured, limited access location.

C. The analyst ensures that the seal is intact prior to use in the calibration procedure.

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 CRM 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 RMs and CRMs used to perform instrument calibrations, the reference material product information sheets and the certificate of analysis records 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.*

7.2 Receiving the Instrument into the Calibration Laboratory

A. The date an instrument is received into the calibration laboratory is defined as the date when any portion of the calibration procedure is started.

1. An instrument exits the calibration laboratory when the calibration procedure is completed (e.g., issuance of calibration certificate or calibration failure).

B. 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;
3. The laboratory name and address (i.e., the laboratory where the calibration is performed);
4. The customer name and address (i.e., the laboratory responsible for the management of the instrument); and
5. The operating condition of the instrument (refer to **Section 7.2 C.**).
6. Note: For DPS calibration laboratories, the laboratory and/or customer name includes the designated laboratory location (e.g., DPS Breath Alcohol Laboratory – San Angelo).

C. 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 (refer to **Section 7.4**).
   a) *Subsequent calibration attempts may not occur until the defects have been remediated or eliminated.*
   b) *Refer to the* OSD-TST-01 – Standard Operating Procedures: Evidential Breath Alcohol Testing *chapter 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 of 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°C ± 0.20°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°C ± 0.20°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°± 0.20°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 (OSD-CAL-03); and
2. The label from the reference solution bottle.

E. The calibration analyst initials/signs the ACA printout.

F. The calibration procedure is successfully completed before an Evidential Breath Alcohol Testing Instrument Calibration Certificate (OSD-CAL-06) is issued.

7.4 Termination of the Calibration Procedure (Calibration Failure)

A. It may be 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.

B. Completion of the Calibration Analyst Worksheet (OSD-CAL-04)

1. All information and ACA data generated up to the point of termination is entered into the Calibration Analyst Worksheet (OSD-CAL-04).
    a) *The first 5 ACA results for each reference solution are not recorded on the Calibration Analyst Worksheet, consistent with the calibration procedure (refer to 8.2 B.). In the event the calibration procedure is terminated prior to the 6th ACA result, no results are entered.*
2. The reason for the termination (i.e., unsuccessful attempt or calibration failure) is documented on the Calibration Analyst Worksheet (OSD-CAL-04).
3. The “Calibration Analyst” and “Date Analysis Completed” fields are additionally completed.
    a) *The “Date Analysis Completed” on the Calibration Analyst Worksheet is the date on which the last ACA of the terminated calibration procedure is performed.*
4. The calibration analyst affixes their electronic signature to the completed Calibration Analyst Worksheet (OSD-CAL-04) PDF.

C. All technical records generated up to the point of termination are combined electronically into a single PDF document and emailed to the BAL Quality Manager to be included in the Instrument Calibration Record, including:

1. The signed Calibration Analyst Worksheet (OSD-CAL-04); and
2. The ACA printouts which include the appropriate Calibration Notes label (OSD-CAL-03) and the label from the reference solution bottle.
3. If Calibration Notes label(s) are partially completed, and no ACA results are generated, the Calibration Notes label(s) are attached to a blank page(s) with the label(s) from the reference solution bottle(s).
    a) *The calibration analyst signs and dates the partial Calibration Notes label(s) (OSD-CAL-03).*
    b) *The instrument serial number, calibration analyst initials/signature, and date are recorded on the page(s).*

7.5 Corrections or Amendments to Records

A. When corrections or amendments are made to the Calibration Notes label (OSD-CAL-03) 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.
    a) *It is only acceptable to make additions without the need for the calibration analyst to initial and date the record if the additions are made prior to submitting the record for technical and administrative review.*
3. When corrections or amendments involve both an addition and a deletion, the correct information is added near the deletion, where possible.
4. If a label has content that must be corrected, the original label will not be obliterated or obscured using the corrected label. The incorrect label is crossed out by single line strikethrough with handwritten initials of the person making the alteration and the date. The new label is affixed in such a way so that the previous label remains legible.
5. All alterations or amendments made to records generated and/or maintained in an electronic form are tracked to the same extent as required for printed and/or handwritten records.

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.

1. The Calibration Certificate Workbook restricts entry or alteration of the information contained on the Calibration Analyst Worksheet (OSD-CAL-04) to the calibration analyst via the provided password.

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.

1. Measurement results (i.e., ACA measurements) are reported by the instrument 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 reported to four decimal places (rounded).

3. The standard deviation of the nominal 0.040, 0.080, and 0.150 g/210 L CRMs is reported 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 reported 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 uploads the data to COBRA and submits the Calibration Certificate Workbook and all associated ACA printouts to a reviewing analyst for technical and administrative review.

1. In the event the COBRA upload is unsuccessful, it is recommended that a "Download All" is attempted in order to remediate the issue(s). If the COBRA upload is still unsuccessful, the calibration procedure is terminated due to the inability to meet the data technical review requirements (refer to **Section 7.4**).

G. 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.

1. The technical and administrative review includes both a review of the submitted calibration records and associated COBRA data.

2. COBRA data is reviewed to:

a) Ascertain information pertaining to any calibration adjustment performed since the previous calibration certificate date; and

b) Ensure that the calibration procedure was properly completed in regard to the requirement for each reference solution to only be used once to provide 20 consecutive ACA measurements.

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 (OSD-CAL-03) follow the requirements specified in **Section 7.5**.

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 instrument is labeled with information pertaining to the current calibration using the Instrument Calibration label (OSD-CAL-11) which includes the following information:

1. The name of the breath alcohol calibration laboratory which performed the work (refer to **Section 7.2 B.3.**);

2. The serial number of the instrument;

3. The date of the current calibration; and

a) *The date of the current calibration is the "Date Analysis Completed" as provided on the Calibration Analyst Worksheet (OSD-CAL-04).*

4. A reference to the calibration certificate issued in respect to the calibration.

D. 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.

E. The instrument may not be placed into evidential testing service until the calibration certificate has been issued.

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;

v. Reason for calibration; and

vi. 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 (OSD-CAL-03), 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 7.5**.
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 (OSD-CAL-03) follow the requirements specified in **Section 7.5**.*

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. Non-DPS 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);
3. Any additional documentation generated during the proficiency test, as applicable; and
4. The individual report provided by the proficiency test supplier, documenting the participant's submitted results.

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), solutions created and verified by the OSD, or previously unused proficiency test samples.

1. For CRMs, the solutions' certificate 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.
3. For previously unused proficiency test samples, the associated proficiency test provider summary report is retained by the OSD in an examiner assessment administrative record.

a) Previously unused proficiency test samples may additionally be analyzed on a calibrated instrument prior to distribution in order to verify 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 tests, the prescribed concentration is reported as the grand mean of the associated consensus results.
2. For intralaboratory and interlaboratory comparisons, the prescribed concentration is:

a) The certified vapor concentration of the CRM;

b) The mean of the associated OSD analysis results; or

c) *The grand mean of the associated consensus results as reported by the proficiency test provider.*

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 in 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 non-DPS 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. Measurement uncertainty is determined for breath alcohol instrument calibration at each ethanol-water reference solution, per instrument, per calibration activity.

B. The measurand is defined as the concentration of ethanol expressed as g/210 L.

C. Documentation pertaining to the estimation and evaluation of measurement uncertainty is comprised of each individual breath alcohol instrument calibration certificate in conjunction with the applicable procedures/policies specified in this manual.

D. The measurement uncertainty evaluation process undergoes periodic evaluation at least annually during routine document revision.

1. Updates to the measurement uncertainty evaluation process may depend on, but not be limited to, the following factors:

a) Changes to the breath alcohol instrument calibration method or measurement process;

b) Changes to the measurement uncertainty budget items or uncertainty components, which may include changes to reference standards, equipment, and/or personnel;

c) Changes to the frequency with which the calibration method is performed; and

d) BAL administrative decisions.

12.2 Uncertainty Components

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, the measurement procedure, constants, and repeatability. Multiple sources may contribute to a single uncertainty component.

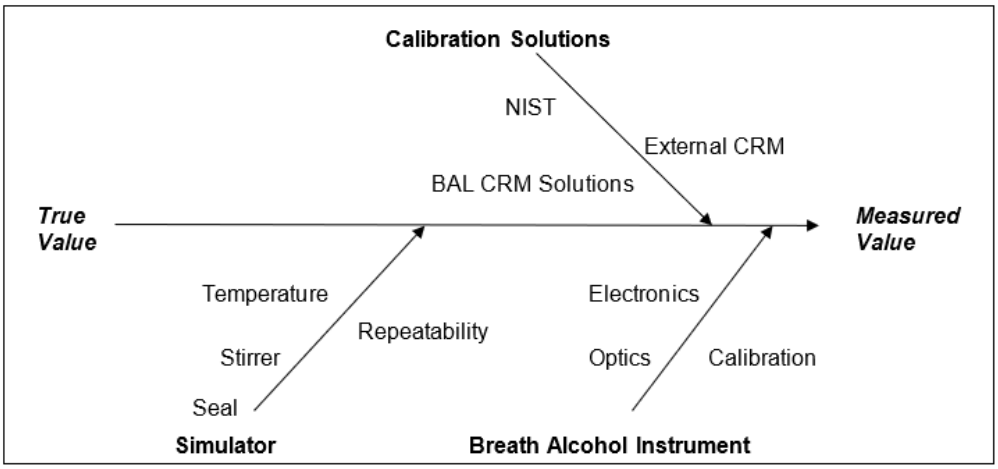

Figure 1: Cause and effect diagram for the calibration of the breath alcohol instrument

2. Human factors (e.g., inter-analyst variation, training, and experience), environmental conditions (e.g., temperature, radio frequency interference, ambient air contaminants), and variability of the instrument over time are adequately represented by the evaluation of the process repeatability data.

3. The simulator temperature is verified before and after the analysis of each RM and CRM, using a NIST-traceable thermometer, to ensure the temperature stability during analysis.

B. Calibration Solutions

1. A purified water RM and multiple ethanol-water CRMs, obtained from the DPS CRM Laboratory, are analyzed during the calibration of the breath alcohol instrument.

2. The vapor concentration and combined standard uncertainty of each CRM (i.e., SD_{Comb}), traceable to the SI through an unbroken chain of comparisons to a NIST Standard Reference Material, is obtained from the applicable certificate of analysis.

C. 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.

4. The variability of the ACA measurements is represented through calculation of the standard deviation (SD_{Intox}) from the repeated testing of the CRM. The ACA measurement data is representative of the performance of the breath alcohol instrument.

12.3 Calculations and Reporting

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

B. All values are rounded to the appropriate number of reported decimal places at the completion of the calculation using conventional rounding:

1. Means are reported to four decimal places.

2. Standard deviations are reported to five decimal places.

3. Rounded means and expanded uncertainties are reported to three decimal places.

4. Combined standard uncertainties are not reported.

C. The mean of the ethanol concentration for each ethanol-water CRM as analyzed on the breath test instrument ($Mean_{Intox}$) is calculated using the following equation:

$$Mean_{Intox} = \frac{1}{n}\sum x_i \qquad \textit{Eq. 1}$$

Where:

n = the number of ACA measurements (i.e., sample size)

x_i = each individual ACA measurement result

D. The standard deviation of the ethanol concentration for each ethanol-water CRM as analyzed on the breath test instrument (SD_{Intox}) is calculated using the following equation:

$$SD_{Intox} = \sqrt{\frac{\sum(x_i - Mean_{Intox})^2}{n-1}} \qquad \textit{Eq. 2}$$

Where:

$Mean_{Intox}$ = the mean of the ACA measurements

n = the number of measurements (i.e., sample size)

x_i = each individual ACA measurement result

E. The combined standard uncertainty of the ethanol concentration for each of the ethanol-water CRMs ($u_C Intox$) is an estimated standard deviation that characterizes the dispersion of the values that could reasonably be attributed to the measurand and is calculated using the root sum of the squares method, using the following equation:

$$u_C Intox = \sqrt{SD_{Intox}{}^2 + SD_{Comb}{}^2} \qquad \textit{Eq. 3}$$

Where:

SD_{Intox} = the standard deviation of the ACA measurements

SD_{Comb} = the combined standard uncertainty of the CRM obtained from the applicable CRM certificate of analysis

F. The expanded uncertainty for each of the ethanol-water CRMs as analyzed on the breath test instrument (U_{Intox}) is calculated using the following equation:

$$U_{Intox} = u_C Intox \times k \qquad \textit{Eq. 4}$$

Where:

$u_C Intox$ = the combined standard uncertainty of the ethanol concentration of the CRM as analyzed on the breath test instrument

k = coverage factor determined using a Student's t-distribution based on the degrees of freedom to provide the desired level of confidence

1. Expanded uncertainties are reported at the 99% confidence level, based on a two-tailed evaluation using *n*-1 degrees of freedom, where *n* is the number of measurements (i.e., sample size).

G. The measurement uncertainty of the breath alcohol instrument calibration procedure for each of the ethanol-water CRMs is expressed as the rounded mean of the ACA measurement results ± expanded uncertainty at the 99% level (*k*=2.977).

13 Literature References or Supporting Documentation

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02 FORMS

DIRECTORY OF FORMS

	Document Name	FRN
1	Calibration Notes *(Label)*	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
8	Instrument Calibration *(Label)*	OSD-CAL-11

[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