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REVISION HISTORY

Effective Date	Brief Description of Change(s)
5/25/2022	Original Issue Previous revision history for individual chapters included in archived documents
10/02/2023	**Revision:** Sections 2 – 6 **New:** Section 8
10/01/2024	**Revision:** Unit 01

ACTIVE DEVIATIONS

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

Deviation	Related Chapter(s)	Deviation From

01 OVERVIEW

OSD-TST-01 STANDARD OPERATING PROCEDURES: EVIDENTIAL BREATH ALCOHOL TESTING

1 Scope

To describe evidential breath alcohol testing program policies and procedures for instrument testing and location management, instrument calibration adjustment, solution preparation and use, and record keeping.

2 Related Documents

CLD Manual: Forensic Disclosure and Compliance Policy

CLD Manual: Court Testimony and Monitoring

CRM Manual: Reagents and Standards (CRM-02-02)

CRM Manual: Use of the CRM Laboratory for the Production of Breath Alcohol Testing Reference Solutions (CRM-02-08)

Texas Breath Alcohol Program Calibration Manual: OSD-CAL-01 – Standard Operating Procedures: Evidential Breath Alcohol Instrument Calibration

3 Terms

3.1 Definitions

ABA – An instrument testing sequence which analyzes a series of air blanks (A) and breath samples (B).

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.

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.

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.

Should – An expectation unless specific, non-routine circumstances prevent compliance.

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.

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

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

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

3.2 Abbreviations

ACE	Acetone
COBRA	Computer Online BReath Archive
Dev	Deviation**DPS** Texas Department of Public Safety
ETOH	Ethanol (ethyl alcohol)
H_2O	Water
IRPCM	Infra-Red Preamp Control Module
ITP	Internal Test Procedure
NIST	National Institute of Standards and Technology
OSD	Office of the Scientific Director
QA	Quality Assurance
Rel	Relative
RF, RFI	Radio frequency, radio frequency interference
SI	Système International d'Unités (International System of Units)
SN	Serial number
SRM	Standard reference material
STD	Standard
STK	Stock

4 Instrument and Location Management

4.1 Instrument Labeling

A. Non-evidential instruments are clearly labeled to prevent unintended use in evidential subject testing.

B. Evidential instruments located or maintained in the technical supervisor's laboratory are labeled with an indication of the instrument status using the Instrument Testing Status label (OSD-TST-04) which contains the following information:

1. Instrument serial number;
2. Status (i.e., ready for service / not ready for service); and
3. Technical supervisor name and date of status update.

C. Instruments located in an evidential testing location are labeled with information pertaining to the current (most recent) instrument calibration using the Instrument Calibration label (OSD-CAL-11).

4.2 Instrument Inspections

A. General Requirements

1. An instrument inspection is only conducted at the evidential testing location and only by a certified technical supervisor.
2. An instrument inspection is performed each time an instrument is placed into or returned to evidential service at the evidential testing location.

3. Each active testing location should have an inspection performed at least once per calendar month.

a) If an inspection is not completed during a calendar month, the evidentiary tests conducted during that month are not automatically invalidated.

i. The technical supervisor makes notification to the appropriate BAL regional manager regarding an instrument inspection that was not completed.

ii. Potential impacts to the validity of the tests conducted on the instrument are determined by the Scientific Director.

iii. Documentation regarding the missed inspection and evaluation of potential impacts are retained in the instrument maintenance record.

b) More than one inspection may be performed in any given month.

4. An instrument inspection includes an evaluation of not only the instrument, but the associated devices and the test environment.

B. Inspection Procedure

a) During an inspection, the technical supervisor conducts a breath test. Select "Other" as the type of test and enter "QA INSPECTION" in the subject last name field.

2. Acceptance Criteria

a) In order for the test to be considered properly completed, the analytical report meets the following criteria:

i. The analytical report is complete;

ii. All air blank results are 0.000;

iii. Both subject results are 0.000; and

iv. The analytical report is signed by the technical supervisor.

4.3 Use of Breath Alcohol Testing Reference Solutions

A. The breath alcohol testing reference solution at each active evidential testing location should be replaced with a new solution at least once per calendar month.

B. Upon replacement, a properly completed inspection is performed, and the lot number of the new solution is recorded in the subject name field of the inspection.

4.4 Instrument Calibration Adjustment

A. General

1. Breath alcohol instruments are adjusted due to maintenance, repair, or at the discretion of the technical supervisor.

2. Breath alcohol instruments which have been adjusted by non-certified technical supervisors must be readjusted and calibrated by a certified technical supervisor prior to evidential testing use (refer to OSD-CAL-01).

3. Laboratory-prepared solution nominal values used for calibration adjustment are selected to produce a linear response on the instrument. Linearity is confirmed through the successful completion of the instrument calibration procedure (refer to OSD-CAL-01).

B. Procedure

1. Approximately 500 mL of purified water and four non-zero laboratory-prepared solutions are used to perform the calibration adjust procedure (refer to **Section 5.4**).

   a) During the adjustment procedure, the 500 mL of purified water is analyzed twice (at the beginning and end of the procedure).

2. Each solution is placed into a simulator and pre-heated to approximately 34.00ºC prior to analysis.

3. Start the calibration adjust procedure on the instrument:

   a) Input "4" for the "number of solutions to be run (excluding water)."

   b) Input the solution nominal values to be analyzed, using three decimal places; and

   c) Follow the prompts on the instrument for the analysis of each solution until the process is complete.

      i. When prompted for "Dry Gas Calibration?", select "No."

4. The adjustment procedure must be started and completed on the same day.

5 Reagents and Solutions

5.1 200 Proof Ethanol

A. General Requirements

1. ACS/USP grade 200 proof ethanol, certified by the manufacturer to contain at least 99.5% ethanol, or equivalent is required for use.

2. 200 proof ethanol is purchased and maintained by the DPS CRM Laboratory and distributed for use.

3. A copy of the manufacturer certificate of analysis is provided to technical supervisors upon distribution.

4. 200 proof ethanol lots may not be distributed for technical supervisor use until verification has been completed by the DPS CRM Laboratory (refer to CRM-02-02).

B. Storage, Expiration, and Disposal

1. 200 proof ethanol is stored at room temperature, away from direct sunlight and heat, in a manner that prevents or limits evaporation.

2. 200 proof ethanol expires three years from the manufacture date provided on the manufacturer's certificate of analysis. The DPS CRM Laboratory provides the expiration date on each 200 proof ethanol container for technical supervisor awareness.

3. 200 proof ethanol is considered to be non-hazardous material under normal conditions of use and may be discarded via drain disposal without additional special considerations.

5.2 Ethanol Stock Solutions

A. Ethanol stock solutions are used in the laboratory preparation of adjustment solutions and may additionally be used in the preparation of solutions for instrument evaluation purposes.

B. Preparation Procedure

1. In a 1000 mL volumetric flask, add a small amount of purified water.
2. Using a volumetric pipette, add 78 mL of unexpired 200 proof ethanol to the flask.
3. Add purified water to the 1000 mL mark of the flask.
4. Stopper the flask and gently mix to combine.

C. Identification and Labeling

1. Ethanol stock solutions are labeled with, at a minimum, the solution identity (e.g., ethanol stock solution), the solution lot number, and solution expiration date.
2. Ethanol stock solution lot numbers utilize a **STK-MMDDYY-[TS Cert #]** format, where MMDDYY is the date of preparation and [TS Cert #] is the four-digit certification number of the technical supervisor who prepared the solution.
    a) *For example, an ethanol stock solution produced on August 5, 2022, will have the lot number STK-080522-0001.*
3. Ethanol stock solution preparations are recorded on the Ethanol Stock Solution Preparation Log (OSD-TST-05).

D. Storage, Expiration, and Disposal

1. Ethanol stock solutions are stored at room temperature, away from direct sunlight and heat, in a manner that prevents or limits evaporation. Alternatively, ethanol stock solutions may be stored refrigerated.
2. Ethanol stock solutions expire no later than the end of the month, 6 months from the date of preparation.
    a) *For example, an ethanol stock solution prepared on February 27th will expire at 11:59 PM on August 31st.*
3. Ethanol stock solutions are considered to be non-hazardous material under normal conditions of use and may be discarded via drain disposal without additional special considerations.

5.3 1:20 Acetone Solutions

A. 1:20 acetone solutions are used for instrument certification and instrument evaluation purposes.

B. 1:20 acetone solutions are prepared by the DPS CRM Laboratory and distributed for use.

C. There are no verification requirements for the use of 1:20 acetone solutions.

D. Storage, Expiration, and Disposal

1. 1:20 acetone solutions are stored at room temperature, away from direct sunlight and heat, in a manner that prevents or limits evaporation.
2. 1:20 acetone solutions expire 5 years from the date of preparation. The DPS CRM Laboratory provides the expiration date on each 1:20 acetone solution container for technical supervisor awareness.
3. 1:20 acetone solutions are considered to be non-hazardous material under normal conditions of use and may be discarded via drain disposal without additional special considerations.

5.4 Laboratory-Prepared Solutions

A. Laboratory-prepared solutions are used for calibration adjustment or instrument evaluation purposes. Laboratory-prepared solutions are typically dilute ethanol-water solutions but may contain additional components depending on the evaluation being performed (e.g., 1:20 acetone solution).

B. Laboratory-prepared solutions may only be used one time, on the day of preparation, and are discarded after use.

1. Laboratory-prepared solutions that are not used on the day of preparation are discarded.
2. Laboratory-prepared solutions are considered to be non-hazardous material under normal conditions of use and may be discarded via drain disposal without additional special considerations.

C. Preparation Procedure

1. In a 500 mL volumetric flask, add a small amount of purified water.
2. Using a volumetric pipette, add the necessary amount of unexpired ethanol stock solution required to obtain the desired solution concentration to the flask.
3. Add any additional components, as necessary.
   a) *Note: Laboratory-prepared solutions created for calibration adjustment do not contain any additional components.*
4. Add purified water to the 500 mL mark of the flask.
5. Stopper the flask and gently mix to combine.

D. Identification and Labeling

1. If a solution is maintained in the flask prior to use on the day of preparation, the flask is labeled with the identity of the solution (e.g., 0.300 g/210 L) and the preparer's initials.
2. Laboratory-prepared solution preparations are recorded on the applicable printout (e.g., adjustment, ACA / ABA, etc.) or in a maintenance addendum. The preparation details include, at a minimum:
   a) *The identity of the solution (e.g., the nominal value);*
   b) *Date of solution preparation;*
   c) *Ethanol stock solution lot number;*
   d) *Identification of any additional components used, including lot number, as applicable; and*
   e) *Identity of the preparer of the laboratory-prepared solution.*

5.5 Breath Alcohol Testing Reference Solutions

A. Breath alcohol testing reference solutions are a specific set of solutions which require traceability and are primarily utilized at evidential testing locations for breath alcohol subject testing and inspection purposes.

B. Preparation

1. DPS technical supervisors utilize the DPS CRM Laboratory for the preparation of breath alcohol testing reference solutions. Refer to CRM-02-08 for specific preparation instructions.
2. Non-DPS technical supervisors may utilize the DPS CRM Laboratory for the preparation of breath alcohol testing reference solutions upon request. Alternatively, non-DPS technical supervisors may prepare breath alcohol testing reference solutions in their laboratory, following the requirements provided for identification, labeling, storage, expiration, and disposal.

C. Identification and Labeling

1. Breath alcohol testing reference solutions are uniquely identified by lot number.
2. Each container of breath alcohol testing reference solution is labeled with the:
   a) *Reference material producer;*
   b) *Lot number;*
   c) *Nominal value (i.e., 0.080 g/210 L);*
   d) *Expiration date; and*
   e) *Identification as a NIST-traceable reference material.*
3. For additional identification and labeling specifications for breath alcohol testing reference solutions prepared in the DPS CRM Laboratory, refer to CRM-02-08.

D. Storage, Expiration, and Disposal

1. Breath alcohol testing reference solutions are stored at room temperature, away from direct sunlight and heat, in a manner that prevents or limits evaporation.
2. Breath alcohol testing reference solutions expire no later than the end of the month, two years from the date of preparation.
   a) *For example, a breath alcohol testing reference solution prepared on December 15, 2019, will expire at 11:59 PM on December 31, 2021.*
3. Breath alcohol testing reference solutions are considered to be non-hazardous material under normal conditions of use and may be discarded via drain disposal without additional special considerations.

E. Breath Alcohol Testing Reference Solution Traceability

1. Metrological traceability is established for each breath alcohol testing reference solution lot by an unbroken chain of comparison to an externally provided certified reference material that is traceable to the SI through NIST (e.g., analytically verified against a NIST SRM).
2. The vapor concentration and uncertainty of the alcohol concentration of the breath alcohol testing reference solution is determined using the Solution Traceability Worksheet (OSD-TST-02) for each lot.
3. Procedure
   a) *Using an unexpired 0.080 g/210 L CRM and three samples of the breath alcohol testing reference solution, conduct the following:*
      i. *Place the solution into the simulator and heat to 34.00°C ± 0.20°C;*

ii. Connect the simulator to the instrument and conduct twenty consecutive ACAs; and

iii. Enter the last fifteen ACAs of the solution into the applicable column of the Solution Traceability Worksheet.

b) The 0.080 g/210 L CRM and the three samples of the breath alcohol testing reference solution may be run in any order.

c) When the Solution Traceability Worksheet is complete, the technical supervisor affixes their electronic signature and sends the worksheet to a reviewing analyst for technical/administrative review, along with the following:

i. Instrument ACA printouts;

ii. Breath Alcohol Testing Reference Solution Lot Preparation Notes (LAB-CRM-15), as applicable; and

iii. Ethanol certificate of analysis.

d) Discrepancies noted during the technical/administrative review are brought to the attention of the technical supervisor and resolution takes place prior to use of the solution at an evidential testing location(s).

e) When the technical/administrative review is complete, the reviewing analyst affixes their electronic signature to the Solution Traceability Worksheet and returns the completed documentation to the technical supervisor.

4. Traceability Acceptance Criteria

a) The calculated vapor concentration of the breath alcohol testing reference solution must be within ±0.0030 when compared to the nominal value (0.080 g/210 L).

6 Technical Records

6.1 General Requirements

A. The technical supervisor maintains all breath alcohol testing records (e.g., analytical report, instrument maintenance, solution, and simulator maintenance records, etc.) and fulfills the role of records custodian on behalf of DPS.

B. Records are maintained in paper and/or electronic form separate from the COBRA database.

C. All analytical reports are maintained regardless of whether generated in the laboratory or at a testing location.

D. Records are organized and detailed enough to allow another technical supervisor to render an opinion.

E. Where abbreviations or codes are used, the meaning of the abbreviations or codes is defined in this manual or in each associated record (e.g., instrument maintenance record, simulator maintenance record, or reference solution record).

F. All breath alcohol testing records are retained by DPS per the DPS Records Retention Schedule.

G. Records are made available on the DPS Breath Alcohol Laboratory website for convenience. Subject dates of birth are excluded from the publicly available records, if present.

6.2 Analytical Report Records

A. Analytical reports are uniquely identified by report number and date.

B. No alterations are made to the data on an analytical report.

C. If an analytical report is missing, the technical supervisor makes a reasonable effort to retrieve the missing record. If the record is permanently lost, documentation pertaining to the missing record is retained.

6.3 Instrument Maintenance Records

A. Instruments are uniquely identified by serial number.

B. Instrument maintenance records contain the required technical records generated during an inspection, evaluation, or maintenance/repair of each certified instrument. Types of documentation which may be found in an instrument maintenance record includes, but is not limited to:

1. Records generated by the technical supervisor during an inspection, instrument installation, instrument removal, or laboratory practice test;
2. Calibration adjustment records and documentation of adjustment solutions used;
3. Flow calibration adjustment records;
4. Records for evaluations or maintenance/repairs completed by a technical supervisor, the DPS Breath Alcohol Electronics Laboratory, or the instrument manufacturer; and
5. Administrative records (e.g., addendums or maintenance notes), as applicable.

C. Instrument maintenance records include, but are not limited to:

1. Instrument serial number;
2. Date the inspection, evaluation, or maintenance/repair was performed;
3. Initials/signature or name of the individual who performed the inspection, evaluation, or maintenance/repair;
4. Documentation of what evaluation or maintenance/repair was performed, including the documentation of any solutions used in the evaluation; and
    a) *Examples of documentation include calibration adjustments, laboratory practice tests, and ACAs / ABAs performed to evaluate the instrument.*
    b) *Examples of solutions used in the evaluation include laboratory-prepared solutions, expired CRMs, breath alcohol testing reference solutions, etc.*
5. Reference to instrument specific deviation requests and/or quality incidents/quality action plans, as applicable.

6.4 Breath Alcohol Testing Reference Solution Records

A. Breath alcohol testing reference solutions are uniquely identified by lot number.

B. Breath alcohol testing reference solution records for each lot include, but are not limited to the:

1. Solution Traceability Worksheet (OSD-TST-02);
2. Instrument ACA printouts;

3. Breath Alcohol Testing Reference Solution Lot Preparation Notes (LAB-CRM-15), as applicable; and
4. Ethanol certificate of analysis.

C. Each page of the breath alcohol testing reference solution records for each lot contain the:

1. Lot number; and
2. Identity (e.g., signature or initials) of the individual(s) responsible for the lot preparation, analysis, and/or traceability.

6.5 Simulator Maintenance Records

A. Simulators are uniquely identified by serial number.

B. Simulator maintenance/repair is documented on the Simulator Maintenance Log (OSD-TST-03) which includes the following information:

1. Simulator model and serial number;
2. Date(s) the maintenance/repair action was performed;
3. Documentation of what maintenance/repair action was performed;
    a) *Documentation includes simulator status codes and messages encountered, as applicable.*
4. Name of the individual who performed the maintenance/repair action (e.g., action individual), if different than the technical supervisor who updated the log for the maintenance/repair action item;
5. Location of the simulator; and
6. Technical supervisor name and date the simulator maintenance log was updated for each maintenance/repair action item.

C. All supporting documentation pertaining to simulator maintenance/repair is additionally retained in the simulator maintenance record.

D. Refer to the manufacturer's instructions for detailed information on status codes, messages, and troubleshooting.

7 COBRA Database and Reports

A. COBRA is the approved database for collection, recording, reporting, and storage of data.

B. Breath alcohol personnel are prohibited from using or sharing COBRA information for personal interest, personal gain, or in ways not otherwise authorized for the performance of their assigned duties.

C. Modification or creation of COBRA reports

1. All breath alcohol personnel may recommend changes to report formats or suggest the creation of new reports.
2. Any recommended changes to reports are submitted in writing to the Scientific Director.
3. Once approved, only authorized users are able to create or modify COBRA reports.

8 Testimony and Court Preparation

8.1 General Requirements

A. All technical supervisors are responsible for:

1. Accurately representing their education, training, experience, and areas of expertise;
2. Accurately and completely disclosing their involvement in the legal proceeding;
3. Testifying in a manner which is clear, straightforward, and objective;
4. Limiting testimony to information based on reliable, accurate, and factual information supported by the breath alcohol testing and/or calibration records and the breath alcohol scientific community;
5. Avoiding phrasing testimony in an ambiguous, biased, or misleading manner; and
6. Attempting to qualify their responses while testifying if a simple “yes” or “no” would be misleading to the judge or the jury.

B. DPS technical supervisors follow requirements specified in the DPS CLD Manual for personnel-specific disclosure and court testimony and monitoring.

8.2 Court Preparation

A. Technical supervisors may be asked to testify on a wide range of breath alcohol and other toxicology-related topics, which can include but is not limited to:

1. Breath alcohol subject testing;
2. Breath alcohol instrument calibration procedures;
3. Scientific principles regarding breath alcohol instrumentation;
4. Physiological effects of alcohol on the human body;
5. Retrograde extrapolation and Widmark calculations; and
6. Serum/whole blood conversions.

B. Each technical supervisor maintains a professional obligation and responsibility to adequately prepare for court testimony.

1. At a minimum, preparation includes a review of relevant:
   a) *Breath alcohol testing subject records;*
   b) *Operator certificate records;*
   c) *Instrument calibration records;*
   d) *Instrument maintenance records; and*
   e) *Procedures, deviations, and quality incidents/corrective actions.*
2. Other records and information which may also be considered for review:
   a) *Simulator maintenance records;*
   b) *Reference solution records;*
   c) *Associated validation records;*
   d) *Technical supervisor training records;*

e) Current predicate questions for DWI/traffic offenses; and

f) Relevant scientific literature.

C. Requests for a pre-trial conference are recommended in order to better understand the testimony scope, limitations, and discuss any disclosure-related issues prior to testimony.

9 Literature References or Supporting Documentation

Guth Laboratories, Inc. *Wet Simulator Model 12V500 Operator's Manual.* Revision 1F, 2015.

02 FORMS

DIRECTORY OF FORMS

	Document Name	FRN
1	Simulator Maintenance Log	OSD-TST-03
2	Instrument Testing Status *(Label)*	OSD-TST-04
3	Ethanol Stock Solution Preparation Log	OSD-TST-05

DIRECTORY OF WORKBOOKS

OSD

	Document Name	FRN
1	Solution Traceability Worksheet	OSD-TST-02