



## **STANDARD OPERATING PROCEDURES: EVIDENTIAL BREATH ALCOHOL TESTING**

### **1 Scope**

To describe evidential breath alcohol testing policies and procedures for testing location management, record keeping, and Technical Supervisor proficiency testing.

### **2 Abbreviations**

<b>COBRA</b>	Computer Online BReath Archive
<b>CRM</b>	Certified Reference Material
<b>NIST</b>	United States National Institute of Standards and Technology
<b>OSD</b>	Office of the Scientific Director
<b>TXDPS</b>	Texas Department of Public Safety

### **3 Instrument and Testing Location Management**

- A. An instrument inspection may only be conducted at the evidential testing location.
- B. An inspection shall be conducted by a certified Technical Supervisor and includes not only the instrument, but the associated devices and the test environment.

#### **3.1 Instrumental Procedures**

- A. During an inspection of an Intoxilyzer 9000, the Technical Supervisor must conduct a breath test. Select "Other" as the type of test and enter "**QA INSPECTION**" in the subject last name field.
- B. In order for the test to be considered properly completed, the Analytical Report must have all of the following:
  - 1. The Analytical Report must be complete.
  - 2. All air blank results must be 0.000.
  - 3. Subject results must be 0.000.
  - 4. The signature of the Technical Supervisor.
- C. Additional tests or checks of the instrument and associated devices may be conducted as determined by the Technical Supervisor.
- D. An inspection shall be performed each time an instrument is placed into or returned to service.
- E. Each active testing location should have an inspection performed at least once per calendar month.
- F. The reference solution at each active evidential testing location should be replaced with a new solution at least once per calendar month. The lot number of the solution shall be recorded.
- G. The result of an analysis of a reference solution conducted on a certified instrument at an evidential testing location must agree within  $\pm 0.010$  g/210 L of the nominal value.



- H. The Technical Supervisor shall note in the Instrument Maintenance Record when an instrument is removed from service.
- I. Should an inspection not be completed during a calendar month, the tests conducted during that month shall not be automatically invalidated. The Technical Supervisor shall make notification to the appropriate Regional Manager regarding an instrument inspection that was not completed and a determination as to the validity of the tests conducted at the location shall be made by the Scientific Director. A Quality Incident/Quality Action Plan should be initiated, as appropriate.
- J. A Technical Supervisor may conduct an evidential subject test if the need arises. A Technical Supervisor is not required to maintain a separate certification as a breath test operator.

#### **4 Reference Solution Traceability**

The vapor concentration and uncertainty of the alcohol concentration of the reference solution shall be determined using the Solution Traceability Worksheet (OSD-TST-02) for each reference solution lot.

##### **4.1 Reference Solution Traceability Procedure**

- A. Place a 0.080 CRM into the simulator and heat to 34.0 °C ±0.2°C.
- B. Connect the simulator to the instrument and conduct twenty sequential ACAs.
- C. Repeat this procedure for the three samples of the reference solution.  
Note: The CRM and three samples of the reference solution may be run in any order.
- D. Enter the last fifteen ACAs of each solution into the applicable column of the Solution Traceability Worksheet.
- E. When the Solution Traceability Worksheet is complete, the Technical Supervisor shall sign and send to a reviewing analyst for administrative review.
- F. Discrepancies noted during the administrative review shall be brought to the attention of the Technical Supervisor and resolution taken place prior to use of the solution at evidential testing locations.
- G. When the administrative review is complete, the reviewing analyst shall affix their electronic signature to the Solution Traceability Worksheet.

##### **4.2 Reference Solution Traceability Acceptance Criteria**

- A. The nominal value of the reference solution shall be within ±0.0030 or 3%, whichever is greater, when compared to the vapor concentration of a NIST traceable standard.
- B. Reference solutions shall expire no later than the end of the month, two years from the year of preparation (i.e. a solution prepared 12/15/2019 shall expire at 11:59 PM on 12/31/2021).

#### **5 Technical Records**

The Technical Supervisor fulfills the role of custodian of all breath testing records on behalf of the Department. Analytical Report Records, Instrument Maintenance Records, Solution Records and Simulator Maintenance Records shall be retained for 100 years as per the Texas DPS Records Retention Schedule. These technical records shall be maintained in paper or electronic form separate from the COBRA database.



### **5.1 Analytical Report Records**

- A. All analytical reports, including analytical reports generated in the lab and testing locations, shall be maintained and stored by the Technical Supervisor.
- B. No alterations shall be made to the data on an analytical report.
- C. If an analytical report is missing, the Technical Supervisor should make a reasonable effort to retrieve the missing record. If the record is permanently lost, then the record shall be replaced with documentation in relation to the missing record.

### **5.2 Instrument Maintenance Records**

- A. Instrument Maintenance Records shall contain the required technical records generated during an inspection, evaluation, or maintenance/repair of each certified instrument which shall include but is not limited to:
  - 1. Records generated by the Technical Supervisor during an inspection, instrument installation, instrument removal, or laboratory practice test conducted by a Technical Supervisor.
  - 2. Calibration adjustment records and documentation of solutions used.
  - 3. Flow calibration adjustment records.
  - 4. Records for repairs completed by a Technical Supervisor, Breath Alcohol Electronics Laboratory, or the instrument manufacturer.
  - 5. Administrative records (i.e., addendums or maintenance notes), as applicable.
  - 6. Instrument specific corrective actions, as applicable.
- B. Instrument maintenance records should be organized and detailed enough to allow another Technical Supervisor to render an opinion in potential litigation concerning the maintenance history of any instrumentation.
- C. Instrument maintenance records shall be maintained by the Technical Supervisor and a copy made available on the Texas DPS Public Website.
- D. Instrument Maintenance Records shall include, at a minimum, the following:
  - 1. The name, serial number, or other identifying information of the instrument.
  - 2. Date the inspection, evaluation, or maintenance/repair was performed.
  - 3. The 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.
- E. If abbreviations or codes unique to the Technical Supervisor Area are used to document instrument maintenance/repair, the **Instrument Maintenance Records** shall contain a document clearly defining all abbreviations or codes used.

### **5.3 Solution Records**

- A. Solution Records pertaining to reference solutions used at evidential testing locations shall be maintained by the Technical Supervisor and a copy made available on the Texas DPS Public Website.



- B. These records shall include, but are not limited to:
  - 1. Solution Traceability Worksheet
  - 2. Instrument ACA printouts
  - 3. TS Reference Notes, as applicable
  - 4. Ethanol Certificate of Analysis
  - 5. Certified Reference Material Certificate of Analysis

#### **5.4 Simulator Maintenance Records**

- A. Simulator Maintenance Records pertaining to simulator maintenance and repairs shall be maintained by the Technical Supervisor and a copy made available on the Texas DPS Public Website.
- B. Simulator maintenance/repair records should be organized and detailed enough to allow another Technical Supervisor to render an opinion in potential litigation concerning the maintenance history and shall include, at a minimum, the following:
  - 1. The simulator serial number
  - 2. Date the maintenance/repair was performed
  - 3. The initials/signature or name of the individual who performed the maintenance/repair
  - 4. Documentation of what maintenance/repair was performed
  - 5. Location of simulator device
  - 6. If abbreviations or codes are used to document simulator maintenance, the Simulator Maintenance Records shall contain a document clearly defining all abbreviations or codes used.

### **6 COBRA Database Reports**

- A. COBRA is the approved database for collection, recording, reporting, and storage of data.
- B. Changes to COBRA Reports
  - 1. Any 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 Deputy Scientific Director (Calibration Laboratories).
  - 3. Once approved, only authorized users are able to create or modify COBRA reports.

### **7 Examiner Assessment**

- A. Once per calendar year all certified Technical Supervisors shall be competency tested on their ability to prepare a solution of a concentration prescribed by the OSD by means of interlaboratory comparison or intralaboratory comparison.
- B. The comparison test procedure shall be provided to each Technical Supervisor being tested.



**Texas Breath Alcohol Testing Program**  
*Office of the Scientific Director*  
*Directive from the Scientific Director*

OSD-TST-01  
Version: 07a  
Page 5 of 5

- 
- C. The prepared solution submitted by the Technical Supervisor shall be analyzed by the TXDPS CRM Laboratory.
  - D. To pass the comparison test, the vapor concentration of the solution shall be within  $\pm 0.0030$  or 3%, whichever is greater, of the prescribed concentration.
  - E. An Examiner Assessment Report (LAB-312) or electronic equivalent shall be issued to each Technical Supervisors to document the assessment and capture acknowledgement of participants of the outcome. Results are designated as "Satisfactory" on the assessment report if the expected results have been obtained.
  - F. For DPS Technical Supervisors, potential inconsistencies are evaluated in accordance with Texas DPS CLS Manual policy.
  - G. Local Technical Supervisors who are unsuccessful on their first attempt shall be asked to prepare another solution and given a new deadline for submission. If the Technical Supervisor is unsuccessful on the second attempt, they shall be asked to come to the OSD to demonstrate their ability to prepare solutions and provided remedial training as necessary. Any unsuccessful attempt shall be documented as a Quality Incident.



**Revision History**

Version #	Effective Date	Brief Description of Change(s)
00	03/01/2013	Original Issue; Standard Operating Guidelines for Technical Supervisors (1/30/2012)
00a	03/01/2013	Minor revisions- Administrative
01	09/27/2013	Major Revision: Sections 4, 6, 7
02	08/24/2015	Major Revision – All Sections
03	12/07/2015	Major Revision – Section 3.1
04	9/12/2016	Major Revision – Sections 3.1, 4, 5
05	09/01/2017	Major Revision – Sections 3.1 and 6
06	05/15/2019	Revision – Sections 2, 3, 4, 5, and 6
07	09/01/2020	Revision – All Sections New – Section 06 (COBRA Database Reports)
07a	6/01/2021	Administrative Revision – renumbered 3.2 (Instrumental Procedures) to 3.1