

# TEXAS DEPARTMENT OF PUBLIC SAFETY

## Breath Alcohol Laboratory

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## Standard Operating Guidelines for Technical Supervisors\*

### 1 Instrument and testing location management

**1.1** An official inspection by a Technical Supervisor can only be conducted at the evidential testing location. Each part of the inspection shall occur at the testing location and includes not only the instrument, but the associated equipment and the testing environment as a whole.

**1.1.1** The capability of the instrument to detect and subtract the effect of acetone shall be tested.

**1.1.1.1** A Technical Supervisor shall conduct a printed ACA test and introduce acetone sufficient to cause the instrument to flag the test as an interferent while producing a reference result of 0.000.

**1.1.2** A Technical Supervisor shall conduct a breath test in the normal subject testing mode used for evidential testing. The subject last name for this test is **INSP TS**.

**1.1.3** A Technical Supervisor may conduct additional tests or checks of the instrument and simulator as he/she deems necessary.

**1.2** A complete inspection (**1.1**) shall be performed by a Technical Supervisor each time an instrument is placed into or returned to service at a testing location.

**1.2.1** Each time an instrument is placed into or returned to service at a testing location, a Technical Supervisor shall handwrite on the INSP TS test record the

1. Date on which the instrument was originally certified.
2. Date on which the instrument was last autocaled.
3. Date on which the last Calibration Certificate was issued.

**1.3** If possible, a complete inspection (**1.1**) shall be performed each time an instrument is removed from service at a testing location.

\*The effective date of these Guidelines is March 1, 2012. Any changes which occur as a result of the implementation of these Guidelines apply only to breath tests that are done after March 1, 2012. Previous policies are not nullified and nothing herein should be construed as limiting or canceling the effect of old policies on tests done under these previous policies.

- 1.4 Each active testing location should have a complete inspection (1.1) personally conducted by a Technical Supervisor at least once per calendar month.
- 1.5 Once per calendar month the reference solution at each evidential testing location should be replaced with a new solution and the lot number of the solution should be recorded on the test record.
- 1.5.1 The result of an analysis of a reference solution conducted on a certified instrument at an evidential testing location must agree within  $\pm 0.01\text{g}/210\text{L}$  of the predicted value.
- 1.6 A certified Technical Supervisor may conduct an evidential subject test if the need arises. A certified Technical Supervisor is not required to maintain a separate certification as a breath test operator.
- 2 **Record keeping: Instrument Certificate File, Solution File, Subject File and Maintenance File**
- 2.1 Evidential Breath Alcohol Testing Instrument Certificates and Letters of Certification will be kept in the **Instrument Certificate File**.
- 2.1.1 Prior to being placed into evidential service an instrument must have either:
1. A current Calibration Certificate and an Evidential Breath Alcohol Testing Instrument Certificate issued by the Office of the Scientific Director or
  2. An instrument certification letter signed by the Scientific Director.
- 2.1.2 Upon receipt of the initial Calibration Certificate from a Technical Supervisor for each instrument, the Office of the Scientific Director will issue an Evidential Breath Alcohol Testing Instrument Certificate and it will be placed into the Technical Supervisor's **Instrument Certificate File**. Additional Evidential Breath Alcohol Testing Instrument Certificates will not be issued when subsequent Calibration Certificates are submitted for an instrument.
- 2.2 Records pertaining to reference solutions used at evidential testing locations shall be kept in the **Solution File**.
- 2.2.1 These documents shall include, but are not limited to, the Certificate of Analysis and documents necessary to establish the NIST traceability, unbiased estimate, nominal value and the combined uncertainty of the reference solution.
- 2.2.1.1 The predicted value of the reference shall be the nominal value of the solution.
- 2.2.1.2 The nominal value of a reference solution shall be within  $\pm 0.003$  or 3%, whichever is greater, of the unbiased estimate of the alcohol concentration in g/210 L as traceable to NIST.
- 2.2.1.3 The unbiased estimate and uncertainty of the alcohol concentration of the solution shall be determined via a procedure establishing traceability of measurement through an unbroken chain of comparisons to the National Institute of Standards and Technology (NIST), all having stated uncertainties.

- 2.3** The Technical Supervisor is the custodian of the breath test records for an assigned area. The Technical Supervisor shall collect and maintain a copy of each breath test record produced at the testing locations in the assigned area. These records shall be kept in the **Subject File**.
- 2.3.1** Evidential subject test records are produced by a certified instrument in an approved evidential testing location and contain a sequential test record number. Evidential subject test records shall not be produced unless the instrument is placed in an approved evidential testing location.
- 2.3.2** No alterations shall be made to the data on a printed subject test record.
- 2.3.3** If a test record is missing from the subject file, the Technical Supervisor shall make a reasonable effort to retrieve the missing record. If the record is permanently lost, then the record shall be replaced with the following information:
1. A non-evidential test record data printout generated from the database.
  2. A written explanation from the operator describing the reason for the lost record.
  3. Documentation of any other actions taken by the Technical Supervisor in relation to the missing record if necessary.
- 2.3.4** Test records produced in a laboratory are not evidential and shall not be kept in the **Subject File**.
- 2.4** Records pertaining to instrument and simulator maintenance and repairs and certificates of calibration for thermometers used in the calibration procedure shall be kept in the **Maintenance File**.
- 2.4.1** Maintenance records shall be organized and detailed enough to allow another Technical Supervisor to render an opinion in potential litigation concerning the maintenance history of any instrument. Completeness of maintenance records will be evaluated when the files are inspected by the Office of the Scientific Director.
- 2.4.2** The **Maintenance File** shall contain a copy of each **INSP TS** performed on each certified instrument in the assigned area **(1.1.2)**.
- 2.4.3** The **Maintenance File** shall contain a copy of each ACA test record generated as a part of an official inspection to demonstrate the ability of the instrument to detect and subtract acetone performed on each certified instrument in the assigned area **(1.1.1.1)**.
- 2.4.4** The **Maintenance File** shall contain notes regarding the major components of each certified instrument that are replaced or repaired.
- 2.4.4.1** If abbreviations or codes are used to document instrument maintenance and repairs, the **Maintenance File** shall contain a document clearly defining all abbreviations or codes used.
- 2.4.5** The **Maintenance File** shall contain notes regarding the major components of each simulator that is replaced or repaired.

**2.4.5.1** If abbreviations or codes are used to document simulator maintenance and repairs, the **Maintenance File** shall contain a document clearly defining all abbreviations or codes used.

**2.4.6** The **Maintenance File** shall contain the documentation establishing NIST traceability of thermometers used in the instrument calibration procedure.

**2.4.7** The **Maintenance File** shall contain any other documents kept in the normal course of business by the Technical Supervisor regarding the maintenance of certified instruments, simulators and thermometers.

### **3 Electronic data management**

**3.1** While the electronic data is not evidential, it is a powerful management tool and invaluable to the Texas Forensic Breath Alcohol Testing Program. It allows Technical Supervisors and the Office of the Scientific Director to monitor tests, operators and instruments. The data is extremely useful in the operator certification renewal process as well as for statistical analysis. The TS Monthly Activity Report, which is generated from Technical Supervisor instrument inspection data, is used by the Office of the Scientific Director to monitor required Technical Supervisor duties. To be useful the data must be standardized, accurate and complete. The Technical Supervisor shall assure that an electronic record exists in the database for each evidential subject record that is generated on an instrument. Data from tests that were not conducted in an approved evidential testing location shall not be kept in the subject test database.

**3.1.1** Instrument test data shall be transferred into the database management system via electronic means in all but the most exceptional circumstances.

**3.1.2** Test record data shall be manually entered into the database only in the event of instrument inoperability or data loss. The Technical Supervisor shall make every attempt to repair the instrument sufficiently to allow electronic data transfer. Manual data entry shall be considered a last resort. Should all attempts at electronic data transfer fail, notify the Office of the Scientific Director when tests are entered manually.

**3.2** The **TS Monthly Activity Report** records on-site maintenance inspections, reference solution changes, instrument data transfers to a Technical Supervisor's computer, and instrument data transfers to the Office of the Scientific Director for each Technical Supervisor Area.

**3.2.1** The **TS Monthly Activity Report** is to be submitted by the end of each calendar month.

**3.2.1.1** If the **TS Monthly Activity Report** is complete (no omissions) and does not require any additional information, press the send button in Black Mamba and then press the second send button, also in Black Mamba to send the report.

**3.2.1.2** If the **TS Monthly Activity Report** is missing data (has omissions) or requires additional information, a Technical Supervisor shall

1. Print the report and the memo that explains the missing data;
2. Scan the report, memo and all of the documents (INSP TS test records) necessary to reconcile the missing data into a single pdf document; and

3. Email the pdf document to the appropriate Regional Manager, not the OSD.

**3.2.1.3** If a Technical Supervisor Area has more than one Technical Supervisor, all Technical Supervisors in the Area will be held equally responsible for the report.

#### **4 Record retention and release**

**4.1** Test records produced at evidential testing locations shall be retained for five years plus the current year. Electronic records shall be retained indefinitely.

**4.2** Records shall be provided by the Technical Supervisor when requested through open records requests, discovery motions and subpoenas.

**4.2.1** A governmental record has the meaning assigned in Texas Government Code Sect. 552.002. Generally speaking, any document held in the possession of a Technical Supervisor is considered to be a government document. A record can be paper or electronic.

**4.3** Electronic data is important, but shall not substitute for printed evidential test records generated by a certified instrument in an approved evidential testing location.

**4.3.1** The breath alcohol test data stored in electronic form is insufficient to reproduce an evidential test. Air blank data is not stored and invalid tests produced during the last air blank appear valid in the database. Furthermore, the electronic data may be altered or fabricated entirely. For these reasons, it is recommended that only printed test records be submitted to comply with subpoenas, public open records requests and discovery motions. The Texas Forensic Breath Alcohol Testing Program recognizes only a printed evidential test record as evidence of a breath alcohol test. Other documents, such as those commonly generated by a database, are summaries or reports and are not evidence of a breath alcohol test.

**4.4** Database printouts do not always match the information contained on the actual printed test records. A disclaimer shall be included when database printouts are generated to comply with an open records requests, court orders and other such requests (**4.6.1**).

**4.5** Discovery motions signed by a judge and subpoenas shall be complied with by providing the actual printed records contained in the subject and maintenance files, unless a judge specifically requires the Technical Supervisor to generate a database report. A disclaimer shall be included when database printouts are generated to comply with orders from a judge (**4.6.1**).

**4.6** When a database printout of breath alcohol data is submitted to either the courts or to the public, the disclaimer included shall state:

**4.6.1 The information in this report is generated by a computer database. This data may not accurately reflect the information printed on evidential test records generated by the Intoxilyzer.**

## **5 Breath Alcohol Instrument Calibration**

- 5.1** For the purposes of this document, calibration is defined as a procedure that establishes the accuracy, precision, uncertainty of measurement and linear response of a breath alcohol measuring instrument by the measurement of known standards. It is not defined as any other action to repair, adjust, clean, autoclave or test an instrument. These actions are maintenance and are not part of the calibration procedure.

Instruments are to be calibrated in the Technical Supervisor's laboratory which has limited access. Handling and storage of instruments while in the laboratory shall be exercised with care in order to preserve their scientific integrity.

If the Technical Supervisor determines that an environmental or other condition might affect the quality of the calibration, the procedure shall be terminated and not resumed until the cause for concern has been eliminated.

- 5.2** The calibration procedure shall be performed under any of the following conditions:

1. Prior to an instrument being placed into evidential service for the first time.
2. The instrument has undergone a calibration adjustment.
3. As determined by the Technical Supervisor.

- 5.3** Calibrations must be performed using simulators which appear on the Breath Alcohol Laboratory approved simulator list. While conducting this procedure the Technical Supervisor shall complete the Calibration Analyst Worksheet.

- 5.3.1** The nominal reference values 0.000, 0.040, 0.080, 0.150, and 0.400 will be used to perform the calibration. The 0.000 solution shall consist of purified water. The remaining solutions used to calibrate the instrument will be provided by the Office of the Scientific Director.

- 5.3.1.1** The Office of the Scientific Director shall make available, in a digital format, the documents necessary to establish NIST traceability, unbiased estimate, nominal value and combined uncertainty of the reference solutions used to perform instrument calibrations.

- 5.3.2** These reference solutions will be analyzed in the following order:

1. 0.000 g/210 L
2. 0.040 g/210 L
3. 0.080 g/210 L
4. 0.150 g/210 L
5. 0.400 g/210 L

- 5.3.3** The following steps shall be performed for each nominal reference value:

1. Ensure the simulator is properly sealed by acknowledging sufficient back pressure when blowing into the inlet port while the outlet port is blocked.
2. Visually ensure the stirring mechanism is turning.

3. Before beginning the analysis of each reference solution, ensure that the reference solution in the simulator is  $34.0 \pm 0.2^{\circ}\text{C}$  with a NIST traceable thermometer.
4. Attach the simulator's vapor outlet tube to the instrument's simulator inlet port.
5. Attach the simulator's vapor inlet tube to the instrument's simulator return port.
6. Place the instrument in the mode to conduct and print calibration checks.
7. Conduct twenty sequential calibration checks and affix the label from the nominal reference standard bottle to the printed calibration check.
8. Initial and/or sign the calibration check printed by the instrument during the calibration and scan into a digital format.
9. In order to ensure ethanol vapor equilibration between the simulator and instrument, record only the final fifteen sequential calibration checks in the Calibration Analyst Worksheet.
  - a. Each of the fifteen analyses of the 0.000 g/210 L standard must be 0.000.
  - b. The mean of the fifteen analyses of each ethanol reference standard must be within  $\pm 0.003$  or 3% (whichever is greater) of the unbiased estimate of the standard.
  - c. The standard deviation of the nominal 0.040, 0.080, and 0.150 g/210 L reference standards must be less than 0.001.
  - d. The standard deviation of the nominal 0.400 g/210 L reference standard must be less than 0.002.

**5.3.4** If at any time during the calibration procedure it becomes necessary to terminate the calibration procedure due to unacceptable results or instrument or equipment in need of adjustment or repair, or for any other reason, all records generated to that point will be retained and the reason for the unsuccessful attempt will be documented on the Calibration Analyst Worksheet. A complete calibration procedure shall be accomplished before a Calibration Certificate is issued.

**5.3.5** When a calibration procedure has been successfully completed and the information and the data entered in the Calibration Analyst Worksheet meet all of the specifications for results, the Technical Supervisor who performed the calibration shall affix their electronic signature to the Calibration Analyst Worksheet. The information and the data shall then be transferred to the Calibration Certificate and the Technical Supervisor who performed the calibration shall affix their electronic signature to the Calibration Certificate. The spreadsheet containing the Calibration Analyst Worksheet, the Technical and Administrative Review Checklist and the Calibration Certificate along with all initialed/signed and scanned instrument calibration checks printed by the instrument during calibration shall be submitted to another Technical Supervisor for technical and administrative review. These documents may be submitted to the reviewer by any electronic means other than facsimile transmission.

- 5.4** Prior to issuing an instrument Calibration Certificate, it must be reviewed by another Technical Supervisor. Using the Technical and Administrative Review Checklist, the reviewing Technical Supervisor shall check all of the information and data entered in the Calibration Certificate. When the technical and administrative review has been completed, the reviewing Technical Supervisor shall affix their electronic signature to the Technical and Administrative Review Checklist. Discrepancies identified, if any, shall be brought to the attention of the Technical

Supervisor who performed the calibration and resolution shall take place prior to issuance of the certificate. If the reviewing Technical Supervisor determines that the Calibration Certificate has been properly completed and meets all of the requirements, the reviewing Technical Supervisor shall affix their electronic signature to the Calibration Certificate.

- 5.5** Any Technical Supervisor who performed, participated in, observed, supervised or scientifically reviewed the calibration procedure may issue the Calibration Certificate by affixing their electronic signature to the Calibration Certificate. After review, it is permissible for the reviewing Technical Supervisor to issue the Calibration Certificate. However, if a Technical Supervisor other than the reviewing Technical Supervisor is to issue the Calibration Certificate, the reviewing Technical Supervisor shall electronically transmit the spreadsheet containing the Calibration Analyst Worksheet, the Technical and Administrative Review Checklist and the Calibration Certificate along with the initialed/signed and scanned instrument calibration checks to the Technical Supervisor who is to issue the Calibration Certificate.
- 5.6** Once issued, the certificate and all of the relevant documents generated during the calibration of the instrument shall be emailed to the Office of the Scientific Director. An electronic file for each instrument, accessible to all Technical Supervisors, will be maintained by the Office of the Scientific Director.

## **6 Thermometers Used in the Instrument Calibration Procedure**

- 6.1** The purpose of this section is to establish quality assurance guidelines for NIST traceable thermometers used in the instrument calibration procedure.
- 6.1.1** A NIST traceable thermometer will be used to verify the proper operational temperatures of simulators used in the instrument calibration procedure.
- 6.1.2** NIST traceable thermometers are to be maintained in the Technical Supervisor's calibration laboratory which has limited access. Handling and storage of thermometers in the laboratory shall be exercised with care to ensure proper readings.
- 6.1.3** NIST traceable thermometers will be calibrated by an approved vendor and once calibrated are considered to be suitable for use for a period of one year.
- 6.1.3.1** NIST traceable thermometers will be submitted to an ISO 17025 accredited laboratory capable of issuing a calibration certificate establishing traceability to a NIST reference standard.
- 6.1.3.2** Records generated by the calibration laboratory for each NIST traceable thermometer shall be kept in the **Maintenance File (2.4.6)**.