

# Washington State Patrol

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## BREATH TEST PROGRAM

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### Technical Manual

Revision March 2020

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Impaired Driving Section  
Forensic Laboratory Services Bureau  
811 East Roanoke Street  
Seattle, WA 98102

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# 1 TECHNICAL SERVICES PROGRAM

This manual describes the Technical Services Program of the Washington State Patrol (WSP) Breath Test Program as it relates to its breath alcohol calibration functions.

The Toxicology Laboratory Division (TLD) and the Breath Test Program (BTP) are both responsible for the breath alcohol calibration functions of the Forensic Laboratory Services Bureau (FLSB). Simulator solutions will be ordered from approved external vendors. For the Draeger Alcotest 9510 instruments (Draeger), a certified ethanol dry gas standard is used to verify the accuracy and proper working order of these instruments as part of a field evidential breath test.

Unless otherwise indicated, the Draeger Alcotest 9510 may be referred to here or in other manuals as the Draeger, Dräger, Drager, 9510 or Alcotest 9510.

The purpose of this manual is to specify in detail the policies and procedures that shall be followed in order for the BTP to fulfill its breath alcohol calibration responsibilities.

The official version of this manual is the electronic version as it appears on the FLSB SharePoint site (FLSB Portal). This manual covers all work done by responsible personnel, to include but not limited to work done in the individual calibration laboratories within the BTP, in addition to duties outside the laboratory, whether in court, training venues, or anywhere else the duties of responsible personnel might be employed.

## 1.1 POLICY

The BTP shall document its policies and procedures to the extent necessary to assure the quality of the calibration results. Compliance with pre-established and carefully designed policies and procedures is important to ensure the work product and services are accurate and fit-for-purpose. The policies and procedures outlined in this manual shall be communicated to, available to, understood by, and implemented by the responsible personnel.

All calibration and related services performed by the BTP shall meet generally recognized standards of the forensic community and its accrediting organizations. Specifically, the BTP shall perform all calibration activities in accordance with the specified program policies and the ISO/IEC 17025: 2017 ANAB 17025: 2017 Forensic Science Calibration Laboratories Accreditation Requirements accreditation standards.

All employees are required to familiarize themselves with this manual and implement the policies and procedures specified herein. In doing so, the BTP will maintain the highest level of expertise and analytical confidence for the criminal justice system and comply with the ISO/IEC 17025 2017 and ANAB accreditation standards described above.

Any adjustments or deviations from the policies and procedures detailed in this manual must be approved by the Impaired Driving Section (IDS) Commander, Quality Assurance Manager and/or the State Toxicologist, and appropriately documented.

## 1.2 DEFINITIONS

### 1.2.1 ACCURACY

The proximity of a measured value to a reference value.

### 1.2.2 ADJUSTMENT

The process by which known traceable standard(s) having reference value(s) are introduced into an instrument. The instrument is then adjusted or programmed (either by software, hardware, electronics, etc.) to report a measurement based on the known reference value(s).

### 1.2.3 ANAB

ANSI-ASQ National Accreditation Board (ANAB) is an organization that accredits forensic science calibration laboratories to ISO/IEC 17025 standards and the ANAB ISO/IEC 17025 – Forensic Science Calibration Laboratories Accreditation Requirements.

### 1.2.4 BACK-UP TECHNICIANS

Personnel who are fully trained and certified as Breath Test Technicians. Their assignments, however, are typically in the WSP Field Operations Bureau. They will assist the local full-time Breath Test Technician, as required.

### 1.2.5 BIAS

The difference between a measurement result and the true reference value of the property being measured. The bias quantifies the accuracy of the measurement.

### 1.2.6 BREATH TEST TECHNICIANS / TECHNICIANS

Currently qualified Operators who are trained and certified in the following areas of responsibility: instrument calibration, certification, repair, maintenance, documentation, training of operators and expert court testimony. Technicians are also qualified as Instructors, and Preliminary Breath Test Technicians.

### 1.2.7 CALIBRATION

The process where a range of simulator solutions with different concentrations are tested to ensure that their values satisfy the requirements for precision and accuracy. Previously known as linearity checks.

### 1.2.8 CALIBRATION CERTIFICATE

The final result sheet produced at the end of the process of calibrating a breath test instrument, known herein as the Quality Assurance Procedure (QAP).

### 1.2.9 CALIBRATION FILE

Refers to documents kept as part of the QAP File.

### 1.2.10 CALIBRATION RECORDS

Refers to documents kept as part of the Instrument Record.

#### 1.2.11 CERTIFICATE OF ANALYSIS (COA)

Documentation provided by the manufacturer of ethanol dry gas standards and QAP reference solutions which states the tested concentration, analytical accuracy of the reported value, and traceability.

#### 1.2.12 COEFFICIENT OF VARIATION (CV)

The relative standard deviation expressed as a percentage of the mean.

#### 1.2.13 COMBINED UNCERTAINTY

The estimate of measurement uncertainty that includes the contribution from all components significantly influencing a measurement result.

#### 1.2.14 EVIDENTIARY BREATH TEST INSTRUMENT

An instrument approved by the State Toxicologist that is calibrated and verified for measuring breath alcohol content. The state of Washington currently uses the Draeger Alcotest 9510.

#### 1.2.15 EXTERNAL STANDARD

The reference standard attached to the instrument and used to provide a known alcohol concentration to verify the accuracy and proper working order of the instrument as part of a field evidentiary breath test. This is a dry gas (Dry Gas External Standard) consisting of an ethanol/nitrogen mixture.

#### 1.2.16 INSTRUCTORS

Personnel that are currently qualified Operators and additionally trained and certified to have the responsibility for training other Operators on the use of the breath test instruments.

#### 1.2.17 INSTRUMENT RECORD

All records and documentation related to a specific breath test instrument. In addition to the QAP file, records may include maintenance files, status sheets, solution change records, instrument printouts, etc.

#### 1.2.18 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST)

A federal agency located within the Department of Commerce with final authority for metrology in the United States.

#### 1.2.19 OPERATORS

Personnel trained and certified to be Operators of the evidentiary breath test instruments. This includes most law enforcement officers within the state.

#### 1.2.20 PRECISION

The ability of a technique to perform a measurement in a reproducible manner. Precision is quantified by the standard deviation.

#### 1.2.21 PRELIMINARY BREATH TEST (PBT) INSTRUMENT

A handheld breath alcohol screening device that includes both the Alco-Sensor FST and Alco-Sensor III instruments. These instruments are approved by the State

Toxicologist and are used by law enforcement officers at the roadside to measure breath alcohol and help establish probable cause for arrest.

#### 1.2.22 QUALITY ASSURANCE PROCEDURE (QAP)

A testing procedure for evidentiary breath test instruments in which known traceable reference materials are used to set and confirm the adjustment and establish quantitative estimates for bias and precision. Several other performance measures are also evaluated in order to ensure the proper working order and evidential suitability of the instrument.

#### 1.2.23 QUALITY ASSURANCE PROCEDURE FILE (QAP FILE)

A file containing all documentation produced as a result of the QAP process. Documents include the QAP Worksheet, the Calibration Certificate, any printouts produced by the instrument, and the QAP Review Form. All or portions of the QAP file may be electronic.

#### 1.2.24 QUALITY ASSURANCE PROCEDURE SOLUTION (QAP SOLUTION)

The solution used within the simulator to provide a known alcohol vapor concentration to set and confirm the adjustment of the evidentiary breath test instrument.

#### 1.2.25 QUALITY ASSURANCE (QA) MANAGER

Operationally, the Toxicology Laboratory Quality Assurance Manager.

#### 1.2.26 ROUNDING

When rounding is performed for computational purposes, normal rules of rounding are followed unless otherwise specified.

#### 1.2.27 SIMULATOR

A device, when filled with a certified simulator solution maintained at a known temperature, that provides a vapor sample of a known ethanol concentration.

#### 1.2.28 STANDARD UNCERTAINTY

The uncertainty of a measurement result expressed as a standard deviation.

#### 1.2.29 TRACEABILITY

The property of a measurement result whereby it can be related to standard references, usually national or international, through an unbroken chain of comparisons all having stated uncertainties.

#### 1.2.30 UNCERTAINTY / MEASUREMENT UNCERTAINTY

A parameter, associated with a measurement result that characterizes the dispersion of the values that could reasonably be attributed to the true value being measured.

## 2 RECEIPT AND STORAGE OF SIMULATOR SOLUTIONS AND DRY GAS STANDARDS

### 2.1 POLICY

Certified ethanol simulator (QAP) solutions and Dry Gas External Standards shall be ordered from an approved vendor. On receipt of the solutions/Dry Gas External Standards, the Technician must verify and inspect the order for correct ethanol concentration and quantity ordered, document receipt of the shipment, and store the solutions/canisters appropriately.

### 2.2 PROCEDURE

2.2.1 On receipt of the simulator solutions, the Technician shall sign and date the packing slip, indicating:

- Verification of order – adequate amount, correct concentrations, etc.
- Inspection of bottles – no damage, leaking, broken seals, etc.
- Appropriate Test Report(s) included
- Record of receipt

2.2.2 Once receipt has been verified the person receiving the shipment shall notify BTP headquarters and forward the completed packing slip.

2.2.3 On receipt of the Dry Gas External Standard, the Technician will sign and date the packing slip, indicating:

- Verification of order – adequate amount, correct concentrations, etc.
- Inspection of canisters – no damage, leaking, broken valves, etc.
- Appropriate Certificate(s) of Analysis included
- Record of receipt

2.2.4 Once receipt has been verified the person receiving the shipment shall notify BTP headquarters and forward the completed packing slip.

2.2.5 If any discrepancies are noted, the Technician should contact the Breath Test Program headquarters. Discrepancies may include insufficient quantity of the standards, incorrect concentration, damaged and/or leaking bottles or canisters, and broken seals or valves. Any discrepancies and subsequent resolution will be

documented on Solution Request/Packing Slip or the dry gas manufacturer packing slip.

- 2.2.6 On receipt of the standards, the Technician should store them in a secure cabinet/closet separate from any volatile chemicals. Extreme temperature should be avoided.
- 2.2.7 A laboratory may receive an amount of dry gas cylinders that exceeds the locked cabinet storage capacity. Technicians at these laboratories are authorized to secure the cylinders outside of locked storage cabinets with the following restrictions:
- Cylinders must be kept in the laboratory.
  - The laboratory must be locked when the Technician is not present.
  - Cylinders shall be checked for tampering prior to use.
  - Cylinders must be stored away from heat sources, volatile chemicals, and impact/puncture hazards.
- 2.2.8 The QAP solutions are valid and approved for use for a period of two years from the date of preparation. Expired solutions may be discarded down a drain with additional water, and the solution containers discarded in the trash or recycled. If expired solutions are retained for training purposes then each container must bear identification that reads similar to “Training Purposes Only” and be stored separate from non-expired QAP solutions.
- 2.2.9 Dry Gas External Standards are valid for use for a period of three years from the date of certification. The canisters are clearly labeled with expiration date and lot number. Standards that have expired shall be discarded by removing the pressure pin and releasing the remaining pressurized gas into the atmosphere. If expired standards are retained for training purposes then each canister must bear identification that reads similar to “Training Purposes Only.” These shall be stored separate from non-expired dry gas standards.
- 2.2.10 When a QAP solution is transferred to a simulator, the simulator is to be labeled with the identity of the QAP solution and the QAP solution lot number.
- 2.2.11 If solutions or dry gas standards need to be transported to sites other than a permanent laboratory facility, care shall be taken to protect their integrity and avoid damage, leakages and extreme heat.

### **3 DRAEGER ALCOTEST 9510 QUALITY ASSURANCE PROCEDURE**

The Draeger Quality Assurance Procedure (QAP) ensures the accuracy, precision and forensic acceptability of the Draeger breath test instrument for the purpose of quantitative evidential measurement of the alcohol concentration of a person's breath. The procedure evaluates critical systems within the instrument to ensure their compliance with strict predetermined criteria. When complying with the standards required in the QAP, the Draeger can be confidently placed in the field for evidential use.

When the QAP is undertaken at sites other than a permanent laboratory facility, the location should provide moderate environmental conditions of temperature and humidity as commonly found under normal laboratory conditions. Calibration shall be stopped if the Technician determines that environmental conditions in any calibration location jeopardize the results of the calibration. The transportation, handling and storage of instruments being calibrated shall be done in such a way as to protect the integrity of the instrument. While undergoing transport and whenever stored in a permanent laboratory facility, the instruments will be treated with the care deserving of a precision measurement device and any storage both before and after conducting the QAP will be in a secure, limited-access location.

For any equipment requiring transportation to sites other than the permanent laboratory facility, the transportation and handling shall be done in such a way as to protect the integrity of the equipment.

When documenting the calibration item and/or equipment used, the serial number shall act as the unique identifier, unless otherwise noted.

Throughout this procedure, all tests conducted utilizing QAP solutions must be conducted utilizing Guth model 2100 or 34C simulators containing thermometers that have been certified according to Simulator Thermometer Certification procedure.

Prior to pouring contents of solution into the simulator ensure the following routine maintenance has occurred:

- Ensure the O ring is in place and shows no signs of tearing or breaking.
- Dry the simulator tubing by removing excess moisture, replace tubing if necessary.
- The outlet tubing from the simulator should be kept as short as possible while still allowing a connection to be made to the instrument without kinking of the tubing.

#### **3.1 CONDITIONS REQUIRING THE QAP**

The procedure described below is to be followed when performing the QAP on Draeger instruments. This procedure shall be completed in the following circumstances:

- A. Prior to an instrument being initially installed in the field for evidentiary use.
- B. After an instrument has been returned from service by the manufacturer.

- C. After replacing any of the following components and prior to being placed back into the field for evidentiary use:
  - 1. Measurement System Firmware (M16 Processor)
  - 2. IR-Transmitter
  - 3. IR-Detector
  - 4. Cuvette
  - 5. Fuel Cell
- D. After disassembly and then reassembly of cuvette or fuel cell.
- E. If instrument requires recalibration for any reason.
- F. At least once every 12 months.
- G. Software updates affecting analytical components of the instrument.

3.1.1 If an instrument has had a current QAP performed and is in spare status, it does not need another QAP if deployed in evidential mode.

### 3.2 DRAEGER INSTRUMENT ASSESSMENT

Prior to calibrating the instrument, the “As Found” performance of the Draeger shall be assessed on all evidential instruments, including those in spare status. The assessment may be conducted at the installation site or the laboratory. The “As Found” assessment will be completed by the Technician by running one complete breath test on the instrument. For data entry purposes the Technician performing the assessment may use their own name as the operator and terminology similar to “AS FOUND” in the subject name. The other data entry is irrelevant and need not follow any particular format. One copy of the printed breath test document shall be maintained in the calibration file along with the QAP. The results from the external standard sample on the “As Found” assessment shall be recorded on the Calibration Certificate as well as by hand on the Calibration/Adjustment Record generated by the Draeger at the end of the procedure.

- A. Acceptability of the assessment is defined as an “As Found” external standard result between 0.072 and 0.088 g/210 L, inclusive, for both the IR and EC. In the event that the assessment indicates an unacceptable result, the QAP is immediately halted and a supervisor is contacted.
- B. The intention of the “As Found” is to show the condition or working order of the instrument before being calibrated. Therefore, if a successful “As Found” test is obtained those results are to be recorded on the required documents. If a “Repair” is needed and no “As Found” results can be obtained the “As Found” test will not be applicable. Similarly, if the instrument was not previously calibrated within the timelines set forth in this chapter, the test will not be applicable and is not required.
- C. The “As Found” will be completed one time and those results recorded on the final Draeger Alcotest 9510 Calibration/Adjustment Record and the Draeger Alcotest 9510 Calibration

Certificate. The date of the “As Found” may or may not be the same date as the final calibration QAP procedure documents.

To complete the “As Found” the following procedure should be followed:

- A. Press the green run button on the instrument.
- B. Enter applicable data.
- C. Run a complete breath test.
- D. Sign or initial one copy of the printed document that is produced by the instrument. Maintain the document in the QAP File and enter the external standard results on the Calibration/Adjustment Record and Calibration Certificate.

### 3.3 PROCEDURE

The following shall be conducted by the Breath Test Technician performing the calibration. The Technician shall follow the procedures outline in this chapter and the final “Draeger Alcotest 9510 Calibration Record” will be printed at the completion of the QAP. If at any point throughout the QAP, it becomes necessary to begin the entire QAP again, all of the paperwork up to that point shall be retained while noting the reason on the Draeger Alcotest 9510 Calibration/Adjustment Record that is generated by the instrument.

The Technician shall verify the active software versions match the approved software versions by the Washington State Toxicologist. Using the internal printer, the Technician shall print, initial and date the active software versions. The active software printout includes all four software versions. No other documents are to be printed on the internal printer.

#### 3.3.1 Barometric Pressure Adjustment

Prior to calibration of the Draeger the current barometric pressure shall be compared to the internal pressure sensor reading of the instrument. Use a reference barometer that has been certified according to the Barometer Certification Procedure. Follow the steps below to complete this process:

- A. Select “Menu”
- B. Select “Maintenance”
- C. Select “Calibration”
- D. Select “Ambient Pressure Correction”
  - 1. If the pressure listed in the box titled “Ambient Pressure” is within  $\pm 10$  Hectopascals (hPa) inclusive of the pressure reading on the reference barometer, the readings need not be recorded. Adjustments within the acceptable range may be made at the discretion of the technician. If the value listed in the “Ambient Pressure” box lies outside the acceptable range when compared to the reference barometer, record the differences in the measurement on a Repair Record. Then select the “EXT Pressure

Meter” dialogue box and change the pressure reading to the reading found on the reference barometer.

2. Select “Save” and return to main menu.

### 3.3.2 Adjustment Procedure

- A. Select “Menu” on the display screen
- B. Select Maintenance
- C. Select “QAP”
- D. Use a certified QAP Solution (0.08 value) (with a different batch number than the calibration) for the adjustment function. The 0.08 QAP solutions should be a fresh transfer to the simulator or have been transferred on the date of calibration as noted on the simulator label. The maximum use for any QAP solution transferred to a simulator is a single day.
- E. Select “Adjustment”
- F. Follow data entry prompts from the instrument. Only complete entries will be accepted.
- G. Connect the simulator to the instrument and follow instructions as prompted on the instrument display to successfully complete an adjustment

### 3.3.3 Internal Standard Adjustment

After successful adjustment of the instrument the Internal Standard Adjustment Function must be completed. Follow the below steps to complete the process:

- A. Exit the QAP screen. From the Menu tab, select Maintenance
- B. Select “Calibration”
- C. Select “Internal Standard Adjust”
- D. Instrument will display “Do you really want to start an internal standard adjust?” Select “Yes”
- E. Once completed, return to the QAP screen and proceed to next step.

On final Draeger Alcotest 9510 Calibration Certificate a data entry section for the internal standard adjustment must be selected. Using the drop down selection menu, select, “Completed”.

### 3.3.4 Complete Calibration

NOTE: THE 0.08 QAP SOLUTION USED FOR THE CALIBRATION CHECKS MUST HAVE A DIFFERENT BATCH NUMBER THAN THE QAP SOLUTION USED FOR THE ADJUSTMENT.

The following steps shall be performed using certified QAP 0.04, 0.08, 0.15, and 0.20 solutions. The order in which the calibration checks are performed is left to the discretion of the Technician. Each QAP solution should be a fresh transfer to its simulator or have been transferred on the date of certification as noted on the simulator label.

Use only Guth Model 34C or 2100 simulators which contain a certified QAP solution. Verify that the certified thermometer indicates that the temperature of the simulator solution is  $34.0 \pm 0.2$  °C.

For each calibration concentration use the following procedure:

- A. On the QAP display select the linearity check to be performed. The display will allow you to select one of four options titled: "Lin Test 1, Lin Test 2, Lin Test 3, or Lin Test 4". There is no particular order in which the test must be performed. However, note that Lin Test 1 will print in column one, Lin Test 2 in column two, etc.
- B. Ensure that the appropriate boxes are checked on the display screen for the QAP at the end of each linearity test.

The Technician shall be allowed to repeat the calibration steps if necessary in order to achieve optimum instrument performance. All original generated documents must be retained in the instrument file.

### 3.3.5 Perform the Interference Test

- A. Use a simulator containing approximately 0.08 g/210L of ethanol to which approximately 1.5 ml of acetone has been added.
- B. After selecting the "INTERFERENCE TEST" from the menu, follow the data entry procedures provided by the instrument.
- C. Verify that the instrument displays "INTERFERENCE DETECTED".
- D. Ensure the appropriate Interference Test box is checked on the display screen for the QAP upon completion of the test.

### 3.3.6 Perform the Mouth Alcohol/Invalid Sample Test

- A. Select the "INVALID SAMPLE TEST" from the menu on the instrument and follow the procedures provided by the instrument.
- B. A human subject is to exhale into the instrument during the PLEASE BLOW phase shortly after introducing into the mouth a substance containing ethyl alcohol (i.e., mouthwash, beverage alcohol, etc.).

- C. Verify that the instrument displays “INVALID SAMPLE”.
- D. Ensure the “INVALID SAMPLE” box is checked on the display screen for the QAP upon completion of the test.

### 3.3.7 Perform a Complete Breath Test (Verification)

- A. Ensure that a certified, non-expired, dry gas external standard is connected to the instrument, at gas inlet #1, to complete the breath test.
- B. Select the “BREATH TEST” option on the display screen and complete the data entry as prompted.
- C. Follow instructions on the display until the breath test sequence is complete.
- D. Ensure that the external standard result reading was within 0.072-0.088 g/210L inclusive, for IR and EC.
- E. Ensure the appropriate “Breath Test” box is checked on display screen for the QAP upon completion of the test.

### 3.3.8 QAP Printout

- A. Select the “Printout” option from the display screen.
- B. Ensure the printed document “DRAEGER ALCOTEST 9510 CALIBRATION/ ADJUSTMENT RECORD” displays appropriate data entry and all tests are printed in appropriate location.
- C. Examine the results reported on the Draeger Alcotest 9510 Calibration/Adjustment Record for each concentration. Ensure that the bias is less than or equal to  $\pm 5\%$  using the first formula below. If greater than 5%, the results are still satisfactory if the difference between the reference value and the sample mean is less than or equal to  $\pm 0.005$  g/210 L using the second formula below.

$$\text{Bias}(\%) = \left[ \frac{\bar{Y}-R}{R} \right] \times 100 \quad (\text{Rounded to two decimal places})$$

or  $\bar{Y} - R = \pm 0.005 \text{ g/210L of R}$

where:  
 $\bar{Y}$  = arithmetic mean  
R = reference value

- D. Examine the results reported on the Draeger Alcotest 9510 Calibration/Adjustment Record for each concentration and ensure that the results for the coefficient of variation are within 3% according to the following equation:

$$CV(\%) = \left[ \frac{SD}{\bar{Y}} \right] \times 100 \text{ (Rounded to two decimal places)}$$

where:

SD = Standard deviation

- E. Once the results have been confirmed to ensure they comply with the stated criteria for accuracy (% bias) and precision (% CV), set the QAP date using the “Set Certification” option. Verify the date and save.
- F. If the data is found to be outside the stated criteria the Technician may terminate the QAP and repeat it in total at any time during the certification procedure.
- G. The Technician shall include all produced documents, including the ‘As Found’ printout to the reviewer for their review.

### 3.3.9 Calibration Certificate

- A. The Draeger 9510 Calibration Certificate shall be completed when the above steps have been successfully performed as described. The certificate shall be transferred for technical/administrative review and issuance as outlined in the Certificate Issuance and Technical/Administrative review section.
- B. The results of the certification procedure shall be examined to ensure they comply with the stated tolerances of accuracy (% bias) and precision (% CV) and all entries are consistent with the corresponding values on the Draeger Alcotest 9510 Calibration/Adjustment record.
- C. The entire QAP shall be repeated if, during the QAP any of the circumstances described in “Conditions Requiring a QAP” occur.

3.3.10 The technical record submitted by the Breath Test Technician for certificate technical/administrative review and issuance is complete when the worksheet and all data generated, which includes a date, have been initialed.

## 3.4 CERTIFICATE TECHNICAL/ADMINISTRATIVE REVIEW AND ISSUANCE

Prior to installing the instrument in the field, the results of the QAP must be reviewed by both the technical/administrative reviewer and the issuer of the certificate. Both reviewers must be authorized by the IDS Commander to conduct reviews/issue certificates. The review conducted by the issuer and the technical/administrative reviewer may be accomplished based on faxed or e-mailed copies of all relevant pages of documentation in the instrument record. This shall include the Draeger Calibration Certificate, the QAP Worksheet, and all instrument printouts. The technician shall affix signatures to the Calibration/Adjustment Record and Calibration

Certificate . The Technician shall review scanned material for accuracy and legibility before electronically sending to the reviewer.

The technical/administrative reviewer of the certificate shall review the QAP and the review will be documented on the QAP Review Form. The technical/administrative reviewer shall check the data entry and ensure that all data entry from the Draeger Alcotest 9510 Calibration Record matches the corresponding data on the Draeger Alcotest 9510 Calibration Certificate. The technical/administrative reviewer will ensure that the current approved software versions are installed on the instrument. The technical/administrative reviewer shall verify that all documentation is included and matches the Calibration/Adjustment record and the Calibration Certificate. The reviewer should also verify that the ethanol reference values were entered correctly. Any discrepancies identified in the review process shall be brought to the attention of the Technician performing the calibration who will resolve them as soon as possible. Discrepancies not resolved at this level shall be brought to the attention of a BTP Supervisor who may notify the QA Manager and/or IDS Commander as appropriate.

Once the review is complete and deemed acceptable, the technical/administrative reviewer will sign and date the QAP Review Form, and print and sign the Draeger 9510 Calibration Certificate. The signed documents will then be provided to the issuer.

The issuer will review the QAP and the review will be documented on the Quality Assurance Procedure Review Form Draeger Alcotest 9510. The issuer shall check the data entry and ensure that all data entry from the Draeger Alcotest 9510 Calibration Record matches the corresponding data on the Draeger Alcotest 9510 Calibration Certificate. The issuer will ensure that the current approved software versions are installed on the instrument. The issuer reviewing the Calibration Certificate shall verify that all documentation is included and matches the Calibration/Adjustment record and the Calibration Certificate. The issuer shall also verify that the ethanol reference values were entered correctly. Any discrepancies identified in the review process shall be brought to the attention of the Technician performing the calibration who will resolve them as soon as possible. Discrepancies not resolved at this level shall be brought to the attention of a BTP Supervisor who may notify the QA Manager and/or IDS Commander as appropriate.

Once the review is complete and deemed acceptable, the issuer shall sign and date the QAP Review Form, print and sign the Draeger 9510 Calibration Certificate. The issuer will then notify the Technician who performed the QAP that the review is complete and that the instrument can be returned to the field for evidential use.

The issuer will provide the Draeger Alcotest 9510 Calibration Certificate and QAP documents to IDS headquarters. The Technician may retain copies of the Draeger Alcotest 9510 Calibration Certificate, Draeger Alcotest 9510 Calibration/Adjustment Record, QAP Review Form and original instrument printouts for their records.

### **3.5 FIELD INSTALLATION**

Complete the following:

- Confirm the dry gas canister(s) are not expired.
- Reattach the gas enclosure.

- Conduct one breath test to confirm normal operation. Send the breath test document to BTP Headquarters.
- Ensure the instrument has the most current drinking location codes from the Liquor and Cannabis Board. This should be done on a quarterly basis.
- Ensure the supervisory key has been removed.

## **4 EXTERNAL STANDARD CHANGING PROCEDURE FOR DRAEGER ALCOTEST 9510 INSTRUMENTS**

### **4.1 POLICY**

The following protocol shall apply to qualified personnel who change external standard dry gas cylinders in the Draeger.

### **4.2 RESPONSIBILITIES**

- Only certified personnel shall change external standard dry gas cylinders.
- Certified personnel shall be responsible for monitoring and changing external standard dry gas cylinders.
- Ensure that only certified, non-expired, gas cylinders are used that contain an ethanol value of 0.08 g/210L. Note: The 0.08 value is the nominal value that is ordered from the supplier. During the External Standard Testing of the instrument, the result must lie between 0.072-0.088, inclusive.
- External standard dry gas cylinders shall be stored in secure locations with limited access. Acceptable locations include: Satellite calibration facilities and locked containers maintained by approved personnel approved to perform cylinder changes.
- External standard dry gas cylinders shall be stored in climate-controlled locations under moderate conditions. External standard cylinders may not be stored in a vehicle other than during transport.

### **4.3 EXTERNAL STANDARD GAS CYLINDER SUPPLY**

- Only certified external standard cylinders from an approved vendor are to be used.
- Only cylinders labeled with a batch or lot number and expiration date are to be used.
- Only non-expired cylinders are to be used.

### **4.4 EXTERNAL STANDARD GAS CYLINDER CHANGING SCHEDULE**

The Draeger utilizes a dual tank connection. Therefore, two separate cylinders may be deployed. When the current cylinder is emptied, or reaches its expiration, it will automatically switch to the second cylinder, provided cylinder two has a non-expired tank with sufficient amount of dry gas. The cylinder expiration and volume are monitored by the instrument. The instrument does not permit an expired cylinder, or one with insufficient volume, to be used during any evidential test sequence.

Cylinders should be changed as soon as practical once insufficient volume is identified by the instrument or once a cylinder has expired.

#### 4.5 PROCEDURE

- A. Use the key to access the cylinder storage unit on the back of the instrument.
- B. Remove (if applicable) the cylinder that needs to be changed by unscrewing the cylinder from the regulator unit.
- C. Insert the new cylinder into the empty space and secure the cylinder to the regulator unit.
- D. Insert the Technician access rights USB into the Draeger to access the maintenance menu on the display screen.
- E. Select "Menu".
- F. Select "Maintenance".
- G. Select "External Standard Change".
- H. The instrument will display "Scan Operator Card" and you may select "Yes" or "No". If you choose "Yes" your operator data will automatically be entered into the instrument. If you select "No" you will need to manually enter the following data:
  1. Enter last name
  2. Enter first name
  3. Enter your operator expiration date
  4. Select the "Summary" tab on the display screen and if all of the data is correct, select the "Save" tab on the display screen.
- I. The screen will display "Install new cylinder?"; select "Yes" then enter the appropriate data as described below:
  1. Which cylinder? Choose "cylinder one or cylinder two". (Cylinder one will always be the cylinder located on the top of the storage compartment and cylinder two will always be on the bottom.) Once selected you will be prompted to confirm the cylinder you selected with "Yes" or "No".
  2. Cylinder Lot Number? Enter the correct number and select "Next". You will be prompted to enter the lot number a second time to confirm the number was entered correctly.
  3. Concentration? Enter the ethanol concentration indicated on the Certificate of Analysis. Record the concentration to three decimal

places. You will be prompted to enter the concentration a second time to confirm it was entered correctly.

4. Cylinder Expiration? Enter the expiration date listed on the cylinder. You will be prompted to enter the expiration date a second time to confirm the date was entered correctly.
5. Review the data as displayed on the screen to ensure it was entered appropriately and select "Save".
6. Install cylinder into position one or two: This may be done at this time if not already completed at the beginning of the process. When this installation prompt appears and the cylinder is installed, select "OK".

The instrument will run a series of three samples on the cylinder. Once the samples are completed a document shall be printed indicating the results of the external standard results. All three samples will be inspected to ensure that the results are each between 0.072 and 0.088 g/210L, inclusive.

Send the document generated to BTP Headquarters. A copy may also be retained at the local level. Complete the electronic form in instrument tracking titled, "Cylinder Change Record" and record each of the results to three digits.

#### **4.6 ADDITIONAL RESPONSIBILITIES**

- Ensure that the instrument has adequate supplies: mouthpieces, DUI arrest forms and printer supplies.
- Ensure the instrument display has the correct date and time and adjust if necessary.
- Check the data line connection to instrument.
- Update, if necessary, the "Drinking Location Codes" via USB.

## 5 TRACEABILITY

### 5.1 POLICY

Traceability is established for measurement results, not for laboratories, methods or personnel. Traceability shall be established for the individual measurement results and the mean calculations resulting from all results generated within the BTP. Traceability should establish an unbroken chain of comparisons for these measurement results back to national or international measurement standards such as NIST. Traceability will allow for comparability between different analytical instruments and methods.

### 5.2 PROCEDURE

- A. All measurement results, mean calculations, batch numbers, and reference values will be recorded on the appropriate forms.
- B. Traceability documentation of the QAP reference solution and Dry Gas Standard will be provided by the manufacturer in the form of a Certificate of Analysis (COA) and maintained by BTP Headquarters.
- C. The COA shall specify the lot number and analytical concentration. The COA should also specify that the measurements performed by the manufacturer of the controls have been performed by methods and equipment that also measured Standard Reference Materials obtained from NIST.
- D. The following documents shall document and ensure traceability:
  1. The COA from the commercial manufacturer of the standards and controls
  2. The Calibration Certificate
- E. The traceability links will be from:
  1. The measurement results and mean reported on the Calibration Certificate to:
  2. NIST as documented on the COA from the control manufacturer, where applicable.

## 6 ALCO-SENSOR PBT CERTIFICATION PROTOCOL

### 6.1 POLICY

Certified PBT Technicians within the BTP shall be responsible for certifying the PBT instruments used only by members of the WSP. Certifying PBT instruments owned and operated by other agencies shall not be the responsibility of members of the BTP. However, this does not preclude the certifying of PBT instruments owned and operated by other agencies. This shall only be done in a limited number of circumstances and only when it is in the best judgment of the PBT Technician.

BTP personnel will not hold or store Preliminary Breath Test (PBT) instruments. BTP will only certify PBTs, document and track certifications, conduct accuracy checks, assist with determining condition, and help facilitate returns to manufacturers for repair if necessary. Custodians of PBTs shall be directed to their chain of command and WSP Supply regarding lost, damaged, ordering and returns of PBTs.

### 6.2 PROCEDURE FOR ALCO-SENSOR FST PBT

- A. Obtain certified dry gas alcohol standards for which the reference value is known and an Intox Regulator is attached.
- B. Use the altitude chart or altitude correction factor on the side of the tank to determine the adjusted reference value.
- C. Attach a new mouthpiece and power the instrument on by first pressing and holding the **OFF** button and then simultaneously pressing the **ON** button.
- D. The display should show the **RCL** message, which is the first option in the function menu. Momentarily depress and release the **ON** button until the displayed message reads ACC.
- E. With **ACC** on the display, press the **OFF** button to select the Accuracy Check option. The temperature will be displayed. Ensure a Blank Test result of 0.000 g/210L is displayed. A flashing **ACC** message will appear.
- F. While the display is flashing **ACC**, make an airtight connection between the delivery tube of the regulator and the open end of the mouthpiece.
- G. Depress the regulator control button for approximately seven (7) seconds. At approximately five (5) seconds depress and release the **ON** button (while the gas continues to flow) to manually accept the sample. Some of the newer or modified regulators will dispense the gas at a higher rate enabling the FST to automatically accept the sample and eliminating the need to manually accept the sample.
- H. The result will automatically be displayed.
- I. If the results are within  $\pm 0.010$  g/210L from the adjusted reference value for the gas standard, the PBT is properly calibrated and acceptably accurate and only one test is

necessary. Adjustments within the acceptable range may be made at the discretion of the technician. Following all calibration adjustments, a complete test shall be performed. Proceed to the Record Keeping steps.

- J. If the result is not within the acceptable limits, proceed to the Calibration process.

### 6.3 CALIBRATING THE ALCO-SENSOR FST PBT INSTRUMENT

- A. To calibrate the instrument its temperature must be between 20 °C and 35 °C. If the temperature is not within the range, the unit will display **E09** or **E10** and block the calibration procedure.
- B. Attach a new mouthpiece and power the instrument **ON** by first pressing and holding the **OFF** button and then simultaneously pressing the **ON** button.
- C. The display should show the **RCL** message, which is the first option in the function menu. Momentarily depress and release the **ON** button until the displayed message reads CAL.
- D. Once **CAL** is displayed, depress the **OFF** button, this will initiate calibration sequence.
- E. The temperature will be displayed, ensure a Blank Test result of 0.000 g/210L is also displayed. A flashing **CAL** message will appear.
- F. While the display is flashing **CAL**, make an airtight connection between the delivery tube of the regulator and the open end of the mouthpiece.
- G. Depress the regulator control button for approximately seven (7) seconds. At approximately five (5) seconds depress and release the **ON** button (while the gas continues to flow) to manually accept the sample.
- H. The result will automatically be displayed. If the result equals the expected value of the standard depress the **OFF** button. You will see that each time you depress the **OFF** button, the cursor moves from the left most digit of the number to the right. After depressing the button three times, the value displayed will be accepted as the calibration value and will flash three times before the instrument will power down.
- I. If the result **does not** match the expected value of the standard gas, you will need to adjust the displayed result to the proper value. The result displayed will have the digit furthest to the left flashing. If the flashing digit is incorrect, press and release the **ON** button as many times as it is necessary to cycle the displayed digit to the correct number. When the digit is correct, press the **OFF** button to move the flashing highlight to the digit to the right. After you have adjusted the furthest to the right digit and the **OFF** button is depressed, the new calibration value will be flashed on the display three times. If you need to adjust this number further, pressing the **OFF** button again, while the entire calibration number is flashing, will provide you this option by displaying the most recently entered number with the digit furthest to the left flashing. If the calibration value is correct and you have not pressed the **OFF** button a second time, after the third flash the new calibration value will be accepted.

- J. Cycle the power on the instrument **OFF** and **ON** and repeat the certification process to verify the accuracy of the instrument.

#### 6.4 PROCEDURE FOR ALCO-SENSOR III PBT

- A. Obtain certified dry gas alcohol standards for which the reference value is known and an Intox Regulator is attached.
- B. Use the altitude chart or altitude correction factor on the side of the tank to determine the adjusted reference value.
- C. Verify the PBT temperature is between 20.0 °C and 36.0 °C.
- D. Push **SET** button. Push and hold the **READ** button.
- E. The digits should go to 0.003 or less within 10 seconds. If the digits do not go to 0.003 or less, push **SET**, wait one minute and push and hold the **READ** button again.
- F. Attach the straight white tube mouthpiece to the instrument receptacle.
- G. Attach mouthpiece to the gas standard source and provide the sample. Allow approximately three seconds of gas flow.
- H. Push and hold the **READ** button while the sample is still being provided. Continue to hold the **READ** button until the result stabilizes.
- I. If the results are within  $\pm 0.010$  g/210L from the adjusted reference value for the gas standard, the PBT is properly calibrated and acceptably accurate and only one test is necessary. Proceed to Record Keeping steps. If the result is not within the acceptable limits, proceed to the Calibration process.

#### 6.5 CALIBRATING THE ALCO-SENSOR III PBT INSTRUMENT

- A. If the result is outside  $\pm 0.010$  g/210L of the adjusted reference value, first zero the instrument to 0.003 or less, then turn the calibration screw clockwise two full turns.
- B. Re-introduce the gas standard and while holding the **READ** button, turn the calibration screw counter-clockwise slowly to value on gas standard. Avoid adjusting to below the reference gas standard value during this procedure.
- C. Repeat steps Calibration steps as often as necessary to obtain results within the acceptable range.
- D. If results following calibration are acceptable, only perform one certified test.
- E. Where instruments are not outside  $\pm 0.010$  g/210L, Technicians are authorized to make small calibration adjustments without first turning the calibration screw clockwise two full turns. Following all calibration adjustments, a complete test shall be performed.

## **6.6 DOCUMENTATION**

- A. Complete the PBT Certification Record.
- B. Record results to three decimal places.
- C. Documentation shall be retained at the satellite laboratories.

## **6.7 FREQUENCY OF PBT CERTIFICATION**

The PBT instruments are to be certified at least every six months according to the Washington Administrative Code (WAC) 448-15-040.

## 7 DATA ENTRY FOR BREATH TEST PROGRAM PERSONNEL

### 7.1 POLICY FOR DRAEGER 9510 INSTRUMENTS

When performing breath tests on Draeger instruments for tests that will appear in the database, Breath Test Technicians will use the following, or similar, entries.

#### 7.1.1 Data Entry Format For Draeger 9510

|                                              |                                                   |
|----------------------------------------------|---------------------------------------------------|
| Observation time                             | At least 16 minutes prior to current Draeger time |
| Operator observed subject entire time?       | Yes                                               |
| Subject smoke, vomit, put anything in mouth? | No                                                |
| Citation/case number                         | AS/Found or Test                                  |
| County of arrest                             | Can be left blank or current county               |
| Crime arrested for                           | Officer Self Test                                 |
| Collision involved                           | No                                                |
| Subject drinking at specific establishment   | No (FOLLOW PROMPTS)                               |
| Select appropriate drinking location         | Other or Unknown                                  |
| PBT given                                    | No                                                |
| Operator name                                | TYPE IN OR SCAN CARD<br>Last<br>First<br>Middle   |
| Operator Agency Code                         | WSP1057                                           |
| Subject ethnic group                         | Other                                             |
| Subject driver license state                 | Other                                             |
| Subject last name                            | Test or As                                        |
| Subject first name                           | Test or Found                                     |
| Subject middle initial                       | leave blank                                       |
| Subject DOB                                  | 01/01/1950                                        |
| Subject gender                               | Male                                              |
| Subject driver license number                | Test or As/Found                                  |

## 8 BREATH TEST INSTRUMENT CODE INTERPRETATION

### 8.1 DRAEGER ALCOTEST 9510 POLICY

The Draeger 9510 breath test instrument will record and store in memory the occurrence of several different codes. These are ultimately downloaded to the server for storage in the instruments database. The following is a list of the codes generated by the instrument and their interpretation.

#### Software Status Codes

*\*Codes display in the "Sts" field in WebDMS*

| Number | Status Code Name       | Description                                                                                                                                  |
|--------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | TEST ABORTED           | Test procedure was aborted                                                                                                                   |
| 3      | CAL GAS SUPPLY         | Minimum flow not observed from dry-gas cylinder or simulator. Simulator or cylinder not                                                      |
| 4      | ADJUST ERROR           | An IR or EC sensor problem was observed during the Calibration Procedure                                                                     |
| 5      | BLANK CHECK INCORRECT  | The IR difference between the pre- and post purge (calculated concentration) too high                                                        |
| 6      | ALCOHOL IN AMBIENT AIR | After purging, the ec measured ambient alcohol concentration being greater than threshold level                                              |
| 7      | INVALID SAMPLE         | Mouth alcohol detected                                                                                                                       |
| 8      | INTERFERENT            | Interfering substances detected                                                                                                              |
| 9      | DETECTOR OVERFLOW      | The calculated breath alcohol concentration exceeded the maximum range.                                                                      |
| 10     | SAMPLES OUTSIDE 10%    | The comparison of calculated breath test results failed. IR values from subject sample 1 and 2 were compared and exceeded acceptable limits. |
| 11     | DETECTOR OVERFLOW      | Calculated breath test concentration > max.                                                                                                  |
| 12     | ALC. CONC. NOT         | Requirements for plateau detection not met.                                                                                                  |
| 13     | BLOWING NOT ALLOWED    | Flow through breath hose is detected when the instrument is not expecting a flow                                                             |
| 14     | TIMED OUT              | Maximum time for delivering a breath sample is                                                                                               |
| 15     | BLOWING TIME TOO       | Blowing time is too low                                                                                                                      |
| 17     | MIN. VOLUME NOT        | Delivered breath volume is too low                                                                                                           |
| 21     | CAL. STANDARD FAILED   | The calculated cal-check gas concentration did not meet the tolerance limits                                                                 |
| 23     | COMMUNICATION ERROR    | A communication error occurred between processors within the instrument                                                                      |
| 24     | QUICK RESET            | A quick reset is executed                                                                                                                    |
| 28     | PUMP ERROR             | Minimum purging volume (0.5l) was not met. Or maximum purging time was exceeded                                                              |

|    |                         |                                                                                                                                            |
|----|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 34 | INHALATION              | Negative breath flow was detected during                                                                                                   |
| 37 | RTC PROBLEM             | Real Time Clock hardware error detected                                                                                                    |
| 38 | HARDWARE ERROR          | General indicator for hardware related error                                                                                               |
| 39 | INTERNAL STANDARD ERROR | The results of the internal standard measurement were outside of the tolerance limits.                                                     |
| 40 | CHECK AIRWAY            | Observed flow rate during purging indicates possible blockage of the breath hose.                                                          |
| 41 | DATA INPUT TIMEOUT      | Data entry activity was not completed within the allowable time. No keyboard activity.                                                     |
| 42 | BATTERY VOLTAGE         | The DC power supply drops below 10.5 VDC.                                                                                                  |
| 43 | FLASH DELAY ERROR       | A potential problem was observed during the                                                                                                |
| 45 | DATALOGGING ERROR       | A problem was observed while sending or storing information to the database                                                                |
| 46 | REFUSAL                 | Subject Refusal                                                                                                                            |
| 49 | OPERATOR TIMEOUT        | Time for operator's response (e.g. no button pressed on message box) is expired                                                            |
| 50 | PUMP ERROR 2            | The instrument was not able to sufficiently clear the cuvette following analysis of a high-                                                |
| 51 | PRINTER ERROR           | Any hardware-related problem with the internal                                                                                             |
| 52 | SMARTCARD PIN ERROR     | Problem with smartcard that can cause problems with communication with the host PC                                                         |
| 53 | SMARTCARD TIME ERROR    | Problem with smartcard that can cause problems with communication with the host PC                                                         |
| 54 | SMARTCARD CANCEL ERROR  | Problem with smartcard that can cause problems with communication with the host PC                                                         |
| 55 | SMARTCARD LOCK ERROR    | Problem with smartcard that can cause problems with communication with the host PC                                                         |
| 56 | INCOMPLETE TEST         | Operator assessment option was exercised (after pressing the "Stop" button).                                                               |
| 61 | EC AGING COMP. ERROR    | A problem was observed with the aging compensation algorithm, caused by an invalid                                                         |
| 68 | DIAGNOSTIC CHECK        | Any of the internal functionality tests were                                                                                               |
| 70 | DRYGAS CHECK ERROR      | An empty or expired drygas cylinder was observed while checking the pressure of the dry                                                    |
| 71 | EC_SENSOR_STRESSED      | May occur when the EC sensor's alcohol load is too high due to previously performed tests                                                  |
| 72 | OPERTOR INPUT ERROR     | During the data entry sequence, the operator entered an invalid observation start time (in the future compared to current instrument time) |
| 73 | OPERTOR CERT EXPIRED    | During the data entry sequence, the operator expiration date associated with the scanned                                                   |

### Hardware Status Codes

*\*Codes do not display in the "Sts" field in WebDMS*

| Number | Name                    | Description                                                                                                              |
|--------|-------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 100    | EEPROM_DEFEKT           | Previously calculated and stored checksum does not match the current calculated one.                                     |
| 101    | RAM_DEFEKT              | Triggered if write operations to RAM buffer failed.                                                                      |
| 103    | CLOCK_DATA_LOSS         | Is triggered in case the plausibility check of the received time string (from WinCe) failed. (e.g. month=14 , or day=32) |
| 104    | SRC_CODE_CHECKSUM_ERROR | Is triggered if the cyclic calculation of the M16 Flash checksum failed.                                                 |
| 106    | U_SUPPLY_FAILURE        | main power is below minimum limit                                                                                        |
| 107    | IR_PERIOD_AVG_FAILURE   | IR period average too low or device not ready within 20 minutes of switching on the instrument                           |
| 108    | EC_OFFSET_FAILURE       | Offset voltage of the ec-sensor out of range                                                                             |
| 109    | EC_SENSOR_SYSTEM_DEFEKT | The motor of the sampling unit does not move the piston as expected.                                                     |
| 110    | EC_MAXIMUM_NOT_FOUND    | No EC signal maximum found                                                                                               |

|     |                                              |                                                                                                                             |
|-----|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| 113 | PUMPE_DEFJEKT                                | Volume of 0,5l is not purged within predefined time or a blockage of any tube.                                              |
| 118 | NTC_CUVETTE_DEFJEKT                          | The voltage drop at the NTC of the cuvette heater indicates the NTC is likely broken or the temperature is higher than 75°C |
| 119 | NTC_HOSE_DEFJEKT                             | The voltage drop at the NTC of the hose heater indicates the NTC is likely broken or the temperature is higher than 60°C    |
| 121 | HEATER_REGULATION_ERROR<br>FLASH_ERASE_ERROR | Temperature of cuvette or hose out of range                                                                                 |
| 123 | FLASH_ERASE_ERROR                            | Measurement System Flash memory Erase operation failed during configuration files update                                    |
| 124 | COM_ERROR                                    | error in communication between WinCE and M16 (measurement system)                                                           |
| 127 | EEPROM_DATA_LOSS                             | Verification of the calculated checksum does not match with the previously stored one                                       |
| 128 | CONFIGURATION_ERROR                          | Fault in configuration files; possibly forbidden combination of settings/parameters;                                        |
| 135 | EEPROM_DEFJEKT_6                             | eeprom programming error                                                                                                    |
| 137 | GP_EEPROM_DEFJEKT                            | eeprom programming error (of the second eeprom area)                                                                        |
| 138 | GP_ERASE_ERROR                               | error while eeprom programming                                                                                              |
| 139 | GP_CHECKSUM_ERROR                            | eeprom checksum incorrect                                                                                                   |
| 141 | CRC_CFG_DATA LOGGER                          | CRC check of configuration file failed                                                                                      |
| 142 | CRC_CFG_PRINTOUT                             | CRC check of configuration file failed                                                                                      |

|      |                                 |                                                                                                                                            |
|------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 143  | CRC_CFG_GRAPHIC                 | CRC check of configuration file failed                                                                                                     |
| 144  | CRC_CFG_TEXTS                   | CRC check of configuration file failed                                                                                                     |
| 145  | CRC_CFG_FONT                    | CRC check of configuration file failed                                                                                                     |
| 146  | CRC_CFG_PARAMETER               | CRC check of configuration file failed                                                                                                     |
| 147  | CRC_CFG_MEAS_PROC               | CRC check of configuration file failed                                                                                                     |
| 148  | SMARTCARD_ID_ERROR              | Problem with instrument serial number on smart card. Either the value stored does not match the value in EEPROM or there was a read error. |
| 149  | GP_WRITE_PTR_ERROR              | Instrument attempted to store data out of the address range of the general purpose eeprom                                                  |
| 150  | GPEEPROM_COPY_CONSISTENCY_ERROR | CRC of the contents of the general purpose eeprom does not match the one in RAM                                                            |
| 151  | PRINTOUT_CONFIGURATION_ERROR    | Configuration error for internal printer                                                                                                   |
| 152  | SMARTCARD_INIT_ERROR            | Smart card initialization failed                                                                                                           |
| 153  | TRANSDUCER_DEFECT               | Output value of transducer indicates transducer may be defective                                                                           |
| 1000 | FW_ERROR_RESET                  | Error while resetting target (measurement system update)                                                                                   |
| 1001 | FW_ERROR_ID                     | Error while getting information from bootloader (measurement system update)                                                                |
| 1002 | FW_ERROR_CLEAR                  | Error while clearing target (measurement system update)                                                                                    |
| 1003 | FW_ERROR_BLANK                  | Error while blank check (measurement system update)                                                                                        |
| 1004 | FW_ERROR_PROG                   | Error while programming target (measurement system update)                                                                                 |

|      |                       |                                                             |
|------|-----------------------|-------------------------------------------------------------|
| 1005 | FW_ERROR_VALID        | Error while making target valid (measurement system update) |
| 2000 | FILE_ERROR_SIGNATURE  | File may already exist                                      |
| 2001 | FILE_ERROR_FLOW_BAC   | File may already exist                                      |
| 3007 | COMM_ERROR_DEFTIMEACT | Internal communication delay                                |
| 5000 | ACT_ERROR_PENDING     | Could not store activity. An activity is pending.           |
| 5001 | ACT_ERROR_ACTIVE      | Could not store activity. Another activity is active.       |
| 5002 | ACT_ERROR_REQUESTED   | Could not store activity. Another activity is requested.    |
| 5003 | ACT_ERROR_ACTIVE_M16  | Could not store activity. Another activity is active.       |
| 5004 | ACT_ERROR_ACTIVE_PC   | Could not store activity. Another activity is active.       |
| 5005 | ACT_ERROR_ACTIVE_UNK  | Could not store activity. Another activity is active.       |
| 5006 | ACT_ERROR_ACTIVE_CE   | Could not store activity. Another activity is active.       |
| 5007 | ACT_ERROR_ACTIVE_LNE  | Could not store activity. Another activity is active.       |
| 5010 | AUTODEL_FIRMWARE      | Automatic deletion triggered due to firmware update.        |
| 5011 | AUTODEL_CONFIGURATION | Automatic deletion triggered due to configuration update.   |
| 5014 | AUTODEL_ERROR         | Automatic deletion failed.                                  |
| 5015 | AUTODEL_WRITEERROR    | Writing to logfile failed.                                  |
| 5016 | AUTODEL_TIMEOUT       | Communication response received after timeout.              |
| 5017 | AUTODEL_UNKNOWN       | Automatic deletion triggered due to an unknown update.      |
| 5018 | AUTODEL_DELError      | Deletion failed. Bootloader sent an unknown response.       |
| 5019 | AUTODEL_EMPTYRESP     | The bootloader sent an empty response.                      |
| 5020 | AUTODEL_RETRYFAIL     | Retrying failed. (Retried operation three times)            |
| 5021 | AUTODEL_NOTINIT       | Deletion failed during initialization.                      |

|      |                       |                                   |
|------|-----------------------|-----------------------------------|
| 5022 | AUTODEL_CLEARREQFAIL  | Eventlogger clear request failed. |
| 5023 | AUTODEL_CLEARREQSTATE | Eventlogger clear request failed. |
| 5024 | AUTODEL_REQFAIL       | Eventlogger clear request failed. |
| 5025 | AUTODEL_TIMEOUTSET    | Timeout occurred.                 |

## 9 DIGITAL REFERENCE THERMOMETER CERTIFICATION

### 9.1 POLICY

Digital reference thermometers are to be calibrated at least once every 12 months.

### 9.2 PROCEDURE

Digital reference thermometers are to be submitted to a NIST traceable calibration laboratory for calibration. The laboratory is to be capable of providing calibration certificates traceable to NIST or a similar national or international reference standard.

Digital Reference Thermometers will be calibrated in accordance with manufacturer specifications to include:

Readout Resolution 0.01°C

Accuracy Tolerance +/-0.020°C

Nominal Temperature Test Points 33°C, 34°C, and 35°C.

### 9.3 CALIBRATION ORDERING PROCEDURE

BTP personnel will follow the instructions listed in SharePoint on completing the calibration order form. This will ensure the above specifications are met and if the device needs to be adjusted during calibration, provide “As Found” values, return the device to “In Tolerance” conditions and provide “As Left” values.

### 9.4 RECEIPT PROCEDURE

On receipt of returned digital reference thermometers, Technicians will verify the calibration meets the specifics listed above in 9.2 by reviewing the submitted calibration report.

- Check the recalibration date is one year from the calibration date report.
- Ensure the calibration sticker is accurate and placed on the thermometer not obstructing any information.
- Check the calibration range is 33 – 35 °C.
- Check the readout resolution is 0.01°C.
- Check the tolerance is +/-0.020°C.
- Ensure all three test points passed.
- If any “As Left” corrections are recorded, apply to any temperature readings during thermometer certification.
- Initial and date the front page of the calibration report to document review of the report and confirm the calibration meets the BTP calibration standards.
- Scan and email the signed calibration report to BTP Headquarters. The calibration report will be retained electronically on SharePoint and posted on WebDMS.
- Notify a BTP supervisor if the calibration report does not meet the BTP calibration standards.

## 9.5 RECORDS RETENTION

- Records received from the calibration laboratory shall indicate that the digital reference thermometer was tested, adjusted if necessary and returned properly calibrated.
- Records received from calibration laboratory are to be maintained as part of the BTP's regular business records.
- The BTP Headquarters shall maintain the original certificates received from the calibration laboratory.
- The Breath Test Technician shall maintain copies of the certificate received from the calibration laboratory.

## 10 SIMULATOR THERMOMETER CERTIFICATION

### 10.1 POLICY

All Guth Model 34C or Guth Model 2100 simulators used during the QAPs are to employ a thermometer that has been verified for accuracy at least once every 12 months. Following verification, the thermometers are considered suitable for use for a 12 month period. A new thermometer certification record shall be entered into the Access Breath Test Instrument Tracking, QA Simulator Certification.

### 10.2 PROCEDURE

- A. Have the mercury thermometer to be tested placed in a fully warm and equilibrated Guth Model 34C simulator.
- B. Install the standard reference thermometer probe in the same simulator in the location designed for this purpose. For the Guth Model 2100, place the probe within the same Guth Model 2100 simulator being evaluated.
- C. Ensure that the temperatures of both the tested thermometer and the standard reference thermometer have stabilized.
- D. Ensure the tested thermometer indicates a temperature within  $\pm 0.10\text{C}$  inclusive of the standard reference thermometer. Record the fully displayed standard reference thermometer results (including all digits) on the record form in instrument tracking. Record also the result indicated on the mercury thermometer to the second decimal place which will have to be estimated.
- E. If the thermometer results are acceptable, record "Yes" in the thermometer certification record.
- F. If the thermometer results are not acceptable record "No" on the thermometer certification record. Depending on the type of thermometer, one of the following steps may be followed:
  1. Mercury thermometer: check for separation of mercury and attempt to correct
  2. Digital thermometer: send back to Guth

After performing one of these steps, complete again the above procedure.

- G. If the thermometer does not comply with the standards outlined above then a new thermometer shall be installed (in the case of the mercury thermometer) or re-calibrated (in the case of the digital simulator) and a repair record shall be completed. The new thermometer shall be certified as outlined in this policy.

If a thermometer is ever found to exceed the limits of  $34.0 \pm 0.2 \text{ }^{\circ}\text{C}$ , then the thermometer must be re-calibrated and certified according to the procedure outlined in this policy.

## **11 BAROMETER CERTIFICATION**

### **11.1 POLICY**

Barometers used to check the ambient air pressure sensor contained within the Draeger instrument shall be calibrated at least once every 12 months.

### **11.2 PROCEDURE**

Reference barometers shall be checked for accuracy at least once every 12 months by submitting the device to an approved vendor for calibration. The approved vendor must perform the accuracy testing and provide a calibration certificate traceable to NIST or a similar national or international reference standard. Reference barometers shall be sent in for annual certification by the BTP Headquarters. Once calibrated, the records shall be maintained at the BTP Headquarters.

Reference Barometers will be calibrated in accordance with manufacturer specifications to include:

Accuracy (Error) Limit 0.030% R

Pressure Range 8.0 – 17.0 psi.

### **11.3 CALIBRATION ORDERING PROCEDURE**

BTP personnel will follow the instructions listed in SharePoint on completing the calibration order form. This will ensure the above specifications are met and a one year calibration interval.

### **11.4 RECEIPT PROCEDURE**

On receipt of returned reference barometers, technicians will verify the calibration meets the specifics listed above in 11.2 by reviewing the submitted calibration certificate.

- Check the recalibration date is one year from the calibration certificate date
- Check the Min Range is 8.0 psi and Max Range is 17.0 psi
- Check the Limit of Error is  $\pm 0.030\%R$
- Check there are 11 test points from 8.00-17.00 and the Errors are  $\pm 0.030\%R$
- Ensure the calibration sticker is accurate. Place it on the barometer not obstructing any information
- Initial and date the bottom of the front page of the calibration certificate to document review of the certificate and confirm the calibration meets the BTP calibration standards
- Scan and email the signed calibration certificate to BTP Headquarters. The calibration certificate will be retained electronically on SharePoint and posted on WebDMS.
- Notify a BTP supervisor if the calibration certificate does not meet the BTP standards.

## 11.5 RECORDS RETENTION

- Records received from the calibration laboratory shall indicate that the reference barometer was tested, adjusted if necessary and returned properly calibrated.
- Records received from the calibration laboratory are to be maintained as part of the BTP's regular business records.
- The BTP Headquarters shall maintain the original certificates received from the calibration laboratory.
- The Breath Test Technician shall maintain copies of the certificate received from the calibration laboratory.

## 12 INSTRUMENT TRACKING

### 12.1 POLICY

The following shall apply when entering information into Instrument Tracking. The purpose is to provide guidelines for when it is to be completed and the information it should contain. All information should be entered by certified Breath Test Technicians clearly and concisely to allow others to interpret the information.

### 12.2 ENTRIES

A. QA Simulator Certification

Complete for every QA simulator thermometer certification

B. QA Simulator Repair/Adjust

Complete any time a repair or adjustment is made to a QAP simulator

C. QA Schedule

Update for every instrument upon completion of QAP

D. Preliminary Breath Test (PBT)

Complete for every PBT certification

E. Cylinder Change Record

Complete for every cylinder change done on an instrument

F. Repair Record

The form needs to be completed in the following situations:

1. Replacement or repair of any components or parts not included as exceptions below
2. Adjustment of the instrument clock if it is more than 20 minutes off
3. Any time an instrument or dry gas enclosure is sent back to the manufacturer for repair, or repaired by the Technician.
4. Any time an internal standard adjust is performed in the field.
5. Instrument Re-calibration (except where part of the routine QAP)
6. Other necessary repairs or adjustment to restore an instrument to proper working order
7. When a repair is performed requiring the form to be completed, a complete breath test shall be conducted and noted on the form. When conducting the complete breath test the printer shall be turned off. When in the discretion of the Technician the particular repair will not influence the analytical performance of the instrument (e.g., correcting the clock time) then a complete breath test is not required.

The form shall not be completed in the following situations:

1. Prior to the instrument's initial QAP
2. Powering the instrument off and on to clear a lock-up condition
3. When changing time to correspond to changes in daylight saving time
4. When problem is due to operator error
5. When the display indicates any of the possible error messages and the problem is corrected on the subsequent test. A record of these situations is preserved in the database
6. When the problem is corrected over the phone with an operator
7. When an instrument is transferred to a permanent training status
8. When replacing a toner cartridge
9. As part of the routine QAP

#### G. Instrument Status

The form needs to be completed in the following situations:

1. When an instrument is initially placed in service, and
2. When an instrument is taken out of service for QAP or repair for more than 12 hours.

#### H. Instrument Serial Number

To be completed when a new instrument is deployed, or if the polling phone number, location, city, technician name, lab code, WSP District and/or county is modified.

## 13 ESTIMATION OF MEASUREMENT UNCERTAINTY

### 13.1 POLICY

Measurement uncertainty will be estimated for results obtained during calibration of the breath alcohol measuring instruments. The BTP has attempted to identify all the components that contribute to the uncertainty and have made reasonable estimates of each component for inclusion in the uncertainty budget. The estimation of uncertainty does not replace any existing policies established for the maintenance of quality control nor does it supersede any established legal, statutory or regulatory guidance on breath alcohol testing or breath alcohol measuring instrument calibration.

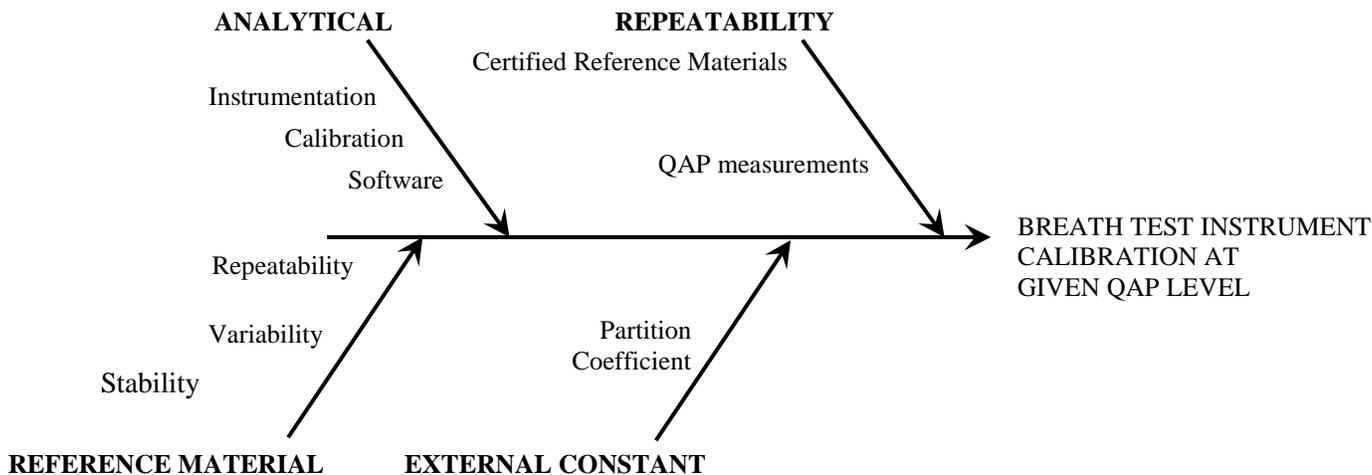
Uncertainty is not synonymous with error, inaccuracy or bias. Restrictions on measurement error have been integrated into the procedure for instrument calibration. Refer to the Draeger Alcotest 9510 QAP chapter of this Technical Manual for a description of the restrictions applicable to breath alcohol measuring instrument calibration.

This policy applies only to the functions of the BTP breath alcohol calibration program as defined in its scope of accreditation. The application of measurement uncertainty to individual breath alcohol tests is not covered by this policy and any such calculations should not be construed as having either been reviewed or endorsed by representatives of any accrediting organization.

### 13.2 UNCERTAINTY BUDGET

An uncertainty budget describes those components that have been identified as contributing to the overall measurement uncertainty for a given calibration activity. These components include contributions from reference standards, inexact values of reference materials, equipment used, approximations in the measurement procedure, inexact values of constants and variations in repeated observations (repeatability). Multiple sources may contribute to a single uncertainty component. When a component is estimated from a source external to the BTP, it is first converted to its standard uncertainty based on the reported coverage factor.

The figure below shows the cause and effect diagram for the uncertainty sources contributing to the breath alcohol measuring instrument's calibration uncertainty. It includes the uncertainty associated with the QAP solution (reference material) and adds the variability of repeated measurements of the QAP solution measured using the Breath Test Instrument.



### 13.3 MEASUREMENT UNCERTAINTY OF BREATH ALCOHOL CALIBRATION REFERENCE MATERIALS (QAP SOLUTIONS)

QAP solutions used in calibration of the Draeger Alcotest 9510 are certified reference materials (CRM) sourced from an approved vendor (Alcohol Countermeasure Systems Corp., ACS). A Reference Material Certificate of Analysis (COA) is provided with each lot of solution, which includes the stated expanded uncertainty range. The Vapor Equivalent Concentration and Uncertainty worksheet documents the review of the COA for each lot of ACS solution, as well as calculation of the equivalent vapor concentration ( $EVC_{Sol}$ ) and the combined equivalent vapor concentration uncertainty ( $u_{Sol-vend}$ ) specific to that lot.

The vendor name, solution lot number and date of production of the solution listed on the COA are entered in the worksheet. The “Reference concentration” listed on the COA is entered in the worksheet as the “Nominal Equivalent Vapor Concentration.” The “Analytical concentration” listed on the COA is entered as the “Reference Solution Concentration” in the worksheet (this value is lot-specific).

#### 13.3.1 UNCERTAINTY OF THE REFERENCE MATERIAL CONCENTRATION

The expanded uncertainty for the ACS solutions is entered in the Vapor Equivalent Concentration and Uncertainty worksheet as the “Expanded Uncertainty of CRM (k=2).” This value was set as 0.0012 g/L (0.00012 g/100 mL), based on the reported measurement uncertainty listed on ACS COAs. The worksheet converts the expanded uncertainty to the standard uncertainty ( $u_{RM}$ ), with coverage factor k=1.

The  $EVC_{Sol}$  and  $u_{RM}$  are used in the calculation described in 13.3.3.

#### 13.3.2 UNCERTAINTY FROM INEXACT VALUES OF CONSTANTS

The uncertainty associated with the constant used to convert ethanol solution concentrations (g/100 mL) to ethanol vapor concentrations (g/210 L) is determined from fitting data to the exponential model describing the relationship between the water/air partition coefficient and temperature. The equivalent vapor concentration conversion

factor used is 1.21, which represents the conversion factor used by the reference material provider (ACS).

The uncertainty for this constant ( $CV_{Part\ Coef}^2$ ) is calculated using the following equation.

$$CV_{Part\ Coef}^2 = \left(\frac{0.0124}{1.21}\right)^2$$

### 13.3.3 COMBINED UNCERTAINTY FOR THE QAP SOLUTION

The combined standard uncertainty of the QAP solution ( $u_{Sol-vend}$ ) is calculated using the following equation, on the Vapor Equivalent Concentration and Uncertainty worksheet.

$$u_{Sol-vend} = EVC_{Sol} \times \sqrt{u_{RM}^2 + CV_{Part\ Coef}^2}$$

## 13.4 UNCERTAINTY FROM REPEATABILITY MEASUREMENTS OF QAP SOLUTIONS ON THE DRAEGER ALCOTEST 9510

The variability in repeated measurements of the QAP solution during instrument calibration comes from a combination of instrumental, software and simulator uncertainty sources. Five samplings of each linearity concentration are analyzed on the Draeger Alcotest 9510, and the mean value is calculated for that concentration ( $\overline{EVC}$ ). The uncertainty from repeatability measurements on the instrument ( $CV_{BTI}^2$ ) is calculated using the following equation, on the Draeger Alcotest 9510 Calibration Certificate:

$$CV_{BTI}^2 = \left(\frac{SD}{\sqrt{5}} / \overline{EVC}\right)^2$$

Each of the four calibration concentration levels has an associated  $CV_{BTI}^2$  uncertainty component.

## 13.5 COMBINED UNCERTAINTY FOR THE INSTRUMENT CALIBRATION

The uncertainty of each QAP solution and the uncertainty from repeatability measurements of that QAP concentration on the breath alcohol measuring instrument are combined for the uncertainty of the instrument calibration ( $u_{BTI}$ ). The calculations are performed in the Draeger Alcotest 9510 Calibration Certificate.

$$u_{BTI} = \overline{EVC} \times \sqrt{CV_{BTI}^2 + \left(\frac{u_{Sol-vend}}{EVC_{Sol}}\right)^2}$$

where:

$\overline{EVC}$  = mean of repeatability measurements of the QAP solution in the calibration

$EVC_{Sol}$  = EVC (reference value in g/210 L) of the QAP solution

$u_{BTI}$  is calculated at each of the four QAP levels and expanded uncertainties are produced for each with a coverage factor (k) of 2 which is equivalent to a 95.45% confidence interval.

## 14 LIST OF CHANGES – TECHNICAL MANUAL HISTORY

Since Revision (10/10/11 of TLDCalTM)

| Section and Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Date Approved           | Author/Reviewer                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------------------------------------|
| <p>Overall Text and Format</p> <p>Changed title page.<br/>                     Reformatted header and footer. Changed chapter numbers where relevant.<br/>                     Removed most procedures relating to reference material calibration functions. New document ID BTPCaTM.<br/>                     TLDCalTM revised and remains in use for TLD.</p> <p>Replaced Chapter 2 with procedure for receipt and storage of simulator solutions only. Deleted Chapters 3, 4 and 9 entirely.</p> | <p>October 15, 2012</p> | <p>Black/Sharpe</p>                                                      |
| <p><b>Rev. #1</b><br/>                     Removed language from 1.2.24, added language to 2.2 (solution handling and transport) and to Chapter 3 (equipment ID and handling, acceptance criteria for breath test after certification).</p>                                                                                                                                                                                                                                                         | <p>March 15, 2013</p>   | <p>Black/Sharpe</p>                                                      |
| <p><b>Rev. #2</b><br/>                     Removed “Calibration” from Manual Title.<br/>                     Introduced new chapter (4) for the Draeger Alcotest 9510 QAP. Added dry gas handling to chapter 2 and new chapter 6. Where appropriate changed references to DataMaster to “breath test instrument”.<br/>                     Added chapter on barometer certification (14).<br/>                     Consolidated definitions.</p>                                                    | <p>October 30, 2014</p> | <p>Neilson, Denton,<br/>                     Villanti/Sharpe, Couper</p> |

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| <p>Changed Uncertainty of Measurement to Measurement Uncertainty. Added formula for calculating Draeger instrument uncertainty (17.4)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                      |                                       |
| <p><b>Rev. #3</b></p> <p>Removed handheld barometer references. Added procedures to have reference barometer to be submitted to an approved vendor for annual certification.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>November 2014</p> | <p>Villanti/Sharpe/Neilson/Couper</p> |
| <p><b>Rev. #4</b></p> <p>2.1 Policy</p> <p>This change reflects the shift from internally prepared ESS and QAP solution to solutions prepared by an external vendor. The language was also updated for the dry gas standard to match the ESS and QAP solutions.</p> <p><i>2.2.5 Added information about cylinder receipt and storage.</i></p> <p>2.2.6 Struck “Not for use in Calibration” from being allowed for use when marking expired solution.</p> <p>2.2.7 Changed the reference from batch to lot concerning cylinder markings.</p> <p>3.1 Clarified Conditions Requiring the QAP (DataMaster)</p> <p>3.2 Instrument Assessment<br/>                 This changes the language for the “As Found” test for both the Draeger and the Datamaser so that the requirements for both instruments are the same.</p> | <p>July 2016</p>     | <p>Mosley/Neilson/Sharpe</p>          |

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| <p>3.3.8-PERFORM A DIAGNOSTIC TEST AND RETAIN THE DOCUMENT IN THE QAP FILE.</p> <p>This change reflects an update to the combined standard uncertainty language because all older solutions have been used or are expired. The k=1 procedure is no longer necessary. The Cal Cert is also being updated to reflect this update.</p> <p>3.3.9 DataMaster test document shall be preserved by photocopy. Once it's checked for accuracy and legibility the photocopy becomes the original. Carbon copies are not kept.</p> <p>3.3.10 The technical record submitted by the Breath Test Technician for technical review is complete when the worksheet and all data generated, which includes a date, have been initialed.</p> <p>3.4 QAP Review and Certificate Issuance</p> <p>These changes are for the purposes of using the same wording throughout the entire document.</p> <p>4.1 Clarified Conditions Requiring the QAP (Draeger)</p> <p>4.2 Instrument Assessment Modifies the "As Found" procedures for the Draeger and Datamaster so that they are the same.</p> <p>4.3 Procedure (Draeger)</p> <p>Clarifies which version is used.</p> <p>4.3.1 Barometric Pressure Adjustment</p> |  |  |
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| <p>The change from millibars to Hectopascals mirrors the language the Draeger uses in their documentation and literature. Step four reflects the fact that the barometric pressure only needs to be verified when no adjustment is needed.</p> <p>4.3.2. Calibration Procedure</p> <p>Step B. accurately reflects the procedure.</p> <p>4.3.6 and 4.3.7 were swapped to match the Draeger order.</p> <p>4.3.8 QAP Printout (Draeger)</p> <p>Clarified technicians shall include all produced documents, including the 'As Found' printout.</p> <p>4.3.9 Calibration Certificate</p> <p>This change reflects an update to the combined standard uncertainty language because all older solutions have been used or are expired. The k=1 procedure is no longer necessary. The Cal Cert is also being updated to reflect this update.</p> <p>4.3.10 Added: The technical record submitted by the Breath Test Technician for technical review is complete when the worksheet and all the data generated, which includes a date, have been initialed.</p> <p>4.4 QAP Review and Certificate Issuance (Draeger)</p> <p>Second paragraph third and fourth sentences added:<br/> <i>summary – technician reviewing and issuing calibration certificate will verify "Software Verified" has been written, all documents are included, and match the</i></p> |  |  |
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| <p><i>calibration certificate. See 4.3 above for reason.</i></p> <p>10.4 DataMaster Helps</p> <p>10.4.1 Policy</p> <p><b>INTERFERENCE DETECTED</b><br/> <i>Change: removed implied consent for blood and added request search warrant for blood. Reason law changed under U.S. v McNeely</i></p> <p><i>PUMP Error Added run test again then if fails put out of service.</i></p>                                                                                                                                                                                                                                                                                                                                                                                               |                       |                                    |
| <p><b>Rev#005</b></p> <p>2.1 Policy</p> <p><i>This change reflects the shift from internally prepared ESS and QAP solution to solutions prepared by an external vendor. The language was also updated for the dry gas standard to match the ESS and QAP solutions.</i></p> <p>3.2 Instrument Assessment<br/> <i>This changes the language for the "As Found" test for both the Draeger and the DataMaster so that the requirements for both instruments are the same.</i></p> <p>3.3.8 PERFORM A DIAGNOSTIC TEST AND RETAIN THE DOCUMENT IN THE QAP FILE.</p> <p><i>This change reflects an update to the combined standard uncertainty language because all older solutions have been used or are expired. The Cal Cert is also being updated to reflect this update.</i></p> | <p>September 2016</p> | <p>Jones/Neilson/Sharpe/Couper</p> |

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| <p>3.3.9 <i>This change reflects an ASCLD/LAB requirement that thermal paper documents, or documents that degrade be retained in manner where degradation isn't a concern.</i></p> <p>3.3.10 <i>This change is an addition to meet ISO supplemental 4.13.1.1.1</i></p> <p>3.4 QAP Review and Certificate Issuance<br/> <i>These changes are for the purposes of using the same wording throughout the entire document. Breath test document replaces, instrument printout, copies of instrument printouts, and photocopied instrument printouts.</i></p> <p>4.2-Instrument Assessment<br/> <i>This change mirrors the change to 3.2 and modifies the "As Found" procedures for the Draeger and Datamaster so that they are the same.</i></p> <p>4.3 Procedure<br/> <i>The Draeger provides the ability to print the current software. Switching to this procedure will provide proof that the software is verified and it will provide a cleaner document for the QAP.</i></p> <p>4.3.1 Barometric Pressure Adjustment<br/> <i>The change from millibars to Hectopascals mirrors the language the Draeger uses in their documentation and literature. Step four reflects the fact that the barometric pressure only needs to be verified when no adjustment is needed.</i></p> <p>4.3.2 Calibration Procedure</p> |  |  |
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| <p>Step B. accurately reflects the procedure.</p> <p>4.3.5 Perform the Mouth Alcohol/Invalid Sample Test</p> <p>A. Select the “INVALID SAMPLE TEST” from the menu on the instrument and follow the procedures provided by the instrument.</p> <p>B. A human subject is to exhale into the instrument during the PLEASE BLOW phase shortly after introducing into the mouth a substance containing ethyl alcohol (i.e., mouthwash, beverage alcohol, etc.).</p> <p>C. Verify that the instrument displays “INVALID SAMPLE”.</p> <p>D. Ensure the “INVALID SAMPLE” box is checked on the display screen for the QAP upon completion of the test.</p> <p><i>4.3.6 and 4.3.7 were swapped to match the Draeger order.</i></p> <p>4.3.9 Calibration Certificate</p> <p>A. The Draeger 9510 Calibration Certificate shall be filled out when the above steps have been successfully performed as described. The certificate will be transferred for technical and administrative review as described in the Review and Certificate Issuance section.</p> <p>B. The results of the certification procedure will be examined to ensure they comply with the stated tolerances of accuracy (%bias) and precision (%CV).</p> <p>C. The entire QAP shall be repeated if, during the QAP the Technician is required to replace any parts or components.</p> |  |  |
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| <p>D. The Expanded Uncertainty value (k=2) listed on the QAP Solution Test Report must be divided by a factor of two. This is automatically computed by the Calibration Certificate when documented in the appropriate column for the Combined Standard Uncertainty.</p> <p>The Cal Cert has been updated to reflect this change.</p> <p>4.3.10 The technical record submitted by the Breath Test Technician for technical review is complete when the worksheet and all data generated, which includes a date, have been initialed.</p> <p><i>This change is an addition to meet ISO supplemental 4.13.1.1.1</i></p> |                     |                                                                               |
| <p>REVISION #6</p> <p>Updated language to reflect merge of ASCLD/LAB into ANAB throughout.</p> <p>Refined language throughout to be more concise.</p> <p>Chapter 1 – Definitions added, terms changed to match current ASCLD/LAB and ANAB terminology</p> <p>Chapter 2 – Changes reflect the BTP taking over ESS and QAP distribution. Clarification of External standard receipt process and use of approved vendors.</p> <p>Chapter 3 - Clarified QAP procedures for DataMaster</p> <p>3.1 Changed order of conditions requiring a QAP.</p>                                                                         | <p>October 2017</p> | <p>Couper/Sharpe/Jones/Neilson/<br/>                 Dearmore/Maier/Divis</p> |

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| <p>3.2 Allowed use of simulator solution for the “As Found” procedure.</p> <p>3.3 Clarified that reason for restarting a QAP will be noted in comments section.</p> <p>3.3.2 Language updated to reflect ANAB ASCLD/LAB terminology.</p> <p>3.3.3 language changed to reflect ANAB ASCLD/LAB terminology and a note was added to remind techs to use a separate QAP batch for the adjustment and calibration and changed combined uncertainty language.</p> <p>3.3.4 Complete breath test now also referred to as “verification”.</p> <p>3.3.9-14 formatting change</p> <p>3.3.8 change reflects using the start of the diagnostic test as the end time of the QAP, which is the current practice</p> <p>3.3.9 Clarified new order that Calibration Certificates will be transferred for reviews and to IDS for final retention.</p> <p>3.4 updated to reflect changes in the way QAP certificates and technical/administrative reviewers are completed</p> <p>3.5 ESS change added to clarify what is required (also addressed in solution change chapter)</p> <p>Chapter 4 - Clarified QAP procedures for Draeger</p> <p>4.1 format change</p> <p>4.2 ANAB language change</p> |  |  |
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| <p>4.3 Internal printer to print current software, then deactivate internal printer</p> <p>4.3.1 Update procedure to exit the screen</p> <p>4.3.2 reflects the requirement for separate batch numbers for the adjustment and calibration</p> <p>4.3.4 Same requirement as 4.3.2</p> <p>4.3.7 Procedure clarifications</p> <p>4.3.9 Update current review policies and expanded uncertainty method</p> <p>4.3.10 the language was changed to reflect the new certificate issue/tech review process</p> <p>4.4 Updated the order of the reviews and issuing certificates</p> <p>4.5 Reminder to ensure most current LCB location codes added</p> <p>Chapter 5 - Clarified when solution change is performed on Datamaster instruments. Stated how often to update codes.</p> <p>5.2 ANAB terminology updates</p> <p>5.4 solution change update</p> <p>5.6 Cannabis term and timetable</p> <p>Chapter 6 - Clarified External Standard Changing details for Draeger</p> <p>6.2 ANAB terminology updates</p> <p>6.5 Changed to use COA concentration</p> |  |  |
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| <p>Chapter 7 ANAB terminology updates and punctuation</p> <p>Chapter 8 - Clarified PBT Certification Protocol to instruct use of altitude chart or correction factor</p> <p>8.1 ANAB terminology updates</p> <p>8.2 Use of altitude chart</p> <p>8.4 Use of Chart and ANAB terminology updates</p> <p>8.5 ANAB terminology updates</p> <p>8.6 ANAB terminology updates</p> <p>Chapter 9</p> <p>9.1 Use of clear language to eliminate variability</p> <p>9.2 Claification of words for uniformity</p> <p>Chapter 10 - Added Draeger Help Sheet</p> <p>Chapter 11</p> <p>11.3 ANAB terminology updates</p> <p>Chapter 12</p> <p>12.3 ANAB terminology updates</p> <p>Chapter 13 - Added when to verify thermometers for accuracy; send digital thermometer to Guth when unacceptable results</p> <p>13.1 Clarification for tracking</p> <p>13.2 We do not calibrate digital thermometers and ANAB terminology updates</p> <p>Chapter 14</p> <p>14.2 ANAB terminology updates</p> |  |  |
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| <p>14.3 ANAB terminology updates</p> <p>Chapter 15 - Turn off printer when conducting complete breath test.</p> <p>15.2G removed to reflect new QAP process</p> <p>Chapter 16 – Proficiency Testing Removed</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                      |                                    |
| <p>Revision #7</p> <p>Changes throughout the Breath Test Program Technical Manual include:</p> <ul style="list-style-type: none"> <li>• Update to reflect that the Breath Test Program no longer utilizes solutions made by the Toxicology Laboratory.</li> <li>• All references to the DataMaster have been removed.</li> <li>• All references to External Standard Changers have been removed.</li> <li>• References to FLSSB Standards and Accountability and Toxicology Laboratory Manager have been replaced with Quality Assurance Manager.</li> <li>• All Temporary Policy Directives made during the year have been incorporated to include .</li> </ul> <p>The specifics of additional changes are outlined below.</p> <p>Chapter 1</p> <p>Updates to 2017 rather than 2005 ISO standards.</p> | <p>November 2019</p> | <p>Benante/Harbour/Black/Maier</p> |

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| <p>1.2.6 removed reference to External Standard Changers.</p> <p>Chapter 2</p> <p>Changed date of solution expiration to two years from date of preparation.</p> <p>Chapter 3 Removed</p> <p>Chapter 4 (now Chapter 3)</p> <p>4.3.1 Added software update to list of conditions requiring QAP.</p> <p>4.3.2 Clarified when an As Found is required.</p> <p>4.3.3 Removed language about when instrument is fully warm as it will not allow one to do anything until it has warmed up.</p> <p>4.3.3 Clarified Barometric Pressure Adjustment procedure.</p> <p>4.3.4 Changed maximum use for QAP solution from “single day” to 24 hours.</p> <p>4.3.5 – 4.3.7 Changed the order of Invalid Sample test, Interference Test, and Complete Breath Test to Interference, Breath, then Invalid Sample.</p> <p>4.3.8 Clarified procedure by which one ensures results are within acceptable ranges for Bias and CV; added instruction to set the QAP date on the instrument.</p> <p>4.4 Changed language about scanning/emailing documents.</p> <p>4.5 Simplified language; added instruction to send printed breath test document to BTP Headquarters.</p> <p>Chapter 5 Removed</p> |  |  |
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| <p>Chapter 6 (now Chapter 4)</p> <p>6.3 Clarified extandard cylinders must be from an approved vendor.</p> <p>6.4 Removed language indicating technician had remote access.</p> <p>6.5 Added instruction to send generated documents to BTP Headquarters.</p> <p>6.6 Removed “code book” and indication that location codes could be added via data line.</p> <p>Chapter 7 (now Chapter 5)</p> <p>7.2 C. Changed reference value to analytical concentration</p> <p>Chapter 8 (now Chapter 6)</p> <p>8.1 Added language to indicate PBT custodians are responsible for their PBT in terms of storage, loss, damage, and ordering.</p> <p>8.2 Added language to indicate technician may make PBT adjustments if the PBT is in the acceptable range.</p> <p>8.6 Removed C.</p> <p>Chapter 9 (now Chapter 7)</p> <p>9.2 Clarified data entry format.</p> <p>Chapter 10 (now Chapter 8)</p> <p>Updated to only include Draeger codes.</p> <p>Removed tables that were oriented to operators and replaced with most complete list available.</p> <p>Chapter 11 (now Chapter 9)</p> |  |  |
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| <p>11.1 Clarified language on when to calibrate digital reference thermometer</p> <p>11.2-11.4 Replaced “testing” with “calibration” and updated to include specifications to which calibrations are required to be made as per the IOC dated 7/26/2018 (effective 8/30/2018) regarding calibration specifications and receipt of equipment.</p> <p>Chapter 12 Multi-Meter Certification Removed and Instrument Tracking instructions updated to reflect exclusive Draeger use</p> <p>Chapter 13 (now Chapter 10)</p> <p>13.1 Updated language to reflect Guth simulators are only used during QAPs; replaced “certified” with “verified”; clarified how to track in instrument tracking.</p> <p>13.2 H. Removed instruction on retaining forms at the local level.</p> <p>Chapter 14 (now Chapter 11)</p> <p>14.1 Clarified language on when to calibrate digital reference thermometer</p> <p>14.2-14.4 Replaced “testing” with “calibration” and updated to include specifications to which calibrations are required to be made as per the IOC dated 7/26/2018 (effective 8/30/2018) regarding calibration specifications and receipt of equipment.</p> <p>Chapter 15 (now Chapter 12)<br/>         Renamed “Instrument Tracking”</p> <p>15.1 Wrote policy to encompass entering information into instrument tracking rather than</p> |  |  |
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| <p>just for the "Repair/Adjustment" form.</p> <p>15.2 Changed this to be specific to Repair/Adjust form and updated to reflect conditions it is/is not required.</p> <p>Chapter 16 (now Chapter 13)</p> <p>Removed references to Datamaster or solutions prepared by the TLD.</p> <p>13.3 – 13.5 Updated uncertainty of measurement calculations to reflect calculations based on use of the ACS ethanol solutions and the Draeger instrument only. Added procedure for verification of new ACS lot numbers using the Vapor Equivalent Concentration and Uncertainty worksheet.</p> |  |  |
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