Washington State Patrol

BREATH TEST PROGRAM

Technical Manual

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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 RECORDS

Refers to documents kept as part of the Instrument Record.

1.2.10 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.

1.2.11 COEFFICIENT OF VARIATION (CV)

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

1.2.12 COMBINED UNCERTAINTY

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

1.2.13 DRAEGER CALIBRATION/ADJUSTMENT RECORD

The form produced by the Draeger at end of the QAP.

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, external standard 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.

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

As technicians receive ordered QAP solutions, they will verify whether the batch number is posted on WebDMS. If not, the technician will notify BTP headquarters of the new batch received. The initial Equivalent Vapor Concentrations (Reference Value) and the Combined Equivalent Vapor Concentration uncertainty in g/210L of each solution batch will be calculated on the Vapor Equivalent Combined Uncertainty document. A second person will review the completed form (e.g., QA Manager, Technical Lead or designee). BTP headquarters will post the COA and batch Vapor Equivalent Combined Standard Uncertainty document on Web DMS and notify technicians.

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

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

The technician shall verify each canister's lot number and expiration date are consistent with Certificate of Analysis (compare COA manufacture date with expiration date of 3 years). Report any issues with packaging or missing documents.

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

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 *(e.g., ensure solution bottles are tightly capped/sealed, secure in the vehicle to prevent movement while in transit)*.

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 in a facility other than a permanent laboratory, the location must provide moderate environmental conditions of temperature and humidity as commonly found under normal laboratory conditions (normal conditions, as defined in validation, is 68-74°F). 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.

Prior to transporting instruments, disconnect cords and cables and ensure cover is in place. Keep the instrument upright and secure in the vehicle to prevent excessive movement while driving. When returning the instrument to Draeger for repair, ship the instrument in a sturdy box with protective packing (e.g., foam bumpers, bubble wrap or paper cushion).

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 approved 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 between the simulator and the instrument should be no more than 2" excluding the overlap with the connectors.

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)
1. IR-Transmitter
2. IR-Detector
3. Cuvette
4. 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 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 a Technician by running one complete breath test on the instrument. For data entry purposes see Chapter 7 Data Entry for Breath Test Program Personnel. One signed and dated 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 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 outlined 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, a repair record will be created. Verify the date and time on the Draeger is correct and verify the internal printer is not selected.

3.3.1 Current Software Verification

The Technician shall verify the active software versions match the approved software versions by the Washington State Toxicologist. Using the internal printer and preferably on the same day as the QAP is performed, 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.

3.3.2 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 ±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.

3.3.3 Adjustment Procedure

A. Use a certified, non-expired QAP solution (0.08 nominal value) for the adjustment function. The 0.08 solution used for the adjustment shall be a different batch number than the 0.08 solution used for calibration. All QAP solutions are valid for use for a maximum of 24 hours from the time the solution is first opened/transferred to a simulator. Allow the simulator solution to equilibrate prior to introducing the vapor to the instrument.

B. Connect the simulator to the instrument

C. Select “Menu”

D. Select “Maintenance”

E. Select “QAP”

F. Select “Adjustment”

G. Follow data entry prompts from the instrument

3.3.4 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 the 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.”

3.3.5 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, non-expired 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.

Use only approved simulators which contain a certified QAP solution. Verify that the certified thermometer indicates that the temperature of the simulator solution is 34.0 ± 0.2 ºC.

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 box is 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. The Technician may exhale into the tubing to ensure the flow path from the simulator is primed prior to running calibration level replicates. The Technician also has the option to observe the results for the first replicate of a calibration level, to evaluate the performance of the simulator. The Technician may stop the linearity test to check the simulator components (e.g., seal, gasket, tubing) prior to restarting the linearity test. This is not considered part of the calibration and documentation is not required. This may only be done once at each QAP level.

If a complete linearity test is repeated, a repair record shall be completed to indicate the appropriate action:

- The tolerance agreement failed during the *x* calibration while conducting a QAP. It was repeated and passed within the tolerance limits.

- The tolerance agreement failed during the *x* calibration while conducting a QAP. A new adjustment was done followed by a repeat of all calibration levels which passed within the tolerance limits.

Note: “*x*” refers to the specific solution value (0.04, 0.08, 0.15, or 0.20)

3.3.6 Perform the 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).

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 the Interference Test

A. Use a simulator containing a 0.08 g/210L QAP solution 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.

3.3.8 Perform a Complete Breath Test

A. Ensure that a certified, non-expired, dry gas external standard is connected to the instrument, at gas inlet #1.

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 the appropriate “Breath Test” box is checked on display screen for the QAP upon completion of the test.

NOTE: Above steps 3.3.6 through 3.3.8 may be done in any order.

3.3.9 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 ± 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 ± 0.005 g/210 L using the second formula below.

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

or $\quad \bar{Y} - R = \pm$ 0.005 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:

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

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.

3.3.10 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.

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

3.4 DRAEGER CALIBRATION 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 and/or issue certificates. The review conducted by the issuer and the technical/administrative reviewer may be accomplished based on 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, including the "As Found" printout, if applicable. 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 shall review the QAP Certificate and supporting documents and the review will be documented on the Quality Assurance Procedure Review Form. The technical/administrative reviewer shall verify all items listed on the on the review form. 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 and supporting documentation will then be provided to the issuer.

The issuer shall review the QAP Certificate and supporting documents and the review will be documented on the Quality Assurance Procedure Review Form Draeger Alcotest 9510. The issuer shall verify all items listed on the on the review form. 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 and 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 scan 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 associated gas enclosure. Verify the cylinder information is correct.
- 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.
- Ensure the technician key has been removed.

4 EXTERNAL STANDARD CHANGING PROCEDURE FOR DRAEGER ALCOTEST 9510

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, 0.08 g/210L nominal value gas cylinders are used.
- 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 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. Each cylinder replacement requires a cylinder change procedure.

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 and secure it to the regulator unit.

D. Insert the technician key 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 0.080. 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 RESPONSIBLITIES

- Ensure the instrument has adequate supplies: mouthpieces, DUI arrest forms, alcohol-based wipes, 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.

The PBT instruments are to be certified at least every six months.

6.2 PROCEDURE FOR ALCO-SENSOR FST PBT

A. Obtain a certified dry gas alcohol standard 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 messaged 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 ± 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 15 ˚C and 35 ˚C. If the temperature is not within the calibration 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 messaged 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 0.0 ˚C and 40.0 ˚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 intake port.

G. Attach mouthpiece to the gas standard source and introduce 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 ± 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 ± 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 slowly counter-clockwise to the gas standard value. Avoid adjusting to below the reference gas standard value during this procedure.

C. Repeat 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. When results are not outside ± 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 RECORD KEEPING

A. Complete the PBT Certification Record.

B. Record results to three decimal places.

C. Documentation shall be retained at the satellite laboratories.

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 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	Test or AS/FOUND
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
PBT given	No
Operator name	TYPE IN OR SCAN CARD Last First Middle
Operator Agency Code	WSP(your region)57
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 attached.
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 DETECTED	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. range +25%
12	ALC. CONC. NOT STABLE	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 expired.
15	BLOWING TIME TOO SHORT	Blowing time is too low
17	MIN. VOLUME NOT ACHIEVED	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 DETECTED	Negative breath flow was detected during PLEASE BLOW prompt
37	RTC PROBLEM	Real Time Clock hardware error detected
38	HARDWARE ERROR	General indicator for hardware related error messages
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 ERROR	The DC power supply drops below 10.5 VDC.
43	FLASH DELAY ERROR	A potential problem was observed during the write cycle of EEPROM
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-concentration sample.
51	PRINTER ERROR	Any hardware-related problem with the internal printer
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 time difference.
68	DIAGNOSTIC CHECK FAILED	Any of the internal functionality tests were outside of tolerance
70	DRYGAS CHECK ERROR	An empty or expired drygas cylinder was observed while checking the pressure of the dry gas cylinder(s).

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 operator ID has expired.

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_DEFEKT	Volume of 0,5l is not purged within predefined time or a blockage of any tube.

118	NTC_CUVETTE_DEFEKT	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_DEFEKT	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 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_DEFEKT_6	eeprom programming error
137	GP_EEPROM_DEFEKT	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_DATALOGGER	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. When sending thermometers to the calibration provider, ship the equipment in the original case/box from the manufacturer or a sturdy box with protective packaging.

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.

- Records received from the calibration laboratory shall indicate that the digital reference thermometer was tested, adjusted if necessary and returned properly calibrated.
- 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 calibration report to document review of the report and confirm the calibration meets the BTP calibration standards.
- Scan and email the calibration report to BTP Headquarters. The calibration report will be 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 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 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 simulator.

B. Install the standard reference thermometer probe in the same simulator in the location designed for this purpose.

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 ± 0.10C 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: follow manufacturer recommendations

After performing one of these steps, repeat 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 ± 0.2 ºC, then the thermometer must be re-calibrated and certified according to the procedure outlined in this policy.

10.3 CLEANING, MAINTENANCE AND STORAGE

A. Cleaning

1. Clean simulators as necessary and at least once every 12 months as part of the QA Simulator Certification procedure. Record this maintenance on the "Simulator Maintenance Log."
2. Clean top housing using mild detergent with a soft cloth or cotton swab (no bleach on housing unit).
3. Soak simulator and components in a solution of 1 Tablespoon bleach per 1 Gallon of room temperature water for approximately 30 minutes:
    a. either mix a gallon jug of solution and fill simulator jar to 500 ml mark, replace top housing, and leave to soak for approximately 30 minutes;
    b. or, fill the simulator jar to 500 ml mark with room temperature water, add 2 ml of bleach using a pipette, agitate to mix the solution, replace top housing, and leave to soak for approximately 30 minutes.
4. Simulators are **not to be heated** while containing bleach solution.
5. Rinse with cold water and air dry before storage or use.

B. Simulator Maintenance

1. Prior to each use:
    a. Inspect jars to ensure edges are smooth and there are no cracks or chips.
    b. Wipe down housing and threads with a damp cloth.
    c. Check O-rings and/or gaskets for uneven wear, cracking, and tears.
2. Ensure O-rings and/or gaskets are lubricated periodically with gasket grease as provided by manufacturer.
3. Replace O-rings and/or gaskets annually or as needed. Record this maintenance on the "Simulator Maintenance Log."

C. Storage

4. Wipe down and air-dry simulators prior to storage.
5. Store simulators dry and clear of moisture.

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. 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. When sending barometers to the calibration provider, ship the equipment in the original case/box from the manufacturer or a sturdy box with protective packaging.

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 ±0.030%R
- Check there are 11 test points from 8.00-17.00 and the Errors are +/-0.030% R
- Ensure the calibration sticker is accurate. Place it on the barometer not obstructing any information
- Initial and date the calibration certificate to document review of the certificate and confirm the calibration meets the BTP calibration standards
- Scan and email the calibration certificate to BTP Headquarters. The calibration certificate will be 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.

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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. Technicians will take care to not inadvertently overwrite or delete records. A new record shall be created for each new entry.

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 and certificate issuance

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 (See Chapter 7 Data Entry for Breath Test Program Personnel) and noted on the form. 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.

8. If a calibration level fails or when a new adjustment was done during a QAP using the following language:

   The tolerance agreement failed during the x calibration while conducting a QAP. It was repeated and passed within the tolerance limits.

   OR

   The tolerance agreement failed during the x calibration while conducting a QAP. A new adjustment was done followed by a retry of all calibration levels which passed within the tolerance limits.

   x = specific solution value (0.04, 0.08, 0.15, 0.20)

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.

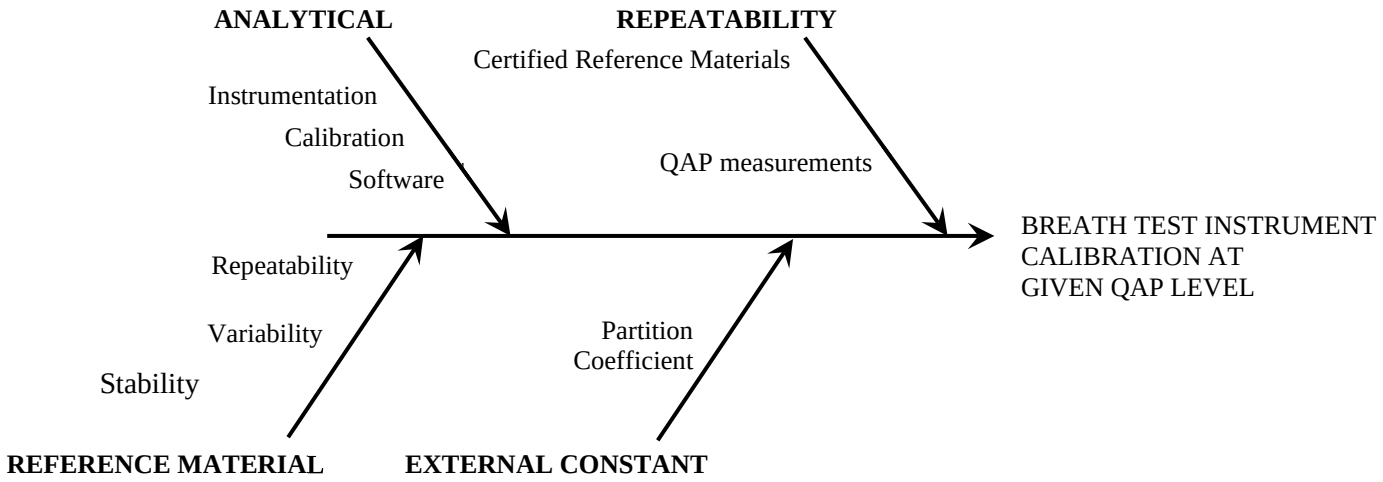
Uncertainty is not synonymous with error, inaccuracy or bias. Restrictions on measurement error have been integrated into the procedure for instrument calibration. Refer to the Draeger Alcotest 9510 QAP chapter of this Technical Manual for a description of the restrictions applicable to breath alcohol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

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

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

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.

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

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^2_{BTI}) is calculated using the following equation, on the Draeger Alcotest 9510 Calibration Certificate:

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

Each of the four calibration concentration levels has an associated CV^2_{BTI} 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.

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

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 2.87 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
Overall Text and Format Changed title page. Reformatted header and footer. Changed chapter numbers where relevant. Removed most procedures relating to reference material calibration functions. New document ID BTPCalTM. TLDCalTM revised and remains in use for TLD. Replaced Chapter 2 with procedure for receipt and storage of simulator solutions only. Deleted Chapters 3, 4 and 9 entirely.	October 15, 2012	Black/Sharpe
Rev. #1 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).	March 15, 2013	Black/Sharpe
Rev. #2 Removed “Calibration” from Manual Title. 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”. Added chapter on barometer certification (14). Consolidated definitions.	October 30, 2014	Neilson, Denton, Villanti/Sharpe, Couper

Section and Comments	Date Approved	Author/Reviewer
Changed Uncertainty of Measurement to Measurement Uncertainty. Added formula for calculating Draeger instrument uncertainty (17.4)		
Rev. #3 Removed handheld barometer references. Added procedures to have reference barometer to be submitted to an approved vendor for annual certification.	November 2014	Villanti/Sharpe/Neilson/Couper
Rev. #4 2.1Policy 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. *2.2.5 Added information about cylinder receipt and storage.* 2.2.6 Struck "Not for use in Calibration" from being allowed for use when marking expired solution. 2.2.7 Changed the reference from batch to lot concerning cylinder markings. 3.1 Clarified Conditions Requiring the QAP (DataMaster) 3.2 Instrument Assessment This changes the language for the "As Found" test for both the	July 2016	Mosley/Neilson/Sharpe

Section and Comments	Date Approved	Author/Reviewer
Draeger and the Datamaser so that the requirements for both instruments are the same. 3.3.8-PERFORM A DIAGNOSTIC TEST AND RETAIN THE DOCUMENT IN THE QAP FILE. 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. 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. 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. 3.4 QAP Review and Certificate Issuance These changes are for the purposes of using the same wording throughout the entire document. 4.1 Clarified Conditions Requiring the QAP (Draeger) 4.2 Instrument Assessment Modifies the "As Found" procedures for the Draeger and Datamaster so that they are the same.		

Section and Comments	Date Approved	Author/Reviewer
4.3 Procedure (Draeger) Clarifies which version is used. 4.3.1 Barometric Pressure Adjustment 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. 4.3.2. Calibration Procedure Step B. accurately reflects the procedure. 4.3.6 and 4.3.7 were swapped to match the Draeger order. 4.3.8 QAP Printout (Draeger) Clarified technicians shall include all produced documents, including the 'As Found' printout. 4.3.9 Calibration Certificate 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. 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.		

Section and Comments	Date Approved	Author/Reviewer
4.4 QAP Review and Certificate Issuance (Draeger) Second paragraph third and fourth sentences added: *summary – technician reviewing and issuing calibration certificate will verify "Software Verified" has been written, all documents are included, and match the calibration certificate.* See 4.3 above for reason. 10.4 DataMaster Helps 10.4.1 Policy INTERFERENCE DETECTED *Change: removed implied consent for blood and added request search warrant for blood.* Reason law changed under U.S. v McNeely PUMP Error *Added run test again then if fails put out of service.*		
Rev#005 2.1 Policy *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.* 3.2 Instrument Assessment *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.* 3.3.8 PERFORM A DIAGNOSTIC TEST AND	September 2016	Jones/Neilson/Sharpe/Couper

RETAIN THE DOCUMENT IN THE QAP FILE. *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.* 3.3.9 *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.* 3.3.10 *This change is an addition to meet ISO supplemental 4.13.1.1.1* 3.4 QAP Review and Certificate Issuance *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.* 4.2-Instrument Assessment *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.* 4.3 Procedure *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.* 4.3.1 Barometric Pressure Adjustment		

Section and Comments	Date Approved	Author/Reviewer
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. 4.3.2 Calibration Procedure Step B. accurately reflects the procedure. 4.3.5 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. *4.3.6 and 4.3.7 were swapped to match the Draeger order.* 4.3.9 Calibration Certificate A. The Draeger 9510 Calibration Certificate shall be filled out when the above steps have been successfully performed as described. The		

Section and Comments	Date Approved	Author/Reviewer
certificate will be transferred for technical and administrative review as described in the Review and Certificate Issuance section. B. The results of the certification procedure will be examined to ensure they comply with the stated tolerances of accuracy (%bias) and precision (%CV). C. The entire QAP shall be repeated if, during the QAP the Technician is required to replace any parts or components. 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. The Cal Cert has been updated to reflect this change. 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. *This change is an addition to meet ISO supplemental 4.13.1.1.1*		
REVISION #6 Updated language to reflect merge of ASCLD/LAB into ANAB throughout. Refined language throughout to be more concise.	October 2017	Couper/Sharpe/Jones/Neilson/ Dearmore/Maier/Divis

Section and Comments	Date Approved	Author/Reviewer
Chapter 1 – Definitions added, terms changed to match current ASCLD/LAB and ANAB terminology Chapter 2 – Changes reflect the BTP taking over ESS and QAP distribution. Clarification of External standard receipt process and use of approved vendors. Chapter 3 - Clarified QAP procedures for DataMaster 3.1 Changed order of conditions requiring a QAP. 3.2 Allowed use of simulator solution for the “As Found” procedure. 3.3 Clarified that reason for restarting a QAP will be noted in comments section. 3.3.2 Language updated to reflect ANAB ASCLD/LAB terminology. 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. 3.3.4 Complete breath test now also referred to as “verification”. 3.3.9-14 formatting change 3.3.8 change reflects using the start of the diagnostic test as the end time of the QAP, which is the current practice 3.3.9 Clarified new order that Calibration Certificates will be		

Section and Comments	Date Approved	Author/Reviewer
transferred for reviews and to IDS for final retention. 3.4 updated to reflect changes in the way QAP certificates and technical/administrative reviewers are completed 3.5 ESS change added to clarify what is required (also addressed in solution change chapter) Chapter 4 - Clarified QAP procedures for Draeger 4.1 format change 4.2 ANAB language change 4.3 Internal printer to print current software, then deactivate internal printer 4.3.1 Update procedure to exit the screen 4.3.2 reflects the requirement for separate batch numbers for the adjustment and calibration 4.3.4 Same requirement as 4.3.2 4.3.7 Procedure clarifications 4.3.9 Update current review policies and expanded uncertainty method 4.3.10 the language was changed to reflect the new certificate issue/tech review process 4.4 Updated the order of the reviews and issuing certificates 4.5 Reminder to ensure most current LCB location codes added		

Section and Comments	Date Approved	Author/Reviewer
Chapter 5 - Clarified when solution change is performed on Datamaster instruments. Stated how often to update codes. 5.2 ANAB terminology updates 5.4 solution change update 5.6 Cannabis term and timetable Chapter 6 - Clarified External Standard Changing details for Draeger 6.2 ANAB terminology updates 6.5 Changed to use COA concentration Chapter 7 ANAB terminology updates and punctuation Chapter 8 - Clarified PBT Certification Protocol to instruct use of altitude chart or correction factor 8.1 ANAB terminology updates 8.2 Use of altitude chart 8.4 Use of Chart and ANAB terminology updates 8.5 ANAB terminology updates 8.6 ANAB terminology updates Chapter 9 9.1 Use of clear language to eliminate variability 9.2 Clarification of words for uniformity 9.3 Added thermometer transport care		

Section and Comments	Date Approved	Author/Reviewer
Chapter 10 - Added Draeger Help Sheet Chapter 11 11.3 ANAB terminology updates; added barometer transport care Chapter 12 12.3 ANAB terminology updates Chapter 13 - Added when to verify thermometers for accuracy; send digital thermometer to Guth when unacceptable results 13.1 Clarification for tracking 13.2 We do not calibrate digital thermometers and ANAB terminology updates Chapter 14 14.2 ANAB terminology updates 14.3 ANAB terminology updates Chapter 15 - Turn off printer when conducting complete breath test. 15.2G removed to reflect new QAP process Chapter 16 – Proficiency Testing Removed		
Revision #7 Changes throughout the Breath Test Program Technical Manual include: • Update to reflect that the Breath Test Program no longer utilizes solutions made by the Toxicology Laboratory.	November 2019	Benante/Harbour/Black/Maier

Section and Comments	Date Approved	Author/Reviewer
• All references to the DataMaster have been removed. • All references to External Standard Changers have been removed. • References to FLSB Standards and Accountability and Toxicology Laboratory Manager have been replaced with Quality Assurance Manager. • All Temporary Policy Directives made during the year have been incorporated to include . The specfics of additional changes are outlined below. Chapter 1 Updates to 2017 rather than 2005 ISO standards. 1.2.6 removed reference to External Standard Changers. Chapter 2 Changed date of solution expiration to two years from date of preparation. Chapter 3 Removed Chapter 4 (now Chapter 3) 4.3.1 Added software update to list of conditions requiring QAP. 4.3.2 Clarified when an As Found is required. 4.3.3 Removed language about when instrument is fully warm		

Section and Comments	Date Approved	Author/Reviewer
as it will not allow one to do anything until it has warmed up. 4.3.3 Clarified Barometric Pressure Adjustment procedure. 4.3.4 Changed maximum use for QAP solution from “single day” to 24 hours. 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. 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. 4.4 Changed language about scanning/emailing documents. 4.5 Simplified language; added instruction to send printed breath test document to BTP Headquarters. Chapter 5 Removed Chapter 6 (now Chapter 4) 6.3 Clarified extandard cylinders must be from an approved vendor. 6.4 Removed language indicating technician had remote access. 6.5 Added instruction to send generated documents to BTP Headquarters.		

Section and Comments	Date Approved	Author/Reviewer
6.6 Removed “code book” and indication that location codes could be added via data line. Chapter 7 (now Chapter 5) 7.2 C. Changed reference value to analytical concentration Chapter 8 (now Chapter 6) 8.1 Added language to indicate PBT custodians are responsible for their PBT in terms of storage, loss, damage, and ordering. 8.2 Added language to indicate technician may make PBT adjustments if the PBT is in the acceptable range. 8.6 Removed C. Chapter 9 (now Chapter 7) 9.2 Clarified data entry format. Chapter 10 (now Chapter 8) Updated to only include Draeger codes. Removed tables that were oriented to operators and replaced with most complete list available. Chapter 11 (now Chapter 9) 11.1 Clarified language on when to calibrate digital reference thermometer 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		

Section and Comments	Date Approved	Author/Reviewer
specifications and receipt of equipment. Chapter 12 Multi-Meter Certification Removed and Instrument Tracking instructions updated to reflect exclusive Draeger use Chapter 13 (now Chapter 10) 13.1 Updated language to reflect Guth simulators are only used during QAPs; replaced "certified" with "verified"; clarified how to track in instrument tracking. 13.2 H. Removed instruction on retaining forms at the local level. Chapter 14 (now Chapter 11) 14.1 Clarified language on when to calibrate digital reference thermometer 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. Chapter 15 (now Chapter 12) Renamed "Instrument Tracking" 15.1 Wrote policy to encompass entering information into instrument tracking rather than just for the "Repair/Adjustment" form. 15.2 Changed this to be specific to Repair/Adjust form and updated to reflect conditions it is/is not required.		

Section and Comments	Date Approved	Author/Reviewer
Chapter 16 (now Chapter 13) Removed references to Datamaster or solutions prepared by the TLD. 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.		
Revision 008 Updated effective date and revision number Throughout: updated formatting for consistency and presentation; typographical errors; grammar Replaced references to “Guth simulators” with “approved simulators” 1.2 Added “Draeger Calibration/Adjustment Record” definition Deleted “Calibration Records” definition (redundant) Replaced “solution change” with “external standard change” 1.2.19 Deleted “This includes most law enforcement officers within the state.” 2.2 Added procedures upon receipt of QAP solutions and external standards 3 Modified language regarding length of tubing: The outlet tubing between the simulator and the instrument should be no more than 2” excluding the overlap with the connectors.	November 2023	Benante/Harbour/Black/Leonard

Section and Comments	Date Approved	Author/Reviewer
3.2 Referenced Chapter 7 Data Entry for As Found Test 3.3 Deleted redundant information. Replaced “a single day” with “24 hours” 3.3.2 Reorganized Adjustment Procedure. Added solution equilibration requirement 3.3.4 Added solution equilibration requirement 3.3.4B Added option to run one test to equilibrate system during linearity test. Added repair record requirement if a complete linearity test fails or if a new adjustment was performed. 3.3.5 Reordered the test sequence 3.3.7 Deleted redundant information 3.3.8 Deleted redundant information 3.3.9 Deleted redundant information 3.4 Referenced Quality Assurance Procedure Review Form and deleted narrative 4.5H.3 Concentration value set at 0.080 6.1 Moved Frequency of PBT Certification (6.7) to under 6.1 Policy 9.4 Moved reference to contents of records received from the calibration lab from 9.5 Records Retention to 9.4 Receipt Procedure 10.2 G Deleted redundant information		

Section and Comments	Date Approved	Author/Reviewer
10.3 Added to address Simulator Cleaning, Maintenance and Storage 11.2 Deleted redundant information 12.2 F7 Deleted the instruction to turn off printer and referenced Chapter 7 Data Entry for Breath Test Personnel; added verbiage for repair record if tolerance agreement fails 13.3 Deleted reference to Alcohol Countermeasure Systems Corp., ACS 13.5 Updated coverage factor (k) to 2.87 to reflect revision to Draeger certificate effective July 2023.		