BREATH ALCOHOL CALIBRATION

TECHNICAL MANUAL

TOXICOLOGY LABORATORY DIVISION

WASHINGTON STATE PATROL

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1.0 TECHNICAL SERVICE PROGRAM

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

The Toxicology Laboratory (Toxicology Lab) and the Breath Test Program (BTP) are both responsible for the breath alcohol calibration functions of the TLD. The Toxicology Lab prepares and certifies two types of simulator solutions: the Quality Assurance Procedure (QAP) solutions and the External Standard solution. These solutions are then used by the BTP, where the QAP solutions are used to set and confirm the calibration of the evidentiary breath test instruments, and the External Standard solution is used to verify the accuracy and proper working order of the instruments as part of a field evidential breath test.

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

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

1.0.1 POLICY

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

All calibration and related services performed by the TLD shall meet generally recognized standards of the forensic community and its accrediting organizations. Specifically, the TLD shall perform all calibration activities in accordance with the specified program protocols and the ISO 17025:2005 accreditation standards.

All employees are required to familiarize themselves with this manual and implement the protocols and procedures specified herein. In doing so, the TLD will maintain the highest level of expertise and analytical confidence for the criminal justice system and comply with the ISO 17025:2005 accreditation standards and ASCLD/LAB-*International* supplemental standards.

Any adjustments or deviations from the policies and procedures detailed in this manual must be approved by the State Toxicologist or the Quality Assurance (QA) Manager, and appropriately documented in the Batch Record and/or the Instrument Record.

1.0.2 DEFINITIONS

1.0.2.1 ACCURACY

The proximity of a measured value to a reference value.

1.0.2.2 BACK-UP TECHNICIANS

Personnel who are fully trained as Breath Test Technicians. Their assignments, however, are typically in the WSP Field Operations Bureau (*see TLD Calibration Operations Manual Appendix A*). They will assist the local full-time Breath Test Technician, as required.

1.0.2.3 BATCH FILE

A file containing documentation produced as a result of certifying either an external standard solution or QAP solutions. Documents include the Simulator Solution Data Entry Review form, the QAP or External Standard Solution Calibration Certificate, the Solution Certificate Review, analyst affidavits/certifications, sequence tables and corresponding chromatograms, and the Solution Preparation Worksheet.

1.0.2.4 BATCH RECORD

Documentation related to the preparation and/or certification of either an external standard solution or QAP solutions, in addition to those contained within the batch file. Documents may include simulator solution preparation log, alcohol preparation log, alcohol control log, instrument maintenance records, etc.

1.0.2.5 BIAS

The difference between a measurement result and the true reference value of the property being measured. The bias can be absolute or relative. The bias quantifies the accuracy of the measurement.

1.0.2.6 BREATH TEST TECHNICIANS / TECHNICIANS

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

1.0.2.7 CALIBRATION

The process by which known traceable standards having unbiased reference values 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).

1.0.2.8 CALIBRATION CERTIFICATE

The final result sheet produced at the end of either a QAP solution or external standard solution certification process. It includes ethanol concentrations from individual solution aliquots, ethanol control results, statistical data, signatures of the preparer and other certifying analysts, and dates of preparation, certification and issuance.

1.0.2.9 CALIBRATION FILE

Refers to documents kept as part of either the Batch File and/or QAP File.

1.0.2.10 CALIBRATION RECORD

Refers to documents kept as part of either the Batch Record and/or the Instrument Record.

1.0.2.11 COEFFICIENT OF VARIATION (C.V.)

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

1.0.2.12 COMBINED UNCERTAINTY

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

1.0.2.13 CONFIDENCE INTERVAL

An interval that is symmetric about a statistical estimate (i.e., the mean) determined from a multiple of the standard deviation for the statistical estimate and in which the true measured value is expected to lie with a stated level of probability. A confidence interval is one way to report the expanded uncertainty.

1.0.2.14 DATAMASTER

The evidential breath testing instrument, including both the BAC DataMaster and BAC DataMaster CDM.

1.0.2.15 EXPANDED UNCERTAINTY

A multiple of the standard uncertainty which provides an interval within which the true quantitative result is expected to lie with a stated level of confidence. For a multiple of k=2, the interval will yield approximately 95% confidence that it contains the true property being measured.

1.0.2.16 EXTERNAL STANDARD SOLUTION

The solution used within the simulator to provide a known alcohol vapor concentration to test the accuracy and proper working order of the instrument as part of a field evidential breath test.

1.0.2.17 FORENSIC SCIENTISTS / ANALYSTS

Personnel trained and assigned to the Toxicology Lab for the purpose of solution preparation and certification.

1.0.2.18 INSTRUCTORS (BREATH TEST PROGRAM)

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

1.0.2.19 INSTRUMENT RECORD

All records and documentation related to a specific breath test instrument. Documents may include maintenance files, status sheets, solution change records, etc.

1.0.2.20 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.

1.0.2.21 OPERATORS (BREATH TEST PROGRAM)

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

1.0.2.22 PBT

A handheld Preliminary Breath Test (PBT) instrument. These are breath alcohol screening devices that include both the Alco-Sensor FST and Alco-Sensor III instruments. These instruments are used by law enforcement officers at the roadside to measure breath alcohol and help establish probable cause for arrest.

1.0.2.23 PRECISION

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

1.0.2.24 QUALITY ASSURANCE PROCEDURE (QAP)

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

1.0.2.25 QUALITY ASSURANCE PROCEDURE (QAP) FILE

A file containing all documentation produced as a result of the QAP process. Documents include the QAP Worksheet, the DataMaster QAP Form, the QAP Review Form, and a copy of the Simulator Solution Calibration Certificate.

1.0.2.26 QUALITY ASSURANCE PROCEDURE (QAP) SOLUTION

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

1.0.2.27 ROUNDING

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

1.0.2.28 SIMULATOR

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

1.0.2.29 SOLUTION CHANGERS

Currently qualified Operators who are trained to change the external standard solutions located with each breath test instrument.

1.0.2.30 STANDARD UNCERTAINTY

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

1.0.2.31 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.

1.0.2.32 UNCERTAINTY

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

2.0 PREPARATION OF QUALITY ASSURANCE PROCEDURE (QAP) SOLUTIONS

2.0.1 POLICY

The Quality Assurance Procedure (QAP) solutions are a mixture of water and ethanol formulated to provide a standard ethanol vapor concentration when used in a breath alcohol simulator heated to 34.0 ± 0.2 ˚C. The QAP solutions are used to set and confirm the calibration of, and verify the accuracy and precision of, evidentiary breath test instruments.

The QAP program requires target vapor concentrations of 0.04, 0.08, 0.10 and 0.15 g/210L vapor. The reference value concentration of a given QAP solution is determined from replicate measurements by gas chromatography.

2.0.2 EQUIPMENT

- Volumetric glassware/flasks
- 6 L Erlenmeyer flask
- Mechanical mixer and stir rod
- 18 L containers
- Storage bottles/containers
- Tamper evident tape, or equivalent

2.0.3 REAGENTS

- 200 proof absolute ethanol (USP Grade)
- Laboratory grade deionized water

2.0.4 PROCEDURE

1. The preparer will assign a batch number to the QAP solution. The first two digits of the batch number represent the year in which the solution was made, followed by a sequential three-digit number, beginning with 001. Therefore, the first batch of 2008 would be 08001.

2. Prepare a Batch File marked with the batch number to store all relevant results and documents.

3. Using the Simulator Solution Preparation Log, record the batch number of the solution, the date of solution preparation, the preparer's name, the lot number of the absolute ethanol reagent, and the date this reagent was opened.

4. Use the values in Table 1 to prepare each QAP solution.

Table 1:

Target Vapor Concentration	Ethanol/Water Dilution Factor
0.04	11.2 mL/18 L
0.08	22.4 mL/18 L
0.10	28.1 mL/18 L
0.15	42.0 mL/18 L

5. Using a 6 L Erlenmeyer flask, fill the flask to approximately 80% of the 6 L mark with deionized water.

6. Using volumetric glassware, add appropriate volume of absolute ethanol to the Erlenmeyer flask, as indicated in Table 1.

7. Fill the Erlenmeyer flask to the 6 L mark with deionized water. Add the 6 L of ethanol/water mixture to the 18 L vessel.

8. Fill the same Erlenmeyer flask to the 6 L mark with deionized water and add this to the 18 L vessel. Repeat this step. In total, the contents of the 6 L Erlenmeyer flask should be emptied into the 18 L vessel three (3) times.

9. Tighten the cap of the 18 L vessel. Mix the solution by applying mechanical mixing for a minimum of 30 minutes.

10. Once mixing is complete, purge the spigot then remove an aliquot of the solution for certification (*see 4.0 Certification of Simulator Solutions*).

11. Documentation of the preparation of the QAP solutions should be recorded on the Solution Preparation Worksheet. This worksheet will be placed in the batch file.

2.0.5 PACKAGING AND DISTRIBUTION

1. The QAP solutions are provided in containers of convenient size.

2. Prior to filling, each container is labeled with “QAP”, the batch number, the appropriate target vapor concentration, the preparer’s initials, and the preparation and expiration date.

3. The containers are sealed with tamper evident tape, or equivalent.

4. Once the QAP solutions are certified and approved for use, they may be provided to breath test technicians for use with the breath test instruments.

5. Solutions are boxed and sent by Consolidated Mail Services, or equivalent.

6. Insert a laboratory prepared “packing slip”. Retain a copy of the packing slip in the batch record.

2.0.6 RECEIPT AND STORAGE OF QAP SOLUTIONS

1. On receipt of the QAP Solutions, the Technician will sign and date the packing slip, indicating:
   a. Verification of order – adequate amount, correct concentrations, etc
   b. Inspection of bottles – no damage, leaking, broken seals, etc
   c. Record of receipt

2. If any discrepancies are noted, the Technician should contact the Toxicology Lab. Discrepancies may include insufficient quantity of QAP solutions, incorrect concentration, damaged and/or leaking bottles, and broken seals. Based on the specific discrepancy, the Toxicology Lab will endeavor to resolve the issue to the satisfaction of the Technician. Any discrepancies and subsequent resolution will be documented in the Batch Record.

3. On receipt of the QAP solutions, the Technicians should store them separately in a secure cabinet/closet. Extreme heat should be avoided.

4. The QAP solutions are valid and approved for use for a period of one year from the date of preparation. QAP solutions that have expired must be discarded.

5. Expired solutions may be discarded down a drain with additional water, and the solution containers discarded in the trash or recycled.

3.0 PREPARATION OF THE EXTERNAL STANDARD SOLUTION

3.0.1 POLICY

The External Standard solution is a mixture of water and ethanol formulated to provide a standard ethanol vapor concentration when used in a breath alcohol simulator heated to 34.0 ± 0.2 ˚C, of between 0.072 and 0.088 grams of ethanol per 210 liters (g/210L) of air, inclusive. To allow for depletion of ethanol from the solution during its use, the target starting ethanol vapor concentration is 0.082 g/210L.

Based on a water/air partition coefficient at 34 ˚C of 2585.9 (Jones, 1983), the external standard solution concentration required to produce a 0.082 g/210L of vapor equivalent is 0.101 g/100ml. The reference value concentration of a given external standard solution is determined from replicate measurements by gas chromatography.

3.0.2 EQUIPMENT

- Volumetric glassware/flasks
- Mechanical mixer and stir rod
- 52 L container
- Storage bottles/containers
- Tamper evident tape, or equivalent

3.0.3 REAGENTS

200 proof absolute ethanol (USP Grade)
Laboratory grade deionized water

3.0.4 PROCEDURE

1. The preparer will assign a batch number to the external standard solution. The first two digits of the batch number represent the year in which the solution was made, followed by a sequential three-digit number, beginning with 001. Therefore, the first batch of 2008 would be 08001.

2. Prepare a Batch File marked with the batch number to store all relevant results and documents.

3. Using the Simulator Solution Preparation Log, record the batch number of the solution, the date of solution preparation, the preparer's name, the lot number of the absolute ethanol reagent, and the date this reagent was opened.

4. Fill the 52 L vessel to approximately 80% of the 52 L mark with deionized water.

5. In a volumetric flask, fill to approximately 50% with deionized water. Using volumetric glassware, add 66.5 mL of absolute ethanol. Stopper the flask and mix well and add the contents of the flask to the 52 L vessel. Rinse the flask with deionized water and add this to the 52 L vessel.

6. Fill the vessel to 52 L with deionized water and tighten the cap. Mix the solution by applying mechanical mixing for a minimum of two hours.

7. Once mixing is complete, purge the spigot then remove an aliquot of the solution for certification (*refer to 4.0 Certification of Simulator Solutions*).

8. Documentation of the preparation of the external standard solution should be recorded on the Solution Preparation Worksheet. This worksheet will be placed in the batch file.

3.0.5 PACKAGING AND DISTRIBUTION

1. The external standard solution is provided in containers of convenient size.

2. Prior to filling, each container is labeled with “External Standard” or “Ext. Std.”, the batch number, the appropriate target vapor concentration, the preparer’s initials, and the preparation and expiration date.

3. The containers are sealed with tamper evident tape, or equivalent.

4. Once the external standard solution is certified and approved for use, it may be provided to breath test technicians for use with the breath test instruments.

5. Solutions are boxed and sent by Consolidated Mail Services, or equivalent.

6. Insert a laboratory prepared “packing slip”. Retain a copy of the packing slip in the batch record.

3.0.6 RECEIPT AND STORAGE OF EXTERNAL STANDARD SOLUTIONS

1. On receipt of the external standard solutions, the Technician will sign and date the packing slip, indicating:
    a. Verification of order – correct amount, correct concentrations, etc
    b. Inspection of bottles – no damage, leaking, broken seals, etc
    c. Record of receipt

2. If any discrepancies are noted, the Technician should contact the Toxicology Lab. Discrepancies may include insufficient quantity of external standard solutions, incorrect concentration, damaged and/or leaking bottles, and broken seals. Based on the specific discrepancy, the Toxicology Lab will endeavor to resolve the issue to the satisfaction of the Technician. Any discrepancies and subsequent resolution will be documented in the Batch Record.

3. On receipt of the external standard solutions, the Technicians should store them separately in a secure cabinet/closet. Extreme heat should be avoided.

4. The external standard solutions are valid and approved for use for a period of one year from the date of preparation. External standard solutions that have expired must be discarded.

5. Expired solutions may be discarded down a drain with additional water, and the solution containers discarded in the trash or recycled.

3.0.7 REFERENCE(S)

A.W. Jones. Determination of Liquid/Air Partition Coefficients for Dilute Solutions of Ethanol in Water, Whole Blood and Plasma. *Journal of Analytical Toxicology*, 7, 1983 pp 193-197.

4.0 CERTIFICATION OF SIMULATOR SOLUTIONS

4.0.1 POLICY

Each external standard and QAP solution must be certified by forensic scientists prior to its distribution to breath test technicians. The forensic scientists must have a valid Blood Alcohol Analyst Permit issued by the State Toxicologist.

A minimum of three (3) analysts shall test each solution before the average solution concentration can be calculated. Typically, three (3) analysts certify each set of QAP solutions, and seven to eight (7-8) analysts certify the external standard solution. Each analyst who has results included in the final computation of the average solution concentration has certified the batch.

Batches that do not certify as specified below are not approved for use and a Calibration Certificate is not generated. However, a batch record and batch file are still produced, including documentation of why the batch did not certify.

Any adjustments or deviations from the procedures below must be approved by the State Toxicologist or the QA Manager, and appropriately documented in the batch file.

4.0.2 EQUIPMENT

- Balance: Denver Instrument P-203, or equivalent
- Volumetric glassware
- Class A Pipettes
- Storage bottles/containers
- Microlab 500 Autopipette, Hamilton Automatic Diluter, or equivalent
- Headspace autosampler vials, 10 mL
- Headspace autosampler crimp tops
- Cap crimper
- Cap de-crimper
- Agilent (Hewlett Packard) 7694/G1888 Headspace Autosampler or equivalent
- Agilent (Hewlett Packard) 6890 gas chromatograph; equipped with a J&W DBALC1 megabore (0.53 mm) 30 meter capillary column and/or with a J&W DBALC2 megabore (0.53 mm) 30 meter capillary column or equivalent
- Computer System equipped with HP GC Chem Station

4.0.3 REAGENTS

- 1-Propanol
- Sodium chloride
- 200 proof absolute ethanol (USP Grade)
- Laboratory grade deionized water (d.H_2O)
- Compressed air, helium and hydrogen

4.0.3.1 INTERNAL STANDARD

The Internal Standard (ISTD) is prepared as follows:

ISTD Fill a 2000 mL volumetric flask to approximately 80 % with d.H_2O. Add 20 gm sodium chloride and 0.30 mL 1-propanol to the flask. Fill to the 2000 mL line with d.H_2O. Mix thoroughly.

Transfer to clean, labeled storage bottles. The internal standard can be stored at room temperature. Preparation of the Internal Standard is documented in the Alcohol Standard Preparation Log and the Internal Standard Preparation Worksheet. The Internal Standard expires 30 days after preparation.

4.0.3.2 ETHANOL CALIBRATORS

Three ethanol calibrators (CAL) are used, at concentrations of:
0.079, 0.158, and 0.316 g/100 mL

Using volumetric glassware, prepare the following:

CAL1	0.079 g/100 mL	Mix 1.0 mL absolute ethanol in 1000 mL d.H_2O
CAL2	0.158 g/100 mL	Mix 1.0 mL absolute ethanol in 500 mL d.H_2O
CAL3	0.316 g/100 mL	Mix 1.0 mL absolute ethanol in 250 mL d.H_2O

Transfer to clean, labeled storage bottles. Store refrigerated when not in use. Calibrators shall be brought to room temperature before use. Preparation of the Ethanol Calibrators is documented in the Alcohol Standard Preparation Log and the Ethanol Calibrator Preparation Worksheet. The Ethanol Calibrators expire 30 days after preparation.

4.0.4 CONTROLS

Commercially prepared ethanol controls (CTL) are purchased for use with each assay. The source and lot number of each control is documented in the Alcohol Control Log. Controls are stored per manufacturer specifications.

Three ethanol controls are used, at concentrations of:

CTL1	0.04 g/100 mL
CTL2	0.10 g/100 mL
CTL3	0.20 g/100 mL

Controls other than the aforementioned may be approved for use by the State Toxicologist or QA Manager, with appropriate documentation.

4.0.5 PROCEDURE FOR THE ANALYSIS OF SIMULATOR SOLUTIONS

The analyst who prepared the solution(s), and each subsequent analyst, will analyze the aliquot taken from the original mixture (either 18 or 52 L). Each analyst will analyze five separate aliquots of the solution(s).

External Standard Solution batches should be set up using the following sequence:

1. Blank (d.H20, no Internal Standard added)	9. Negative Control
2. CAL 1 (0.079 g/100 mL)	10. Solution aliquot #1
3. CAL 2 (0.158 g/100 mL)	11. Solution aliquot #2
4. CAL 3 (0.316 g/100 mL)	12. Solution aliquot #3
5. Negative Control (d.H20 plus Internal Standard)	13. Solution aliquot #4
6. Control 1 (0.04 g/100 mL)	14. Solution aliquot #5
7. Control 2 (0.10 g/100 mL)	15. Control 0.10 g/100 mL
8. Control 3 (0.20 g/100 mL)	16. Negative Control

QAP Solution batches should be set up using the following sequence:

1. Blank (d.H20, no Internal Standard added)	20. QAP 0.08 aliquot #4
2. CAL 1 (0.079 g/100 mL)	21. QAP 0.08 aliquot #5
3. CAL 2 (0.158 g/100 mL)	22. Control 0.10 g/100 mL
4. CAL 3 (0.316 g/100 mL)	23. Negative Control
5. Negative Control (d.H20 plus Internal Standard)	24. QAP 0.10 aliquot #1
6. Control 1 (0.04 g/100 mL)	25. QAP 0.10 aliquot #2
7. Control 2 (0.10 g/100 mL)	26. QAP 0.10 aliquot #3
8. Control 3 (0.20 g/100 mL)	27. QAP 0.10 aliquot #4
9. Negative Control	28. QAP 0.10 aliquot #5
10. QAP 0.04 aliquot #1	29. Control 0.10 g/100 mL
11. QAP 0.04 aliquot #2	30. Negative Control
12. QAP 0.04 aliquot #3	31. QAP 0.15 aliquot #1
13. QAP 0.04 aliquot #4	32. QAP 0.15 aliquot #2
14. QAP 0.04 aliquot #5	33. QAP 0.15 aliquot #3
15. Control 0.10 g/100 mL	34. QAP 0.15 aliquot #4
16. Negative Control	35. QAP 0.15 aliquot #5
17. QAP 0.08 aliquot #1	36. Control 0.10 g/100 mL
18. QAP 0.08 aliquot #2	37. Negative Control
19. QAP 0.08 aliquot #3	

1. Using the Auto-pipetter, extract 200 µL of the calibrators, controls or simulator solution and 2 mL of the Internal Standard solution.

2. Elute the aliquot/extract into a clean, labeled 10 mL headspace vial.

3. Seal the vial tightly.

See IOC_Modification of tech manual_20090113

4. Between each aliquot/extract, rinse and wash the pipette tip appropriately (e.g. rinse pipette tip with diluted bleach and/or d.H_2O. Repeat if necessary).

5. Load and edit a sequence on the headspace gas chromatograph. Enter the blank, calibrators, controls and simulator solutions into the sequence table, and identify them appropriately under Sample Type.

6. Place each headspace vial in the appropriate position on the headspace autosampler and verify this placement against the sequence log.

7. Run sequence under method SIMALC.

8. Upon completion of testing, analysts will initial their chromatograms and sequence table.

If two or more separate external standard solution batches are prepared close together, each batch may be certified using the same calibration and controls. For the analysis of multiple external standard solution batches and QAP solution batches, each set of 5 aliquots should be separated by a 0.10 g/100 mL control and a negative control. It is the 0.10 g/100 mL control run at the end of each set of 5 aliquots that is entered into the database.

4.0.6 ACCEPTANCE PARAMETERS

If the analysis of the batch meets the criteria listed below, the results for the simulator solution(s) are accepted and can be entered into the Simulator Information Management System (SIMS).

- Ensure that the blank is devoid of any significant peaks
- Ensure that the negative control is devoid of any significant peaks other than the internal standard. Should the negative control read above 0.005 g/100 mL for ethanol, the analyst re-aliquots and reanalyzes their sequence
- Verify that each calibrator and control quantifies to within ± 0.01 g/100 mL of the target values. Should one of the calibrators or controls read outside ± 0.01 g/100 mL for ethanol, the analyst re-aliquots and reanalyzes their sequence

4.0.7 CERTIFICATION, DOCUMENTATION AND REVIEW

1. The preparer shall open SIMS and create a new entry for the batch.
2. The preparer will enter the appropriate batch number and the date of the batch preparation. The 0.10 g/100 mL control lot number and expiration date shall also be entered.
3. Analysts will then enter the individual ethanol concentrations of all five (5) aliquots, the 0.10 g/100 mL control result, and the date of testing. In the event that a sequence is started on one day and completes after midnight, the date the sequence began shall be the date of testing. Analysts shall verify the data from the chromatograms and preparation/testing dates are correctly entered in the database. The chromatograms and sequence tables are placed in the batch file.
4. After obtaining and entering all valid measurement results, the average solution concentration (arithmetic mean) rounded to four decimal places, and the standard deviation rounded to five decimal places, is determined. A Calibration Certificate is then printed.
5. When a single outlier value is observed, the value will be removed from the data set and the test for outliers repeated. The final average solution concentration and standard deviation will be determined based on the remaining results found to be in acceptable agreement. (Note: the single outlier will be removed from the final solution calculations; however, the value will appear in the Calibration Certificate with an asterisk). If there are two or more outliers then the batch will not be certified and will be discarded.

6. The solution meets the standards required by the State Toxicologist if:

    i. For the external standard solution, the average solution concentration (final arithmetic mean) is within the range 0.096 – 0.106 g/100mL, inclusive

    ii. For the QAP solutions, the average solution concentration (final arithmetic mean) is within the ranges specified in Table 2

Table 2:	Target Vapor Concentration	Equivalent Solution Concentration	Acceptable Range (inclusive)
	0.04	0.049	0.047 - 0.052
	0.08	0.098	0.093 - 0.103
	0.10	0.123	0.117 - 0.129
	0.15	0.185	0.175 - 0.194

    iii. The CV is 5% or less

7. The equivalent vapor concentration is calculated by dividing the final average solution concentration by 1.23 and rounding to four decimal places.

8. The batch file will be forwarded to a Toxicology Lab supervisor or designee for an initial technical and administrative review. At this stage, the batch file should contain the printed Calibration Certificate, the chromatograms and sequence tables, ad the Solution Preparation Worksheet.

    The supervisor or designee will verify all preparation and testing dates are correct, the expiration dates of reagents, individual chromatograms are initialed, the correct ethanol concentrations were entered into SIMS, that the calibrators and controls were within the acceptable range, etc.

9. Upon completion of the supervisor's review, the batch file is returned to the analysts.

    Each analyst should again verify that the preparation/testing dates and the data from their chromatograms correctly appear on the printed Calibration Certificate before signing on the corresponding signature line. Their signature will also reflect that the results are the results of tests that they personally performed.

    Each analyst who certified the batch will also sign an affidavit as described in CrRLJ 6.13(c)(1), certification of simulator solution. These affidavits are typically prepared by administrative personnel. Affidavits are placed in the batch file.

10. A second technical and administrative review of the batch file will be performed by personnel from the BTP. The reviewer(s) will verify all preparation and testing dates are correct, chromatogram data is entered correctly, all chromatograms are included, accuracy and precision requirements are met, affidavits are signed and properly dated, etc. This review will be documented on the Simulator Solution Data Entry Review form, which will be added to the batch file.

11. The tests for outliers and final solution calculations will be independently verified by a reviewer(s) and this verification is documented on the Simulator Solution Data Entry Review form.

12. A Toxicology Lab supervisor or designee will then perform a final administrative review, and will sign and date the bottom of the Calibration Certificate indicating that the batch file is complete and the above procedures have been reviewed. The final review date will be the issue date of the certificate and the batch. Simulator Solutions must not be distributed for use prior to this issue date.

13. The final batch file should contain:
    i. The original QAP or External Standard Calibration Certificate, signed by each analyst
    ii. The Solution Certificate Review form
    iii. Copies of the analyst's affidavits
    iv. All relevant sequence tables and chromatograms
    v. The Solution Preparation Worksheet

5.0 QUALITY ASSURANCE PROCEDURE

The Quality Assurance Procedure (QAP) ensures the accuracy, precision and forensic acceptability of the DataMaster breath testing 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 DataMaster can be confidently placed in the field for evidential use.

5.0.1 CONDITIONS REQUIRING THE QAP

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

1. Prior to an instrument being installed in the field for evidentiary use.

2. After replacing any of the following components and prior to being placed back into the field for evidentiary use:

    a. Central Processing Unit (CPU) Board
    b. Infrared Detector
    c. Infrared Detector Block
    d. Infrared Detector Board
    e. Software

3. After disassembly and then reassembly of sample chamber.

4. If instrument requires recalibration for any reason.

5. At least once every year.

5.0.2 PROCEDURE

The following shall be performed or personally observed by each individual certifying the instrument. This procedure shall be performed when the instrument is fully warm. While conducting the following procedure, the Breath Test Technician shall complete the QAP Work Sheet. If at any point throughout the QAP protocol it becomes necessary to begin the entire QAP again, all of the paperwork up to that point shall be retained while noting the reason on the QAP Work Sheet.

1. ELECTRICAL CHECKS

A) <u>Sample Chamber Control Board</u>

1) Version #101226

a) Flow Detector

-Place black voltmeter lead on Test Point (TP)5
-Place red voltmeter lead on bottom of R28
-Adjust R26 to 0.200 (+/- 0.005) Volts Direct Current (VDC)

-Move red lead to TP2
-Adjust R29 to 1.40 (+/- 0.10) VDC
-Move red lead back to bottom of R28
-Adjust R26 to 0.020 (+/- 0.010) VDC

b) Sample Threshold

-Leave black voltmeter lead on TP5
-Place red voltmeter lead on TP1
-Adjust R34 to 2.40 (+/- 0.10) VDC

2) Sample Control Board (Version #41625)

a) Breath Volume Circuit

-Place black voltmeter lead on TP5
-Place red voltmeter lead on TP8
-Adjust R26 to 0.200 (+/- 0.005) VDC
-Move red lead to TP2
-Adjust R29 for 1.40 (+/- 0.10) VDC
-Move red lead back to TP8
-Adjust R26 to 0.020 (+/- 0.010) VDC

B) Detector Board: (TP4 is ground)

1) Infrared (IR) Detector Cooler (DetClr):

a) TP1: Adjust R4 to voltage indicated on tag attached to cable coming from J37 on Detector Board (±0.01) VDC.

b) If the tag listing the cooler voltage is not present, turn the instrument off and let it cool down to room temperature (approximately 30 minutes). Turn the instrument on and place voltmeter across R26 on Detector Board. Adjust R4 for 0.475 (±0.010) VDC. Recheck voltage at TP1. Note this voltage as the new Detector Cooler voltage.

2) Detector Bias (DetBias):

a) Top of R45 or TP13 depending on board version: 120.0 (±0.5) VDC unless a tag indicates a different value: Adjust R1

3) IR Source Intensity (MTR)

a) Activate Meter (MTR) on keyboard so the Detector voltage is displayed. Adjust R16 on the Sample Control Board for a displayed detector voltage of 0.000 (±0.100) VDC.

C) Analog-to-Digital Converter Reference (CPU)

a) The ground is TP0, or lower left corner pad.

b) Versions with TP2 and R37 present: TP2 or U29 pin 2: 2.00(±0.01) VDC: Adjust R37

c) No adjustment performed on Versions without TP2 and R37

D) Radio Frequency Interference (RFI) Threshold: (Top of R8 is ground)

1) Antenna must be installed.

2) Activate MTR on keyboard

3) Left side of L2. If reading is 4-6 VDC, adjust R18 clockwise (CW) to read 0-1 VDC. If reading is at 0-1 VDC, adjust R18 counter clockwise (CCW) to read 4-6 VDC. When the R18 turning point is reached, turn R18 one turn clockwise. When the voltage is between 4-6 VDC the MTR should display "RADIO INTERFERENCE".

2. CALIBRATION PROCEDURE

1) Reagents to be used include certified QAP solution and tap water.

2) Record the batch number of the solution used on the Datamaster QAP form.

3) Use only Guth Model 34C or 2100 simulators with a thermometer that has been certified according to the Simulator Thermometer Certification procedure (*see Chapter 14*).

4) The simulator inlet port should be attached to the pump via the "Calibrate" port on the instrument and the simulator outlet port to the breath tube.

5) Set the "ETHANOL CONCENTRATION" in the supervisory options to the vapor concentration of the reference value of the certified solution. Round the four digit reference value to three digits.

6) Ensure that the simulator thermometer indicates 34.0 ± 0.2 °C.

7) Use the F1-F2 keys on the keyboard to initiate the calibration procedure.

8) Follow the displayed instructions.

a) When the display reads "BLOW WATER VAPOR", introduce water vapor into the breath tube. Push NOVOL (NV) if necessary to accept the sample.

b) When the display reads "BLOW ETHANOL", introduce the known ethanol solution vapor into the breath tube until a stable reading is obtained. Push NOVOL (NV) to accept the sample if necessary.

9) Printout the calibration (CAL) factors and retain the document in the QAP file.

10) The technician shall be allowed to perform the calibration procedure as often as they determine to be necessary in order to achieve optimum instrument performance. Only the final breath test document needs to be retained.

3. CERTIFICATION PROCEDURE

The following steps shall be performed for all concentrations including 0.04, 0.08, 0.10, and 0.15.

1) Use only Guth Model 34C or 2100 simulators which contain a certified QAP solution.

2) Set the supervisory test option for ten tests.

3) Set keyboard and data collection to off.

4) Simulator check to off.

5) Use a thermometer which has been certified according to the Simulator Thermometer Certification Policy and Protocol. Verify that the thermometer indicates that the temperature of the simulator solution is 34.0 ± 0.2 °C.

6) Insert the document (except on DataMaster CDM) and push the SUP key.

7) When the ten tests are completed indicate if temperature is 34.0 ± 0.2 °C on the QAP Work Sheet.

8) Use the mean (arithmetic mean) and standard deviation values that are printed out by the Datamaster instrument to compute the % accuracy and the % CV. The mean and standard deviation have been rounded to four decimal places.

a) Determine the percent bias and ensure that it is within ± 5.00% according to the following equation:

$$\%\ bias = \left[\frac{\overline{Y} - R}{R}\right] \bullet 100$$

where:

$\overline{Y} = arithmetic\ mean$

$R = reference\ value$

b) Determine the coefficient of variation according to the following equation and ensure that the result is within ± 3.00%:

$$\%CV = \frac{SD}{\overline{Y}} \bullet 100$$

where:

$SD = standard\ deviation$

$\overline{Y} = arithmetic\ mean$

c) The % accuracy and % CV shall both be rounded to two decimal places and recorded on the Datamaster QAP Form

9) Perform a complete Breath Test according to the following:

a) Set supervisory test to one. Set keyboard, Simulator Check, and Sample Check to "ON". Conduct a complete breath test on the instrument using a live subject's breath sample. Use a certified external standard simulator solution

b) Retain the Breath Test Document

10) Perform the Interferent Detector Test according to the following:

a) Use a simulator containing approximately 0.08 g/210L of ethanol to which approximately 0.5 ml of acetone has been added

b) Verify the simulator thermometer indicates the temperature is 34.0 ± 0.2 °C and conduct one supervisory test

c) Verify that the instrument displays INTERFERENCE DETECTED

d) Push the ABT key and then push the COPY key and retain document in the QAP file

11) Perform the Filter Error check according to the following:

See IOC_Modification of tech manual_20081204

a) Using the SUP mode, prevent the acetone filter from going into place by removing the electrical connection. The instrument should stop the test and display FILTER ERROR

b) Push the ABT key and then push the COPY key and retain document in the QAP file

12) Perform the Mouth Alcohol Test according to the following:

a) Set instrument up to perform a breath test

b) A human subject is to exhale into 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 instrument displays INVALID SAMPLE

d) Push the ABT key and then push the copy key and retain the document in the QAP file

13) Perform the Radio Frequency Interference (RFI) Detector Test according to the following:

a) Set the instrument up to display PLEASE BLOW

b) Transmit a hand held (portable) police radio in the proximity of the instrument

c) Verify that instrument displays RADIO INTERFERENCE

d) Push the ABT key and then push the COPY key and retain the document in the QAP file

14) Perform a Diagnostic Test and retain the document in the QAP file.

15) The Datamaster QAP Form shall be completed and signed when the above steps have been successfully performed as described. The original completed and signed form will be sent to the BTP Headquarters and a copy retained locally.

The entire QAP shall be repeated if one of the following conditions exist during the QAP:

a) Readjustment of voltages that are outside of tolerances.

b) Any replacement of parts or components.

4. QAP REVIEW

Prior to installing the instrument in the field, the results of the QAP must be reviewed by a second qualified Technician. This technical and administrative review may be accomplished based on a faxed copy of the Datamaster QAP Form, the QAP Work Sheet and all corresponding print outs/documents. The reviewer also checks the technician's calculations for agreement, using the Excel QAP computation program.

Once the technical and administrative review is complete and acceptable, the reviewer completes and signs the QAP Form they received and the QAP Review Form. The reviewer then notifies the breath test technician that the instrument can be installed for use. A copy of the signed QAP Form and QAP Review Form will be sent to the breath test technician, while all original signed documents will be sent to the BTP Headquarters.

Any discrepancies identified in the review process will be brought to the attention of the breath test technician and the BTP Supervisor. Discrepancies not resolved at this level will be brought to the attention of the QA Manager and/or Appointing Authority (*see TLD Calibration Quality Manual, Chapters 3 and 9.3*).

5. FIELD INSTALLATION

. Prior to re-installing the instrument in the field, complete the following:

1) Employ the RESET OPTIONS function with the F1 and F2 keys

2) Ensure the simulator standard is set to 0.080 ± 0.008.

3) Ensure the INTERFERENCE level is set to 0.010

6.0 EXTERNAL STANDARD SOLUTION CHANGING PROTOCOL

6.0.1 POLICY

The following protocol shall apply to qualified personnel who change external standard solutions.

6.0.2 RESPONSIBILITIES

1. Only trained personnel shall change external standard solutions.
2. Trained personnel shall be responsible for monitoring and changing external standard solutions.
3. Solution measurements can be monitored through the host computer or by completing a supervisor test.
4. Ensure that only Guth Model 34C or 2100 simulators are employed for field use.

6.0.3 EXTERNAL STANDARD SOLUTION SUPPLY

1. Only certified external standard solutions are to be used.
2. Only solutions within a sealed container labeled with the batch number and preparation date are to be used.
3. Only non-expired external standard solutions are to be used.

6.0.4 EXTERNAL STANDARD SOLUTION CHANGING SCHEDULE

1. Solutions shall be changed at least every 60 days regardless of number of tests or measurement value.
2. When the instrument is removed from the facility for a QAP, repair or any other reason and then re-installed.

6.0.5 PROCEDURE

1. Turn off and disconnect simulator.
2. Discard old solution.
3. Dry the simulator tubing by removing excess moisture, replace tubing if necessary.
4. Check the instrument simulator ports for obvious excess moisture and dry if necessary.
5. The outlet tubing from the simulator should be kept as short as possible.

6. Ensure simulator elements and jar are clean and dry, pour contents of container into jar, tighten jar to simulator, and ensure the appropriate batch # label is attached.

7. Re-attach simulator and turn on.

8. Ensure that the thermometer indicates the correct temperature of: 34.0 ± 0.2 °C
    a) Adjust potentiometer if necessary
    b) Ensure that the power and heater lamps are working properly

9. Run one complete breath test entering data according to the steps outlined in Data Entry For BTP Personnel (hyperlink) and using a live subject's breath sample.

10. Keep the document of the completed test. Complete the form entitled Simulator Solution Change Record recording the results to three digits. The expiration date is one calendar year following the preparation date appearing on the solution container.

6.0.6 ADDITIONAL RESPONSIBILITIES

1. Ensure that the instrument has adequate supplies: mouthpieces, breath test document, DUI arrest forms, code book and printer supplies.

2. Ensure breath tube is warm or hot to the touch.

3. Check date and time and adjust if necessary.

4. Check RFI antenna and phone connections.

5. Replace "Drinking Location Codes" in code book with updates from the Liquor Control Board.

7.0 TRACEABILITY

7.0.1 POLICY

Traceability is established for measurement results, not for laboratories, methods or personnel. Traceability will be established for the individual measurement results and the mean calculations resulting from all results generated within the TLD. Traceability should establish an unbroken chain of comparisons for these measurement results back to NIST where each link will have uncertainty estimates. Traceability will allow for comparability between different analytical instruments and methods.

7.0.2 PROCEDURE

1. All measurement results, mean calculations, batch numbers, and reference values will be recorded on the appropriate forms.

2. A copy of the Simulator Solution Calibration Certificate issued by the Toxicology Lab will be maintained by the responsible breath test technician. This certificate will record the simulator solution batch number along with all measurement results obtained by the analysts in the Toxicology Lab. The certificate will also contain the results of control measurements along with the control lot number and reference value. One control measurement shall be performed along with the set of five aliquots of the simulator solution. All control measurements performed shall be within ± 0.01 g/100ml of the control reference value which will ensure the accuracy of the gas chromatograph instrument and the resulting reference value assigned to the simulator solutions.

3. The Toxicology Lab shall obtain and maintain a Certificate of Analysis (COA) from the reference material producer of the controls they purchase to be used during the testing of simulator solutions. The COA shall specify the lot number and reference value assigned to the purchased control solutions. 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.

4. The following three documents shall document and ensure traceability:

   a. The COA from the commercial manufacturer of the controls
   b. The Simulator Solution Calibration Certificate
   c. The DataMaster Quality Assurance Procedure Data Form

5. The traceability links will be from:

   a. The measurement results and mean reported on the DataMaster QAP Data Form to:
   b. The measurement results and mean reported on the Simulator Solution Calibration Certificate to:
   c. The control measurement results along with lot number and reference value for the controls reported on the Simulator Solution Calibration Certificate to:
   d. The reference value reported on the Certificate of Analysis from the control manufacturer to:
   e. NIST as documented on the Certificate of Analysis from the control manufacturer, where applicable

8.0 ALCO-SENSOR PBT CERTIFICATION PROTOCOL

8.0.1 POLICY

Qualified 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 operator 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.

8.0.2 PROCEDURE FOR ALCO-SENSOR FST PBT

1. Obtain certified dry gas alcohol standards for which the reference value is known and an Intox Regulator is attached.

2. If using a True-Cal device, the expected value of the standard will be displayed and will be the value that the PBT will be certified and/or calibrated to. If not using a True-Cal device, the altitude chart on the side of the tank will give you the stated value of your tank adjusted for the pressure changes due to the elevation at which you are using the dry gas standard.

3. Attach a new mouthpiece and power the instrument on by first pressing and holding the **OFF** button and then simultaneously pressing the **ON** button.

4. 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.

5. 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.

6. While the display is flashing **ACC,** make an airtight connection between the delivery tube of the regulator and the open end of the mouthpiece.

7. 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.

8. The result will automatically be displayed.

9. If the results are within ± 0.010 g/210L from the reference value for the gas standard, the PBT is properly calibrated and acceptably accurate and only one test is necessary. Proceed to the Record Keeping steps.

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

8.0.3 CALIBRATING THE ALCO-SENSOR FST PBT INSTRUMENT

1. To calibrate the instrument its temperature must be between 20 °C and 35 °C. If the temperature is not within the range, the unit will display **E09** or **E10** and block the calibration procedure.

2. Attach a new mouthpiece and power the instrument **ON** by first pressing and holding the **OFF** button and then simultaneously pressing the **ON** button.

3. 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.

4. Once **CAL** is displayed, depress the **OFF** button, this will initiate calibration sequence.

5. The temperature will be displayed, ensure a Blank Test result of 0.000 g/210L is also displayed. A flashing **CAL** message will appear.

6. While the display is flashing **CAL,** make an airtight connection between the delivery tube of the regulator and the open end of the mouthpiece.

7. 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.

8. 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.

9. 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.

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

8.0.4 PROCEDURE FOR ALCO-SENSOR III PBT

1. Obtain certified dry gas alcohol standards for which the reference value is known and an Intox Regulator is attached.

2. If using a Tru-Cal device, this will determine the concentration and will be the value that the PBT will be certified and/or calibrated to. If not using a Tru-Cal device, refer to the altitude chart on the side of the tank for the correct reference value.

3. Verify the PBT temperature is between 20.0 ˚C and 36.0 ˚C.

4. Push **SET** button. Push and hold the **READ** button.

5. 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.

6. Attach the mouthpiece in one of the following configurations:
    a. Attach the straight white tube mouthpiece to the instrument receptacle
    b. Attach the straight white mouthpiece with one-way valve so that the air will flow in the proper direction

7. Attach mouthpiece to the gas standard source and provide the sample. Allow approximately three seconds of gas flow.

8. Push and hold the **READ** button while the sample is still being provided. Continue to hold the **READ** button until the result stabilizes.

9. Observe digital reading to determine if acceptably accurate.
    a. If the results are within ± 0.010 g/210L from the 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
    b. If the result is not within the acceptable limits, proceed to step 10

10. Calibrating the PBT Instrument
    a. If the result is outside ± 0.010 g/210L of the reference value, first zero the instrument to 0.003 or less, then turn the calibration screw clockwise two full turns
    b. Re-introduce the gas standard and while holding the READ button, turn the calibration screw counter-clockwise slowly to value on gas standard. Avoid adjusting to below the reference gas standard value during this procedure
    c. Repeat steps 1 through 10 as often as necessary to obtain results within the acceptable range
    d. If results following calibration are acceptable, only perform one certified test as required in step 9.a
    e. Where instruments 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 will be performed according to steps 1 through 9.a. outlined above

8.0.5 DOCUMENTATION

1. Complete the Alco-Sensor PBT Certification Record.

2. Record results to three decimal places.

3. Note if it was necessary to calibrate the instrument.

4. Documentation will be retained at the satellite laboratories.

8.0.6 FREQUENCY OF PBT CERTIFICATION

The PBT instruments are to be certified at time intervals corresponding to those outlined in the Washington Administrative Code (WAC) 448-15.

9.0 CALCULATIONS FOR DETERMINING ACCEPTABLE AGREEMENT BETWEEN DUPLICATE BREATH ALCOHOL RESULTS

9.0.1 POLICY

The following summarizes the computational steps involved in determining whether duplicate breath alcohol measurements are within plus or minus ten percent (10%) of their mean as required in RCW 46.61.506 for the admissibility of evidential breath test results. These calculations are also performed automatically by the DataMaster instrument. However, these calculations are not performed within the DataMaster instrument where the mean of the duplicate results are less than 0.010 g/210L. These calculations are to be performed on the three digit breath alcohol results.

9.0.2 CALCULATION

1. To determine the mean of the two values, add the two results together and divide the sum by two. Round the mean to four decimal places.
2. Determine the lowest acceptable value by multiplying the mean value obtained above by 0.9 and truncate to three decimal places.
3. Determine the highest acceptable value by multiplying the mean value obtained above by 1.1 and truncate to three decimal places.
4. The appropriate equations to employ are as follows:

$$mean = \overline{Y} = \frac{1}{n}\sum_{i=1}^{n} Y_i$$

$$lower\ limit = \overline{Y} \bullet 0.9 \qquad upper\ limit = \overline{Y} \bullet 1.1$$

5. The range from the low to the high limits must include both sample results if the test is to be presumed valid as defined in RCW 46.61.506.

9.0.3 CALCULATION EXAMPLE

Assume the following duplicate breath alcohol test results: 0.155 and 0.181 g/210L

$$mean = \overline{Y} = \frac{1}{n}\sum_{i=1}^{n} Y_i = \frac{0.155 + 0.181}{2} = 0.1680\ g/210L$$

$$lower\ limit = \overline{Y} \bullet 0.9 = 0.1680 \bullet 0.9 = 0.1512 \Rightarrow 0.151\ g/210L$$

$$upper\ limit = \overline{Y} \bullet 1.1 = 0.1680 \bullet 1.1 = 0.1848 \Rightarrow 0.184\ g/210L$$

Since both breath sample results are within the range from 0.151 to 0.184 g/210L, the test has acceptable agreement.

10.0 DATA ENTRY FOR BREATH TEST PROGRAM PERSONNEL

10.0.1 POLICY

For uniformity, the following data entry codes are to be used by Breath Test Technicians and Solution Changers when performing breath tests on DataMaster instruments for new solutions, tests, etc. that will appear on the instrument database.

10.0.2 DATA ENTRY FORMAT

Simulator temp.?	Y
Observation Began	00:00
Citation Number	NEW/SOLUTION, SOLUTION or TEST
Operator	Correct Name
Arresting Agency	WSP1057
Subject's Name	NEW/SOLUTION, TEST, TEST/"TECHNICIAN'S OPTIONS"
Subject's DOB	00/00/0000
Subject's Sex	M
Subject's Ethnic Group	U
D.L. State/Number	OO
County of Arrest	00
Crime Arrested For	00
Collision Involved?	N
Drinking Location	0O000000
Batch #	Correct Number
PBT TEST GIVEN? (Y/N):	N

11.0 DATAMASTER CODE INTERPRETATION

11.0.1 POLICY

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

11.0.2 NUMERIC CODE AND INTERPRETATION

CODE NUMBER	MESSAGE CODE	INTERPRETATION
1.*	**SYSTEM WON'T ZERO**	Unable to zero detector voltage.
2.	**TEMPERATURE LOW**	Sample chamber temperature at 45 ˚C or below.
3.	**TEMPERATURE HIGH**	Sample chamber temperature at 55 ˚C or above.
5.*	**RADIO INTERFERENCE**	Radio frequencies detected.
6.	**FATAL SYSTEM ERROR (ADDRESS)**	Random Access Memory (RAM), Read Only Memory (ROM), or Peripheral Interface Adapter (PIA) not responding properly.
7.*	**CALIBRATION ERROR**	Internal standard does not read within 10% of the value determined at time of calibration.
8.*	**PRINTER ERROR**	Printer not responding properly.
9.*	**RAM ERROR (ADDRESS)**	RAM checksum does not match the value calculated following the last write.
10.	**PUMP ERROR**	Flow detector does not detect pump operation.
11.	**BLANK ERROR**	Instrument obtains reading greater than 0.003 g/210L during blank test.
12.	**DETECTOR OVERFLOW**	Detector output exceeds the 1.999V that is readable by the instruments Analog/Digital converter.
13.	**FILTER ERROR**	Filter solenoid not activating properly.
15.	**SIMULATOR OUT OF RANGE**	Simulator reading outside acceptable limits.
17.	**DATA MEMORY BATTERY LOW**	RAM battery backup failing.
19.	**AMBIENT FAIL**	Ethanol or other substance detected in sample chamber after purge.
20.	**SAMPLES OUTSIDE 10%**	

11.0.3 NON-NUMERIC CODE AND INTERPRETATION

V	**INVALID SAMPLE**
R	**REFUSED TEST**
X	**INTERFERANT**
I	**INCOMPLETE TEST**

* Codes found in the DataMaster instruments prior to 1995

12.0 DATAMASTER HELPS

12.0.1 POLICY

The DataMaster will generate several different error messages when specific criteria are not met during a test procedure. These messages are displayed on the instrument for the operator to respond to. The following are the messages that an operator may see and their interpretation. In addition, specific instructions for the operator are given here. This list should be posted on the wall near every DataMaster evidential breath test instrument in field use. The instructions provided here are considered guidelines only. They are not mandatory. Qualified operators may use their own training and discretion in responding to these messages.

MESSAGE DISPLAYED	INTERPRETATION AND INSTRUCTIONS
INVALID SAMPLE	Check Mouth, wait 15 minutes, try one or more tests and then call **WSP** if fails. **TAG** instrument "Out of Service"
AMBIENT FAIL	Check for odors, check to see if mouth piece is removed, try one or more tests and then call **WSP** if fails. **TAG** instrument "Out of Service"
SYSTEM WON'T ZERO	Unable to zero detector voltage. Try one or more tests and then call **WSP** if fails. **TAG** instrument "Out of Service"
DETECTOR OVERFLOW	Try one or more tests and then call **WSP** if fails. **TAG** instrument "Out of Service"
RADIO INTERFERENCE	Radio transmission detected, remove source, rerun test.
CALIBRATION ERROR	Try one or more tests and then call **WSP** if fails. **TAG** instrument "Out of Service"
INTERFERENCE DETECTED	Try one more test, if interference is noted on the second test, request blood sample under implied consent.
SAMPLES OUTSIDE 10%	Try one or more tests. Coach the subject to provide similar samples to the instrument.
SIMULATOR OUT OF RANGE	Simulator reading outside of 0.072-0.088 inclusive limits. Call **WSP** and **TAG** instrument "Out of Service". Go to another instrument to perform the test**.**
PRINTER ERROR	Call **WSP**; **TAG** the instrument “Out of Service”. Go to another instrument.
JAMMED/ILLEGIBLE DOCUMENT**	Printer not performing properly. Call **WSP**; **TAG** the instrument “Out of Service”. **Do not** press RUN.
BLANK ERROR	Try one or more tests and then call **WSP** if fails. **TAG** instrument "Out of Service"
FILTER ERROR	Try one or more tests and then call **WSP** if fails. **TAG** instrument "Out of Service"
TEMPERATURE LOW	Out of service, call **WSP** and **TAG** instrument "Out of Service"

TEMPERATURE HIGH	Out of service, call **WSP** and **TAG** instrument "Out of Service"
FATAL SYSTEM ERROR	Out of service, call **WSP** and **TAG** instrument "Out of Service"
RAM ERROR	Out of service, call **WSP** and **TAG** instrument "Out of Service"
PUMP ERROR	Out of service, call **WSP** and **TAG** instrument "Out of Service"
DATA MEMORY	Out of service, call **WSP** and **TAG** instrument "Out of Service"
BATTERY LOW	
EXTERNAL STANDARD TEMPERATURE	The simulator temperature must be within 0.2 (two lines above or below) of 34.0 ˚C.
OUT OF SERVICE	Call **WSP** at _____ and advise specific problem, serial number and **TAG** instrument out of service.

** Will not be a displayed message

13.0 DIGITAL REFERENCE THERMOMETER CERTIFICATION

13.0.1 POLICY

Digital reference thermometers are to be certified for compliance with this policy at least once per calendar year. Digital reference thermometers found to be acceptably accurate according to the following protocol are deemed to have been correct during the previous year and capable of providing accurate temperature measurements for another calendar year.

13.0.2 PROCEDURE

Digital reference thermometers are to be submitted to a NIST Traceable calibration laboratory for testing.

13.0.3 RECORDS RETENTION

1. Records received from the calibration laboratory shall indicate that the digital reference thermometer was tested and adjusted if necessary.

2. Records received from calibration laboratory are to be maintained as part of the Breath Test Program's regular business records.

3. The BTP Headquarters will maintain the original certificates received from the calibration laboratory.

4. The Breath Test Technician will maintain copies of the certificate received from the calibration laboratory.

14.0 SIMULATOR THERMOMETER CERTIFICATION

14.0.1 POLICY

All Guth Model 34C or Guth Model 2100 simulators used during the performance of field evidentiary tests or the QAP are to employ a thermometer that has been verified for accuracy at least once per calendar year. Thermometers found to be acceptably accurate according to the following protocol are deemed to have been correct during the previous year and capable of providing accurate temperature measurements for another calendar year.

14.0.2 PROCEDURE

1. Have the mercury thermometer to be tested placed in a fully warm and equilibrated Guth Model 34C simulator.

2. Install the standard reference thermometer probe in the same simulator in the location designed for this purpose. For the Guth Model 2100, place the probe within the same Guth Model 2100 simulator being evaluated.

3. Ensure that the temperatures of both the tested thermometer and the standard reference thermometer have stabilized.

4. Ensure the tested thermometer indicates a temperature within $\pm$ 0.1^{0}C inclusive of the standard reference thermometer. Record the fully displayed standard reference thermometer results (including all digits) on the record form. Record also the result indicated on the mercury thermometer to the second decimal place which will have to be estimated.

5. If the thermometer results are acceptable, record "Yes" on the thermometer check record form.

6. If the thermometer results are not acceptable record "No" on the thermometer check form. Depending on the type of thermometer, one of the following steps may be followed:
   a. Mercury thermometer: check for separation of mercury and attempt to correct
   b. Digital thermometer: re-calibrate the thermometer
   c. After performing one of these steps, complete again the above protocol

7. Retain the forms in the appropriate files as outlined in the Filing Policy for the BTP in the TLD Calibrations Operations Manual. Forms are to be kept by the local responsible technician only.

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

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

15.0 BREATH TEST INSTRUMENT REPAIR/ADJUSTMENT FORM

15.0.1 POLICY

The following policy shall apply when completing the DataMaster Repair/Adjustment Form. This policy shall apply to those repairs made to field breath test instruments and simulators and not sub-components thereof, which have been replaced. The purpose is to provide guidelines for when it is to be completed and the information it should contain.

15.0.2 PROCEDURE

1. The form is to be completed only by certified Breath Test Technicians.

2. The form shall be written clearly and concisely to allow others to interpret the information.

3. The form needs to be completed only in the following situations:

   - Following the instrument's initial QAP
   - Replacement of any components or parts not included as exceptions below
   - Repair to any components or parts
   - Adjustment to any potentiometer that is outside of manufacturer's specifications
   - Adjustment of the clock at the instrument that is more than 20 minutes off (See number 4 below)
   - Replacement of the simulator
   - Simulator repairs for the following reasons:
     a. Replacing the thermometer. When the thermometer is replaced, form will contain the simulator serial number, the serial number of the thermometer replaced, the serial number of the new thermometer installed and the reason the thermometer was replaced. If the thermometer is replaced because it does not comply with the standards outlined in the Simulator Thermometer Certification section (see *Chapter 14*), then the magnitude and direction of deviation will be recorded. The new installed thermometer will have been certified according to the Simulator Thermometer Certification section (see *Chapter 14*).
     b. Re-calibration of the Guth Model 2100 Simulator thermometer
     c. Temperature adjustment that is outside 34.0 ± 0.2 °C
     d. Repairing simulator stirring mechanism

   - Instrument Re-calibration (except where part of the routine QAP)
   - Other necessary repairs or adjustment to restore an instrument to proper working order
   - When a repair is performed requiring the form to be completed, a complete breath test will be conducted according to the procedure outlined in the External Standard Solution Changing Procedure (see *Chapter 6*) 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

4. The form shall not need to be completed in the following situations:

   - Prior to the instrument's initial QAP
   - Powering the instrument off and on to clear a lock-up condition
   - When changing time to correspond to changes in daylight savings time
   - When removing a stuck ticket when there is no apparent problem with the printer
   - When problem is due to operator error
   - Obtaining copies of ticket for operators when there is no apparent printer problem
   - 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
   - When the problem is corrected over the phone with an operator or Solution Changer
   - When performing routine purging of the instrument
   - When replacing simulator tubing
   - When an instrument is transferred to a permanent training status
   - When replacing a normally worn or faded printer ribbon or toner cartridge
   - As part of the routine QAP

5. When completed, the original copy shall be sent to and retained by the BTP Headquarters. Copies of the form are to be kept in the office of the Technician having geographical responsibility for a particular instrument. The exception will be when form is completed for a QAP simulator. In this case, the form will be retained only by the responsible technician and not sent to the BTP Headquarters.

16.0 PROFICIENCY TESTING PROGRAM

16.0.1 POLICY

Each forensic scientist and breath test technician within the TLD will complete at least one proficiency test per year. All forensic scientists and breath test technicians will be trained on the importance and procedures for proficiency testing as outlined in this policy. The training will include the procedures to be followed as well as forms to be completed. The purpose of proficiency testing will be to ensure the overall program's fitness-for-purpose.

The objectives of the proficiency testing program are to:

- Demonstrate the current competence of the technicians and analysts
- Demonstrate the current competence of the program
- Ensure that quality work is being performed and maintained
- Identify areas where additional training or resources would be beneficial
- Verify the validity of technical procedures

Proficiency test samples (e.g. simulator solutions, blood) will be handled by breath test technicians and/or analysts in a similar manner to those samples routinely received by the TLD for calibration and/or testing purposes.

The QA Manager will oversee the Proficiency Testing Program for the TLD, including assigning proficiencies to all personnel, submitting results, maintaining records, and notifying individual personnel and the TLD Commander of proficiency test results. Refer to the *TLD Calibration Quality Manual, Chapter 8.1 Proficiency Testing* for further details.

16.0.2 DEFINITIONS

16.0.2.1 APPROVED PROFICIENCY TEST PROVIDER

An individual, organization or company which has applied for and obtained approval from ASCLD/LAB to prepare and provide proficiency tests to participating forensic laboratories, in the forensic disciplines, for which the provider has been approved.

16.0.2.2 PROFICIENCY TEST

A proficiency test is an internal or external test that is provided to evaluate the capability of analysts, technical support personnel and the overall quality performance of a laboratory.

16.0.2.3 PROFICIENCY TEST REVIEW COMMITTEE (PRC)

A committee of individuals appointed by the Board of ASCLD/LAB, because of their experience and expertise, to give guidance to ASCLD/LAB in the proficiency testing program for specific forensic disciplines.

16.0.2.4 PROFICIENCY TEST MATERIAL/SAMPLE

For the BTP, proficiency test material includes simulator solutions obtained either from an Approved Proficiency Test Provider or from the Toxicology Lab. For the Toxicology Lab, proficiency test material may include blood or simulator solutions obtained either from an Approved Proficiency Test Provider or from within the Toxicology Lab. The State Toxicologist and/or the QA Manager may approve other types and sources of proficiency test samples.

16.0.3 PROCEDURE

1. Breath Test Program

a) Proficiency Testing Process – External proficiency tests

Proficiency test samples will be provided to the breath test technicians. A written protocol and data entry form from the Approved Proficiency Test Provider (or equivalent) will also be provided. The Technician will be directed to follow the protocol and documentation steps as outlined. The testing will be completed within the directed time period and documentation provided back to the QA Manager. Normal procedures for the technical and administrative review of results will apply. The QA Manager or designee will forward the final documentation to the Approved Proficiency Test Provider (or equivalent).

b) Proficiency Testing Process – Internal proficiency tests

Simulator solutions to be used as internal proficiency tests will be prepared by the Toxicology Lab. Protocols for the preparation and certification of Simulator Solutions will be similar to those outlined in Chapter 2. The final equivalent vapor concentration will be the reference value for that proficiency test solution. Records of the test results performed in the Toxicology Lab will be maintained which identify these solutions for proficiency test purposes. The solutions will be placed in evidence sealed 500 mL bottles with a label identifying a unique proficiency identifier and expiration date.

One bottle of each solution will be provided to each breath test technician and/or back-up technician. A written protocol will also be provided. The proficiency test samples will be treated similarly to QAP samples when performing the tests on a selected breath test instrument. The results will be recorded on the Datamaster QAP Form and QAP Work Sheet. The forms will be signed and dated by the responsible Technician and sent along with the corresponding documents to a technical reviewer. Normal procedures for the technical and administrative review of results will apply prior to sending the package to the QA Manager.

c) Results

For external proficiency tests, individual technician results are typically compared to the summary results of all participants provided by the Provider.

For internal proficiency tests, the arithmetic mean and standard deviation of the proficiency samples will be compared to the final equivalent vapor concentration determined by the Toxicology Lab. The mean of each Technician's results should typically be within ± 5 % of the pre-determined reference value.

Additional statistical criteria may be applied to proficiency tests and will be documented and communicated to the technicians prior to testing.

2. Toxicology Lab

a) Proficiency Testing Process – External proficiency tests

Proficiency test samples will be provided to the analysts. A written protocol and data entry form from the Approved Proficiency Test Provider (or equivalent) will also be provided. The analyst will be directed to follow the protocol and documentation steps as outlined. The testing will be completed within the directed time period and documentation provided back to the QA Manager. Normal procedures for the technical and administrative review of results will apply. The QA Manager or designee will forward the final documentation to the Proficiency Test Provider (or equivalent).

b) Proficiency Testing Process – Internal proficiency tests

Internal proficiency tests may be prepared by the Toxicology Lab, independently to the analyst(s) being proficiency tested. Protocols for the preparation and certification of Simulator Solutions will be similar to those outlined in Chapter 2. The final arithmetic mean will be the reference value for that proficiency test solution. Protocols for the preparation of blood proficiency samples will be documented and retained by the QA Manager. Records of the test results performed in the Toxicology Lab will be maintained which identify these samples for proficiency test purposes.

One bottle, blood vial/tube or aliquot of the proficiency test sample will be provided to the analyst(s). A written protocol and data collection form will also be provided. Five aliquots of a simulator solution proficiency will be tested, while blood proficiency samples will be tested in duplicate. The results will be recorded on the collection form provided. The forms will be signed and dated by the responsible analyst and sent along with the corresponding documents to a technical reviewer. Normal procedures for the technical and administrative review of results will apply prior to sending the results to the QA Manager.

c) Results

For external proficiency tests, individual analyst results are typically compared to the summary results of all participants provided by the Provider.

For internal proficiency tests, the arithmetic mean of the proficiency samples shall be compared to the arithmetic mean determined independently by the Toxicology Lab. The mean of each analyst's results should typically be within ± 5 % of the pre-determined mean.

Additional statistical criteria may be applied to proficiency tests and will be documented and communicated to the technicians prior to testing.

3. Discrepancies and Non-Conformities

Procedures for proficiency test discrepancies and non-conformities are outlined in the TLD Calibration Quality Manual (*see Chapters 3 and 8.1*).

INTEROFFICE COMMUNICATION

WASHINGTON STATE PATROL

TO: See Distribution Below

FROM: Mr. Jason H. Sklerov, Toxicology Laboratory Division

SUBJECT: Modification to Chapter 5 of Calibration Technical Manual

DATE: December 4, 2008

This communication is to inform you about a modification to the Quality Assurance Procedure. This procedure is detailed in Chapter 5 of the Breath Alcohol Calibration Technical Manual (TLDCalTM_01) and applies to the original revision with the effective date of September 10, 2008.

The modification is to the Certification Procedure which is described on pages 22 through 24. The modification involves the elimination of the Filter Error check described in step 11 on page 23. The Filter Error check will no longer be required as part of the Quality Assurance Procedure effective December 8, 2008.

The specific language describing the eliminated step is as follows:

11) Perform the Filter Error check according to the following:

   a) Using the SUP mode, prevent the acetone filter from going into place by removing the electrical connection. The instrument should stop the test and display FILTER ERROR

   b) Push the ABT key and then push the COPY key and retain document in the QAP file

The Filter Error check has also been eliminated as part of the Quality Assurance Procedure Worksheet. This is reflected on the replacement Quality Assurance Procedure Worksheet (TLDQAP_WS, Revision: Original) which also becomes effective December 8, 2008.

This modification is being shared through interoffice communication to allow for timely implementation. It is recommended that a copy of the IOC be included in any printed, uncontrolled copies of the Breath Alcohol Calibration Technical Manual (Revision Original) until such time as the change is incorporated into the Manual and a new revision is released.

Management is committed to compliance with the International Standard and to improving the effectiveness of the management system. If any additional information is required, you are encouraged to bring it to the attention of management so that we may continue to meet both customer requirements and statutory and regulatory requirements.

JHS:jhs
cc: Dr. Fiona J. Couper, Toxicology Laboratory Division
Mr. Rod Gullberg, Breath Test Program
Lieutenant Robin Reichert, Impaired Driving Section
Sergeant Robert Sharpe, Breath Test Program

Distribution: Trooper Marc W. Barger, Wenatchee
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Trooper Denny J. Stumph, Tacoma
Trooper James P. Van Diest, Bellingham
Trooper Shawn J. Williams, Walla Walla

INTEROFFICE COMMUNICATION

WASHINGTON STATE PATROL

TO: See Distribution Below

FROM: Dr. Fiona J. Couper, Toxicology Laboratory Division
Mr. Jason H. Sklerov, Toxicology Laboratory Division

SUBJECT: Modification to Chapter 4 of Calibration Technical Manual

DATE: January 13, 2009

This communication is to inform you about a modification to the procedure for the certification of simulator solutions. This procedure is detailed in 4.0 Certification of Simulator Solutions of the Breath Alcohol Calibration Technical Manual (TLDCalTM_01) and applies to the original revision with the effective date of September 10, 2008.

The modification is to section 4.0.5, Procedure for the Analysis of Simulator Solutions, which is described on pages 14 through 16. The modification involves the addition of language to step number four appearing on page 15. This modification is being made to clarify the rinse/wash process when multiple samples are taken from a single source such as an individual simulator solution.

The original language being modified is as follows:

4. Between each aliquot/extract, rinse and wash the pipette tip appropriately (e.g. rinse pipette tip with diluted bleach and/or d.H2O. Repeat if necessary).

The modified language that applies to this step is as follows:

4. Between each aliquot/extract, rinse and wash the pipette tip appropriately (e.g. rinse pipette tip with diluted bleach and/or d.H2O. Repeat if necessary). It is not necessary to rinse and wash the pipette tip in-between repeated aliquots from a single simulator solution.

This modification is being shared through interoffice communication to allow for timely implementation. It is recommended that a copy of the IOC be included in any printed, uncontrolled copies of the Breath Alcohol Calibration Technical Manual (Revision Original) and any copies of 4.0 Certification of Simulator Solutions until such time as the change is incorporated into the Manual and a new revision is released.

Management is committed to compliance with the International Standard and to improving the effectiveness of the management system. If any additional information is required, you are encouraged to bring it to the attention of management so that we may continue to meet both customer requirements and statutory and regulatory requirements.

FJC:JHS:jhs

cc: Dr. Fiona J. Couper, Toxicology Laboratory Division
Lieutenant Robin Reichert, Impaired Driving Section

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