PROCEDURE FOR THE PREPARATION OF QUALITY ASSURANCE SOLUTIONS FOR USE WITH A BREATH TEST INSTRUMENT

Introduction:

The breath test instrument is equipped with a Guth Breath Alcohol Simulator. This device produces a predictable, known vapor concentration by passing air though a heated aqueous solution of known alcohol concentration.

Principle and Purpose

The quality assurance simulator solutions are water and ethanol mixtures formulated to provide a standard ethanol vapor concentration when used in a breath alcohol simulator at 34 $\pm$ 0.2 degrees Centigrade. The solutions are used to verify the accuracy and precision of the BAC Verifier DataMaster Quality Assurance Program of the Washington State Patrol Breath Test Section. The 0.100 g/210L solution may also be used to calibrate the BAC DataMaster.

The preparation is carried out at room temperature using deionized water and 200 proof, absolute ethanol.

The water/air partition ratio at 34 degrees Centigrade is 2585.8 (Jones, 1983). The reference vapor concentration used is the average value of the solution concentration (rounded to four decimal places) divided by 1.23 (Jones 1983, Dubowski 1983) and rounded to four decimal places to give the alcohol concentration in grams per 210 liters of vapor (Jones 1983, Dubowski 1983).

The quality assurance program operated by the Washington State Patrol Breath Test Section requires vapor concentrations of approximately 0.08, 0.10, 0.15 and 0.20 g/210L vapor. Other solutions required periodically for instrument evaluation will produce vapor concentrations of 0.04 and 0.30 g/210L vapor. The exact concentration of a given solution is measured by gas chromatography.

Equipment:

Agilent (Hewlett Packard) 7694 Headspace Autosampler or equivalent
Agilent (Hewlett Packard) 6890 gas chromatograph; one equipped with a J&W DBALC1 megabore (0.53 mm) 30 meter capillary column and another system equipped with J&W DBALC2 megabore (0.53 mm) 30 meter capillary column. (For information on the columns, see Headspace Protocol)
Computer System equipped with HP GC Chem Station
Compressed gases; air, nitrogen, hydrogen
Autosampler vials
Cap crimper
Hamilton Automatic Diluter
~~1mL~~ volumetric flask, grade A
10mL, 5mL, 2mL, 1 mL volumetric pipette, grade A

dnw 10-29-04

1 L

Approved:

Barry K. Logan, PhD

Date: 10/27/04

100mL Buret
Mechanical mixer and stir rod
Calibrated 18L containers
Tamper evident Tape or tamper evident caps
Plastic storage bottles

Reagents:

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

Controls:

Commercially prepared controls are included in run.

Preparation:

1) Fill the 18L vessel to approximately 80% of the 18L mark with deionized water.

2) Use the values in Table 1 to prepare each solution.

Table 1:

Vapor Concentration	Solution Concentration	Acceptable Range	Ethanol/Water Dilution Factor
0.04	0.049	0.047 - 0.052	11.1 mL/18 L
0.08	0.098	0.092 - 0.102	22.2 mL/18 L
0.10	0.127	0.123 - 0.133	28.9 mL/18L
0.15	0.185	0.176 - 0.194	42.3 mL/18L
0.2	0.246	0.234 - 0.258	56.1 mL/18L
0.3	0.368	0.350 - 0.385	84.6mL/18L

3) In a 1L volumetric flask, add approximately 900mL deionized water. Using volumetric glassware, add precisely the appropriate volume as indicated in table 1 of absolute ethanol. Stopper the flask and mix well by inverting several times and add the contents of the flask to the 18 L vessel. Rinse the flask with approximately 1L deionized water and add this to the 18 L vessel. Fill the vessel to the 18L mark with deionized water and tighten the cap. Mix the solution by applying mechanical mixing.

4) Assign a batch number to the solution. The first two digits represent the year in which the solution was made, followed by sequential three digit numbering, beginning with 001. Therefore, the first batch of 2002 would be 02001.

5) Remove approximately 10 mL of the mixed solution for testing.

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Certification:

1) An individual with a valid Blood Analyst Permit, authorized by the State Toxicologist, analyzes five separate aliquots of the simulator solution, by headspace gas chromatography.

2) Record the results of the testing in the solution certification database, including the date and the results of the contemporary external control.

3) A minimum of three (3) analysts must certify the solution prior to its certification.

4) The average of the results from all of the analysts are computed (rounded to four decimal places). The standard deviation and relative standard deviation (CV) on all results are computed. (Freedman and al., 1978).

5) The solution is acceptable for use and therefore certified if it meets the following criteria. The solution concentration meet the criteria in Table I. The CV must be 5% or less.

6) The reference vapor concentration is calculated by dividing the solution concentration by 1.23 and rounding to four decimal places.

7) A solution is valid for use for a period of one year following its preparation.

8) The solution is acceptable for use in establishing linearity, precision and accuracy on the Quality Assurance program of the Washington State Patrol Breath Test Section.

Packaging:

1) The solution is provided to breath test technicians of the Washington State Patrol in containers of convenient size.

2) Each bottle is labeled with the batch number and its preparation date.

3) The bottles are sealed with tamper evident tape. Alternatively, tamper evident caps may be used in lieu of regular caps with tamper evident tape.

4) Once the solution is certified, it may be provided to the BAC technicians for use with the breath test instruments.

References:

AW 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.

K.M. Dubowski, Breath Alcohol Simulators: Scientific Basis and Actual Performance. Journal of Analytical Toxicology, **3**, 1983 pp177-182

G.J. Shugar, R.A. Shugar and L. Bauman, Chemical Technicians Ready Reference Handbook. McGraw-Hill Book Co. 1978.

Approved: Date: 10/23/04

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BAC Verifeer DataMaster Operator Instruction Manual, WSP Forensic Laboratories Services Bureau, May 1985, pp27-28.

D. Freedman, R. Pisano and R. Purves, Statistics, W.W. Norton & Co. N.Y. 1978.

STATEMENT OF STATE TOXICOLOGIST –
In my capacity as Washington State Toxicologist, and by my authority outlined in RCW 46.61.506, I have reviewed this protocol and find it to be proper and adequate in form and substance for the purpose it was intended. I, therefore, approve and authorize its use.

Barry K. Logan Ph.D.
Washington State Toxicologist

Date: 10/23/04

Reviewed By: _____ Date: 10-29-04
Ann Marie Gordon
Laboratory Manager

Reviewed By: _____ Date: 11/2/04
Edward Formoso
Supervisor

Reviewed By: _____ Date: 11-01
Melissa Pemberton
Supervisor

The following toxicologists have read the Quality Assurance Solution Protocol and agree to follow the this procedure as it is written. Any deviations from the procedure must be documented in writing and approved by the laboratory manager and/or the State Toxicologist.

Reviewed By: _____ Date: 11/1/04

Reviewed By: _____ Date: 11/2/04

Reviewed By: _____ Date: 11/2/04

Approved: _____ Date: 10/23/04
Barry K. Logan, PhD

Reviewed By: _____ Date: 11/02/04

Reviewed By: _____ Date: 11-2-04

Reviewed By: _____ Date: 11/3/04

Reviewed By: _____ Date: 11/3/04

Reviewed By: _____ Date: 11/5/04

Reviewed By: _____ Date: 03/21/05

Reviewed By: _____ Date: 3/21/05

Reviewed By: _____ Date: _____

Reviewed By: _____ Date: _____

Approved: _____ Date: 10/27/04

Barry K. Logan, PhD