

Department of Forensic Science

BREATH ALCOHOL PROCEDURES MANUAL

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1 INTRODUCTION

1.1 Introduction

The information in this manual was collected from numerous sources and is presented here for easy reference for breath alcohol staff. This manual presents a basic outline of the types of repairs made, a source book on reagent and standard preparation and procedure(s) for adjustment (calibration) and certification of instruments. This manual is not all-inclusive, and will reference other sources where appropriate. It is always the technician's responsibility to choose the best troubleshooting scheme for each individual situation. It is expected that the Program Manager will be consulted for extraordinary procedures.

1.2 Documentation

Worksheets are provided as controlled forms and should be used as designed. Technicians are reminded to properly document maintenance and procedures performed which will allow for another technician/supervisor to repeat the procedure under conditions as close as possible to the original, evaluate the data, interpret the results, and come to the same conclusion.

1.2.1 Documents that require signatures and/or initials may be marked with a secure electronic equivalent to initials or signatures (e.g., Adobe Dynamic Stamp, Adobe Digital Certificate Signature, Adobe Sign, or similar programs).

1.3 Technical Factors

The following technical factors have been taken into consideration in the development of these procedures: personnel, environmental conditions, methods and their validation, equipment, traceability, sampling, and the handling of calibration items.

1.3.1 The Department’s laboratory facilities provide sufficient environmental conditions to conduct all tests listed in this manual with no further consideration required. Offsite activities shall only be conducted after technical personnel have determined that no detrimental conditions exist and have documented this in the site specifications area of the appropriate QA form.

1.3.2 Environmental conditions that are to be considered include: adequate ventilation, excessive temperature, and contaminants (e.g., dust, moisture).

1.3.3 Additional considerations for testing activities include: secure internal location, dedicated analog phone line (for Intox EC/IR II), active communications port (for Draeger Alcotest 9510), adequate space, and a stable power source.

1.4 Validation

New methods must be validated before use. Prior to beginning a validation process, consult the Program Manager for an appropriate validation plan.

1.5 Changes

Due to the extensive travel performed by the Breath Alcohol Section (the Section), procedures that will affect instrument maintenance will not be changed and adopted while staff is working off-site.

2 AQUEOUS REFERENCE MATERIAL

2.1 Overview

Aqueous reference material may be used for different purposes, such as initial acceptance testing, measurement assurance, and for research. They are not used to certify the instrumentation for accuracy and as such will not have an estimation of the uncertainty of measurement calculated. A partition ratio of $K_{w/a} = 2587$ is used to prepare reference material for use in evidential breath alcohol instrumentation (e.g., a 0.123 g/100mL liquid EtOH concentration equals a 0.100 g/210 L vapor EtOH concentration).

Aqueous reference materials may also be purchased from reference material providers.

2.2 Preparation of Ethanol Stock Solution

2.2.1 Equipment and Materials

- 5 liter glass volumetric flasks with stoppers (Class A)
- 100 mL glass volumetric pipet
- 50 mL glass volumetric pipet
- 20 mL glass volumetric pipet
- Pipet filler
- 1000µL pipet
- 10 liter storage container
- 500 mL volumetric flask with stopper (Class A, TC)
- 10 mL glass volumetric pipet
- 10 mL glass serological pipet
- Ethyl alcohol, USP grade, dehydrated, 200 proof (unopened)
- Deionized water (dH2O)
- Plastic water fill bottle
- 250-F103 Stock Solution Worksheet

2.2.2 Procedure

2.2.2.1 Ensure that all glassware is clean, empty, dry and in good condition.

2.2.2.2 Fill a 5 liter volumetric flask approximately half-full with dH2O.

2.2.2.3 Using the volumetric pipets (3 x 100mL, 1 x 50 mL, 2 x 20 mL) and the 1000 µL pipet (set to 200 uL) add 390.2 mL of ethanol to the 5 liter volumetric flask.

2.2.2.4 Stopper the 5 liter flask and mix well.

2.2.2.5 Add dH2O to the flask, filling to the calibration mark, using a plastic fill bottle if necessary to bring the meniscus to the mark.

2.2.2.6 Stopper the flask and mix well.

2.2.2.7 Leave the stoppered flask sitting overnight at room temperature.

2.2.2.8 Complete the Stock Solution Worksheet (250-F103).

2.2.2.9 Pour the solution into the 10 liter storage container labeled with the lot number, preparation date and initials of preparer.

2.2.2.9.1 Each batch of solution is given a sequential lot number.

2.2.2.10 Prepare and test an Ethanol Working Standard according to procedure.

2.2.2.11 Upon successful testing of the working standard (e.g., accuracy and precision parameters have been met), have the Supervisor or Program Manager indicate approval for use on the Stock Solution Worksheet.

2.2.2.12 Should the working standard not meet the accuracy and precision parameters, the working standard may be tested once more. If the second test remains outside of acceptable parameters, discard the working standard and notate on the Ethanol Working Standard Worksheet.

2.2.2.12.1 One additional working standard may be prepared. Should that working standard not meet the accuracy and precision parameters, both the working standard and stock solution will be discarded and notations made on both worksheets.

2.3 Preparation of Ethanol Working Standards

2.3.1 Equipment and Material

- Volumetric flask with stopper (Class A)
- Volumetric pipets
- Pipet filler
- Plastic water fill bottle
- 500 mL graduated cylinder (Class A)
- Ethanol Stock Solution
- dH2O
- 250-F125 Working Standard Worksheet

2.3.2 Procedure

2.3.2.1 Table 1 provides examples of dilutions of the stock solution to achieve specific working standard concentrations. Other concentrations may be prepared as needed.

2.3.2.2 Ensure that all glassware is clean, empty, dry and in good condition.

2.3.2.3 Fill a volumetric flask approximately half-full with dH2O.

2.3.2.4 Using volumetric pipet(s), add the appropriate amount of ethanol to the volumetric flask.

2.3.2.5 Stopper the flask and mix well.

2.3.2.6 Add dH2O to the flask, filling to the calibration mark, using a plastic fill bottle if necessary to bring the meniscus to the mark.

2.3.2.7 Stopper the flask and mix well.

2.3.2.8 Complete the Working Standard Worksheet.

2.3.2.9 Label the flask with the batch identification, initials of preparer, and date of expiration.

2.3.2.9.1 The batch will be identified by the compound, preparation date, and concentration (e.g., Ethanol 052413 0.02 g/210 L or EtOH 052413 0.02 g/210 L).

2.3.2.9.2 Should it be necessary to prepare multiple batches of the same concentration in a single day, each successive batch will add a letter designation after the date

(e.g., batch #1 is identified as “052413 0.02g/210L, batch #2 would be identified as “052413B 0.02g/210L).

2.3.2.9.3 The expiration date will be one year from the date of preparation (e.g., batch 052413 0.02g/210L will expire on 05/24/2014).

2.3.2.10 Leave the stoppered flask sitting overnight at room temperature.

2.3.2.11 Perform quality control testing.

2.3.2.11.1 Use an instrument that is certified for evidential use.

2.3.2.11.2 Pour approximately 500 mL of working standard into simulator.

2.3.2.11.3 Perform an accuracy check function (4 replicates).

2.3.2.11.4 Discard first value and evaluate accuracy and precision with remaining three values.

2.3.2.11.4.1 Intox EC/IR II

Accuracy parameter = values within 3% or 0.003g/210L (whichever is greater) of the target value.

Precision parameter = no more than 0.003g/210L difference in all three replicate values.

2.3.2.11.4.2 Alcotest 9510

Accuracy parameter = values within 5% or 0.005g/210L (whichever is greater) of the target value.

Precision parameter = no more than 0.005g/210L difference in all three replicate values.

2.3.2.12 Notate successful quality control testing on the Working Standard Worksheet.

2.3.2.12.1 Should the working standard not meet the accuracy and precision parameters, the working standard may be tested once more. If the second test remains outside of acceptable parameters, discard the working standard and notate on the Working Standard Worksheet.

2.3.2.13 Bottle remaining solution, in 500mL aliquots, and label each bottle with batch identification, initials of preparer, and date of expiration.

Table 1 Examples of EtOH dilutions

Target Concentration	Final Volume	Final Volume
g/210 L vapor	500 mL	5 L
0.015	1.5 mL EtOH Stock	15.0 mL EtOH Stock

0.020	2.0 mL EtOH Stock	20.0 mL EtOH Stock
0.080	8.0 mL EtOH Stock	80.0 mL EtOH Stock
0.100	10.0 mL EtOH Stock	100.0 mL EtOH Stock
0.160	16.0 mL EtOH Stock	160.0 mL EtOH Stock
0.250	25.0 mL EtOH Stock	250.0 mL EtOH Stock
0.300	30.0 mL Etoh Stock	300.0 mL Etoh Stock
0.500	50.0 mL EtOH Stock	500.0 mL EtOH Stock

2.4 Preparation of Instrument Specificity Solutions

2.4.1 Equipment and Materials for Stock Solution Preparation

- 100 – 1000 µL pipet
- 10 – 100 µL pipet
- 20 – 200 µL pipet (or comparable volume pipet)
- 500 mL volumetric flask with stopper (Class A, TC)
- 20mL volumetric pipet
- 10 mL glass volumetric pipet
- 8 mL glass volumetric pipet
- Pipet filler
- Acetone
- Isopropanol
- Methanol
- Deionized water (dH_2O)
- Stock Solution Worksheet

2.4.2 Procedure for addition of other volatile compounds to simulator solutions

2.4.2.1 This procedure will be used to add either acetone, isopropanol, or methanol to 500 mL of simulator solution to achieve the desired approximate concentrations. The prepared solutions are only used for qualitative purposes.

2.4.2.2 The following calculations are adapted from reference: Watterson, JH. Assessment of Response of the Intoxilyzer 8000C to Volatiles of Forensic Relevance in Vitro, Part I: Acetone, Isopropanol, and Methanol. *Journal of Analytical Toxicology*, Vol. 33, Iss. 2, March 2009, pages 109-117.

2.4.2.2.1 Methanol: ~0.010 g/210 L vapor equivalent

0.010 g/210 L * 3330/2100 = 0.0159 g/100 mL

0.0159 g/100 mL * 500 mL = 0.0795 g

0.0795 g methanol * 1 mL/0.7913 g = 0.100 mL = 100 µL

2.4.2.2.2 Isopropanol: ~0.010 g/210 L vapor equivalent

0.010 g/ 210 L * 1500/2100 = 0.00714 g/100 mL

0.00714 g/100 mL * 500 mL = 0.0357 g

0.0357 g isopropanol * 1 mL/0.7854 g = 0.045 mL = 45 µL

2.4.2.2.3 Acetone: ~0.100 g/210 L vapor equivalent

0.100 g/210 L * 395/2100 = 0.01881 g/100 mL

0.01881 g/100 mL * 500 mL = 0.09405 g

0.09405 g acetone * 1 mL/0.79 g = 0.119 mL = 119 µL

2.4.2.3 The following calculations are adapted from references:

2.4.2.3.1 Toxic Drugs and Chemicals in Man, 4th Edition, 1995 Randal Baselt and Robert F. Cravey.

2.4.2.3.2 The Response of the Intoxilyzer 4011AS-A to a Number of Possible Interfering Substances. *Journal of Forensic Sciences*, JFSCA. Vol. 35, No. 4, July 1990, pages 797-812.

2.4.2.3.3 Methanol: ~0.010 g/210 L vapor equivalent

0.010 g/210 L * 3229/2100 = 0.0154 g/100 mL

0.0154 g/100 mL * 500 mL = 0.077 g

0.077 g methanol * 1 mL/0.7913 g = 0.097 mL = 97 µL

2.4.2.3.4 Isopropanol: ~0.010 g/210 L vapor equivalent

0.010 g/ 210 L * 1671/2100 = 0.00796 g/100 mL

0.00796 g/100 mL * 500 mL = 0.0398 g

0.0398 g isopropanol * 1 mL/0.7854 g = 0.051 mL = 51 µL

2.4.2.3.5 Acetone: ~0.100 g/210 L vapor equivalent

0.100 g/210 L * 330/2100 = 0.01571 g/100 mL

0.01571 g/100 mL * 500 mL = 0.07855 g

0.07855 g acetone * 1 mL/0.79 g = 0.0994 mL = 99 µL

2.4.2.4 Considering the above calculations, the following volumes will be used for the preparation of approximate vapor equivalent concentrations to be added to 500 mL simulator solutions:

2.4.2.4.1 Methanol: 100 µL (~0.020 g/210 L vapor equivalent)

2.4.2.4.2 Isopropanol: 50 µL (~0.020 g/210 L vapor equivalent)

2.4.2.4.3 Acetone: 100 µL (~0.100 g/210 L vapor equivalent)

2.4.3 Procedure for Acetone/Methanol/Isopropanol Stock Solution

Note: Only one volatile compound per stock solution for instrument validation and verification testing.

2.4.3.1 Ensure that all glassware is clean, empty, dry and in good condition.

2.4.3.2 Fill a 500 mL volumetric flask approximately half-full with dH2O.

2.4.3.3 Using the volumetric pipets (1 x 20mL, 1 x 10 mL, 1 x 8 mL) and the 1000 µL pipet to add the volume indicated below for the desired volatile compound to the 500 mL volumetric flask.

2.4.3.3.1 Acetone = 38.485 mL

2.4.3.3.2 Methanol = 38.413 mL

2.4.3.3.3 Isopropanol = 38.929 mL

2.4.3.4 Stopper the 500 mL flask and mix well.

2.4.3.5 Add dH2O to the flask, filling to the calibration mark, using a plastic fill bottle if necessary to bring the meniscus to the mark.

2.4.3.6 Stopper the flask and mix well.

2.4.3.7 Leave the stoppered flask sitting overnight at room temperature.

2.4.3.8 Complete the Stock Solution Worksheet.

2.4.3.9 Pour the solution into the 500 mL storage bottle labeled with the lot number, preparation date and initials of preparer.

2.4.3.9.1 Each batch of solution is given a sequential lot number.

2.4.4 Equipment and Materials for Working Solution Preparation

- Volumetric pipets
- Pipet filler
- 1000µL pipet
- Volumetric flask with stopper (Class A, TC)
- Acetone Stock Solution
- Isopropanol Stock Solution
- Methanol Stock Solution
- Deionized water (dH2O)
- Working Standard Worksheet

2.4.5 Procedure for Working Standard Solution

2.4.5.1 The table below provides examples of dilutions of the stock solution to achieve specific working standard concentrations. Other concentrations may be prepared as needed.

Target	Final Volume	Final Volume
g/210 L vapor	**500 mL**	**5L**
0.100 Acetone	1.292 mL	12.92 mL
0.020 Methanol	2.529 mL	25.29 mL

0.020 Isopropanol	1.299 mL	12.99 mL

2.4.5.2 Ensure that all glassware is clean, empty, dry and in good condition.

2.4.5.3 Fill a volumetric flask approximately half-full with dH_2O.

2.4.5.4 Using volumetric pipet(s), add the appropriate amount of the desired interfering substance stock solution to the volumetric flask.

2.4.5.5 Stopper the flask and mix well.

2.4.5.6 Add dH_2O to the flask, filling to the calibration mark, using a plastic fill bottle if necessary to bring the meniscus to the mark.

2.4.5.7 Stopper the flask and mix well.

2.4.5.8 Complete the Working Standard Worksheet.

2.4.5.9 Label the flask with the batch identification, initials of preparer, and date of expiration.

2.4.5.9.1 The batch will be identified by the compound, preparation date, and concentration (e.g., Isopropanol 052413 0.02g/210L).

2.4.5.9.2 Should it be necessary to prepare multiple batches of the same concentration in a single day, each successive batch will add a letter designation after the date (e.g., batch #1 is identified as “052413 0.02g/210L, batch #2 would be identified as “052413B 0.02g/210L).

2.4.5.9.3 The expiration date will be one year from the date of preparation (e.g., batch 052413 0.02g/210L will expire on 05/24/2014).

2.4.5.10 Leave the stoppered flask sitting overnight at room temperature.

2.4.5.11 Perform quality control testing by submitting an aliquot to Toxicology section for analysis.

2.4.5.12 Notate successful quality control testing on the Working Standard Worksheet.

2.4.5.12.1 Should the working standard not meet the accuracy and precision parameters, the working standard may be tested once more. If the second test remains outside of acceptable parameters, discard the working standard and notate on the Working Standard Worksheet.

2.4.5.13 Bottle remaining solution, in 500mL aliquots, and label each bottle with batch identification, initials of preparer, and date of expiration.

2.5 References

2.5.1 Jones, A.W., Determination of Liquid/Air Partition Coefficients for Dilute Solutions of Ethanol in Water, Whole Blood and Plasma, *J Anal Tox*, 7: 193-197 (1983)

2.5.2 OIML R126:2021 (E)

2.5.3 Watterson, JH. Assessment of Response of the Intoxilyzer 8000C to Volatiles of Forensic Relevance in Vitro, Part I: Acetone, Isopropanol, and Methanol. *Journal of Analytical Toxicology*, Vol. 33, Iss. 2, March 2009, pages 109-117.

2.5.4 Toxic Drugs and Chemicals in Man, 4th Edition, 1995 Randal Baselt and Robert F. Cravey

2.5.5 The Response of the Intoxilyzer 4011AS-A to a Number of Possible Interfering Substances. *Journal of Forensic Sciences*, JFSCA. Vol. 35, No. 4, July 1990, pages 797-812.

3 INSTRUMENT ACCEPTANCE FOR THE INTOX EC/IR II

3.1 Initial Instructions

3.1.1 Initial instructions for Firmware/Software Testing

3.1.1.1 This testing will be performed on a new firmware/software version on a minimum of 2 instruments prior to installation in instruments already deployed for evidential (field) use.

3.1.1.2 Upload new software/firmware version after ensuring the instrument has been downloaded, if applicable. If instrument is displaying a message (e.g., disabled, certification warning) perform a single certification test (i.e., 1 point cert) to return instrument to a ready state prior to uploading firmware/software.

3.1.1.3 Print Firmware/Software Versions.

3.1.1.4 Calibrate the instrument (¶ 5).

3.1.1.5 Perform Instrument Certification (¶ 6 - omit 6.6).

3.1.1.6 Proceed to 3.2.

3.1.2 Initial instructions for Instrument Acceptance.

3.1.2.1 This testing will be performed on every new instrument prior to evidential (field) use.

3.1.2.2 Complete The EC/IR II First Receipt of Instrument worksheet (250-F112), if not already done (for new instruments only).

3.1.2.3 Upload approved Firmware/Software version.

3.1.2.4 Print Firmware/Software Versions.

3.1.2.5 Calibrate the instrument (¶ 5).

3.1.2.6 Perform Instrument Certification (¶ 6 - omit 6.6).

3.2 Additional Instructions

3.2.1 Utilize the Instrument Acceptance Testing Worksheet to document completion of criteria.

3.2.2 Retain all printouts.

3.2.2.1 Place procedure number on the printout following ¶3.2.7, unless otherwise noted.

3.2.2.2 Initial the upper right hand corner of the printouts.

3.2.2.3 Ensure the instrument serial number is on all pages.

3.2.3 ¶¶ 3.3-3.13 may be conducted in any order except for 3.4.9 and 3.9 which shall be performed as written.

3.2.4 Unless otherwise specified, vapor equivalents are obtained from wet bath simulators blown through the breath tube.

3.2.4.1 Simulators should be primed (blown through) for 3-5 seconds immediately prior to use.

3.2.5 In this protocol, information within quotation marks denotes data entry on the instrument or information shown on the digital display.

3.2.6 For any portion of this procedure that does not fall within expected/acceptable results or messages, due to undeterminable reasons, testing will be stopped until the Program Manager or Section Supervisor can be consulted. Testing may be resumed at the direction of the Program Manager or Section Supervisor. The Program Manager or Section Supervisor will ensure that proper documentation is generated and maintained pursuant to ¶ 3.17.

3.2.7 Unless otherwise noted, subject information will be "LAST NAME = PRACTICETEST" and "FIRST NAME = [insert PM#]" or Virginia Driver's License or Identification Card (exceptions may be made, consult with the Program Manager, Section Supervisor, or Group Supervisor).

3.3 Linearity

3.3.1 Change "Default Standard" to "Std 2 – wet sim".

3.3.2 Run an accuracy check (4 samples) with a 0.300 wet bath solution.

3.3.3 Run an accuracy check (4 samples) with a 0.400 wet bath solution.

3.3.4 Expected results for each of the above listed solutions.

3.3.4.1 For accuracy, the 2nd, 3rd and 4th sample values from each concentration must be within 3% of the target.

3.3.4.2 For precision, the 2nd, 3rd and 4th sample values must be within 0.003 of each other.

3.3.5 Return "Default Standard" to "Std 1 – Dry Gas"

3.4 Sample Reporting

3.4.1 Conduct a test and provide both breath samples with your own breath. For Court, type in "DFS".

3.4.1.1 Expected final result is "0.00 g/210 L".

3.4.2 Conduct a test - For Court, type in "DFS".

3.4.2.1 Sample 1 = own breath.

3.4.2.2 Sample 2 ~ 0.015 g/210 L vapor equivalent.

3.4.2.3 Expected final result is "0.00 g/210 L".

3.4.3 Conduct a test - For Court, type in "DFS".

3.4.3.1 Sample 1 ~ 0.015 g/210 L vapor equivalent.

3.4.3.2 Sample 2 = own breath.

3.4.3.3 Expected final result is "0.00 g/210 L".

3.4.4 Change the time to 23:55 – Conduct a test and provide both breath samples with your own breath. For Court, type in "DFS".

3.4.5 Return the date to today's date and change the time to 23:55. Conduct a test – For Court, type in "DFS".

3.4.5.1 Sample 1 = own breath.

3.4.5.2 Sample 2 ~ 0.015 g/210 L vapor equivalent.

3.4.5.3 Expected final result is “0.00 g/210 L” with today’s date (time prior to midnight).

3.4.6 Return the date to today’s date and change the time to 23:55 – Conduct a test – For Court, type in “DFS”.

3.4.6.1 Sample 1 ~ 0.015 g/210 L vapor equivalent.

3.4.6.2 Sample 2 = own breath.

3.4.6.3 Expected final result is “0.00 g/210 L” with tomorrow’s date (time after midnight).

3.4.6.4 Return instrument to current date and time.

3.4.7 No Sample Given Tests

The No Sample Given subroutine will be tested individually on all three subject samples. Expected final result is “No Sample Given”. For Court, type in “NO SAMPLE GIVEN”.

3.4.7.1 Conduct a test.

3.4.7.1.1 Sample 1 – allow instrument to time out, do not provide a sample.

3.4.7.1.2 “Retest Y/N” will be displayed, type “Y”, press enter.

3.4.7.2 Conduct a test.

3.4.7.2.1 Sample 1 = own breath.

3.4.7.2.2 Sample 2 - allow instrument to time out, do not provide a sample.

3.4.7.2.3 “Retest Y/N” will be displayed, type “Y”, press enter.

3.4.7.3 Conduct a test.

3.4.7.3.1 Sample 1 = own breath.

3.4.7.3.2 Sample 2 > 0.03 g/210 L vapor equivalent.

3.4.7.3.3 Sample 3 - allow instrument to time out, do not provide a sample.

3.4.7.3.4 “Retest Y/N” will be displayed, type “N”, press enter.

3.4.8 Deficient Sample Tests

The Deficient Sample subroutine will be tested individually on all three subject samples. Expected final result is “Deficient Sample”. For Court, type in “DEFICIENT SAMPLE”.

3.4.8.1 Conduct a test.

3.4.8.1.1 Sample 1 – provide a sample that does not meet sample parameters.

3.4.8.1.2 “Retest Y/N” will be displayed, type “Y”, press enter.

3.4.8.2 Conduct a test.

3.4.8.2.1 Sample 1 = own breath.

3.4.8.2.2 Sample 2 - provide a sample that does not meet sample parameters.

3.4.8.2.3 “Retest Y/N” will be displayed, type “Y”, press enter.

3.4.8.3 Conduct a test.

3.4.8.3.1 Sample 1 = own breath.

3.4.8.3.2 Sample 2 > 0.03 g/210 L vapor equivalent.

3.4.8.3.3 Sample 3 - provide a sample that does not meet sample parameters.

3.4.8.3.4 “Retest Y/N” will be displayed, type “N”, press enter.

3.4.9 Invalid Sample Tests

The Invalid Sample subroutine will be tested individually on all three subject samples. Fill one simulator with 0.300 g/210 L vapor equivalent solution and one simulator with 0.080 g/210 L vapor equivalent solution. Use t-piece tubing to connect the inlets and outlets of the simulator. For Court, type in “INVALID SAMPLE”.

3.4.9.1 Conduct a test.

3.4.9.1.1 “LAST NAME = PRACTICETEST”, “FIRST NAME = [insert PM#]”.

3.4.9.1.2 Sample 1 – Blow through both simulators for approximately 2 seconds then stop inlet flow to the 0.300 g/210 L simulator. Continue to provide the sample until it is accepted.

3.4.9.1.3 Expected final result is “Invalid Sample”.

3.4.9.1.4 “Retest Y/N” will be displayed, type “Y”, press enter.

3.4.9.1.5 Ensure the instrument does not allow test to proceed because of the same subject information.

3.4.9.1.6 Abort the test.

3.4.9.2 Conduct a test.

3.4.9.2.1 “LAST NAME = PRACTICETEST”, “FIRST NAME = [insert PM#]”.

3.4.9.2.2 Sample 1 = own breath.

3.4.9.2.3 Sample 2 - Blow through both simulators for approximately 2 seconds then stop inlet flow to the 0.300 g/210 L simulator. Continue to provide the sample until it is accepted.

3.4.9.2.4 Expected final result is “Invalid Sample”.

3.4.9.2.5 “Retest Y/N” will be displayed, “type N”, press enter.

3.4.9.3 Conduct a test, using the same subject information entered in 3.4.9.2.1.

3.4.9.3.1 Ensure the instrument does not allow test to proceed because of the same subject information.

3.4.9.3.2 Abort the test.

3.4.9.4 Conduct a test.

3.4.9.4.1 "LAST NAME = PRACTICETEST, FIRST NAME = [insert PM#]".

3.4.9.4.2 Sample 1 = own breath.

3.4.9.4.3 Sample 2 > 0.03 g/210 L vapor equivalent.

3.4.9.4.4 Sample 3 - Blow through both simulators for approximately 2 seconds then stop inlet flow to the 0.300 g/210 L simulator. Continue to provide the sample until it is accepted.

3.4.9.4.5 Expected final result is "Invalid Sample".

3.4.9.4.6 "Retest Y/N" will be displayed, type "N", press enter.

3.4.9.5 Conduct a test, using the same subject information entered in 3.4.9.4.1.

3.4.9.5.1 Ensure the instrument does not allow test to proceed because of the same subject information.

3.4.9.5.2 Abort the test.

3.4.10 Radio Frequency Interference Tests

Expected final result is "0.00 g/210 L". For Court, type in "RFI".

3.4.10.1 Conduct a test that requires all 3 samples and key the radio during each portion of the test sequence (e.g., during data entry, during diagnostics, during every PURGE, during every BLANK CHECK, and while providing breath samples).

3.4.11 Improper Sequence Tests

The Improper Sequence subroutine will be checked on all blanks of evidential tests. Expected final result is "Sequence". For Court, type in "SEQUENCE".

3.4.11.1 Initiate a test.

3.4.11.1.1 When the instrument starts performing the diagnostics, provide a breath sample.

3.4.11.2 Initiate a test.

3.4.11.2.1 Allow instrument to complete diagnostics.

3.4.11.2.2 When the instrument starts performing the first blank, provide a breath sample.

3.4.11.3 Initiate a test.

3.4.11.3.1 Allow instrument to complete diagnostics.

3.4.11.3.2 Allow instrument to complete first blank.

3.4.11.3.3 Allow instrument to perform dry gas check.

3.4.11.3.4 When the instrument starts performing the second blank, provide a breath sample.

3.4.11.4 Initiate a test.

3.4.11.4.1 Allow instrument to complete diagnostics.

3.4.11.4.2 Allow instrument to complete first blank.

3.4.11.4.3 Allow instrument to perform dry gas check.

3.4.11.4.4 Allow instrument to complete second blank.

3.4.11.4.5 Sample 1 = own breath.

3.4.11.4.6 When the instrument starts performing the third blank, provide a breath sample.

3.4.11.5 Initiate a test.

3.4.11.5.1 Allow instrument to complete diagnostics.

3.4.11.5.2 Allow instrument to complete first blank.

3.4.11.5.3 Allow instrument to perform dry gas check.

3.4.11.5.4 Allow instrument to complete second blank.

3.4.11.5.5 Sample 1 = own breath.

3.4.11.5.6 Allow instrument to complete third blank.

3.4.11.5.7 Sample 2 = own breath.

3.4.11.5.8 When the instrument starts performing the fourth blank, provide a breath sample.

3.4.11.6 Initiate a test.

3.4.11.6.1 Allow instrument to complete diagnostics.

3.4.11.6.2 Allow instrument to complete first blank.

3.4.11.6.3 Allow instrument to perform dry gas check.

3.4.11.6.4 Allow instrument to complete second blank.

3.4.11.6.5 Sample 1 = own breath.

3.4.11.6.6 Allow instrument to complete third blank.

3.4.11.6.7 Sample 2 > 0.03 g/210 L vapor equivalent.

3.4.11.6.8 Allow instrument to complete fourth blank.

3.4.11.6.9 Sample 3 = own breath.

3.4.11.6.10 When the instrument starts performing the fifth blank, provide a breath sample.

3.4.12 Ambient Tests

The Ambient subroutine will be checked. Expected final result is “0.00 g/210 L” (AMBIENT/RFI DETECTED may also be received, repeat until final expected result is achieved). For Court, type in “AMBIENT”.

3.4.12.1 Place an open bottle of pure ethanol at the opening of the breath tube and allow it to remain there during the entire test sequence.

3.4.12.2 Conduct a test.

3.4.12.2.1 Sample 1 = own breath.

3.4.12.2.2 Sample 2 > 0.03 g/210 L vapor equivalent.

3.4.12.2.3 Sample 3 = own breath.

3.4.13 Out of Tolerance Tests

The Out of Tolerance subroutine will be checked. Expected final result is “OUT OF TOLERANCE”. For Court, type in “TOLERANCE”.

3.4.13.1 Install a 0.150 BrAC gas cylinder.

3.4.13.1.1 Enter password and update tank lot #.

3.4.13.1.2 Target value (at sea level) should remain “0.100”.

3.4.13.2 Initiate a test.

3.4.13.3 Install a 0.080 BrAC gas cylinder.

3.4.13.3.1 Enter password and update tank lot #.

3.4.13.3.2 Target value (at sea level) should remain “0.100”.

3.4.13.4 Initiate a test.

3.4.13.5 The instrument will be disabled, run a .100 certification to resume testing.

3.5 Ensure the Instrument Properly Tracks Daylight Saving Time Transitions

3.5.1 Change the date to the next transition date and 1:58am.

3.5.1.1 If Autumn/Fall, ensure the instrument changes the time to the 1am hour and EST.

3.5.1.2 If Spring, ensure the instrument changes the time to the 3am hour and EDT.

3.5.2 Repeat the above for the next three transitions.

3.5.3 Return the instrument to current date and time.

3.5.4 Certification with a 0.100 BrAC gas tank may be performed to resume testing.

3.6 Certification Expired

3.6.1 Ensure that the certification due date is 180 days from the last successful certification performed.

3.6.2 Change the tank expiration to beyond 180 days.

3.6.3 Change the date to the day before the certification is due to expire and time to 2358.

3.6.4 Ensure instrument is “DISABLED” (will not allow subject test to be performed) after the time advances to the next day.

3.6.5 Return the instrument to current date and time and correct tank information.

3.6.6 The instrument will be disabled, certification with a 0.100 BrAC gas tank may be performed to resume testing.

3.7 Three Sample Tests

The firmware shall be tested to ensure the final result is the lowest of the three sample values. Expected final result is “0.00g/210 L”. For Court, type in “3 SAMPLE”.

3.7.1 Conduct a test.

3.7.1.1 Sample 1 = own breath.

3.7.1.2 Sample 2 = ≥ 0.08 g/210 L vapor equivalent.

3.7.1.3 Sample 3 ~ 0.015 g/210 L vapor equivalent.

3.7.2 Conduct a test.

3.7.2.1 Sample 1 = ≥ 0.08 g/210 L vapor equivalent.

3.7.2.2 Sample 2 = own breath.

3.7.2.3 Sample 3 ~ 0.015 g/210 L vapor equivalent.

3.7.3 Conduct a test.

3.7.3.1 Sample 1 = ≥ 0.08 g/210 L vapor equivalent.

3.7.3.2 Sample 2 ~ 0.015 g/210 L vapor equivalent.

3.7.3.3 Sample 3 = own breath.

3.8 Sample Parameters Not Met

The firmware shall be tested to ensure the 0.02 agreement between samples is functioning properly. Expected final result is “Sample parameters not met”. For Court, type in “SPNM”.

3.8.1 Conduct a test.

3.8.1.1 Sample 1 = own breath.

3.8.1.2 Sample 2 ~ 0.08 g/210 L vapor equivalent.

3.8.1.3 Sample 3 ~ 0.160 g/210 L vapor equivalent.

3.8.1.4 “Retest Y/N” will be displayed, type “Y”, press enter.

3.8.2 Conduct a test.

3.8.2.1 Sample 1 ~ 0.08 g/210 L vapor equivalent.

3.8.2.2 Sample 2 = own breath.

3.8.2.3 Sample 3 ~ 0.160 g/210 L vapor equivalent.

3.8.2.4 “Retest Y/N” will be displayed, type “Y”, press enter.

3.8.3 Conduct a test.

3.8.3.1 Sample 1 ~ 0.08 g/210 L vapor equivalent.

3.8.3.2 Sample 2 ~ 0.160 g/210 L vapor equivalent.

3.8.3.3 Sample 3 = own breath.

3.8.3.4 “Retest Y/N” will be displayed, type “N”, press enter.

3.9 Over Range Tests

The Over Range subroutine will be tested individually on all three subject samples. Expected final result is “Test result over range or Sample over range”. For Court, type in “OVER RANGE”.

3.9.1 Conduct a test.

3.9.1.1 “LAST NAME = PRACTICETEST”, “FIRST NAME = [insert PM#]”.

3.9.1.2 Sample 1 ~ 0.60 vapor equivalent.

3.9.1.3 Expected result is “Test result over range” or “Sample over range”.

3.9.1.4 “Retest Y/N” will be displayed, type “Y”, press enter.

3.9.1.5 Ensure the instrument does not allow this test to proceed because of the same subject information.

3.9.1.6 Abort the test.

3.9.2 Conduct a test.

3.9.2.1 “LAST NAME = PRACTICETEST”, “FIRST NAME = [insert PM#]”.

3.9.2.2 Sample 1 = own breath.

3.9.2.3 Sample 2 ~ 0.60 vapor equivalent.

3.9.2.4 Expected result is “Test result over range” or “Sample over range”.

3.9.2.5 “Retest Y/N” will be displayed, type “N”, press enter.

3.9.2.6 Start another test with the same subject information from previous test. Ensure the instrument does not allow this test to proceed because of the same subject information.

3.9.2.7 Abort the test.

3.9.3 Conduct a test.

3.9.3.1 “LAST NAME = PRACTICETEST”, “FIRST NAME = [insert PM#]”.

3.9.3.2 Sample 1 = own breath.

3.9.3.3 Sample 2 > 0.03 but less than 0.50.

3.9.3.4 Sample 3 ~ 0.60 vapor equivalent.

3.9.3.5 Expected result is “Test result over range” or “Sample over range”.

3.9.3.6 “Retest Y/N” will be displayed, type “Y”, press enter.

3.9.3.7 Ensure the instrument does not allow this test to proceed because of the same subject information.

3.9.3.8 Abort the test.

3.10 Communication Software

3.10.1 Create new instrument location, if necessary.

3.10.1.1 Instrument Name is the serial number of the instrument.

3.10.2 Set Communications to “outgoing modem”.

3.10.3 Set the System Phone Number.

3.11 Verify Communication with the Host Computer

3.11.1 Connect instrument modem to analog phone line.

3.11.2 Using the Breath Alcohol Laboratory (the Laboratory) Intoxnet call the instrument.

3.11.3 Verify that the call was successful.

3.12 Set the Call Out Telephone Number

3.12.1 Access the proper menu.

3.12.2 Call out telephone number = (see Program Manager or designee for appropriate information).

3.13 Verify Call Out Function

3.13.1 Connect Instrument modem to analog phone line.

3.13.2 Remove dry gas tank or initiate callout

3.13.3 Verify that there is a call made to the host computer

3.14 Perform Instrument Certification (¶ 6)

3.14.1 For acceptance testing, this will be denoted in BrAD as “CALIBRATED, ACCEPTED AND CERTIFIED”.

3.14.2 There will not be a notation in BrAD for Software/Firmware Testing.

3.15 Download the Instrument

3.15.1 This may be performed multiple times during any portion of this procedure, if necessary.

3.15.2 If download was performed “Direct to PC”, return “Connection Type” to “E-seek”.

3.15.3 Information will be printed for review and possible approval by the Program Manager or Section Supervisor.

3.16 Use

No instrument shall be used as an evidential instrument prior to meeting all of the above listed criteria and being approved by the Program Manager or Section Supervisor. No firmware/software shall be used on an evidential instrument for evidential breath tests (field use) prior to meeting all of the above listed criteria and being approved by the Program Manager.

3.16.1 The approver will verify that information contained on instrument printouts mirrors that on the reports generated from the instrument downloads.

3.16.1.1 Not all information contained in the downloads is on the instrument printouts.

3.16.1.2 Acceptance testing documentation will be retained in the instrument folder.

3.16.2 Approved firmware/software versions will have the documentation retained within the Section.

4 Instrument Acceptance - Draeger Alcotest 9510

4.1 Initial Instructions

4.1.1 Initial instructions for new system software acceptance testing for the Draeger Alcotest 9510.

4.1.1.1 For acceptance testing of new versions of system software, the testing shall be performed on a minimum of two (2) instruments prior to the installation of new system software on already deployed instruments.

4.1.1.2 Upload new system software. Download any data, if applicable.

4.1.1.3 Perform the instrument certification for the Draeger Alcotest 9510 (without the addendum tests). If necessary, perform the instrument adjustment (calibration) for the Draeger Alcotest 9510.

4.1.1.4 Perform all testing listed below.

4.1.2 Initial instructions for new instrument acceptance testing for the Draeger Alcotest 9510.

4.1.2.1 This testing will be performed on every new instrument prior to evidential use.

4.1.2.2 Upload the appropriate system software, if applicable.

4.1.2.3 Perform the instrument certification for the Draeger Alcotest 9510 (without addendum tests). If necessary, perform the instrument adjustment (calibration) for the Draeger Alcotest 9510.

4.1.2.4 Perform all testing listed below.

4.2 Additional Instructions

4.2.1 Utilize the appropriate worksheet to document completion of criteria.

4.2.2 Retain all printouts and indicate the procedure number on the appropriate printout and initial all printouts.

4.2.3 Unless otherwise specified, vapor equivalents are obtained from wet bath simulators blown through the breath hose. The source of the flow through the simulator may be from the instrument outlet pump or from the analyst.

4.2.3.1 Simulators should be primed (blown through) for 3-5 seconds immediately prior to use.

4.2.3.2 Using a NIST-traceable thermometer, ensure that the temperature is between 33.8°C and 34.2°C.

4.2.4 In this protocol, information within quotation marks denotes data entry on the instrument or information shown on the instrument display.

4.2.5 Unless otherwise noted, the subject information will be that the last name is “Test” and the first name will be “[insert PM#]” or the practice identification card/driver’s license.

4.2.6 For Court, choose “Other”.

4.2.7 For any portion of this procedure that does not fall within expected/acceptable results or messages, due to undeterminable reasons, testing will be stopped until the Program Manager or Section Supervisor can be consulted. Testing may be resumed at the direction of the Program Manager or Section Supervisor. The Program Manager or Section Supervisor will ensure that proper documentation is generated and maintained.

4.3 Linearity

4.3.1 Run as CalCheck (in lab tests) – Change Test-Gas to wet or dry, change test numbers to 4 samples for wet bath or 3 samples for dry gas, change Gas-Input to Gas Inlet 1 or Cuvette Inlet. Set the concentration. Using a NIST-traceable thermometer, ensure that the simulator temperature is between 33.8°C and 34.2°C. Run the test with a 0.300 g/210 L vapor equivalent wet bath solution or dry gas standard.

4.3.2 Run as CalCheck (in lab tests) – Change Test-Gas to wet or dry, change test numbers to 4 samples for wet bath or 3 samples for dry gas, change Gas-Input to Gas Inlet 1 or Cuvette Inlet. Set the concentration. Using a NIST-traceable thermometer, ensure that the simulator temperature is between 33.8°C and 34.2°C. Run the test with a 0.400 g/210 L vapor equivalent wet bath solution or dry gas standard.

4.3.3 Expected results for each of the above wet bath solutions for the 2nd, 3rd, and 4th samples or all 3 samples for dry gas:

4.3.3.1 Accuracy: individual results within ±5% of the target value within each detector system.

4.3.3.2 Precision: all values within 0.005 g/210 L (i.e., range of values ≤0.005 g/210 L) of each other for each detector system.

4.4 Sample Reporting – "Conduct a test" means that the analyst will perform an evidential breath test.

4.4.1 Conduct a test and provide both breath samples with your own breath.

4.4.1.1 Expected result: "0.00 g/210 L".

4.4.2 Conduct a test.

4.4.2.1 Sample 1 = own breath.

4.4.2.2 Sample 2 ~0.015 g/210 L vapor equivalent.

4.4.2.3 Expected result: "0.00 g/210 L".

4.4.3 Conduct a test.

4.4.3.1 Sample 1 ~0.015 g/210 L vapor equivalent.

4.4.3.2 Sample 2 = own breath.

4.4.3.3 Expected result: "0.00 g/210 L"

4.4.4 Ready to Blow Expired: The "Ready to Blow Expired" protocol will be tested individually on all three subject samples. Expected result is "Ready to Blow Exp.".

4.4.4.1 Conduct a test and allow the instrument to time out, do not provide a sample.

4.4.4.2 Conduct a test.

4.4.4.2.1 Sample 1 = own breath.

4.4.4.2.2 Sample 2 – allow the instrument to time out, do not provide a sample.

4.4.4.3 Conduct a test.

4.4.4.3.1 Sample 1 = own breath.

4.4.4.3.2 Sample 2 >0.03 g/210 L vapor equivalent.

4.4.4.3.3 Sample 3 – allow the instrument to time out, do not provide a sample.

4.4.5 Max Sample Attempts: The “Max Sample Attempts” protocol will be tested individually on all three subject samples. Expected results is “Max Sample Attempts”.

4.4.5.1 Conduct a test. Provide a breath sample that does not meet the minimum sample parameters for each attempt that the instrument requests.

4.4.5.2 Conduct a test.

4.4.5.2.1 Sample 1 = own breath.

4.4.5.2.2 Sample 2 – Provide a breath sample that does not meet the minimum sample parameters for each attempt that the instrument requests.

4.4.5.3 Conduct a test.

4.4.5.3.1 Sample 1 = own breath.

4.4.5.3.2 Sample 2 >0.03 g/210 L vapor equivalent.

4.4.5.3.3 Sample 3 – Provide a breath sample that does not meet the minimum sample parameters for each attempt that the instrument requests.

4.4.6 Mouth Alcohol: The “Mouth Alcohol” protocol will be tested individually on all three subject samples. Fill one simulator with 0.300 g/210 L vapor equivalent solution and one simulator with 0.080 g/210 L vapor equivalent solution. Use a t-piece tubing connection to connect the inlets and outlets of the simulators. Expected result is “Mouth Alcohol Detected”.

4.4.6.1 Conduct a test.

4.4.6.1.1 Sample 1 – blow through both simulators for ~ 2seconds then stop the inlet flow to the 0.300 g/210 L simulator. Continue to provide the sample until it is accepted.

4.4.6.2 Conduct a test.

4.4.6.2.1 Sample 1 = own breath.

4.4.6.2.2 Sample 2 – blow through both simulators for ~ 2seconds then stop the inlet flow to the 0.300 g/210 L simulator. Continue to provide the sample until it is accepted.

4.4.6.3 Conduct a test.

4.4.6.3.1 Sample 1 = own breath.

4.4.6.3.2 Sample 2 > 0.03 g/210 L vapor equivalent.

4.4.6.3.3 Sample 3 – blow through both simulators for ~ 2seconds then stop the inlet flow to the 0.300 g/210 L simulator. Continue to provide the sample until it is accepted.

4.4.7 Radio Frequency Interference: Expected result is “0.00 g/210 L”.

4.4.7.1 Conduct a test that requires all three subject samples and key the radio transmit button during each portion of the test sequence (e.g, during data entry, blank checks, ambient air checks, and while providing the subject breath samples).

4.4.8 Blowing Not Allowed: The “Blowing Not Allowed” protocol will be checked. Expected result (displayed and/or printed) is “Blowing Not Allowed”.

4.4.8.1 Conduct a test that requires all three subject samples.

4.4.8.1.1 Provide a breath sample when the instrument is performing each “Blank Check”.

4.4.8.1.2 If the test is aborted with the expected result, initiate another test and provide a breath sample when the instrument is performing the remaining, untested “Blank Checks”.

4.4.8.2 Conduct a test that requires all three subject samples.

4.4.8.2.1 Provide a breath sample when the instrument is performing each “Ambient Air Check”.

4.4.8.2.2 If the test is aborted with the expected result, initiate another test and provide a breath sample when the instrument is performing the remaining, untested “Ambient Air Checks”.

4.4.9 Alcohol in Ambient Air: The “Alcohol in Ambient Air” protocol will be checked. Expected result is “0.00 g/210 L” or “Alcohol in Ambient Air”.

4.4.9.1 Place an open bottle of ethanol near the instrument. Hold the breath hose opening near the open ethanol bottle while the instrument is conducting all non-subject breath sample protocols.

4.4.9.2 Conduct a test. If necessary, conduct a test that requires three subject samples.

4.4.10 External Standard Out of Tolerance: The “External Standard Out of Tolerance” protocol will be checked. Expected result is “Ext. Std Out of Tol”.

4.4.10.1 Install a 0.150 g/210 L BrAC or higher gas cylinder and keep the target value at 0.100 g/210 L.

4.4.10.2 Conduct a test.

4.4.11 Three Samples: The instrument software will be tested to ensure that the reported result is the lowest of the three subject sample values. Expected result is “0.00 g/210 L”.

4.4.11.1 Conduct a test.

4.4.11.1.1 Sample 1 = own breath.

4.4.11.1.2 Sample 2 ~0.08 g/210 L vapor equivalent (or greater).

4.4.11.1.3 Sample 3 ~0.015 g/210 L.

4.4.11.2 Conduct a test.

4.4.11.2.1 Sample 1 ~0.08 g/210 L vapor equivalent (or greater).

4.4.11.2.2 Sample 2 = own breath.

4.4.11.2.3 Sample 3 ~0.015 g/210 L vapor equivalent.

4.4.11.3 Conduct a test.

4.4.11.3.1 Sample 1 ~0.08 g/210 L vapor equivalent (or greater).

4.4.11.3.2 Sample 2 ~0.015 g/210 L vapor equivalent.

4.4.11.3.3 Sample 3 = own breath.

4.4.12 No Sample Agreement: The “No Sample Agreement” protocol will be tested. Expected result is “No Sample Agreement”.

4.4.12.1 Conduct a test.

4.4.12.1.1 Sample 1 = own breath.

4.4.12.1.2 Sample 2 ~0.08 g/210 L vapor equivalent.

4.4.12.1.3 Sample 3 ~0.160 g/210 L vapor equivalent (or greater).

4.4.12.1.4 Retest – “No”

4.4.12.2 Conduct a test.

4.4.12.2.1 Sample 1 ~0.08 g/210 L vapor equivalent.

4.4.12.2.2 Sample 2 = own breath.

4.4.12.2.3 Sample 3 ~0.160 g/210 L vapor equivalent (or greater).

4.4.12.2.4 Retest – “No”

4.4.12.3 Conduct a test.

4.4.12.3.1 Sample 1 ~0.08 g/210 L vapor equivalent.

4.4.12.3.2 Sample 2 ~0.160 g/210 L vapor equivalent (or greater).

4.4.12.3.3 Sample 3 = own breath.

4.4.12.3.4 Retest – “No”

4.4.13 Sample Over Range: The “Sample Over Range” protocol will be tested individually on all three subject samples. Expected result is “Sample Over Range”.

4.4.13.1 Conduct a test.

4.4.13.1.1 Sample 1 ~0.60 g/210 L vapor equivalent (or greater).

4.4.13.2 Conduct a test.

4.4.13.2.1 Sample 1 = own breath.

4.4.13.2.2 Sample 2 ~0.60 g/210 L vapor equivalent (or greater).

4.4.13.3 Conduct a test.

4.4.13.3.1 Sample 1 = own breath.

4.4.13.3.2 Sample 2 > 0.03 g/210 L vapor equivalent but less than 0.50 g/210 L vapor equivalent.

4.4.13.3.3 Sample 3 ~0.60 g/210 L vapor equivalent (or greater).

4.4.14 Interferent Detected: The “Interferent Detected” protocol will be tested individually on all three subject breath samples for methanol, isopropanol, and acetone. Expected result is “Interferent Detected” or meets OIML R126:2021 specifications. Dry gas mixtures that are equivalent to the supplemented simulator solutions below may be used in place of wet bath simulator solutions.

4.4.14.1 Test the ~0.080 g/210 L vapor equivalent simulator solution or 0.080 g/210L dry gas cylinder.

4.4.14.2 Methanol:

4.4.14.2.1 Add 100 µL methanol to 500 mL of ~0.080 g/210 L ethanol vapor equivalent simulator solution.

4.4.14.2.2 Conduct a test

4.4.14.2.2.1 Sample 1 - methanol supplemented simulator solution

4.4.14.2.2.2 Sample 2 - methanol supplemented simulator solution (if necessary)

4.4.14.2.3 Conduct a test

4.4.14.2.3.1 Sample 1 = own breath

4.4.14.2.3.2 Sample 2 - methanol supplemented simulator solution

4.4.14.2.3.3 Sample 3 – methanol supplemented simulator solution (if necessary)

4.4.14.3 Isopropanol:

4.4.14.3.1 Add 50 µL isopropanol to 500 mL of ~0.080 g/210 L ethanol vapor equivalent simulator solution.

4.4.14.3.2 Conduct a test.

4.4.14.3.2.1 Sample 1 – isopropanol supplemented simulator solution

4.4.14.3.2.2 Sample 2 - isopropanol supplemented simulator solution

4.4.14.3.3 Conduct a test

4.4.14.3.3.1 Sample 1 = own breath

4.4.14.3.3.2 Sample 2 – isopropanol supplemented simulator solution

4.4.14.3.3.3 Sample 3 – isopropanol supplemented simulator solution

4.4.14.4 Acetone:

4.4.14.4.1 Add 100 µL acetone to 500 mL of ~ 0.080 g/210 L ethanol vapor equivalent simulator solution.

4.4.14.4.2 Conduct a test.

4.4.14.4.2.1 Sample 1 – acetone supplemented simulator solution

4.4.14.4.2.2 Sample 2 - acetone supplemented simulator solution

4.4.14.4.3 Conduct a test

4.4.14.4.3.1 Sample 1 = own breath

4.4.14.4.3.2 Sample 2 - acetone supplemented simulator solution

4.4.14.4.3.3 Sample 3 – acetone supplemented simulator solution

4.5 Certification Expired

4.5.1 Select the Set Certification Date protocol. Ensure that the certification due date is 180 days from the current date.

4.5.2 Change the dry gas tank expiration to beyond 180 days.

4.5.3 Change the date and time to the day before the certification is due and the time to 23:58.

4.5.4 Ensure the instrument is disabled (i.e., will not allow a subject test to be performed) after the time advances to the next day.

4.5.5 Return the instrument to the current date and time and correct the tank information.

4.6 Daylight Saving Time Transition Verification

4.6.1 Change the date to the next Spring transition date and the time to 1:58 am. Verify that the time changes correctly.

4.6.2 Change the date to the day before the next Autumn/Fall transition date and the time to 11:50 pm (23:50). Verify that the time falls back when the clock time is 2:00 am.

4.6.3 Return the instrument to the current date and time. If these tests are completed between other tests, ensure that the instrument is returned to the current date and time before conducting further tests.

4.7 Perform Instrument Certification (without addendum tests)

4.7.1 For acceptance testing, this will be denoted in BrAD as “Accepted and Certified”. If an adjustment (calibration) was performed, this will be denoted in BrAD as “Calibrated, Accepted, and Certified.”

4.7.2 There will not be a notation in BrAD for software acceptance testing.

4.8 Use

4.8.1 **No instrument shall be used as an evidential instrument prior to meeting all of the above listed criteria and being approved by the Program Manager or Section Supervisor. No software shall be used on an evidential instrument for evidential breath tests (i.e., field use) prior to meeting all of the above listed criteria and being approved by the Program Manager and Section Supervisor.**

4.8.2 New instrument acceptance testing documentation will be retained either in the instrument folder or in the FA BrAD object repository.

4.8.3 New system software approval documentation will be retained in the section and electronically.

5. INSTRUMENT VERIFICATION FOR THE INTOX EC/IR II

5.1. Initial Instructions

5.1.1. Initial instructions for Instrument Verification.

5.1.1.1. This testing will be performed on instruments that are returned from the manufacturer after repair and/or maintenance unless that instrument has completed Firmware/Software Acceptance (¶ 3).

5.1.1.2. Upload approved Firmware/Software version, if applicable.

5.1.1.3. Print Firmware/Software Versions.

5.1.1.4. Calibrate the instrument (¶ 5).

5.1.1.5. Perform Instrument Certification (¶ 6 - omit 6.6).

5.2. Additional Instructions

5.2.1. Utilize the Instrument Verification Worksheet to document completion of all specifications.

5.2.2. Retain all printouts.

5.2.2.1. Place procedure number on the printout, unless otherwise noted (¶4.2.6).

5.2.2.2. Initial the upper right hand corner of the printouts.

5.2.2.3. Ensure instrument serial number is on all pages.

5.2.3. Unless otherwise specified, vapor equivalents are obtained from wet bath simulators blown through the breath tube.

5.2.3.1. Simulators should be primed (blown through) for 3-5 seconds immediately prior to use.

5.2.4. In this protocol, information within quotation marks denotes data entry on the instrument or information shown on the digital display.

5.2.5. For any portion of this procedure that does not fall within expected/acceptable results or messages, due to undeterminable reasons, testing will be stopped until the Program Manager or Section Supervisor can be consulted. Testing may be resumed at the direction of the Program Manager or Section Supervisor. The Program Manager or Section Supervisor will ensure that proper documentation is generated and maintained pursuant to ¶ 4.15.

5.2.6. Unless otherwise noted subject information will be “LAST NAME = PRACTICETEST” and “FIRST NAME = [insert PM#]” or Virginia Driver’s License or Identification Card (exceptions may be made, consult with the Program Manager, Section Supervisor, or Group Supervisor).

5.3. Linearity

5.3.1. Change “Default Standard” to “Std 2 – wet sim”.

5.3.2. Run an accuracy check (4 samples) with a 0.300 wet bath solution.

5.3.3. Run an accuracy check (4 samples) with a 0.400 wet bath solution.

5.3.4. Expected results for each of the above listed solutions.

5.3.4.1. For accuracy, the 2nd, 3rd and 4th sample values from each concentration must be within 3% of the target.

5.3.4.2. For precision, the 2nd, 3rd and 4th sample values must be within 0.003 of each other.

5.3.5. Return “Default Standard” to “Std 1 – Dry Gas”

5.4. Sample Reporting

5.4.1. Subject Test

5.4.1.1.1. A Subject Test will be conducted where your own breath is provided as the first sample and a solution that is within 0.02 g/210 L will be provided as the second sample.

5.4.1.2. Conduct a test - For Court, type in “DFS”.

5.4.1.2.1. Sample 1 = own breath.

5.4.1.2.2. Sample 2 ~ 0.015 g/210 L vapor equivalent.

5.4.1.2.3. Expected final result is “0.00 g/210 L”.

5.4.2. No Sample Given Test

5.4.2.1.1. The No Sample Given subroutine will be tested. Expected final result is “No Sample Given”. For Court, type in “NO SAMPLE GIVEN”.

5.4.2.2. Conduct a test.

5.4.2.2.1. Sample 1 – allow instrument to time out, do not provide a sample.

5.4.2.2.2. “Retest Y/N” will be displayed, type “N”, press enter.

5.4.3. Deficient Sample Test

5.4.3.1.1. The Deficient Sample subroutine will be tested. Expected final result is “Deficient Sample”. For Court, type in “DEFICIENT SAMPLE”.

5.4.3.2. Conduct a test.

5.4.3.2.1. Sample 1 = own breath.

5.4.3.2.2. Sample 2 - provide a sample that does not meet sample parameters.

5.4.3.2.3. “Retest Y/N” will be displayed, type “N”, press enter.

5.4.4. Invalid Sample Test

5.4.4.1.1. The Invalid Sample subroutine will be tested. For Court, type in “INVALID SAMPLE”.

5.4.4.2. Conduct a test.

5.4.4.2.1. “LAST NAME = PRACTICETEST”, “FIRST NAME = [insert PM#]”.

5.4.4.2.2. Sample 1 – rinse mouth with an alcohol based aqueous solution and provide sample.

5.4.4.2.3. Expected final result is “Invalid Sample”.

5.4.4.2.4. “Retest Y/N” will be displayed, “type Y”, press enter.

5.4.4.2.5. Ensure the instrument does not allow test to proceed because of the same subject information.

5.4.4.2.6. Abort the test.

5.4.5. Improper Sequence Test

5.4.5.1.1. Expected final result is “Sequence”. For Court, type in “SEQUENCE”.

5.4.5.2. Initiate a test.

5.4.5.2.1. Allow instrument to complete diagnostics.

5.4.5.2.2. Allow instrument to complete first blank.

5.4.5.2.3. Allow instrument to perform dry gas check.

5.4.5.2.4. When the instrument starts performing the second blank, provide a breath sample.

5.4.6. Ambient Test

5.4.6.1.1. The Ambient subroutine will be checked. Expected final result is “0.00 g/210 L” (AMBIENT/RFI DETECTED may also be received, repeat until final expected result is achieved). For Court, type in “AMBIENT”.

5.4.6.2. Place an open bottle of pure ethanol at the opening of the breath tube and allow it to remain there during the entire test sequence.

5.4.6.3. Conduct a test.

5.4.6.3.1. Sample 1 = own breath.

5.4.6.3.2. Sample 2 > 0.03 g/210 L vapor equivalent.

5.4.6.3.3. Sample 3 = own breath.

5.4.7. Out of Tolerance Test

5.4.7.1.1. The Out of Tolerance subroutine will be checked. Expected final result is “OUT OF TOLERANCE”. For Court, type in “TOLERANCE”.

5.4.7.2. Install a 0.150 BrAC gas cylinder.

5.4.7.2.1. Enter password and update tank lot #.

5.4.7.2.2. Target value (at sea level) should remain “0.100”.

5.4.7.3. Initiate a test.

5.4.7.4. Certification with a 0.100 BrAC gas tank may be performed to resume testing.

5.5. **Three Sample Test**

5.5.1. The firmware shall be tested to ensure the final result is the lowest of the three sample values. Expected final result is “0.00g/210 L”. For Court, type in “3 SAMPLE”.

5.5.2. Conduct a test.

5.5.2.1. Sample 1 = own breath.

5.5.2.2. Sample 2 = ≥ 0.08 g/210 L vapor equivalent.

5.5.2.3. Sample 3 ~ 0.015 g/210 L vapor equivalent.

5.6. **Sample Parameters Not Met**

5.6.1. The firmware shall be tested to ensure the 0.02 agreement between samples is functioning properly. Expected final result is “Sample parameters not met”. For Court, type in “SPNM”.

5.6.2. Conduct a test.

5.6.2.1. Sample 1 ~ 0.08 g/210 L vapor equivalent.

5.6.2.2. Sample 2 = own breath.

5.6.2.3. Sample 3 ~ 0.160 g/210 L vapor equivalent.

5.6.2.4. “Retest Y/N” will be displayed, type “N”, press enter.

5.7. **Over Range Tests**

5.7.1. The Over Range subroutine will be tested. Expected final result is “Test result over range or Sample over range”. For Court, type in “OVER RANGE”.

5.7.2. Conduct a test.

5.7.2.1. “LAST NAME = PRACTICETEST”, “FIRST NAME = [insert PM#]”.

5.7.2.2. Sample 1 ~ 0.60 vapor equivalent.

5.7.2.3. Start another test, ensure the instrument does not allow this test to proceed because of the same subject information.

5.7.2.4. Abort the test.

5.8. **Interfering Substances Tests**

The Interfering Substances subroutine will be tested. For Court, type in “INTERFERENT”. Expected final results include “INTERFERENT DETECTED” or “FUEL CELL TIMEOUT” or “0.00 g/210 L”.

5.8.1. Conduct a test.

5.8.1.1. “LAST NAME = ACETONEINWATER”, “FIRST NAME = [insert PM#]”.

5.8.1.2. Sample 1 – 0.100 g/210 L Acetone.

5.8.1.3. Sample 2, if required – 0.100 g/210 L Acetone.

5.8.1.4. Expected final result is “INTERFERENT DETECTED” or “FUEL CELL TIMEOUT” or “0.00 g/210 L”.

5.8.2. Conduct a test

5.8.2.1. “LAST NAME = METHANOLINWATER”, “FIRST NAME = [insert PM#]”.

5.8.2.2. Sample 1 – 0.020 g/210 L Methanol.

5.8.2.3. Sample 2, if required – 0.020 g/210 L Methanol.

5.8.2.4. Expected final result is “INTERFERENT DETECTED” or “FUEL CELL TIMEOUT” or “0.00 g/210 L”.

5.8.3. Conduct a test.

5.8.3.1. “LAST NAME = ISOPROPANOLINWATER”, “FIRST NAME = [insert PM#]”.

5.8.3.2. Sample 1 – 0.020 g/210 L Isopropanol.

5.8.3.3. Sample 2, if required – 0.020 g/210 L Isopropanol.

5.8.3.4. Expected final result is “INTERFERENT DETECTED” or “FUEL CELL TIMEOUT” or “0.00 g/210 L”.

5.9. **Communication Software**

5.9.1. Create new instrument location, if necessary.

5.9.1.1. Instrument Name is the serial number of the instrument.

5.9.2. Set Communications to “outgoing modem”.

5.9.3. Set the System Phone Number.

5.10. **Verify Communication with the Host Computer**

5.10.1. Connect instrument modem to analog phone line.

5.10.2. Using the Breath Alcohol Laboratory (the Laboratory) Intoxnet call the instrument.

5.10.3. Verify that the communication was successful.

5.11. **Set the Call Out Telephone Number**

5.11.1. Access the proper menu.

5.11.2. Call out telephone number = (see Program Manager or designee for appropriate information).

5.12. **Verify Call Out Function**

5.12.1. Connect Instrument modem to analog phone line.

5.12.2. Remove dry gas tank or initiate callout.

5.12.3. Verify that there is a call made to the host computer.

5.13. Perform Instrument Certification (¶ 6)

5.13.1. For verification testing, this will be denoted in BrAD as “CALIBRATED, VERIFIED AND CERTIFIED”.

5.13.2. If firmware/software was uploaded, this will be denoted in BrAD as “FIRMWARE/SOFTWARE UPGRADED.”

5.14. **Download the Instrument**

5.14.1. This may be performed multiple times during any portion of this procedure, if necessary.

5.14.2. If download was performed “Direct to PC”, return “Connection Type” to “E-seek”.

5.14.3. Information will be printed for review and possible approval by the Program Manager, Section Supervisor, or Group Supervisor.

5.15. **Use**

5.15.1. **No instrument shall be used as an evidential instrument prior to meeting all of the above listed criteria (¶4) and being approved by the Program Manager, Section Supervisor, or Group Supervisor.**

5.15.2. The approver will verify that information contained on instrument printouts mirrors that on the reports generated from the instrument downloads.

5.15.2.1. Not all information contained in the downloads is on the instrument printouts.

5.15.2.2. Verification testing documentation will be retained in the instrument folder.

6 Instrument Verification for the Draeger Alcotest 9510

6.1 Initial Instructions

6.1.1 This testing will be performed on instruments that are returned from the manufacturer after repair/maintenance unless that instrument has completed Instrument Acceptance testing after the repair/maintenance.

6.1.2 Upload approved software version, if applicable.

6.1.3 Perform the instrument certification (without addendum tests) for the Draeger Alcotest 9510. If necessary, perform instrument adjustment (calibration) for the Draeger Alcotest 9510.

6.2 Additional Instructions

6.2.1 Utilize the appropriate worksheet to document the completion of all specifications.

6.2.2 Retain all printouts.

6.2.2.1 Indicate the procedure number on the printouts either through the data entry or handwritten.

6.2.2.2 Indicate instrument serial number on all printouts.

6.2.2.3 Initial all printouts.

6.2.3 Unless otherwise specified, vapor equivalents are obtained from wet bath simulators blown through the breath hose. The source of the flow through the simulator may be from the instrument outlet pump or from the analyst.

6.2.3.1 Simulators should be primed (blown through) for 3-5 seconds immediately prior to use.

6.2.4 In this protocol, information within quotation marks denotes data entry on the instrument or information shown on the digital display.

6.2.5 Unless otherwise noted, the subject information will be that the last name is “Test” and the first name will be “[insert PM#]” or the practice identification card/driver’s license.

6.2.6 For Court, choose “Other”.

6.2.7 For any portion of this procedure that does not fall within expected/acceptable results or messages, due to undeterminable reasons, testing will be stopped until the Program Manager or Section Supervisor can be consulted. Testing may be resumed at the direction of the Program Manager or Section Supervisor. The Program Manager or Section Supervisor will ensure that proper documentation is generated and maintained.

6.3 Linearity

6.3.1 Run a CalCheck (in lab tests) – Change Test-Gas to wet or dry, change test numbers to 4 samples for wet bath or 3 samples for dry gas, change Gas-Input to Gas Inlet 1 or Cuvette Inlet. Set the concentration. Using a NIST-traceable thermometer, ensure the simulator temperature is between 33.8°C and 34.2°C. Run the tests with a 0.300 g/210 L vapor equivalent wet bath solution or dry gas standard.

6.3.2 Run a CalCheck (in lab tests) – Change Test-Gas to wet or dry, change test numbers to 4 samples for wet bath or 3 samples for dry gas, change Gas-Input to Gas Inlet 1 or Cuvette Inlet. Set the concentration. Using a NIST-traceable thermometer, ensure the simulator temperature is between 33.8°C and 34.2°C. Run the tests with a 0.400 g/210 L vapor equivalent wet bath solution or dry gas standard.

6.3.3 Expected results for each of the above solutions for the 2nd, 3rd, and 4th samples (wet bath) or all three samples (dry gas):

6.3.3.1 Accuracy: individual results within ±5% of the target value within each detector system.

6.3.3.2 Precision: all values within 0.005 g/210 L (i.e., range of values ≤0.005 g/210 L) of each other for each detector system.

6.4 Sample Reporting - "Conduct a test" means that the analyst will perform an evidential breath test.

6.4.1 Conduct a test.

6.4.1.1 Sample 1 = own breath.

6.4.1.2 Sample 2 ~0.015 g/210 L vapor equivalent.

6.4.1.3 Expected result: "0.00 g/210 L".

6.4.2 Ready to Blow Expired: The "Ready to Blow Expired" protocol will be tested. Expected result is "Ready to Blow Exp.".

6.4.2.1 Conduct a test and allow the instrument to time out, do not provide a sample.

6.4.3 Max Sample Attempts: The "Max Sample Attempts" protocol will be tested. Expected result is "Max Sample Attempts".

6.4.3.1 Conduct a test. Provide breath samples that do not meet the minimum sample parameters for each attempt that the instrument requests.

6.4.4 Mouth Alcohol: The "Mouth Alcohol" protocol will be tested. Fill one simulator with 0.300 g/210 L vapor equivalent solution and one simulator with ~0.080 g/210 L vapor equivalent solution. Use a t-piece tubing connection to connect the inlets and outlets of the simulators. Expected result is "Mouth Alcohol Detected".

6.4.4.1 Conduct a test.

6.4.4.1.1 Sample 1 – blow through both simulators for ~ 2seconds then stop the inlet flow to the 0.300 g/210 L simulator. Continue to provide the sample until it is accepted.

6.4.5 Radio Frequency Interference: Expected result is "0.00 g/210 L".

6.4.5.1 Conduct a test that requires all three subject samples and key the radio transmit button during each portion of the test sequence (e.g, during data entry, blank checks, ambient air checks, and while providing the subject breath samples).

6.4.6 Blowing Not Allowed: The "Blowing Not Allowed" protocol will be checked. Expected result is "Blowing Not Allowed".

6.4.6.1 Conduct a test.

6.4.6.1.1 Provide a breath sample when the instrument is performing the first "Ambient Air Check" after the initial purge.

6.4.7 Alcohol in Ambient Air: The "Alcohol in Ambient Air" protocol will be checked. Expected result is "0.00 g/210 L" or "Alcohol in Ambient Air".

6.4.7.1 Place an open bottle of ethanol near the instrument. Hold the breath hose opening near the open ethanol bottle while the instrument is conducting all non-subject breath sample protocols.

6.4.7.2 Conduct a test. If necessary, conduct a test that requires three subject samples.

6.4.8 External Standard Out of Tolerance: The "External Standard Out of Tolerance" protocol will be checked. Expected result is "Ext. Std Out of Tol".

6.4.8.1 Install a 0.150 g/210 BrAC gas cylinder and keep the target value at 0.100 g/210 L.

6.4.8.2 Conduct a test.

6.4.9 Three Samples: The instrument software will be tested to ensure that the reported result is the lowest of the three subject sample values. Expected result is "0.00 g/210 L".

6.4.9.1 Conduct a test.

6.4.9.1.1 Sample 1 ~0.08 g/210 L vapor equivalent (or greater).

6.4.9.1.2 Sample 2 = own breath.

6.4.9.1.3 Sample 3 ~0.015 g/210 L vapor equivalent.

6.4.10 No Sample Agreement: The "No Sample Agreement" protocol will be tested. Expected result is "No Sample Agreement".

6.4.10.1 Conduct a test.

6.4.10.1.1 Sample 1 ~0.08 g/210 L vapor equivalent.

6.4.10.1.2 Sample 2 ~0.160 g/210 L vapor equivalent (or greater).

6.4.10.1.3 Sample 3 = own breath.

6.4.10.1.4 Retest – "No"

6.4.11 Sample Over Range: The "Sample Over Range" protocol will be tested. Expected result is "Sample Over Range".

6.4.11.1 Conduct a test.

6.4.11.1.1 Sample 1 ~0.60 g/210 L vapor equivalent (or greater).

6.4.12 Interferent Detected: The "Interferent Detected" protocol will be tested for methanol, isopropanol, and acetone. Expected result is "Interferent Detected" or meets OIML R126:2021 specifications. Dry gas mixtures that are equivalent to the supplemented simulator solutions below may be used in place of wet bath simulator solutions.

6.4.12.1 Test the ~0.080 g/210 L vapor equivalent simulator solution or 0.080 g/210L dry gas cylinder.

6.4.12.2 Methanol

6.4.12.2.1 Add 100 µL methanol to 500 mL of ~0.0.80 g/210 L vapor equivalent simulator solution.

6.4.12.2.2 Conduct a test.

6.4.12.2.2.1 Sample 1 – methanol supplemented simulator solution.

6.4.12.2.2.2 Sample 2 – methanol supplemented simulator solution (if necessary).

6.4.12.3 Isopropanol

6.4.12.3.1 Add 50 µL isopropanol to 500 mL of ~0.080 g/210 L vapor equivalent simulator solution.

6.4.12.3.2 Conduct a test.

6.4.12.3.2.1 Sample 1 – isopropanol supplemented simulator solution

6.4.12.3.2.2 Sample 2 – isopropanol supplemented simulator solution

6.4.12.4 Acetone

6.4.12.4.1 Add 100 µL acetone to 500 mL of ~0.080 g/210 L vapor equivalent simulator solution.

6.4.12.4.2 Conduct a test.

6.4.12.4.2.1 Sample 1 – acetone supplemented simulator solution

6.4.12.4.2.2 Sample 2 – acetone supplemented simulator solution

6.5 Perform Instrument Certification (without addendum tests)

6.5.1 For verification testing, this will be denoted in BrAD as “Verified and Certified”. If an adjustment (calibration) was performed, this will be denoted in BrAD as “Calibrated, Verified, and Certified.”

6.5.2 If software was uploaded/updated, this will be denoted in BrAD as “Software Upgraded”.

6.6 Use

6.6.1 No instrument shall be used as an evidential instrument prior to meeting all of the above listed criteria for instrument verification and being approved by the Program Manager, Section Supervisor, or Group Supervisor.

6.6.2 Verification documentation will be retained either in the instrument folder or in the FA BrAD object repository.

7 CALIBRATION PROCEDURE FOR THE INTOX EC/IR II

7.1 Background Information

7.1.1 Calibration involves the analysis of a known ethanol standard and the use of that result as the reference for calculating the value of an unknown result.

7.1.2 Calibrations are performed as needed.

7.1.3 An instrument must be certified, pursuant to ¶ 6 after a successful calibration (this verifies the calibration).

7.2 Supplies Needed

7.2.1 Ethanol Standard equivalent to 0.100 BrAC vapor (272 ppm) ethanol dry gas cylinder verified by the Department (DFS) per ¶ 7.3 (different lot number or manufacturer than the dry gas cylinder that is in the instrument).

7.2.2 Key to the tank compartment.

7.3 Calibration Procedure

7.3.1 Install calibration dry gas tank.

7.3.2 Enter tank information. Ensure that information is entered under Standard 1.

7.3.2.1 Include tank number after the lot number.

7.3.2.2 Separate the two numbers with a hyphen.

7.3.2.2.1 For example: “Lot no.-tank no.”.

7.3.3 Initiate the “Calibration” subroutine.

7.3.4 Verify that the standard to use is “**Std 1 – Dry Gas**”. Press Space to toggle through options as needed. Press Enter.

7.3.5 Verify that the standard value is “**0.100**”. Press Enter.

7.3.6 If the calibration is successful as specified on the instrument printout, initial the printout and certify the instrument for accuracy.

7.3.7 If the calibration is not successful, initial the printout, another calibration or troubleshooting may need to be performed.

7.3.8 All paperwork is to be retained in the instrument folder

8 Adjustment (Calibration) for the Draeger Alcotest 9510

8.1 Background Information

8.1.1 Adjustment – set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured.

8.1.2 Adjustments are performed as necessary.

8.1.3 An instrument must be certified after a successful adjustment.

8.2 Supplies Needed

8.2.1 Ethanol standard equivalent to 0.100 g/210 L (260 ppm) BrAC ethanol dry gas cylinder verified by DFS.

8.2.2 Wet bath simulator solution equivalent to 0.100 g/210 L vapor equivalent – certified reference material obtained from an ISO 17034 accredited vendor.

8.2.3 Wet bath simulator – Guth 12V500 or similar.

8.2.4 NIST-traceable thermometer.

8.3 Wet Bath Adjustment Procedure

8.3.1 Fill simulator with 0.100 g/210 L vapor equivalent and allow simulator to warm up for at least 60 minutes.

8.3.1.1 Using the NIST-traceable thermometer, ensure that the temperature is between 33.8°C and 34.2°C.

8.3.2 Initiate the wet-adjust protocol.

8.3.3 Initial all printouts and retain with the certification documentation.

8.4 Dry Gas Adjustment Procedure

8.4.1 Install a 0.100 g/210 L BrAC ethanol dry gas cylinder.

8.4.1.1 Update tank information, as necessary.

8.4.2 Initiate the dry-adjust protocol.

8.4.3 Initial all printouts and retain with the certification documentation.

8.5 Reference

8.5.1 JCGM 200:2012, International vocabulary of metrology – Basic and general concepts and associated terms (VIM). 3rd edition. (Sevres, France: IPM, 2008).

9 CERTIFICATION PROCEDURE FOR THE INTOX EC/IR II

9.1 Background Information

Pursuant to Code of Virginia §9.1-1101, DFS is to "test the accuracy of equipment used to test the blood alcohol content of breath at least once every six months" and "only equipment found to be accurate shall be used to test the blood alcohol content of breath." This procedure is used by DFS to satisfy the statutory requirements and issue a Certificate of Instrument Accuracy (CoIA).

Prior to performing the Certification Procedure on-site, ensure a successful instrument test and a successful measurement assurance check have been performed, if possible.

9.2 Supplies Needed

Ethanol standard content equivalent to 0.020 BrAC (54 ppm) dry gas cylinder verified by DFS.
Ethanol standard content equivalent to 0.080 BrAC (218 ppm) dry gas cylinder verified by DFS.
Ethanol standard content equivalent to 0.150 BrAC (408 ppm) dry gas cylinder verified by DFS.
Ethanol standard content equivalent to 0.250 BrAC (680 ppm) dry gas cylinder verified by DFS.
Ethanol content equivalent to 0.100 BrAC (272 ppm) dry gas cylinder verified by DFS.
Ethanol content equivalent to 0.300 BrAC (816 ppm) dry gas cylinder verified by DFS.

9.3 Certification Procedure

9.3.1 Verify Barometer

9.3.1.1 Access the proper menu.

9.3.1.2 Confirm that the reference barometer is reading 800 mm Hg or less. If the reading is greater than 800 mm Hg, do not continue. The instrument will not be certified until the reference barometer is reading 800 mm Hg or less.

9.3.1.3 Visually confirm that the difference between the instrument barometer reading and the reference barometer reading is equal to or less than 7 mm Hg.

9.3.1.3.1 If the above listed criterion is not met, troubleshooting may need to be performed.

9.3.1.4 Record readings on the approved Intox EC/IR II Certification Worksheet.

9.3.2 Initiate the "Certification" subroutine.

9.3.3 Install dry gas tank to be used to start Certification (0.020, 0.080, 0.150 or 0.250 BrAC). Press the Enter key.

9.3.4 When prompted, type in your initials. Press the Enter key.

9.3.5 Verify that the standard to use is "**Std 1 – Dry Gas**". Press Space to toggle through options as needed. Press Enter.

9.3.6 Update Std 1 Data and press Space to Continue.

9.3.6.1 Include tank number after the lot number. Separate the two numbers with a hyphen, e.g., "Lot no.-tank no.".

9.3.7 Type in target value of the first standard you will test. Press the Enter key.

9.3.8 The instrument will perform the analysis of the standard.

9.3.9 When prompted with "**Continue? [Y/N]**" Choose "Y" and continue until each of the standards has been analyzed: 0.020, 0.080, 0.150, 0.250 BrAC. Ensure that the tank is not changed until "Y" has been chosen.

9.3.10 Initial and transcribe the data from the instrument printout into the Intox EC/IR II Certification Worksheet.

9.3.11 Evaluate accuracy and precision parameters.

9.3.11.1 Accuracy parameter = values within 3% or 0.003 g/210L (whichever is greater) of the target value.

9.3.11.2 Precision parameter = no more than 0.003 g/210L difference in all three values.

9.3.11.3 Successful completion of the check requires that both accuracy and precision parameters are met. These values are the "as found/as left" data on the Intox EC/IR II Certification Worksheet (¶6.3.9).

9.3.11.3.1 If the reference material does not meet the accuracy and/or precision parameter(s), the data generated in this attempt will be considered as "as found" data, and the check ~~it~~ may be attempted again.

9.3.11.3.2 If the reference material does not meet the parameter(s) on the second attempt, Calibration or troubleshooting followed by Calibration must be performed prior to returning instrument to service.

9.3.11.3.3 After performing the calibration or troubleshooting, the technician/analyst/examiner will repeat the Certification procedure and the generated data will be considered "as left" data.

9.3.12 After all standards have been completed choose "N" at the "**Continue? [Y/N]**" prompt.

9.3.13 Choose "Y" when prompted with "**Certification complete and successful? [Y/N]**" prompt.

9.3.13.1 **The print-out from the final dry gas cylinder will not print until the "Y" is entered.**

9.3.14 Finalize the Intox EC/IR II Certification Worksheet

9.3.14.1 For field use, work is considered completed upon leaving the instrument site.

9.3.14.2 The Intox EC/IR II Certification Worksheet will be printed and reviewed upon staff return to the Laboratory. Any corrections or additions will be documented per the DFS Quality Manual.

9.4 Measurement Assurance Checks

Note: Measurement Assurance Checks are not necessary for a certification procedure performed at the VA DFS Breath Alcohol Laboratory. Measurement Assurance Checks are not part of the certification procedure to generate a CoIA. Measurement Assurance Checks (all supporting documentation and worksheets) may be completed electronically. Any hardcopy printouts will be stored in the corresponding instrument folder.

9.4.1 Install Measurement Assurance Check dry gas cylinder (0.100 or 0.300 g/210 L)

9.4.2 Enter password

9.4.3 Update tank information on instrument

9.4.4 Initiate the "Accuracy Check" subroutine (3 replicates).

9.4.5 Evaluate accuracy and precision parameters.

9.4.5.1 Accuracy parameter = values within 3% or 0.003 g/210L (whichever is greater) of the target value.

9.4.5.2 Precision parameter = no more than 0.003 g/210L difference in all three values.

9.4.5.3 Successful completion of the check requires that both accuracy and precision parameters are met.

9.4.5.3.1 If the reference material does not meet the accuracy and/or precision parameter(s), it may be attempted again.

9.4.5.3.2 If the reference material does not meet the parameter(s) on the second attempt, Calibration or troubleshooting followed by Calibration must be performed prior to returning instrument to service.

9.4.6 Repeat with remaining Measurement Assurance Check cylinder.

9.4.7 Complete the Intox EC/IR II Measurement Assurance Worksheet.

9.5 Instrument Test

9.5.1 The associated verification test (dry gas cylinder) also tests and demonstrates the accuracy of the instrument in addition to the satisfactory condition of the item.

9.5.2 Last name = “Instrument”, First Name = “Test”.

9.5.3 For Court, type in “DFS”.

9.5.4 Provide both breath samples with your own breath.

9.5.4.1 Expected final result is “0.00 g/210 L”.

9.5.4.2 Should any other result be obtained, troubleshooting may need to be performed or seek additional guidance from the Supervisor.

9.5.5 Upon successful completion of the Instrument Test, download all tests from the instrument

9.6 Generation and Issuance of the Certificate of Instrument Accuracy

9.6.1 Upon completion of the above listed procedures, enter the information into BrAD.

9.6.2 Generate the printout titled Certificate of Instrument Accuracy (CoIA) from BrAD, which is page 1 of 2 for the CoIA. The Intox EC/IR II Certification Worksheet is page 2 of 2 for the CoIA.

9.6.3 Collate the CoIA (BrAD CoIA printout and Intox EC/IR II Certification Worksheet) and, supporting data (instrument printouts) in the instrument folder and give this instrument folder to the Examiner.

9.6.3.1 Examiner will initial or sign all pages indicating that they have conducted, participated in, observed, supervised, or scientifically reviewed the calibration/certification activities.

9.6.3.2 Examiner will sign the Intox EC/IR II Certification Worksheet.

9.6.3.3 Examiner will sign the CoIA and then have the technical review performed.

9.6.4 After completion of the technical review, Reviewer will give the instrument folder including the CoIA to the Notary.

9.6.4.1 Notary will notarize the CoIA.

9.6.4.2 Notary will return the notarized CoIA and instrument folder to the Examiner.

9.6.4.3 DFS will deliver a copy of the notarized CoIA to the agency to which the instrument is assigned.

9.6.4.3.1 The aforementioned agency may not be known at the time of certification, therefore the agency name and address cannot be included on the CoIA.

9.6.4.4 The original CoIA will be maintained in the instrument folder.

9.6.4.5 The CoIA and supporting documentation will be scanned and stored in BrAD.

10 Certification Procedure for the Draeger Alcotest 9510

10.1 Background Information

Pursuant to Code of Virginia §9.1-1101, DFS is to "test the accuracy of equipment used to test the blood alcohol content of breath at least once every six months" and "only equipment found to be accurate shall be used to test the blood alcohol content of breath." This procedure is used by DFS to satisfy the statutory requirements and issue a Certificate of Instrument Accuracy (CoIA).

Prior to performing the Certification Procedure on-site, ensure a successful instrument test and successful measurement assurance checks have been performed, if possible.

10.2 Supplies Needed

10.2.1 Ethanol dry gas standard, verified by DFS, content equivalent to the following:

0.020 g/210 L (52 ppm)
0.080 g/210 L (208 ppm)
0.150 g/210 L (391 ppm)
0.250 g/210 L (651 ppm)
0.100 g/210 L (260 ppm) – for Measurement Assurance
0.300 g/210 L (781 ppm) – for Measurement Assurance

10.2.2 Wet bath simulator solutions equivalent to 0.300 g/210 L vapor equivalent and 0.100 g/210 L vapor equivalent.

10.2.3 Methanol.

10.2.4 Wet bath simulator – Guth 12V500 or similar.

10.3 Certification Procedure

10.3.1 Enter the Measurement menu and scan operator's license.

10.3.2 Initiate the Certification protocol, verify information and press "Save".

10.3.3 Enter location information.

10.3.4 Enter reference barometer serial number, calibration expiration date, and barometric pressure. If the pressure difference between the reference barometer and the instrument barometer is greater than 9 hPa, the instrument will abort the protocol. Assess and troubleshoot.

10.3.5 Select the appropriate level number (1-4), select 3 replicates.

10.3.6 Enter the information for the dry gas for the current level – vendor name, lot number, expiration date.

10.3.7 Select Test-Gas as "Dry", enter the concentration in g/210 L, and Gas-Input as "Cal Gas Inlet 1".

10.3.8 Install appropriate dry gas tank as prompted. Press "OK". The Alcotest 9510 will now sample the dry gas cylinder three times.

10.3.9 If the standard is out of tolerance, the instrument will ask if you want to repeat the level. The out of tolerance level may be repeated once. If the repeated test is out of tolerance, the certification procedure will be ended. Adjustment (calibration) and/or troubleshooting may be conducted.

10.3.10 When prompted to test another level:

10.3.10.1 If you need to test any other level, choose “Yes” and repeat 10.3.4 – 10.3.8 until all levels have been tested.

10.3.10.2 If this is the final level to test, choose “No”.

10.3.11 Evaluate certification printout for accuracy and precision parameters. Accuracy shall be within 5% or 0.005 g/210 L, whichever is greater, for each detector system. Precision shall be within 0.005 g/210 L of each other for each detector system. Finalize the certification.

10.3.11.1 Successful completion of the certification requires that both accuracy and precision parameters are met. The values listed will be considered the “as found/as left” data.

10.3.11.2 If the certification does not meet the accuracy and/or precision parameter(s), the data generated in this attempt will be considered as “as found” data and the certification procedure may be attempted again.

10.3.11.3 If the reference material does not meet the parameter(s) on the second attempt, adjustment (calibration) and/or troubleshooting may be conducted. An adjustment (calibration) must be performed prior to returning the instrument to service.

10.3.11.4 After the adjustment, the certification will be repeated and the generated data will be considered “as left” data.

10.4 Certification Addendum Tests

10.4.1 Mouth Alcohol: The “Mouth Alcohol” protocol will be tested. Fill one simulator with 0.300 g/210 L vapor equivalent solution and one simulator with 0.100 g/210 L vapor equivalent solution. Use a t-piece tubing connection to connect the inlets and outlets of the simulators. Expected result is “Mouth Alcohol Detected”.

10.4.1.1 Conduct a test. Subject information: Last Name = “PracticeTest”, First Name =”[insert PM#]”

10.4.1.2 Sample 1 – blow through both simulators for ~ 2seconds then stop the inlet flow to the 0.300 g/210 L simulator. Continue to provide the sample until it is accepted.

10.4.2 Interferent Detected: The “Interferent Detected” protocol will be tested for methanol. Expected result is “Interferent Detected” or meets OIML R126:2021 specifications.

10.4.2.1 Methanol: prepare the simulator solution by adding 100 µL methanol to 500 mL of distilled water. If available, dry gas mixtures may be used for this step.

10.4.2.2 Conduct a test.

10.4.2.3 Sample 1 – methanol supplemented simulator solution

10.5 Measurement Assurance Checks

Note: Measurement Assurance Checks are not necessary for a certification procedure performed at the VA DFS Breath Alcohol Laboratory. Measurement Assurance Checks are not part of the certification procedure to generate a CoIA. Measurement Assurance Checks (all supporting documentation and worksheets) may be completed electronically. Any hardcopy printouts will be stored in the corresponding instrument folder.

10.5.1 Enter the Measurement menu and scan operator’s license.

10.5.2 Initiate the Measurement Assurance protocol and verify operator information, press “Save”.

10.5.3 Enter location information.

10.5.4 Enter reference barometer serial number, calibration expiration date, and barometric pressure. If pressure difference between the reference barometer and the instrument barometer is greater than 9 hPa, the instrument will abort the protocol. Assess and troubleshoot.

10.5.5 Select whether this is an installation. If it is an “Installation”, select “Yes”. If it is a “Removal”, select “No”.

10.5.6 Select appropriate level number (1-2).

10.5.7 Enter the information for the dry gas for the current level – vendor name, lot number, expiration date.

10.5.8 Select Test-Gas as “Dry”, enter the concentration in g/210 L, and Gas-Input as “Cal Gas Inlet 1”.

10.5.9 Install appropriate dry gas tank as prompted. Press “OK”. The Alcotest 9510 will now sample the dry gas cylinder three times.

10.5.10 If the standard is out of tolerance, the instrument will ask if you want to repeat the level. The out of tolerance level may be repeated once. If the repeated test is still out of tolerance, the procedure will be ended. Adjustment (calibration) and/or troubleshooting may be conducted.

10.5.11 When prompted to test another level:

10.5.11.1 If you need to test any other level, choose “Yes”. Repeat 10.5.6 to 10.5.10.

10.5.11.2 If this is the final level to test, choose “No”.

10.5.12 Evaluate printout and finalize.

10.6 Instrument Test

10.6.1 The associated verification test (dry gas cylinder) also tests and demonstrates the accuracy of the instrument in addition to the satisfactory condition of the item.

10.6.2 Last name = “Instrument”, First Name = “Test”.

10.6.3 For Court, choose “Other”.

10.6.4 Provide both breath samples with your own breath.

10.6.5 Expected final result is “0.00 g/210 L”.

10.6.6 Should any other result be obtained, troubleshooting may need to be performed or seek additional guidance from the Supervisor.

10.6.7 For installations only: In the Measurement menu, switch the active dry gas cylinder to the Cylinder #2. Repeat the instrument test.

10.6.8 Reset the active dry gas cylinder to Cylinder #1.

10.7 Generation and Issuance of Certificate of Instrument Accuracy

10.7.1 Upon completion of the above listed procedures, conduct the Set Certification Date procedure.

10.7.2 Enter the information into BrAD.

10.7.3 Generate the printout titled Certificate of Instrument Accuracy (CoIA) from BrAD, which is page 1 of 2 for the CoIA. The certification printout is page 2 of 2 (or adjusted page count as necessary) for the CoIA.

10.7.4 Collate the CoIA (BrAD CoIA printout and Certification printout) and any supporting data in the instrument folder.

10.7.5 Examiner will initial or sign all pages indicating that they have conducted, participated in, observed, supervised, or scientifically reviewed the calibration/certification activities.

10.7.6 Examiner will sign the Certification printout.

10.7.7 Examiner will sign the CoIA and then have the technical review performed.

10.7.8 After completion of the technical review, Reviewer will give the instrument folder including the CoIA to the Notary.

10.7.9 Notary will notarize the CoIA.

10.7.10 Notary will return the notarized CoIA and instrument folder to the Examiner.

10.7.11 DFS will deliver a copy of the notarized CoIA to the agency to which the instrument is assigned.

10.7.11.1 The aforementioned agency may not be known at the time of certification, therefore the agency name and address cannot be included on the CoIA.

10.7.12 The original CoIA will be maintained in the instrument folder.

10.7.13 The CoIA and supporting documentation will be scanned and stored in BrAD.

11 Dry Gas Cylinder Quality Assurance

11.1 Purchasing

11.1.1 Reference Material used for evidential procedures shall be traceable to the International System of Units (SI Units).

11.1.2 Dry gas cylinders used for Calibration, Certification, and Measurement Assurance will be purchased from approved laboratories that are accredited as Calibration Laboratories to ISO/IEC 17025 (refer to QM 8.3.3).

11.2 Receipt

Upon receipt, Dry Gas cylinders will be inspected and inventoried against the packing slip and the purchase document. Discrepancies will be brought to the attention of the vendor immediately. When a purchased supply or material fails to meet established laboratory standards it should be discarded or returned to the vendor.

11.2.1 Upon receipt of Dry Gas Cylinders, the following shall be recorded on each cylinder.

- Date of receipt
- Initials of person receiving

11.2.2 Upon receipt of Dry Gas Cylinders, the following shall be recorded on a Dry Gas Approval Worksheet (250-F127).

- Tank Concentration
- Lot number
- Tank number(s)
- Expiration date
- Date of receipt

11.3 Verification

Every dry gas cylinder used for evidential purposes shall be verified.

11.3.1 For dry gas cylinders used with the Intox EC/IR II, these checks will be performed on an instrument that was calibrated with a wet bath simulator, another dry gas lot or with a dry gas cylinder from another manufacturer.

11.3.1.1 Prior to and at the end of the verification process, the technician/analyst/examiner will perform an instrument test.

11.3.1.2 If the instrument test is unsuccessful, further troubleshooting may be necessary.

11.3.1.3 Each cylinder will be run through 3 accuracy checks.

11.3.1.4 The 3 values must be within 3% or 0.003, whichever is greater, of the pressure adjusted target value and within 0.003 g/210 L of each other for acceptance.

11.3.1.4.1 If the dry gas cylinder meets the above parameters the cylinder label will be initialed, dated and marked as “verified”.

11.3.1.4.2 If the dry gas cylinder does not meet the above parameters, troubleshooting of the instrument/and or cylinder will be conducted.

11.3.1.4.3 Printouts will be initialed and dated by the verifier. The worksheet and printouts will be reviewed by the Toxicology Program Manager or Section Supervisor.

Upon completion of the review, the Toxicology Program Manager or Section Supervisor will sign (or secure electronic equivalent) the worksheet. The signed Dry Gas Approval Worksheet will serve to designate approval. The printouts will be retained with the certificate of analysis for the dry gas cylinder.

11.3.1.4.4 All documentation will be kept in the Section or on the BA-Shared server file.

11.3.2 For dry gas cylinders used with the Alcotest 9510, these checks will be performed on an instrument that was calibrated with a wet bath simulator, another dry gas lot, or with a dry gas cylinder from another manufacturer.

11.3.2.1 Prior to and at the end of the verification process, the technician/analyst/examiner will perform an instrument test. If the instrument test is unsuccessful, further troubleshooting may be necessary.

11.3.2.2 Each cylinder will be run through the CalCheck protocol with three replicates.

11.3.2.3 Each replicate value must be within 5% or 0.005 g/210 L, whichever is greater, of the target value and within 0.005 g/210 L of each other for each detector system to be considered acceptable.

11.3.2.3.1 If the dry gas cylinder meets the above parameters, the cylinder label will be initialed, dated, and marked as “verified”.

11.3.2.3.2 If the dry gas cylinder does not meet the above parameters, troubleshooting of the instrument and/or cylinder will be conducted.

11.3.2.3.3 Printouts will be initialed and dated by the verifier. The worksheet and printouts will be reviewed by the Toxicology Program Manager or Section Supervisor. Upon completion of the review, the Toxicology Program Manager or Section Supervisor will sign (or secure electronic equivalent) the worksheet. The signed Dry Gas Approval Worksheet will serve to designate approval. The printouts will be retained with the certificate of analysis for the dry gas cylinder.

11.3.2.3.4 All documentation will be kept in the Section or any Breath Alcohol specific server storage.

11.4 Storage

11.4.1 The cylinders shall be stored in Breath Alcohol secure storage.

11.4.2 Cylinders that are being transported for field use will not be left in an unoccupied/unattended vehicle for more than 60 minutes. An unattended vehicle shall be locked.

12 ESTIMATION OF THE UNCERTAINTY OF MEASUREMENT FOR INTOX EC/IR II CALIBRATIONS (CERTIFICATIONS)

12.1 Scope

12.1.1 An estimation of the Uncertainty of Measurement (UoM) shall be calculated for the calibration (*Certification)* of Breath Alcohol measuring instruments.

12.1.2 The International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM) defines calibration as the operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. This is referred to as *Calibration* in the ISO/IEC community and *Certification* in this manual. This section will hereafter refer to this process as *Certification* (as outlined in ¶ 6)

12.1.3 The UoM is an expression of the confidence or certainty associated with the Certification procedure.

12.2 Measurement Uncertainty Elements

12.2.1 The measurand is the concentration of ethanol expressed as grams per 210 L (g/210L).

12.2.2 Traceability is established through the use of reference materials obtained from an ISO/IEC 17025 accredited calibration laboratory with an appropriate scope of accreditation.

12.2.3 The measuring instrument is the Intox EC/IR II, utilizing an electrochemical detector, manufactured by Intoximeters, Inc. using Virginia approved firmware/software.

12.2.4 UoM budget

12.2.4.1 A budget is the written representation of factors that contribute to the source of uncertainty, the mathematical calculations, and the final calculated value.

12.2.4.2 The budget will contain components of uncertainty, corrections, correction factors, calculations, and the method for combining uncertainties.

12.2.4.3 Two separate budgets will be maintained encompassing the following concentration ranges:

- Tier 1: Less than or equal to 0.100 g/210 L EtOH (≤ 0.100 g/210 L)
- Tier 2: Greater than 0.100 g/210 L EtOH (> 0.100 g/210 L)

12.2.4.4 Repeatability and reproducibility data

12.2.4.5 Measurement Assurance data will be collected for all instruments used for evidential breath testing purposes.

12.2.4.6 The Measurement Assurance data will be collected for standards at concentrations of 0.100 g/210L EtOH and 0.300 g/210L EtOH. Each level will be assessed individually.

12.2.5 Statistical analysis of Measurement Assurance data

12.2.5.1 Each analytical result will be normalized to standard atmospheric pressure (760 mm Hg) using the following formula:

Normalized result = (Result x 760 mm Hg)/ Barometric pressure mm Hg (at the time of that standard's analysis)

12.2.5.2 The mean of the 3 normalized results for each concentration will be calculated.

12.2.5.3 The standard deviation of the mean values will be calculated.

12.2.6 Type B Standard Uncertainty Contribution(s)

12.2.6.1 Ethanol dry gas standards - used during the Certification process.

UoM, distribution type, and coverage factor will be found on the manufacturer's Calibration Certificates.

12.2.6.2 Calculate the combined uncertainty by the use of Root Sum Squares.

12.3 Reporting

12.3.1 The CoIA shall contain:

12.3.1.1 The combined expanded uncertainty, rounded to the third (thousandth) decimal place (refer to QM ¶5.4.6.3).

12.3.1.2 The coverage factor shall be k=3.

12.3.1.3 The coverage probability shall be 99.73%.

12.3.2 The reported expanded uncertainty will be concentration dependant.

12.3.2.1 The expanded uncertainty developed from the 0.100 g/210L EtOH standard will be reported for Certification concentrations ≤ 0.100 g/210L EtOH.

12.3.2.2 The expanded uncertainty developed from the 0.300 g/210L EtOH standard will be reported for Certification concentrations > 0.100 g/210L EtOH.

12.4 UoM Review

12.4.1 The uncertainty of measurement process and calculations will be reevaluated upon changes to instrumentation, staffing, or other significant changes.

12.4.2 At a minimum, the process will be reevaluated and documented annually by the Program Manager.

12.5 References

12.5.1 ISO/IEC 17025:2017 6.5 Metrological traceability.

12.5.2 ASCLD/LAB Policy on Measurement Uncertainty (AL-PD-3060 Ver 1.1 effective date May 22, 2013).

12.5.3 JCGM 200:2012, International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd ed. (Sevres, France: IPM, 2008).

13 Estimation of Measurement Uncertainty for the Draeger Alcotest 9510

13.1 Scope

13.1.1 An estimation of the Measurement Uncertainty (MU) shall be calculated for the calibration (*Certification)* of Breath Alcohol measuring instruments.

13.1.2 The International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM) defines calibration as the operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. This is referred to as *Calibration* in the ISO/IEC community and *Certification* in this manual. This section will hereafter refer to this process as *Certification*.

13.1.3 The MU is an expression of the confidence or certainty associated with the Certification procedure

13.2 Measurement Uncertainty Elements

13.2.1 The measurand is the concentration of ethanol expressed as grams per 210 L (g/210L).

13.2.2 Traceability is established through the use of reference materials obtained from an ISO/IEC 17025 accredited calibration laboratory with an appropriate scope of accreditation.

13.2.3 The measuring instrument is the Alcotest 9510, utilizing an infrared detector and an electrochemical detector, manufactured by Draeger, Inc. using Virginia approved software.

13.2.4 MU budget

13.2.4.1 A budget is the written representation of factors that contribute to the source of uncertainty, the mathematical calculations, and the final calculated value.

13.2.4.2 The budget will contain components of uncertainty, corrections, correction factors, calculations, and the method for combining uncertainties.

13.2.4.3 Two separate budgets will be maintained encompassing the following concentration ranges:

- Tier 1: Less than or equal to 0.100 g/210 L EtOH (≤ 0.100 g/210 L)
- Tier 2: Greater than 0.100 g/210 L EtOH (> 0.100 g/210 L)

13.2.4.4 Repeatability and reproducibility data

13.2.4.5 Measurement Assurance data will be collected for all instruments used for evidential breath testing purposes.

13.2.4.6 The Measurement Assurance data will be collected for standards at concentrations of 0.100 g/210L EtOH and 0.300 g/210L EtOH. Each level will be assessed individually.

13.2.5 Statistical analysis of Measurement Assurance data

13.2.5.1 The mean of the results for each concentration will be calculated.

13.2.5.2 The standard deviation of the mean values will be calculated.

13.2.6 Type B Standard Uncertainty Contribution(s)

13.2.6.1 Ethanol dry gas standards - used during the Certification process.

MU, distribution type, and coverage factor will be found on the manufacturer's Calibration Certificates.

13.2.7 Calculate the combined uncertainty by the use of Root Sum Squares.

13.3 Reporting

13.3.1 The CoIA shall contain:

13.3.1.1 The combined expanded uncertainty, rounded to the third (thousandth) decimal place.

13.3.1.2 The coverage factor shall be k=3.

13.3.1.3 The coverage probability shall be 99.73%.

13.3.2 The reported expanded uncertainty will be concentration dependent.

13.3.2.1 The expanded uncertainty developed from the 0.100 g/210L EtOH standard will be reported for Certification concentrations ≤ 0.100 g/210L EtOH.

13.3.2.2 The expanded uncertainty developed from the 0.300 g/210L EtOH standard will be reported for Certification concentrations > 0.100 g/210L EtOH.

13.4 MU Review

13.4.1 The uncertainty of measurement process and calculations will be reevaluated upon changes to instrumentation, staffing, or other significant changes.

13.4.2 At a minimum, the process will be reevaluated and documented annually by the Program Manager.

13.5 References

13.5.1 ISO/IEC 17025:2017 6.5 Metrological traceability.

13.5.2 ASCLD/LAB Policy on Measurement Uncertainty (AL-PD-3060 Ver 1.1 effective date May 22, 2013).

13.5.3 JCGM 200:2012, International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd ed. (Sevres, France: IPM, 2008).

14 ADDITIONAL INSTRUMENT PROCEDURES

14.1 Installation of an Instrument

14.1.1 Power up the instrument.

14.1.2 The following may be performed in any order for Intox EC/IR II.

14.1.2.1 Call back to the Laboratory to have instrument dialed up.

14.1.2.1.1 Ensure successful communication.

14.1.2.1.2 If communication was unsuccessful, troubleshooting may need to be performed or seek additional guidance.

14.1.2.2 Ensure the instrument has been properly Certified.

14.1.2.2.1 If Certification has been performed prior to installation, perform the Measurement Assurance Checks and Instrument Test.

14.1.2.3 Complete the Intox EC/IR II Measurement Assurance Worksheet.

14.1.3 The following may be performed in any order for the Alcotest 9510.

14.1.3.1 Ensure successful communication. If unsuccessful, troubleshooting may be performed.

14.1.3.2 Ensure the instrument has been properly Certified. If the Certification has been performed prior to installation, perform the Measurement Assurance Checks and Instrument Tests.

14.1.3.3 Complete the necessary documentation.

14.2 Removing an Instrument to the Breath Alcohol Laboratory

14.2.1 For the Intox EC/IR II

14.2.1.1 Perform an Instrument Test, if possible.

14.2.1.2 Perform the Measurement Assurance Checks, if possible.

14.2.1.3 Download all tests, if possible, while in field.

14.2.1.3.1 If unable to download while in field, attempt to download tests upon return to the Laboratory.

14.2.1.4 Complete the Intox EC/IR II Measurement Assurance Worksheet

14.2.1.5 Remove instrument.

14.2.2 For the Alcotest 9510

14.2.2.1 Perform an instrument test with the active dry gas cylinder only, if possible. It is not necessary to perform an instrument test on the non-active cylinder.

14.2.2.2 Perform the Measurement Assurance Checks, if possible.

14.2.2.3 Complete the necessary documentation.

14.2.2.4 Remove instrument.

14.3 Troubleshooting/Maintenance

14.3.1 Breath Alcohol staff may use either the Troubleshooting/Maintenance Worksheet (250-F119) or Intox EC/IR II Certification Worksheet, Intox EC/IR II Measurement Assurance, or Alcotest Certification and Measurement Assurance printouts as appropriate for troubleshooting and/or maintenance.

14.3.2 Each time work is performed on the instrument, the description of activity, date, and initials of the person performing the activity will be documented.

14.3.3 Worksheet(s) for ongoing troubleshooting and/or maintenance will be maintained in the Section secure storage area while in progress.

14.3.4 Upon completion of troubleshooting and/or maintenance, the worksheet(s) will be placed in the instrument folder and submitted for review.

14.4 Dry Gas Cylinder or UPS Back Up Battery Replacement

14.4.1 Prior to replacing the dry gas cylinder or back up battery, perform an Instrument Test on the active dry gas cylinder, if possible.

14.4.2 Upon installation of a new cylinder in an Intox EC/IR II instrument installed in the field, the O-ring will be replaced. This may be performed on an Alcotest 9510, if necessary.

14.4.3 If installing a new UPS back up battery, power off the instrument, replace the back up battery, and power the instrument and UPS on.

14.4.4 For the Intox EC/IR II, verify Barometer.

14.4.5 Perform the Measurement Assurance Checks.

14.4.6 Perform an Instrument Test. For the installation of a dry gas cylinder in the Alcotest 9510, perform the instrument test(s) on the newly installed cylinder(s) and then return the active cylinder to the previously installed cylinder. For a backup battery replacement on the Alcotest 9510, perform the instrument test on the active dry gas cylinder.

14.4.7 Replacement shall be recorded in BrAD as “REPLACED DRY GAS STANDARD” or “REPLACED UPS BACK-UP BATTERY”.

14.5 Firmware/Software Upgrade

14.5.1 New, approved Firmware/Software may be uploaded onto approved instruments. If the instrument is displaying a message (e.g., disabled, certification warning), perform a certification test (or a 1 point certification for the Intox EC/IR II) to return instrument to a ready state prior to uploading Firmware/Software.

14.5.2 Perform an Instrument Test.

14.5.3 Perform the Measurement Assurance Checks.

14.5.4 Ensure the instrument has been downloaded, if applicable.

14.5.5 Upload new software version.

14.5.6 Print Firmware/Software versions (for Intox EC/IR II). Retain printout with certification paperwork. Print instrument parameters for Alcotest 9510.

14.5.7 Calibrate the instrument.

14.5.8 Perform instrument Certification.

14.5.9 The uploading of new Firmware/Software versions will be denoted in BrAD as "FIRMWARE/SOFTWARE UPGRADE" (for Intox EC/IR II) or "SOFTWARE UPGRADE" (for Alcotest 9510).

14.6 Maintenance of Peripherals

14.6.1 Performing maintenance or replacement of peripherals (e.g., printer, E-SEEK card reader) does not affect instrument accuracy or precision, and therefore does not require the Calibration, Certification, or Measurement Assurance checks procedures to be performed.

14.6.2 Prior to conducting maintenance or replacement of peripherals, perform an Instrument Test, if possible. For the Alcotest 9510, the instrument test only needs to be performed with the active dry gas cylinder.

14.6.3 Perform the required maintenance.

14.6.4 Perform Instrument Test. For the Alcotest 9510, the instrument test only needs to be performed with the active dry gas cylinder.

14.6.5 Complete the EC/IR II Measurement Assurance_Worksheet or necessary documentation for the Alcotest 9510.

14.6.6 Maintenance and/or replacement shall be recorded in BrAD.

15 Quality Assurance

15.1 Introduction

15.1.1 The purpose of this section is to provide a uniform Quality Assurance Program for the Section.

15.1.2 It is expected that the technicians, analysts, or examiners will report any unacceptable or anomalous behavior of any analytical system immediately to either their supervisor or the Program Manager. It is further expected that appropriate actions will follow as soon as possible and be properly documented.

15.2 Reagents/Standards

15.2.1 Chemicals used in qualitative and quantitative analyses should be of at least American Chemical Society (ACS) reagent grade.

15.2.2 Water used in standard preparation should be either deionized or reverse osmosis.

15.2.3 Reagents, chemicals and supplies shall be handled, transported, stored and used in a manner that maintains their quality at an acceptable level. In general, the manufacturer's recommendations for storage conditions as specified on the product label should be followed.

15.2.4 Date of expiration

15.2.4.1 All chemicals and commercial reagents should be replaced when their stated expiration date or shelf life has expired and/or when they fail the quality check.

15.2.4.2 Ethanol Standard: Due to the volatility of ethanol, the initial verification of concentration is confirmed concurrently with the QC process each time a stock solution/premix is prepared. Unopened bottles are used each time so no periodic verification is necessary. Previously opened bottles of ethanol may be used for training/research purposes.

15.2.4.3 Stock solution is initially verified pursuant to ¶ 2 regarding preparation of stock solution. A periodic check (verification) is performed concurrently with the QC process for each standard prepared from this solution.

15.2.4.4 Working standards are initially verified pursuant to ¶ 2 regarding preparation for each concentration. For each successive use, verify that the initial verification, or a periodic check, has been performed within the previous month.

15.2.4.4.1 Periodic checks will be performed as needed. Periodic checks (as needed) for non-ethanol working standards shall be conducted in coordination with the toxicology section.

15.2.4.4.2 Complete the periodic check section on the Working Standard Worksheet.

15.2.4.4.3 Accuracy and precision parameters will be successfully met for the continued use of the ethanol working standard.

15.2.4.4.4 Should the working standard not meet the accuracy and precision parameters, the working standard may be tested once more. If the second test remains outside of acceptable parameters, discard the working standard and notate on the Ethanol Working Standard Worksheet.

15.2.5 All Laboratory prepared reagents, solutions and standards shall be prepared using good laboratory practices.

15.3 Laboratory Equipment

15.3.1 Fume Hoods

15.3.1.1 Refer to the DFS Safety Manual.

15.3.2 Temperature Meters

15.3.2.1 All temperature meters used to perform maintenance/troubleshooting on the instrument calibrated by a laboratory that can demonstrate competence, measurement capability and traceability. Calibrations will be traceable to the International System of Units (SI Units).

15.3.2.2 Temperature meters are to be calibrated according to manufacturer's instructions, generally one year. They will be calibrated by the manufacturer or equivalent calibration body. Temperature meters may be replaced instead of being calibrated, if necessary or appropriate.

15.3.2.3 Periodic maintenance of the temperature meters will follow any manufacturer guidelines.

15.3.3 Reference Barometers

15.3.3.1 All external barometers will be calibrated by a laboratory that can demonstrate competence, measurement capability and traceability. Calibrations will be traceable to the International System of Units (SI Units).

15.3.3.2 Barometers will be calibrated annually unless otherwise indicated by the calibration certificate of accuracy. Replacement of calibrated barometers, instead of recalibration, may be necessary or more appropriate.

15.3.3.3 Periodic maintenance of the barometers will follow the manufacturer's guidelines.

16 ADMINISTRATIVE AND CERTIFICATION DOCUMENTATION

16.1 Introduction

The purpose of this section is to provide uniform handling of administrative and certification records for the Section.

16.2 Storage and Documentation

Technical and Section records will be stored within the Section or the Breath Alcohol Archives.

16.3 Maintenance of Documentation

Documentation will be maintained by Breath Alcohol authorized staff to ensure security, access, and completeness of documentation.

16.4 Disposal of Documentation

Technical and Section records will be disposed of according to The Library of Virginia Specific Schedule Number 778-001, Department of Forensic Science.

16.5 Records and Security

16.5.1 Policy

The Section will ensure the security, confidentiality and integrity of records, both written and electronic.

16.5.2 Instrument Records

16.5.2.1 It is the policy of DFS to treat Instrument records including all information received from FOIA requests and SDTs as **confidential.** Compliance with this policy is mandatory and is considered a condition of continued employment.

16.5.2.2 Employees will not release the content of instrument folders to any individual or entity that does not have the need to know. Essentially, those with the need to know are limited to appropriate members of the staff, the agency conducting the investigation, the submitting defense counsel and the Commonwealth's Attorney of the jurisdiction involved. Any deviation from this guideline must have the prior approval of one of the individuals specified in QM ¶ 15.12.1.3. Requests shall be forwarded to the Forensic Administrative Specialist III, CF570 or Forensic Administrative Specialist III, CF064 for processing and final release authorized by one of the individuals specified in QM ¶ 15.12.1.3.

16.5.2.3 When information in instrument files must be removed from the Laboratory for purposes such as court testimony, every effort should be made to avoid loss of original documentation. This includes photocopying portions of, or the entire instrument folder as practicable.

17 COMMONLY USED ABBREVIATIONS

ABT	Abort
Adj.	Adjusted
AMB	Ambient Detected
A9510	Alcotest 9510
BA	Breath Alcohol
Bar	Barometer
BrAC	Breath Alcohol Concentration
BrAD	Breath Alcohol Database
Cal	calibrated or calibration
Cert	certified or certification
CoIA	Certificate of Instrument Accuracy
Comm	Communication(s)
Conc	concentration
DEF	Deficient Sample
DFS	Department of Forensic Science
dH_20	Deionized water
DL	download
D/L	download
EC	electrochemical
EC/IR II	Intox EC/IR II
Elec	electronic
EtOH	Ethanol
Exp	expired
Ext	external
FC	fuel cell
FOIA	Freedom of Information Act
F/S	Firmware/Software
IA	interactive
I/A	interactive
Interf	Interferent Detected
Instr	Instrument
I/P	input
INV	Invalid Sample
IPS	Improper Sequence
IR	infrared
MA	mouth alcohol
N/A	Not Applicable
NIST	National Institute of Standards and Technology
NSG	No Sample Given
OOT	out of tolerance
O/P	output
Prct	Precinct
PA	pressure adjusted
PM	procedures manual
P/S	Power supply
Pwr	power
Repl	replaced
RFI	radio frequency interference
SDT	Subpoena duces tecum
Sim	simulator
SN	serial number
SOL	solution
Std	standard
temp.	temperature
tol	tolerance

TOL	Out of Tolerance
T/S	Troubleshoot/troubleshooting/troubleshot
UPS	Uninterruptible power supply
W/	with