

3 FIRMWARE/SOFTWARE TESTING – 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 (¶ 4).
- 3.1.1.5 Perform Instrument Certification (¶ 5 - omit 5.6).
- 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 (¶ 4).
- 3.1.2.6 Perform Instrument Certification (¶ 5 - omit 5.5).

3.2 Additional Instructions

3.2.1 Retain all printouts.

- 3.2.1.1 Place specification number on the printout.
- 3.2.1.2 Initial the upper right hand corner of the printouts.

3.2.2 If there is no printout, please initial by the criteria on a printed hard copy of this procedure to signify that a particular item was completed.

- 3.2.2.1 Place the instrument serial number and date that testing began on the top of the first page.
- 3.2.2.2 Place the instrument serial number 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 1-2 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 will ensure that proper documentation is generated and maintained pursuant to ¶ 3.16.

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

Unless otherwise noted subject information will be “LAST NAME = PRACTICE” and “FIRST NAME = TEST” or Virginia Driver’s License or Identification Card (exceptions may be made, consult with the Program Manager).

- 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. For Court, type in “INVALID SAMPLE”.

- 3.4.9.1 Conduct a test.
 - 3.4.9.1.1 “LAST NAME = INVALID”, “FIRST NAME = TEST 1”.
 - 3.4.9.1.2 Sample 1 – rinse mouth with an alcohol based aqueous solution and provide sample.
 - 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 = INVALID”, “FIRST NAME = TEST 2”.
 - 3.4.9.2.2 Sample 1 = own breath.
 - 3.4.9.2.3 Sample 2 - rinse mouth with an alcohol based aqueous solution and provide sample.
 - 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 = INVALID, FIRST NAME = TEST 3”.
 - 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 - rinse mouth with an alcohol based aqueous solution and provide sample.
 - 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.
 - 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.

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- 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”.

- 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 upon return to scrolling.

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

- 3.5.2 Repeat the above for the next three transitions.

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

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

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

3.6.4 Return the instrument to current date and time.

3.6.5 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 = OVER”, “FIRST NAME = RANGE 1”.
 - 3.9.1.2 Sample 1 ~ 0.60 vapor equivalent.
 - 3.9.1.3 Start another test, ensure the instrument does not allow this test to proceed because of the same subject information.
 - 3.9.1.4 Abort the test.
- 3.9.2 Conduct a test.
 - 3.9.2.1 “LAST NAME = OVER”, “FIRST NAME = RANGE 2”.
 - 3.9.2.2 Sample 1 = own breath.
 - 3.9.2.3 Sample 2 ~ 0.60 vapor equivalent.
 - 3.9.2.4 Start another test, ensure the instrument does not allow this test to proceed because of the same subject information.
 - 3.9.2.5 Abort the test.
- 3.9.3 Conduct a test.
 - 3.9.3.1 “LAST NAME = OVER”, “FIRST NAME = RANGE 3”.
 - 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 Start another test, ensure the instrument does not allow this test to proceed because of the same subject information.
- 3.9.3.6 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 (§ 5)

- 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.

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.

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4 CALIBRATION PROCEDURE FOR THE INTOX EC/IR II

4.1 Background Information

- 4.1.1 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.
- 4.1.2 Calibrations are performed as needed.
- 4.1.3 An instrument must be certified, pursuant to ¶ 5 after a successful calibration (this verifies the calibration).

4.2 Supplies Needed

- 4.2.1 Ethanol Standard equivalent to 0.100 BrAC vapor (272 ppm) ethanol dry gas cylinder verified by the Department (DFS) per ¶ 6.3 (different lot number or manufacturer than the dry gas cylinder that is in the instrument).
- 4.2.2 Key to the tank compartment.

4.3 Calibration Procedure

- 4.3.1 Install calibration dry gas tank.
- 4.3.2 Enter tank information. Ensure that information is entered under Standard 1.
 - 4.3.2.1 Include tank number after the lot number.
 - 4.3.2.2 Separate the two numbers with a hyphen.
 - 4.3.2.2.1 For example: “Lot no.-tank no.”.
- 4.3.3 Initiate the “Calibration” subroutine.
- 4.3.4 Verify that the standard to use is “Std 1 – Dry Gas”. Press Space to toggle through options as needed. Press Enter.
- 4.3.5 Verify that the standard value is “0.100”. Press Enter.
- 4.3.6 If the calibration is successful as specified on the instrument printout, initial the printout and certify the instrument for accuracy.
- 4.3.7 If the calibration is not successful, initial the printout, another calibration or troubleshooting may need to be performed.
- 4.3.8 All paperwork is to be retained in the instrument folder.

5 CERTIFICATION PROCEDURE FOR THE INTOX EC/IR II

5.1 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).

5.1.1 Prior to performing the Certification Procedure, ensure successful Instrument Test and Measurement Assurance Checks have been performed, if possible.

5.2 Supplies Needed

- Ethanol standard content equivalent to 0.020 BrAC (54 ppm) dry gas cylinder verified by DFS pursuant to ¶ 6.3.
- Ethanol standard content equivalent to 0.080 BrAC (218 ppm) dry gas cylinder verified by DFS pursuant to ¶ 6.3.
- Ethanol standard content equivalent to 0.150 BrAC (408 ppm) dry gas cylinder verified by DFS pursuant to ¶ 6.3.
- Ethanol standard content equivalent to 0.250 BrAC (680 ppm) dry gas cylinder verified by DFS pursuant to ¶ 6.3.
- Ethanol content equivalent to 0.100 BrAC (272 ppm) dry gas cylinder verified by DFS pursuant to ¶ 6.3.
- Ethanol content equivalent to 0.300 BrAC (816 ppm) dry gas cylinder verified by DFS pursuant to ¶ 6.3.

5.3 Certification Procedure

5.3.1 Verify Barometer

5.3.1.1 Access the proper menu.

5.3.1.2 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.

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

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

5.3.1.4 Record readings on the approved Intox EC/IR II Quality Assurance Worksheet (250-F113).

5.3.2 Initiate the “Certification” subroutine.

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

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

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

5.3.5 Update Std 1 Data and press Space to Continue.

5.3.5.1 Include tank number after the lot number.
Separate the two numbers with a hyphen, e.g., “Lot no.-tank no.”.

- 5.3.6 Type in target value of the first standard you will test. Press the Enter key.
- 5.3.7 The instrument will perform the analysis of the standard.
- 5.3.8 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.
- 5.3.9 Initial and transcribe the data from the instrument print-out into the Intox EC/IR II Quality Assurance Worksheet.
- 5.3.10 Evaluate accuracy and precision parameters.
- 5.3.10.1 Accuracy parameter = values within 3% or 0.003g/210L (whichever is greater) of the target value.
- 5.3.10.2 Precision parameter = no more than 0.003g/210L difference in all three values.
- 5.3.10.3 Successful completion of the check requires that both accuracy and precision parameters are met.
- 5.3.10.3.1 If the reference material does not meet the accuracy and/or precision parameter(s), it may be attempted again.
- 5.3.10.3.2 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.
- 5.3.11 After all standards have been completed choose “N” at the “**Continue? [Y/N]**” prompt.
- 5.3.12 Choose “Y” when prompted with “**Certification complete and successful? [Y/N]**” prompt.
- 5.3.12.1 **The print-out from the final dry gas cylinder will not print until the “Y” is entered.**
- 5.3.13 Complete the Intox EC/IR II Quality Assurance Worksheet
- 5.3.13.1 For field use, work is considered completed upon leaving the instrument site.
- 5.3.13.2 The Intox EC/IR II Quality Assurance Worksheet will be printed and reviewed upon staff return to the Laboratory. Any corrections or additions will be documented per the DFS Quality Manual.

5.4 Measurement Assurance Checks

- 5.4.1 Install Measurement Assurance Check dry gas cylinder (0.100 or 0.300 g/210 L)
- 5.4.2 Enter password
- 5.4.3 Update tank information on instrument
- 5.4.4 Initiate the “Accuracy Check” subroutine (3 replicates).
- 5.4.5 Evaluate accuracy and precision parameters.
- 5.4.5.1 Accuracy parameter = values within 3% or 0.003g/210L (whichever is greater) of the target value.

- 5.4.5.2 Precision parameter = no more than 0.003g/210L difference in all three values.
- 5.4.5.3 Successful completion of the check requires that both accuracy and precision parameters are met.
 - 5.4.5.3.1 If the reference material does not meet the accuracy and/or precision parameter(s), it may be attempted again.
 - 5.4.5.3.2 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.
- 5.4.6 Repeat with remaining Measurement Assurance Check cylinder.

5.5 Instrument Test

- 5.5.1 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.
- 5.5.2 Last name = “Instrument”, First Name = “Test”.
- 5.5.3 For Court, type in “DFS”.
- 5.5.4 Provide both breath samples with your own breath.
 - 5.5.4.1 Expected final result is “0.00 g/210 L”.
 - 5.5.4.2 Should any other result be obtained, troubleshooting may need to be performed or seek additional guidance from the Supervisor.

5.6 Generation and Issuance of the Certificate of Instrument Accuracy

- 5.6.1 Upon completion of the above listed procedures, enter the information into BrAD.
- 5.6.2 Generate the Certificate of Instrument Accuracy (CoIA).
- 5.6.3 Collate the QA Sheet, supporting data (instrument printouts) and CoIA in the instrument folder and give this instrument folder to the Issuing Analyst.
 - 5.6.3.1 Analyst will initial or sign all pages indicating that they have conducted, participated in, observed, supervised, or scientifically reviewed the calibration activities .
 - 5.6.3.2 Analyst will sign the Intox EC/IR II Quality Assurance Worksheet.
 - 5.6.3.3 Analyst will sign the CoIA and then have the technical review performed.
- 5.6.4 After completion of the technical review, Reviewer will give the instrument folder including the CoIA to the Notary.
 - 5.6.4.1 Notary will notarize the CoIA.
 - 5.6.4.2 Notary will return the notarized CoIA and instrument folder to the Issuing Analyst.
 - 5.6.4.3 DFS will deliver a copy of the notarized CoIA to the agency to which the instrument is assigned.
 - 5.6.4.4 The original CoIA will be maintained in the instrument folder.

5.6.4.5 The CoIA, QA sheets, and supporting documentation will be scanned and stored in BrAD.

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6 DRY GAS CYLINDER QUALITY ASSURANCE

6.1 Purchasing

- 6.1.1 Reference Material used for evidential procedures shall be traceable to the International System of Units (SI Units).
- 6.1.2 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).

6.2 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.

- 6.2.1 Upon receipt of Dry Gas Cylinders, the following shall be recorded on each cylinder.
- Date of receipt
 - Initials of person receiving
- 6.2.2 Upon receipt of Dry Gas Cylinders, the following shall be recorded on a Dry Gas Inventory Worksheet (250-F114).
- Tank Concentration
 - Lot number
 - Tank number
 - Expiration date
 - Date of receipt
 - Initials of person receiving

6.3 Verification

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

- 6.3.1 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.
- 6.3.1.1 Prior to and at the end of the verification process, the analyst will perform an instrument test.
- 6.3.1.2 If the instrument test is unsuccessful, further troubleshooting may be necessary.
- 6.3.1.3 Each cylinder will be run through 3 accuracy checks.
- 6.3.1.4 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.
- 6.3.1.4.1 If the dry gas cylinder meets the above parameters the cylinder label will be initialed, dated and marked as "verified".
- 6.3.1.4.2 If the dry gas cylinder does not meet the above parameters, troubleshooting of the instrument/and or cylinder will be conducted.

6.3.1.4.3 Printouts will be initialed and dated by Program Manager or Section Supervisor to designate approval. These checks will be retained with the certificate of analysis for the dry gas cylinder.

6.3.1.4.4 All documentation will be kept in the Section.

6.4 Storage

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

6.4.2 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.

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

7.1 **Scope**

- 7.1.1 An estimation of the Uncertainty of Measurement (UoM) shall be calculated for the calibration (*Certification*) of Breath Alcohol measuring instruments.
- 7.1.2 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 ¶ 5)
- 7.1.3 The UoM is an expression of the confidence or certainty associated with the Certification procedure.

7.2 **Measurement Uncertainty Elements**

- 7.2.1 The measurand is the concentration of ethanol expressed as grams per 210 L (g/210L).
- 7.2.2 Traceability is established through the use of reference materials obtained from an ISO/IEC 17025:2005 accredited calibration laboratory with an appropriate scope of accreditation.
- 7.2.3 The measuring instrument is the Intox EC/IR II, utilizing an electrochemical detector, manufactured by Intoximeters, Inc. using Virginia approved firmware/software.
- 7.2.4 UoM budget
- 7.2.4.1 A budget is the written representation of factors that contribute to the source of uncertainty, the mathematical calculations, and the final calculated value.
- 7.2.4.2 The budget will contain components of uncertainty, corrections, correction factors, calculations, and the method for combining uncertainties.
- 7.2.4.3 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)
- 7.2.5 Repeatability and reproducibility data
- 7.2.5.1 Measurement Assurance data will be collected for all instruments used for evidential breath testing purposes.
- 7.2.5.2 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.
- 7.2.6 Statistical analysis of Measurement Assurance data
- 7.2.6.1 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)

7 Estimation of the Uncertainty of Measurement for Intox EC/IR II Calibrations (Certifications)

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

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

7.2.7 Type B Standard Uncertainty Contribution(s)

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

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

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

7.3 Reporting

7.3.1 The CoIA shall contain:

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

7.3.1.2 The coverage factor shall be $k=3$.

7.3.1.3 The coverage probability shall be 99.73%.

7.3.2 The reported expanded uncertainty will be concentration dependant.

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

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

7.4 UoM Review

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

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

7.5 References

7.5.1 ISO/IEC 17025:2005(E) 5.4.6 Estimation of uncertainty of measurement.

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

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

8 **ADDITIONAL INSTRUMENT PROCEDURES****8.1 Installation of an Instrument**

- 8.1.1 Power up the instrument.
- 8.1.2 The following may be performed in any order.
 - 8.1.2.1 Call back to the Laboratory to have instrument dialed up.
 - 8.1.2.1.1 Ensure successful communication.
 - 8.1.2.1.2 If communication was unsuccessful, troubleshooting may need to be performed or seek additional guidance.
 - 8.1.2.2 Ensure the instrument has been properly Certified.
 - 8.1.2.2.1 If Certification has been performed prior to installation, perform the Measurement Assurance Checks per ¶ 5.4 and Instrument Test per ¶ 5.5.
- 8.1.3 Complete the Intox EC/IR II Quality Assurance Worksheet.

8.2 Removing an Instrument to the Breath Alcohol Laboratory

- 8.2.1 Perform an Instrument Test per ¶ 5.5, if possible.
- 8.2.2 Perform the Measurement Assurance Checks per ¶ 5.4, if possible.
- 8.2.3 Download all tests, if possible, while in field.
 - 8.2.3.1 If unable to download while in field, attempt to download tests upon return to the Laboratory.
- 8.2.4 Complete the Intox EC/IR II Quality Assurance Worksheet
- 8.2.5 Remove instrument.

8.3 Troubleshooting/Maintenance

- 8.3.1 Breath Alcohol staff may use either the Troubleshooting/Maintenance Worksheet (250-F119) or Intox EC/IR II Quality Assurance Worksheet (250-F113), as appropriate for troubleshooting and/or maintenance.
- 8.3.2 Each time work is performed on the instrument, the description of activity, date, and initials of the person performing the activity will be documented.
- 8.3.3 Worksheet(s) for ongoing troubleshooting and/or maintenance will be maintained in the Section secure storage area while in progress.
- 8.3.4 Upon completion of troubleshooting and/or maintenance, the worksheet(s) will be placed in the instrument folder and submitted to an analyst for review.

8.4 Dry Gas Cylinder Replacement

- 8.4.1 Upon installation of a new cylinder in an instrument installed in the field, the O-ring will be replaced.
- 8.4.2 Verify Barometer per ¶ 5.3.1

- 8.4.3 Perform the Measurement Assurance Checks per ¶ 5.4
- 8.4.4 Perform an Instrument Test per ¶ 5.5
- 8.4.5 This will be denoted in BrAD as “REPLACED DRY GAS STANDARD”.

8.5 Firmware/Software Upgrade

- 8.5.1 New, approved Firmware/Software may be uploaded onto approved instruments. If the instrument is displaying a message (e.g., disabled, certification warning), perform a single certification test (i.e., 1 point cert) to return instrument to a ready state prior to uploading Firmware/Software.
- 8.5.2 Perform an Instrument Test per ¶ 5.5.
- 8.5.3 Perform the Measurement Assurance Checks per ¶ 5.4.
- 8.5.4 Ensure the instrument has been downloaded.
- 8.5.5 Upload new firmware/software version.
- 8.5.6 Print Firmware/Software versions. Retain printout with certification paperwork.
- 8.5.7 Calibrate the instrument (¶ 4).
- 8.5.8 Perform instrument Certification (¶ 5).
- 8.5.9 The uploading of new Firmware/Software versions will be denoted in BrAD as “FIRMWARE/SOFTWARE UPGRADE”.

8.6 Maintenance of Peripherals

- 8.6.1 Performing maintenance or replacement of peripherals (e.g., printer, UPS/back-up battery, E-SEEK card reader) does not affect instrument accuracy or precision, and therefore does not require the Calibration or Certification procedures to be performed.
- 8.6.2 Prior to conducting maintenance or replacement of peripherals, perform an Instrument Test per ¶ 5.5, if possible.
- 8.6.3 Power off the instrument and UPS, if necessary.
- 8.6.4 Perform maintenance or replace the peripheral.
- 8.6.5 Power on the UPS (if applicable), and instrument.
- 8.6.6 Perform Measurement Assurance Checks per ¶ 5.4.
- 8.6.7 Perform Instrument Test per ¶ 5.5.
- 8.6.8 Complete the EC/IR II Quality Assurance Worksheet.
- 8.6.9 Maintenance and/or replacement shall be recorded in BrAD.

9 **QUALITY ASSURANCE****9.1 Introduction**

- 9.1.1 The purpose of this section is to provide a uniform Quality Assurance Program for the Section.
- 9.1.2 It is expected that the analyst 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.

9.2 Reagents/Standards

- 9.2.1 Chemicals used in qualitative and quantitative analyses should be of at least American Chemical Society (ACS) reagent grade.
- 9.2.2 Water used in standard preparation should be either deionized or reverse osmosis.
- 9.2.3 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.
- 9.2.4 Date of expiration
- 9.2.4.1 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.
- 9.2.4.2 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.
- 9.2.4.3 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.
- 9.2.4.4 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.
- 9.2.4.4.1 Periodic checks will be performed as needed. Follow the quality control testing procedure specified in ¶ 2.3.2.11.
- 9.2.4.4.2 Complete the periodic check section on the Working Standard Worksheet (250-F120).
- 9.2.4.4.3 Accuracy and precision parameters will be successfully met for the continued use of the working standard.
- 9.2.4.4.4 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.
- 9.2.5 All Laboratory prepared reagents, solutions and standards shall be prepared using good laboratory practices.

9.3 Laboratory Equipment

9.3.1 Fume Hoods

9.3.1.1 Refer to the DFS Safety Manual.

9.3.2 Voltmeters

9.3.2.1 All voltmeters used to perform maintenance/troubleshooting on the instrument will be calibrated and certified to NIST traceable standards.

9.3.2.2 Voltmeters are to be calibrated according to manufacturer's instructions, generally one year. They will be calibrated by the manufacturer or equivalent calibration body.

9.3.2.3 Periodic maintenance of the voltmeter will follow any manufacturer's guidelines.

9.3.3 Temperature Meters

9.3.3.1 All temperature meters used to perform maintenance/troubleshooting on the instrument will be calibrated and certified to NIST traceable standards.

9.3.3.2 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.

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

9.3.4 Reference Barometers

9.3.4.1 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).

9.3.4.2 Barometers will be calibrated annually.

9.3.4.3 Periodic maintenance of the barometers will follow the manufacturer's guidelines

10 ADMINISTRATIVE AND CERTIFICATION DOCUMENTATION

10.1 Introduction

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

10.2 Storage and Documentation

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

10.3 Maintenance of Documentation

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

10.4 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.

10.5 Records and Security

10.5.1 Policy

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

10.5.2 Instrument Records

- 10.5.2.1 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.
- 10.5.2.2 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.
- 10.5.2.3 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.

11 **COMMONLY USED ABBREVIATIONS**

ABT	Abort
Adj.	Adjusted
AMB	Ambient Detected
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
DL	download
D/L	download
EC	electrochemical
EC/IR II	Intox EC/IR II
Elec	electronic
FC	fuel cell
IA	interactive
I/A	interactive
Interf	Interferent Detected
Instr	Instrument
I/P	input
INV	Invalid Sample
IPS	Improper Sequence
IR	infrared
N/A	Not Applicable
NSG	No Sample Given
OOT	out of tolerance
O/P	output
Prc	Precinct
PA	pressure adjusted
P/S	Power supply
Pwr	power
Repl	replaced
RFI	radio frequency interference
Sim	simulator
SN	serial number
SOL	solution
Std	standard
temp.	temperature
TOL	Out of Tolerance
T/S	Troubleshoot/troubleshooting/troubleshot
UPS	Uninterruptible power supply
W/	with

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