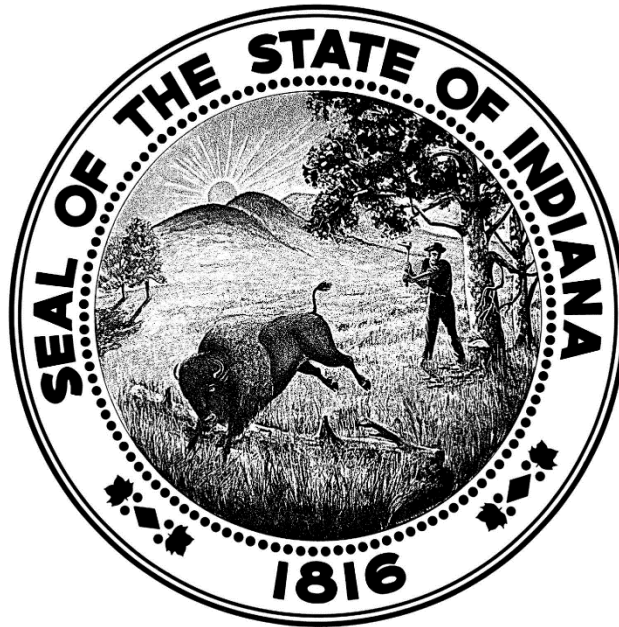


Indiana State Department of Toxicology



Breath Test Program Methods

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Introduction

The methods in this document outline the procedures to be followed in the forensic toxicology calibration laboratory.

Deviations to the following procedures may be employed with supervisory or quality assurance manager approval.

1. Simulator Inspection

- 1.1. Scope
 - 1.1.1. This procedure shall be used to ensure simulators are functioning properly.
- 1.2. Precautions/Limitations
 - 1.2.1. A simulator in need of repair shall be removed from service and clearly labeled as being out of service until repaired and inspected.
- 1.3. Related Information
 - 1.3.1. N/A
- 1.4. Instruments/Equipment
 - 1.4.1. Reference thermometer, calibrated and certified within 12 months prior to use
- 1.5. Reagents/Materials
 - 1.5.1. Water or ethanol/water solution
- 1.6. Hazards/Safety
 - 1.6.1. N/A
- 1.7. Reference Materials/Controls/Calibrators/Solutions
 - 1.7.1. N/A
- 1.8. Procedures/Instructions
 - 1.8.1. Each simulator shall be inspected within 12 months prior to use.
 - 1.8.2. Visual check
 - 1.8.2.1. The simulator jar, tubing, mixer blade, head, gasket, baffle plates, and heater element shall be examined to ensure they are clean and free of breaks and cracks. If any part is found to be unacceptable, it shall be replaced before continuing, or the simulator shall be taken out of service (ref. 1.8.5.2).
 - 1.8.3. Leak test
 - 1.8.3.1. The simulator jar shall be filled with approximately 500 mL of water or ethanol/water solution and the top securely attached.
 - 1.8.3.2. The exit port shall be closed off and a mouthpiece placed on the end of the input tubing. Air shall be blown through the mouthpiece to simulate a breath test. Bubbles will appear initially, then stop. If bubbling does not stop, this indicates a leak.
 - 1.8.3.2.1. If there is a leak, it shall be repaired, and 1.8.3.2. shall be repeated. If the leak cannot be repaired, the simulator shall be taken out of service (ref. 1.8.5.2.).
 - 1.8.4. Temperature control
 - 1.8.4.1. Simulator with digital thermometer
 - 1.8.4.1.1. The simulator jar shall be filled with approximately 500 mL of water or ethanol/water solution and the top securely attached.

- 1.8.4.1.2. The simulator shall be turned on and allowed to warm up and reach a stable temperature.
- 1.8.4.1.3. A reference thermometer shall be positioned in the simulator and allowed to reach a stable temperature.
- 1.8.4.1.4. Solution temperature readings of the reference thermometer and the simulator thermometer shall be recorded and shall agree within ± 0.2 °C.
 - 1.8.4.1.4.1. If the simulator thermometer reading is not ± 0.2 °C of the reference thermometer reading, replace or repair the simulator thermometer and repeat 1.8.4.1.2. If a repair is required, the simulator shall be taken out of service (ref. 1.8.5.2).
- 1.8.4.1.5. If the solution temperature reading of the simulator thermometer is not within 34 ± 0.2 °C, adjust the heater control, if possible, so that the solution temperature obtained is within these specifications. If adjustments to the heater have been made, repeat from 1.8.4.1.2. If the heater control does not maintain the correct solution temperature, the simulator shall be taken out of service (ref. 1.8.5.2).
- 1.8.4.2. Simulator with analog thermometer
 - 1.8.4.2.1. The simulator jar shall be filled with approximately 500 mL of water or ethanol/water solution and the top securely attached.
 - 1.8.4.2.2. The simulator shall be turned on and allowed to warm up and reach a stable temperature.
 - 1.8.4.2.3. The solution temperature reading of the simulator thermometer shall be recorded.
 - 1.8.4.2.4. The simulator thermometer shall be removed and replaced with a reference thermometer. Allow reference thermometer to reach a stable temperature and record solution temperature reading.
 - 1.8.4.2.5. Solution temperature readings of the reference thermometer and the simulator thermometer shall agree within ± 0.2 °C.
 - 1.8.4.2.5.1. If the simulator thermometer reading is not ± 0.2 °C of the reference thermometer reading, replace the simulator thermometer and repeat from 1.8.4.2.2. If the thermometer readings are not within specifications, the simulator shall be taken out of service (ref. 1.8.5.2).

- 1.8.4.2.6. If the solution temperature reading of the simulator thermometer is not within 34 ± 0.2 °C, adjust the heater control, if possible, so that the solution temperature obtained is within these specifications. If an adjustment to the heater has been made, repeat from 1.8.4.2.2. If the heater control does not maintain the correct solution temperature, the simulator shall be taken out of service (ref. 1.8.5.2).
 - 1.8.5. Simulator Inspection Label
 - 1.8.5.1. If a simulator passes the visual check (ref. 1.8.2.), the leak test (ref. 1.8.3.), and temperature control (ref. 1.8.4.), place a label on simulator head indicating simulator inspection date, initials of person performing the simulator inspection, and due date of next simulator inspection.
 - 1.8.5.2. If the simulator is not operational, it shall be labeled “Out of Service.”
 - 1.8.6. Breath test program records are stored electronically using the following naming convention: serial#_activity_date_intials (e.g., DR3178_INS_08-03-15_TK):
 - 1.8.6.1. The simulator is listed first.
 - 1.8.6.2. A description of activity is listed second as one of the following:
INS – Simulator inspection; or
TOS – Simulator taken out of service.
 - 1.8.6.3. The date of the activity as documented on the record is listed third in the format mm-dd-yy.
 - 1.8.6.4. The initials of the person making the entry are listed last.
- 1.9. Records
 - 1.9.1. Simulator Inspection Worksheet
 - 1.10. Interpretation of Results
 - 1.10.1. N/A
 - 1.11. Report Writing
 - 1.11.1. N/A
 - 1.12. References
 - 1.12.1. Guth Laboratories, Inc. Model 2100 Simulator Operation Manual.

2. Traceability and Estimation of Measurement Uncertainty for Intox EC/IR II Calibration

2.1. Scope

- 2.1.1. This procedure shall be used to verify traceability of reference materials used with the Intox EC/IR II and estimate the MU of the calibration method for the Intox EC/IR II. The MU is an expression of the confidence or certainty of the ethanol concentration of each ethanol dry gas reference material used in the calibration method for the Intox EC/IR II.

2.2. Precautions/Limitations

- 2.2.1. A minimum number of 10 replicates shall be used to determine the % RSD for calculations for the measurement process reproducibility.

2.3. Related Information

- 2.3.1. N/A

2.4. Instruments/Equipment

- 2.4.1. Intox EC/IR II
- 2.4.2. Reference barometer, calibrated and certified within 12 months prior to use

2.5. Reagents/Materials

- 2.5.1. N/A

2.6. Hazards/Safety

- 2.6.1. N/A

2.7. Reference Materials/Controls/Calibrators/Solutions

- 2.7.1. Nominal 0.020 g/210 L ethanol dry gas reference material
- 2.7.2. Nominal 0.080 g/210 L ethanol dry gas reference material
- 2.7.3. Nominal 0.082 g/210 L ethanol dry gas reference material
- 2.7.4. Nominal 0.100 g/210 L ethanol dry gas reference material
- 2.7.5. Nominal 0.150 g/210 L ethanol dry gas reference material

2.8. Procedures/Instructions

2.8.1. Reference materials

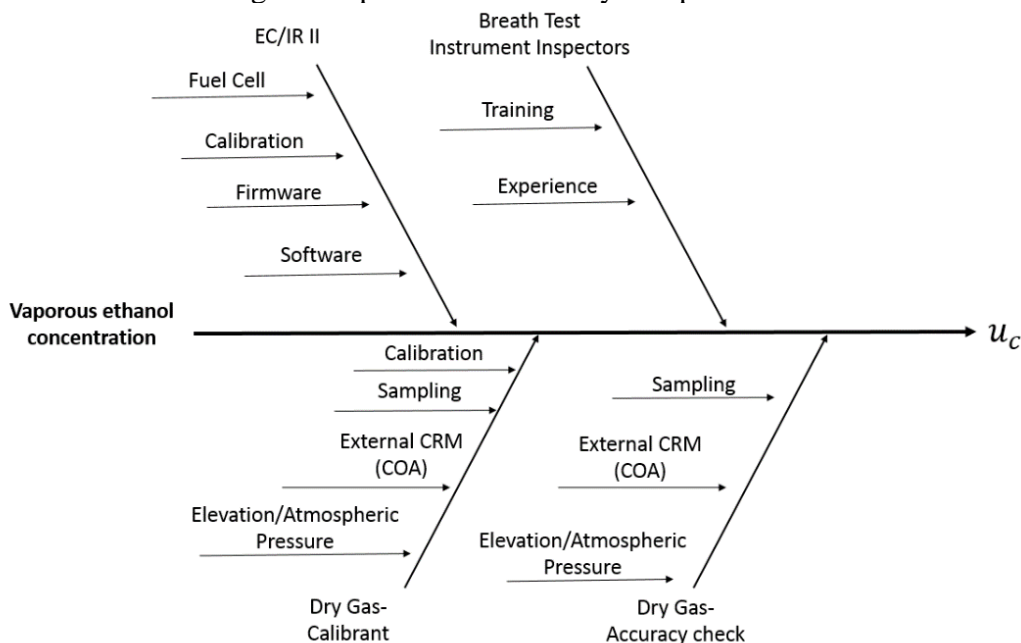
- 2.8.1.1. Each ethanol dry gas reference material shall be NIST traceable and accompanied by an uncertainty at a stated level of confidence. COAs for reference materials shall be electronically stored using the following naming convention: COA_lot# or COA_lot#_tank number (if COA indicates the certificate is for a specific tank number).

- 2.8.2. Each verified tank of ethanol dry gas reference material shall be dated and initialed prior to release for use. Verification of analyzed concentration of ethanol dry gas reference materials

- 2.8.2.1. Nominal 0.020 g/210 L, 0.080 g/210 L, 0.082 g/210 L, and 0.150 g/210 L ethanol dry gas reference material may be verified concurrently with Intox EC/IR II Instrument Inspections (ref. 3.8).
- 2.8.2.2. Nominal 0.100 g/210 L ethanol dry gas reference material shall be verified prior to release for use for adjusting the calibration of an Intox EC/IR II instrument.
 - 2.8.2.2.1. A previously verified nominal 0.100 g/210 L ethanol dry gas reference material shall be used to adjust the calibration of two Intox EC/IR II instruments (ref. 4.8.10) on the day of the verification of nominal 0.100 g/210 L ethanol dry gas reference material(s).
 - 2.8.2.2.1.1. An RM from a lot different than the lot being verified shall be used to adjust the instrument, if available.
 - 2.8.2.2.1.2. If an RM from a lot different than the lot being verified is not available, a different RM tank shall be used to adjust the instrument.
 - 2.8.2.2.2. To verify accuracy of the instrument prior to performing verification, the calibration method shall be performed on each instrument (ref. 3.8.6.10 through 3.8.6.14).
 - 2.8.2.2.3. The verification of each nominal 0.100 g/210 L ethanol dry gas reference material shall be performed on two instruments with a minimum of 10 replicates per instrument.
- 2.8.2.3. Acceptability
 - 2.8.2.3.1. Each result shall be ± 0.003 g/210 L of the dry gas target.
 - 2.8.2.3.1.1. If each result is not within the allowable range, the verification shall be repeated on the instrument from which each result was not within the allowable range.
 - 2.8.2.3.1.2. If after repeating the verification, each result is not within the allowable range, additional tests should be performed to evaluate the RM (e.g., analyze on a different instrument, adjust instrument with another 0.100 g/210 L ethanol dry gas reference material).
 - 2.8.2.3.1.3. The tank shall not be used for a calibration adjustment of a deployed instrument for evidentiary use if the above criteria are not met.

- 2.8.2.4. The initial verification shall be technically and administratively reviewed prior to use of the tank to adjust the calibration of an instrument deployed for evidentiary use.
- 2.8.3. Intermittent verifications using the procedure in 2.8.2 shall also be performed at least every six months. If acceptance criteria listed in 2.8.2.3 are met, a tank may be used to adjust the calibration of instruments deployed for evidentiary use prior to completion of technical/administrative review of the record of intermittent verification.
- 2.8.3.1. If the verification does not meet the criteria in 2.8.2 and has any result ± 0.004 g/210 L or ± 0.005 g/210 L from the dry gas target, do not use the tank for calibration adjustment of a deployed instrument for evidentiary use.
- 2.8.3.2. If the verification does not meet the criteria in 2.8.2 and has any result > 0.005 g/210 L from the dry gas target, do not use the tank for calibration adjustment of a deployed instrument for evidentiary use. Investigate all instruments adjusted with that tank between the last acceptable verification and the failed verification.
- 2.8.4. Estimation of measurement uncertainty
- 2.8.4.1. The MU is a non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.
- 2.8.4.1.1. The measurand is the vaporous ethanol concentration in g/210 L as measured by the Intox EC/IR II manufactured by Intoximeters, Inc.
- 2.8.4.1.2. The measuring instrument is the Intox EC/IR II, which utilizes an electrochemical detector (fuel cell) to determine the concentration of ethanol in a sample using Indiana-approved firmware/software.
- 2.8.4.1.3. Traceability is established by using ethanol dry gas reference materials obtained from an ISO 17034:2016 accredited calibration laboratory with an appropriate scope of accreditation for reference material production for ethanol gas mixture.
- 2.8.4.2. Measurement process
- 2.8.4.2.1. The uncertainty of the measurand is represented by the following formula:
- $$uc = \sqrt{RM_{AC}^2 + RM_{Adj}^2 + IA_{Reproducibility}^2}$$
- uc: combined uncertainty
RM_{AC}: ethanol reference material used in accuracy checks
RM_{Adj}: ethanol reference material used in calibration adjustments
IA_{Reproducibility}: Instrument (Intox EC/IR II) analytical reproducibility

2.8.4.3. Fish diagram of possible uncertainty components



2.8.4.4. Use of the Measurement Uncertainty Estimation Summary Worksheet

- 2.8.4.4.1. The Inspector/Analyst name, location of the instrument, instrument serial number, and inspection date shall be included in the appropriate fields of the Measurement Uncertainty Estimation Summary.
- 2.8.4.4.2. The ethanol dry gas reference material lot number, DEV Code, and analyzed concentration for each ethanol dry gas reference material used in the inspection shall be documented in the appropriate fields.
- 2.8.4.4.2.1. The barometric pressure determined by the instrument shall be entered in order for the dry gas target to be calculated and populated in the correct field.
- 2.8.4.4.3. Results of a minimum of ten replicate accuracy checks with each ethanol dry gas reference material shall be entered in each of the appropriate fields (e.g., Result 1, Result 2, etc.).
- 2.8.4.4.4. The Measurement Uncertainty Estimation Summary automatically calculates the MU by:
- 2.8.4.4.4.1. Normalizing all results to 760 mmHg (adjusted results);
- 2.8.4.4.4.2. Calculating the average of the adjusted results;

- 2.8.4.4.4.3. Calculating the standard deviation (sample) of the adjusted results;
- 2.8.4.4.4.4. Calculating the % RSD by dividing the standard deviation by the average then multiplying by 100;
- 2.8.4.4.4.5. Calculating the standard uncertainty by dividing the % RSD by the degrees of freedom (number of replicates minus 1);
- 2.8.4.4.4.6. Calculating the expanded uncertainty as a percentage with a confidence interval of approximately 99% and a coverage probability of $k=3.25$ by taking the square root of the sum of squares of the standard uncertainty for each of the following:
 - measurement reproducibility component (replicate adjusted results), calibration adjustment ethanol dry gas reference material, and ethanol dry gas reference materials used in the calibration method; and
 - 2.8.4.4.4.6.1. The standard uncertainty for each of the ethanol dry gas reference materials is calculated by dividing the total relative uncertainty on the COA by the k value of 2.
- 2.8.4.4.4.7. Calculating the MU in g/210 L by multiplying the average of the adjusted results by the expanded uncertainty.
 - 2.8.4.4.4.7.1. The calculated MU is rounded to the nearest thousandths place using normal rounding.
- 2.8.4.4.5. The average result and associated MU shall be reported as the average \pm MU g/210 L for each ethanol dry gas reference material used in the inspection (ref. 3.8.6.8).

- 2.8.4.4.5.1. The average for each ethanol dry gas reference material shall be rounded to the nearest thousandths place using normal rounding

2.9. Records

- 2.9.1. Ethanol dry gas reference material tank list
- 2.9.2. Ethanol dry gas reference material packing slip
- 2.9.3. Certificate of analysis of ethanol dry gas reference material used in the calibration adjustment
- 2.9.4. Certificates of analysis of ethanol dry gas reference materials used in Inspection Mode and Accuracy Checks
- 2.9.5. Measurement Uncertainty Estimation Summary
- 2.9.6. Certificate of Compliance of Breath Test Instrument and Chemicals
- 2.9.7. 0.100 tank verification, however named

2.10. Interpretation of Results

- 2.10.1. N/A

2.11. Report Writing

- 2.11.1. The average result and associated MU shall be reported on the Calibration Certificate as the average \pm MU g/210 L for each ethanol dry gas reference material used in the inspection (ref. 3.8.6.8).
 - 2.11.1.1. A minimum of 10 replicates shall be used to calculate the MU.
 - 2.11.1.2. The MU shall not be reported with greater than two significant figures.
 - 2.11.1.3. The MU shall be reported to the same level of significance as the average for each ethanol dry gas reference material (ref. 3.8.6.8).

2.12. References

- 2.12.1. International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM 3rd edition), JCGM 200:2012

3. Intox EC/IR II Instrument Inspection

- 3.1. Scope
 - 3.1.1. This procedure shall be used to inspect and/or maintain Intox EC/IR II breath test instruments.
- 3.2. Precautions/Limitations
 - 3.2.1. A breath test instrument inspection shall not be performed or shall be stopped when environmental conditions jeopardize the results of the inspection, and the condition shall be documented in the inspection record.
- 3.3. Related Information
 - 3.3.1. 260 IAC 2.5
 - 3.3.2. Certificates of Analysis for ethanol dry gas reference material
- 3.4. Instruments/Equipment
 - 3.4.1. Intox EC/IR II
 - 3.4.2. Reference barometer, calibrated and certified within 12 months prior to use
- 3.5. Reagents/Materials
 - 3.5.1. Chemicals and reagents beyond their expiration date shall not be used in breath test instrument inspections or as controls in the performance of evidentiary breath tests.
- 3.6. Hazards/Safety
 - 3.6.1. Use care not to directly breathe ethanol dry gas reference material.
 - 3.6.2. Ethanol dry gas reference materials should be protected from sunlight when ambient temperature exceeds 52 °C/125 °F.
 - 3.6.3. Ethanol dry gas reference materials shall
 - 3.6.3.1. be transported and stored in the upright or horizontal position, as appropriate;
 - 3.6.3.2. not be allowed to strike each other with force when handling or transporting; and
 - 3.6.3.3. be securely connected into the instrument pressure gauge when in use in the instrument.
- 3.7. Reference Materials/Controls/Calibrators/Solutions
 - 3.7.1. Nominal 0.020 g/210 L ethanol dry gas reference material
 - 3.7.2. Nominal 0.080 g/210 L ethanol dry gas reference material
 - 3.7.3. Nominal 0.082 g/210 L ethanol dry gas reference material
 - 3.7.4. Nominal 0.100 g/210 L ethanol dry gas reference material
 - 3.7.5. Nominal 0.150 g/210 L ethanol dry gas reference material
- 3.8. Procedures/Instructions
 - 3.8.1. A breath test instrument deployed for evidentiary use shall have a breath test instrument inspection performed at its established location:
 - 3.8.1.1. prior to being put into service for evidentiary use;
 - 3.8.1.2. at least once every 180 days; and

- 3.8.1.3. after maintenance requiring an inspection (ref 4.8.3).
- 3.8.2. The inspection procedure includes at least one test to demonstrate that the instrument meets the requirements of 260 IAC 2.5-3-2. Additional tests may also be performed.
- 3.8.3. An inspection shall be performed by a breath test instrument inspector or analyst.
- 3.8.4. The person performing the inspection shall complete the Intox EC/IR II Breath Test Instrument Inspection and Maintenance Worksheet (Worksheet) at the time of the inspection.
 - 3.8.4.1. The Worksheet shall also be used to document an instrument calibration adjustment, maintenance, or removal from service.
- 3.8.5. If an instrument is to be taken out of service or moved beyond the length of its power cord, the following shall be completed, if possible:
 - 3.8.5.1. Verify that the instrument is in ready mode. Record any other display messages or if the instrument was not in ready mode.
 - 3.8.5.2. Inspect the instrument case, keyboard, breath tube, and instrument and printer cords for physical signs of damage, if possible.
 - 3.8.5.3. Verify that environmental conditions, including, but not limited to, those listed in the ISDT SOP Admin-016, do not impede functionality of the instrument, if possible.
 - 3.8.5.4. If the instrument is in ready mode, perform a Subject Test with 0.000 g/210 L breath.
 - 3.8.5.4.1. The analytical result for each 0.000 g/210 L breath sample should be 0.000 g/210 L.
 - 3.8.5.5. Check instrument barometer reading against a reference barometer. Reference barometric pressure values should be rounded to the nearest whole number using normal rounding prior to documentation on the Worksheet.
 - 3.8.5.6. Document the reason for removal of the instrument from service.
 - 3.8.5.7. Verify that the Worksheet is completed and that the correct date and time, instrument serial number, reference material lot number, DEV code, tank number, expiration date, reference material manufacturer (as applicable), agency name, and instrument location address are printed on each instrument report.
 - 3.8.5.8. If the instrument was taken out of service or moved beyond the length of its power cord by an inspector, an analyst shall review the inspection record.
 - 3.8.5.8.1. The analyst shall ensure that the removal was completed following the appropriate method and that the Worksheet is properly completed and accurate. The analyst shall document the review and approval by signing the last page of the Worksheet.
 - 3.8.5.8.2. Upon review, the analyst may add notes, make corrections to the Worksheet and instrument reports, and/or return the inspection record to the inspector for correction.

- 3.8.6. Inspection
 - 3.8.6.1. If the location of the instrument has changed since the last inspection, document it on the Worksheet.
 - 3.8.6.2. Verify that the instrument is in ready mode. Record any other display messages, including if the instrument is powered off, then proceed to 3.8.6.3.
 - 3.8.6.3. Inspect the instrument case, keyboard, breath tube, and instrument and printer cords for physical signs of damage.
 - 3.8.6.4. Verify that environmental conditions, including, but not limited to, those listed in the ISDT SOP Admin-016, do not impede functionality of the instrument.
 - 3.8.6.5. Perform a Subject Test with 0.000 g/210 L breath. If the inspection is performed on a breath test instrument at the time of its installation for evidentiary use or if an installed instrument is not operational, this Subject Test may be omitted.
 - 3.8.6.5.1. If the Subject Test is omitted, the reason shall be documented.
 - 3.8.6.5.2. The analytical result for each 0.000 g/210 L breath sample should be 0.000 g/210 L.
 - 3.8.6.5.2.1. If any result is outside the acceptable range, make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument.
 - 3.8.6.6. If the inspection is performed on a breath test instrument at the time of its installation for evidentiary use, an instrument calibration adjustment for the Ethanol and CO₂ IR System and fuel cell shall be performed (ref. 4.8.10).
 - 3.8.6.6.1. Prior to performing a calibration adjustment, verify the instrument barometer is within 5 mmHg of the reference barometer (ref. 4.8.10.1). If the difference is greater than 5 mmHg, adjust instrument barometer (ref. 4.8.4).
 - 3.8.6.6.1.1. Reference barometric pressure values should be rounded to the nearest whole number using normal rounding prior to documentation on the Worksheet.
 - 3.8.6.6.2. Perform an Ethanol and CO₂ IR calibration adjustment using a nominal 0.100 g/210 L ethanol dry gas reference material (ref. 4.8.10.2).
 - 3.8.6.6.3. Perform a fuel cell calibration adjustment using a nominal 0.100 g/210 L ethanol dry gas reference material (ref. 4.8.10.3).
 - 3.8.6.6.4. Proceed to 3.8.6.9.
 - 3.8.6.7. Check instrument barometer reading against a reference barometer. Reference barometric pressure values should be rounded to the

- nearest whole number using normal rounding prior to documentation on the Worksheet.
- 3.8.6.7.1. The calibration of the instrument barometer shall be adjusted if the difference in the reading of the instrument barometer and the reading of the reference barometer is greater than ± 5 mmHg of the reference barometer reading (ref. 4.8.4).
 - 3.8.6.8. A calibration adjustment of the Ethanol and CO₂ IR System and fuel cell (ref. 4.8.10) may be performed at the discretion of the inspector or analyst.
 - 3.8.6.8.1. Prior to performing a calibration adjustment, verify the instrument barometer is within 5 mmHg of the reference barometer (ref. 4.8.10.1). If the difference is greater than 5 mmHg, adjust instrument barometer (ref. 4.8.4).
 - 3.8.6.8.1.1. Reference barometric pressure values should be rounded to the nearest whole number using normal rounding prior to documentation on the Worksheet.
 - 3.8.6.8.2. Perform an Ethanol and CO₂ IR calibration adjustment using a nominal 0.100 g/210 L ethanol dry gas reference material (ref. 4.8.10.2).
 - 3.8.6.8.3. Perform a fuel cell calibration adjustment using a nominal 0.100 g/210 L ethanol dry gas reference material (ref. 4.8.10.3).
 - 3.8.6.9. At any point during or after the calibration method has been performed, an inspector may choose to perform a calibration adjustment of the Ethanol and CO₂ IR System and fuel cell (ref. 4.8.10) but shall perform the calibration method described in 3.8.6.13 and 3.8.6.14 following this adjustment.
 - 3.8.6.10. To determine the bias and precision of the instrument across a range of ethanol concentrations (ref. 2.8.1), a minimum of 10 replicate accuracy checks with each of the 3 nominal concentrations listed below shall be completed in any order (ref. 3.8.6.13 and 3.8.6.14):
 - 3.8.6.10.1. Nominal 0.020 g/210 L ethanol dry gas reference material;
 - 3.8.6.10.2. Nominal 0.082 g/210 L ethanol dry gas reference material; and
 - 3.8.6.10.3. Nominal 0.150 g/210 L ethanol dry gas reference material.
 - 3.8.6.11. At least one Inspection Mode shall be completed with any one of the ethanol dry gas reference materials listed in 3.8.6.10.
 - 3.8.6.12. A test diagnostic should be printed following at least one Accuracy Check or Inspection Mode.

Note: The steps described in 3.8.6.13 and 3.8.6.14 may be performed in any order or combination to meet the requirements in 3.8.6.10 and 3.8.6.11 and shall be used to determine the MU.

- 3.8.6.13. Perform an Inspection Mode with an ethanol dry gas reference material (ref. 3.8.6.10). Enter the analyzed ethanol concentration (rounded to 3 decimal places using normal rounding), lot number-DEV code, tank number, expiration date, and manufacturer of the ethanol dry gas reference material. Verify each result is within ± 0.005 or 5%, whichever is greater, of the dry gas target.
 - 3.8.6.13.1. If a status message other than “Standard Out of Range” is printed on the instrument report, perform an Inspection Mode (ref. 3.8.6.13), make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument, as appropriate.
 - 3.8.6.13.2. If an accuracy check result is outside the acceptable range and a status message of “Standard Out of Range” is printed on the instrument report, print a test diagnostic, remove the ethanol dry gas reference material, and verify the correct tank was installed.
 - 3.8.6.13.2.1. If the incorrect dry gas reference material tank was installed, perform an Inspection Mode (ref. 3.8.6.13) using a nominal dry gas reference material tank from 3.8.6.10.
 - 3.8.6.13.2.2. If the correct dry gas reference material tank was installed, check the O-ring. Either reinstall the nominal dry gas reference material tank and perform an Inspection Mode (ref. 3.8.6.13) or adjust the calibrations of the IR and fuel cell and using a nominal 0.100 g/210 L ethanol dry gas reference material (ref. 4.8.10) and proceed to 3.8.6.8.
 - 3.8.6.13.2.2.1. If any result is still outside the acceptable range or a status message of “Standard Out of Range” is printed on the instrument report, print a test diagnostic, make the necessary adjustment or repair (ref. 4.8), or replace

- the breath test
instrument.
- 3.8.6.14. Perform Accuracy Checks with an ethanol dry gas reference material (ref. 3.8.6.10). Enter the analyzed ethanol concentration (rounded to 3 decimal places using normal rounding), lot number-DEV code, tank number, and expiration date of each ethanol dry gas reference material. Verify each result is within ± 0.005 or 5%, whichever is greater, of the dry gas target.
- 3.8.6.14.1. If a status message other than “Standard Out of Range” is printed on the instrument report, perform an Inspection Mode (ref. 3.8.6.13), make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument, as appropriate.
- 3.8.6.14.2. If an accuracy check result is outside the acceptable range and a status message of “Standard Out of Range” is printed on the instrument report, print a test diagnostic, remove the ethanol dry gas reference material, and verify the correct tank was installed.
- 3.8.6.14.2.1. If the incorrect dry gas reference material tank was installed, perform an Inspection Mode (ref. 3.8.6.13) using a nominal dry gas reference material tank from 3.8.6.8.
- 3.8.6.14.2.2. If the correct dry gas reference material tank was installed, check the O-ring. Either reinstall the dry gas reference material tank and perform an Inspection Mode (ref. 3.8.6.13) or adjust the calibrations of the IR and fuel cell using a nominal 0.100 g/210 L ethanol dry gas reference material (ref. 4.8.10) and proceed to 3.8.6.10.
- 3.8.6.14.2.2.1. If any result is still outside the acceptable range or a status message of “Standard Out of Range” is printed on the instrument report, print a test diagnostic, make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument.

- 3.8.6.15. Reference materials other than those listed in 3.8.6.10 may be used during the inspection for additional testing.
- 3.8.6.16. Install a nominal 0.080 g/210 L ethanol dry gas reference material (ref. 2.8.1) and confirm or enter the analyzed ethanol concentration (rounded to 3 decimal places using normal rounding), lot number-DEV code, tank number, expiration date, and manufacturer of the ethanol dry gas reference material, as applicable.
- 3.8.6.17. Perform a Subject Test with 0.000 g/210 L breath and verify the analytical result for each 0.000 g/210 L breath sample is 0.000 g/210 L.
 - 3.8.6.17.1. If a status message other than “Standard Out of Range” is printed on the instrument report, perform a Subject Test (ref. 3.8.6.17), make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument, as appropriate.
 - 3.8.6.17.2. If an accuracy check result is outside the acceptable range and a status message of “Standard Out of Range” is printed on the instrument report, print a test diagnostic, remove the ethanol dry gas reference material, and verify the correct tank was installed.
 - 3.8.6.17.2.1. If the incorrect ethanol dry gas reference material tank was installed, perform an Inspection Mode (ref. 3.8.6.13) using a nominal ethanol dry gas reference material tank from 3.8.6.10, and then perform a Subject Test (ref. 3.8.6.17).
 - 3.8.6.17.2.2. If the correct ethanol dry gas reference material tank was installed, check the O-ring. Either perform an Inspection Mode (ref. 3.8.6.13) using a nominal ethanol dry gas reference material tank from 3.8.6.8, and then perform a Subject Test (ref. 3.8.6.17), or adjust the calibrations of the IR and fuel cell using a nominal 0.100 g/210 L ethanol dry gas reference material (ref. 4.8.10) and proceed to 3.8.6.10.
 - 3.8.6.17.2.2.1. If any result is still outside the acceptable range or a status message of “Standard Out of Range” is printed on the instrument report,

- print a test diagnostic, make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument.
- 3.8.6.18. Verify that the Worksheet is completed and that the correct date and time, instrument serial number, reference material lot number, DEV code, tank number, expiration date, reference material manufacturer (Inspection Mode only), agency name, and instrument location address are printed on each instrument report.
- 3.8.6.19. Once started, if it is necessary to terminate an inspection before completion, all records generated up to that point shall be attached to the Worksheet, and the date, the reason for stopping, and the identity of the person authorizing the action shall be recorded on the Worksheet.
- 3.8.6.19.1. As long as 180 days have not elapsed since the previous inspection, the previous breath test instrument certification remains in effect, and the breath test instrument may be left in service for evidentiary use unless an action listed in 3.8.1.3 has been performed or the instrument is not in ready mode or displays a message requiring service.
- 3.8.6.20. Complete Measurement Uncertainty Estimation Summary with the results from accuracy checks performed as part of the calibration method (ref. 3.8.6.13 and 3.8.6.14).
- 3.8.6.20.1. Results from calibration method performed before and after an adjustment/repair shall not be combined in the same line.
- 3.8.6.20.2. If two different tanks were used, enter the second reference material lot number, DEV code, barometric pressure, and results in the lower section in the corresponding Gas RM row number for that nominal dry gas reference material. (e.g., If results from the first nominal 0.150 g/210L ethanol dry gas reference material are entered in the top section in Gas RM row number 2, then results entered in the lower section from the second nominal 0.150 g/210L ethanol dry gas reference material should also be in Gas RM row number 2.)
- 3.8.6.20.3. If more than one inspection mode and/or accuracy check is used to obtain ten replicates, document the barometric pressure from the first test on the MU.
- 3.8.6.20.4. Results from accuracy checks performed as part of the calibration method between two adjustments and/or repairs, or any combination thereof, within

the same inspection should not be included on the Measurement Uncertainty Estimation Summary. Verify that the ethanol dry gas reference material analyzed value and instrument barometric pressure was entered correctly on the Measurement Uncertainty Estimation Summary for each reference material. Correct, as necessary.

3.8.6.20.4.1. If either the ethanol dry gas reference material analyzed value or the instrument barometric pressure is entered incorrectly, the target concentration on the Measurement Uncertainty Estimation Summary will be incorrect.

3.8.6.20.5. Verify the target concentration(s) calculated by the Measurement Uncertainty Estimation Summary are consistent with the dry gas target(s) given by the instrument in 3.8.6.13 and 3.8.6.14.

3.8.6.20.5.1. If a dry gas target on an instrument report does not equal the applicable target concentration calculated by the Measurement Uncertainty Estimation Summary, correct the dry gas target on the instrument report to reflect the target concentration calculated by the Measurement Uncertainty Estimation Summary. The incorrect dry gas target on the inspection report shall be corrected by placing one line through the incorrect concentration, writing the correct dry gas target, and placing initials/signature and date near the correction.

3.8.6.20.5.1.1. Verify each result on the corrected instrument report is within ± 0.005 or 5%, whichever is greater, of the corrected dry gas target. If any result is outside the acceptable range, make the necessary adjustment or repair (ref. 4.8), or replace

the breath test
instrument.

- 3.8.6.21. If an inspector performs the inspection, an analyst shall review the inspection record.
 - 3.8.6.21.1. The analyst shall ensure that the inspection was completed following the appropriate method and that the inspection record is properly completed and accurate. The analyst shall document the review and approval by signing the last page of the Worksheet.
 - 3.8.6.21.2. Upon review, the analyst may add notes, make corrections to the Worksheet, instrument reports, and Measurement Uncertainty Estimation Summary, and/or return the inspection record to the inspector for correction.
- 3.8.7. Proficiency Testing
 - 3.8.7.1. A proficiency test may be performed at 3.8.6.15, if applicable.
 - 3.8.7.2. Check the barometric pressure from the instrument and record the value on the Breath Test Program Proficiency Test Worksheet.
 - 3.8.7.3. Perform an Accuracy Check with the proficiency test dry gas mixture. Enter 0.080 for the tank concentration.. Enter the proficiency dry gas tank identification information, however named, for the lot number, tank number, and expiration date. Specify the number of samples as 5, at a minimum.
 - 3.8.7.3.1. Since the ethanol concentration for the proficiency test gas mixture is unknown, the analysis will likely result in a status message of “Standard Out of Range.”
 - 3.8.7.3.1.1. If the analysis results in a status message of “Standard Out of Range,” perform an Inspection Mode with the proficiency test gas mixture. Enter the ethanol result in g/210L shown on the instrument report from the Accuracy Check performed in 3.8.7.3 for the tank concentration. Enter the proficiency test tank identification information as listed in 3.8.7.3. Specify the number of samples as 5, at a minimum.
 - 3.8.7.4. Enter the results from the analysis with the status message of “Complete” (Accuracy Check or Inspection Mode) on the Breath Test Program Proficiency Test Worksheet.
 - 3.8.7.5. Add a note to the Intox EC/IR II Breath Test Instrument Inspection and Maintenance Worksheet explaining that a proficiency test was incorporated into the instrument inspection and list the corresponding test numbers.

- 3.8.7.6. The Breath Test Program Proficiency Test Worksheet and associated Intox EC/IR II instrument reports shall be reviewed for accuracy by the person performing the inspection and submitted for technical and administrative review with the instrument inspection record.
 - 3.8.7.6.1. If the proficiency test was performed by an inspector, an analyst shall review the Breath Test Program Proficiency Test Worksheet and associated Intox EC/IR II instrument reports prior to submitting the records for technical and administrative review.
 - 3.8.7.6.2. After the technical and administrative review has been completed (ref. 3.8.10), the reviewer shall sign the Breath Test Program Proficiency Test Worksheet and notify the quality assurance manager or designee of the completion of the proficiency test.
- 3.8.7.7. The proficiency test results for the designated inspector or analyst shall be submitted to the proficiency test provider by the quality assurance manager or designee by using the form provided by the proficiency test provider.
- 3.8.8. Analyst Review
 - 3.8.8.1. The analyst review of an inspection or maintenance record shall be performed by an analyst.
 - 3.8.8.2. The review shall include all items in the technical and administrative review, as applicable (ref. 3.8.9.2).
 - 3.8.8.2.1. The breath test instruments spreadsheet should be updated with the correct inspection information (e.g., date of inspection, fuel cell time 4, fuel cell gain).
 - 3.8.8.2.2. If there is a discrepancy in the inspection documents, the analyst shall correct the discrepancy or return the inspection record to the inspector for remedy.
 - 3.8.8.3. The review should include the Test Diagnostics for an Accuracy Check or Inspection Mode, if any, to determine if additional instrument maintenance is needed. The Fuel Cell Time 4 and Fuel Cell Gain should be evaluated.
 - 3.8.8.4. The reviewer shall document the review by signing the Worksheet, Measurement Uncertainty Estimation Summary, Breath Test Program Proficiency Worksheet, and shall prepare the Calibration Certificate, as applicable.
- 3.8.9. Preparation of the Calibration Certificate
 - 3.8.9.1. The analyst who performed or approved the inspection may prepare a Calibration Certificate if the inspection record documents that the instrument is in good operating condition and meets the accuracy requirements of 260 IAC 2.5-3-2(e) (ref. 3.10.1).
 - 3.8.9.2. The Calibration Certificate shall include the following information:
 - 3.8.9.2.1. Instrument serial number;
 - 3.8.9.2.2. Inspector or analyst's name;

- 3.8.9.2.3. Date of the inspection;
- 3.8.9.2.4. Location of the instrument;
- 3.8.9.2.5. Calibration method used (e.g., Intox EC/IR II Inspection Method);
- 3.8.9.2.6. Results from accuracy checks performed as part of the calibration method for each ethanol dry gas reference material (i.e., 0.020, 0.082, 0.150 g/210L) with less than 10 replicates performed prior to an adjustment or repair of the instrument (ref. 4.8.3) shall be reported in a note using one of the following options:
 - 3.8.9.2.6.1. One replicate with the nominal X (nominal concentration listed on the ethanol dry gas reference material) g/210 L NIST-traceable ethanol reference material with a result of X (result from accuracy check) g/210 L was performed prior to X (e.g., a calibration adjustment, a repair).
 - 3.8.9.2.6.2. X (Number of replicates) replicates with the nominal X (nominal concentration listed on the ethanol dry gas reference material) g/210 L NIST-traceable ethanol reference material with an average result of X (average of replicates) g/210 L were performed prior to X (e.g., a calibration adjustment, a repair).
- 3.8.9.2.7. Results from accuracy checks performed as part of the calibration method for each ethanol dry gas reference material (i.e., 0.020, 0.082, 0.150 g/210L) with at least 10 replicates shall be reported as the average \pm the MU (ref. 2.8.4.4 and 3.10.2) in units of g/210 L (e.g., 0.079 \pm 0.003 g/210 L); and
- 3.8.9.2.8. Signature of the analyst
- 3.8.9.3. If a repair or adjustment is performed, including an instrument calibration adjustment, pre and post repair and/or adjustment accuracy results shall be retained and reported on the Calibration Certificate, if applicable. The Calibration Certificate should indicate which results were obtained prior to the repair and/or adjustment.
 - 3.8.9.3.1. A minimum of 10 replicates of an ethanol dry gas reference material concentration is required for inclusion of the MU on the Calibration Certificate (ref. 2.11.1).

- 3.8.9.4. Results from accuracy checks performed as part of the calibration method between two adjustments and/or repairs, or any combination thereof, within the same inspection shall not be included on the certificate.
- 3.8.9.5. An approved Calibration Certificate may be amended and/or corrected as needed. The amended and/or corrected Calibration Certificate shall contain a note describing the amendment and/or correction. A technical/administrative reviewer shall observe and verify the amendment and/or correction prior to release.
- 3.8.10. Technical and administrative review
 - 3.8.10.1. The technical and administrative review of an inspection or maintenance record shall be performed by an analyst, who shall be a person other than the person who performed the inspection, calibration adjustment, or maintenance or authored the Calibration Certificate under review.
 - 3.8.10.2. The reviewer shall document the review by completing the Breath Test Instrument Inspection and Maintenance Technical and Administrative Review Checklist.
 - 3.8.10.2.1. Appropriate reference documents shall be used to verify correct instrument serial number, instrument location, and tank information during review.
 - 3.8.10.2.1.1. A Tableau Data Verification may be used as a tool to complete the review when a service, maintenance, calibration, and/or inspection is performed. Colored text (blue, orange, or red) indicates the reference document was automatically compared to the inspection record.
 - 3.8.10.2.1.1.1. Blue text indicates the entry is correct and the information does not need to be manually verified with reference documents.
 - 3.8.10.2.1.1.2. Information in orange, red, or gray text shall be manually reviewed and compared to reference documents and/or the inspection record, as applicable.

- 3.8.10.2.2. If there is a discrepancy in the inspection documents or Calibration Certificate, the reviewer shall return the inspection record to the analyst for remedy and/or reject the Calibration Certificate and document the issue and date of discovery in the notes section on the TAC.
 - 3.8.10.2.2.1. If the discrepancy cannot be corrected and the inspection and certification are rejected, the technical and administrative reviewer shall document the reason in the notes section on the TAC and complete and sign the TAC.
 - 3.8.10.2.2.2. If a Calibration Certificate was authored, it shall be marked as “Rejected” and saved according to 3.8.11.
- 3.8.10.3. All technical and administrative reviews shall include review of the following:
 - 3.8.10.3.1. Intox ECIR II Breath Test Instrument Inspection and Maintenance Worksheet
 - 3.8.10.3.1.1. Ensure Worksheet is correct version, filled out completely and accurately, and contains all necessary signatures.
 - 3.8.10.3.1.2. Ensure instrument reports are included in sequential order and contain correct page numbering, time zone label, tank information (lot number, DEV code, tank number, expiration date, and dry gas target), and RMs used are within expiration dates.
 - 3.8.10.3.1.2.1. Result of each subject test shall be 0.000 g/210L and performed with a nominal 0.080 g/210L dry gas RM.
 - 3.8.10.3.1.3. Ensure barometer serial number is correct, barometer calibration was completed within the past 12 months of the date of instrument inspection, and barometer reading (after calibration, if performed) is within 5 mm Hg of reference barometer reading.

- 3.8.10.3.2. Ensure each document containing instrument serial number, instrument location and/or address, dates, inspector/analyst names and/or signatures, is consistent with the information on the Worksheet.
- 3.8.10.4. For maintenance only (ref. 4.8.2) or instrument taken out of service (ref. 3.8.5), review shall include 3.8.10.3 with subject test only.
 - 3.8.10.4.1. If instrument was disabled and unable to perform any tests, the Worksheet shall contain appropriate notes.
- 3.8.10.5. If inspection (ref. 3.8.6) was performed, review shall include 3.8.10.3 and the following:
 - 3.8.10.5.1. Breath test instrument inspection mode instrument report(s)
 - 3.8.10.5.1.1. All system checks Pass.
 - 3.8.10.5.1.2. Report contains correct RM manufacturer.
 - 3.8.10.5.2. Breath test instrument accuracy checks
 - 3.8.10.5.2.1. Ensure 10 replicates of each RM at nominal 0.020, 0.082, and 0.150 g/210L are performed.
 - 3.8.10.5.2.2. Replicates from the inspection mode may be used as part of the total number of replicates for the accuracy checks.
 - 3.8.10.5.2.3. Ensure each replicate result is within ± 0.005 or 5%, whichever is greater, of the dry gas target.
 - 3.8.10.5.3. Intox EC/IR II test diagnostics
 - 3.8.10.5.3.1. Ensure Test Diagnostic is present where applicable.
 - 3.8.10.5.4. Measurement Uncertainty Estimation Summary
 - 3.8.10.5.4.1. Ensure the correct lot number, DEV code, dry gas target, and barometric pressure is entered correctly for each RM.
 - 3.8.10.5.4.1.1. The DEV code should automatically fill in the dry gas tank lot number and dry gas target.
 - 3.8.10.5.4.2. Ensure each replicate result is accurately recorded.
 - 3.8.10.5.5. Calibration Certificate
 - 3.8.10.5.5.1. Calibration Certificates shall only be issued for inspections performed on deployed evidentiary instruments.

- 3.8.10.5.5.2. Ensure the correct instrument serial number, inspection date, inspector, instrument location, instrument method, and analyst signature are present.
- 3.8.10.5.5.3. Ensure the Certificate contains the appropriate calibration results with measurement uncertainty values from the Measurement Uncertainty Estimation Summary.
- 3.8.10.5.5.4. If calibration included pre-adjustment results, results with less than 10 replicates, or if certificate was “amended” or “corrected,” ensure proper notation is present.
- 3.8.10.6. If an instrument calibration (ref. 3.8.6.8) was performed, review shall include 3.8.10.3, 3.8.10.5, and the following:
 - 3.8.10.6.1. Intox EC/IR II calibration test report
 - 3.8.10.6.1.1. Calibration adjustments shall be completed with a nominal 0.100 g/210L RM.
 - 3.8.10.6.1.2. Ensure the correct rounded, analyzed concentration of the RM was entered into the instrument.
 - 3.8.10.6.1.3. The calibration test report shall state “Complete.”
 - 3.8.10.6.1.4. If the fuel cell was replaced, instrument calibration adjustment and inspection shall be performed.
 - 3.8.10.6.1.5. A full calibration method (3.8.6.13 and 3.8.6.14) shall be performed after the calibration adjustment is performed.
- 3.8.10.7. If a proficiency test (ref. 3.8.7) was performed during inspection, review shall include 3.8.10.3 and the following:
 - 3.8.10.7.1. Ensure there is a note on the Worksheet referencing the test number(s) of the proficiency test.
 - 3.8.10.7.2. Breath Test Program Proficiency Test Worksheet.
 - 3.8.10.7.2.1. Ensure the appropriate proficiency test identifier (i.e., tank or lot number) is present.
 - 3.8.10.7.2.2. Verify each proficiency test replicate result and barometric pressure is recorded.
 - 3.8.10.7.3. Breath test instrument inspection mode and accuracy check, if necessary, instrument reports contain

- results from a minimum of 5 replicates of the proficiency test tank.
- 3.8.10.8. If a verification of an adjustment RM (ref. 2.8.2.2) was performed during an inspection, review shall include 3.8.10.3 and the additional following:
- 3.8.10.8.1. Ensure a different, previously-verified nominal 0.100 g/210 L ethanol dry gas RM was used to adjust the instrument and the calibration method was performed prior to accuracy checks with the 0.100 g/210 L RM being verified.
 - 3.8.10.8.2. Ensure a minimum of 10 replicates of the 0.100 g/210 L RM being verified are tested and the results of each accuracy check are within ± 0.003 g/210 L of the dry gas target.
 - 3.8.10.8.3. Ensure each RM was analyzed on two instruments. Ensure the 0.100 verification spreadsheet was updated correctly.
- 3.8.11. Breath test instrument records are stored electronically using the following naming convention: serial#_activity_date_intials (e.g., 011100_CER_04-25-16_TK).
- 3.8.11.1. The instrument serial number is listed first.
 - 3.8.11.2. A description of activity is listed second, using an approved abbreviation.
 - 3.8.11.3. The date of the activity as documented on the record is listed third in the format mm-dd-yy.
 - 3.8.11.4. The initials of the person making the entry are listed last.
- 3.9. Records
- 3.9.1. Ethanol dry gas reference material tank list
 - 3.9.2. Ethanol dry gas reference material packing slip
 - 3.9.3. Certificate of analysis of ethanol dry gas reference material used in the instrument calibration adjustment, if applicable.
 - 3.9.4. Certificates of analysis of ethanol dry gas reference materials used in Inspection Mode and Accuracy Checks
 - 3.9.5. Inspection Record:
 - 3.9.5.1. Intox EC/IR II Breath Test Instrument Inspection and Maintenance Worksheet (Worksheet)
 - 3.9.5.2. Intox EC/IR II instrument reports or IntoxNet download data from tests performed during the inspection or maintenance
 - 3.9.6. Service request, if applicable
 - 3.9.7. Measurement Uncertainty Estimation Summary
 - 3.9.8. Certificate of Compliance of Breath Test Instrument and Chemicals
 - 3.9.9. Breath Test Instrument Inspection and Maintenance Technical and Administrative Review Checklist
 - 3.9.10. Tableau breath test instrument data verification, if applicable
 - 3.9.11. Breath Test Program Proficiency Test Worksheet, if applicable
 - 3.9.12. Simulator Inspection Worksheet, if applicable

3.9.13. Certificate of Calibration for reference barometer

3.10. Interpretation of Results

3.10.1. The Intox EC/IR II breath test instrument is in good operating condition and meets the accuracy requirements of 260 IAC 2.5-3-2(e) if:

3.10.1.1. At least one test was performed with an ethanol dry gas reference material for which each certified concentration is accompanied by an uncertainty at a stated level of confidence (ref. 3.8.6.13 and 3.8.6.14);

3.10.1.2. Results of the tests in 3.10.1.1 are within 0.005 g/210L or 5%, whichever is greater; of the ethanol dry gas target, and

3.10.1.3. The result of each Subject Test with 0.000 g/210 L breath performed in 3.8.6.17 is 0.000 g/210 L.

3.10.2. When a breath test instrument deployed for evidentiary use has been adjusted or repaired (ref. 4.8.3), the inspection results before and after any adjustment or repair, if available, shall be reported on the Calibration Certificate.

3.10.2.1. Only results from accuracy checks performed as part of the calibration method with at least 10 replicates shall be reported with an MU (ref. 2.11.1.1).

3.10.2.2. The results from accuracy checks performed as part of the calibration method prior to an adjustment or repair shall be reported (ref. 3.8.9.2.6 and 3.8.9.3).

3.10.2.3. Results from accuracy checks performed as part of the calibration method between two adjustments and/or repairs, or any combination thereof, within the same inspection shall not be reported.

3.11. Report Writing

3.11.1. The analyst who performed or approved the inspection may prepare a Calibration Certificate effective on the date of inspection.

3.11.2. The technical and administrative reviewer may approve and release the Calibration Certificate if the instrument is in good operating condition and meets the accuracy requirements of 260 IAC 2.5-3-2 (e) (ref. 3.10.1).

3.12. References

3.12.1. Intox EC/IR II Technical Training, Intoximeters, Inc., St. Louis, MO.

4. Intox EC/IR II Instrument Maintenance

- 4.1. Scope
 - 4.1.1. These procedures shall be used to perform maintenance on Intox EC/IR II breath test instruments.
- 4.2. Precautions/Limitations
 - 4.2.1. N/A
- 4.3. Related Information
 - 4.3.1. Certificates of Analysis for ethanol dry gas reference material
- 4.4. Instruments/Equipment
 - 4.4.1. Intox EC/IR II
 - 4.4.2. Reference barometer, calibrated and certified within 12 months prior to use
 - 4.4.3. Vacuum pump assembly
 - 4.4.4. Phillips screwdriver
 - 4.4.5. Flow gauge apparatus
 - 4.4.6. Hex screwdriver
 - 4.4.7. 0.010" thickness gauge
 - 4.4.8. Brush or lint free wipes
- 4.5. Reagents/Materials
 - 4.5.1. Ionic cleaning solution
 - 4.5.2. Thermopaste
- 4.6. Hazards/Safety
 - 4.6.1. Use care not to directly breathe ethanol dry gas reference material.
 - 4.6.2. Ethanol dry gas reference materials should be protected from sunlight when ambient temperature exceeds 52 °C/125 °F.
 - 4.6.3. Ethanol dry gas reference materials shall
 - 4.6.3.1. be transported and stored in the upright or horizontal position, as appropriate;
 - 4.6.3.2. not be allowed to strike each other with force when handling or transporting; and
 - 4.6.3.3. be securely connected into the instrument pressure gauge when in use in the instrument.
- 4.7. Reference Materials/Controls/Calibrators/Solutions
 - 4.7.1. 0.080 g/210 L ethanol dry gas reference material
 - 4.7.2. 0.100 g/210 L ethanol dry gas reference material
- 4.8. Procedures/Instructions
 - 4.8.1. Replacement or repair of the keyboard, card reader, printer, ethanol dry gas reference material/gasket, breath tube, power cord, and/or an external cable are not adjustments and/or repairs to the Intox EC/IR II instrument for purposes of the Breath Test Program Test Methods.

- 4.8.2. If only the keyboard, card reader, printer, ethanol dry gas reference material/gasket, breath tube, power cord, and/or an external cable is repaired or replaced:
 - 4.8.2.1. Perform 3.8.6.1, 3.8.6.2, 3.8.6.3, 3.8.6.4, and 3.8.6.5 prior to repair or replacement.
 - 4.8.2.1.1. If 3.8.6.5 is not performed, the reason shall be documented.
 - 4.8.2.2. Perform 3.8.6.16, 3.8.6.17, and 3.8.6.18 to verify the instrument is in good operating condition after the repair or replacement.
 - 4.8.2.3. No further inspection is required if the analytical result for each 0.000 g/210 L breath sample is 0.000 g/210 L.
- 4.8.3. If any internal component other than listed in 4.8.1 is adjusted, repaired, or replaced, or if an instrument calibration adjustment is performed, or if the instrument is moved beyond the length of its power cord, an inspection shall be performed (ref. 3.8.2).
- 4.8.4. Barometer Adjustment (instrument's barometer)
 - 4.8.4.1. Remove outer case from instrument as well as the fitting from the barometer block.
 - 4.8.4.2. Attach vacuum pump to the barometer block and the reference barometer.
 - 4.8.4.3. Calibrate Pressure. Set baseline, then lower the reading on the manometer to between 500 and 550.
 - 4.8.4.4. Repeat 4.8.4.3.
 - 4.8.4.5. Check linearity by reducing pressure to three different values (e.g., 400, 500, and 600 mmHg).
 - 4.8.4.6. Remove vacuum pump, and reattach instrument fitting.
 - 4.8.4.7. Verify instrument barometer value is within 5 mmHg of the reference barometer. If not, return to 4.8.4.2.
 - 4.8.4.8. Replace outer case.
 - 4.8.4.9. Perform Intox EC/IR II instrument calibration adjustment (ref. 4.8.10).
- 4.8.5. Flow Adjustment
 - 4.8.5.1. Using the flow gauge apparatus, introduce air into the breath tube at 0.500 L/sec until the instrument beeps.
 - 4.8.5.2. Introduce air again and verify the reading displayed on the instrument is between 0.450 and 0.550 L/sec.
 - 4.8.5.2.1. If reading is not within the acceptable range, repeat the flow calibration.
 - 4.8.5.2.1.1. If the reading is still not within the acceptable range, repeat the flow calibration using a different flow gauge apparatus.
- 4.8.6. Fuel Cell Replacement
 - 4.8.6.1. Turn off power and remove outer case from instrument.
 - 4.8.6.2. Disconnect ribbon cable and wire bundle from motherboard.

- 4.8.6.3. Remove screws securing fuel cell to IR assembly and slide fuel cell bracket away from IR bench.
- 4.8.6.4. Insert and connect new fuel cell assembly.
- 4.8.6.5. Reconnect cables and wires.
- 4.8.6.6. Replace outer case and turn on power.
- 4.8.6.7. Perform Intox EC/IR II instrument calibration adjustment (ref. 4.8.10).
- 4.8.7. Sample Solenoid Adjustment
 - 4.8.7.1. Turn off power and remove outer case from instrument.
 - 4.8.7.2. Disconnect ribbon cable and wire bundle from motherboard.
 - 4.8.7.3. Remove screws securing fuel cell to IR assembly and slide fuel cell bracket away from IR bench.
 - 4.8.7.4. Loosen the two screws securing the sample solenoid to the plate.
 - 4.8.7.5. Adjust the sampling coil for ~0.010 inch clearance between the solenoid actuator plate and the sample arm.
 - 4.8.7.6. Tighten the screws to secure the solenoid.
 - 4.8.7.7. Insert the fuel cell bracket and reconnect all cables.
 - 4.8.7.8. Replace outer case and turn on power.
 - 4.8.7.9. Perform Intox EC/IR II instrument calibration adjustment (ref. 4.8.10).
- 4.8.8. Set Solenoid Adjustment
 - 4.8.8.1. Turn off power and remove outer case from instrument.
 - 4.8.8.2. Disconnect ribbon cable and wire bundle from motherboard.
 - 4.8.8.3. Remove screws securing fuel cell to IR assembly and slide fuel cell bracket away from IR bench.
 - 4.8.8.4. Loosen the hex screw in the side of the solenoid block and remove the solenoid retainer.
 - 4.8.8.5. Hold the solenoid plunger all the way up and rotate the set solenoid to change the depth of the plunger to desired location.
 - 4.8.8.6. Attach solenoid retainer and tighten hex screw.
 - 4.8.8.7. Insert the fuel cell bracket and reconnect all cables.
 - 4.8.8.8. Replace outer case and turn on power.
 - 4.8.8.9. Perform Intox EC/IR II instrument calibration adjustment (ref. 4.8.10).
- 4.8.9. IR Chamber Cleaning
 - 4.8.9.1. Turn off power and remove outer case from instrument.
 - 4.8.9.2. Disconnect ribbon cable and wire bundle from the motherboard, simulator tubing from sampling assembly, dry gas tank tube fitting, and barometer block tube fitting.
 - 4.8.9.3. Remove detector block from instrument and separate the fuel cell bracket from the detector block.
 - 4.8.9.4. Remove the IR source assembly and disassemble.
 - 4.8.9.5. Remove metal shield from detector board.
 - 4.8.9.6. Clean the IR chamber with ionic cleaning solution.
 - 4.8.9.7. Clean the IR filter.
 - 4.8.9.8. Rinse the chamber and window with distilled water and dry.

- 4.8.9.9. Change the O ring on the IR bench.
- 4.8.9.10. Reassemble IR source assembly.
 - 4.8.9.10.1. Apply thermopaste to the appropriate cavity of the IR Chamber Gas Cell prior to reinsertion of the PCB Heater Assembly.
- 4.8.9.11. Replace outer case and turn on power.
- 4.8.9.12. Perform Intox EC/IR II instrument calibration adjustment (ref. 4.8.10).
- 4.8.10. Intox EC/IR II Instrument Calibration Adjustment
 - 4.8.10.1. Check instrument barometer against a reference barometer, and verify instrument barometer reading is within ± 5 mmHg of the reference barometer reading. If the instrument barometer reading is not within ± 5 mmHg of the reference barometer reading, perform instrument barometer adjustment (ref. 4.8.4).
 - 4.8.10.2. Ethanol and CO₂ IR System Calibration Adjustment
 - 4.8.10.2.1. To calibrate the IR for Ethanol:
 - 4.8.10.2.1.1. Insert a nominal 0.100 g/210L ethanol dry gas reference material, select type of reference material being used, and enter the ethanol dry gas reference material concentration.
 - 4.8.10.2.2. To calibrate the IR for CO₂:
 - 4.8.10.2.2.1. Run CO₂ through breath tube using human breath.
 - 4.8.10.2.2.2. Introduce CO₂ again while watching the mV reading. It should drop to approximately 50% of the original reading.
 - 4.8.10.2.2.2.1. If it does not drop to approximately 50% of the original reading, repeat the CO₂ calibration. If the value is still not acceptable, clean the IR bench (ref. 4.8.9) and return to 4.8.10.2
 - 4.8.10.3. Fuel Cell Calibration Adjustment
 - 4.8.10.3.1. Perform a calibration adjustment of the fuel cell using a nominal 0.100 g/210 L ethanol dry gas reference material (ref. 2.8.1).
 - 4.8.10.3.2. Enter the analyzed ethanol concentration (rounded to 3 decimal places using normal rounding), lot number-DEV code, tank number, and expiration date of the ethanol dry gas reference material.

- 4.8.11. Documentation of maintenance
 - 4.8.11.1. A Worksheet shall be completed to document maintenance performed on an instrument, regardless of whether the instrument is deployed for evidentiary use.
 - 4.8.11.2. A technical and administrative review shall be performed (ref. 3.8.10).
 - 4.8.11.3. Records shall be stored electronically as specified in 3.8.11.
- 4.9. Records
 - 4.9.1. Ethanol dry gas reference material tank list
 - 4.9.2. Ethanol dry gas reference material packing slip
 - 4.9.3. Certificate of analysis of ethanol dry gas reference material used in the instrument calibration adjustment, if applicable.
 - 4.9.4. Certificates of analysis of ethanol dry gas reference materials used in Inspection Mode and Accuracy Checks
 - 4.9.5. Intox EC/IR II Breath Test Instrument Inspection and Maintenance Worksheet
 - 4.9.6. Intox EC/IR II instrument reports or IntoxNet download data from tests performed during the inspection or maintenance
 - 4.9.7. Breath Test Instrument Inspection and Maintenance Technical and Administrative Review Checklist
 - 4.9.8. Service request, if applicable
 - 4.9.9. Certificate of Calibration for reference barometer
 - 4.9.10. Simulator Inspection Worksheet, if applicable
- 4.10. Interpretation of Results
 - 4.10.1. N/A
- 4.11. Report Writing
 - 4.11.1. N/A
- 4.12. References
 - 4.12.1. Intox EC/IR II Technical Training, Intoximeters, Inc., St. Louis, MO.

5. Appendix

5.1. Glossary

- 5.1.1. Accuracy Check/Inspection Mode – A procedure using ethanol dry gas reference materials to confirm the accuracy and precision of a breath test instrument at known ethanol concentrations.
- 5.1.2. Analyst – A person who complies with or is exempt from the educational requirements outlined in ANAB accreditation documents and is authorized to perform the duties of an analyst.
- 5.1.3. Breath test instrument – An instrument selected and owned by the Department for use for evidentiary breath testing that measures the concentration of alcohol in an exhaled sample of human breath. Also known as breath alcohol instrument.
- 5.1.4. Breath test instrument inspector – A person who is authorized to perform inspections, calibration adjustments, and maintenance of breath test instruments.
- 5.1.5. Calibration adjustment – The procedure for assigning a quantity value to an instrument response.
- 5.1.6. Calibration Certificate – Certificate of Compliance of Breath Test Instrument and Chemicals
- 5.1.7. Calibration method – Confirms the accuracy and precision of a breath test instrument at 0.020 g/210L, 0.082 g/210L, and 0.150 g/210L ethanol concentrations, at minimum, using ethanol dry gas reference materials. The calibration method is included in an inspection and indicated on the Certificate of Compliance of Breath Test Instrument and Chemicals under “Method” as Intox EC/IR II Inspection Method.
- 5.1.8. Certificate of Compliance of Breath Test Instrument and Chemicals – A document (also known as Calibration Certificate) stating that a breath test instrument and chemicals used in the performance of evidentiary breath tests comply with the requirements of IAC Title 260.
- 5.1.9. Dry gas target – The analyzed concentration of the dry gas reference material (rounded to 3 decimals), divided by 760 mmHg and then multiplied by the current barometric pressure (product rounded to 4 decimals and then rounded to 3 decimals).
- 5.1.10. Inspection – Breath Test Instrument Inspection
- 5.1.11. Inspection Record – Intox EC/IR II Breath Test Instrument Inspection and Maintenance Worksheet, Measurement Uncertainty Estimation Summary, Breath Test Program Proficiency Test Worksheet, the breath test instrument reports generated during the inspection, calibration adjustment, and/or maintenance, as applicable.
- 5.1.12. Instrument calibration adjustment – The procedure for assigning a quantity value to an instrument response for the ethanol and CO₂ for the IR and ethanol for the fuel cell.
- 5.1.13. Measurand – Quantity intended to be measured.
- 5.1.14. Measurement Uncertainty – A symmetrical interval that characterizes the variation that could reasonably be attributed to a measured quantity or result within which the true value is expected to lie with some level of certainty.

- 5.1.15. May – An option.
 - 5.1.16. Normal rounding – Digits 1, 2, 3, and 4 rounds down and digits 5, 6, 7, 8, and 9 rounds up.
 - 5.1.17. Proficiency test – An evaluation used to verify the performance (i.e., testing, calibration) of the Department against pre-established criteria in order to verify the continued capability and quality of the laboratory's operations.
 - 5.1.18. Quantity values – Number and reference together expressing magnitude of a quantity.
 - 5.1.19. Shall – A requirement.
 - 5.1.20. Should – A recommendation.
- 5.2. Abbreviations
- 5.2.1. EC – Electrochemical
 - 5.2.2. FC - Fuel cell
 - 5.2.3. IR – Infrared
 - 5.2.4. mmHg – Millimeter of mercury
 - 5.2.5. NIST – National Institute of Science and Technology
 - 5.2.6. Pre-Adj – Pre-Adjustment

6. Document History

Effective Date	Version	Description of Activity or Revision	Approved By
08/03/15	1	Initial issue	Ed Littlejohn Sheila A. Arnold, PhD
08/31/15	2	Added requirement for certification of barometer to 1.4.1 and 3.4.3	Ed Littlejohn Sheila A. Arnold, PhD
05/18/16	3	Removed: Ethanol-Water Standard and Ethanol-Gas Standard Verification and removed the use of simulator solutions during breath test instrument inspections	Ed Littlejohn Sheila A. Arnold, PhD
06/05/17	4	Added: Traceability and Estimation of MU for Intox EC/IR II Calibration and Intox EC/IR II Instrument Maintenance	Ed Littlejohn Sheila A. Arnold, PhD
01/29/19	5	Added: Appendix and removed definitions and abbreviations from the methods. Added: 2.8.5.4.7.1.1, 2.12.1, 3.8.5.6, 3.8.5.11.1, 3.8.5.11.2, 3.8.5.12.1, 3.8.5.12.2, 3.8.5.13, 3.8.5.18.1, 3.8.7.2.4, 3.8.7.3, 3.8.8.3.1.1.1, 3.8.8.3.1.1.2, 3.10.2.1, 4.8.3.7 - 4.8.3.9, 4.8.7.1 – 4.8.7.3, and 4.8.8.1 – 4.8.8.3 Modified: Introduction, 2.1.1, 3.8.1.1, 3.8.5.4, 3.8.5.7, and 3.8.5.17.1 Deleted: 3.8.5.13 Additional minor edits were made throughout the document.	Ed Littlejohn Sheila A. Arnold, PhD
08/05/19	6	Added: 2.8.5.2.1, 2.11.1.1, 3.8.5, 3.8.6.5.1, 3.8.7.2, 3.8.7.6.1, 4.8.1.1.1, and 5.1.8. Modified: 3.8.6.2, 3.8.6.11.2.2, 3.8.6.12.2.2, 3.8.6.14, 3.8.6.15.2.2, 3.8.9.2, 3.8.9.3.1, 3.8.10.2, 3.11.2, 4.8.1.1.2, 4.8.6.3, 4.8.7.3, and 4.8.8.3 Deleted: 4.8.1.2	Ed Littlejohn Sheila A. Arnold, PhD
09/11/19	7	Fixed bookmarks and internal links in the document.	Ed Littlejohn Sheila A. Arnold, PhD

Effective Date	Version	Description of Activity or Revision	Approved By
03/01/21	8	Added 3.5.1, 3.8.6.8, 3.8.8, 3.8.9.3.1, 3.10.2, 3.10.2.2, 5.1.8, and 5.2.12. Added requirement to adjust the calibration for the IR when the fuel cell calibration is adjusted. Other minor edits are included throughout the document.	Ed Littlejohn Sheila A. Arnold, PhD
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12/13/23	12	Incorporated MFRs: 2023_MFR_0517 Breath Test Method Updates, 2023_MFR_0707 Breath Test Method Updates 2.pdf, 2023_MFR_0808 Breath Test Method Updates 3 Removed abbreviations covered by SOP Admin-022 Minor edits throughout	Christina Beymer Kathleen Toomey
8/26/24	13	Added specificity for technical and administrative review. Removed document name abbreviations. Minor edits to correct typos throughout and to clarify.	Christina Beymer Kathleen Toomey