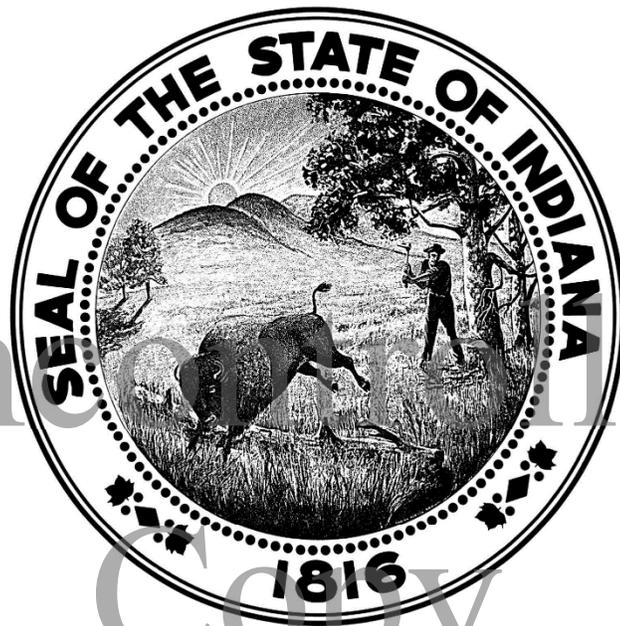


Indiana State Department of Toxicology



Breath Test Program Methods

Table of Contents

Introduction.....	4
1. Simulator Inspection	5
1.1. Scope	5
1.2. Precautions/Limitations.....	5
1.3. Related Information.....	5
1.4. Instruments/Equipment	5
1.5. Reagents/Materials	5
1.6. Hazards/Safety.....	5
1.7. Reference Materials/Controls/Calibrators/Solutions.....	5
1.8. Procedures/Instructions	5
1.9. Records	7
1.10. Interpretation of Results	7
1.11. Report Writing.....	7
1.12. References	7
2. Traceability and Estimation of Measurement Uncertainty for Intox EC/IR II Calibration ...	8
2.1. Scope	8
2.2. Precautions/Limitations.....	8
2.3. Related Information.....	8
2.4. Instruments/Equipment	8
2.5. Reagents/Materials.....	8
2.6. Hazards/Safety.....	8
2.7. Reference Materials/Controls/Calibrators/Solutions.....	8
2.8. Procedures/Instructions	8
2.9. Records	10
2.10. Interpretation of Results	11
2.11. Report Writing.....	11
2.12. References	11
3. Intox EC/IR II Instrument Inspection	12
3.1. Scope	12
3.2. Precautions/Limitations.....	12
3.3. Related Information.....	12
3.4. Instruments/Equipment	12
3.5. Reagents/Materials	12
3.6. Hazards/Safety.....	12
3.7. Reference Materials/Controls/Calibrators/Solutions.....	12
3.8. Procedures/Instructions	12

3.9.	Records	22
3.10.	Interpretation of Results	22
3.11.	Report Writing.....	23
3.12.	References	23
4.	Intox EC/IR II Instrument Maintenance	24
4.1.	Scope	24
4.2.	Precautions/Limitations.....	24
4.3.	Related Information.....	24
4.4.	Instruments/Equipment	24
4.5.	Reagents/Materials	24
4.6.	Hazards/Safety.....	24
4.7.	Reference Materials/Controls/Calibrators/Solutions.....	24
4.8.	Procedures/Instructions	24
4.9.	Records	27
4.10.	Interpretation of Results	28
4.11.	Report Writing.....	28
4.12.	References	28
5.	Appendix.....	29
5.1.	Glossary.....	29
5.2.	Abbreviations	30
6.	Document History	31

Uncontrolled
Copy

Introduction

The mission of the Indiana State Department of Toxicology (ISDT) is to provide quality forensic toxicological services and education for the state of Indiana.

The ISDT Breath Test Program provides accurate and reliable breath alcohol testing through professional, ethical, and unbiased interpretation of results and instrument inspections and certifications pursuant to Title 260 of the Indiana Administrative Code.

Deviations from the following procedures may be permitted with supervisory approval.

Uncontrolled
Copy

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.
- 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 before first use or 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 or 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 initially appear, 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. 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_initials (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
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 calculate the MU for the calibration method of the Intox EC/IR II. The MU is an expression of the confidence or certainty of the ethanol concentration of each ethanol dry gas CRM 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

2.5. 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 CRM
2.7.2. Nominal 0.082 g/210 L ethanol dry gas CRM
2.7.3. Nominal 0.100 g/210 L ethanol dry gas CRM
2.7.4. Nominal 0.150 g/210 L ethanol dry gas CRM

2.8. Procedures/Instructions

2.8.1. CRMs

- 2.8.1.1. Each ethanol dry gas CRM shall be NIST traceable and accompanied by an uncertainty at a stated level of confidence.
- 2.8.1.1.1. Each lot number, tank number, DEV code, and expiration date on each ethanol dry gas CRM tank shall be verified against the tank list provided by the manufacturer. The tank list and each verified tank of ethanol dry gas CRM shall be dated and initialed prior to release for use.
- 2.8.1.2. COAs for CRMs 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. The MU is a non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

- 2.8.2.1. The measurand is the vaporous ethanol concentration in g/210 L as measured by the Intox EC/IR II manufactured by Intoximeters, Inc.
- 2.8.2.2. 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.
- 2.8.2.3. Traceability is established by using ethanol dry gas CRMs obtained from an ISO/IEC 17025:2005 accredited calibration laboratory with an appropriate scope of accreditation for calibration adjustments and accuracy checks.

2.8.3. Measurement process

2.8.3.1. The uncertainty of the measurand is represented by the following

$$\text{formula: } u_c = \sqrt{\text{CRM}_{AC}^2 + \text{CRM}_{Adj}^2 + \text{IA}_{\text{Reproducibility}}^2}$$

$$u_c = \sqrt{\text{CRM}_{AC}^2 + \text{CRM}_{Adj}^2 + \text{IA}_{\text{Reproducibility}}^2}$$

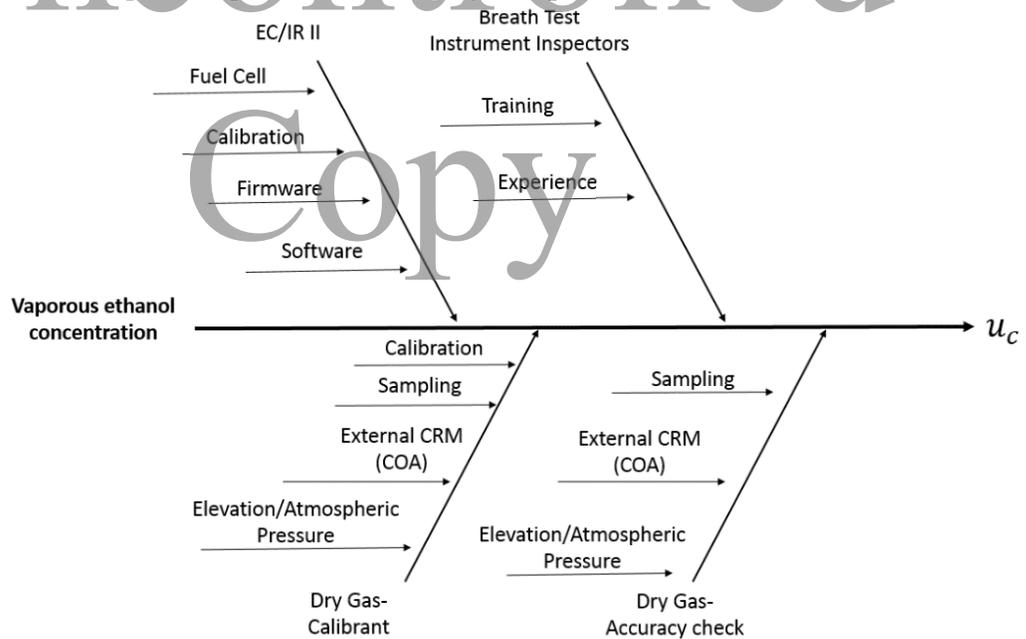
CRM_{AC}: ethanol CRM used in accuracy checks

CRM_{Adj}: ethanol CRM used in calibration adjustments

IA_{Reproducibility}: Instrument (Intox EC/IR II) analytical reproducibility

u_c: combined uncertainty

2.8.4. Fish diagram of possible uncertainty components



2.8.5. Use of the Measurement Uncertainty Estimation Summary

2.8.5.1. 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.

- 2.8.5.2. The ethanol dry gas CRM lot number, DEV Code, and analyzed concentration for each ethanol dry gas CRM used in the inspection shall be documented in the appropriate fields.
 - 2.8.5.2.1. The barometric pressure determined by the instrument shall be entered in order for the target concentration to be calculated and populated in the correct field.
- 2.8.5.3. Results of the ten replicate accuracy checks with each ethanol dry gas CRM shall be entered in each of the appropriate fields labeled Results 1 through Results 10.
- 2.8.5.4. The Measurement Uncertainty Estimation Summary automatically calculates the MU by:
 - 2.8.5.4.1. Normalizing all results to 760 mmHg (adjusted results);
 - 2.8.5.4.2. Calculating the average of the adjusted results;
 - 2.8.5.4.3. Calculating the standard deviation (sample) of the adjusted results;
 - 2.8.5.4.4. Calculating the % RSD by dividing the standard deviation by the average then multiplying by 100;
 - 2.8.5.4.5. Calculating the standard uncertainty by dividing the % RSD by the degrees of freedom (number of replicates minus 1);
 - 2.8.5.4.6. Calculating the expanded uncertainty as a percentage with a confidence interval of 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 (ten replicate adjusted results), calibration adjustment ethanol dry gas CRM, and ethanol dry gas CRM used in the calibration method;
 - 2.8.5.4.6.1. The standard uncertainty for each of the ethanol dry gas CRM is calculated by dividing the total relative uncertainty on the COA by the k value of 2.
 - 2.8.5.4.7. Calculating the MU in g/210 L by multiplying the average of the adjusted results by the expanded uncertainty.
 - 2.8.5.4.7.1. The calculated MU is rounded to the nearest thousandths place using normal rounding rules.
- 2.8.5.5. The average result and associated MU shall be reported as the average \pm MU g/210 L for each ethanol dry gas CRM used in the inspection (ref. 3.8.6.8).

2.9. Records

2.9.1. Ethanol dry gas CRM tank list

- 2.9.2. Ethanol dry gas CRM packing slip
 - 2.9.3. Certificate of analysis of ethanol dry gas CRM used in the calibration adjustment
 - 2.9.4. Certificates of analysis of ethanol dry gas CRMs used in Inspection Mode or Accuracy Checks
 - 2.9.5. Measurement Uncertainty Estimation Summary
 - 2.9.6. Certificate of Compliance of Breath Test Instrument and Chemicals
- 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 as the average \pm MU g/210 L for each ethanol dry gas CRM used in the inspection (ref. 3.8.6.8) on the Calibration Certificate.
 - 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 CRM (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

Uncontrolled
Copy

3. Intox EC/IR II Instrument Inspection

- 3.1. Scope
 - 3.1.1. This procedure shall be used to inspect and/or service Intox EC/IR II breath test instruments.
- 3.2. Precautions/Limitations
 - 3.2.1. A breath test instrument inspection 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
 - 3.3.2. Certificate of Analysis for ethanol dry gas CRM
- 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. N/A
- 3.6. Hazards/Safety
 - 3.6.1. Use care not to directly breathe ethanol dry gas CRM.
 - 3.6.2. Ethanol dry gas CRMs should be protected from sunlight when ambient temperature exceeds 52 °C/125 °F.
- 3.7. Reference Materials/Controls/Calibrators/Solutions
 - 3.7.1. Nominal 0.020 g/210 L ethanol dry gas CRM
 - 3.7.2. Nominal 0.080 g/210 L ethanol dry gas CRM
 - 3.7.3. Nominal 0.082 g/210 L ethanol dry gas CRM
 - 3.7.4. Nominal 0.100 g/210 L ethanol dry gas CRM
 - 3.7.5. Nominal 0.150 g/210 L ethanol dry gas CRM
- 3.8. Procedures/Instructions
 - 3.8.1. A breath test instrument deployed for evidentiary analysis 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 4.8.2).
 - 3.8.2. The inspection procedure includes at least one test to demonstrate that the instrument meets the requirements of 260 IAC 2-3-2. 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 at the time of the inspection.

- 3.8.4.1. The Worksheet shall also be used to document an instrument calibration adjustment, service, 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 by the inspector, 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 Evidentiary Breath Test Instrument Maintenance Agreement, 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, CRM lot number, DEV code, tank number, expiration date, CRM manufacturer, agency name, and instrument location address are printed on each instrument report.
 - 3.8.5.8. If an inspector is taking the instrument out of service or moving the instrument beyond the length of its power cord, 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 service record 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, instrument reports, and/or return the service 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 or service, document it on the Worksheet.
 - 3.8.6.2. Verify that the instrument is in ready mode. Record any other display messages, 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 Evidentiary Breath Test Instrument Maintenance Agreement, 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 shall be performed.
- 3.8.6.6.1. Prior to performing a calibration adjustment, verify the instrument barometer is within 5 mmHg of the reference barometer. Adjust instrument barometer, if the difference is greater than 5 mmHg (ref. 4.8.3).
- 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. Adjust the instrument's calibration using a nominal 0.100 g/210 L ethanol dry gas CRM (ref. 4.8.10).
- 3.8.6.6.3. A test diagnostic should be printed after the calibration adjustment.
- 3.8.6.6.4. Proceed to 3.8.6.8
- 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.
- $$\left(\frac{|\text{Reference barometer} - \text{Instrument barometer}|}{\text{Reference barometer}} \right) \times 100 < 1.5$$
- 3.8.6.7.1. The calibration of the instrument barometer shall be adjusted if the difference in the two readings is $> \pm 1.5\%$ of the reference barometer reading (ref. 4.8.3).
- 3.8.6.8. 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. 3.8.6.11 and 3.8.6.12):
- 3.8.6.8.1. Nominal 0.020 g/210 L ethanol dry gas CRM;

- 3.8.6.8.2. Nominal 0.082 g/210 L ethanol dry gas CRM; and
- 3.8.6.8.3. Nominal 0.150 g/210 L ethanol dry gas CRM.
- 3.8.6.9. At least one Inspection Mode shall be completed with any one of the ethanol dry gas CRMs listed in 3.8.6.8.
- 3.8.6.10. A test diagnostic should be printed following at least one Accuracy check or Inspection Mode.

Note: The calibration method described in 3.8.6.11 and 3.8.6.12 may be performed in any order or combination to meet the requirements in 3.8.6.8 and 3.8.6.9 and shall be used to determine the MU.

- 3.8.6.11. Perform an Inspection Mode with an ethanol dry gas CRM (ref. 3.8.6.8). 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 CRM. Verify each result is within ± 0.005 or 5%, whichever is greater, of the target concentration.
 - 3.8.6.11.1. If a status message other than “Standard Out of Range” appears on the instrument report, perform an Inspection Mode (ref. 3.8.6.11), make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument, as appropriate.
 - 3.8.6.11.2. If an accuracy check is outside the acceptable range and a status message of “Standard Out of Range” appears on the instrument report, print a test diagnostic, remove the ethanol dry gas CRM, and verify the appropriate tank was installed.
 - 3.8.6.11.2.1. If the incorrect dry gas CRM tank was installed, perform an Inspection mode (ref. 3.8.6.11) using a nominal dry gas CRM tank from 3.8.6.8.
 - 3.8.6.11.2.2. If the correct dry gas CRM tank was installed, uninstall the dry gas CRM tank and check the O-ring. Either reinstall the nominal dry gas CRM tank and perform an Inspection mode (ref. 3.8.6.11) or adjust the instrument’s calibration using a nominal 0.100 g/210 L ethanol dry gas CRM (ref. 4.8.10) and proceed to 3.8.6.8.
 - 3.8.6.11.2.2.1. If any result is still outside the acceptable range or a status message of “Standard Out of Range” appears on the instrument report,

print a test diagnostic, make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument.

3.8.6.12. Perform Accuracy Checks with an ethanol dry gas CRM (ref. 3.8.6.8). 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 CRM. Verify each result is within ± 0.005 or 5%, whichever is greater, of the target concentration.

3.8.6.12.1. If a status message other than “Standard Out of Range” appears on the instrument report, perform an Inspection Mode (ref. 3.8.6.11), make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument, as appropriate.

3.8.6.12.2. If an accuracy check is outside the acceptable range and a status message of “Standard Out of Range” appears on the instrument report, print a test diagnostic, remove the ethanol dry gas CRM, and verify the appropriate tank was installed.

3.8.6.12.2.1. If the incorrect dry gas CRM tank was installed, perform an Inspection mode (ref. 3.8.6.11) using a nominal dry gas CRM tank from 3.8.6.8.

3.8.6.12.2.2. If the correct dry gas CRM tank was installed, uninstall the dry gas CRM tank and check the O-ring. Either reinstall the dry gas CRM tank and perform an Inspection mode (ref. 3.8.6.11) or adjust the instrument’s calibration using a nominal 0.100 g/210 L ethanol dry gas CRM (ref. 4.8.10) and proceed to 3.8.6.8.

3.8.6.12.2.2.1. If any result is still outside the acceptable range or a status message of “Standard Out of Range” appears on the instrument report, print a test diagnostic, make the necessary adjustment or repair (ref. 4.8), or replace

the breath test
instrument.

- 3.8.6.13. Reference materials other than those listed in 3.8.6.8 may be used during the inspection for additional testing.
- 3.8.6.14. Install a nominal 0.080 g/210 L ethanol dry gas CRM (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 CRM, as applicable.
- 3.8.6.15. 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.
 - 3.8.6.15.1. If a status message other than “Standard Out of Range” appears on the instrument report, perform a Subject Test (ref. 3.8.6.15), make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument, as appropriate.
 - 3.8.6.15.2. If an accuracy check is outside the acceptable range and a status message of “Standard Out of Range” appears on the instrument report, print a test diagnostic, remove the ethanol dry gas CRM, and verify the appropriate tank was installed.
 - 3.8.6.15.2.1. If the incorrect dry gas CRM tank was installed, perform an Inspection mode (ref. 3.8.6.11) using a nominal dry gas CRM tank from 3.8.6.8, and then perform a Subject Test (ref. 3.8.6.15).
 - 3.8.6.15.2.2. If the correct dry gas CRM tank was installed uninstall the dry gas CRM tank and check the O-ring. Either perform an Inspection mode (ref. 3.8.6.11) using a nominal dry gas CRM tank from 3.8.6.8, and then perform a Subject Test (ref. 3.8.6.15) or adjust the instrument’s calibration using a nominal 0.100 g/210 L ethanol dry gas CRM (ref. 4.8.10) and proceed to 3.8.6.8.
 - 3.8.6.15.2.2.1. If any result is still outside the acceptable range or a status message of “Standard Out of Range” appears on the instrument report,

print a test diagnostic, make the necessary adjustment or repair (ref. 4.8), or replace the breath test instrument.

- 3.8.6.16. Verify that the Worksheet is completed and that the correct date and time, instrument serial number, CRM lot number, DEV code, tank number, expiration date, CRM manufacturer (Inspection Mode only), agency name, and instrument location address are printed on each instrument report.
- 3.8.6.17. Once started, if it is necessary to terminate an inspection before completion, all records generated 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.
 - 3.8.6.17.1. As long as 180 days have not elapsed from 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.
- 3.8.6.18. Complete Measurement Uncertainty Estimation Summary.
 - 3.8.6.18.1. Verify the target concentration(s) given by the instrument for each CRM used in calculating the MU is consistent with the target concentration given by the instrument in 3.8.6.11 and 3.8.6.12.
 - 3.8.6.18.1.1. If the target concentration(s) on the instrument report(s) does not equal the target concentration on the Measurement Uncertainty Estimation Summary, correct the target concentration on the instrument report to reflect the target concentration on the Measurement Uncertainty Estimation Summary. The incorrect target concentration shall be corrected by placing one line through the incorrect concentration, writing the correct target concentration, and placing initials/signature and date near the correction. This should only occur if the analyzed tank concentration is entered improperly.

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

3.8.6.19. If an inspector performs the inspection, an analyst shall review the inspection record.

3.8.6.19.1. 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.

3.8.6.19.2. Upon review, the analyst may add notes, make corrections to the Worksheet, instrument reports, and Measurement Uncertainty Estimation Summary 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 3.8.6.13, if applicable.

3.8.7.2. Check the barometric pressure from the reference barometer 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, the cylinder number for the lot number (leave the tank number blank), and expiration date of the ethanol dry gas CRM. 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, the cylinder number for the lot number (leave the tank number blank), expiration date, and manufacturer of the ethanol dry gas CRM. 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 Service 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 inspector performing the inspection and submitted for technical and administrative review with the instrument inspection record.
 - 3.8.7.6.1. If the inspector is not an analyst, 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. 3.8.9), the results of the proficiency test shall be submitted to the proficiency test provider, if applicable, using the form provided by the proficiency test provider.
- 3.8.8. Preparation of the Calibration Certificate
 - 3.8.8.1. The analyst who performed or approved the inspection may prepare a Calibration Certificate if the instrument is in good operating condition and meets the accuracy requirements of 260 IAC 2-3-2(f) (ref. 3.10.1).
 - 3.8.8.2. The Calibration Certificate shall include the following information:
 - 3.8.8.2.1. Instrument serial number;
 - 3.8.8.2.2. Inspector or analyst’s name;
 - 3.8.8.2.3. Date of the inspection;
 - 3.8.8.2.4. Location of the instrument;
 - 3.8.8.2.5. Calibration method used (e.g., Intox EC/IR II Inspection Method);
 - 3.8.8.2.6. Results for each ethanol dry gas CRM used in the inspection reported as the average \pm the MU (ref. 2.8.5 and 3.10.2) in units of g/210 L (e.g., 0.079 \pm 0.003 g/210 L); and

- 3.8.8.2.7. Signature of the analyst
- 3.8.8.3. If a repair or adjustment, including calibration adjustment is performed, pre and post adjustment accuracy results shall be retained and reported on the Calibration Certificate, if applicable. The Calibration Certificate should clearly indicate which results were obtained prior to the calibration adjustment.
- 3.8.9. Technical and administrative review
- 3.8.9.1. The technical and administrative review of an inspection or service record shall be performed by an analyst, who shall be a person other than the person who performed the inspection, calibration adjustment, or service, or the person who authored the Calibration Certificate under review.
- 3.8.9.2. The review shall include the Worksheet, Measurement Uncertainty Estimation Summary, Breath Test Program Proficiency Test Worksheet, the breath test instrument reports generated during the inspection, calibration adjustment, and/or service; and the Calibration Certificate, as applicable.
- 3.8.9.3. The reviewer shall document the review by completing the Breath Test Instrument Inspection and Service Technical and Administrative Review Checklist.
- 3.8.9.3.1. If there is a discrepancy in the inspection documents or Calibration Certificate, the reviewer shall return the inspection record and Calibration Certificate to the analyst for remedy and document date of discovery and the reason in the notes section on the TAC.
- 3.8.9.3.1.1. If the discrepancy from the method cannot be corrected and the inspection and certification are rejected, the TAC shall be completed, reason for the rejection of the inspection and Calibration Certificate documented in the notes section and signed by the technical and administrative reviewer.
- 3.8.9.3.1.2. If a Calibration Certificate was authored, it shall be marked as “Rejected,” saved, and maintained according to 3.8.10.
- 3.8.10. Breath test instrument records are stored electronically using the following naming convention: serial#_activity_date_initials (e.g., 011100_CER_04-25-16_TK):
- 3.8.10.1. The instrument serial number is listed first
- 3.8.10.2. A description of activity is listed second as one of the following:
CAL – External certificate or report of calibration for a reference standard

CER – Certificate of Compliance of Breath Test Instrument and Chemicals

INI – Initial breath test instrument inspection

INS – Breath test instrument inspection

INS-CAL – Breath test instrument inspection with instrument calibration adjustment

OTH – Other

PM – Preventive maintenance

PT – Breath Test Program Proficiency Test Worksheet

SVC – Service request or service with no inspection required

TAC – Technical and Administrative Review Checklist

TOS – Breath test instrument or simulator taken out of service

MU – Measurement Uncertainty Estimation Summary

3.8.10.3. The date of the activity as documented on the record is listed third in the format mm-dd-yy.

3.8.10.4. The initials of the person making the entry are listed last.

3.9. Records

3.9.1. Ethanol dry gas CRM tank list

3.9.2. Ethanol dry gas CRM packing slip

3.9.3. Certificate of analysis of ethanol dry gas CRM used in the calibration adjustment, if applicable.

3.9.4. Certificates of analysis of ethanol dry gas CRMs used in Inspection Mode or Accuracy Checks

3.9.5. Inspection Record:

3.9.5.1. Intox EC/IR II Breath Test Instrument Inspection and Service Worksheet

3.9.5.2. Intox EC/IR II instrument reports or IntoxNet download data from tests performed during the inspection or service

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 Service Technical and Administrative Review Checklist

3.9.10. Breath Test Program Proficiency Test Worksheet, if applicable

3.9.11. Simulator Inspection Worksheet, if applicable

3.9.12. 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 2-3-2(f) if:

3.10.1.1. At least one test was performed with an ethanol dry gas CRM for which each certified concentration is accompanied by an uncertainty at a stated level of confidence (ref. 3.8.6.11 and 3.8.6.12); and

3.10.1.2. The result of each Subject Test with 0.000 g/210 L breath performed in 3.8.6.15 is 0.000 g/210 L.

3.10.2. When a breath test instrument deployed for evidentiary use has been adjusted or repaired (ref. 4.8.2), the inspection results before and after any adjustment or repair, if available, shall be reported on the Calibration Certificate.

3.10.2.1. The results for accuracy checks before an adjustment or repair shall only be reported if there are at least 10 replicates obtained (ref. 2.11.1.1).

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 2-3-2 (f) (ref. 3.10.1).

3.12. References

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

Uncontrolled
Copy

4. Intox EC/IR II Instrument Maintenance

- 4.1. Scope
 - 4.1.1. These procedures shall be used to service Intox EC/IR II breath test instruments.
- 4.2. Precautions/Limitations
 - 4.2.1. N/A
- 4.3. Related Information
 - 4.3.1. Certificate of Analysis for ethanol dry gas CRM
- 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 CRM.
 - 4.6.2. Ethanol dry gas CRMs should be protected from sunlight when ambient temperature exceeds 52 °C/125 °F.
- 4.7. Reference Materials/Controls/Calibrators/Solutions
 - 4.7.1. 0.080 g/210 L ethanol dry gas CRM
 - 4.7.2. 0.100 g/210 L ethanol dry gas CRM
- 4.8. Procedures/Instructions
 - 4.8.1.1. If only the keyboard, card reader, printer, ethanol dry gas CRM/gasket, breath tube, power cord, and/or an external cable is repaired or replaced:
 - 4.8.1.1.1. 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.
 - 4.8.1.1.1.1. If 3.8.6.5 is not performed, the reason shall be documented.
 - 4.8.1.1.2. Perform 3.8.6.14, 3.8.6.15, and 3.8.6.16 to verify the instrument is in good operating condition after the repair or replacement.

- 4.8.1.1.3. No further inspection is required if the analytical result for each 0.000 g/210 L breath sample is 0.000 g/210 L.
- 4.8.2. If any internal component other than listed 4.8.1.1 is adjusted, repaired, or replaced, or the calibration of the instrument is adjusted, or if the instrument is moved beyond the length of its power cord, an inspection shall be performed (ref. 3.8.2)
- 4.8.3. Instrument Barometer Calibration Adjustment
 - 4.8.3.1. Remove outer case from instrument as well as the fitting from the barometer block.
 - 4.8.3.2. Attach vacuum pump to the barometer block and the reference barometer.
 - 4.8.3.3. Calibrate Pressure. Set baseline, then lower the reading on the manometer to between 500 and 550.
 - 4.8.3.4. Repeat 4.8.3.3.
 - 4.8.3.5. Check linearity by reducing pressure to three different values (e.g., 400, 500, and 600 mmHg).
 - 4.8.3.6. Remove vacuum pump, and reattach instrument fitting.
 - 4.8.3.7. Verify instrument barometer value is within 5 mmHg of the reference barometer. If not, return to 4.8.3.2.
 - 4.8.3.8. Replace outer case.
 - 4.8.3.9. Perform Intox EC/IR II calibration adjustment (ref. 4.8.10).
- 4.8.4. Ethanol and CO₂ IR System Calibration Adjustment
 - 4.8.4.1. To calibrate the IR for Ethanol, select type of reference material being used and enter the ethanol dry gas CRM concentration.
 - 4.8.4.2. To calibrate the IR for CO₂:
 - 4.8.4.2.1. Run CO₂ through breath tube using human breath.
 - 4.8.4.2.2. Introduce CO₂ again while watching the mV reading.
 - 4.8.4.2.2.1. If it does not drop to approximately 50% of the original reading, repeat the CO₂ calibration.
 - 4.8.4.2.2.1.1. If the value is still not acceptable, clean the IR bench (ref. 4.8.9) and return to 4.8.4.1.
- 4.8.5. Flow Calibration 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 reading at 0.500 L/sec is within $\pm 10\%$.
 - 4.8.5.2.1. If reading is not within $\pm 10\%$, repeat the flow calibration.
 - 4.8.5.2.1.1. If the value 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 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.
- 4.8.8. 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.
- 4.8.9. 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 ethanol and CO₂ IR system calibration adjustment (ref. 4.8.4).
- 4.8.10. Intox EC/IR II 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 calibration adjustment (ref. 4.8.3).
 - 4.8.10.2. Perform a calibration adjustment of the Intox EC/IR II using a nominal 0.100 g/210 L ethanol dry gas CRM (ref. 2.8.1).
 - 4.8.10.3. 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 CRM.
 - 4.8.10.3.1. Print a test diagnostic.
 - 4.8.10.3.2. If the Fuel Cell Gain is 8 or Time 4 ≥ 8000 , a supervisor shall be notified in order to plan for preventative maintenance.
 - 4.8.10.3.2.1. If the fuel cell is replaced, an instrument calibration adjustment shall be performed (ref. 4.8.10).
- 4.8.11. Documentation of maintenance
 - 4.8.11.1. A Worksheet shall be filled out after maintenance is performed on an instrument, regardless of whether the instrument is currently deployed for evidentiary use.
 - 4.8.11.2. A technical and administrative review shall be performed (ref. 3.8.9).
 - 4.8.11.3. Records shall be stored electronically as specified in 3.8.10.
- 4.9. Records
 - 4.9.1. Ethanol dry gas CRM tank list
 - 4.9.2. Ethanol dry gas CRM packing slip
 - 4.9.3. Certificate of analysis of ethanol dry gas CRM used in the calibration adjustment, if applicable.
 - 4.9.4. Certificates of analysis of ethanol dry gas CRMs used in Inspection Mode or Accuracy Checks
 - 4.9.5. Intox EC/IR II Breath Test Instrument Inspection and Service Worksheet
 - 4.9.6. Intox EC/IR II instrument reports or IntoxNet download data from tests performed during the inspection or service
 - 4.9.7. Breath Test Instrument Inspection and Service 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.

Uncontrolled
Copy

5. Appendix

5.1. Glossary

- 5.1.1. Accuracy Check/Inspection Mode – A procedure, using ethanol dry gas CRMs, 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, service, and maintenance of breath test instruments.
- 5.1.5. Calibration adjustment – The procedure for assigning a quantity value to an instrument response from an ethanol dry gas CRM.
- 5.1.6. 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 CRMs. 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.
- 5.1.7. 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.
- 5.1.8. 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 service, as applicable.
- 5.1.9. Measurand – Quantity intended to be measured.
- 5.1.10. 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.
- 5.1.11. May – An option.
- 5.1.12. Normal rounding – Digits 1, 2, 3, and 4 round down and digits 5, 6, 7, 8, and 9 round up.
- 5.1.13. 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.
- 5.1.14. Quantity values – Number and reference together expressing magnitude of a quantity.
- 5.1.15. Shall – A requirement.
- 5.1.16. Should – A recommendation.

5.2. Abbreviations

- 5.2.1. % RSD – Percent relative standard deviation
- 5.2.2. Calibration Certificate – Certificate of Compliance of Breath Test Instrument and Chemicals
- 5.2.3. COA – Certificate of Analysis
- 5.2.4. CRM – Certified reference material
- 5.2.5. EC – Electrochemical
- 5.2.6. g – Grams
- 5.2.7. IAC – Indiana Administrative Code
- 5.2.8. Inspection – Breath Test Instrument Inspection
- 5.2.9. IR – Infrared
- 5.2.10. L – Liter
- 5.2.11. mmHg – Millimeter of mercury
- 5.2.12. MU – Measurement uncertainty
- 5.2.13. NIST – National Institute of Science and Technology
- 5.2.14. PT – Proficiency test
- 5.2.15. TAC – Breath Test Instrument Inspection and Service Technical and Administrative Review Checklist
- 5.2.16. Worksheet – Intox EC/IR II Breath Test Instrument Inspection and Maintenance Worksheet

Uncontrolled
Copy

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.	 J. E. Littlejohn 2019.09.09 15:13:31 -04'00'  Sheila A. Arnold 2019.09.09 14:33:41 -04'00'