BREATH ALCOHOL ANALYTICAL METHODS

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Revision History

Revision #	Description of Changes
1	Original issue: combination of analytical methods Previous revisions and revision section numbering may not correspond to the current method. Refer to the archived method for the sections in place at the time of edit for section specific edits.
2	Changes were made to AM #1 sections: 3.1, 4.1, 4.1.2.1, 4.1.2.2, 4.3.1.1, 4.3.2.1, 4.4.1, 4.4.1.3.1, 4.4.1.3.2. AM#2 sections: 3.1, 3.3.1, 4.1, 4.1.1.1, 4.1.1.3.3.2, 4.1.1.3.4, 4.1.3.2.3.2, 4.1.3.3 (added), 4.1.4.2.3.2, 4.1.5.1, 4.1.5.3.3.2, 4.1.5.4 (added), 4.1.5.4.4, 4.2.1.2, 4.3.1.4, 4.3.2.4, 4.3.3.4, 4.4.1, 4.4.2, AM#3 sections: 4.1, 4.4.1.1-5, 4.4.1.2, 4.4.1.2.1, AM#5 sections: 4.1.1.7.1, 4.1.2.7.1, 4.3.1.1, 4.4.1.1-5, Work instructions added to methods 2 and 4
3	Updated table of contents
4	Changes were made to AM #1 sections 3.1, 4.1.1.3.6, 4.1.4.2.5, 4.1.5.3.6, AM #5 sections: 3.3.3, 4.1.1.4.1, 4.1.1.4.3, 4.4.1.1, 4.4.1.2.1, 4.4.1.3.1, 4.4.1.1, 4.4.1.2.1, 4.4.1.3.1, 4.4.1.4.1, 4.4.1.4.1.1, and 4.4.1.5.1. Sections 4.1.1.11, 4.1.1.11.1 and 4.6 were added. Work instructions were added to AM #5
5	AM#1: Changes were made to section 4.2.1.1, 4.2.2.1, 4.4.1.3.1. Changes were made to AM #5: section 4.2.3, Added AM #6.
6	AM#1: Changes made to 3.1. AM#2: added sections 4.1.3.3.5-7 and 4.1.5.4.5-7. Changes made to 3.1, 3.2, 4.1.3.3.3, 4.1.5.4, and 4.1.5.4.3. AM#4: change to 5.1.1.1.6. AM#6: added section 4.4.2. Changes to 4.4.1.

Analytical Method #1: Approving Simulator Solutions

1.0 Background/References

1.1 Background:

Idaho Administrative Code, IDAPA 11.03.01 requires that each breath testing instrument have performance verifications on a schedule established by the Idaho State Police Forensic Services Laboratory. The verifications are performed using a premixed alcohol simulator solution provided by the Forensic Laboratory or by an approved source. Each premixed alcohol simulator solution lot must be approved by the Idaho State Police according to a procedure establish by the ISP Forensic Services Laboratory. The vendor/manufacturer/provider of the premixed alcohol solution lot is approved as the source when ISPFS approves of the corresponding lot.

1.2 References:

- Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.
- Caplan, Y.H., The Determination of Alcohol in Blood and Breath. in: Forensic Science Handbook, edited by Richard Saferstein, pp. 594-648, Prentice-Hall New Jersey, 1982.
- Levine, B. and Caplan, Y.H., Alcohol. in: Principles of Forensic Toxicology, edited by Barry Levine, pp. 169-184, AACC Press, 2006.
- Gullberg, R. (2005). Determining the Air/Water Partition Coefficient to Employ when Calibrating Forensic Breath Alcohol Test Instruments. Can. Soc. Forensic Sci. J., 38 (4), 205-212.
- Idaho Statutes, 18-8004 (4). Title 18, Crimes and Punishments, Chapter 80 Motor Vehicles. Persons under the influence of alcohol, drugs or any other intoxicating substances.
- http://www.legislature.idaho.gov/idstat/Title18/T18CH80SECT18-8004.htm

2.0 Scope

2.1 This method discusses the Idaho State Police Forensic Services (ISPFS) requirements for the approval of premixed ethyl alcohol solutions used for field performance verifications. Use of approved premixed alcohol simulator solutions (as a quality control) is required. Premixed alcohol simulator solutions are provided by ISPFS or an approved independent contractor and shall meet the standards contained in this method before they will be approved for use by ISP. Solutions that are not used in the field, but used for calibration activities within the laboratory, need only a certificate of analysis to be on file.

3.0 Equipment/Reagents

3.1 Equipment:

- Refer to Blood Alcohol Discipline Analytical Method 1.0

3.2 Reagents:

- Refer to Blood Alcohol Discipline Analytical Method 1.0
- Premixed Ethyl Alcohol Solution. Premixed ethyl alcohol solutions shall be packaged in plastic bottles capable of maintaining the alcohol solution within specifications until the solutions expire. Each bottle shall be designated to contain 500 mL of solution and have a non-absorptive seal and a screw top lid. Bottles will have an integrity seal to insure the product has not been tampered with prior to its use. Freezing renders the solutions useless; therefore bottles of solution will not be shipped if there is a likelihood they will freeze during shipment. Bottles of solution shall be stored at room temperature or refrigerated (not frozen).

3.3 Reference Materials:

- Refer to Blood Alcohol Discipline Analytical Method 1.0

3.4 Safety Concerns

- Chemicals must be handled according to safety guidelines in the Idaho State Police Forensic Services Health and Safety Manual.

4.0 Procedure

4.1 Certification Process:

4.1.1 General

4.1.1.1 Refer to Blood Alcohol Analytical Method 1.0 for Gas Chromatograph (GC) configured with a Flame Ionization Detector (FID) analysis requirements.

4.1.1.2 New lots of pre-mixed reference solutions will be provided by ISPFS or an independent contractor and shall meet the following acceptance criteria before they will be released to law enforcement agencies in Idaho.

4.1.1.2.1 The supplier must provide a certificate of analysis, a manufacture date, and an expiration date of the lot from which the sample was taken.

4.1.1.2.2 The supplier shall provide to ISPFS a random sampling of each new lot (manufactured batch) consisting of four (4) 500 mL samples.

4.1.2 Analysis Requirements

4.1.2.1 Two (2) 500 mL samples will be sent to an ISP laboratory performing blood alcohol and other volatiles analysis for analysis by GC-FID following the protocol in the AM #1: Analysis for Volatiles by Headspace GC. The results obtained from analysis will not be truncated (they will be reported to four digits).

4.1.2.2 Premixed alcohol simulator solution samples to be analyzed may be included as part of a larger run or sequence, but should be run prior to running evidentiary samples. A premixed alcohol simulator solution sample shall not be the last sample on a run. These samples must be followed by at least one sample or a reagent blank.

4.1.2.3 Results in g/100cc shall be converted to g/210L by dividing by the number 1.23. The results from the two ISP labs will be provided to the ISPFS Alcohol Discipline Leader for evaluation.

4.2 Solution Acceptance Criteria

4.2.1 Evaluation and Approval

4.2.1.1 When the results are received from the ISP Laboratories, the ISP Alcohol Discipline Leader will review the results and the accompanying quality control(s). ISPFS will not establish a new target value for each solution lot. The raw data points provided by both laboratories will be used to determine a combined mean. The result will be rounded to three significant digits (e.g. 0.200). The standard deviation will also be evaluated. If the values of the tested premixed alcohol simulator solution (the combined mean as reflected in raw data and as the g/100cc converted data) are within the parameters listed below, a certificate of approval will be issued by the ISPFS Alcohol Discipline Leader. The raw data combined mean result (in g/100cc) shall be converted to g/210L by dividing by the number 1.23.

4.2.2 Approval Criteria

4.2.2.1 Results of analysis must be within +/- 5% or .004 (whichever is greater) of the suppliers target value as listed on their certificate of analysis.

4.2.3 Rejection

4.2.3.1 If the above criteria are not met, the solution lot will be rejected. If a solution lot is rejected, the supplier shall be notified. The supplier will be required to submit a new lot of solution and a new authentication process will be conducted

4.3 Authentication Documentation

4.3.1 Approval Documentation

4.3.1.1 Data sheets, chromatograms, the certificate of analysis from the supplier and the lot approval certificate (signed and dated by the Alcohol Discipline Leader) shall be retained in the Alcohol Section for all approved lots. The approval shall also be posted on the ISP Internet Site.

4.3.2 Rejection Documentation

4.3.2.1 Data sheets, chromatograms, and the lot rejection letter (signed and dated by the Alcohol Discipline Leader) shall be retained in the Alcohol Section for all rejected lots. A copy of an email or fax to the supplier documenting the lot rejection will also be retained.

4.4 Vendor Approval

4.4.1 Vendor Approval: In conformity with IDAPA 11.03.01.013.01 the vendor approval process will be as follows:

4.4.1.1 ISPFS shall approve the vendor by the vendor agreeing to the technical specifications required by ISPFS, and by the vendor providing a solution that is certified by ISPFS as meeting those specifications.

4.4.1.2 Any proposed vendor shall be provided with the ISPFS current technical specification form. The technical specifications form will detail any solution specifications placed on the manufacture by Idaho State Police Forensic Services. The technical specifications form shall be signed by the Alcohol Discipline Leader and a representative of the manufacture/provider/vendor before any of the lots associated with the vendor will be tested by ISPFS.

4.4.1.3 Each solution lot provided by a potential vendor shall be tested.

4.4.1.3.1 Each new lot of solution will be tested using the process in section 4.1 of this AM.

4.4.1.3.2 Each solution lot will be evaluated and accepted or rejected based on the requirements in section 4.2 this AM. Approval of a solution lot explicitly approves the lot for sale/distribution within Idaho, as well as approval of the vendor as the source/manufacturer/provider of that lot.

4.4.1.3.3 For lots certified after the date of June 28, 2010, the vendor approval shall be documented on the lot approval certificate for the premixed alcohol simulator solution.

4.4.1.4 The Alcohol Discipline Leader shall keep the signed technical specifications form on file.

Analytical Method #2: Portable Instrument Certification

1.0 Background/References

1.1 Background:

Idaho Administrative Code, IDAPA 11.03.01 requires that each breath testing instrument have performance verifications on a schedule established by the Idaho State Police Forensic Services Laboratory. Breath testing has been in use within the State of Idaho for several decades dating back to the early 80's. The technology used within the instruments date back even further, and helps to solidify the science of alcohol testing in human expired breath. The approved portable instruments allow for the time sensitive testing of a subjects breath in a convenient, accurate, precise and timely fashion. This method is advantageous due to the quick and relatively simple methods for performing the test, as well as the non-invasive method for collecting the sample itself. The use of portable breath testing instruments within the state is a valuable tool for conducting criminal investigations for driving under the influence as well as other alcohol related crimes.

1.2 References:

- Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.
- Caplan, Y.H., The Determination of Alcohol in Blood and Breath, Forensic Science Handbook, edited by Richard Saferstein, pp. 594-648, Prentice-Hall New Jersey, 1982.
- Levine, B. and Caplan, Y.H., Alcohol. in: Principles of Forensic Toxicology, edited by Barry Levine, pp. 169-184, AACC Press, 2006.
- Gullberg, R. (2005). Determining the Air/Water Partition Coefficient to Employ when Calibrating Forensic Breath Alcohol Test Instruments. Can. Soc. Forensic Sci. J. , 38 (4), 205-212.
- Idaho Statutes, 18-8004 (4). Title 18, Crimes and Punishments, Chapter 80 Motor Vehicles. Persons under the influence of alcohol, drugs or any other intoxicating substances.
- http://www.legislature.idaho.gov/idstat/Title18/T18CH80SECT18-8004.htm

2.0 Scope

2.1 This method discusses the Idaho State Police Forensic Services (ISPFS) requirements for the approval of portable breath testing instruments used to perform evidentiary breath testing in the field. The requirements are such that the instrument shall be certified through an approval for use certificate and shall respond to known standards within defined criteria. The initial certifications are performed prior to being used within the state for evidentiary breath testing and if the instrument needs recertification. Approval of the instrument within the state for evidentiary breath testing concurrently approves the manufacturer as the source of the instruments.

3.0 Equipment/Reagents

3.1 Equipment:

- Alco-Sensor III/and IIIa
- Lifeloc FC20/FC20BT with Idaho specific software
- Premixed alcohol simulator solutions in the concentrations of ~0.040, ~0.080 , ~0.100 and ~0.200
- Breath alcohol simulators (Guth models 2100, 12v-500, 34C, MarkIIa, or equivalent)
- Refrigerator capable of temperatures below 10º C
- Incubator capable of maintaining temperature of 35º C
- Label maker with vinyl coated labels or equivalent
- Timer
- Precision plastic screwdriver (Alco-Sensor only)
- Voltmeter
- Dry gas cylinders in the concentrations of 0.040, 0.080, 0.160 and 0.200
- EasyCal® Station and manufacturer's ZOC software

Simulator bottle containing an ~0.100 v/v acetone/water mixture

3.2 Reagents:

3.2.1 Refer to Breath Alcohol Discipline Analytical Method 1.0 for reagent requirements.

3.2.2 Acetone solution: add approximately 2 ml reagent grade or equivalent of acetone to approximately 500 ml of water in a simulator bottle. The amount of acetone should be such that it can be easily detected by odor upon sampling.

3.3 Reference Material: Refer to Breath Alcohol Discipline Analytical Method 1.0

3.3.1 Quantitative Simulator solutions used for certification of instruments should only be used a maximum of 25 times. Qualitative solutions can be changed at the analyst's discretion (see acetone solution description)

3.4 Safety Concerns

Chemicals must be handled according to safety guidelines in the Idaho State Police Forensic Services Health and Safety Manual.

4.0 Procedure

4.1 Certification Process

4.1.1 Lifeloc FC20/FC20BT: Initial Certification (wet bath only)

4.1.1.1 Check the following settings within the menus of the Lifeloc to verify they are correctly set: Military time, date, calibration is set to "wet check", wet check standard is set to 0.080, the subject ID option is set, sequence mode is "on", print format is set to short, printer type is set, the test order is Auto-Manual-Passive, Pass limit is set to 0.000, Fail limit is set to 0.001, display is set to numeric results, Trigger mode is set to "end of breath", battery status is above 90%.

4.1.1.2 On the certification checklist (BrALC Portable Instrument Certification), identify the instrument being evaluated by its serial number, the ownership agency, the date of evaluation, and if the instrument arrived with a printer.

4.1.1.3 Using wet bath breath alcohol simulators, prepare three premixed alcohol simulator solutions for testing. Use the approximate 0.040, 0.080, and 0.200 levels.

4.1.1.3.1 Heat the solutions for approximately 15 minutes to a temperature of 34 ° C (+/- 0.5 °C). The lid of the simulator should feel as warm as the jar of the simulator before proceeding.

4.1.1.3.2 Provide a steady breath through the simulator and analyze a duplicate sample of the solution at each level. The breath should be approximately 4 seconds and should continue through the sampling of the alcohol vapor.

4.1.1.3.3 Acceptance criteria for the samples at each level are +/- 5% of the target value or 0.004 whichever is greater. Duplicate samples need to be within 5% or 0.004 of each other, whichever is greater, in order to be acceptable.

4.1.1.3.3.1 Failure to meet the acceptance criteria may require the instrument to be adjusted in order to pass its initial certification.

4.1.1.3.3.2 Failure at any individual sample/level allows the analyst to abort the certification process and proceed to section 4.3 of this analytical method to adjust the instrument and then attempt the initial certification process again.

4.1.1.3.4 Using the Acetone/Water mixture, take a sample of the vapor from the acetone/water solution. Results must be 0.000 or NEG (if passive mode is used). An "invalid check" response given in the calibration check menu is defined as a result of 0.000.

4.1.1.3.5 Place the instrument in a refrigerator and monitor its temperature periodically. When it reaches below 10º C verify that the instrument will not allow sampling.

4.1.1.3.6 Place the instrument in an incubator and allow it to reach approximately 35º C. Take a sample from the ~0.080 or ~0.200 simulator solution and verify that the instrument does not exceed +/- 5% of the highest initial value reported from 4.1.1.3.

4.1.1.3.6.1 Care should be taken not to overheat the instrument as it may dry out the fuel cell.

4.1.1.3.7 Document all of the testing results on the certification checklist.

4.1.2 Alco-Sensor III: Initial Certification

4.1.2.1 In the event that a new Alco-Sensor III/IIIa needs initial certification, the re-certification protocol shall suffice for its initial certification for use within the state for evidentiary breath testing

4.1.3 Lifeloc FC20/FC20BT: Re-Certification (wet bath only)

4.1.3.1 When an instrument comes into the lab, document on the certification checklist at a minimum (BrALC Portable Instrument Recertification), the identity of the instrument being evaluated by its serial number, the ownership agency, the date of evaluation.

4.1.3.2 Using wet bath alcohol simulators, prepare three premixed alcohol simulator solutions for testing. Use the approximate 0.040, 0.080, and 0.200 levels.

4.1.3.2.1 Heat the solutions for approximately 15 minutes to a temperature of 34 ° C (+/- 0.5 °C). The lid of the simulator should feel as warm as the jar of the simulator before proceeding.

4.1.3.2.2 Provide a steady breath through the simulator and analyze a duplicate sample of the solution at each level. The breath should be approximately 4 seconds and should continue through the sampling of the alcohol vapor.

4.1.3.2.3 Acceptance criteria for the samples at each level are +/- 5% of the target value or 0.004 whichever is greater. Duplicate samples need to be within 5% or 0.004 of each other, whichever is greater, in order to be acceptable.

4.1.3.2.3.1 Failure to meet the acceptance criteria may require the instrument to be adjusted in order to pass its re-certification.

4.1.3.2.3.2 Failure at any individual sample/level allows the analyst to abort the certification process and proceed to section 4.3 to adjust the instrument and then attempt the re-certification process again.

4.1.3.2.4 Using a wet bath simulator filled with the Acetone/Water mixture take a sample of the vapor from the acetone/water solution. Results must be 0.000.

4.1.3.3 At the discretion of the analyst, section 4.1.3.2 may be replaced with a gain check using a ~0.100 level solution and/or adjustment. An example of when this would be applicable would be if the instrument is submitted with a detailed history/log of failed performance verifications.

4.1.3.3.1 Heat the solution for approximately 15 minutes to a temperature of 34 ° C (+/- 0.5 °C). The lid of the simulator should feel as warm as the jar of the simulator before proceeding.

4.1.3.3.2 Using the ZOC program, use the 'set gain' function and take a sample of the 0.100 simulator vapor with the instrument.

4.1.3.3.3 If the instruments gain check returns a value as 'not adjustable', it must be sent back to the agency with a notation in the comment section that the fuel cell needs to be replaced if/when the instrument fails future performance verifications.

NOTE: a non-adjustable gain check does not mean results obtained from the instrument are invalid. A non-adjustable gain check indicates that the fuel cell is nearing the end of its lifecycle and its signal/response ratio is beyond the scope of adjustment.

4.1.3.3.4 If the instrument passes its gain check and adjustment, proceed to section 4.3 to adjust the instrument and then attempt the re-certification process again (section 4.1.3.2 or 4.1.5.3).

4.1.3.3.5 Troubleshooting: The gain check may not pass initially if the fuel cell is dehydrated. At the discretion of the analyst, attempts may be made to rehydrate the fuel cell and the gain check may be attempted again.

4.1.3.3.6 Maintenance: In the event that an instrument is submitted for maintenance and/or maintenance is required that ISP does not perform (eg. Li Ion Battery replacement), the analyst should evaluate the fuel cell performance with a gain check. This should be done on instruments prior to sending the instrument back to the agency with a maintenance recommendation, and that the instrument needs to be sent to Lifeloc Technologies for the required maintenance.

4.1.3.3.7 Documentation: On the worksheet, document that results obtained from the gain check test (wet bath test results). The actual gain setting does not need to be recorded.

4.1.4 ASIII and ASIIIa: Re-Certification

4.1.4.1 When an instrument comes into the lab, document on the certification checklist, the identity of the instrument being evaluated by its serial number, the ownership agency, the date of evaluation, and if the instrument arrived with a printer. 4.1.4.2 Using wet bath alcohol simulators, prepare three premixed alcohol simulator solutions for testing. Use the approximate 0.040, 0.080, and 0.200 levels.

4.1.4.2.1 Heat the solutions for approximately 15 minutes to a temperature of 34 ° C (+/- 0.5 °C). The lid of the simulator should feel as warm as the jar of the simulator before proceeding.

4.1.4.2.2 Provide a steady breath through the simulator and analyze a duplicate sample of the solution at each level. The breath should be approximately 4 seconds and should continue through the sampling of the alcohol vapor.

4.1.4.2.3 Acceptance criteria for the samples at each level are +/- 5% of the target value or 0.004 whichever is greater. Duplicate samples need to be within 5% or 0.004 of each other, whichever is greater, in order to be acceptable.

4.1.4.2.3.1 Failure to meet the acceptance criteria may require the instrument to be adjusted in order to pass its re-certification.

4.1.4.2.3.2 Failure at any individual sample/level allows the analyst to abort the certification process and proceed to section4.3to adjust the instrument and then attempt the re-certification process again.

4.1.4.2.4 Using a wet bath simulator filled with the Acetone/Water mixture take a sample of the vapor from the acetone/water solution. Results must be 0.000.

4.1.4.2.5 Place the instrument in an incubator and allow it to reach approximately 35º C. Take a sample from the ~0.080 or ~0.200 simulator solution and verify that the instrument does not exceed +/- 5% of the highest initial value reported from 4.1.4.2.2. Provide a steady breath instructions

4.1.5 Lifeloc FC20/FC20BT: Initial Certification/Recertification utilizing the EasyCal® station

4.1.5.1 (Initial certification only) Check the following settings within the menus of the Lifeloc to verify they are correctly set: Military time, date, calibration is set to "wet check", wet check standard is set to 0.080, the subject ID option is set, sequence mode is "on", print format is set to short, printer type is set, the test order is Auto-Manual-Passive, Pass limit is set to 0.000, Fail limit is set to 0.001, display is set to numeric results, Trigger mode is set to "end of breath", battery status is above 90%.

Note: when connected to the EasyCal® Station, the unit automatically recognizes and switches the standards being used to "dry gas" so there is no need to manually change it to "dry" from the "wet check" default. The unit automatically switches back to 'Wet check' when detached from the EasyCal®.

4.1.5.2 On the certification checklist (BrALC Portable Instrument Certification/Recertification), identify the instrument being evaluated by its serial number, the ownership agency, the date of evaluation, and if the instrument arrived with a printer.

4.1.5.3 Using the EasyCal® station, prepare the dry gas cylinders for use. Use the approximate 0.040, 0.080, and 0.200 levels.

4.1.5.3.1 The cylinders should be allowed to reach room temperature prior to use.

4.1.5.3.2 Attach the unit to the EasyCal® station and use the performance verification function to check the instrument using the 0.040, 0.080, and 0.200 levels in duplicate.

4.1.5.3.3 Acceptance criteria for the samples at each level are +/- 5% of the target value or 0.004 whichever is greater. Duplicate samples need to be within 5% or 0.004 of each other, whichever is greater, in order to be acceptable.

4.1.5.3.3.1 Failure to meet the acceptance criteria may require the instrument to be adjusted in order to pass its initial certification.

4.1.5.3.3.2 Failure at any individual sample/level allows the analyst to abort the certification process and proceed to section 4.3 to adjust the instrument and then attempt the initial certification process again.

4.1.5.3.4 Using a wet bath simulator filled with the Acetone/Water mixture take a sample of the vapor from the acetone/water solution. Results must be 0.000.

4.1.5.3.5 (Initial certification only) Place the instrument in a refrigerator and monitor its temperature periodically. When it reaches below 10º C verify that the instrument will not allow sampling.

4.1.5.3.6 (Initial certification only) Place the instrument in an incubator and allow it to reach approximately 35º C. Take a sample at the ~0.080 or ~0.200 level and verify that the instrument does not exceed +/- 5% of the highest initial value reported from testing under ambient conditions.

4.1.5.3.6.1 Care should be taken not to overheat the instrument for extended periods of time as it may dry out the fuel cell.

4.1.5.4 Gain Checks: At the discretion of the analyst, section 4.1.5.3 may be replaced with a gain check using a ~0.100 level solution and/or adjustment. An example of when this would be applicable would be if the instrument is submitted with a detailed history/log of failed performance verifications.

4.1.5.4.1 Heat the solution for approximately 15 minutes to a temperature of 34 ° C (+/- 0.5 °C). The lid of the simulator should feel as warm as the jar of the simulator before proceeding.

4.1.5.4.2 Using the ZOC program, use the 'set gain' function and take a sample of the 0.100 simulator vapor with the instrument.

4.1.5.4.3 If the instruments gain check returns a value as 'not adjustable', it must be sent back to the agency with a notation in the comment section that the fuel cell needs to be replaced if/when the instrument fails future performance verifications.

NOTE: a non-adjustable gain check does not mean results obtained from the instrument are invalid. A non-adjustable gain check indicates that the fuel cell is nearing the end of its lifecycle and its signal/response ratio is beyond the scope of adjustment.

4.1.5.4.4 If the instrument passes its gain check and adjustment, proceed to section 4.3 to adjust the instrument and then attempt the re-certification process again (section 4.1.5.3).

4.1.5.4.5 Troubleshooting: The gain check may not pass initially if the fuel cell is dehydrated. At the discretion of the analyst, attempts may be made to rehydrate the fuel cell and the gain check may be attempted again.

4.1.5.4.6 Maintenance: In the event that an instrument is submitted for maintenance and/or maintenance is required that ISP does not perform (eg. Li Ion Battery replacement), the analyst should evaluate the fuel cell performance with a gain check. This should be done on instruments prior to sending the instrument back to the agency with a maintenance recommendation, and that the instrument needs to be sent to Lifeloc Technologies for the required maintenance.

4.1.5.4.7 Documentation: On the worksheet, document that results obtained from the gain check test (wet bath test results). The actual gain setting does not need to be recorded.

4.1.5.5 Using wet bath alcohol simulators, prepare two premixed alcohol simulator solutions for testing. Use the approximate 0.080 and 0.200 levels.

4.1.5.5.1 Heat the solutions for approximately 15 minutes to a temperature of 34 ° C (+/- 0.5 °C). The lid of the simulator should feel as warm as the jar of the simulator before proceeding.

4.1.5.5.2 Provide a steady breath through the simulator and analyze a single sample of the solution at each level. The breath should be approximately 4 seconds and should continue through the sampling of the alcohol vapor.

4.1.5.5.3 Acceptance criteria for the samples at each level are +/- 5% of the target value or 0.004 whichever is greater. Duplicate samples need to be within 5% or 0.004 of each other, whichever is greater, in order to be acceptable.

4.1.5.6 Document all of the testing results and maintenance on the appropriate certification checklist.

4.2 Instrument Acceptance Criteria

4.2.1 Acceptance

4.2.1.1 If the instrument passes all of the requirements for certification, the instrument shall be certified in writing.

4.2.1.2 The instrument shall be sent to the user agency. The laboratory certificate indicating the serial number of the instrument that is being certified for use will be made available online at the ISP website.

4.2.1.2.1 The instrument is fit for use upon the date indicated on the certification paperwork.

4.2.1.2.2 The ASIII/IIIa shall have the label placed over the adjustment screw and covered with tamper evident tape.

4.2.2 Rejection

4.2.2.1 If the instrument fails to pass the certification process, the instrument may be adjusted in the laboratory in order to meet the acceptance criteria.

4.2.2.2 Refer to the instrument adjustment section for instructions on how to adjust each of the instruments.

4.2.2.3 If the instrument is rejected for certification, the agency shall be notified in writing. The instrument may then be sent back to the manufacturer for service and re-evaluated by ISPFS upon completion of the manufacturer service.

4.3 Instrument Adjustment

4.3.1 Procedure using wet bath simulators: Lifeloc FC20/FC20BT

4.3.1.1 Fill a wet bath simulator with ~500 mL of ~0.200 alcohol performance verification solution and allow it to warm for approximately 15 minutes to a temperature of 34 °C (+/- 0.5 °C), until the lid feels as warm as the jar.

4.3.1.1.1 A different lot number of solution should be used for the adjustment process of the instrument.

4.3.1.2 Access the calibration menu option and set the calibration standard to the target value of the solution being used (~0.200).

4.3.1.3 Using a steady breath, take a sample of the alcohol simulator solution vapor to adjust the instrument to the target value of the solution. The breath should continue through the sampling process.

4.3.1.4 Return to the appropriate section to attempt the certification/re-certification process again.

4.3.2 Procedure using wet bath simulators: Alco-Sensor III/IIIa

4.3.2.1 Fill a wet bath simulator with ~500 mL of ~0.080 alcohol performance verification solution and allow it to warm for approximately 15 minutes to a temperature of 34 °C (+/- 0.5 °C), until the lid feels as warm as the jar.

4.3.2.1.1 A different lot number of solution should be used for the adjustment process of the instrument.

4.3.2.2 Remove the protective tamper evident covering to access the instrument adjustment screw for the Alco-Sensor III, or access the instrument adjustment menu for the ASIIIa.

4.3.2.2.1 To access the instrument adjustment menu on the ASIIIa, press and hold the set and read buttons. Release the read button as soon as the temperature is displayed, and press the read button three times quickly. When bLn is displayed, press the read button to take a blank.

4.3.2.3 Using a steady breath, take a sample of the alcohol simulator solution vapor to adjust the instrument to the target value of the solution.

4.3.2.3.1 For the ASIII, upon taking the sample, adjust the instrument to above the target value and then slowly readjust it downward back to the target value as it climbs over the target value. Always adjust downward to the target.

4.3.2.3.2 For the newer ASIIIa, the instrument will auto adjust to the target value and is complete when the display brightens. Adjust the instrument to the target value and press the set button to accept the instrument adjustment.

4.3.2.4 Return to the appropriate section to attempt the certification/re-certification process again.

4.3.3 Procedure using the EasyCal® Station: Lifeloc FC20/FC20BT

4.3.3.1 Install the dry gas cylinder into the EasyCal® station. The level used for adjustment within the lab shall be the 0.160 level.

4.3.3.2 Enter the password protected calibration menu function on the EasyCal® station.

4.3.3.3 Perform a calibration adjustment on the instrument.

4.3.3.4 Return to the appropriate section to attempt the certification/re-certification process again.

4.3.4 Rejection Documentation

4.3.4.1 If the instrument fails its instrument adjustment process, the agency will receive written notice that the instrument in not certifiable and a manufacturer service should be suggested.

4.3.4.2 At the discretion of the scientist, ISPFS may return the instrument to the agency or send the instrument to the manufacturer for service upon documentation and agreement from the instrument owner agency.

4.4 Lifeloc Maintenance and Troubleshooting

4.4.1 The Manufacturer has provided proprietary software for the adjustment of the Lifeloc FC20/FC20BT (ZOC) and the EasyCal® system. Using the ZOC software, the gain of the fuel cell can be adjusted to increase the relative response of the cell. This may be necessary if the cell is getting older or has dried out due to lack of use, or from improper storage conditions. Follow the manufacturer's instruction on how to adjust the fuel cell gain of the fuel cell.

4.4.2 Utilizing the ZOC programming may also be necessary in order to update the instrument software/firmware to current versions. This may be necessary in order to render the unit compatible with the EasyCal® system. Manufacturer's instructions are provided within the software itself and may be obtained by contacting Lifeloc Technologies.

5.0 Work Instructions

5.1 Equipment: ZOC program, ZOC USB, cable and FC20

5.1.1 If you still have version 6.44 on your thumb drive, you will need to load the following files to the thumb drive: FC20Idaho_REV3v6_50 Aug 26 2015.id. Save this file to the thumb drive in the following folder: \Firmware and software updates\FC Rev 3. Delete the existing .id file dated 12-17-2013

5.1.2 FC20Idaho_REV3v6_50 Aug 26 2015.mot. Save this file to the thumb drive in the following folder: \Firmware and software updates\FC Rev 3. Delete the existing .mot file dated 12-17-2013

5.1.3 ReProgram.zrx Save this file to the thumb drive in the following location. Replace the existing "ReProgram.zrx" file.

5.2 Procedure:

5.2.1 FIRST TIME WITH A SPECIFIC COMPUTER

5.2.1.1 Before inserting cable insert memory stick (thumb drive)

5.2.1.2 In the FTDI Driver folder, run *CDM20828_setup.exe* to install cable driver.

5.2.1.3 After cable driver installation is complete, insert programming cable

5.2.1.4 Computer should find cable. You only have to do this the *first time you connect the cable on a new computer.*

5.3.1 CLICK ON *FC_SERVICE.EXE*

5.3.1.1 Power on the FC and make sure "Air Blank" is on the display. Connect to programming cable.

5.3.1.2 In Zoc, click on the *Communication Setup* button.

"Ready for communication".

5.3.1.3 At this point you can check unit temperature or software version by clicking on those buttons to verify communications if you like. It is not required.

- CLICK ON THE *REPROGRAM* BUTTON NOW.

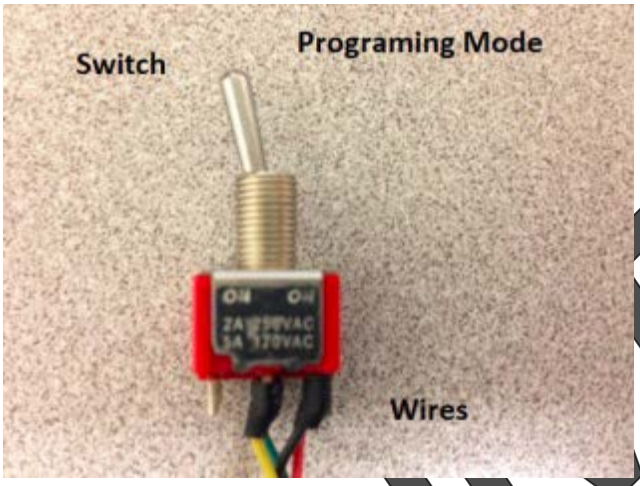
- The Zoc program button will query the unit and verify it can be updated. Then the instruction will be displayed in ZOC.

-Perform steps 1-4.

5.3.1.3.1 IDAHO SOFTWARE FIELD UPDATE INSTRUCTIONS

LIFELOC TECHNOLOGIES

1. Turn off the unit.
2. Flip the cable switch to Program Mode. (Towards the prongs on the bottom)



3. Push power on the unit. The display should remain off.
4. Re-program the unit via instructions below

5.3.1.4 Be sure to select the current programming option in the menu option.

5.3.1.5 Click *Erase and Program*. If an error occurs, remove and replace a battery and try again.

5.3.1.6 Upon completion, a read check will run automatically.

5.3.1.7 When the unit programming is complete you will see the following screen:

-"Program OK"

-click OK

5.3.1.8 Click on Exit and the following instruction will appear in ZOC.

1. Flip the cable switch back to Normal Mode
2. Remove and replace a battery
3. Turn unit on

5.3.1.9 After the unit re-boots it will need to be re-initialized to complete the programming process. Click on OK.

Analytical Method #3: Intoxilyzer 5000 Series Certification

1.0 Background/References

1.1 Background: Idaho Administrative Code, IDAPA 11.03.01 requires that each breath testing instrument have performance verifications on a schedule established by the Idaho State Police Forensic Services Laboratory. Breath testing has been in use within the State of Idaho for several decades dating back to the early 80's. The technology used within the instruments date back even further, and helps to solidify the science of alcohol testing in human expired breath. The approved instruments allow for the non-invasive testing of a subjects breath in a convenient, accurate, precise and timely fashion. This method is advantageous due to the quick and relatively simple methods for performing the test, as well as giving immediate results. The use of breath testing instruments within the state is a valuable tool for conducting criminal investigations for driving under the influence as well as other alcohol related crimes.

1.2 References:

- Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.
- Caplan, Y.H., The Determination of Alcohol in Blood and Breath, Forensic Science Handbook, edited by Richard Saferstein, pp. 594-648, Prentice-Hall New Jersey, 1982.
- Levine, B. and Caplan, Y.H., Alcohol. In: Principles of Forensic Toxicology, edited by Barry Levine, pp. 169-184, AACC Press, 2006.
- Gullberg, R. (2005). Determining the Air/Water Partition Coefficient to Employ when Calibrating Forensic Breath Alcohol Test Instruments. Can. Soc. Forensic Sci. J. , 38 (4), 205-212.
- Idaho Statutes, 18-8004 (4). Title 18, Crimes and Punishments, Chapter 80 Motor Vehicles. Persons under the influence of alcohol, drugs or any other intoxicating substances.
- http://www.legislature.idaho.gov/idstat/Title18/T18CH80SECT18-8004.htm
- Intoxilyzer 5000EN Technical Reference Guide, ©2005 CMI

2.0 Scope

2.1 This method discusses the Idaho State Police Forensic Services (ISPFS) requirements for the approval of Intoxilyzer 5000 series instruments used to perform evidentiary breath testing in the field. The requirements are such that the instrument shall be certified through an approval for use certificate and shall respond to known standards within defined criteria. The initial certifications are performed prior to being used within the state for evidentiary breath testing and if the instrument needs recertification. Approval of the instrument within the state for evidentiary breath testing concurrently approves the manufacturer as the source of the instruments.

3.0 Equipment/Reagents

3.1 Equipment:

- Intoxilyzer 5000 series instrument
- Premixed alcohol simulator solutions in the concentrations of ~0.040, ~0.080 and ~0.200
- A total of 4 breath alcohol simulators (Guth models 2100, 34C, Mark IIa, or equivalent)
- Distilled water or equivalent

3.2 Reagents:

- Refer to Breath Alcohol Discipline Analytical Method 1.0 for reagent requirements.
- Simulator bottle containing an acetone/water mixture
- 3.2.1 Acetone solution: add approximately 2 ml reagent grade or equivalent of acetone to approximately 500 ml of water in a simulator bottle. The amount of acetone should be such that it can be easily detected by odor upon sampling.

3.3 Reference Material:

- Refer to Breath Alcohol Discipline Analytical Method 1.0

3.4 Safety Concerns:

- Chemicals must be handled according to safety guidelines in the *Idaho State Police Forensic Services Health and Safety Manual.*

4.0 Procedure

4.1 Certification Process

4.1.1 Intoxilyzer 5000 series: Certification

Note: In the event that an Intoxilyzer 5000 (model 66) is purchased that has not previously been approved for use in the state of Idaho, the discipline leader shall write a deviation to this procedure to cover the earlier model instrument.

Note: For purposes of ease, the esc esc menu functions will be listed as the capital letter in parentheses for the entirety of this document.

4.1.1.1 On the certification checklist, identify the instrument being evaluated by its serial number, the ownership agency, the date of evaluation, and if the instrument arrived with an external printer.

4.1.1.2 Upon startup, enter the test setup using the (W) menu function and answer the following questions accordingly for the testing of the instrument:

4.1.1.2.1

STD TEST (1-5)	-	2
ABA test?	-	Y
3 digits on?	-	Y
Prelim Results?	-	Y
Data entry?	-	N
Print Inhib?	-	N
Int STD?	-	N
Print Volume?	-	N
Auto Temp CK?	-	Y or N
(depending on simulator capability)		

-Review the setup if needed and save the setup to proceed.

4.1.1.3 Run a diagnostic check (D) and retain the printout for the records. If the instrument passes, continue with the testing.

4.1.1.4 Check the motor speed of the instrument (S) and document the results on the checklist.

4.1.1.5 Access the flow check menu (K) and select option S to print the current flow settings for the instrument.

4.1.1.6 Run a temp check on the instrument sample chamber (U). When prompted with D,P,Q, choose the P option to print the results. Retain the printouts for the records.

4.1.1.7 Run and internal standards check (I). Retain the printouts for the records.

4.1.1.8 Check the software version of the instrument (V). Document the version on the checklist.

4.1.1.9 Enter DVM Mode (H) and monitor the channel noise counts for 5 cycles. Document the noise counts are below 20 on the checklist for each channel. Turn the pump motor on by pressing F3 on the keyboard and monitor the channels for another 5 cycles. The counts should rise, but still be below 20 counts.

4.1.1.10 Enter the simulator solution setup (X) and enter the following values:

Low Reference Value - 0.000

High Reference Value - 0.500

Reset counter? - Y

Solution lot number? - 0

-You will have to enter the lot of solution being used manually on each of the solution check printouts.

4.1.1.11 Run a reference solution check using the approximate reference solution values of 0.040, 0.080 and 0.200. The solutions used should be new bottles of solution. Heat the solutions for approximately 15 minutes to a temperature of 34 ° C (+/- 0.5 °C). The lid of the simulator should feel as warm as the jar of the simulator before proceeding. Sign, date, and enter the solution lot numbers for the solution being used on the printouts and retain the printouts for the records.

4.1.1.12 Run a sample using the simulator containing the acetone solution. Log the results of the test to indicate if the instrument detected acetone as an interferent.

4.1.2 If the instrument passes its certification process, set the reference solution (X) to the current lot of 0.080 reference solution being used in the state. Also, return the instrument to the following settings (user agency may update to their preferences upon return):

STD TEST (1-5)	-	1
Custom test?	-	Y
3 digits on?	-	Y
Prelim Results?	-	Y
Data entry?	-	Y
Print Inhib?	-	N
Int STD?	-	N
Print Volume?	-	N
Auto Temp CK?	-	N

4.1.3 Upon returning the instrument to its custom test setup, run a performance verification check through the breath hose (B). Log the results on the checklist,

4.1.4 Run a simulated subject test using two simulators that differ by more than 0.020 in solution concentration. For the first and second samples, make sure that the results are more than 0.020 apart and then log the results. The instrument should prompt for a third test. Provide the third sample from either solution and log the results.

4.2 Acceptance Criteria

4.2.1 The following are used for the acceptance criteria for certification of the instruments.

4.2.1.1 Diagnostic Check	- Pass all sections
Motor speed:	- 2400 +/- 200 RPM
Flow	- slope is between 10 and 20
Cell Temp Check	- between 45 to 47 °C
Internal STD check	- +/- 5% of targets

DVM channel counts - below 20 counts

Reference Solution checks - +/- 5% of target values

4.2.1.2 If any of the above criteria are not met, the instrument should be adjusted or it may need to be sent back to the agency or manufacturer for repair. See the Instrument Adjustment section for the procedure for adjusting the instrument

4.3 Instrument Adjustment

4.3.1 The following procedure is for adjusting the instrument response to meet the criteria for certification. The adjustment can be repeated at the discretion of the analyst.

4.3.1.1 Enter DVM mode (H) and then press esc esc twice in rapid succession. The selections on the menu should be CH,C,D,I,R, and Q.

4.3.1.1.1 Press '0' to lock channel 0 onto the display. Monitor the channel for 3 minutes to ensure that the voltage counts don't jump more than 2 counts at a time.

4.3.1.1.2 Repeat the above process for the remaining 4 channels.

4.3.1.1.3 Select R from the menu to begin the auto ranging function. When it is complete and begins cycling through the channels again, you can proceed with the adjustment procedure.

4.3.1.2 Enter the menu from 4.3.1.1 again and press T (the T option is hidden so as to not accidentally access the adjustment option of the instrument).

4.3.1.3 Enter the current time, time zone, and date.

4.3.1.4 Enter the number of reference solutions being used (3), and then enter the target values of the solutions being used in g/210L x 1000.

4.3.1.5 When prompted with "Acetone Check Y/N", select N and press enter to proceed. This will deactivate the acetone subtraction feature of the instrument. Select Y when prompted to "Continue".

4.3.1.6 Connect the properly warmed reference solutions to the calibration port when prompted by the instrument. Press the green start button to proceed with the instrument adjustments It should prompt you with the water reference first and then the 0.040, 0.080 and 0.200 solutions.

4.3.1.7 Store the data in the EEPROM.

4.3.1.8 Printout the "auto cal data" by accessing the (H) menu then T, and after cycling through the date and time entries, select '0' for the number of solutions.

4.3.2 Acceptance criteria for a proper adjustment should be as follows:

4.3.2.1 The water subtraction results should indicate the following values:

Channel 1 value of +/- 6.50

Channel 2 value of between 4 and 30

Channel 3 value of +/- 6.5

Channel 4 value of between 10 and 40

4.3.2.2 The curve fit data, which prints after the final reference solution is analyzed, should indicate a curve fit of 0.998 or greater and the standard deviations for the solutions should be less than 3%.

4.3.2.3 If the instrument passes the adjustment and the results are within the acceptance criteria, return to section 4.7 to repeat any of the sections that may have failed the certification process.

4.4 Instrument Documentation

4.4.1 Acceptance Documentation

4.4.1.1 If the instrument passes all of the requirements for certification, the instrument shall be certified in writing. Documentation shall be kept by ISPFS.

4.4.1.2 The instrument shall be sent to the user agency with a copy of the certification checklist and printouts indicating the serial number of the instrument that is being certified for use.

4.4.1.2.1 The instrument is fit for use upon the date indicated on the certification paperwork.

4.4.1.3 The instruments shall have a label placed on them displaying the date that the certification took place and that the instrument has been certified.

4.4.2 Rejection Documentation

4.4.2.1 If the instrument fails its instrument adjustment process, the agency will receive written notice that the instrument in not certifiable and a manufacturer service should be suggested.

4.4.2.2 At the discretion of the scientist, ISPFS may return the instrument to the agency or send the instrument to the manufacturer for service upon documentation and agreement from the instrument owner agency.

Analytical Method #4: EasyCal® Dry Gas System

1.0 Background/References

1.1 Background

Lifeloc Technologies has developed a system to deliver dry gas ethanol standards to their instruments for performance verification and calibration adjustment purposes. This system is the EasyCal® station. It employs dual barometric pressure sensors. The alcohol standard concentration based on the barometric pressure where the unit is located. This system delivers a quantity of precise dry gas ethanol concentration to the unit for the purpose of evaluating its fuel cell response to a specific level of ethanol standard. Much like the currently used wet bath performance verification system, this system will employ certified ethanol standards to comply with the IDAPA guidelines for performance verification in field use. Within the Idaho State Police laboratory, the system will be used in the same manner, but the system will also be employed should the calibration need adjustment. This system can be used in the same manner as the wet bath systems that have been in use for decades.

1.2 References:

- Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.
- Idaho Statutes, 18-8004 (4). Title 18, Crimes and Punishments, Chapter 80 Motor Vehicles. Persons under the influence of alcohol, drugs or any other intoxicating substances.
- http://www.legislature.idaho.gov/idstat/Title18/T18CH80SECT18-8004.htm

2.0 Scope

2.1 This method discusses the Idaho State Police Forensic Services (ISPFS) use and requirements for the use of the EasyCal® stations within the laboratory as well as in the field. The method will discuss the proper initial certification of the units that are to be used in Idaho. It will also discuss the ongoing maintenance and checks necessary to continue the use of the instrument in the lab and in the field.

3.0 Equipment/Reagents

3.1 Equipment: EasyCal® unit

- Currently approved or previously approved software version installed in the unit
- Dry gas cylinders provided by an ISO 17025 accredited laboratory/supplier
- Calibrated and certified barometer (1 mbar resolution, within +/- 5 mbar accuracy)

3.2 Reagents:

- Refer to Breath Alcohol Discipline Analytical Method 1.0 "Premixed alcohol simulator solutions" for reagent requirements.
- Dry gas cylinders provided by an ISO 17025 accredited laboratory/supplier in the concentrations of 0.040, 0.080, 0.160 and 0.200.

3.3 Reference Material:

- Refer to Breath Alcohol Discipline Analytical Method 1.0 "Premixed alcohol simulator solutions"

3.4 Safety Concerns

- Chemicals must be handled according to safety guidelines in the *Idaho State Police Forensic Services Health and Safety Manual.*

4.0 Procedure

4.1 Certification Process

4.1.1 EasyCal®: Initial Certification

Check the unit to verify that the most current version of the software is installed in the unit. Check that the date and time are correctly set. Check to ensure that the calibration menu is password protected.

4.1.1.1 Using a calibrated and traceable barometer, verify that the dual barometers are both within +/- 10 mBar or the barometric pressure indicated by the calibrated and certified barometer.

4.1.1.1.1 If the barometers are not both within 10mBar of the indicated pressure, reset them using the manufacturer provided ZOC software.

4.1.1.2 Using a dry gas cylinder of 0.080, check the delivery of the gas to a calibrated lifeloc FC20 or FC20BT unit. The results are acceptable if within 10% of the target value. This is a check of the plumbing of the EasyCal® station. If the check fails, troubleshooting should be employed to determine if the lifeloc unit used was properly calibrated, or if there is a leak in the plumbing with the EasyCal® unit.

4.1.1.3 Document all of the testing results on the certification checklist.

4.1.2 EasyCal®: Re-Certification

4.1.2.1 The EasyCal® stations shall be checked and recertified by approved personnel from the ISP forensic services laboratory at least once per calendar year. Instruments expire at midnight on the last day of the year following the scheduled maintenance. A sticker should be placed on the unit indicating the expiration date of the certification.

4.1.2.2 The re-certification check may be done within the laboratory, or on site at the owner agency of the EasyCal® unit.

4.1.2.3 The re-certification check will consist of the following:

4.1.2.3.1 Using a calibrated and traceable barometer, verify that the dual barometers are both within 10 mBar or the barometric pressure indicated by the calibrated and certified barometer. +/- 5 mbar will serve as the warning level for the barometric pressure measurement.

4.1.2.3.1.1 If the Barometers are not both within 10mBar of the indicated pressure, reset them using the manufacturer provided ZOC software.

4.1.2.3.1.2 It is the analysts' discretion to reset the barometers if they are within the acceptance criteria.

4.2 Rejection Documentation

4.2.1 Failure

Should the EasyCal® unit fail the certification and is unable to be repaired/fixed/adjusted so as to be compliant within the specifications of the method, the owning agency will be notified.

4.2.1.1 The unit will be sent back to the agency so that it may be sent to the manufacturer for maintenance.

4.2.1.2 After factory maintenance, the unit must be certified by the ISP laboratory prior to being used in the field.

5.0 Work Instructions

5.1 Cal Station ZOC instructions – password and barometer adjustment

5.1.1 Supplies: Zoc program USB drive, Female serial to female serial connection cable, US male to male serial connection cable.

5.2.1 Procedure:

5.2.1.1 Plug in the ZOC USB drive to the computer/laptop being used for the update

5.2.1.2 Connect the usb-serial cable, and the serial-serial cables and connect the computer to the cal station

5.2.1.3 Open the USB drive and run the CalStation_Service ZOC program

5.2.1.4 Power on the cal station

5.2.1.5 In the cal station, go into settings -> advanced

5.2.1.6 In the ZOC program, press the cal station connect button

5.2.1.7 The ZOC will prompt to put the cal station into testing mode

5.2.1.1 To enter testing mode, you need to double tap the screen in the upper right corner. Scroll down to press the testing button

5.2.1.8 Click 'OK' in the ZOC

5.2.1.9 Once connected, you can change the password, or the barometric pressure setting in the cal stations.

5.2.1.10 To end the session, get out of the testing mode in the cal station and return to the home screen

NOTE: If you unplug the station before exiting testing mode, the station can/will lock up

5.2.1.11 Once the cal station is at the home screen and no longer in testing mode, you can power off the station and exit the ZOC program or connect another cal station.

5.1 EasyCal Software Upgrade Procedure:

5.1.1 Procedure:

5.1.1.1 Download and unzip the file saved at I:Alcohol/Breath/EasyCal Software Upgrade/calibration_station.zip.

5.1.1.2 Also move the following file to the same USB. I:Alcohol/Breath/EasyCal Software Upgrade/init.

5.1.1.3 Insert the USB device into the EASYCAL USB port.

5.1.1.4 The EASYCAL may ask users if they would like to copy print log from the unit.

5.1.1.5 If it does, Click No.

5.1.1.6 The EASYCAL will then ask users if they are sure they want to load calibration_station software on the unit.

5.1.1.7 The EASYCAL will then ask users if they are sure they want to load calibration_station software on the unit.

5.1.1.8 Click Yes.

5.1.1.9 The system will automatically upload the software.

5.1.1.10 The system will then ask users if they would like to copy Tech Log from the unit.

5.1.1.11 Click No.

5.1.1.12 The system will notify users that it is safe to unplug the USB device now.

5.1.1.13 Go ahead and remove the USB device.

5.1.1.14 Once complete users will need to restart the EASYCAL for the changes to take effect.

5.1.1.15 After restarting, go to "Settings" and "About".

5.1.1.16 Ensure software is the most current approved version.

5.1.1.17 The process is now complete.

Analytical Method #5: Draeger 9510 Series Certification

1.0 Background/References

1.1 Background

Idaho Administrative Code, IDAPA 11.03.01 requires that each breath testing instrument have performance verifications on a schedule established by the Idaho State Police Forensic Services Laboratory. Breath testing has been in use within the State of Idaho for several decades dating back to the early 80's. The technology used within the instruments dates back even further, and helps to solidify the science of alcohol testing in human expired breath. The approved instruments allow for the non-invasive testing of a subject's breath in a convenient, accurate, precise, and timely fashion. This method is advantageous due to the quick and relatively simple methods for performing the test, as well as giving immediate results. The use of breath testing instruments within the state is a valuable tool for conducting criminal investigations for driving under the influence as well as other alcohol-related crimes.

1.2 References:

1.2.1 Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.

1.2.2 Caplan, Y.H., The Determination of Alcohol in Blood and Breath, Forensic Science Handbook, edited by Richard Saferstein, pp. 594-648, Prentice-Hall New Jersey, 1982.

1.2.3 Levine, B. and Caplan, Y.H., Alcohol. In: Principles of Forensic Toxicology, edited by Barry Levine, pp. 169-184, AACC Press, 2006.

1.2.4 Gullberg, R. (2005). Determining the Air/Water Partition Coefficient to Employ when Calibrating Forensic Breath Alcohol Test Instruments. Can. Soc. Forensic Sci. J. , 38 (4), 205-212.

1.2.5 Idaho Statutes, 18-8004 (4). Title 18, Crimes and Punishments, Chapter 80 Motor Vehicles. Persons under the influence of alcohol, drugs or any other intoxicating substances.

1.2.6 http://www.legislature.idaho.gov/idstat/Title18/T18CH80SECT18-8004.htm

1.2.7 Draeger Diagnostics Technical Reference Guide, ©2016 Draeger Diagnostics.

2.0 Scope

2.1 This method discusses the Idaho State Police Forensic Services (ISPFS) requirements for the approval of Draeger 9510 series instruments used to perform evidentiary breath testing in the field. The requirements are such that the instrument shall be certified through an approval for use certificate and shall respond to known standards within defined criteria. The initial certifications are performed prior to being used within the state for evidentiary breath testing and if the instrument needs recertification. Approval of the instrument within the state for evidentiary breath testing concurrently approves the manufacturer as the source of the instruments.

3.0 Equipment/Reagents

3.1 Equipment

3.1.1 Draeger 9510 series instrument

3.1.2 Traceable calibrated barometer (1 mBar resolution, +/- 5 mBar accuracy)

3.1.3 A total of 4 breath alcohol simulators (Guth models 2100, 34C, MarkIIa, or equivalent)

3.2 Reagents:

3.2.1 Distilled water or equivalent

3.2.2 Simulator bottle containing a methanol/water mixture

3.2.2.1 Methanol solution: add approximately 0.5 ml of methanol to approximately 500 ml of water in a simulator bottle. The amount of methanol should be such that it can be easily detected by odor upon sampling.

3.3 Reference Material:

3.3.1 Refer to Breath Alcohol Discipline Analytical Method 1.0

3.3.2 Dry gas ethanol standards in the concentrations of ~0.040, ~0.080, 0.100, 0.160 and ~0.200

3.3.3 Premixed alcohol simulator solutions in the concentrations of ~0.080, 0.100, ~0.200, and ~0.400.

3.4 Safety Concerns

3.4.1 Pressurized gasses should be stored so as to prevent damage and rupture

3.4.2Chemicals must be handled according to safety guidelines in the *Idaho State Police Forensic Services Health and Safety Manual.*

4.0 Procedure

4.1 Certification Process

4.1.1 Draeger 9510 series: Initial Certification

4.1.1.1 On the certification checklist, identify the instrument being evaluated by its serial number, the ownership agency, and the date of evaluation.

4.1.1.2 Upon startup, verify that the instrument has the most current approved version of software installed. Document the results on the checklist and retain the current version software printout.

4.1.1.3 Run an instrument self-test. Document that the instrument has passed its memory check, voltage check, temperature check, pressure flow check and EC-sensor check on the checklist. Retain the self-test printout.

4.1.1.4 Check to ensure that the following parameters are set:

4.1.1.4.1 Date and time

4.1.1.4.2 Monthly Performance Verification (PV) is set for the first Tuesday of the month. The day of the monthly performance verification can be set for a different day, upon agency request, and determined on an 'as needed' basis.

4.1.1.4.3 Using a random number generator, set the time of the monthly automatic 0.200 PV to between 5:00am and 5:30 am. This is to stagger the data transmission to the database to avoid any bottlenecks. Document the time on the checklist. The time of the monthly performance verification can be set for a different time, upon agency request and determined on an 'as needed' basis.

4.1.1.4.4 Document the values for the following on the checklist: Adsorption, Calgas Inlet Drygas %, IR Slope Multiplier, EC Quadratic Correction Factor, EC Drygas Offset %, Cal Factor EC and IR.

4.1.1.4.5 Document all of the results on the checklist.

4.1.1.5 In the Control Mode menu option, select standby 2 to set the standby parameters to reduce the cuvette temperature and turn the IR, hose and Bluetooth off. The cuvette reduction temperature should be set at 30 degrees C or below. Document on the checklist that Standby 2 was set.

4.1.1.6 Using the Ambient Pressure Correction menu function, check the current ambient pressure using a traceable calibrated barometer. Document the results on the checklist.

4.1.1.7 Run a reference standard check using the approximate dry gas standard values of 0.040, 0.080 and 0.200. Enter the lot numbers for the standard being used on the printouts and retain the printouts for the records. Document the results on the checklist.

4.1.1.7.1 If the instrument fails any of the checks during any portion of the certification process, the analyst can abort the certification process and proceed to the adjustment of the instrument.

4.1.1.8 Run a wet bath reference standard check using the approximate reference solution values of 0.080 and 0.200. Enter the lot numbers for the standard being used on the printouts and retain the printouts for the records. Document the results on the checklist

4.1.1.9 Run a sample using the simulator containing the methanol solution. Log the results of the test to indicate if the instrument detected methanol as an interferent. This test should be run through the evidential testing sequence. Document the results on the checklist and retain the printouts.

4.1.1.10 Run a simulated subject test using two simulators that differ by more than 0.020 in solution concentration. For the first and second samples, make sure that the results are more than 0.020 apart and then log the results. The instrument should prompt for a third test. Provide the third sample from either solution and log the results. Document the results on the checklist and retain the printouts.

4.1.1.10.1 It is acceptable to use one simulator containing more than 0.020 alcohol solution and the second sample from alcohol free breath from the analyst.

4.1.1.11 Optional Leak Test: Upon completion of the initial analytical certification of the Draeger 9510, the unit should be connected to pressurized cylinders and left to sit for a period of time. During that time, any pressure drops should be noted. Pressure drops of more that 2-3 pound of pressure overnight may be indicative of a leak within the Dry Gas Enclosure (DGE) or within the unit itself.

4.1.1.11.1 If a leak is detected within the unit, an attempt should be made to isolate the source of the leak to either the 9510 unit or the DGE. The corresponding part (or whole instrument) should be sent back to Draeger Diagnostics for repair.

4.1.2 Draeger 9510 series: Re-Certification

Recertification is only necessary if the instrument fails its periodic performance verification checks.

4.1.2.1 On the certification checklist, identify the instrument being evaluated by its serial number, the ownership agency, and the date of evaluation.

4.1.2.2 Upon startup, verify that the instrument has the most current approved version of software installed. Document the results on the checklist and retain the current version software printout.

4.1.2.3 Run an instrument self-test. Document that the instrument has passed its memory check, voltage check, temperature check, pressure flow check and EC-sensor check on the checklist. Retain the self-test printout.

4.1.2.4 Check to ensure that the following parameters are set:

4.1.2.4.1 Date and time

4.1.2.4.2 Monthly Performance Verification (PV) is set for the first Tuesday of the month

4.1.2.4.3 Using a random number generator, set the time of the monthly automatic 0.200 PV to between 5:00am and 5:30 am. This is to stagger the data transmission to the database to avoid any bottlenecks. Document the time on the checklist.

4.1.2.4.4 Document the values for the following on the checklist: Adsorption, Calgas Inlet Drygas %, IR Slope Multiplier, EC Quadratic Correction Factor, EC Drygas Offset %, Cal Factor EC and IR.

4.1.2.4.5 Document all of the results on the checklist.

4.1.2.5 In the Control Mode menu option, verify that standby 2 is selected. Document the results on the checklist.

4.1.2.6 Using the Ambient Pressure Correction menu function, check the current ambient pressure using a traceable calibrated barometer. Document the results on the checklist.

4.1.2.7 Run a reference standard check using the approximate dry gas standard values of 0.040, 0.080 and 0.200. If at any point during the evaluation, any of the checks fall outside of the acceptance criteria, it is at the analyst discretion to proceed to instrument adjustment. Enter the lot numbers for the standard being used on the printouts and retain the printouts for the records. Document the results on the checklist.

4.1.2.7.1 If the instrument fails any of the checks during any portion of the re-certification process, the analyst can abort the re-certification process and proceed to the adjustment of the instrument.

4.1.2.8 Run a wet bath reference standard check using the approximate reference solution values of 0.080 and 0.200. If at any point during the evaluation, any of the checks fall outside of the acceptance criteria, it is at the analyst discretion to proceed to instrument adjustment. Enter the lot numbers for the standard being used on the printouts and retain the printouts for the records. Document the results on the checklist.

4.1.2.9 Run a sample using the simulator containing the methanol solution. Log the results of the test to indicate if the instrument detected methanol as an interferent. This test should be run through the evidential testing sequence. Document the results on the checklist and retain the printouts.

4.1.2.10 Run a simulated subject test using two simulators that differ by more than 0.020 in solution concentration. For the first and second samples, make sure that the results are more than 0.020 apart and then log the results. The instrument should prompt for a third test. Provide the third sample from either solution and log the results. Document the results on the checklist and retain the printouts.

4.1.2.10.1 It is acceptable to use one simulator containing more than 0.020 alcohol solution and the second sample from alcohol free breath from the analyst.

4.2 Draeger 9510 series: Scheduled maintenance

4.2.1 These checks will be performed on a per calendar year basis.

4.2.2Using the Ambient Pressure correction menu function, check the current ambient pressure using a traceable calibrated barometer. Document the results on the checklist and/or spreadsheet.

4.2.3 The instrument should have a label placed on it indicating the date of the scheduled maintenance, and its expiration date. Instruments expire at midnight on the last day of the year following the scheduled maintenance.

4.2.4 NOTE: Example: Scheduled maintenance performed at any time during the year 2016, has a corresponding instrument expiration date of December 31st, 2017.

4.3 Acceptance Criteria

4.3.1 The following are used for the acceptance criteria for certification of the instrument.

4.3.1.1 Self-Test	- Pass all sections
Reference checks	- +/- 5% of target values (or 0.004 whichever is greater)
Methanol solution	-flagged as interferrent
Ambient Pressure	- +/- 10 mBar

4.3.1.2 If any of the above criteria are not met, the instrument should be adjusted or it may need to be sent back to the agency to send to the manufacturer for repairs. The lab may elect to ship directly to the manufacturer on behalf of the agency. . See the Instrument Adjustment section for the procedure for adjusting the instrument.

4.4 Instrument Adjustment

4.4.1 The following procedure is for adjusting the instrument response to meet the criteria for certification. The adjustment can be repeated at the discretion of the analyst.

4.4.1.1The instrument may be adjusted at the discretion of the analyst:

-utilizing the calibration procedure through the menu options of the instrument and a 0.160 dry gas standard.

-by using a 0.100 wet bath standard and the auto adjustment procedure through the menu options of the instrument.

-By running a 0.100 wet bath standard and manual adjustment by adjusting the EC/IR cal factors.

4.4.1.2 Upon completion of an adjustment, run a reference standard check using the approximate wet bath standard value of 0.080. Enter the lot number for the standard being used on the checklist.

4.4.1.2.1 If needed, utilizing the adjustment matrix from section 4.6, adjust the EC results to match those of the IR results, and once the results are paired, match the paired results to the target value of the standard. Document the results on the checklist and retain the printouts for the records. Return to section 4.4.1.2.

4.4.1.3 Run a dry gas reference standard check using the approximate reference solution values of 0.080. Enter the lot numbers for the standard being used on the checklist.

4.4.1.3.1 If needed, utilizing the adjustment matrix from section 4.6, adjust the EC results to match those of the IR results, and once the results are paired, match the paired results to the target value of the standard. Document the results on the checklist and retain the printouts for the records. Return to section 4.4.1.2 if an adjustment is made.4.4.1.4 Run a reference standard check using the approximate wet bath standard value of 0.200. Enter the lot number for the standard being used on the printouts.

4.4.1.4.1 If the results do not match within specifications, adjust utilizing the adjustment guide or adjust the linearity of the instrument with a ~0.400 wet bath solution and the Draeger provided linearity program. Return to section 4.4.1.2 if an adjustment is made.

4.4.1.4.1.1 If a linearity adjustment is made with the ~0.400 wet bath standard, wait ~30 minutes before performing more checks and ~3 hours before performing the adjustments detailed in 4.4.1.1.

4.4.1.5 Run a dry gas reference standard check using the approximate reference solution values of 0.200. Enter the lot numbers for the standard being used on the checklist.

4.4.1.5.1 If needed, adjust the EC results to match those of the IR results, and once the results are paired, match the paired results to the target value of the standard. Document the results on the checklist and retain the printouts for the records. Return to section 4.4.1.2 if an adjustment is made.

4.4.1.5 Once the results are satisfactory for both the wet and dry standards at the 0.080 and 0.200 levels, the analyst can return to sections 4.1.1/4.1.2 to resume the certification/recertification process.

4.4.1.6 Manual Adjustments: At the discretion of the analyst, other adjustments may be performed on the instrument in conjunction with the calibration procedure.

4.4.1.6.1 Other calibration menu functions not mentioned may be adjusted on an as needed basis upon direction through Draeger diagnostics technical support. Document on the checklist if any other adjustments were performed.

4.4.1.6.2 Wet bath solutions may be used to perform adjustments on the instruments in lieu of dry gas standards.

4.4.1.6.3 Manual adjustments include, but are not limited to, adjustments of the Adsorption, Calgas Inlet Drygas %, IR Slope Multiplier, EC Quadratic Correction Factor, EC Drygas Offset %, Cal Factor EC and IR. Document the final values of any adjusted parameter on the checklist.

4.5 Instrument Documentation

4.5.1 Acceptance Documentation

4.5.1.1 If the instrument passes all of the requirements for certification, the instrument shall be certified in writing. Documentation shall be kept by ISPFS in hard copy and/or electronic copy format.

4.5.1.2 The instrument shall be sent to the user agency with a copy of the certification paperwork indicating the serial number of the instrument that is being certified for use.

4.5.1.2.1 If the instrument is tracked and documented via the online laboratory evidence tracking system, sending a hard copy of the data along with the instrument is optional.

4.5.1.3 The instruments should have a label placed on them displaying the date that the certification took place and that the instrument has been certified.

4.5.2 Rejection Documentation

4.5.2.1 If the instrument fails its instrument adjustment process, the agency will receive written notice that the instrument in not certifiable and a manufacturer service should be suggested.

4.5.2.2 At the discretion of the scientist, ISPFS may return the instrument to the agency or send the instrument to the manufacturer for service. Sending the instrument for service on behalf of the agency requires documentation and agreement from the instrument owner agency.

4.6 Maintenance Tasks

4.6.1 Definition and documentation: Activities that are undertaken outside of the complete calibration protocol are considered to be maintenance tasks and can be recorded on a maintenance task sheet and attached to the instrument record within the electronic file system. These activities include, but are not limited to: Barometer checks, field performance verification checks, instrument setup and checks, software updates, configuration file updates, firmware updates, WinCE updates.

4.6 Adjustment Guide

		wet	wet	dry	dry		
Type of adjustment:	**Relation**	**ir**	**ec**	**ir**	**ec**	**low**	**high**
Adsorption	Direct	X	X			X	X
Calgas Inlet drygas %	Direct			X	X	X	X
IR Slope Multiplier	Inverse	X		X		X	XXX
EC quadratic correction factor	Direct		X		X	X	XXX
EC drygas Offset %	Direct				X	X	X
Cal Factor EC	Direct		X		X	X	X
Cal Factor IR	Direct	X		X		X	X

*The EC quadratic and IR slope multiplier effect the high end more than the low end.

5.0 Work instructions:

5.1 Procedure:

5.1.1 Select 'About' from the instrument menu and print the instrument identification.

5.1.2 Run a selftest and print the results.

5.1.3 Start with an assessment of 0.080 Wet bath:

5.1.3.1 if the results match move on.

5.1.3.2 If the results do not match, then adjust the instruments accuracy using either manual adjustment to the EC/IR cal factors after running a sample with the 0.100 wet bath standard, the auto adjust with 0.100 wet bath solution, or using the 0.160 dry gas calibration procedure.

5.1.3.3 Repeat this process until the 0.080 wet bath results are satisfactory.

5.1.4 Check the instruments response with 0.080 dry gas.

5.1.4.1 if the results match move on.

5.1.4.2 if the results do not match, adjust the EC to match the IR results using the EC drygas offset %, then move the pair of results to match the target value as a pair using the Calgas Inlet Drygas % (do this even if the EC results are dead on accurate with the target value and the IR results are the only value needing adjustment).

5.1.5 Check the instrument with 0.200 wet bath and dry gas.

5.1.5.1 if the results match move on.

5.1.5.2 if the results are not linear, adjust the linearity of the instrument utilizing the 0.400 wet bath solution and the draeger linearity program. Rerun the 0.200 solution and assess the results. At the discretion of the analyst, the linearity adjustment may be repeated.

5.1.5.3 If the results need further adjustment, assess the average result and split the difference between the results and the target value.

5.1.6 Check the instrument with 0.040 dry gas.

5.1.6.1 if the results match move on.

5.1.6.2 The results should not be out of specs at this point in the assessment. If they are out of specs, you should consult with Draeger for technical support.

5.1.7 Check the instrument with a training test using 0.100 v/v solution of methanol.

5.1.7.1 the instrument should flag an interferent.

5.1.8 Check the instrument with blank breath and the 0.040 wet bath solution to see if the instrument prompts for the third test if the first 2 are outside the 0.020 correlation.

5.1.8.1 Document the results on the checklist.

5.1.9 Connect the unit to two pressurized cylinders and document the initial pressure after stabilization. Let the unit sit overnight (minimum of 6 hours) and document that pressure drop, if any, as well as the start and end time of monitoring.

5.1.10 NOTE:

-keep in mind that the instrument can fatigue if you run too many samples in a short period of time. Wait ~30 minutes to perform more checks after the linearity adjustment is complete. Wait ~3 hours before performing any adjustments after the linearity adjustment is complete.

-If you adjust a parameter during the assessment process, you will need to retest at previous levels after all adjustments have been completed.

-The first few samples through a new instrument may be low due to priming the lines and the analytical components of the instrument. This is normal, do not try and adjust from these low results.

-If you are having difficulty and seem like you are chasing the calibration, try starting over from the initial adjustment. Sometimes a simple issue at the start can lead to issues that propagate throughout the calibration.

Analytical Method #6: Competency and Proficiency

1.0 Background/References

1.1 In accordance with the *Volatiles Analysis Training Plan,* a trainee will complete a competency test consisting of calibrating instruments currently in use within the state. Thereafter, the analyst will only be required to maintain proficiency through the completion of minimum casework requirements within the laboratory.

2.0Scope

2.1 This method describes the criteria to be applied to the evaluation of results obtained for both competency and proficiency testing for instrument calibration.

3.0Equipment/Reagents

3.1None Applicable to this Analytical Method Specifically

4.0Procedure

4.1 Competency Tests

4.1.1 The competency test will consist of instruments currently in approved for use within that State of Idaho.

4.1.2 The acceptable results are determined by the reanalysis (verification) of the instrument by another competent analyst.

4.1.3 Reported values must fall within ±5% of the target value of the standards used for verification of the calibration.

4.1.4 If value(s) reported do not fall within the allowable range, calibration and adjustment procedures will be reviewed and additional training may be required as deemed appropriate by the Discipline Leader. The analyst will be required to perform an additional competency test.

4.2 Proficiency Tests

4.2.1 A breath alcohol proficiency test can be ordered through an approved vendor (if available). *Currently there are no approved proficiency test providers available for breath testing instruments/calibration.*

4.2.1.9 If the value reported does not fall within the allowable range, analysis procedures will be reviewed and additional training may be required as deemed appropriate by the Discipline Leader. The analyst will be required to perform a competency test prior to resuming casework.

4.4 Maintaining Proficiency:

4.4.1 In order to maintain proficiency within the breath testing discipline, and analyst with less than five years of experience must complete a minimum of 24 instrument calibrations throughout the calendar year. This is independent of instrument type, but it is recommended that at least one of the calibrations be a benchtop unit if available.

4.4.2 The criteria set forth in 4.4.2 can be substituted with case reviews at a rate of 5 calibration case reviews per instrument not analyzed.