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.
7	No changes
8	AM#1 changes to 4.1.2.3. AM#2 changes to 3.1, 4.1.5.2. Added section 4.1.5.3.1.1. AM#4 changes to 3.1, 4.1.2.3.3.1, 4.1.2.3.3.2, 4.2.1.2. Added sections 4.1.2.3.1-2. AM#5 changes to 3.1, 4.2.3. Added 4.2.2, deleted 4.5.1.3. ASIII and Intox sections marked as Obsolete –deleted @ next revision
9	Changed Title of AM#1, Replaced AM#2 and AM #5 with Calibration methods, AM#3 removed *(obsolete)* remaining methods renumbered. Added new AM #6 Added new AM #7
10	AM #2 Added sections 4.1.5 and 4.6.7.1. Changes to 4.3.1.2, 4.4.1.2, 4.4.2, 4.6.1, and 4.6.2. AM #3 Changes made to section 4.1.1.2 and 4.1.2.3.3. AM #4 Changes made to section 4.1.7. Clarified the location for documentation of data.

Revision History

Revision #	Description of Changes
11	AM#2 added section 2.2.1, 4.2.1, 4.3.1.3, 4.3.3, 4.4.2.1, 4.6.5.3, 4.6.5.4, Changes to 3.1.7.2, 4.1.4, 4.1.5.1, 4.3.1, AM#3 added 4.1.2.1.1, AM#4 added 2.2.1, 4.1.2, 4.4.6, 4.6, changes to 4.9.3, 4.9.4, AM#5 added 4.3.3, changes to 4.2.1
12	AM#2 Edited/added section 4.1.1, 4.1.5, 4.2.2, 4.2.5, 4.4.1.3, 4.5.2, 4.6.5.1, and 4.6.5.4.1. Deleted sections 4.1.3 and 4.10.4.1-4. AM#4 Edited/added section 4.1.2.4, 4.4.1.1, 4.7.1, 4.8.1, and 4.9.1. Deleted section 4.1.4. AM#7 edited section 1.1
13	Changes made to AM#1 4.1.1.4, 4.1.2.3, 4.2.1.1, 4.4.1.1, AM#2 2.2.2, 4.3.1.4, 4.6.5.3, 4.6.5.4, 4.6.6, 4.6.10, AM3# 4.1.1.1.1, AM#4 3.3.3.1, 4.10.5, 4.10.9, and AM#5 1.1. AM#5 4.3 was removed

Analytical Method #1: Simulator Solution Requirements

1.0 Background/References

1.1 Background:

1.1.1 The Idaho Administrative Procedure Act, 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. In accordance with IDAPA 11.03.01 and the definition of 'Standards', premixed alcohol simulator solutions provided by ISO 17025:2005, ISO 17025:2017, 17034 certified providers (or equivalent standard) are explicitly approved by the department for use in Idaho without evaluation by the department.

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.
- https://adminrules.idaho.gov/rules/current/11/110301.pdf

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. Premixed alcohol simulator solutions purchased from a manufacturer that is certified to the ISO 17025:2005, 17025:2017, or 17034 (or equivalent) standards need not be independently verified by ISP Forensic Services and are not subject to the authentication processes contained within this method.

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

3.2.1 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 be sealed to ensure the product has not been tampered with prior to its use. Freezing to the point of breaking the seal compromises the integrity of the solution; therefore, bottles of solution should 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).

3.2.2 Certified Reference Materials (CRM) utilized for quantitative purposes shall be sourced from providers certified to the ISO 17025:2005, ISO 17025:2017, or ISO 17034 standard (or equivalent) within the scope of their accreditation for the production of calibration reference materials.

3.3 Reference Materials:

- Refer to Blood Alcohol Discipline Analytical Method 1.0

3.4 Safety Concerns

3.4.1 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 requirement.

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.

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

4.1.1.4 The supplier shall provide to ISPFS a random sampling of each new lot (manufactured batch) consisting of two (2) 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 1.21 and 1.23. The results 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, 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 will be used to determine an overall 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 1.21 and 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 supplier's 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 Simulator Solution Use

4.4.1 Quantitative Simulator solutions used for certification of instruments should only be used for a maximum of 25 total samples.

4.4.1.1 A sample consists of a single blow through the simulator that provides a result on the instrument's detector(s).

4.4.2 Qualitative solutions may be sourced from non-certified providers and do not need to be authenticated prior to use.

4.4.3 Qualitative solutions can be changed at the analyst's discretion.

4.5 Vendor Approval

4.5.1 Vendor Approval: In conformity with IDAPA 11.03.01.013.01 the vendor approval process will be as follows (for vendors not certified to the ISO 17025/17034 (or equivalent) standard)-

4.5.1.1 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.

4.5.1.2 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.

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

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

4.5.1.5 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.

4.5.1.6 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.

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

Analytical Method #2: FC20/FC20BT Instrument Calibration

1.0 Background/References

1.1 Background:

1.1.1 Idaho Administrative Code, IDAPA 11.03.01 requires that each breath testing instrument have performance verifications and calibrations 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 portable instruments allow for the time sensitive 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 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

- https://www.lifeloc.com/download/userManualFC20BT.pdf
- https://www.lifeloc.com/download/userManualFC20.pdf
- EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (EPA 600/R-12/531)
- CGA - C-7 -Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers

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 a calibration 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.

2.2 It is the recommendation of ISPFS that the Portable Testing Instruments be recalibrated on a regularly scheduled basis. This schedule is a laboratory recommendation, and the calibration interval shall be set in IDAPA 11.03.01 by administrative rule.

2.2.1 Instruments that are utilized for screening purposes and not utilized for quantitative evidentiary purposes, need not adhere to the calibration schedule recommendations as set forth in this method.

2.2.2 Instruments calibrated using this method shall remain calibrated until the expiration date as indicated on their most recent certification issued by the Idaho State Police Forensic Services Laboratory.

2.3 ISPFS will monitor the calibration frequency for trends to identify if the calibration interval is appropriate or should be adjusted.

3.0 Equipment/Reagents

3.1 Equipment:

3.1.1 Lifeloc FC20/FC20BT with Idaho specific software

3.1.2 Breath alcohol simulators (Guth models 2100, 12v-500 or equivalent)

3.1.3 Refrigerator

3.1.4 Incubator

3.1.5 Label maker with vinyl coated labels or equivalent

3.1.6 EasyCal® Station and manufacturer's ZOC software

3.1.7 Traceable calibrated barometer (1 mBar readability, ±5 mBar accuracy)

3.1.7.1 Barometers: Traceable calibrated barometers are required to be calibrated by an authorized and qualified vendor or replaced prior to their expiration date. Expired barometers shall be labeled as expired and shall not be used for calibration and certification purposes.

3.1.7.2 Barometers with a 2-year certification should be acquired in a staggered yearly format (one per year). Each barometer will have its barometric pressure monitored and recorded on dates in which the instrument is used from the date of acquisition until its certification has expired. Comparison versus the other/new barometers will ensure continued accuracy throughout the lifecycle of the use of all barometers.

3.2 Certified Reference Material (CRM):

3.2.1 Dry gas ethanol standards in the target concentrations of 0.040, 0.080, 0.160 and 0.200 g/210L.

3.2.1.1 Dry Gas Cylinders, when utilized for calibration or adjustment purposes, should be used at their normal operating temperatures (~20° C – 25° C) and only used above ~100PSI or ~10% of tank pressure.

3.2.2 Premixed alcohol simulator solutions in the target concentrations of 0.080, 0.100 and 0.200 g/210L.

3.3 Safety Concerns

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

3.3.2 Dry Gas Cylinders:

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

3.3.2.2 Dry gas cylinders shall be stored within the lab at standard laboratory conditions (comfortable office conditions with thermostats set at ~20-22° C or 68-72° F)

3.3.2.3 When being transported for field use, cylinders shall be transported in the passenger compartment of the vehicle. They shall not be left unattended (for extended periods of time) in the vehicle and allowed to heat in direct sunlight or freeze within the passenger compartment of the vehicle.

3.3.2.4 If cylinders fall outside the above criteria, the cylinders shall not be used for calibration purposed for 24 hours. During which time, the cylinder shall be allowed to equilibrate at room temperature with periodic rolling/rocking to eliminate any condensation or equilibration issues.

3.3.3 Instruments/Equipment:

3.3.3.1 If instruments or laboratory equipment are transported to or from the field for calibrations services, they shall be transported in such a manner to protect them from physical and environmental damage during transit.

3.3.3.2 When being transported for field use, instruments and equipment shall be transported in the passenger compartment of the vehicle. They shall not be left unattended (for extended periods of time) in the vehicle and allowed to heat in direct sunlight or freeze within the passenger compartment of the vehicle.

3.3.3.3 Instruments shall be stored within the lab at standard laboratory conditions (comfortable office conditions with thermostats set at ~20-22° C or 68-72° F)

3.3.3.4 Instruments should be stored with the secure lab in a manner so as to prevent damage.

3.3.4 Simulator solutions:

3.3.4.1 Solutions should be stored in a cool dark cabinet away from sources of heat or kept refrigerated while being stored in the lab.

4.0 Calibration Procedure

4.1 Lifeloc FC20/FC20BT: Initial checks

4.1.1 In the Laboratory Information Management System (LIMS) and/or on the worksheet (Lifeloc Calibration worksheet), identify the instrument being evaluated by its serial number, the ownership agency, the start date of the calibration, and the environmental conditions.

4.1.1.1 Standard Lab conditions: by documenting conditions as 'standard lab conditions' the analyst is acknowledging that the temperature of the room is at a comfortable level, and they have checked the instrument and cylinders' temperatures, and found them to be within range (as specified) for calibration.

4.1.2 Document that the software version installed within the instrument is the current version. If the version is not current, refer to the manufacturers provided software and work instructions for software upgrade instructions to install the current version of software (see Breath Alcohol Maintenance Manual).

4.1.3 Check the following settings within the menus of the Lifeloc to verify they are correctly set: time, date, sequence mode is "on", print format is set to short, 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". These values may be checked through the manufacturer provided software. Document this in the instrument records.

4.1.3.1 The checks in section 4.1.3 can be done as part of the initial check of the instrument or done at the end of the calibration process prior to sending the instrument to the user agency.

4.1.4 Lithium-Ion Battery Status (Li-Ion, Li-Battery): Utilizing the manufacturers provided software, check the status of the Li-Ion battery. Document the status in the instrument records.

4.1.4.1 Acceptable results are readings >2.80v. Readings lower than 2.80v should be documented in the instrument records, and the agency should be notified in writing that the Li-Ion battery needs to be replaced by the manufacturer or trained provider.

4.1.4.2 Failure to meet the Li-Ion battery requirements does not constitute a "calibration failure" but it does present an issue with the retention of the date and time within the instrument. This could cause issues with the calibration lock-out date should the instrument reset to factory default (date and time) settings.

4.1.4.2.1 The instrument will function normally once the date and time are set after powering on the unit.

4.1.5 Document the instrument's gain setting and DGCF (dry gas correction factor) and record the results on the Lifeloc calibration worksheet.

4.2 Lifeloc FC20/FC20BT: As Found Status

4.2.1 To assess the 'as found' performance of the instrument, run a performance verification check with the instrument utilizing a 0.200 CRM. Record the results in the instrument record.

4.2.1.1 If a wet bath solution is used, the simulator solution should be heated to 34 °C (±0.2 °C). Document the serial number and temperature (within range) of the simulator in the instrument record along with the Lot # of the certified solution used.

4.2.1.2 If utilizing a dry gas standard with the EasyCal system, document the serial number and barometric pressure specification in the instrument record along with the Lot # of the certified reference material used.

4.2.2 Check the 'as found' performance of the instrument by performing a simulated evidential breath test with the instrument utilizing a heated simulator and a 0.100 CRM. Record the results in the instrument record.

4.2.2.1 Simulator solution should be heated to 34 °C (±0.2 °C). Document the serial number and temperature (within range) of the simulator in the instrument record along with the Lot # of the certified solution used.

4.2.3 Fuel Cell Response / Gain Check: During the simulated breath test the analysts will assess the fuel cell's response to the 0.100 alcohol standard. If the response is low, then a gain adjustment is required.

4.2.3.1 Acceptable results are ~50% (or greater) of the Y-Axis during analysis.

4.2.4 Failure to meet the acceptable criteria will require the instrument to be taken out of service for maintenance. Document this in the instrument records.

4.2.5 Document the instrument's end gain setting and DGCF (dry gas correction factor) and record the results on the Lifeloc calibration worksheet.

4.3 Lifeloc FC20/FC20BT: Adjustment

4.3.1 Using either an EasyCal system (for Dry Gas standards) and/or a wet bath simulator (for wet gas standards), connect the unit and adjust the instrument with a certified standard in the amount of 0.160 (dry) or 0.200 (wet bath) g/210L of alcohol.

4.3.1.1 Document the adjustment lot # in the instrument records along with the serial # of the EasyCal unit and/or Simulator.

4.3.1.2 Check the barometric pressure on the EasyCal unit and compare it against the NIST traceable barometer. Acceptable results are +/- 1 mBar. If needed, adjust the barometric pressure to match the pressure of the NIST traceable barometer to within +/- 1 mBar. Document in the instrument records.

4.3.1.3 If a wet bath solution is used, the simulator solutions should be heated to 34 °C (±0.2 °C). Document the temperatures (within range) of the simulators in the instrument records along with the Lot # of the certified solution used.

4.3.1.4 If the instrument is adjusted with a 0.200 wet bath solution, it should be followed by the 0.160 dry gas adjustment after sufficient time has passed.

4.3.2 Allow the instrument to rest to allow for the fuel cell to recover before proceeding with the calibration.

4.3.3 Throughout the calibration process, it may be necessary to allow the instrument to rest and/or hydrate the fuel cell periodically in between series of testing sequences. This may be necessary to reduce or eliminate any fatigue that the fuel cell may experience during the calibration process.

4.4 Lifeloc FC20/FC20BT: As Left Status

4.4.1 Using the EasyCal dry gas delivery system and dry gas standards in the target concentrations of 0.040, 0.080 and 0.200 g/210L of alcohol, evaluate the instrument in ascending order.

4.4.1.1 Document the dry gas lot #s in the instrument records along with the serial # of the EasyCal unit.

4.4.1.2 Check the barometric pressure on the EasyCal unit and compare it against the NIST traceable barometer. Acceptable results are +/- 1 mBar. If needed, adjust the barometric pressure to match the pressure of the NIST traceable barometer to within +/- 1 mBar. Document in the instrument records.

4.4.1.3 If dry gas checks are being performed on a date other than the start date, document the date that the checks were performed on the worksheet.

4.4.2 Initiate a performance verification check with the EasyCal system and the portable unit. Analyze each standard 6 times in ascending order and record the results in the instrument records. Let the unit rest between performance checks.

4.4.2.1 The most recent 6 checks at each level are utilized for calibration purposes.

4.4.3 Acceptable results are ± 5% of the target value or ±0.004, whichever is greater.

4.5 Lifeloc FC20/FC20BT: Wet Check Function

4.5.1 Prepare a simulator with a simulator solution in the target concentration of 0.080 g/210 L of alcohol. Document the serial number of the simulator used, the standard lot #, and that the simulator was within 34 °C (±0.2 °C).

4.5.2 Provide a breath sample through the simulator utilizing the 0.080 solution. Document the result in the instrument records.

4.5.2.1 Acceptable results are ± 5% of the target value.

4.6 Lifeloc FC20/FC20BT: Documentation

4.6.1 All entries are made on the instrument calibration worksheet and data is transferred into the Laboratory Information Management System (LIMS) for statistical purposes and future reference. The system is password protected and only the analyst assigned to the instrument may make entries for the instrument being calibrated.

4.6.2 The final calibration worksheet shall be attached as the first page in the notes packet within LIMS to be included with the calibration certificate and all data transfers shall be checked for accuracy during the review process.

4.6.3 All documentation shall be attached within the LIMS electronically to create the case record. Any changes to the case record shall be documented in accordance with the laboratory quality system.

4.6.4 ACCEPTABILITY: If the instrument passes all of the requirements for calibration, the instrument shall be certified in writing.

4.6.5 The laboratory calibration certificate indicating the serial number of the instrument that is being certified for use will be made available online at the ISP website.

4.6.5.1 The calibration certificate will clearly indicate the uncertainty of measurement for the instrument calibration.

4.6.5.2 The calibration certificate will indicate the expiration date for the calibration of the instrument.

4.6.5.3 The instrument will be marked with a calibration 'due date' reminder set at ~365 days from the current calibration date. This timeframe may be adjusted +/- to accommodate laboratory personnel workload and agency instrument supply/demand.

4.6.5.4 It is the discretion of the analyst if the 'lock out" will be set as "disabled / stop tests" or set as "warning". (FC20BT version only) Non-BT units should have their lock out dates set for the calibration expiration date (December 31st of the following year, up to a maximum of 730 days).

4.6.5.4.1 Instruments that fail their calibration may have their lock out date set at 1 day, and "disable/stop tests" as an added measure against agency usage after it is returned.

4.6.6 The certified instrument shall be sent or delivered by ISPFS to the agency. Alternatively, the instrument may be picked up by the agency.

4.6.7 If the instrument fails any part of its calibration process, it will be removed from service for maintenance. Maintenance protocols will be followed in accordance with breath alcohol procedures and documented on the appropriate worksheets, which will be attached electronically to the case record.

4.6.7.1 If the instrument fails a functional test, the test may be repeated, assuming no adjustments are made to the instrument that could affect the calibration. Documentation of the failed checks shall be within the instrument records.

4.6.8 REJECTION: If the instrument fails to meet the requirements for calibration and maintenance cannot resolve the issue, the instrument shall not be certified. The agency shall be notified in writing along with suggested maintenance that may be required by the manufacturer.

4.6.9 The laboratory certificate indicating the serial number of the instrument that has failed its calibration will be made available online at the ISP website.

4.6.9.1 The instrument is not certified for evidential use until it has been calibrated and issued a passing certificate by ISP Forensic Services.

4.6.9.2 Instrument certificates with a "Failed" designation do not need to have their UM calculations performed and made available for incomplete data or testing phases.

4.6.10 The non-certified instrument shall be sent or delivered by ISPFS to the agency. Alternatively, the instrument may be picked up by the agency.

Analytical Method #3: EasyCal® Dry Gas System

1.0 Background/References

1.1 Background

1.1.1 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

3.1.1 Currently approved or previously approved software version installed in the unit

3.1.2 Dry gas cylinders provided by an ISO 17025 (or equivalent) accredited laboratory/supplier

3.1.3 Calibrated and certified barometer (1 mbar readability, within +/- 5 mbar accuracy)

3.1.3.1 Barometers are required to be calibrated by an authorized and qualified vendor prior to the expiration of their calibration or replaced prior to their expiration date. Expired barometers shall be clearly labeled and shall not be used for calibration and certification purposes.

3.2 Certified Reference Material (CRM):

3.2.1 Refer to Breath Alcohol Discipline Analytical Method 2.0

3.3 Safety Concerns

3.3.1 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

4.1.1.1 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.

4.1.1.1.1 If the version is not current, refer to the manufacturers provided software and work instructions for software upgrade instructions to install the current version of software (see Breath Alcohol Maintenance Manual).

4.1.1.2 Check the barometric pressure on the EasyCal unit and compare it against the NIST traceable barometer. Acceptable results are +/- 1 mBar. If needed, adjust the barometric pressure to match the pressure of the NIST traceable barometer to within +/- 1 mBar. Document in the instrument records.

4.1.1.3 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.

4.1.1.4 Document all the testing results on the certification checklist.

4.1.1.5 If the EasyCal has a printer, pair the printer with the unit and test that the print function works.

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.

4.1.2.1.1 Laboratory EasyCal units do not need to be certified on a yearly basis since they are routinely checked during calibration activities.

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 Document the Agency, Serial Number and the Location in which the re-certification is taking place (city, specific building or location). If the location is within the ISPFS lab system, the name of the Lab/Building will suffice.

4.1.2.3.2 List the current software version within the EasyCal, and update to the most current version if applicable. Document on the worksheet.

4.1.2.3.3 Check the barometric pressure on the instrument and compare it against the NIST traceable barometer. Acceptable results are +/- 1 mBar. If needed, adjust the barometric pressure to match the pressure of the NIST traceable barometer to within +/- 1 mBar. Document in the instrument records.

4.2 Rejection Documentation

4.2.1 Failure

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

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

4.2.1.3 After factory maintenance, the unit must be certified by the ISP laboratory (through section 4.1.2) 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.

5.1.2 Procedure:

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

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

5.1.2.3 Open the USB drive and run the CalStation_Service ZOC program

5.1.2.4 Power on the cal station

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

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

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

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

5.1.2.8 Click 'OK' in the ZOC

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

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

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

5.1.2.11 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.

5.2 EasyCal Software Upgrade Procedure:

5.2.1 Procedure:

5.2.1.1 Download and unzip the file saved at I:\ALCOHOL\BREATH\INSTRUMENT VALIDATIONS\EasyCal software 1084 upgrade.

5.2.1.2 Copy the contents of the extracted folder to a USB drive.. .

5.2.1.3 Insert the USB device into the EASYCAL USB port.

5.2.1.4 The EASYCAL <u>may</u> ask users if they would like to copy print log from the unit.

5.2.1.5 If it does, Click No.

5.2.1.6 The EASYCAL will then ask users if they are sure they want to load calibration station software on the unit.

5.2.1.7 Click Yes.

5.2.1.8 The system will automatically upload the software.

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

5.2.1.10 Click No.

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

5.2.1.12 Go ahead and remove the USB device.

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

5.2.1.14 After restarting, go to “Settings” and “About”.

5.2.1.15 Ensure software is the most current approved version.

5.2.1.16 The process is now complete.

Analytical Method #4: Dräger 9510 Series Calibration

1.0 Background/References

1.1 Background:

1.1.1 Idaho Administrative Code, IDAPA 11.03.01 requires that each breath testing 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:

- 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

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2.0 Scope

2.1 This method discusses the Idaho State Police Forensic Services (ISPFS) requirements for the approval of Dräger 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.

2.2 It is the recommendation of ISPFS that the Benchtop Testing Instruments be recalibrated on a yearly basis. This schedule is a laboratory recommendation, and the calibration interval shall be set in IDAPA 11.03.01 by administrative rule.

2.2.1 Instruments that are utilized for screening purposes and not utilized for quantitative evidentiary purposes, need not adhere to the calibration schedule recommendations as set forth in this method.

2.3 ISPFS will monitor the calibration frequency for trends to identify if the calibration interval is appropriate or should be adjusted.

3.0 Equipment/Reagents

3.1 Equipment

3.1.1 Dräger 9510 series instrument

3.1.2 Breath alcohol simulators (Guth models 12v500, 2100 or equivalent)

3.1.3 Label maker with vinyl coated labels or equivalent

3.1.4 Traceable calibrated barometer (1 mBar readability, ±5 mBar accuracy)

3.1.4.1 Barometers are required to be calibrated by an authorized and qualified vendor prior to the expiration of their calibration or replaced prior to their expiration date. Expired barometers shall be labeled as expired and shall not be used for calibration and certification purposes.

3.1.4.2 Barometers with a 2-year certification should be acquired in a staggered yearly format (one per year). Each barometer will have its barometric pressure monitored and recorded on dates in which the instrument is used from the date of acquisition until its certification has expired. Comparison versus the other/new barometers will ensure continued accuracy throughout the lifecycle of the use of all barometers.

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: (0.100 v/v solution) add approximately 0.5 ml of methanol (Reagent Grade) to approximately 500 ml of water in a simulator bottle.

3.3 Certified Reference Material (CRM):

3.3.1 Dry gas ethanol standards in the target concentrations of 0.040, 0.080, and 0.200 g/210L

3.3.1.1 Dry Gas Cylinders, when utilized for calibration or adjustment purposes, should be used at their normal operating temperatures (~20° C – 25° C) and only used above ~100PSI or ~10% of tank pressure.

3.3.2 Premixed alcohol simulator solutions in the target concentrations of 0.040, 0.080, 0.100, 0.200, and 0.400 g/210L.

3.3.3 Quantitative Simulator solutions used for certification of instruments should only be used a maximum of 25 total samples.

3.3.3.1 A sample consists of a single blow through the simulator that provides a result on the instrument's detector(s).

3.3.4 Qualitative solutions can be changed at the analyst's discretion.

3.4 Safety Concerns

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

3.4.2 Dry Gas Cylinders:

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

3.4.2.2 Dry gas cylinders shall be stored within the lab at standard laboratory conditions (comfortable office conditions with thermostats set at ~20-22° C or 68-72° F)

3.4.2.3 When being transported for field use, cylinders shall be transported in the passenger compartment of the vehicle. They shall not be left unattended (for extended periods of time) in the vehicle and allowed to heat in direct sunlight or freeze within the passenger compartment of the vehicle.

3.4.2.4 If cylinders fall outside the above criteria, the cylinders shall not be used for calibration purposed for 24 hours. During which time, the cylinder shall be allowed to equilibrate at room temperature with periodic rolling/rocking to eliminate any condensation or equilibration issues.

3.4.3 Instruments/Equipment:

3.4.3.1 If instruments or laboratory equipment are transported to or from the field for calibrations services, they shall be transported in such a manner to protect them from physical and environmental damage during transit.

3.4.3.2 When being transported for field use, instruments and equipment shall be transported in the passenger compartment of the vehicle. They shall not be left unattended (for extended periods of time) in the vehicle and allowed to heat in direct sunlight or freeze within the passenger compartment of the vehicle.

3.4.3.3 Instruments shall be stored within the lab at standard laboratory conditions (comfortable office conditions with thermostats set at ~20-22° C or 68-72° F)

3.4.3.4 Instruments should be stored with the secure lab in a manner so as to prevent damage.

3.4.4 Simulator solutions:

3.4.4.1 Solutions should be stored in a cool dark cabinet away from sources of heat or kept refrigerated while being stored in the lab.

4.0 Calibration Procedure

4.1 Dräger 9510 series: Initial checks

4.1.1 In the LIMS, document the following: Identify the instrument being evaluated by its serial number, the start date of evaluation, the environmental conditions are suitable for calibration, and serial number of the barometer being used, and the current version of software and firmware installed within the instrument (most current approved version).

4.1.1.1 Standard Lab conditions: by documenting conditions as 'standard lab conditions' the analyst is acknowledging that the temperature of the room is at a comfortable level, and they have checked the instrument and cylinders' temperatures, and found them to be within range (as specified) for calibration.

4.1.2 Prior to any testing or calibration activities, connect the instrument to an ISPFS network cable and download all of the internal data within the instrument to the ISP online database.

4.1.2.1 It may be necessary to set the instruments ComHub settings in order to communicate with the ISP server.

4.1.2.2 Comm Hub settings should be as follows:

- Server IP set to 164.165.246.11
- Port should be set to 9513
- Time should be set to no less than 300 seconds.

4.1.2.3 Once the download has completed, verify that the data download has been completed by searching the instrument serial number on the ISP database.

- https://isp.idaho.gov/DraegerDataViewer/

4.1.2.4 If downloading the data is not possible, copy the existing databases from the unit onto a USB drive, convert the .txt files into semicolon delineated .xls files and provide all database files to the instrument's agency.

4.1.3 If the instrument does not have the most current versions of software, configuration or firmware installed, update the instrument and proceed with the calibration process.

4.1.3.1 To update the instrument software, place the instrument into maintenance and follow the maintenance manual procedures for software, firmware, and configurations updates.

4.1.4 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 in the LIMS. Retain a copy of the self-test printout.

4.1.5 Check to ensure that the following parameters are set:

4.1.5.1 Date and time

4.1.5.2 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.

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

4.1.7 Using the Ambient Pressure Correction menu function, check the barometric pressure on the instrument and compare it against the NIST traceable barometer. Acceptable results are +/- 1 mBar. If needed, adjust the barometric pressure to match the pressure of the NIST traceable barometer to within +/- 1 mBar. Document in the instrument records.

4.2 Dräger 9510 series: As Found Status

4.2.1 Perform an evidential test with the instrument. Utilize a simulator containing a 0.080 CRM as the subject breath sample and enter in the following for the testing parameters for database search consistency:

- Name –As Found Test (any order)
- DOB- 01/01/2001
- DL # -123456 State - ID
- Time of incident- 00:00
- Officer information- enter in your own information
- Agency – ISPFS
- County – current county

4.2.1.1 Simulator solutions should be heated to 34 °C (±0.2 °C). Document the serial number and temperature (within range) of the simulator in the LIMS along with the Lot # of the certified solution used.

4.2.2 Complete the two-test sequence and retain the printout for the calibration records. Record the Internal standard result and the external standard result in the LIMS. All blanks should be below the acceptability threshold of 0.005 for electronic noise.

4.2.3 Record the results of the simulated breath tests in the LIMS.

4.3 Dräger 9510 Adjustment:

4.3.1 Prepare a simulator with a certified reference solution in the target concentration of 0.100 g/210 L of alcohol. Document the serial number of the simulator used, the standard lot #, and that the simulator was within 34 °C (±0.2 °C).

4.3.2 Document the current settings for the instrument for the following values: EC Cal Factor, IR Cal Factor, CalGas Inlet Drygas %, Adsorption %, IR Slope Multiplier, EC Drygas Offset and EC Quadratic Correction Factor.

4.3.3 Utilize the Auto-Adjust procedure and the Wet/CO_2 setting to introduce the adjustment standard into the Dräger 9510.

4.3.4 Document the adjusted settings for the instrument for the following values: EC Cal Factor, IR Cal Factor, CalGas Inlet Drygas %, Adsorption %, IR Slope Multiplier, EC Drygas Offset and EC Quadratic Correction Factor.

4.4 Dräger 9510 series: As Left Status:

4.4.1 Utilizing dry gas standards in the target concentrations of 0.040, 0.080 and 0.200 g/210L of alcohol, analyze each standard 5 times in ascending order through the CalCheck menu function.

4.4.1.1 The most recent 5 checks at each level are utilized for calibration purposes.

4.4.2 Document the Lot #'s of the standards in the LIMS.

4.4.3 Allow the instrument to rest in between tests.

4.4.4 Document the results in the LIMS and the UM worksheet.

4.4.5 Acceptable results are ± 5% of the target value or ±0.004, whichever is greater.

4.4.6 The functional checks described in sections 4.5, 4.6, 4.7, 4.8 and 4.9 may be performed in any order.

4.5 Dräger 9510 series: Wet Check Function

4.5.1 Prepare a simulator with a simulator solution in the target concentration of 0.080 g/210 L of alcohol. Document the serial number of the simulator used, the standard lot #, and that the simulator was within 34 °C (±0.2 °C).

4.5.2 Run a CalCheck test using the Wet setting and acquire a sample from the simulator through the breath tube.

4.5.3 Document the results in the LIMS.

4.5.4 Repeat the process for the 0.200 simulator solution level.

4.5.5 Acceptable results are ± 5% of the target value.

4.6 Combination Check (alternative):

4.6.1 In lieu of section 4.5 and 4.9, the analyst may elect to perform a combination check to accomplish multiple function checks simultaneously.

4.6.2 By utilizing the evidential or training test function and the 0.080 and 0.200 g/210L of alcohol CRM solutions, the analyst may meet the criteria for both sections 4.5 and 4.9 with a single test.

4.6.3 Enter in the following for the testing parameters for database search consistency:

- Name – 0.020 Combination Check (any order)
- DOB- 01/01/2001
- DL # -123456 State - ID
- Time of incident- 00:00
- Officer information- enter in your own information
- Agency – ISPFS
- County – current county

4.6.4 Document the lot#'s used for the 0.080 and 0.200 wet function checks in the instrument case record.

4.7 Dräger 9510 series: Function -Mouth alcohol

4.7.1 Run an evidential or training test on the instrument. Provide the sample utilizing your own breath as the sample.

4.7.2 Enter in the following for the testing parameters for database search consistency:

- Name – Mouth Alcohol Check (any order)
- DOB- 01/01/2001
- DL # -123456 State - ID
- Time of incident- 00:00
- Officer information- enter in your own information
- Agency – ISPFS
- County – current county

4.7.3 Prior to the sample, contaminate your mouth with a source of alcohol (mouthwash, breath spray, etc.). Provide a sample into the instrument.

4.7.4 Acceptable results are if the instrument flags the test as "mouth alcohol detected". Document the results in the LIMS.

4.8 Dräger 9510 series: Function -Interference Check

4.8.1 Interference Check: Run an evidential or training test on the instrument. Provide the sample utilizing a warmed simulator containing ~0.100 v/v solution of methanol.

4.8.2 Enter in the following for the testing parameters for database search consistency:

- Name – 0.100 Methanol Check (any order)
- DOB- 01/01/2001
- DL # -123456 State - ID
- Time of incident- 00:00
- Officer information- enter in your own information
- Agency – ISPFS
- County – current county

4.8.3 Provide a sample into the instrument using the simulator containing the methanol solution.

4.8.4 Acceptable results are if the instrument flags the test as "Interferent Detected". Document the results in the LIMS.

4.9 Dräger 9510 series: Function - 0.020 Correlation Check

4.9.1 Correlation Check: Run an evidential or training test on the instrument. Provide the sample utilizing a warmed simulator containing an alcohol solution in excess of 0.020 and your own breath as well.

4.9.2 Enter in the following for the testing parameters for database search consistency:

- Name – 0.020 Correlation Check (any order)
- DOB- 01/01/2001
- DL # -123456 State - ID
- Time of incident- 00:00
- Officer information- enter in your own information
- Agency – ISPFS
- County – current county

4.9.3 Provide the first sample into the instrument using either your own breath or a simulator containing the alcohol solution more than 0.020.

4.9.4 Provide the second sample into the instrument using the opposite to what was run during the first sample.

4.9.5 Provide the third sample into the instrument using your own breath.

4.9.6 Acceptable results are if the instrument recognizes the lack of 0.020 correlation between sample 1 and sample 2 and requests sample 3 from the subject. Document the results in the LIMS.

4.10 Dräger 9510: Documentation

4.10.1 All entries are made at the time of testing into the Laboratory Information Management System (LIMS). The system is password protected and only the analyst assigned to the instrument may make entries for the instrument being calibrated.

4.10.2 All documentation shall be attached within the LIMS electronically to create the case record. Any changes to the case record shall be documented in accordance with the laboratory quality system.

4.10.3 ACCEPTABILITY: If the instrument passes all of the requirements for calibration, the instrument shall be certified in writing.

4.10.4 The laboratory calibration certificate indicating the serial number of the instrument that is being certified for use will be made available online at the ISP website.

4.10.4.1 The calibration certificate will clearly indicate the uncertainty of measurement for the instrument calibration.

4.10.4.2 The calibration certificate will indicate the expiration date.

4.10.4.3 The instrument should be recalibrated at ~365 days. This timeframe may be adjusted +/- to accommodate laboratory personnel workload and agency instrument supply/demand.

4.10.4.4 Calibration may be performed 'up to' the end of the following calendar year (maximum of 730 days).

4.10.5 The working instrument shall be sent to the user agency to be installed by a BTS or delivered and installed by ISPFS at the agency site. Alternatively, the instrument may be picked up by the agency.

4.10.6 If the instrument fails any part of its calibration process, it will be removed from service for maintenance. Maintenance procedures will be followed in accordance with breath alcohol maintenance manual and documented on the appropriate worksheets, which will be attached electronically to the case record.

4.10.6.1 If the instrument fails a functional test, the test may be repeated, assuming no adjustments are made to the instrument that could affect the calibration. Documentation of the failed checks shall be within the instrument records.

4.10.7 REJECTION: If the instrument fails to meet the requirements for calibration and maintenance cannot resolve the issue, the instrument shall not be certified. The agency shall be notified in writing along with suggested maintenance that may be required by the manufacturer.

4.10.8 The laboratory certificate indicating the serial number of the instrument that has failed its calibration will be made available online at the ISP website.

4.10.8.1 The instrument is not certified for evidential use until it has been calibrated and issued a passing certificate by ISP Forensic Services.

4.10.8.2 Instrument certificates with a "Failed" designation do not need to have their UM calculations performed and made available for incomplete data or testing phases.

4.10.9 The instrument shall be sent to the user agency or delivered by ISPFS. Alternatively, the instrument may be picked up by the agency.

Analytical Method #5: 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, proficiency testing will be done annually according to a schedule set by the discipline lead. Proficiency tests will be distributed in the spring and fall and can either be internal or external provided tests.

2.0 Scope

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.

3.0 Equipment/Reagents

3.1 None applicable to this Analytical Method specifically

4.0 Procedure

4.1 Competency Tests

4.1.1 The competency test will consist of instruments currently 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).

4.2.1.1 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.

Analytical Method #6: Simulator Quality Control and Maintenance

1.0 Background/References

1.1 Background:

1.1.1 During the course of calibration and adjusting the breath alcohol instrumentation within the State of Idaho, it becomes necessary to utilize wet bath solutions to simulate the breath alcohol concentration produced by in a known concentration. This is best accomplished with the utilization of a wet solution of known concentration and a wet bath simulator that is properly calibrated and adjusted to mimic the human body temperatures. Precise and accurate readings are necessary for these simulated alcohol samples to also be precise and accurate. This is accomplished by having a comprehensive quality control and maintenance program to ensure the reliability of the simulators. The Idaho State Police will employ a program to maintain the simulators that it utilizes for the purpose of checking the calibration of the instruments that it certifies for use within the State of Idaho.

1.2 References:

- Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.
- 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 quality control and maintenance of the wet bath alcohol simulators used to perform calibrations of breath testing instruments within the State of Idaho Forensic Laboratory System. The requirements are such that the laboratory instruments shall be maintained upon a schedule set within this document and shall be checked accordingly. This method does not pertain to simulators outside the control and use of the ISPFS laboratory system for the use of calibration activities.

3.0 Equipment/Reagents

3.1 Equipment:

3.1.1 Guth Model 12V500 Alcohol Breath Simulator or equivalent

3.1.2 Label maker with vinyl coated labels or equivalent

3.1.3 Timer

3.1.4 One large slotted screwdriver and one small slotted screwdriver

3.1.5 Digital multimeter

3.1.6 Traceable calibrated thermometer

3.1.6.1 Accuracy ±0.05°C (0°C-70°C)

3.1.6.2 Readability ±0.01°C.

3.1.6.3 Traceable thermometers are required to be calibrated by an authorized and qualified vendor prior to the expiration of their calibration or replaced prior to their expiration date.

3.2 Reagents:

3.2.1 Refer to Breath Alcohol Discipline Analytical Method 2 for reagent requirements.

3.2.2 Cleaning solution: a general cleaning solution can be made by making an approximate 10% solution of bleach in water. In lieu of bleach, an equivalent laboratory grade disinfectant may be used.

3.3 Certified Reference Material

3.3.1 Refer to Breath Alcohol Discipline Analytical Method 1 and 2.

3.3.2 Quantitative Simulator solutions used for certification of instruments should only be used a maximum of 25 total samples. Solution usage shall be recorded in a log on the approved worksheet.

3.4 Safety Concerns

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

4.0 Procedure

4.1 Simulator Maintenance Schedule

4.1.1 Cleaning: Once per calendar year, the simulators will be cleaned and disinfected with the cleaning solution.

4.1.1.1 Cleaning solution will be placed in the simulator and allowed to mix for no less than one hour, and preferably overnight. The solution will then be discarded and the simulators' moving parts will be wiped down, cleaned of any noticeable debris, and dried thoroughly prior to being put back into service.

4.1.1.2 Cleaning will be documented in the simulator logbook.

4.1.2 Temperature checks: temperatures will be checked with a traceable and calibrated thermometer once per calendar month.

4.1.2.1 The simulators will have their performance documented in the logbook.

4.1.2.2 Acceptable performance of the simulator will be agreement with the traceable thermometer within ±0.2°C. A temperature difference of ±0.1°C will serve as a warning level for the simulator, and it will be the analyst's discretion if they will adjust the simulator should it fall outside of the warning limits.

4.1.2.3 Should the simulator fall outside of the acceptable range of ±0.2°C, the simulator shall be adjusted to be within the acceptable range using the adjustment procedure within this document.

4.2 Simulator Temperature Check

4.2.1 Turn on the simulator containing either alcohol solution or water and let the temperature equilibrate for at least 10-15 min.

4.2.2 Use a large, slotted screwdriver, remove the white seal plug from the calibration port on top of the simulator. Be careful not to strip or damage the slot in the white seal plug.

4.2.3 Insert the probe of your NIST digital thermometer through the calibration port until the bottom of the probe is at the same depth as the bottom of the temperature probe. You will have some resistance as the probe penetrates the rubber grommet in the baffle plate. This is normal and will hold the probe in place once it is at the right depth in the solution.

4.2.4 With a digital thermometer, check if the temperature is within 34.00 ± 0.2°C. If it falls within the acceptable range, no further steps are necessary. Document acceptable performance in the log.

4.2.5 If the instrument fails to pass the temperature check, document the results and proceed to the adjustment process.

4.3 Simulator Temperature Adjustment

4.3.1 The analyst has that discretion to send the simulator to the manufacturer (or authorized service provider) for maintenance in lieu of performing 'in-house' adjustments/maintenance on the simulator.

4.3.2 Follow the steps in section 4.2.1 to insert the thermometer into the temperature reading position.

4.3.3 Remove the label covering the three calibration ports on the side of the simulator.

4.3.4 With the simulator filled with ~500mL of water or simulator solution, and the power turned off, use the access ports and small screwdriver to turn on the simulator and access "calibration mode".

4.3.5 Perform a diagnostic check on the simulator and record the results in the log.

4.3.6 Utilizing the calibration ports, adjust the simulator temperature heater and readout to match that of the traceable thermometer.

4.3.7 Document the acceptable performance results in the log.

4.3.8 Rejection Documentation

4.3.8.1 If the simulator fails its temperature check and adjustment process, the simulator will be taken out of service and sent to the manufacturer for service or repaired by an authorized provider.

4.3.8.2 The results will be documented in the log and the steps taken to return the unit to service will be documented.

5.0 Work Instructions

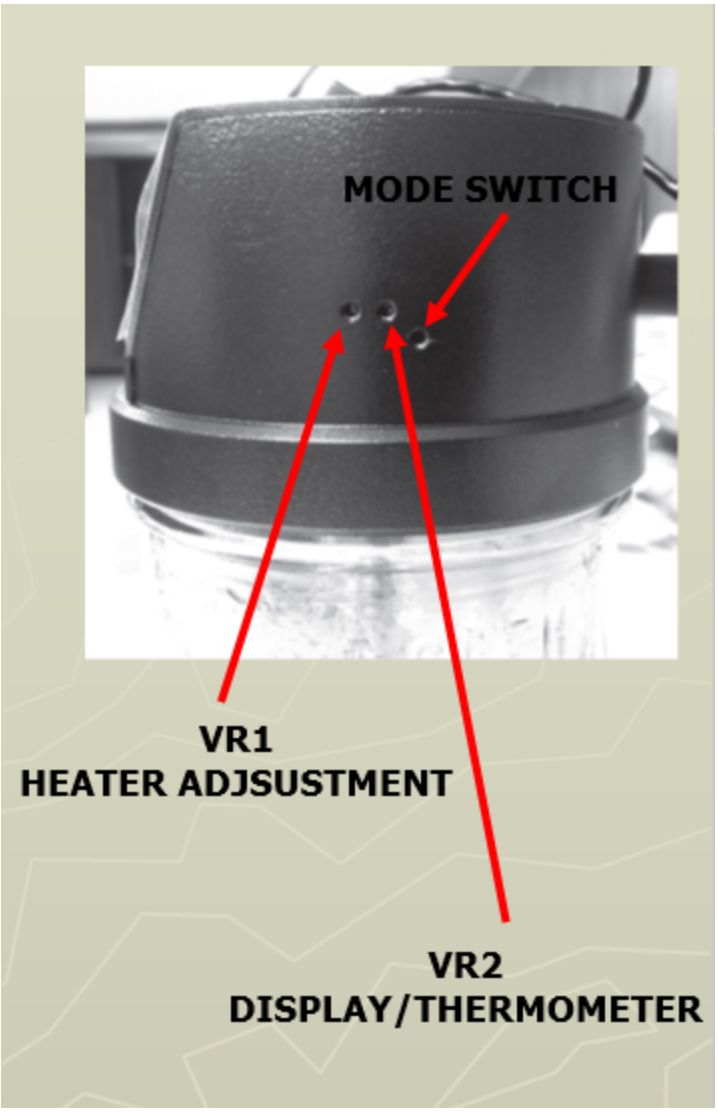
5.1 PRESTEP #1:

5.1.1 Turn on the simulator containing either alcohol solution or water and let the temperature equilibrate for at least 10-15 min. Use a large, slotted screwdriver, remove the white seal plug from the calibration port on top of the simulator. Be careful not to strip or damage the slot in the white seal plug; a dime works well.

5.2 Insert the probe of your NIST digital thermometer through the calibration port until the bottom of the probe is at the same depth as the bottom of the temperature probe. You will have some resistance as the probe penetrates the rubber grommet in the baffle plate. This is normal and will hold the probe in place once it is at the right depth in the solution.

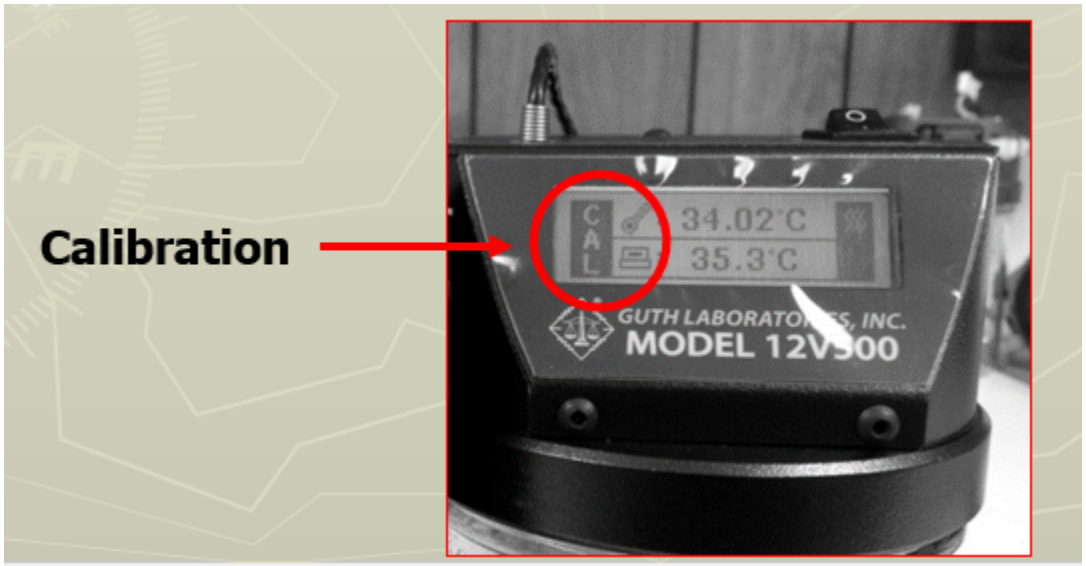
5.3 With a digital thermometer, check if the temperature is within 34.00 ± 0.05°C. If it falls within the acceptable range, no further steps is necessary. If not, proceed ahead.

5.4 **STEP #1:** With simulator facing you so display is visible, locate the calibration label on the right side of the top housing and remove the label to expose the 3 access points to calibrate the simulator.



5.5 **STEP #2:** With power off, insert a small, slotted screwdriver into the mode switch and turn the power on. This will briefly show "Calibration Mode" on the screen. The simulator will perform a diagnostic check. If any problems are encountered a status code will be displayed. If the simulator passes the diagnostic check, you can proceed with the calibration procedure.

5.6 **STEP #3:** Advance first to the final calibration by inserting the small, slotted screwdriver into the mode switch to advance to the display below (press mode switch 2 times to advance to cal adjust screen).



5.7 **STEP #4:** Insert small, slotted screwdriver into slot VR2. Adjust the digital display on the simulator to read the same as display temperature on digital thermometer.

5.8 **STEP #5:** Watch heater indicator light on right of calibration screen on digital display of the simulator.

5.9 **STEP #6:** Insert small, slotted screwdriver into slot VR1. Watch heater indicator on display of simulator and adjust accordingly until digital display on simulator is 34.00 ± 0.05°C. Note: look at how the display responds to determine whether to rotate screwdriver CCW or CW. No need to watch digital thermometer display only heat wave symbol on CAL screen as you change temperature set point until display now reads 34°C.

5.10 **STEP #7:** Adjust the Digital Display (again) with VR2 if necessary to match digital display on digital thermometer. Note: look at how the display responds to determine whether to rotate screwdriver CCW or CW.

5.10.1 If results agree, insert slotted screwdriver into mode switch to exit calibration and return to normal operating display.

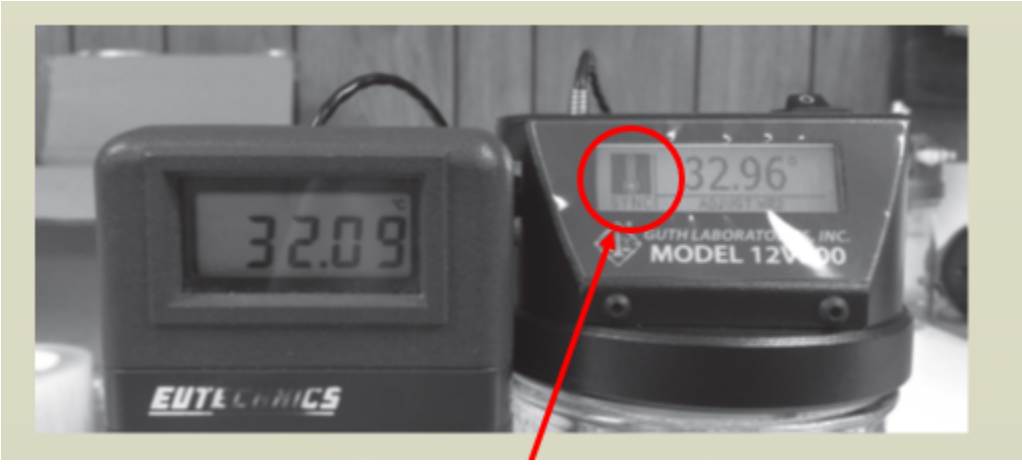
5.10.2 If the results are not in agreement, proceed to the following steps for a full calibration.

5.11 **STEP #8:** Turn off simulator. Optional to let the solution cool to perform the following steps at room temp. Go back into calibration mode (repeat STEP #2)

5.12 **STEP #9:** If the simulator passes the diagnostic check, you should see the display with a temperature reading indicating the display for the heater circuit. (heat wave symbol to the left of the temperature reading on the display of the simulator).

5.12.1 Insert the small, slotted screwdriver into the **VR1** opening and adjust to match the temperature on your NIST traceable digital thermometer. Note: look at how the display responds to determine if whether to rotate screwdriver CCW or CW.

5.13 **<u>STEP #10:</u>** Insert the small, slotted screwdriver into the mode switch and press to advance to the VR2 circuit for the display/thermometer display (thermometer symbol to the left of the temperature reading).



5.13.1 Insert the small, slotted screwdriver into the **VR2** slot to adjust the digital display on the simulator to read the same as the NIST digital thermometer. Note: look at how the display responds to determine if whether to rotate screwdriver CCW or CW.

5.14 **STEP #11:** Insert the small, slotted screwdriver into the mode switch and press to enter final calibration screen. Simulator will now heat up to near 34°C

5.15 **STEP #12:** Once simulator has heated up to near 34°C (display in final calibration mode) repeat STEPS 4 to 7. If results are still not in agreement, then stop and send unit to Guth in accordance with section 4.3.7 of this method.

AM #7 Estimation of Uncertainty of Measurement for Breath Alcohol Calibration

1.0 Background

1.1 An estimation of the Uncertainty of Measurement (UM) shall be calculated for the calibration *(Certification)* of Breath Alcohol measuring instruments that are being utilized for evidential purposes and certified, by ISPFS, through the calibration process within the State of Idaho. The uncertainty of measurement applies to the 'calibration process' of the instruments and does not represent the uncertainty of measurement for the instrument as it pertains to evidential breath testing results.

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

1.3 The UM is an expression of the confidence or certainty associated with a measurement. The UM expressed through this protocol is associated with the calibration process of the breath testing instruments within the Idaho State Police Forensic Services (ISPFS).

1.4 Uncertainty is not synonymous with error, inaccuracy, or bias.

2.0 Uncertainty of Measurement Elements

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

2.2 Traceability is established using reference materials obtained from sources that are certified to the ISO/IEC 17025 / ISO 17034 (or equivalent) standard, and equipment calibrated by 17025 accredited providers.

2.3 Uncertainty elements are provided from each measurement instrument being calibrated.

2.3.1 The Lifeloc FC20/FC20BT is an electrochemical fuel cell based instrument and will contribute via the uncertainty obtained from its single source measurement process.

2.3.2 The Draeger Alcotest 9510 is a dual technology instrument and employs both an electrochemical fuel cell (EC) and an Infra-red (IR) detector to quantitatively measure the ethanol concentration. Both measurement sources will be considered individually and reported separately.

2.4 **Type A Uncertainty** – Random uncertainty results from measurement values being scattered in a random fashion due to the laws of chance and thus have a normal distribution shape.

2.4.1 Type A uncertainty is best determined by analysis of data from repeated measurements.

2.5 **Type B Uncertainty** – Systematic uncertainty results from the inherent biases in a measurement process and analytical method. These uncertainties may be reduced by optimizing the method, or measurement system, but can never be eliminated.

2.5.1 Type B uncertainty is determined from the Certificates of Analysis (COA) from reference materials and other known, reported uncertainties associated with the measurement devices and processes utilized within the method.

2.5.2 Many sources of Type B uncertainty are already incorporated in the acquisition of Type A uncertainty data and are not considered separately.

2.6 ***Elements of Consideration***

2.6.1 **Staff** – Multiple analysts will be utilized throughout the system to produce data associated with the UM budget. These analysts have varying degrees of training and experience that is taken into consideration.

2.6.1.1 Type A evaluation of the process for production of the reproducibility data for each evaluated level.

2.6.2 **Certified Reference Materials (CRM)** – Two types of CRM will be utilized in the calibration process: Variations in repeated measurements of a standard are derived under reproducible conditions. These conditions consist of multiple factors including: the analyst, the instrument calibration, environmental conditions and software calculations associated with algorithms. The variations in these results include uncertainty contributions from each of these factors.

2.6.2.1 Dry Gas CRM is a Type B evaluation

2.6.2.2 Wet Bath Solution CRM is utilized as an adjustment and qualitative check standard during the process and is incorporated in the Type A evaluation for repeatability of the measuring instruments. The qualitative check helps to evaluate bias.

2.6.3 **Barometric Pressure Correction** - This is a standardized correction factor that is applied to the results within the instrument software to correct for the expansion of the compressed gas standard.

2.6.3.1 Type B evaluation – applied as 'within range' of +/- 1mBar per the Analytical Method (AM).

2.6.4 **Temperature** - This is a standardized factor that the instrument software monitors and controls within the instrument to account for the temperature of the instrument and compressed gas standard to protect the integrity of the results.

2.6.4.1 Type B evaluation – applied as 'within range' as defined for each standard, per the Analytical Method (AM). This metric is incorporated in the Type A data and is not considered separately.

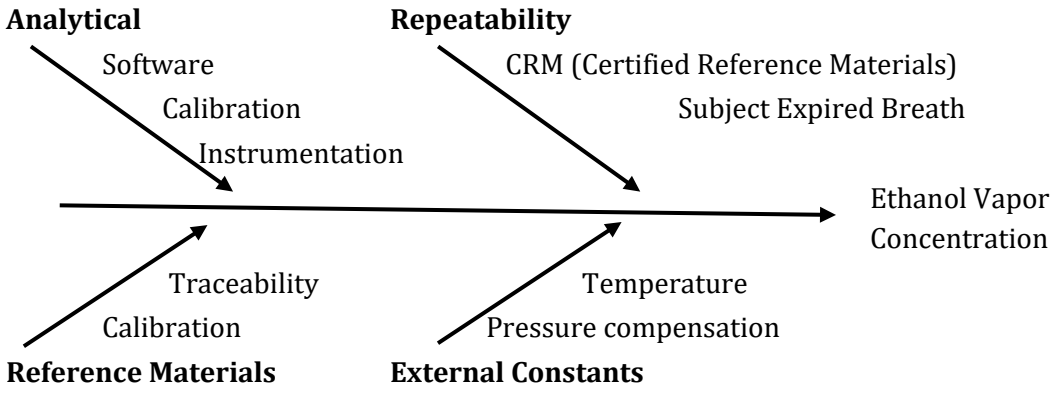
2.6.5 **Instrument Software** – This is standardized for each instrument and each version of software and involves proprietary algorithms for the quantitative determination of ethanol in g/210L.

2.6.5.1 Type B evaluation – This in incorporated in the Type A data

2.6.6 **Calibration/Adjustment** – This is a product of the process of setting the instruments response to a known value of measurand.

2.6.6.1 Type B evaluation – This in incorporated in the Type A data

2.6.7 **Subject Expired Breath** – This is an unknown variable and cannot be evaluated through this protocol, nor can it be measured without knowing the initial target value. This metric is not included in any calculation within this method but is a contributor to the overall UM of a measured breath test results and external to the instrument and other factors herein.



2.6.8 **Figure 1** is a cause-and-effect diagram showing the uncertainty sources incorporated into the budget for the breath alcohol reference materials. It applies to both the external standards and the instrument calibration and measurement process. There are four major components that contribute to the overall uncertainty, and they are broadly categorized as: analytical (Type B), repeatability (Type A), reference materials (Type B) and external constants (Type B).

3.0 Uncertainty of Measurement Budget

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

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

3.3 Two separate budgets will be maintained, one for each instrument series, encompassing the following concentration ranges: *(each level will be assessed and reported separately)*

3.3.1 **Lifeloc FC20/FC20BT**: 0.040 g/210L, 0.080 g/210L, and 0.200g/210L of ethanol.

3.3.2 **Draeger Alcotest 9510** - budgets will be established for each sensor (IR and EC) in the following concentrations: 0.040 g/210L, 0.080 g/210L, and 0.200g/210L of ethanol.

3.4 The budget will contain repeatability and reproducibility data.

3.5 Each analytical result will be normalized to standard atmospheric pressure (760 mm Hg or 1013.25 mBar) using barometric pressure correction.

3.6 For the Lifeloc FC20/FC20BT the normalized results of three performance verification tests (6 total results) will be used in the calculation.

3.7 For the Draeger 9510 the normalized results of 5 tests (10 total results, 5 for each sensor) will be used in the calculation.

3.8 **Repeatability Data** - The standard deviation of the mean values will be calculated. This variability is represented through calculation of the relative standard deviation, or percent coefficient of variation, of the ethanol dry gas concentration. First the average solution concentration is calculated using the following equation.

$$\bar{X} = \frac{1}{n}\sum_{i=1}^{n} X_i$$

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Where:

X = the average ethanol dry gas concentration

n = the number of measurements

Xi = each individual dry gas measurement result

i = incremental measurement results, first through last.

The standard deviation (SD) of the dry gas measurements is calculated using the following equation.

$$SD = \sqrt{\frac{\sum_{i=1}^{n} (X_i - \overline{X})^2}{n-1}}$$

The % coefficient of variation (CV) will be calculated. The % CV it calculated using the following equation:

$$CV\% = \left(\frac{SD}{\overline{X}}\right) x100$$

The coefficient of variation for repeatability of the measured CRM values is calculated using the following equation: (where n is the number of replicates tested)

$$CV_{Inst}^{2} = \left(\frac{SD}{\sqrt{n}} \Big/ \overline{X}\right)^{2}$$

3.9 **Ethanol dry gas standards** - used during the Certification process. UM, distribution type, and coverage factor will be found on the manufacturer's Calibration Certificates.

3.10 **Barometric Pressure Compensation** - The instruments are calibrated within the lab utilizing barometric sensors that are checked with calibrated and certified barometers traceable to NIST certified standards. These instruments have a working range of +/- 1 mBar. The manufacturer provides an ethanol gas conversion ratio chart with their CRM. This chart shows an inverse linear relationship between the increase in elevation above sea level and the ethanol dry gas response factor. For every 1000 feet gain in elevation, a conversion ratio of an average of 0.035 is applied. A 10 mBar change in pressure at 15° C translates to approximately 280 feet of air elevation. This equates 5 mBar of pressure change accounting for a change in the ethanol dry gas concentration by a factor of 0.005 (0.5%). This variable will be used in the uncertainty calculation at its maximum allowable within range value of 0.005 at +/- 5 mBar.

3.11 **Temperature compensation -** The uncertainty associated with the variability of the cylinder temperature during dispensation is directly related to the ideal gas law and its equation PV=*n*RT. Optimal operating temperatures for the cylinders during calibration occur at between 20-25° C (68-77° F). This uncertainty component is incorporated in the repeatability measurement uncertainty contribution, and thus is not included separately in the combined UM calculation.

4.0 Uncertainty of Measurement Reporting

4.1 The combined standard uncertainty of the instrument (CSU_{Inst}) is calculated using the Root Sum Squares method and the following equation. This is accomplished utilizing a controlled uncertainty of measurement spreadsheet.

$$CSU_{Inst} = CRM_{conc}\, x \sqrt{CV_{COA}^2 + CV_{Inst}^2 + CV_{Baro}^2}$$

4.2 The Expanded Standard Uncertainty is calculated using a coverage factor of k=3.

4.3 The coverage probability will be ~95%.

4.4 The expanded standard uncertainty shall be <u>*rounded up*</u> to the third (thousandth) decimal place. This is to match the readability of the measurement device and the acquired repeatability data.

4.5 The format will be reported as the target value +/- the expanded standard uncertainty (g/210L).

4.6 Each CRM target value (level) will have its expanded standard uncertainty reported for the instrument that is calibrated.

5.0 Uncertainty of Measurement Review

5.1 The UM process and calculations will be evaluated and reviewed on an annual basis. This evaluation will take into consideration each instrument platform.

5.2 The review process will cover the entire population of instruments calibrated within ISPFS.

5.3 The data will be evaluated for quality and trends with respect to location, personnel, time/date, and other factors that may affect the quality of calibration services.

5.4 Data will be reported and made available by ISPFS for each instrument platform upon completion of the review.

6.0 References

- Idaho Administration Code, IDAPA 11.03.01, Rules Governing Alcohol Testing.
- http://www.legislature.idaho.gov/idstat/Title18/T18CH80SECT18-8004.htm
- ISO/IEC 17025:2017
- ISO 17034
- https://www.lifeloc.com/download/userManualFC20BT.pdf
- https://www.lifeloc.com/download/userManualFC20.pdf
- https://isp.idaho.gov/forensics/wp-content/uploads/sites/10/documents/currentAMs/Breath%20Alcohol/Idaho%20Draeger%209510%20Technical%20Manual%20rev%201.pdf
- EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (EPA 600/R-12/531)
- JCGM 200:2012, International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd ed. (Sevres, France: IPM, 2008).
- CGA - C-7 -Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers