7.0 Draeger 9510 Series Instrument Calibration and Certification

History Page

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7.0 Draeger 9510 Series Instrument Certification

7.1 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.

7.2 SCOPE

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.

7.3 EQUIPMENT

Draeger 9510 series instrument
Dry gas ethanol standards in the concentrations of ~0.040, ~0.080, 0.100, 0.160 and ~0.200
Premixed alcohol simulator solutions in the concentrations of ~0.080, 0.100 and ~0.200
A total of 4 breath alcohol simulators (Guth models 2100, 34C, MarkIIa, or equivalent)
Distilled water or equivalent
Traceable calibrated barometer (1 mBar resolution, +/- 5 mBar accuracy)

7.4 REAGENTS

Simulator bottle containing a methanol/water mixture

7.4.1 **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.

7.5 REFERENCE MATERIAL

Refer to Alcohol Discipline Analytical Method 1.0

7.6 SAFETY CONCERNS

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

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

7.7 CERTIFICATION PROCESS

7.7.1 **Draeger 9510 series: Initial Certification**

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

7.7.1.2 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.

7.7.1.3 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.

7.7.1.4 Check to ensure that the following parameters are set:
-date and time
-monthly Performance Verification (PV) is set for the first Tuesday of the month
-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.
-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.
- Document all of the results on the checklist.

7.7.1.5 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.

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

7.7.1.7 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.

7.7.1.8 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

7.7.1.9 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.

7.7.1.10 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.

7.7.1.10 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.

7.7.2 **Draeger 9510 series: Re-Certification**

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

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

7.7.2.2 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..

7.7.2.3 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.

7.7.2.4 Check to ensure that the following parameters are set:

-date and time
-monthly Performance Verification (PV) is set for the first Tuesday of the month
-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.
-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.

- Document all of the results on the checklist.

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

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

7.7.2.7 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.

7.7.2.8 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.

7.7.2.9 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.

7.7.2.10 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.

7.7.2.10.1 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.

7.7.3 **Draeger 9510 series: Scheduled maintenance**

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

7.7.3.2 Using 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.

7.7.3.3 The instrument will 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.

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

7.8 ACCEPTANCE CRITERIA

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

7.8.1.1	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
	Wet and Dry results	- match within +/-5% of the mean results

7.8.1.2 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.

7.9 INSTRUMENT ADJUSTMENT

7.9.1 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.

7.9.1.1 Run both a wet and a dry check at the 0.080 level. Evaluate and adjust the wet and dry correlation. Adjust the instrument so that the wet and dry results match to within 5% of each other.

7.9.1.2.1 Utilize the adjustment guide to correct any discrepancies in the instrumental results.

7.9.1.2 Perform an adjustment on the instrument using either the calibration procedure menu option, or the auto adjust menu option.

7.9.1.2.1 Use an ethanol standard of approximate concentration of 0.100 or 0.160.

7.9.1.2.2 Document the target value and lot number of the standard used.

7.9.1.3 After adjustment, return to section 7.7 to repeat any of the sections that may have failed the certification process. If the instrument does not pass its criteria after the adjustment set forth in 7.9.1.2, then manual adjustment of the instrument can be pursued at the analyst's discretion.

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

7.9.1.4.1 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.

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

7.9.1.4.3 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.

7.10 INSTRUMENT DOCUMENTATION

7.10.1 Acceptance Documentation

7.10.1.1 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.

7.10.1.2 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.

7.10.1.2 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.

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

7.10.2 Rejection Documentation

7.10.2.1 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.

7.10.2.2 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.

7.11 REFERENCES AND RECOMMENDED READING

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

7.11.2 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.

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

7.11.4 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.

7.11.5 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.

7.11..6 http://www.legislature.idaho.gov/idstat/Title18/T18CH80SECT18-8004.htm

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

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.