Easy Cal Station, FC20, and Dry Gas Validation

Executive Summary of Results

Scope

Dry gas standards are more consistent than wet bath simulators for the calibration of breath testing instruments. Dry gas standards contain a known concentration of ethanol suspended in pressurized nitrogen gas. Because the ethanol is suspended in the gas, the mixture is homogenous throughout the lifecycle of the cylinder. Furthermore, as long as sufficient pressure exists within the gas tank, and environmental conditions such as barometric pressure and altitude are accounted for, dry gas standards deliver consistent ethanol concentrations for multiple samples. A 105L gas cylinder can deliver over 500 samples that are accurate within $\pm$2%.[1,2] Dry gas ethanol reference material produced by ISO 17025 laboratories will not require secondary confirmation of the target values or further certification beyond the calibration certificate for the cylinder standards. Wet bath simulators, by comparison, are designed to heat an aqueous solution of known ethanol concentration to the temperature of expired human breath. The simulators require an air pump or expired air from the user to deliver a sample. The passage of external air through the simulator decreases the ethanol concentration of the solution. After 20 to 25 samples, the values from a wet bath simulator repeatedly decrease in ethanol concentration, potentially resulting in samples outside of a prescribed tolerance. Portable fuel cell instruments (the Lifeloc FC20) and a dry gas delivery system (EasyCal) are being used for the measurement purposes for an assessment of the software in the FC20 (rev 4.5 and rev 7) as well as the EasyCal dry gas delivery unit. The ethanol contained in the dry gas cylinders is identical to the ethanol contained within the wet bath simulator solutions[3]. Dry gas standards are more convenient, accurate, and consistent over the lifetime of the standard when compared to wet bath simulators. This validation plan will validate the new software versions for the Rev 4.5 and the Rev 7 versions of the Lifeloc FC20 as well as validate the use of the EasyCal system for use in the field as well as in the laboratory.

RESULTS

From the analysis of thirty-four different units with the EasyCal station (both rev 4.5 and rev 7 units) it was determined that the use of the EasyCal dry gas delivery system was acceptable for use in calibration and adjustment of the Lifeloc FC20 units. The unit's software (current versions 6.50 and 8.7.21) are approved for use in the instruments and are fully compatible with the easy cal stations. The results of the testing on the units yielded results that were well within the required specifications of +/- 5% or 0.004 whichever is greater. The units were evaluated using both wet and dry gas standards (at the 0.040, 0.080 and 0.200 level from Repco, Guth and Ilmo gas vendors) and comparisons were made with both wet and dry adjustments to the unit's calibrations. No significant deviations were noted within the testing devices.

Additionally, five units were tested over a three month period to see if there was any drift between the wet bath and dry gas results. This robustness study showed good correlation between the wet bath and dry gas results. Any observable drop in the performance of the fuel cell was noted in both standards' results. The correlation between the wet and dry ethanol forms was well within the required 5% of each other throughout this study.

The raw data summary is being kept electronically by the ISP Volatiles Analysis Discipline leader, and is available upon formal request for viewing. Data was produced within the ISP laboratories in Coeur d' Alene and Pocatello. The Rev 4.5 boards had a robustness correlation of 3.35% and 2.36%, while the rev 7 FC20 instruments had a robustness correlation of 1.93% and 1% respectively at the 0.080 and 0.200 levels. All of the wet bath and dry gas results correlations were well within the criteria for approval.

The instruments were also tested at higher altitude (with a change in the pressure of -56 mBar and -24 mBar using a certified and calibrated barometer) and again showed no appreciable difference between the results at varying altitudes and barometric pressures.

CONCLUSIONS

The EasyCal dry gas delivery system has met the criteria for approval and use as a performance verification system in the field, as well as within the ISP laboratory system for calibration purposes.

REFERENCES

1. http://www.calgaz.com/en/products-1/cylinders/calgaz-105s-cylinder.html

2. "Dry Gas Standard."*Intoximeters.* <http://www.intox.com/t-DryGasStandard.aspx> 1 Dec. 2009.

3. " Confirmation of Ethanol Compressed Gas Standard Concentrations by an NIST-Traceable, Absolute Chemical Method and Comparison with Wet Bath Alcohol Simulators", L. Silverman, K. Wong, and S. Miller, Journal of Analytical Toxicology, Vol. 21, Sept 1997

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