Measurement of Uncertainty Associated With Breath Alcohol Measurement by the BAC Datamaster.

Scope: ***Determination of the measurement uncertainty of alcohol results obtained with the BAC Datamaster in Michigan.***

An uncertainty budget was calculated by the Michigan State Police Alcohol Enforcement Unit for alcohol measurements taken on the BAC Datamaster according to principles enumerated in the *Guide to Uncertainty of Measurement* (GUM). The measurement includes those components which have been identified as contributing to the overall variability of the result: standard reference materials, equipment capabilities and repeatability of standard measurements.

Definitions

Uncertainties inherent in a method are grouped into two categories: those which may be evaluated by statistical methods (generally referred to as Type A uncertainties) and those evaluated by other methods (referred to as Type B uncertainties).

Type A uncertainties: Components characterized by the estimated variances or standard deviations, often obtained by repeated measurements or historical data.

Type B uncertainties: Components characterized by enumerated uncertainties, which are treated as variances or standard deviations in a manner consistent with Type A; often obtained from manufacturer's specifications.

Combined standard uncertainty is the square root of the sum total of Type A and Type B uncertainties

Expanded uncertainties are multiplied by a **coverage factor** (k) to obtain an overall combined expanded uncertainty. A k of 2 covers two standard deviation intervals, and refers to 95.45% confidence level (95.45% of all measurements with a normal distribution expected to lie in this range). A k of 3 covers three standard deviation intervals and refers to 99.73% confidence level (99.73% of all measurements with a normal distribution expected to lie in this range).

Measurand: expressed as Y, the thing that is measured (here, the alcohol concentration from a vapor sample introduced to the BAC Datamaster breath alcohol analyzer from a reference standard or a human subject).

Procedure

1. Express mathematically the relationship between the measurand Y (alcohol concentration) and sources of uncertainty (u_i) on which Y depends.
2. Determine u_i, the estimated value of u_i either on the basis of statistical analysis of a series of observations, or by other means.
3. Evaluate the standard uncertainty of each input u_i[1].
4. Determine the combined standard uncertainty of Y from the standard uncertainties in 3. Combined standard uncertainty is taken as the square root of the sums of each input u_i.
5. Calculate an expanded uncertainty by multiplication of the combined standard uncertainty by a coverage factor k.
   Report as Y with expanded uncertainty according to format *Y ± u at the 95.45% or 99.73% confidence level.* Uncertainty should be expressed to two significant digits. Use of more than two digits should be justified

Sources of Vapor Alcohol Measurement Uncertainty

Type A uncertainties include repeated measurements of standard reference materials and are assumed to have a normal distribution.

Type B uncertainties include the concentration of the certified reference material (calibration solution), obtained from the manufacturer's certificate of analysis. The distribution is not known, but the assumption of a rectangular distribution accounts for a potentially larger variance than does assumption of a normal distribution.

The uncertainty component associated with the simulator device itself is accounted for in the uncertainty associated with repeated measurements of the standard reference materials. The manufacturer (Guth Laboratories)'s specifications state that the simulator is accurate to within 0.05 °C. The certificate of analysis of the standard reference solution provides the variability over the range of 0.2 °C; therefore, variability inherent in the partition coefficient associated with simulator temperature is accounted for in the repeated measurement of the reference standard and is not double-counted as specified in GUM 4.3.10.

---

[1] All factors which contribute to variability in the measurement must be taken into account. However, factors should not be "double-counted":

If a component of uncertainty arising from a particular effect is obtained from a Type B evaluation, it should be included as an independent component of uncertainty in the calculation of the combined standard uncertainty of the measurement result only to the extent that the effect does not contribute to the observed variability of the observations. This is because the uncertainty due to that portion of the effect that contributes to the observed variability is already included in the component of uncertainty obtained from the statistical analysis of the observations. 4.3.10 GUM 2008.

Weekly accuracy checks do not contribute to the overall uncertainty of the measurement as they do not affect the calibration or performance of the instrument. They are measured as unknowns in the same way as are human subject samples and they are not factors contributing to measurement of the latter.

Calculations

U_{srs} = variability of standard reference solution. Derived from %CV/√2
U_{crm} = % variability of certified reference material as given by manufacturer. Derived from % var/√3

Combined Uncertainty (U_{Comb}): $U_{comb} = \sqrt{(U_{SRS})^2 + (U_{CRM})^2}$

Expanded Uncertainty (U_{Exp}): $U_{Exp} = U_{comb} \times 3$ (99% confidence level)

Type A Uncertainties

Pre-mixed reference solutions with varying target values were decanted into a Guth simulator and measured repeatedly to determine the variance associated with each target alcohol level.

Target	n	Mean	Std Dev	%CV	U_{srs}	$(U_{srs})^2$
0.02	19	0.01855	0.000589	2.95%	0.020844813	0.000434506
0.04	19	0.03865	0.000589	1.47%	0.010422406	0.000108627
0.05	19	0.04815	0.000726	1.45%	0.010272871	0.000105532
0.08	19	0.0798	0.00051	0.64%	0.00450762	2.03186E-05
0.10	19	0.10035	0.000609	0.61%	0.004308166	1.85603E-05
0.15	19	0.1491	0.001375	0.92%	0.00648172	4.20127E-05
0.20	19	0.2004	0.001655	0.83%	0.005853234	3.42603E-05
0.25	19	0.24975	0.002547	1.02%	0.007205254	5.19157E-05
0.30	19	0.29865	0.002435	0.81%	0.005739382	3.29405E-05

Type B Uncertainties

Variability of calibration solution: 3.0% at 34.0 °C ± 0.2 °C (manufacturer's certificate of analysis)
$U_{crm} = 0.01732$
$(U_{crm})^2 = 0.000300018$

Calculation of Uncertainty

Uncertainty of measurement was calculated at vapor alcohol concentrations represented by each reference standard:

$$U_{comb} = \sqrt{(U_{SRS})^2 + (U_{CRM})^2}$$

$U_{exp.} = U_{comb} \times 3$

Reference Standard Target Concentration g/210 L	U_{comb}	U_{exp}% 99.73% conf. level	U_{exp} g/210 L 99.73% conf. level
0.02	2.71%	8.13%	0.0016
0.04	2.02%	6.06%	0.0024
0.05	2.01%	6.04%	0.0030
0.08	1.79%	5.37%	0.0043
0.10	1.78%	5.35%	0.0054
0.15	1.85%	5.55%	0.0083
0.20	1.83%	5.48%	0.0110
0.25	1.88%	5.63%	0.0141
0.30	1.82%	5.47%	0.0164

Conclusions:

Combined expanded uncertainty at the 99% confidence level at 0.0800 g/210 L is approximately 7.33% for 5.37%. This equates to 0.0043 g/210 L breath at a BrAC result of 0.08 g/210 L.

For a subject with BrAC result of 0.10 g/210 L breath on the BAC Datamaster, the result with uncertainty statement formatted as directed in the GUM would read as follows:

Average: 0.100 ± 0.004 g/210 L breath at the 99% confidence level
Range: 0.096 to 0.104 g/210 L

The use of three, rather than two, significant digits after the decimal point is necessary to accurately express the desired result. Use of two digits only constitutes the current system, and the requirement to expand the expression of the test results entails an extended mathematical statement.

The current Administrative Rules allow for variability between subject samples of 0.01 g/210 L of breath up to 0.15 g/210 L and ≥ 0.02 at 0.15 g/210 L and above. It should be borne in mind that measurement of duplicate breath samples is not the same as duplicate measurements of the same breath sample. Some variability associated with biological samples and with provision of separate samples is expected; hence the rules have allowed for up to 12.5% variance (0.01 at 0.08 g/210 L) between repeated samples. This allowance takes into account variance associated with both sample provision and instrument function. Here we show that the actual measured variability of the BAC Datamaster is less than that which has been allowed by the administrative rules, and so is well within that considered acceptable by the Michigan Legislature.

Appendix: Guide to Uncertainty of Measurement

The *Guide to the Expression of Uncertainty in Measurement* (GUM) is published by the Joint Committee for Guides in Metrology (JCGM) Member Organizations, which include International Bureau of Weights and Measures (BIPM), International Electrotechnical Commission (IEC), International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), International Laboratory Accreditation Cooperation (ILAC), International Organization for Standardization (ISO), International Union of Pure and Applied Chemistry (IUPAC), International Union of Pure and Applied Physics (IUPAP) and International Organization of Legal Metrology (OIML). This document represents the international consensus on the most valid procedure for evaluating uncertainty and variability in measurement. There are no documents that supersede the GUM by international consensus

Reference

Guide to Expression of Uncertainty of Measurement, JCGM, 2008.