6.14 Measurement Traceability / Measurement Uncertainty

The following section is used to define the framework for measurement traceability and measurement uncertainty calculation and reporting. Specifics for calculations relevant to each method shall be documented and available for review in the Toxicology Unit.

6.14.1 Measurement Traceability

Measurement traceability is documented system of comparisons with each step having the essential elements of metrological traceability to the International System of Units (SI). It is established for the measurement process through certified reference material and the calibration of the equipment where the measurement result is viewed to have a significant effect on the final test result.

6.14.2 Measurement Uncertainty

The uncertainty of measurement is a non-negative parameter characterizing the dispersion of the values being attributed to a measured quantity of interest. It attempts to define both the variability of the measurement process and confidence that exists in the results of any measurement. Potential sources of uncertainty are taken into consideration and a range is then provided in which we expect the true value to lie with a definable probability.

6.14.2.1 The Measurement Process

The quantities intended to be measured are as follows:

6.14.2.1.1 Alcohol and Volatile Compound Analysis

The concentration of ethanol and volatile compounds using the following:

- 8.1 Alcohol Procedure
- Agilent Technologies Headspace Gas Chromatograph/Flame Ionization Detector (7890)

6.14.2.1.2 Drug Analysis

The concentration of drugs using the following:

- 8.4 Acid/Neutral Drug Procedure, 8.5 Basic Drug Procedure, 8.6 Benzodiazepine Procedure, 8.7 Benzoylecgonine Procedure, 8.9 Cannabinoid Procedure, and/or 8.10 Opioid Procedure.
- Agilent Technologies Gas Chromatograph/Flame Ionization Detector (6890/7890 or comparable model) and/or Agilent High Performance Liquid Chromatography (1200 series and 2600 infinity or comparable model), Exion AC Liquid Chromatography (or comparable model), and SCIEX 3200 Q Trap mass spectrometers.

6.14.2.2 Uncertainty Components

The uncertainty components were evaluated and categorized based on their ability to be evaluated by statistical means (type A or type B). Examples of uncertainty components identified for both alcohol/volatile analysis and drug analysis may include:

- Reproducibility (historic control standard data)
- Volume of sample (pipet)
- Volume of internal standard (pipet or diluter)
- Volumetric glassware
- CRM uncertainty (certificate of analysis and/or in-house preparation)

6.14.2.3 Standard Uncertainty Conversion

Each uncertainty value shall be converted to standard uncertainty by dividing the component certainty by the appropriate value.

6.14.2.4 Calculated Combined Uncertainty

The combined standard uncertainty (U) shall be calculated using the Root Sum of Squares method.

$$U_c = \sqrt{U_1^2 + U_2^2 + U_3^2 + U_4^2 \ldots}$$

U_c = combined standard uncertainty
U_x = individual uncertainty contributor ($U_x = U_1, U_2, U_3$, etc.)

6.14.2.5 Expanded Combined Uncertainty

6.14.2.5.1 Multiplying the combined standard uncertainty by a coverage factor k gives the expanded uncertainty in terms of a level of confidence. For routine measurements with a large amount of historical data (n>30) the following associated levels of confidence shall be used:

- Ethanol/alcoholic beverage analysis — k=3: 99.73% level of confidence
- Drug/volatile analysis — k=2: 95.45% level of confidence

6.14.2.5.2 For analysis with reduced confidence due to lack of historical data, a corrected coverage factor ($k_{corrected}$) is used based on the "Table G.2: t-distribution and degrees of freedom" from the GUM (see Appendix section). For example, for an analysis with no historical control data, a control is analyzed 15 times (14 degrees of freedom). Using the t-distribution table, $K_{corrected}$ value of 2.20 would be used to calculate the expanded uncertainty at a 95.45% confidence level.

6.14.2.6 Measurement Uncertainty Evaluation

The expanded uncertainty shall be calculated annually using updated uncertainty components including historical control data. (see section 6.14.2.2).

The uncertainty data will be entered into the electronically shared and accessible control data spreadsheets after each batch of cases. This will be documented on the front page of the batch cover sheet by the analyst's initials and date and shall be included in each technical review. Technical Review of all control data will be an ongoing mechanism to monitor any issues that may arise throughout the year (i.e. inconsistencies in bias, deviation, etc.). Additionally, the technical leader shall monitor this control data throughout the year to ensure consistency until annual measurement uncertainty recalculation occurs.

6.14.2.7 Reporting

6.14.2.7.1 Measurement uncertainty shall be calculated and reported when it impacts evaluation of a specification limit stated by a regulatory body, a statue, case law, or other legal requirement. Therefore, measurement uncertainty shall be reported for all blood alcohol measurements and alcoholic beverage cases.

6.14.2.7.2 The report shall include the measured quantity value, the associated expanded uncertainty (units consistent with measured quantity), and the coverage probability. Uncertainty of measurement for volatile results shall be rounded and reported to the thousandths digit with the exception of alcoholic beverages which shall be rounded and reported to the tenths digit.

6.14.2.7.3 If the calculated measurement of uncertainty for ethanol/volatile/alcoholic beverage analysis is less than the duplicate acceptance criteria, then measurement of uncertainty shall be administratively set equal to the acceptance criteria for that particular compound (e.g., For ethanol, if the calculated measurement of uncertainty at k=3, 99.73% confidence level is 4.622%, then the measurement of uncertainty shall be administratively set equal to the duplicate acceptance criteria; 5% for levels equal to or greater than 0.050 gm% or 10% for levels less than 0.050 gm%).

6.14.2.7.4 Measurement uncertainty will be available for all drug quantitation and volatiles reported in v/v% (excluding alcoholic beverages) and shall be supplied to the customer upon request. This shall be noted on the report.

6.14.2.7.5 Measurement uncertainty will not be reported for qualitative results or for results expressed as "less than" or "greater than" values.