Scientific & Technical Review Panel Final Report for 2020-S-0003 Guidelines for Performing Alcohol Calculations in Forensic Toxicology

Organization of Scientific Area Committees (OSAC) for Forensic Science

STRP Final Report
2020-S-0003
Guidelines for Performing Alcohol Calculations in Forensic Toxicology

Organization of Scientific Area Committees (OSAC) for Forensics Science
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Scientific & Technical Review Panel Members

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Report Summary:

The Scientific and Technical Review Panel (STRP) for "Guidelines for Performing Alcohol Calculations in Forensic Toxicology" is an independent panel appointed by the National Institute of Standards and Technology (NIST). A STRP is established with a range of experts to consider how well a standard meets the needs of the forensic science, law enforcement, and legal communities, and to recommend improvements to the standard under review. The STRP appreciates the efforts of Jennifer Limoges, Forensic Toxicology Subcommittee Affiliate who managed the development of this draft standard, while serving as the subcommittee liaison to this STRP.

The STRP began its review process with a kickoff meeting on September 11, 2020 and concluded with this STRP final report. The panel reviewed the draft standard and prepared comments for the OSAC Forensic Toxicology Subcommittee. After a rigorous review process and discussion between STRP members and the Forensic Toxicology Subcommittee, the subcommittee revised the draft standard in accordance with the panel's comments. The STRP has identified consensus opinions around five areas seen as weaknesses in this standard.

- First, the pharmacokinetic parameters are treated as ranges that suggest each parameter has a rectangular distribution. This implication is not supported by the literature and lacks statistical rigor. As a result, reporting can lead to inferences that extreme values have similar probabilities to more central ones.
- Second, the method for determining the volume of distribution (V_d) alludes to an "anthropometric approach" in one of the references. This method is not adequately described in the standard. Furthermore, the reference discusses and ranks several different approaches.
- Third, the standard could provide more clarity about the treatment of postmortem and urine samples.
- Fourth, the accuracy and precision of the blood/breath alcohol levels is treated as an exact number without describing the required test methods to make this assumption.
- Finally, the term, "uncertainty of measurement," is used to describe the variability of the parameters in the population rather than the actual uncertainty of the measurement.

Report Components:

The STRP reviewed this draft standard against OSAC's *STRP Instructions for Review* which include the following content areas: scientific and technical merit, human factors, quality assurance, scope and purpose, terminology, method description and reporting results. The details below contain a brief description of each reviewed content area and the STRP's assessment of how that content was addressed in the draft OSAC Proposed Standard.

I. **Scientific and Technical Merit:** OSAC-approved standards must have strong scientific foundations so that the methods practitioners employ are scientifically valid, and the resulting claims are trustworthy. In addition, standards for methods or interpretation of results must include the expression and communication of the uncertainties in measurements or other results.

- Consensus Views – While this standard is correct to point out that it is inappropriate to provide point estimates alone, the proposed standard does not propagate various sources of error in a statistically meaningful way. As a result, the ranges obtained from the proposed method do not have a probabilistic meaning. There are several sources of uncertainty that may affect the calculations considered in this report: sampling bias, instrumental measurement error, and variation within the population. An approach grounded in statistical methods, such as measurement error research, could address these sources of error in a scientifically valid way.

- Consensus View – The ranges given for each of the pharmacokinetic parameters could suggest a rectangular distribution. And the references that establish these ranges are based on limited sample types and sizes. These limitations need to be mentioned for each parameter in sections 4.1.1 – 4.1.3, and Section 4.4 should include more cautionary language.

- Minority View – None.

II. **Human Factors:** All forensic science methods rely on human performance in acquiring, examining, reporting, and testifying to the results. In the examination phase, some standards rely heavily on human judgment, whereas others rely more on properly maintained and calibrated instruments and statistical analysis of data.

- Consensus View – This standard adequately addresses this issue.

- Minority View – None.

III. **Quality Assurance:** Quality assurance covers a broad range of topics. For example, a method must include quality assurance procedures to ensure that sufficiently similar results will be obtained when the methodology is properly followed by different users in different facilities.

- Consensus View – Section 6.5 on postmortem samples would be clearer if combined with section 4.3 on specimen considerations.

- Consensus View – Section 4.3.2 on urine could be strengthened as "not amenable" could be interpreted as "not ideal but still usable." Similarly, section 5.1.1 could include a "but not urine" clause.

- Consensus View – The measurement error for alcohol concentration will depend on the method of measurement. This standard assumes that alcohol concentration measured by either blood or breath will both have equivalently trivial degrees of measurement error. The standard should require the reporting of which method was used and the associated measurement error, if known. If the associated measurement error is not known, the standard should require this to be stated as

well. Throughout the standard, alcohol concentrations are treated essentially as an exact number. This assumption needs justification. Requirements for alcohol concentration measurements need to be briefly listed or cited to ensure the results of the subsequent calculations are as precise as hoped.

- Minority View – Experts are advised by this document to include the measurement uncertainty in their calculations when provided, but measurement uncertainty is not currently available for all test results, especially regarding breath testing programs. Requirements for alcohol concentration measurement testing to ensure acceptable levels of precision is well outside the scope of this guideline and should be addressed separately in documents focused on analytical guidelines, some of which are currently in process with ASB.

IV. **Scope and Purpose:** Standards should have a short statement of their scope and purpose. They should list the topics that they address and the related topics that they do not address. Requirements, recommendations, or statements of what is permitted or prohibited do not belong in this section.

- Consensus View – This standard adequately addresses this issue.

- Minority View – None.

V. **Terminology:** Standards should define terms that have specialized meanings. Rarely should they give a highly restricted or specialized meaning to a term in common use among the general public.

- Consensus View – Section 4.4 is titled "Uncertainty of Measurement" which suggests the precision of results of a single measurand. The content in this section, however, seems to have more to do with the variability of these parameters in a population. While both effects can propagate through subsequent calculations, they are not quite the same thing.

- Minority View – None.

VI. **Method Description:** There is no rule as to the necessary level of detail in the description of the method. Some parts of the method may be performed in alternative ways without affecting the quality and consistency of the results. Standards should focus on standardizing the steps that must be performed consistently across organizations to ensure equivalent results. Alternatively, standards can define specific performance criteria that must be demonstrated and met, rather than specifying the exact way a task must be done. For example, it may be sufficient to specify the lower limit of detection for a substance without specifying the equipment or method for achieving it.

- Consensus View – Sections 4.1.2.1, 4.1.2.2, and 5.2.3 refer to an "anthropometric approach" that can be used to calculate V_d in lieu of the provided range. More information about this approach, ideally the actual equations, needs to be

provided. Maskell seems partial to two equations, “The results from the present study seem to favour the anthropometric equations published by Forrest [9] and Watson et al. [6].” These equations are simple and straightforward; including them in the standard would not be too onerous. Further, perhaps this standard, should recommend only these two favored methods. At a minimum, some discussion is needed about the effect of the anthropometric approach on V_d values (i.e., could they fall outside of the prescribed V_d range?). Perhaps, an example could be added to the appendix where this anthropometric approach is used.

- Minority View – None.

VII. **Reporting Results:** Methods must not only be well described, scientifically sound, and comprehensive but also lead to reported results that are within the scope of the standard, appropriately caveated, and not overreaching.

- Consensus View – The ranges for the pharmacokinetic parameters, previously discussed, could lead to reports with results that could be misinterpreted that extreme values are as probable as more central values.

- Minority View – The probability of where an individual subject would likely fall within the calculated range is dependent on a number of factors and would be open to interpretation by the expert. Interpretation of results is outside the scope of this document and is addressed, to some extent, in ANSI/ASB 037 'Guidelines for Opinions and Testimony in Forensic Toxicology'. Applying a full range as stated in this document reduces the possibility that an expert will inadvertently exclude possible concentrations by applying a certainty to the midpoint that does not exist.