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 Document Title: Guidelines for Opinions and Testimony in Forensic Toxicology

Note: a specific Proposed Resolution must accompany each comment or it cannot be considered.

#	Commenter	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
1	Michele Triplett	Title	T	Most guidelines for reports and testimony should be standard for all forensic disciplines, not unique to one/each discipline. Having unique guidelines for each discipline weakens rules, it does not strengthen the forensic disciplines, and it shows short sightedness and unprofessionalism.	The only parts of this that are unique to the discipline are 5.2 and 5.3.	Partial Accept: We agree that 5.2 and 5.3 are unique to this discipline, but feel the inclusion of other sections helps ensure the document is complete.
2	Michele Triplett	3.1 opinion	T	This document is redefining a common word, opinion, to have a new meaning specific for only one discipline and the definition differs from the real meaning. Doing so does not clarify reports and testimony, it continues the lack of transparency because the courts think they know the meaning of the word but experts are using it differently. Equivocating like this is not supported in science because it is a form of trickery. It would be better to use a phrase that clearly indicates the meaning.	Change the word 'opinion' to be 'scientific opinion' or 'scientific conclusion'.	Partial Accept: Section 3.1, has been modified to reflect "Expert Toxicological Opinion".
3	Michele Triplett	4 individual assessment	T	An 'individuals assessment' is not supported by science. The NAS report stated that scientific conclusions are those that LIMIT human interpretation. Supporting individual assessments does not follow science and shows a lack of understanding regarding scientific protocols. Additionally, using the phrase 'individual assessment' seems to be relieving an agency and discipline of responsibility for conclusions, not ensuring conclusions are well supported.	Reported conclusions should be based on data and criteria (set by the discipline or the agency).	ACCEPT: Removed "individual assessment" statement from section 4.3.
4	Michele Triplett	4 expert opinion	T	This document seems to be jumping from using the word 'opinion', 'scientific opinion' and 'expert opinion'. These are not the same thing. Using them the same shows a lack of knowledge.	It would be better to be consistent and use the phrase 'scientific opinion' or 'scientific conclusion'.	Accept: Modifications to the document have been made for consistent use of "expert toxicological opinions" or "opinions (see section 3.1).
5	Michele Triplett	General Comment	T	FRE allows for personal interpretations as long as the basis for that opinion is stated. This document does not seem to follow FRE which would diminish its credibility. For example, a practitioner could say they do not follow this because it does not follow FRE. I would think you would want practitioners to buy into your best practices, not show why they are not best practices.	Acknowledge the difference between a scientific conclusion and a personal interpretation and explain when each is appropriate.	Reject: This intent of this document is not to supersede the FRE, but rather to provide guidance to those interpreting the Federal Rules on what the field finds to be acceptable and unacceptable for a Toxicologist to testify to. All scientific conclusions or personal interpretations offered in legal settings should be based on science.
6	Michele Triplett	5.1 results or opinion	T	results or opinions' is too vague to understand. Does this mean that it applies to either results or opinions because they are different, or does it mean that results or opinions, regardless of what you call them, are the same thing? The reason this is confusing is because the document seems to redefine the would opinio, which then confuses the meaning of other words.	Be consistent in verbiage and only use one term.	Accept: Modifications to the document have been made for consistent use of "expert toxicological opinions" or "opinions (see section 3.1)". Further, modifications have been made to clarify that the interpretations are "their own" in regard to analytical results and opinions (Section 5.1.1.2.)
7	Michele Triplett	5.3 Inappropriate Opinions	T	By labeling these as Inappropriate Opinions, it doesn't say why they are inappropriate.	A better title would be "Limitations" so that it is clear that the reason these are inappropriate is because the statements cannot be supported with current research. Then each statement should be rewritten to follow the new title (and state why each bullet is inappropriate).	Partial Accept: Although the title was not revised, the section was modified to address the commenter's concerns (see 5.3.1).
8	M. Glinn, Avertest	3.1	E	Header needs to be formatted	Capital O, fix line spacing	Accept: Improved formatting of this section.
9	M. Glinn, Avertest	5.3	T	The statement "a toxicologist should not perform body burden calculations to determine dose" doesn't differentiate between dose taken or dose currently in the system and could be taken to mean no volume of distribution or Widmark calculations	Revise to "...should not use body burden calculations to specify dose taken".	Partial Accept: Revised and clarified. See 5.3.1.g and 5.3.1.h
10	M. Glinn, Avertest	5.3	T	"A toxicologist should not perform back extrapolation calculations of a drug other than ethanol" this can be done in the clinical arena and is addressed in the textbook The Clinical Toxicology Laboratory which is recommended for the ABFT exam. Not common in the forensic world, but can be done.	Add a qualifier "unless multiple concentration measurements or other reliable clinical information is available."	Reject: Section 5.3.1.f was not modified as suggested. As the commenter indicated, this is not a common practice in "forensic toxicology" and falls more within the bounds of clinical toxicology, which is outside the scope of this document.
11	M. Glinn, Avertest	5.3	T	"A toxicologist should not opine as to the effects of a drug...on a specific individual or without context of a given case." Seems to contradict Section 5.2	Drop "or" to make it read "without context of a given case".	Accept: Removed "or" from the sentence in 5.3.1.i.
12	Denise Lyons	5.3 (item 5)	T	other matrices may provide useful information in the proper context	insert "solely"	Reject: The Consensus Body agreed that this is appropriate as written.
13	Denise Lyons	5.2	T	No mention of opinion in cases without a toxicology report (e.g., alcohol impairment in a refusal case)	Please address	Reject: The task group felt that this was covered throughout section 4
14	Denise Lyons		E	Bullet points should be number for easier reference	number bullet points (e.g., 5.2.1)	ACCEPT: Document was reformatted.
15	Mark Burry	5.3	T	Why cannot a toxicologist opine to an individual's degree of impairment based solely on a quantitative result for ethanol?	Specify that this guideline is for drugs of abuse and not ethanol	Reject: While the suggested change was rejected by the Consensus Body, 5.3.c was modified that impairment determinations cannot be determined for a specific individual without information to supplement the analytical findings.
16	Mark Burry	5.3	T	Add an additional guideline	A toxicologist shall not omit signs and symptoms known to be caused by a drug that may detract from a narrative. For example, intentionally leaving out that methamphetamine increases sex drive when discussing the impairing effects of methamphetamine on a sexual assault victim known to have bodily possession of methamphetamine. This sounds obvious, but it happens.	Reject: The intent of this document is not to provide individual examples of drugs or drug classes. Further this is addressed in section 5.2.1.

17	Colorado Bureau of Investigation - Dan Anderson	4, tick mark 3	T	Add "Literature/Research" to the area of including because opinions are made based on analytical findings and the literature/research i.e. 0.320 ETOH level--really don't need much else to say the person was impaired.	Insert "Literature/Research" to the sentence	Reject: References that support the opinions or "literature/research" is addressed in 4.3.e.
18	Colorado Bureau of Investigation - Dan Anderson	4, additional tick mark	T	Add a new tick mark that addresses words such as 'scientific certainty' or 'reasonable degree of scientific certainty' should not be used	Insert new tick mark "Should not use words such as scientific certainty or reasonable degree of scientific certainty in written or oral opinions.	Accept: Added this as 5.3.1.j
19	Colorado Bureau of Investigation - Dan Anderson	5.1, tick mark 1	T	Work performed in the laboratory should also include Scientific principles such as methodology, instrumentation, and quality assurance. Also the word "Issues" after chain of custody implies there are problems.	Clarify sentence "Fact witnesses typically testify to the work performed in the laboratory that includes scientific principles, instrumentation, and quality assurance procedures as well as chain of custody of the evidence.	Partial Accept: Generally reworded as suggested.
20	Colorado Bureau of Investigation - Dan Anderson	5.2, tick mark 4	T	Add "stability"	"Discuss the toxicological impact of the presence/absence or stability of drugs or other chemicals."	Accept: Added stability to the bullet.
21	A R Forrest, University of Sheffield, UK	General comment (in email)		I am particularly concerned that the guidelines do not, in my opinion, take into account the need to consider the phenomena of post mortem redistribution and site dependency in interpreting post mortem drug concentrations.		Reject: The intent of this document is not to focus on very specific occurrences within the subdisciplines of forensic toxicology (e.g. postmortem) but to instead provide a broad document that covers all of the forensic toxicology disciplines. It is noted that Section 5.2.1.a does cover the commenter's concern.
22	A R Forrest, University of Sheffield, UK	5.2	T	Opinions need to be expressed with particular care when interpreting drug concentration in post mortem blood and other matrices. In particular, cognisance needs to be taken of the site of blood collection at autopsy.	Use a form of words such as: "qualify a reported concentration in the context of a given case as subtherapeutic, therapeutic, toxic or lethal when that statement can be backed by appropriate references, databases and/or other relevant information. When interpreting post mortem blood drug concentrations particular consideration should be given to the phenomena of post mortem drug redistribution and site dependency".	Reject: The intent of this document is not to focus on very specific occurrences within the subdisciplines of forensic toxicology (e.g. postmortem) but to instead provide a broad document that covers all of the forensic toxicology disciplines. It is noted that Section 5.2.1.a does cover the commenter's concern.
23	Colorado Bureau of Investigation - Dan Anderson	5.2, tick mark 6	T	The 'for example' is implying the back extrap calcs are being performed on single blood draws, but does not state this. There are also states that have 3 blood draw procedures and these calcs are based on 3 blood draws and a calc elimination rate. Just want to make sure this statement does not preclude a calc elim rate to be used	Add clarifying statement for the example.	PARTIAL ACCEPT: A separate document will be developed to specifically address alcohol extrapolations. The sentence was simplified and the modification made does not preclude a laboratory from using a calculated elimination rate.
24	Colorado Bureau of Investigation - Dan Anderson	5.3, tick mark 3	T	Add "including consent" and remove "based solely upon a drug concentration." Regardless of the concentration, addressing intent or consent in an opinion is not within the scope of a Forensic Toxicologist.	"A Toxicologist should not address behavioral intent including consent."	Reject: While a decision was made to remove the example, "consent" is a form of "behavioral intent" and is interpreted as included in this statement.
25	Colorado Bureau of Investigation - Dan Anderson	5.3, additional tick mark	T	Add a new tick mark that addresses words such as 'scientific certainty' or 'reasonable degree of scientific certainty' should not be used	Insert new tick mark "Should not use words such as scientific certainty or reasonable degree of scientific certainty in written or oral opinions.	Accept: Section 5.3.j. was added to indicate these terms should not be used.
26	Dallas County Institute of Forensic Sciences	5.1	T	The current SWGTOX Standard for Laboratory Personnel regarding education and certification required to offer an expert opinion arbitrarily excludes those who have been trained in alternate fields - such as chemistry - or through alternate methods including in-house training and specialized training seminars. Toxicology is a multi-disciplinary field which benefits by attracting biologists, chemists, and other scientists who gain appropriate interpretive knowledge through a variety of mechanisms. This best practice recommendation should not define expertise based upon narrow educational criteria.	We recommend that the SWGTOX standard is not specifically referenced and is replaced with a listing of training criteria which can be met via education, in-house training, and/or specialized training. At a minimum, we recommend that toxicologists trained via alternate means and currently providing interpretive testimony should not be arbitrarily excluded as an expert witness.	Partial Accept: The task group felt that the use of SWGTOX Standard for Laboratory Personnel as a normative reference is appropriate as it has been available to the scientific community for about 3 years and, like this document, provides guidance on the training and educational backgrounds of laboratory personnel. A second normative reference was added for personnel in the breath alcohol discipline. It is also noted that the language around this statement was modified to clarify that it is recommended that the SWGTOX documents be followed (section 5.1).
27	Nick Tiscione, PBSO	4	T	This section seems to have been written with "Written" opinions in mind. Some of the listed criteria that expert opinions should include may not be possible when providing oral opinions. In particular the criteria that expert opinions should: include a comment that states that the opinions may be subject to change based upon new information that becomes available; and include a listing of case specific documents and records reviewed. Depending on the questions that are asked during testimony and any limitations that may be imposed by the judge these may not be possible.	Either remove "Oral" or clarify criteria that in some instances it is beyond the control of the toxicologist to include all of the listed criteria, in particular when providing expert opinions in testimony.	ACCEPT: The section has been slightly reorganized to clarify those requirements that really only apply to written opinions (section 4.2).
28	Nick Tiscione, PBSO	5.3	T	"A toxicologist should not opine as to an individual's degree of impairment based solely on a quantitative result."	Perhaps consider adding some clarification to this statement. A toxicologist may provide some opinion on the degree of impairment with high ethanol results - even in isolation. While certainly the specific effects of any drug, including ethanol, on a specific individual cannot be elucidated, some more information can be provided for ethanol (particularly at high concentrations) even in the absence of observable signs (e.g. single vehicle accident). This statement may be interpreted to mean that such testimony is inappropriate.	Reject: While 5.3.1.c was modified to clarify that a toxicologist cannot opine as to a "specific individual's degree of impairment...", the Consensus Body also recognized that with drugs, especially ethanol, the individual tolerance that may develop to the effects of drugs make it impossible to opine as to a specific individual's degree of impairment unless there is more information available other than a quantitative result. For example, it would be very important to know whether or not the individual was considered an alcoholic, if they were observed driving erratically, or the results from a field sobriety test.
29	Sacramento County DA Laboratory of Forensic Services, Craig Triebold	5.2	T	The recommendations state that a toxicologist may "perform or discuss toxicological calculations that are generally accepted in the field and can be supported by research and references, provided appropriate limitations are cited. For example, ethanol back extrapolation calculations may be performed or addressed if a range of elimination rates is used and if that extrapolation is supported by research and references, and applicable limitations are cited." Requiring that a range of elimination rates is used is overly restrictive.	Modify the language to say that a "range of elimination is used or acknowledged" (or something similar). This would permit the use of an average elimination rate for the purpose of a back extrapolation, but still require that the expert qualify the answer by stating that elimination rates can vary and that the assumed rate can affect the calculated value.	PARTIAL ACCEPT: A separate document will be developed to specifically address alcohol extrapolations. The sentence was simplified.

30	Sacramento County DA Laboratory of Forensic Services, Craig Triebold	5.3	T	The standard states "A toxicologist should not perform back extrapolation calculations of a drug concentration (other than ethanol)." This language may be overly restrictive, depending on the interpretation.	Add language to allow for the practice of applying half-life calculations to provide a reasonable outer window of the time since last use. Example: if a subject's blood methamphetamine concentration is 500 ng/mL, and the question is "how long ago could there most recent use have been?" - it is valid to go back in half-life increments until you reach a point in time where it becomes unreasonable based on the blood concentration that would have been achieved. Clearly, assumptions and limitations need to be properly defined.	Reject: The Consensus Body does not agree that this modification is needed to 5.3.1.f. Drug half-lives reported in the literature have a great deal of variation and are not as widely agreed upon as for alcohol, so it would be difficult to perform these calculations with any reasonable level of scientific supportability.
31	Simon A. Cole	4	T	The 3rd bullet point is inconsistent with the National Commission on Forensic Science Views Document "Ensuring That Forensic Analysis Is Based Upon Task-Relevant Information" as well as much literature in the field.	Limit basis for opinions to information derived from the discipline of toxicology.	Reject: All relevant information needed for the expert toxicological opinion should be considered by the toxicologist. A toxicologist may need to know case facts, reported symptoms, crime scene findings, etc. in order to give a complete, well-informed opinion that is not misleading.
32	The Innocence Project - Kareem Belt	General	E	The <i>Guidelines for Opinions and Testimony in Forensic Toxicology</i> will inform labs how to develop standard operating procedures for reporting and giving testimony. These guidelines do not clearly describe upon which methods and mediums toxicologists are able to opine. This ambiguity leaves a loop hole for questionable and possibly unvalidated methods to be discussed in court.	A section should be added to the guidelines describing the validated methods and sample types for which forensic toxicologists may offer their opinion. In addition, the beginning phrase for the statements in Section 5.2 should be revised to read, "Where validated methods were used, a toxicologist ..."	Reject: This document's scope is to address testifying to results and offering expert toxicological opinions. Section 5.2.1.a requires that limitations be addressed. Limitations would certainly include things such as unvalidated methods, improper quality assurance practices, etc.
33	The Innocence Project - Kareem Belt	General	T/E	Forensic toxicologists may require additional information in offering their opinions that extend beyond data generated in a lab. The following are several statements throughout the document that allude to guidance allowing toxicologists to rely on information beyond analytical findings to render an opinion: • Section 4: Be based on the totality of the information available including case history, observations, circumstances, etc., and not solely based on analytical findings • Section 4: Include listing of case specific documents and records reviewed • Section 5.2 Address impairment to the extent that effects are consistent with documented pharmacodynamic and toxicodynamic properties of the substance and within the context of a given case • Section 5.3 A toxicologist should not opine as to individual's degree of impairment based solely on a quantitative result • Section 5.3 A toxicologist should not opine as to the effects of a drug or combination of drugs on a specific individual or without context of a given case. Extreme care must be taken in the evaluation, application, and weight given to external information generated outside of the forensic toxicology laboratory in the formulation of an opinion. There must be quality control measures in place to avoid the over-reliance on certain data like subjective observations of intoxication or the results of standard field tests (e.g., breathalyzer) and presumptive field tests. Furthermore, tests conducted outside of the forensic toxicology laboratory, notably hospital laboratories, may not be held to the quality assurance standards that are used for forensic toxicology laboratories. Forensic toxicologists should not opine on the reliability of testing that takes place outside of their place of work. For the reasons stated above, caution should be exercised when formulating an opinion based on information given from outside the lab. While it is understood that additional information is needed for a toxicologist to give an opinion, there should never be a situation where subjective information overshadows the objectively derived information. Toxicological analysis should confirm subjective conclusions and not the other way around.	An annex should be developed with examples of case documents that aid in the opinions given by a toxicologist, and should include discussion of limitations and uncertainties of information that influence the formation of an opinion.	Partial Accept: While a new Annex was not added to provide example case documents, additional information on assumptions (4.3.f) and limitations (4.3.g) was added to Section 4.
34	The Innocence Project - Kareem Belt	General	E	It is important to recognize the potential for cognitive bias in formulating opinions. In addition to practices performed in a toxicology laboratory, the use of information from outside of the toxicology laboratory can increase the opportunity for cognitive bias in the analyses performed at the toxicology laboratory. Cognitive bias is not addressed in the guidelines at all.	A definition of cognitive bias should be added to the guidelines' terms and definitions section, a caution for the potential for cognitive bias should be added to Section 5.1 (General), and an annex should be added that would include examples of sources of cognitive bias and describe best practices to reduce potential cognitive biases, such as linear sequential unmasking. The best practices discussion should describe documentation of the procedures undertaken to limit exposure to unnecessary information.	Reject: While the current state of research on cognitive bias does not suggest that this is a significant issue in forensic toxicology analyses, there is a call for research on the impact of cognitive bias in forensic toxicology put forth by the OSAC Toxicology Subcommittee which will help inform this issue for future revisions. It is noted that the requirements throughout this document already help minimize the potential impact for cognitive bias.
35	The Innocence Project - Kareem Belt	3	T/E	The Normative Reference for this document, the <i>Scientific Working Group for Forensic Toxicology (SWGTOX) Standard for Laboratory Personnel</i> , offers two definitions for toxicologist, a general definition and a definition for those that specialize in alcohol. However, the guidelines document conflates the two into a general term of toxicologist. There is only one defined term in this document and no other reference is mentioned, besides the normative reference, where terminology is defined. Are all of the definitions found in the <i>SWGTOX Standard for Laboratory Personnel</i> relevant to this document as well?	Provide a definition for toxicologist and clarify if there is still a distinction between a general toxicologist and one that specializes in alcohol.	ACCEPT: A definition for "toxicologist" has been added. Further the scope has been clarified by defining the subdisciplines of forensic toxicology the document is intended to include as its users.
36	The Innocence Project - Kareem Belt	3	E	Clarity is needed on what constitutes a basic analytical toxicology report.	Provide a definition for basic analytical toxicology report in the terms and definitions section or elaborate on the components of a basic analytical toxicology report in Section 4, Written and Oral Opinions.	Reject: This is beyond the scope of this document and is being addressed in the "Standard for Report Content in Forensic Toxicology" currently under development

37	The Innocence Project - Kareem Belt	3	E	Is the new information that can change an opinion based on additional testing or new case information?	Provide an example of additional information that would call for a change in a reported opinion. Subsequent reports should indicate the difference from the most recent report and those issued earlier, with sections or pages containing the new or changed information clearly identified.	Partial Accept: A comment was added to 4.2 (which we believe the commenter was referencing). It is beyond the scope of this document to address changes to subsequent reports as this is being addressed in "Standard for Report Content in Forensic Toxicology" currently under development.
38	The Innocence Project - Kareem Belt	4	E	It should not be optional to provide citations for references.	The statement "have references that support the opinions; these citations should be provided either on the report or made available upon request;" should be edited to "have references that support opinions; citations should be provided in the report."	Reject: The Consensus Body does not the document as making it optional to "provide" citations. Either they must be cited in the opinion report or provided when requested and either should be sufficient as a best practice.
39	The Innocence Project - Kareem Belt	4	E	The uncertainty and limitations of an analysis should be clearly stated in written documents as well as stated orally.	A statement stating that uncertainty and limitations must be given when applicable should be added to Section 4. This information should include, where applicable, specificity, sensitivity, and estimated measurement uncertainty associated with quantitative findings of a drug, drug metabolite, or other substance. Similar details should be added to the notation in Section 5.2 regarding addressing applicable limitations in opinions and testimony.	Reject: Limitations and measurement uncertainty will be address in the "Report" document. Further, it would be difficult to assign an error rate to a scientific opinion.
40	The Innocence Project - Kareem Belt	4	E	Laboratory reports typically summarize a vast number of procedures condensed into an abbreviated format. Reports generally fail to contain relevant details that can only be found in the documents in the case file. Defense access to case files is variable across the United States and readers of reports should be aware that there is data and information that is not conveyed in the report.	A comment that states that there is a case file associated with the report containing additional documents should be included in all basic and interpretive reports.	Reject: This is addressed in 4.3.d. Further, document currently under development (i.e., "Report Content") will also address this concern.
41	The Innocence Project - Kareem Belt	5	E	Section 5.1 makes no distinction between testifying to your own and testifying to someone else's results or opinions: "Expert witnesses typically testify to interpretation of results or opinions. These results or opinions may be their own or someone else's."	The guidelines should acknowledge the inherent differences between testifying to your own and testifying to someone else's results or opinions, and it should be noted that there may be legal requirements preventing the latter.	Reject: Regardless of whether the expert opinion is based upon their own laboratory's analytical results or those from another laboratory, the best practices recommended in this document apply. Further, it is beyond the scope of this document to address the legal requirements related to the confrontation clause.
42	The Innocence Project - Kareem Belt	5.2	T/E	The standards advise that a toxicologist may "address impairment to the extent that effects are consistent with documented pharmacodynamic and toxicodynamic properties of the substance and within the context of a given case." Greater clarification is needed regarding the contextual information needed to inform an opinion on such topics.	Explain the context of the case that informs the basis of an opinion regarding pharmacodynamic or toxicodynamic properties, specifying the relevant biological and other factors. The toxicologist should also discuss expected variability in human pharmacodynamic and toxicodynamic (and pharmacokinetic and toxicokinetic) properties, rather than characterizing these with a single expected value.	REJECT: Section 4 explains the necessity to define the limitations of the expert toxicological opinion (4.3.f), as well as any assumptions made (4.3.g).
43	The Innocence Project - Kareem Belt	5.2	T/E	The example pertaining to retrograde extrapolation is incomplete as written, and could be mistakenly interpreted as meaning that the only input needed for this calculation is a range of the elimination rate.	Revise to read: "For example, ethanol back extrapolation calculations may be performed or addressed only if a range of elimination and absorption rates are used and if there is sufficient data to indicate that at the time of interest the person was fully in the elimination phase and there was no possibility of absorption ongoing."	PARTIAL ACCEPT: A separate document will be developed to specifically address alcohol extrapolations. The sentence was simplified.
44	Wendy Adams	Comment from Ballot		Annex A of SWGTOX Personnel requires analytical coursework. This is common for chemistry majors, but uncommon for biochemistry and other chemistry-related majors. Allowance should be made for on the job training, especially since instrumental technology is constantly changing. Certification such as ABFT should be able to demonstrate competence in place of coursework.	Change required to recommended or Allow more options to substitute for coursework	ACCEPT: Changed to "recommended"