# Commenter Section Type of Comment 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/discipline. Having unique guidelines for each discipline weakens rules, it does not strengthen the forensic disciplines, and it shows their righteousness and unprofessionalness.
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 The document is defining 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 Toxological Opinion".

3 Michele Triplett 4 individual assessment T An "individual assessment" is not supported by science. The NAS-report stated that scientific conclusions are those that UMR or 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 implying an agency and discipline of responsibility for conclusions, not ensuring conclusions are well
Reported conclusions should be based on data and criteria (set by 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 toxological 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 want practitioners to buy into your best practices, not show why they are not best practices.
Abercply to 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 word opinion, which then confuses the meaning of other words.
Be consistent in verbage and only use one term.
Accept: Modifications to the document have been made for consistent use of "expert toxological opinions" or "opinions" (see section 5.1.2).

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 Heading needs to be formatted
Accepted: 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 "Wildmark"
Review 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 5.3.3.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.
Accept: Removed "or" from the sentence in 5.3.1.i.

11 Denise Lyons 5.3 (item 5) T Other matrices may provide useful information in the proper context
Insert "solely" to make it read "without context of a given case".
Accept: The Consensus Body agreed that this is appropriate as written.

12 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

13 Denise Lyons 5.2 E Bullets should be number for easier reference
Number bullet points (e.g. 5.2.1)
Accept: Document was renumbered.

15 Mark Barry 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 Barry 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. Rather this is addressed in section 5.2.2.
Add "Literature/Research" to the area of including because opinions are made based on analytical findings and the literature/research i.e. 0.320 ETG level–really don’t need much else to say the person was impaired.

Add new tick mark "Should not use words such as scientific certainty or reasonable degree of scientific certainty should not be used.

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.

Discuss the toxicological impact of the presence/absence or stability of drugs or other chemicals.

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.

Opinions need to be expressed with particular care when interpreting drug concentration in post mortem blood and other matrixes. In particular, cognizance needs to be taken of the site of blood collection at autopsy.

The "for example" is implying the back extracaps are being performed on single blood draws, but does not state this. There are also states that have 3 blood draw procedures and these calls 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.

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 - 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.

The 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.

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.

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 a new tick mark that addresses words such as "scientific certainty" or "reasonable degree of scientific certainty should not be used.

The "or" example is implying the back extrapolation is being performed on single blood draws, but does not state this. There are also states that have 3 blood draw procedures and these calls 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.

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 be trained via alternate means and currently providing interpretive testimony should not be arbitrarily excluded as an expert witness.

A toxicologist should not opine as to an individual’s degree of impairment based solely on a quantitative result.

A toxicologist should not be qualified to testify as to a specific individual’s degree of impairment. The consensus Document also recognized that with drugs, especially ethanol, the individual’s tolerance that may develop to 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.

The statements 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.

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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 - 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.

The 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.

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.

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 would 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.
### The Innocence Project - Kareem Belt

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| **32** | The Innocence Project - Kareem Belt | General | E | The Guidelines for Opinions and Testimony in Forensic Toxicology 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 loophole 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. \(\text{In addition, the beginning phrase for the statements in Section 5.2 should be revised to read, "Where validated methods were used, a toxicologist ..."} \)
| **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 all 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 Subcommitte 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 Scientific Working Group for Forensic Toxicology (SWGTOX) Standard for Laboratory Personnel, 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 SWGTOX Standard for Laboratory Personnel 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 re-examine 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 misinterpreting). 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 make 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. |
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.

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.

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.

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).

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.

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"