

Deadline of Submission of Comments: 2-Sep-24  
Document Number: ASB TR 208  
Document Title: Forensic Toxicology: Terms and Definitions

Comment #	Text Line # (s)	Document Section	Type of Comment	Current Document Wording	Proposed Revision	Revision Justification	For Working Group use only, not to be completed by commenter.
			E-Editorial T-Technical				Final Resolution
1		3.1	E	Does [4] refer to the references at the end? If so, start the citations at [1]?	Start citations at [1]		REJECT: The references are listed in alphabetical order and the "4" refers to the 4th reference in Annex A "Bibliography".
2	28	3.5	E	set of standards, controls, or case samples	set of standards, controls, and/or case samples	Statement sounds like it's possible to have a batch with case samples, but no controls	ACCEPT: The proposed revision was used to modify the definition.
3	32	3.6	T	...in an analytical testing scheme	...in an analytical testing scheme, which may or may not include a quantitative range.	From previous Toxicology SC Lexicon review and revision, inclusion of quantitative range where quantitative testing is performed is relevant when defining scope. It may be that Scope and Sensitivity addresses this more satisfactorily now.	REJECT: This definition is very specific to the analytes to be included in an analytical strategy. Analytical sensitivity is specific to the detection limits that must be achieved. The quantitative range for testing is contained within the definition for analytical strategy.
4		3.9-3.11	E	bias terms	check the OSAC lexicon - and where these are preferred terms, the lexicon should be cited	<a href="https://www.nist.gov/system/files/documents/2023/07/21/OSAC%20Preferred%20Terms_July%202023.pdf">https://www.nist.gov/system/files/documents/2023/07/21/OSAC%20Preferred%20Terms_July%202023.pdf</a>	ACCEPT: Citations to the OSAC preferred terms were included.
5		3.11	T	Not sure Note 2 is needed. This note seems out of place	Remove Note 2		REJECT: The note within the definition is from the OSAC preferred terms.
6		3.14	T	Differing language between 3.14 and 3.15	Use similar language for both 3.14 and 3.15 e.g. "quantity value" or "concentration". Add "instrument" before "response" in 3.14		ACCEPT: The proposed revision of using "concentration" and adding "instrument" in 3.14 was used to modify the definition to be consistent with 3.15.
7	52-55	3.12	E	blank matrix sample - biological fluid (e.g., blood, urine, bile, serum, vitreous humor, oral fluid), tissue, or synthetic substitute without target analyte or internal standard	blank matrix sample - material of known composition where a specified component is not present	a blank is analyzed to ensure tests are accurately detecting something so it should be known to not have the target analyte and matrix needs to be general and not specific to just biological fluids, interdisciplinary definition of a blank in the lexicon is "a control where a specified component(s) is not present" so I'd suggest incorporating that	REJECT: As this document is not intended to be interdisciplinary, the working group discussed and the definition will not be modified to ensure it is relevant to the field of forensic toxicology.
8	95	3.21	E	one of which is stationary (stationary phase) while the other (the mobile phase)	one of which is stationary (stationary phase) while the other (mobile phase)	format of parentheticals are inconsistent	ACCEPT: Proposed change was made.
9	116	3.26	E	authority, organization, or person(s)	authority, organization, and/or person(s)	It is possible to service multiple types of customers	ACCEPT: Proposed change was made.
10		3.28	E	Add "limit" to the end of this sentence	Add "limit" to the end of this sentence		ACCEPT: Proposed change was made.
11	139	3.32	T	mass spectrometer instrument that can give at least 10,000 nominal mass resolving power at the full width of the peak at half its maximum height (FWHM) for the compound of interest	acquisition of data using a mass spectrometer that can give at least 10,000 nominal mass resolving power at the full width of the peak at half its maximum height (FWHM) for the compound of interest	mass spectrometry is not an instrument, it is the process of acquiring the data (see current definition for tandem mass spectrometry 3.81)	ACCEPT: Proposed change was made.
12		3.34	T	I don't really follow this. "Assignment to the most specific class attainable" suggests that an individual drug can never be identified?	Determining the name of a specific drug(s) or if not possible the most specific drug class attainable		REJECT: The definition is verbatim from ISO 21043. The note is intended to help clarify its use in forensic toxicology.
13	153	3.35	E	analytical tests that rely upon	analytical test that relies upon	singular "immunoassay" but plural definition	ACCEPT: Proposed change was made.
14	157	3.36	T	non-targeted compounds	compounds remove NOTE	It is possible for target compounds to interfere in a method, for example delta9-THC and delta8-THC.	ACCEPT: Removed "non-targeted" from the definition.
15	162	3.37	T	NOTE: In forensic toxicology, interpretations are the reported findings	or modify NOTE to read: "In forensic toxicology, interpretations are considered reported findings."	As written, this suggests that the only reported findings in forensic toxicology are the interpretations. I don't believe that is the intent of this. Further, interpretation can include inputs outside of the laboratory's observations and calculations. The note should address this and should end with a period if it remains.	ACCEPT: Proposed change was made.
16	174-175	3.40	E	and hence different	and thus different	thus is better grammar than hence	ACCEPT: Proposed change was made.
17	178	3.41	E	Type of...	type of...	All other definitions begin with a lowercase letter except in this instance.	ACCEPT: Proposed change was made.
18	188	3.43	T	mass spectrometer instrument limited to nominal mass resolution measurements	acquisition of data using a mass spectrometer limited to nominal mass resolution measurements	mass spectrometry is not an instrument, it is the process of acquiring the data (see current definition for tandem mass spectrometry 3.81)	ACCEPT: Proposed change was made.
19	190-191	3.44	T	N/A	LLOQ	Add in commonly used abbreviation	ACCEPT: Proposed change was made.
20	198-201	3.46	E	matrix - specific biological fluid or tissue (e.g., blood, plasma, serum, urine, oral fluid, vitreous fluid, hair, and tissue)	matrix - a medium or structure made up of multiple components	define generally as matrix can be a composite material, a medium surrounding something else, etc. The definition as written does not indicate that the biological fluid or tissue is the medium or material that will be analyzed to find something else	REJECT: The intent of the definition is to describe the types of samples that may be analyzed in routine toxicological analysis. The definition was modified to include synthetic substitutes.

21	200-201	3.46	T	fluid or tissue (e.g., blood, plasma, serum, urine, oral fluid, vitreous fluid, hair, and tissue)	fluid (e.g., blood, urine, bile, serum, vitreous humor, oral fluid) or tissue	Matches format of 3.12 definition better	PARTIAL ACCEPT: Examples were moved in the definition to follow biological fluid. The definition was modified to include synthetic substitutes.
22	207	3.47	E	data, or	data or	Remove comma between data, or	ACCEPT: Proposed change was made.
23	223-224	3.50	T	...ability to use a standard test method...	[add language for when method verification is performed for non-standard or laboratory-developed test methods]	Verification is also performed for non-standard or laboratory-developed test methods, such as demonstrating continued fitness of an instrument for use following major maintenance	ACCEPT: Proposed change was made.
24	263-264	3.59	E	N/A	(data)	see observation is mentioned in the definition for data, but data is not mentioned here	ACCEPT: Proposed change was made.
25	269	3.60	E	view,	point-of-view,	Clarifying	REJECT: The definition for "opinion" is verbatim from the OSAC Preferred Terms and a citation was added.
26	269	3.60	E	...considers other information in addition to observations, data, calculations, and interpretations	remove data	data and observations are synonymous (3.27)	REJECT: The definition for "opinion" is verbatim from the OSAC Preferred Terms and a citation was added.
27	289-292	3.66	E	qualitative method- assay designed to determine the presence of an analyte within a sample relative to an established threshold	qualitative method - an analytical approach to describe characteristics or qualities without use of measurements or numerical data	the definition is lacking specificity that this is non-numerical data being analyzed	REJECT: Qualitative methods may include point of care, immunoassay, or chromatography/mass spectrometry. All of which are relative to an established numerical threshold.
28	291	3.66	E	assay designed to determine the presence of an analyte	assay designed to determine the presence (or absence) of an analyte	consistency with phrasing of 3.61, 3.33, 3.25	ACCEPT: Proposed change was made.
29	293-295	3.67	E	quantitative method - assay designed to measure the concentration of an analyte within a sample	quantitative method - an approach that uses measurements or numerical data to analyze relationships and characterize a sample	suggested revision to compare with qualitative and to be more general	REJECT: The group prefers the existing definition to keep it consistent with the definition for qualitative method.
30	298	3.68	E	which have been	which has been	singular "reference material" but plural definition	ACCEPT: Proposed change was made.
31		3.68	E	"material, sufficiently homogenous and stable with reference to specified properties, which have"	"..., which has"		ACCEPT: Proposed change was made.
32		3.70	E	"measurement precision under a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions, same conditions," it's not clear what all the "conditions" are and how they differ	Clarify how "conditions" differ from "operating conditions"		ACCEPT: Definition was corrected by removing the additional "same conditions".
33	313	3.71	E	the Program's specifications	the laboratory's specifications	Program not defined elsewhere in document	ACCEPT WITH MODIFICATION: The definition was restructured.
34	322	3.73	E	observations calculations	observations, calculations	comma is grammatically needed	ACCEPT: Comma was added.
35	323-324	3.73	T	test/calibration results (observations, calculations, and interpretations) are often separated from opinion results.	test/calibration results (observations, calculations) are often separated from opinion results (interpretations).	While they consider test results, interpretations are opinion results, not test results.	REJECT: An opinion is defined as a view, judgment, or belief that considers other information in addition to observations, data, calculations, and interpretations.
36	330	3.75	T	selected ion monitoring	selected ion monitoring (single ion monitoring)	selected and single are used interchangeably in literature	REJECT: Definition and term are verbatim from the "Definitions of terms relating to mass spectrometry (IUPAC Recommendations 2013)." Pure and Applied Chemistry 2013, 85 (7), 1515-1609.
37	342-345	3.78	E	specimen - matrix sample collected from a specific origin for toxicological analysis (e.g., femoral or cardiac blood, left versus right eye vitreous fluid, and liver, brain, or kidney)	Specimen - Material submitted for examination	use the interdisciplinary definition from the OSAC lexicon and then within tox documents specify further - that specificity is not needed in definitions and will just lead to differences in the lexicon among disciplines	REJECT: This document is intended specifically for forensic toxicology so the more focused definition is relevant.
38	344-345	3.78	E	(e.g., femoral or cardiac blood, left versus right eye vitreous fluid, and liver, brain, or kidney)	(e.g., femoral or cardiac blood; left versus right eye vitreous fluid; and liver, brain, or kidney, etc)	Grammar and etc added to acknowledge there are more	REJECT: Grammar is correct and they are listed as examples so "etc" is not needed.
39		3.82	T	No mention of who should do this review e.g. another toxicologist or scientist working at the same level	Include who is qualified to carry this out e.g. "by an appropriately qualified person"		REJECT: A requirement (defining who must do the review) cannot be part of the definition. That level of detail will be included in the document that discusses technical review.
40	372	N/A	N/A	N/A	Measurement Uncertainty	Add definition	ACCEPT: Definition added for measurement uncertainty.
41	373	N/A	N/A	N/A	Confirmation Method	Add definition	REJECT: With the publication of ASB 113, the field is moving away from the concept of classifying methods as "screening" vs. "confirmation".
42			Ballot Comment	Do not believe this is a good idea. Documents should be complete and stand alone. Reference to a technical report in documents just causes another layer of complexity. It also undermines the concept and purpose for the Lexicon.			REJECT: This is consistent with the approach used by ASTM and other consensus bodies within ASB.

43			Ballot Comment	I noticed this document has a definition for "screening method" but not for "confirmation method." If screening is defined, shouldn't confirmation be as well?		ACCEPT with Modification: The working group has removed "screening method" from the definitions. With the publication of ASB 113, the field is moving away from the concept of classifying methods as "screening" vs. "confirmation".
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