Public Commenting Closed on November 22, 2021
ASB 113, Standard for Identification Criteria in Forensic Toxiocology

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
1	Foreward	T	The ASB should reconsider the need for this document in its entirety. The point system is difficult to support objectively. Is this really a consensus standard? Is this really acheivable for forensic toxicology labs? Is this really needed?	This document is a step backwards and does not reflect a true minimum standard of practice. Completely revise this document to follow the guidance format with testing categories that has already been in use for many years in seized drugs. See https://www.swgdrug.org/Documents/SWGDRUG%20Recommendations%20Version%208_FINAL_ForPosting_092919.pdf	REJECT: Please note that comments on a re-circulation are generally accepted only on revised section of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The Working Group supports the proposed concept of points rather than generic categories as SWGDRUG followed. The complexity of biological matrices compared to seized drugs requires additional requirements for identification, when the methods are appropriately validated per this document.
2	1 Scope	T	If the point system is not sufficient to reasonably address the most common analyte in forensic toxicology, ethanol, how is it appropriate for other analytes?	This document should be returned to the concept phase. If it is not sufficient to be able to be used for the most common analyte in forensic toxicology there is a fundamental problem with the entire document. This illustrates the problems with a point system approach and the agenda to push this document through should be abandoned.	REJECT: A standard method is under development for identification (and quantitation) of ethanol to address the fact that ethanol are excluded from this document. Other standard methods are being considered for the other excluded analytes.
9	2	E	in the body of the standard, it refers to the "current" version of these standards	remove "First Edition"	REJECT: Clarified that only the cited version applies to this standard.
10	3	E	The definitions cited to reference 3 Murray et al are cited to the RTI NLCP manual in Std 098	use consistent citations in the 2 standards	REJECT: Not applicable to this document, as these are correctly cited here.
3	4.1.3	T	It is a stretch to consider blood from different anatomical sites as the same "matrix". Chest cavity blood is hardly equivalent to a peripheral site.	If the ASB is going to require "minimum" points for each matrix then different anatomical sites should not be considered one matrix. If this is permisable then it seems reasonable for different matrices to be able to be used. Revise to allow different matrices to be allowed for the total "minimum" points or remove this allowance for PM cases to use matrix from different anatomical sites to be considered the same.	REJECT: The proposed change is in relation to a concept that did not change in this version of the document. The requirement for a minimum of 4 points to identify an analyte in each matrix was maintained throughout the different revisions. The scope of this document is on identification and not quantitation. Thus, points generated using the same matrix from different anatomical sites is allowed for calculating the final point total.
7	4.2.2	T	The second sentence of the secton can be more specific. Does it mean that a lab needs to establish quantifiable criteria to evaluate retention time, peak shape, resolution, and signal to noise?	Clarify how the accpetability criteria shall be specified	REJECT: Please note that comments on a re-circulation are generally accepted only on revised section of a document. Comments made on text not revised from the previous public comment period are generally not accepted. See ANSI/ASB 152 on ASB's website for the requirements related to Analyte Identification Acceptance Criteria.
4	4.3.1.4	T	The examples listed do not make any logical sense. The ELISA benzo example fails to account for the different cross reactivity of the alprazolam and diazepam. Most ELISA benzo assays have >300% cross reactivity for alprazolam. With this example an extremely low level of diazepam (e.g., 5ng/mL) and high level of alprazolam (e.g., 300ng/mL) the ELISA would not be positive if just diazepam was present, yet it can be used as part of the "points"? Yet a technique with higher specificity as stated in the third example (scan GCMS) that identifies norquetiapine cannot be used as part of the identification of the parent compound, quetiapine in an LC-MSMS analysis? This makes no logical sense.	There is a persistant bias in the document towards LC-MSMS and LC-high resolution MS. These techniques are powerful, yet still have limitations. The authors of the document seem to disregard those limitations and allow for identification solely by just one of those techniques. The language to perform even a second test is only a recommendation. Scan GC-MS has long been the gold standard in drug identification and remains so in seized drug analysis. While LC-MS techniques allow for greater sensitivity, the power of scan GC-MS should not be discounted. The value and point system for scan GC-MS, along with examples like these need to be revised and re-evaluated.	REJECT: The importance that method validation plays in determining when points are allowed for immunoassays with broad specificity is key to proper application of the point system. Likewise, as emphasized in 4.3.1.4, understanding the limitations of all techniques as characterized by method validation is also critical for proper application. Scan GC-MS alone is not considered as sufficient for identification of compounds in complex biological matrices.

#	Section	Type of Comment (E-Editorial, T-Technical)	Comments	Proposed Resolution	Final Resolution
5	4.3.2	T	This point system should be abandoned and a similar approach that has been used in Seized Drug Analysis should be adopted. See https://www.swgdrug.org/Documents/SWGDRUG%20Recommendations%20Version%208_FINAL_ForPosting_092919.pdf	Completely revise this document to follow the guidance format with testing categories that has already been in use for many years in seized drugs. See https://www.swgdrug.org/Documents/SWGDRUG%20Recommendations%20Version%208_FINAL_ForPosting_092919.pdf	REJECT: Please note that comments on a re-circulation are generally accepted only on revised section of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The Working Group supports the proposed concept of points rather than generic categories as SWGDRUG followed. The complexity of biological matrices compared to seized drugs requires additional requirements for identification, when the methods are appropriately validated per this document.
6	4.3.2	T	A point system in which scan GC-MS does not result in a sufficient number of points for identification (now that there is a requirement for a concurrently run standard) is unreasonable for a "minimum standard". This has long been the gold standard for drug identification. While GC-MS does have limitaions, so does LC-MSMS (both high and low resolution).	Revise to increase the Low Resolution Full Scan (library search) point value to 3 points, so that this document is consistent with SWGDRUG requirements that have been in effect for a long time (and continue to be in effect). It is unreasonable for High Res full scan to be 1.5 points more, when it often has less detail (fewer fragments) - even though there is accurate mass. See https://www.swgdrug.org/Documents/SWGDRUG%20Recommendations%20Version%208_FINAL_ForPosting_092919.pdf	REJECT: Please note that comments on a re-circulation are generally accepted only on revised section of a document. Comments made on text not revised from the previous public comment period are generally not accepted. SWGDRUG's requirements for seized drugs are not appropriate for identifying analytes in complex biological matrices.
8	4.3.2; footnote b	E	The footnote b could be confusing in its current form in that it could be viewed as an analysis needs to have a chromatographic/electrophoretic separation technique (1 point) AND a minimum of four points. Hence 5 points are required.	Revise the sentence to something like ". . . A minimum of four (4) points shall be required and one of the four points shall be a chromatographic or electrophoretic separation technique"	REJECT: Please note that comments on a re-circulation are generally accepted only on revised section of a document. Comments made on text not revised from the previous public comment period are generally not accepted. The footnote was slightly clarified to direct the reader to Section 4.2.2 where this requirement is initially stated.