

Deadline of Submission of Comments:

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Document Number:

ASB Std 173

Document Title:

Standard for Education, Training, Continuing Education, and Certification of Forensic Toxicology Laboratory Personnel

Comment #	Document Section	Type of Comment	Proposed Revision	Revision Justification	For Working Group and Consensus Body use only, not to be completed by commenter.
		E-Editorial T-Technical			Final Resolution
1	General comment	T	Many laboratories must comply with CAP/CLIA in addition to ABFT.	Please consider aligning the standards to the greatest degree possible.	REJECT: No specific revision was suggested. The scope of this document is forensic toxicology, not clinical toxicology. The current document aligns with the position of the ASB Forensic Toxicology Consensus Body and was not specifically written to comply with any certification or accreditation.
2	Foreword	E	remove past tense	change "stay updated" to "stay up-to-date"	ACCEPT WITH MODIFICATION: The proposed language was not used; however, a modified version was implemented.
3	1, 3.8 and 4.1.3	T	The Scope section states that this document applies to persons performing breath alcohol instrument calibrations and defines someone who performs breath alcohol equipment calibration as an Analyst and as "laboratory personnel". But this person in some (most?) departments is either a manufacturer's representative working under contract or a police officer who has been trained by the manufacturer. It does not seem appropriate to consider either of these categories as "laboratory personnel"; and they may or may not have the four-year science degree that an Analyst must have.	Consider a separate category for breath alcohol calibration personnel and include certification by the manufacturer as an acceptable educational requirement.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The Consensus Body's position is that the following are outside the scope of this document: personnel who exclusively perform administrative or non-technical duties; individuals working as breath alcohol instrument operators; individuals performing calibration adjustments to breath alcohol instruments; or individuals who solely perform instrument maintenance activities. Anyone who actually performs calibration of a breath alcohol instrument must meet the listed requirements for a Technician, at a minimum, because this activity affects test results. If the individual issues a calibration certificate, they must meet the requirements of an Analyst.
4	2	E	After the revision, there is only one reference listed now	The following reference is	ACCEPT: The correction was made.
5	3	E	"ANSI" crossed out but not crossed out in Section 2 Normative References.	not sure which is correct or the intent of the crossout.	ACCEPT: The correction was made.
6	4.1	E	eliminate redundancy	Remove Note about summary of education in Annex B from under 4.1.2, 4.1.3, and 4.1.4	REJECT: The Consensus Body recognizes the redundancy; however, it believes it is helpful to ensure the reader does not skip over this reference if it is inserted only once in the document.

7	4.1.1.3	T	The verification of academic credentials, specifically degrees, are included in standardized background checks.	A laboratory should be able to rely on those systems when they affirm the credentials provided by the candidate, and only require diplomas/transcripts when there is a discrepancy.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The Consensus Body's position is that laboratories must be able to provide proof of their employees' education and specific coursework to meet the requirements outlined in this document.
8	4.1.2 Note 1	E	What is "an equivalent number of semester hours?" This is not specified in the Annex.	Clarify what "an equivalent number of hours" is. Are they just those that apply to science classes? Presumably 60 semester hours of, say, English literature classes would not be acceptable.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. Further clarification was added to make it clear that the course requirements of an Associate's degree in a natural science, applied science, or technology must be met.
9	4.1.3	T	If a qualifying degree is issued by an accredited institution, it should not be necessary to review the transcript.	Compare and align with similar requirements for high complexity testing under CAP/CLIA GEN.54750 and GEN.54400.	REJECT: No specific recommended change was proposed. The Consensus Body's position is that laboratories must be able to provide proof of their employees' education and specific coursework to meet the requirements set forth in this document.
10	4.1.3	E	Individual requirements should have individual numbers, not dashes	Reformat so that all requirements have numbers	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The use of dashes, as in this document, is allowed per the ASB Manual and Style Guide. This was verified with the ASB Secretariat.
11	4.1.4	T	If a qualifying degree is issued by an accredited institution, it should not be necessary to review the transcript.	Compare and align with similar requirements for high complexity testing under CAP/CLIA GEN.53400-54750.	REJECT: No specific recommended change was proposed. The Consensus Body's position is that laboratories must be able to provide proof of their employee's education and specific coursework to meet the requirements within this document.
12	4.1.4	E	change wording to match 4.1.3	"preference in" to "preferably"	ACCEPT: The correction was made.
13	4.1.4	E	change wording to match 4.1.3	"e.g." to "such as" and "forensic science, medical sciences" to "forensic science or medical sciences"	ACCEPT: The correction was made.
14	4.1.4	E	Change the word "preference in" to be consistent with 4.1.3 edit	Preferably	ACCEPT: The correction was made.
15	4.1.4	E	Individual requirements should have individual numbers, not dashes	Reformat so that all requirements have numbers	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The use of dashes, as in this document, is allowed per the ASB Manual and Style Guide. This was verified with the ASB Secretariat.

16	4.2.1.1	T	This requirement is redundant as it is already covered in ISO 17025 6.2. The ASB should limit requirements to those that are not already covered elsewhere by accrediting bodies.	Remove requirement. Add ISO 17025 as a Normative reference	REJECT: This clause is a key part of the document and should remain. The CB does not assume that laboratories following this document are accredited under any particular program. Redundancies across standards are common and help readers interpret the documents logically.
17	4.2.2.1	T	This requirement is redundant as it is already covered in ISO 17025 6.2. The ASB should limit requirements to those that are not already covered elsewhere by accrediting bodies.	Remove requirement. Add ISO 17025 as a Normative reference	REJECT: This clause is a key part of the document and should remain. The CB does not assume that laboratories following this document are accredited under any particular program. Redundancies across standards are common and help readers interpret the documents logically.
18	4.2.2.3	E	Individual requirements should have individual numbers, not dashes	Reformat so that all requirements have numbers	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The use of dashes, as in this document, is allowed per the ASB Manual and Style Guide. This was verified with the ASB Secretariat.
19	4.2.3.2	E	Individual requirements should have individual numbers, not dashes	Reformat so that all requirements have numbers	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The use of dashes, as in this document, are allowed per the ASB Manual and Style Guide. This was verified with the ASB Secretariat.
20	4.2.3	T	Entire section: This requirement is redundant as it is already covered in ISO 17025 6.2. The ASB should limit requirements to those that are not already covered elsewhere by accrediting bodies.	Remove requirement (entire section 4.2.3). Add ISO 17025 as a Normative reference	REJECT: This clause is a key part of the document and should remain. The CB does not assume that laboratories following this document are accredited under any particular program. Redundancies across standards are common and help readers interpret the documents logically.

21	4.2.3	T	If the breath alcohol calibration person is a manufacturer's representative, and thus not an employee of the laboratory, how is the laboratory to determine that they have been undergoing ongoing competency evaluation?	Specify that a laboratory is not required to do this for manufacturers' representatives who perform calibrations as part of a maintenance contract.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The Consensus Body's position is that the following are outside the scope of this document: personnel who exclusively perform administrative or non-technical duties; individuals working as breath alcohol instrument operators; individuals performing calibration adjustments to breath alcohol instruments; or individuals who solely perform instrument maintenance activities. Anyone who actually performs calibration of a breath alcohol instrument must meet the listed requirements for a Technician, at a minimum, because this activity affects test results. If the individual issues a calibration certificate, they must meet the requirements of an Analyst. A laboratory can require, as part of the contract, that representatives who perform breath alcohol instrument calibrations undergo ongoing competency verifications.
22	4.3.3	E	eliminate redundancy	Move "see annex B" to be a Note under 4.3.3	REJECT: Including both the text and the table in Annex B is intentional and helps ensure readers understand the requirements.
23	4.3.3	T	Entire section: This is the role of certification boards. By including specific criteria for CE the ASB is assuming the role of a certification board without meeting the requirements they outline in section 4.4.3	Remove entire section. This is a role for certification boards.	REJECT: Certification bodies have authority only over the people they certify. Because this document requires only that Toxicology Technical Leads be certified, this section ensures that individuals in other positions also maintain a minimum number of CE units per year, even if they are not certified.
24	4.3.3	T	Certification boards already have established CE requirements. Add exemption if personnel is board certified. Otherwise this adds a layer of beauracracy that is not necessary.	Add exemption to these requirements if personnel is board certified (certification board already has CE requirements that include record keeping and submission of objective records to substantiate CE).	REJECT: Certification bodies have authority only over the people they certify. Because this document requires only that Toxicology Technical Leads be certified, this section ensures that individuals in other positions also maintain a minimum number of CE units per year, even if they are not certified. If a certification body requires more CU units for a specific position, its requirements will supersede the requirements in this document. If the reverse is true, individuals will be expected to meet the requirements of this document.

25	4.3.4	T	Entire section: This is the role of certification boards. By including specific criteria for CE the ASB is assuming the role of a certification board without meeting the requirements they outline in section 4.4.3	Remove entire section. This is a role for certification boards.	REJECT: Certification bodies have authority only over the people they certify. Because this document requires only that Toxicology Technical Leads be certified, this section ensures that individuals in other positions also maintain a minimum number of CE units per year, even if they are not certified. However, the note in this section specifically states, "If an individual is certified (see Section 4.4) or licensed, the certification or licensing body has the authority to assign different CE units for the above activities."
26	4.3.4.2	T	It is fairly obvious that most of these point values are based on ABFT. A reference to ABFT should be added to the bibliography.	Add reference to ABFT Board Certification Program in the bibliography	REJECT: A number of certification programs were considered when assigning the CE units in this section. The CB is reluctant to cite a specific certification body to avoid the appearance of endorsing one over others, including certification bodies that were not consulted during the development of the document.
27	4.3.4.2	E	<i>Recommend "formal mentoring of students or other toxicologists"</i>	<i>insert "of"</i>	ACCEPT: The suggested edit was made.
28	4.3.5.1	T	CE organizers or certifying boards should determine how CE is structured.	Remove requirement as this is a role for certification boards.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. Certification bodies have authority only over the people they certify. Since this document requires only that Toxicology Technical Leads be certified, this section ensures that individuals in other positions also maintain a minimum number of CE units per year, even if they are not certified. It also ensures that minimum requirements for continuing education activities include expectations to demonstrate the quality (and value) of the activity.
29	4.3.5.1	T	It should not be up to the laboratory to assess how the CE is structured. That burden should be on the organizers of the CE or certifying boards that pre-approve CE credits.	Remove requirement. This should be a role for certification boards.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. Certification bodies have authority only over the people they certify. Since this document requires only that Toxicology Technical Leads be certified, this section ensures that individuals in other positions also maintain a minimum number of CE units per year, even if they are not certified. It also ensures that minimum requirements for continuing education activities include expectations to demonstrate the quality (and value) of the activity.

30	4.3.5.2	T	This goes beyond a minimum requirement and places another record keeping burden on laboratories that is not necessary.	Remove entire section.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The Consensus Body's position is that CE activities must include an assessment mechanism to determine whether the activity is achieving its intended purpose.
31	4.4.3	E	Individual requirements should have individual numbers, not dashes	Reformat so that all requirements have numbers	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The ASB Manual and Style Guide allow the use of dashes.
32	4.4.3	T	The primary (only) certification board for forensic toxicology does not technically meet the first dash in this section (accredited under ISO/IEC 17024). ABFT is accredited by FSAB which has its own standards that are "consistent with ISO/IEC 17024:2012." (from FAQ on FSAB website)	Revise to "is accredited under ISO/IEC 17024 or standards which are consistent with ISO/IEC 17024" or similar language	ACCEPT WITH MODIFICATION: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The text was changed to remove the requirement of ISO/IEC 17024 accreditation while keeping the required elements of such accreditation. A note was added to state that certifying bodies accredited under 17024 are automatically deemed to meet the requirements of this section.
33	4.4.3	T	ABFT is accredited by FSAB and may not meet the first requirement. FSAB states on its website that "FSAB applies its own standards which are consistent with ISO/IEC 17024:2012"	Revise to "is accredited under ISO/IEC 17024 or in which standards are consistent with ISO/IEC 17024" or similar language.	ACCEPT WITH MODIFICATION: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The text was changed to remove the requirement of ISO/IEC 17024 accreditation while keeping the required elements of such accreditation. A note was added to state that certifying bodies accredited under 17024 are automatically deemed to meet the requirements of this section.
34	4.4.3	T	Some examples of acceptable certification programs or organizations that provide such programs might be helpful.	Add examples here or in an appendix.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The Consensus Body does not find it appropriate to identify specific certification bodies. Any certification body that meets the requirements of this clause will be deemed appropriate.

35	4.4.3	T	ABFT, which is the primary certification board for toxicology does not meet this criteria. They are in alignment with the standards but they are not accredited under ISO/IEC 17024.	Add language to include "Abides by standards consistent with ISO/IEC 12024" or something similar to not make it restrictive where ABFT does not comply.	ACCEPT WITH MODIFICATION: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The text was changed to remove the requirement of ISO/IEC 17024 accreditation while keeping the required elements of such accreditation. A note was added to state that certifying bodies accredited under 17024 are automatically deemed to meet the requirements of this section.
36	5.2, 5.3	E	Changing "employee" to "personnel" means that manufacturer's representatives, as discussed above, who were previously exempted from these requirements appear to be included.	Revert to "employee" or state that manufacturers' representatives are exempt from this requirement.	REJECT: The Consensus Body's position is that the individuals to whom this document does not apply are listed in the scope of this document.
37	5.2.1	T	Permanently is a long time. This is why statutes of limitation exist.	Consider establishing a reasonable sunset. Perhaps 5 years post-termination.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The current language allows state statute, regulation, or law to govern the length of time these records must be maintained. In the absence of such, they are expected to be maintained indefinitely.
38	5.3	T	Entire section. This requirement is redundant as it is already covered in ISO 17025 6.2. The ASB should limit requirements to those that are not already covered elsewhere by accrediting bodies.	Remove requirement. Add ISO 17025 as a Normative reference	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. This clause is a key part of the document and should remain. The CB does not assume that laboratories following this document are accredited under any particular program. Redundancies among different standards are common and help readers interpret the documents logically.
39	5.4	T	Entire section: This is the role of certification boards. By including specific criteria for CE the ASB is assuming the role of a certification board without meeting the requirements they outline in section 4.4.3	Remove entire section. This is a role for certification boards.	REJECT: Since this document only requires that Toxicology Technical Leads be certified, this section ensures that individuals in other positions also maintain a minimum number of CE units per year, even if they are not certified. It also sets minimum documentation requirements for continuing education activities.
40	5.4.1	T	This is redundant if the certification boards are already maintaining this information. Will laboratories have to submit this information or how is it verified that they made the proper conversions of hours to points?	Remove requirement. This should be a role for certification boards.	REJECT: Since this document only requires that Toxicology Technical Leads be certified, this section ensures that individuals in other positions also maintain a minimum number of CE units per year, even if they are not certified. It ensures minimum requirements for documentation of continuing education activities.

41	5.4.1	E	<i>It is unclear if the certificates of completion need to include the following list of items or if these are examples of documentation.</i>	<i>Please clarify</i>	REJECT: As noted, these are "examples".
42	5.4.2	T	This statement is vague. How will it be independently verified and by whom? This should be the role of certification boards or the organization providing the CE	Clarification on how this will be independently verified.	REJECT: This is intended to be independently verified by someone other than the individual requesting the continuing education or professional activity credit.
43	5.4.2	T	Logistically how would this be accomplished by a laboratory? What is an independent verification of CE? Who would conduct the "independent verification"?	Remove requirement or clarify how this can be accomplished.	REJECT: This is intended to be independently verified by someone other than the individual requesting the continuing education or professional activity credit.
44	5.4.2	T	This section is vague and doesn't specify who is independently verifying CE minimum requirements or how it should be done.	Remove requirement or clarify how this should be done by the laboratories.	REJECT: This is implied to be independently verified by someone other than the individual who is requesting the continuing education or professional activity credit.
45	5.5.1	E	Here you have retained "employee" where it says "personnel" in the rest of the section. You should be consistent, but "employee" would be clearer.	Revert to "employee" instead of "personnel" in other sections.	REJECT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The recommendation to change "personnel" to "employee" in other sections was previously addressed.
46	Annex A	E	Since the heading is "(normative)" for Annex A, clarifying language should be added after the Training Content header to be consistent with 4.2.2.3	Add "(as applicable)" after "Training Content" header to be consistent with 4.2.2.3 (first dash)	ACCEPT WITH MODIFICATION: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment. The title was simply updated to include "Applicable."
47	Annex A	E	<i>v. is the standard legal abbreviation for citation of court cases.</i>	<i>"Melendez-Diaz v. Massachusetts; Bullcoming v. New Mexico; and Smith v. Arizona"</i>	ACCEPT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment.
48	Annex A	E	<i>Recommend lower case m for "method development," consistent with document formatting</i>	<i>"method development..."</i>	ACCEPT: In accordance with ASB Procedures, feedback is generally accepted only on revised sections during the recirculation phase. Nevertheless, the Consensus Body felt it was important to consider your comment.
49	Annex B	T	CE: This is the role of certification boards. By including specific criteria for CE the ASB is assuming the role of a certification board without meeting the requirements they outline in section 4.4.3	Remove CE section. This is a role for certification boards.	REJECT: Since this document only requires that Toxicology Technical Leads be certified, this section ensures that individuals in other positions also maintain a minimum number of CE units per year, even if they are not certified. It also sets minimum documentation requirements for continuing education activities.
50	Annex B Analyst	E	change wording to match 4.1.3	"preference in" to "preferably" and "forensic science, medical sciences" to "forensic science or medical sciences"	ACCEPT: The suggested change was made.
51	Annex B Toxicologist	E	change wording to match 4.1.3	"preference in" to "preferably" and "forensic science, medical sciences" to "forensic science or medical sciences"	ACCEPT: The suggested change was made.

52	Annex B Tech Lead	E	change wording to match 4.1.3	"preference in" to "preferably" and "forensic science, medical sciences" to "forensic science or medical sciences"	ACCEPT: The suggested change was made.
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