Significant Changes and Response to Comments Received to the 10th edition of Standards for Perioperative Autologous Blood Collection and Administration

Please note that public comments that were submitted address the proposed 10th edition of Perioperative Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 10th edition of Perioperative Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that what appears below.

Standard	SC/RC	Comment	Change Made?	Outcome
1.0	SC	NA	NA	The committee added the clause "perioperative autologous blood" to the standard articulating what components are covered by this set of Standards. The addition was made for completeness.
1.5	SC	NA	NA	The committee added a cross reference to standard 1.3 to standard 1.5 which focuses on programs having policies, processes and procedures for completeness
1.7 (New)	SC	NA	NA	The committee included new standard 1.7 focused on "risk assessment" for completeness. This requires programs to perform assessments of risk at program defined intervals.
1.7 (New)	RtC	Please define "Risk Assessment" and provide examples	YES	The committee noted this comment and felt that a definition of

		of documented evidence of risk assessment (i.e. process validations or FMEA) that an auditor would request for compliance to this standard.		risk assessment would be appropriate and was included in the glossary. Guidance has also been crafted to assist users in the implementation of this standard.
2.1.3.1	SC	NA	NA	The committee elected to edit standard 2.1.3.1 for clarity, focusing the requirement on corrective action to be taken by adding the term "corrective" to the beginning of the standard.
3.3	SC	NA	NA	The committee elected to replace the clause "manufacturer's written instructions" with "manufacturer's instructions for use." The committee notes that more and more instructions are appearing online and the term "written" could be limiting and antiquated. This change has been made throughout the standards where the term was included, specifically, 3.5.1.2, 5.1.3, 5.1.5.2, 5.4.3,

				reference standards 5.1.8A, and 5.1.8C.
3.5, 3.7	RtC	Should these standards have record retention requirements associated with them? Standard 3.5.1 requires documentation for calibration. When assessing a facility review of maintenance documents is routinely performed, especially temperature accuracy and alarm checks on blood warming devices.	Yes	The committee agreed with the intent of this comment and moved the record retention symbol (✎) that appeared with standard 3.5.1 and moved it to appear at standard 3.5, allowing the record retention requirement to apply to both standards. The committee did not feel that a record retention symbol would be necessary on standard 3.7.
3.6.3.1	SC	NA	NA	The committee added the clause, "as defined by the perioperative program" at the end of the standard for completeness. This puts the onus for determining what are and are not acceptable temperatures of components on the perioperative program itself.
3.6.3.2	SC	NA	NA	The committee elected to add a record retention symbol (✎) to ensure that programs document the

				initiation of the actions taken when an alarm sounds.
3.8.6 (New)	SC	NA	NA	The committee added new standard 3.8.6 requiring all programs have processes in place to minimize the risk of internal and external data breached for completeness. This standard has been incorporated into all sets of AABB Standards to date.
Chapter 4, 4.0	SC	NA	NA	The committee has replaced the title of chapter 4 and standard 4.0 from "Supplier and Customer Issues" to "Suppliers and Customers" to reflect similar changes made in every other set of Standards.
4.3	SC	NA	NA	The committee added the term "and" for clarity, ensuring the standard reads as "…and/or use."
5.1.2	RtC	The Standards do not explain the quality control very well. There are no clear guidelines.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that there is

				guidance to this standard which provides evidence on means to meet this standard.
5.1.3	SC	NA	NA	The committee elected to replace the clause "manufacturer's written instructions" with "manufacturer's instructions for use." The committee notes that more and more instructions are appearing online and the term "written" could be limiting and antiquated.
5.1.5.2	SC	NA	NA	The committee added the term "for use" for completeness to the standard as it relates remaining consistent with manufacturer's instructions.
5.1.6.2.2.2 (5.1.6.2.3)	SC	NA	NA	The committee added the clause, "If the final component is separated from the recipient" for clarity.
5.1.6.2.2.2 (5.1.6.2.3)	RtC	With the addition of "If the final component is separated from the recipient" to this standard, the next natural question is to define separation. Does this mean a	YES	Based on the comment submitted the committee has added the following regulations, 21 CFR 606.121 and 21 CFR 610.40, to the standard for

		separation of the product from the patient physically, or only a separation in terms of space? For instance, separating the unit from the continuous circuit of a cell saver device for storage within the OR room is different than separating the unit from the patient by transporting it out of the OR room, say to the blood bank storage area. If the unit remains in the OR or procedure room with the patient, and does not leave the presence of the patient and those staff members caring for the patient at that time, does the unit need to be labeled as described? I would suggest further definition of "separation" in this case. It seems rather silly to label a unit collected by cell saver with the "Autologous Use Only", "Donor Untested" and "Biohazard" stickers to take the		clarity. These regulations are focused on labeling as discussed in the comment. The guidance to this standard has been updated as well.

		unit from the cell saver device across the OR room to the anesthesiologist to be infused to the patient.		
5.2.2	SC	NA	NA	The committee added the clause "or medical director designee" for completeness. This recognizes that in instances that the medical director has oversight, a designee can provide this role, however the medical director still retains overall oversight.
5.3.1 (New)	SC	NA	NA	The committee created new standard 5.3.1 as a title to the section that appears below. New standard 5.3.1 is now titled "Blood Collection."
5.3.1.1 (5.3.1)	SC	NA	NA	Standard 5.3.1.1 previously appeared as the content of standard 5.3.1. The committee did add a crossreference to standard 5.1.5 which ensures that programs institute methods to prevent contamination.
5.3.1.2 (5.3.2)	SC	NA	NA	Standard 5.3.1.2 previously

				appeared as standard 5.3.2 and has been moved to appear as standard 5.3.1.2 for clarity, and flow. The content of the standard has not changed. The committee did add a crossreference to standard 5.1.5 which ensures that programs institute methods to prevent contamination.
5.4.3	SC	NA	NA	The committee added the clause, "…follow manufacturer's instructions for use to…" to the standard for clarity and parallel construction with other standards noted above.
5.4.5.3.1	SC	NA	NA	The committee added the clause, "for topically applied or injected" to the standard for parallel construction with standard 5.4.5.3.
6.2.1.2, #2	SC	NA	NA	The committee added the term, "indelible" as it relates to "copies" to subnumber 2 for parallel construction with other sets of AABB Standards.
6.2.2	SC	NA	NA	The committee added

				crossreferences to standards 3.8.5 and 3.8.6 which focus on ensuring unauthorized access to information systems and managing the risk of internal and external data breaches. The committee added the crossreferences for completeness.
6.2.10	SC	NA	NA	The committee edited standard 6.2.10 to mirror other changes being put forth in other sets of AABB Standards. The intent of the standard has not changed.
7.1.3	SC	NA	NA	The committee added a crossreference to standard 8.2 for completeness. Standard 8.2 ensures that certain elements of usage are monitored by the perioperative program.
Glossary – Licensed Healthcare Professional	SC	NA	NA	The committee added this term to the glossary for completeness.