Response to Comments Received to the 8th edition of Standards for Perioperative Autologous Blood Collection and Administration

Please note that public comments that were submitted address the proposed 8th edition of *Periop 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. This document does not represent a full summary of significant changes to the 8th edition of *Periop Standards*. Guidance that appears with the 8th edition of *Periop 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	Comment	Change made?	Outcome
4.1.2.2 (New)	"Competent Authority"—How is this defined? With the heparin debacle in China, those pharmaceutical facilities were deemed competent by the Chinese government and we saw how well that worked out. 4.1.2.2 does not cover this in a meaningful manner.	No	The committee reviewed this comment and noted that the term is defined in the glossary. The definition reads as follows: **Competent Authority:** The agency responsible under its national law for regulations applicable to perioperative programs.
5.1.2	This is a section that should not be solely left to the manufacturer's discretion. It should not have meaningless terms like "defined intervals." The AABB should determine specific tests, methods and intervals and provide evidence for those methods.	No	The committee reviewed this standard but did not feel that a change was needed. The standard as written is done so in a manner to allow multiple programs to meet the standard in a way that best fits the policies in place that they have. It should be noted that AABB Standards are written in a manner to not be prescriptive and to allow accredited programs to validate their method or test for meeting the standard.
5.1.5.2	This needs to be more definitively addressed as most manufacturers don't address it or artfully dance around it. To be a meaningful standard, it should be facility based and tested (i.e., the facility shall	NO	The committee noted this comment but did not feel that a change was needed at this time. In the spirit of not being prescriptive, the committee felt it could be left up to each perioperative program to decide "the length of time disposables may be opened and set up before use". The example provided would be an

	setup a disposable…and after the desired time interval shall run ___ml of sterile fluid through it and send __ml to an approved testing facility). No manufacturer can control how a device is set up and stored so it is rather doubtful that they will ever meaningfully address this issue.		acceptable way to define this. The standard in question as written already covers what is included in the comment in the sense that these issues would be covered by program decisions, and those included in the manufacturer's written instructions. Staff are required to ensure that disposables are not used or left out past the time frame/temperature requirements set forth by the manufacturer.
5.1.6.1	I do not understand the purpose of this amount of detail. In high blood loss cases, writing down when you did each step is somewhat superfluous. Policies should cover how blood should be processed, and if it is desired to be electronically capture, then that should be specifically stated.	NO	The committee noted this comment but did not feel that a change was needed at this time. Since many cases are not high blood loss cases, the idea of capturing when each step is performed would not typically be onerous. It can assist in root cause analysis investigations, if needed. The committee notes that program policies & procedures can address how to meet this requirement in emergent situations or a deviation authorization can be created for those cases, but that in routine cases, this requirement is appropriate.
5.1.7	"Facility-defined stages, specified requirements" are terms so broad that they are essentially meaningless. If this is a standard, then define the stages and requirements and provide a basis for those definitions.	NO	The committee noted this comment but did not feel that a change was appropriate at this time. The main point of the standard is to ensure that components are inspected before use. The committee points out that this standard covers many different aspects of autologous collections and not just one type. As such, the standards are written in a way to allow for an approach that requires programs to determine the best methods to meet the standards. A facility should be prepared to show an assessor what each facility's defined stages are for inspection of components and should also be able to show the requirements the

			components need to meet in order to pass inspection.
5.2 - Notification	It is reasonable if a massive transfusion protocol is developed it should include call for use of cell salvage to help reduce patient exposure to allogeneic blood transfusion. Patient's own blood is always the best match.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee felt that this request would fit more appropriately in the Standards for a Patient Blood Management Program. The committee will share this with the PBM SC for their consideration in the 3rd edition of PBM Standards.
5.3	If this is a standard, then things like vacuum requirements and limits, etc. should be defined and the basis for that definition given. It seems to me this entire section could be covered by "the device shall be operated in accordance to the manufacturer's instructions which is to be the basis of the facilities policy on operation of the device."	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The recommended verbiage could be seen as prescriptive and does not necessarily address every desired parameter (e.g. filtration). The committee notes that standard 5.3 is a minimum list of what a program must define for collection parameters. If a facility would want to rely on the manufacturer's instructions, that would be appropriate based on the ability to validate their effectiveness. If a facility would like to base their policies on something more than manufacturer's instructions, that could also be appropriate.
5.3	I agree with the committee's standard wherein post autologous cell salvage or MUF, the 8 hours expiry can be extended to 24 hours if stored in the fridge within 4 hours. Perfusionists at our institution tend to wash a packed cell unit in the cell saver. Where does the AABB stand on washing packed cells intra-operatively in the cell saver by Perfusionists?	NO	The committee noted this comment, but did not feel that a change was appropriate at this time. The committee points out that perioperative programs may validate and perform quality control for all activities for which they are accredited to ensure that the processes in place provide a validated successful outcome.

5.1.8A, #3, 5	Should define start of collection as time of application of a negative pressure to the device and base expiration on this time solely for devices that use vacuum. This is when the device starts to draw large quantities of room air into the collection vessel. If you place a vacuum on a reservoir and don't process that blood for say, 10 hours, what difference does it make when the completion time was with regard to contamination? Should also state the basis for these times (testing method-studies used to derive them) because many seem somewhat arbitrary.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee notes that the times in question are defined as the time of 'processing' to reinfusion, and not the beginning of the act. The committee discussed expiration times at length, wanting to be consistent and realistic with regard to the duration of procedures that use perioperative components, but mindful of FDA expectations with regard to blood storage. Regarding the elements of contamination, the committee is aware that in some circumstances there are elements in the air that can be considered contaminants, specifically where suction is occurring. The committee points to chapter 1 and 10 for standards that cover contamination and the steps programs must take to ensure that the process is as sterile as possible.