Standards for Perioperative Autologous Blood Collection and Administration, 6th edition
Summary of Significant Changes

The following table summarizes many of the significant changes made to the 6th edition of Standards for Perioperative Autologous Blood Collection and Administration; it is not, however, exhaustive. Not all changes contained in the Standards have been incorporated in detail. Many of the changes that result in the reorganization of a section cannot be fully appreciated without consulting the 6th edition of Standards in conjunction with this table; therefore, the numbering follows that of the 6th edition and, where appropriate, the corresponding standard number in the 5th edition is included in parentheses. In cases where a standard has been re-numbered, but the substance of the standard has not changed, there is often no entry listed in the table. Like the crosswalk published with the Standards, this table is offered to assist individuals in updating their facility's policies, processes, and procedures to conform to the 6th edition. Use of this table should not take the place of a thorough, line-by-line analysis of each standard. Please note that this summary includes examples of comments submitted by users of the document, along with the program unit's rationale in making or not making a revision to the document.

6th edition standard number (5th edition number in parentheses if changed)	**Source of Change (Changes are made either in response to public comments or as the result of a program unit decision made prior to the public comment period.)**	**Outcome Following Program Unit Discussion** **(Please note that public comments address the proposed Standards. The changes are best understood when the proposed Standards is compared to the final published version. The program unit has elected to make the substance of public comments a part of this document.)**
1.0	Committee decision	The committee elected to edit standard 1.0 to ensure that the standard remains as broad as possible and less specific as it relates to product names. Specifically included was "bone marrow aspirate concentrate for topical application" to the standard to reflect its use in the perioperative world today. The standard now reads as such: **1.0 Organization** The perioperative program shall have a structure that clearly defines and documents the parties responsible for the following activities: intraoperative acute normovolemic hemodilution; collection, storage, and administration of autologous blood products obtained during intraoperative and postoperative autologous blood recovery; and perioperative autologous product production. Products covered under these activities include but are not limited **to autologous plasma** for **reinfusion, injection, or topical application**, ~~plasma for transfusion, platelet poor plasma for topical application, and thrombin for topical application,~~ thrombin for topical application, **and bone marrow aspirate concentrate for topical application**. The structure shall define and document the relationship of individuals responsible for key quality functions.

6th edition (5th edition)	Source of change	Outcome
1.4	Public comment submitted, no change made	**Comment:** I am slightly confused on what exactly the AABB is wanting here. Our emergency communication system is our cell phone, which we use to respond to OR emergencies also. We do have an emergency system plan for the on call autotransfusionist to cover emergencies. Does the AABB want it recorded that our cell phones work? **Outcome:** The committee noted this comment but did not feel that a change was necessary. The committee notes that in certain cases that a cellular phone can serve as a way to respond to emergencies, however it should be noted that cellular phones can fail and it is important to have a viable back up at all times.
2.1.4 (New)	Committee decision	The committee elected to add new standard 2.1.4 to this edition of *Perioperative Standards*. The committee elected to include this standard concerning continuing education to ensure that facilities are not only ensure that those requirements are met but are also documented and retained. The standard reads as such: ✎ **2.1.4 Continuing Education** The perioperative program shall define continuing education requirements for all personnel and ensure that these requirements are met.
2.1.4 (New)	Public comment submitted, no change made	**Comment:** I feel that the annual competency requirement is adequate to verify education of personnel. The healthcare system is facing large budget constraints so adding requirements such as meeting attendance seems impractical. We find it difficult to fulfill our continuing education requirement of state licensure and national certification. Travel or expense should not be involved. What does the AABB have in mind for continuing education requirements? **Outcome:** The committee noted this comment but did not feel that a change to the standard was needed. The committee notes that continuing education can come in many forms. Continuing education can include internal discussions and does not have to include external travel or the acquiring of expensive resources. The committee notes that most individuals who have met licensure or certification requirements will have met the standard, provided your internal continuing education requirements do not exceed state licensure requirements.
3.5.2	Public comment submitted, change made	**Comment:** We suggest adding a record retention requirement symbol (✎) to this standard and an associated record to be kept. **Outcome:** The committee agreed with this request and has made the necessary addition of the pen symbol.
3.5.2, #5	Committee decision	The committee elected to edit standard 3.5.2, subnumber 5 with the inclusion of the clause "and/or regulatory agencies…" for completeness. **3.5.2 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include the following: 5) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer **and/or regulatory agencies**, when indicated.
3.6, 3.6.1, 3.6.4	Committee decision	The committee elected to edit standard 3.6 by including the term "storage container" (and to 3.6.1 and 3.6.4 as well) for clarity. The committee felt that the inclusion of the term would provide clarity as it related to storage of products. The committee also crafted definitions for the terms "storage container" and "storage device" to ensure that the addition was fully understood. The standard now reads as such: **3.6 Storage Devices <u>and Storage Containers</u> for Perioperative Products** The perioperative program shall have storage devices **<u>and/or storage containers (e.g, portable coolers)</u>** for collected perioperative products, if applicable.
3.6.1	Public comment	In conjunction with the change to standard 3.6, the committee added the clause "and storage containers" to standard 3.6.1, however during the comment period, the committee received the following comment, which they did accept. Comment: Please add in "or containers" in standard 3.6.1 to read as such:

6th edition (5th edition)	Source of change	Outcome
	submitted, change made	**3.6.1** Storage devices and**/<u>or containers</u>** for perioperative products shall have the capacity and design to ensure that the proper temperature is maintained. **Outcome:** The committee agreed with this comment and the standard now reads as such: **3.6.1** Storage devices **and/or containers** for perioperative products shall have the capacity and design to ensure that the proper temperature is maintained.
3.6.4 (New)	Committee decision	In conjunction with the changes to standards 3.6 and 3.6.1 the committee elected to include new standard 3.6.4 in the 6th edition of Perioperative Standards for completeness. The new standard requires that storage containers be qualified for their intended use. The standard reads as such: **3.6.4 Storage containers shall be qualified for their intended use.**
4.1.2.1	Committee decision	The committee elected to edit standard 4.1.2.1 to remove the clause "registered with the FDA…" and replaced it with "…and other regulatory agencies." The interpretation of the new language is no different for U.S. facilities, but it allows for international facilities to meet the standard without the need for a variance. The standard now reads as such: **4.1.2.1** Testing shall be performed in a facility certified by the Centers for Medicare & Medicaid Services (CMS) ~~and registered with the FDA, if indicated by 21 CFR 610.40(f)~~**and other regulatory agencies.**
5.1.2	Committee decision	The committee elected to edit standard 5.1.2 to address a number of questions from the membership concerning the frequency of quality control testing. The committee to respond to this query has included new wording in the standard that ensures that quality control testing is done at perioperative program defined intervals. The standard now reads as such: **5.1.2 Quality Control** A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods function as expected**. Testing shall be performed at defined intervals. Quality control** results shall be reviewed and corrective action taken when appropriate.
5.1.5.1	Committee decision	In an effort to achieve completeness, the committee added a cross reference to Reference Standards 5.1.8A – 5.1.8C as applying to standard 5.1.5.1.
5.1.5.2 (New)	Committee decision	The committee elected to add new standard 5.1.5.2 to this edition for completeness. The committee felt that a standard that focused on the expiration time for disposables held at room temperature needed to be kept and made to expire in conformance with the manufacturer's instructions. The standard reads as such: **5.1.5.2 The perioperative program shall define the length of time disposables may be opened and set up before use. Timeframes shall be consistent with manufacturer's instructions.**
5.1.6.1	Committee decision	The committee elected to add a cross reference to standard 6.2.4 to this standard focusing on what records need to maintained and by whom.
5.1.6.2.1.1 (5.3.3)	Committee decision	The committee elected to move standard 5.3.3 (in the 5th edition) to appear as standard 5.1.6.2.1.1 in the 6th edition as it was felt that the standard better fit under the labeling requirements section as opposed to collection. The standard has been slightly modified in its language to require that products only be labeled in cases where it may leave the patient's bedside. The standard now reads as such: **5.1.6.2.2.1 Intermediate products that may potentially be separated from the patient shall be labeled with two patient identifiers.**
5.1.6.2.2	Committee decision	The committee elected to edit standard 5.1.6.2.2 for clarity to ensure that it applies only to final products and does not include in-process products. The standard now reads as such:

6th edition (5th edition)	Source of change	Outcome
		5.1.6.2.2 ~~Each unit collected perioperatively~~ **Final perioperative products for administration** shall be labeled with the patient's first name, last name, and hospital identification number; the date and time of initiation of collection, and the time of, or conditions for, expiration, as applicable. Reference Standards 5.1.8A and 5.1.8B apply.
5.1.6.2.3	Public comment submitted, no change made	**Comment:** The term "if applicable" should be removed from the statement. When would it not be applicable for a final product of an autologous product? Our institution received a nonconformance on this issue because we didn't really feel "Donor Untested" was required since it was an autologous unit that was never separated from the patient and the label stated it may transmit infectious agents. That is another point since most manufacturers of autologous blood collection systems do not have labels that would pass accreditation with the exact wording of "For Autologous Use Only", "Donor Untested" and "Biohazardous". Our labels from Sorin state "For Autologous Use Only, Intraoperative Autologous Blood" and "Caution: Properly identify intended recipient, This product may transmit infectious agents"; which is basically the same sentiment, just different words. We need to understand the intent of the warning and stop mincing words. What is the difference between the intent of the warnings "Donor Untested" "Biohazardous" and "may transmit infectious agents"? **Outcome:** The committee noted this comment but did not feel that a change was needed at this time. The committee feels that the term "as applicable" is in line with the current FDA regulations and in this case feel that the clause is appropriate. The terms used to appear on the label are in conformance with what is required by the current FDA regulations and as a result the committee felt it necessary to retain this language.
5.1.6.2.3	Committee decision	The committee elected to add the term "Biohazard" as an element of the final label on the perioperative product to remain in conformance with FDA regulations.
5.2.3	Committee decision	The committee elected to add the clause, "for collection, preparation and administration/reinfusion of a perioperative product…" to standard 5.2.3 for clarity. The committee felt that this was previously understood, but that it would best serve the user to have everything spelled out. The standard now reads as such: ✎ **5.2.3** There shall be a physician's order **for collection, preparation and administration/reinfusion of a perioperative product** when blood is to be collected from the patient. There shall be a process to define the communication and documentation of orders.
5.3, #5	Public comment submitted, no change made	**Comment:** I suggest adding new subnumber 5 to standard 5.3: 5) Flowrate / pressure observed in the system if applicable. **Outcome:** The committee noted this comment and agreed with a part of the intent, and as a result added new number 9 to the standard below.
5.3, #9 (New)	Committee decision	Following the review of the comment directly above, the committee elected to add new subnunmber 9 to standard 5.3 which requires that a perioperative program collect and define flow rate parameters for flow rates and system pressures within the circuitry. The rationale behind this inclusion is that this is currently being performed in many accredited AABB perioperative programs at this time and as a result was added to ensure completeness. New subnumber 9 reads as follows: **9) Flow rates and system pressures within the circuitry, if ultrafiltration is utilized for recovery of an autologous product off of cardiopulmonary bypass.**
5.3.3	Public comment	Comment: **5.3.3 Ratio of Blood to Anticoagulant-Preservative Solution** The volume of blood to be ~~drawn~~ **collected** shall be proportional to the amount of anticoagulant-preservative solution in the collection container. There shall be adequate mixing of blood and anticoagulant during collection.

6th edition (5th edition)	Source of change	Outcome
	submitted, change made	Please replace "drawn" with "collected" **Outcome:** The committee agreed with the suggested change and replaced "drawn" with "collected" as stated above. The term collected encompasses more than what "drawn" would thus ensuring that the standard can be applied more broadly.
5.4.1.1	Committee decision	The committee elected to edit standard 5.4.1.1 to mimic language from the 29th edition of Standards for Blood Banks and Transfusion Services, which is language that is currently being implemented across all sets of Standards for which AABB provides accreditation. The standard now reads as such: **5.4.1.1** There shall be positive identification of the recipient by ~~**two individuals**~~ **the transfusionist and one other individual (**or an electronic ~~equivalent~~ **identification system**) using two independent identifiers, eg, patient name and medical record number, whenever the product is separated from the patient or if administration occurs outside of the operating suite or clinical procedure area.
5.4.5.1	Committee decision	The committee elected to edit standard 5.4.5.1 replacing the word "transfusion" with "reinfusion." The term reinfusion better encapsulates what is being asked of the user in this case.
5.4.5.2	Public comment submitted, change made	**Comment:** Suggest removing the highlighted text: "the amount or" **5.4.5.2** For perioperative products intended for reinfusion, the patient's medical record shall contain the date and time of administration, pre- and postadministration vital signs, ~~the amount or~~ volume administered, and the identification of the individual administering the perioperative product. For products that are not used, records of their disposition shall be maintained. Records of adverse reactions shall be maintained. Standards 5.1.5 and 10.3 apply. **Outcome:** The committee agreed with this comment and the change was made.
5.4.5.3	Committee decision	The committee elected to edit standard 5.4.5.3 for accuracy, the standards has been edited as such: **5.4.5.3**For topically applied **or injected** products, the patient's medical record shall contain the date and time of **administration** ~~application~~, the identification of the individual applying the perioperative product, and a record of **administration** ~~application~~. For products that are not used, records of their disposition shall be maintained. Records of adverse reactions shall be maintained. Standards 5.1.5 and 10.3 apply.
5.1.8A, footnote 3 (New)	Public comment submitted, change made	**Comment:** Many programs have read and discussed in public forums the concept of recovering the blood cells that are suspended in laporotomy sponges (a.k.a. - sponge washing). We have been using this technique for a few years now and find that our overall recovery of red cells via traditional cell salvage as well as sponge washing exceeds cell salvage alone. (This observation is in line with the work done by Dr Haynes.) Additionally, during cardiac surgical procedures, sponge wash resuspension fluid aspirated to the cell saver often allows for the processing of a bowl of cell saver product at the onset of CPB when the effects of hemodilution are the greatest and the thresholds for transfusion are tested. To illustrate this I often describe a CABG procedure where the IMA and SVG harvest takes 90 minutes during which time several surgical sponges are used and saturated with blood. We soak these sponges in saline and aspirate that fluid to the cell saver after going on CPB. The combination of cell saver reservoir volume along with the sponge wash fluid is often enough to give the perfusionist a large bowl of RBC's just as the 1st ABG is resulting a HCT around 20%, which is our surgeons threshold for transfusion. Administering the resulting cell salvaged blood increases our HCT to 22-23% and we avoid subjecting our patient to a transfusion. To the best of my efforts, I have been unable to find any formal position regarding the technique of sponge washing by the AABB or AMSECT despite the published descriptions on the technique as well as the adaptation of the technique by many programs. Dr Haynes suggests, in his study, that 30 - 50% of surgical blood loss is due to the loss of blood to sponges and that the rate of red cell recovery from sponges is 67%. This is a substantial source of red cell mass that is able to be returned to our patients. Anecdotally, our program uses this along with several other blood salvage techniques and we enjoy an intra-operative PRBC transfusion rate around 12% consistently which is well below the STS median. My suggested addition to the Reference standard 5.1.8A would be the following:

<table>
<tr><th>6th edition (5th edition)</th><th>Source of change</th><th>Outcome</th></tr>
<tr><td></td><td></td><td>Item # 10, Surgical Sponge re-suspension fluid intended for processing by the cell saver, Room Temperature, Time from the start of collection to Expiration - 4 hrs, Time From Completion of Processing to Expiration - NA, Special Conditions - Sponge wash re-suspension fluid must be aspirated to the cell salvage device for processing and filtered with a particulate filter during re-administration to the patient.
Outcome: The committee noted this comment and while it did not make the specifically requested change, they have added a new footnote to this reference standard which is applicable to row 3. The new footnote reads “Can include blood recovered from surgical sponges.” The inclusion of this footnote will ensure that the Standards reflect the cases in which blood is recovered intraopertatively with processing.</td></tr>
<tr><td>5.1.8C, #4 (New)</td><td>Committee decision</td><td>In conjunction with the addition of bone marrow aspiriate concentrate to standard 1.0, the committee felt it necessary to add new item #4 in reference standard 5.1.8C for completeness. The committee felt that for the special considerations column, that it was necessary to ensure that users understand that the product must be used before the patient leaves the operating room or the clinical procedure area. The entry reads as follows:
<table>
<tr><th colspan="5">Reference Standard 5.1.8C—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Products for Topical Application or Injectable Application</th></tr>
<tr><td>Item No.</td><td>Product Type</td><td>Storage Temperature</td><td>Expiration</td><td>Special Conditions</td></tr>
<tr><td>4.</td><td>Bone Marrow Aspirate Concentrate intended for topical use</td><td>Room temperature</td><td>N/A</td><td>Shall be used before the patient leaves the operating room or clinical procedure area</td></tr>
</table></td></tr>
<tr><td>6.2.4 (6.2.3.1)</td><td>Committee decision</td><td>Standard 6.2.4 previously appeared as standard 6.2.3.1 in the 5th edition of Standards. This change has been made in all sets of Standards for which AABB provides accreditation. The first sentence was edited for clarity and consistency with other sets of Standards as well. The order of the list has been adjusted as well to reflect proper work flow however the terminology has not been changed. The standard now reads as follows:
<s>6.2.3.1</s>6.2.4 <s>The record system shall ensure the traceability of all the following</s> Records shall be created and maintained to include:
1) The facility where the activity was performed.
2) Method(s) used.
3) Equipment used.
4) Critical materials used.
5) Critical activities performed.
6) The individual who performed the activity.
7) When the activity was performed.
8) Results obtained.</td></tr>
<tr><td>7.1 – 7.1.3.1 (New)</td><td>Committee decision</td><td>The committee elected to add new standards 7.1 – 7.1.3.1 as it was noted that there were no standards that specifically addressed deviations. The basis for these standards was what is currently included in the 6th edition of Standards for Cellular Therapy Product Services. The standards appear as follow:
7.1 Deviations</td></tr>
</table>

6th edition (5th edition)	Source of change	Outcome
		The perioperative program shall have a process to capture, investigate, assess, and report events that deviate from accepted policies, processes, or procedures or that fail to meet the acceptable criteria of the facility, these *Perioperative Standards*, or applicable laws and regulations. The evaluation shall include an assessment of the patient and shall not delay proper clinical management of the patient. **7.1.1** Deviations shall be reported as soon as possible after detection. **7.1.2** Deviations shall be evaluated to determine the need for corrective and preventive action. Standards 9.1 and 9.2 apply. **7.1.3** For deviations having the potential to adversely affect the safety of a patient, a product, or an employee, approval of an individual qualified to evaluate the deviation shall be obtained before final release of the product. This approval shall be made by the medical director and/or the patient's physician, depending upon the circumstances. **7.1.3.1** Deviations discovered after administration of the product shall be investigated in the same manner as those discovered before product administration.
7.2 (7.1)	Committee decision	The committee elected to edit the title of standard 7.2 as follows: **7.2 ~~Nonconformities~~ Nonconforming Products or Materials**
7.2.3 (7.1.3)	Committee decision	The committee elected to add the clause "and regulatory agencies" to the end of standard 7.2.3 for completeness. The inclusion of this clause will ensure that in the case where there are any potential fatalities as a result of a perioperative procedure, the appropriate agencies are alerted. The standard now reads as such: ✎ **7.2.3** Perioperative products and critical materials that are determined after release not to conform to specified requirements shall be reported to the patient's physician and, if applicable, the supplier **and regulatory agencies**.
7.3 (7.2)	Committee decision	The committee elected to edit the content of standard 7.3 to ensure that the language of the standard reflects the title of the standard itself and the chapter removing the term "complications" from the *Standards* and adding in its place "adverse events." The standard now reads as follows: ✎**7.3 Adverse Events** The perioperative program shall have processes and procedures for the evaluation of **adverse events related to** ~~complications of~~ perioperative product **collection and/or** administration. In case of an **adverse event**, the **collection and/or** administration shall be interrupted and evaluated. The evaluation shall not delay proper clinical management of the patient.
7.3.1.1 (7.2.1.1)	Committee decision	The committee elected to edit standard 7.3.1.1 replacing the term "blood containers" with "perioperative product containers" for clarity and accuracy. The standard now reads as follows: **7.3.1.1** The label on the **perioperative product** ~~blood~~ containers and all other records shall be compared to the patient identification.
8.0	Committee decision	The committee elected to edit the standard replacing the term "obtained" with "conducted" and deleting "appropriately." The changes were made for clarity. **8.0 Assessments: Internal and External** The perioperative program shall have a process to ensure that external assessments (ie, inspections and surveys) are ~~obtained~~ **conducted** at ~~appropriately~~ defined intervals and that internal assessments of operations and the quality system are scheduled and conducted.
8.2	Committee decision	The committee elected to edit the title of standard 8.0 to ensure that it could be applied more broadly. The title now better reflects the content of the standard. ✎**8.2 ~~Utilization Review~~ Monitoring of the Perioperative Program** In conjunction with this change, the committee also added new subnumbers #3 and #8 to allow the standard to include common elements of the review and monitoring of a perioperative program. Subnumbers #3 and #8 read as follows:

6th edition (5th edition)	Source of change	Outcome
		The perioperative program shall have a process that monitors perioperative collection and administration practices. This process shall be a part of the institutional performance improvement process. Compliance with accepted recommendations shall be monitored. Chapter 9, Process Improvement, applies. The review shall include: **3) Quality control results** **8) Overall program effectiveness and opportunities for improvement.** The committee also elected to edit subnumbers #2 and #7 for clarity as such: 2) Appropriateness of use ~~(eg under and over utilization)~~. 7) Ability of services to meet ~~patient~~ **customer** needs.
8.3 (9.3)	Committee decision	Standard 8.3's content has not changed, however the committee elected to move it from chapter 9 where it was previously located to chapter 8, as it was felt that the content of the standard better fit under the Assessments chapter as opposed to process improvement. This change will be made throughout AABB's other sets of Standards as they become effective.
9.1	Committee decision	The committee elected to edit the content of standard 9.1 to ensure that it remains consistent with the content of the 29th edition of *Standards for Blood Banks and Transfusion Services*. The standard has been edited to read as such: **9.1 Corrective Action** The perioperative program shall have a process for corrective action with regard to deviations, ~~nonconformances~~ **nonconforming products and materials**, and complaints relating to perioperative products, critical materials, and services, which includes the following elements: 1) **Description of the event** 2) Investigation of the **event**~~cause~~. 3) Determination of the ~~corrective action~~ **cause**. 4) Implementation of corrective action. 5) **Monitoring** to ensure that corrective action is **complete and** ~~is taken and it is~~ effective.
9.2.1	Committee decision	The committee elected to replace the term "nonconformances" with "nonconforming products and materials" to ensure consistency with the edits made to chapter 7.
9.2.3	Committee decision	The committee elected to edit standard 9.2.3 for clarity. **9.2.3** Initiation of preventive action and ~~application of controls~~ **monitoring** to ensure that it is effective.
Glossary – Blood Salvage	Public comment submitted, no change made	Comment: We suggest the following definition be included in the Glossary: **Blood Salvage:** Perioperative blood cell recovery and reinfusion is a process of collecting blood lost during surgery and returning it to the patient after being appropriately processed **Outcome:** The committee noted this comment, but during the process of the creation of this document, the committee removed the term "salvage" from the Standards and as a result a definition was not needed. It should be noted that only terms that appear in the *Standards* that have a different meaning than what is understood in common parlance appear in the Glossary.
Glossary – Hemoconcentration	Public comment submitted, change made	**Comment:** We suggest the inclusion of the following definition to the Glossary: **Hemoconcentration:** See Ultrafiltration **Outcome:** The committee agreed with this suggestion and the term and definition were added.

6th edition (5th edition)	Source of change	Outcome

Glossary - Perfusionist	Public comment submitted, no change made	**Comment:** We suggest adding the term "Perfusionist" to the Glossary with the following definition: **Perfusionist:** A certified clinical professional who routinely circulates and manages blood perioperatively. **Outcome:** The committee noted this comment but did not feel that the inclusion of this term would be appropriate at this time. The committee felt that since the term is not used in the Standards, that it would not be appropriate to define it.