

Summary of Significant Changes to *Standards for Perioperative Autologous Blood Collection and Administration*, 2nd edition

2nd edition Standard Number (1st 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 <i>Standards</i> . The changes are best understood when the proposed <i>Standards</i> is compared to the final published version. The program unit has elected to make the substance of public comments a part of this document.)
General	Public comment submitted, requested change not made	<p>Comment: In reviewing the proposed standards, we have noted processing of intraoperative extracorporeal circuit blood post-cardiac surgery procedures has not been addressed. For discussion purposes and possible inclusion in this, or future, standards we propose the following:</p> <p><u>Area of concern:</u> Processing intraoperative autologous extracorporeal circuit blood</p> <p><u>Specific application:</u> Cardiopulmonary bypass (CPB) circuit blood content in the post bypass period</p> <p><u>Proposed standard:</u> <i>“The remaining blood content in the extracorporeal circuit (ECC) should be displaced and returned to the patient safely after the termination of CPB. A procedure guideline with quality indicators should exist that describes one of three means to return the ECC autologous blood to the patient.”</i></p> <p>Three methods for processing and reinfusing remaining autologous pump content blood are:</p> <ol style="list-style-type: none"> 1) reinfusion of unprocessed whole pump blood, 2) cell processing (washing) the pump blood contents prior to reinfusion (1), or 3) hemoconcentrating the pump blood contents prior to reinfusion (2-4). <p>Discarding pump autologous blood content after CPB should be avoided.</p> <p>Outcome: The program unit elected not to create a new standard based on the request. However, the definition of “Blood recovery” in the Glossary was amended to include the following: “This may include the recovery of residual blood in the extracorporeal circuit.”</p>
General	Public comment submitted, requested change not made	<p>Comment: I see only a brief mention of qualifications for the operators of perioperative blood processing equipment such as for cell salvage and platelet rich plasma. There should be more than a brief and nondescript set of qualifications. The operation of this equipment and the knowledge of the medium in which this works should be</p>

		<p>better outlined to include the level of education and experience required.</p> <p>Certainly, certified autotransfusionists and perfusionists would meet these qualifications by their education and experience, which is then tested by a national board exam for each respective specialty. Most other personnel receive no more than a one or two hour in-service visit from a sales representative for the device manufacturer and then consider themselves certified to operate this equipment. The morbidity and the direct effect on the outcome of the patient can be affected by the processes of providing these perioperative blood products. I would hope that the influence of the AABB on these practices can hopefully bring up the standards and the quality of these products.</p> <p>Outcome: The program unit elected not to change the standard and has elected instead to provide guidance on how the medical director at each facility can define the training and experience level necessary for operators of their facility's equipment. The program unit believes that each facility should have a defined process for the qualification of individuals. Consensus on the minimum education requirements and the need for certification does not exist – therefore, the program unit elected not to require any specific degrees or certifications in this standard.</p>
1.0	Change based on public comment	<p>Comment: The wording "platelet rich plasma for use with platelet gel" is a misunderstanding of what platelet gel's composition is. Currently, Platelet Gel is platelet rich plasma combined with a miniscule amount of calcium chloride and a minuscule amount of hydrated thrombin. Thus, the statement should read, "platelet rich plasma for use as platelet gel for topical application." The words "for topical application" must be included because once platelet gel is created it cannot be injected into the vascular system.</p> <p>Outcome: The program unit made the suggested change, and also added the following language regarding perioperative blood products to standard 1.0: “...(including platelet-rich plasma for transfusion, platelet-rich plasma for use as platelet gel for topical application, plasma for transfusion, platelet-poor plasma for topical application, cryoprecipitate for transfusion, cryoprecipitate for topical application, and thrombin for topical application)...”</p>
1.1.1	Program unit decision	<p>The program unit elected to be more specific in what duties the medical director could delegate to another qualified individual by specifically stating that medical director, “...may delegate operational management to another qualified individual...”</p>
1.3.1 (New)	Change based on public comment	<p>Comment: We agree with the Standard as written, however this Standard should include a reference to Chapter 7. Add Chapter, 7 Deviations, Nonconformances, and Complications, as applicable.</p> <p>Outcome: This standard is new to the 2nd edition and was added prior to the comment period by the program unit. Based on the comment, the program unit elected to add a reference to Chapter 7 to this standard.</p>
1.4 (New)	Program unit decision	<p>The program unit elected to add standard 1.4, which requires that all accredited perioperative programs have policies, processes and procedures to respond to the effects of internal and external disasters.</p>
2.1	Public comment submitted, no change made	<p>Comment: How does one determine the appropriate qualifications for each job?</p> <p>Outcome: As this is more of a question, the program unit has elected to create guidance for standard 2.1 to address this query. The Guidance to the <i>Standards for Perioperative Autologous Blood Collection and Administration</i> will be</p>

		available as a cd companion to the <i>Standards</i> .
2.1.3	Program unit decision	The program unit elected to add the clause, “before independent performance of assigned activities and at least annually thereafter” to the standard. Previously, the standard only required that evaluations of competence be performed at assigned intervals. The decision was made to expand and specify the intent of the standard due to the number of questions received while the 1st edition was effective.
2.1.4 (2.1.1)	Public comment submitted, no change made	Comment: We agree with the Standard as written, we ask that you consider removing it from the “Competence” section and adding a new section header, titled “Provision of Service.” Outcome: The program unit elected to re-number standard 2.1.1 from the 1st edition as 2.1.4. The standard was also re-named “Workload.” Further implementation information was added to Guidance.
3.3 (New)	Change based on public comment	Comment: We feel there should be an additional standard related to equipment use: “All equipment used to collect, prepare, process, test, store, or administer perioperative components shall be used in accordance with the manufacturers' written instructions or facility defined procedures.” This Standard can be added as 3.3.1 or incorporated into Chapter 5, Process Control, by changing 5.1.3 to <i>Use of Equipment and Materials</i> Outcome: This standard is new to the 2nd edition and was added prior to the comment period by the program unit. Based on the comment received, the program unit elected to take the language from standard 5.1.3 that referred to using “manufacturers’ written instructions and add it to standard 3.3. The clause, “or facility defined procedures” was also added to standard 3.3 to cover those instances where the facility may deviate from manufacturer’s directions based on acceptable validation data.
3.5.1 (3.3, 3.3.1 #1,3)	Program unit decision	The program unit elected to add the following clause to the standard: “There shall be safeguards to prevent equipment from adjustments that would invalidate the calibrated setting.”
3.5.2 (New)	Change based on public comment	Comment: We agree with the Standard as written, however the assessment should include a reference to Chapter 7. Add Chapter, 7-Deviations, Nonconformances, and Complications, applies. Outcome: This standard is new to the 2nd edition and was added prior to the comment period by the program unit. Based on the comment received, the program unit elected to add the suggested language as deviations remain as nonconformances, planned or otherwise.
3.6.3.1 (3.4.3.1)	Change based on public comment	Comment: We agree with the <i>Standards</i> as written, however for clarity we suggest the word “perioperative” be added to the standard: “The alarm shall be set to activate at a temperature that will allow proper action to be taken before the perioperative blood or component reach unacceptable temperatures.” Outcome: The program unit elected to make this change and the phrase “blood or components” has been removed and replaced with “perioperative products.”
3.6.3.2 (3.4.3.2)	Program unit decision	The program unit elected to rewrite this standard for clarity. It now reads: “Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective action.”

3.8.3 (New)	Program unit decision	A new standard was inserted. It reads, “Personnel responsible for the management of computer systems shall be responsible for compliance with the regulations that affect their use.”
3.8.4 (New)	Program unit decision	A new standard was inserted. It reads, “There shall be processes and procedures to support the management of computer systems.”
3.8.5 (New)	Program unit decision	A new standard was inserted. It reads, “A system designed to prevent unauthorized access to computers and electronic records shall be established and followed.”
4.0	Program unit decision	The program unit elected to add the term “ equipment” to this standard. It should be noted that the definition of “critical” now includes equipment that can affect the quality of products or services provided.
4.1	Change based on public comment	Comment: In general, the perioperative program staff does not have the authority and/or responsibility of vendor selection for all materials (i.e., saline, heparin, etc.) used in the collection, processing, and administration of products. We feel the standard should be changed to reflect this limitation: “The perioperative program shall evaluate and participate in the selection of suppliers, when possible, prior to acceptance of an agreement.” Outcome: The program unit elected to make this change, as some facilities may not have the opportunity to provide input on supplier selection prior to entering the agreement. “When possible” means that if the facility does have the option to provide this input, the requirement applies.
5.1.1.1	Program unit decision	The program unit elected to add a reference to standard 2.1.2 to this standard. This is intended to convey the requirement that all appropriate individuals are trained in new or changed processes.
5.1.5.2.1	Change based on public comment	Comment: Handwritten additions probably should not be written directly on the bag because many inks are absorbed into the fluid inside the bag. Outcome: The program unit elected to change the standard as a result of the received comment. The language now requires that handwritten changes or additions be made to the label.
5.1.5.2.2 5.1.5.2.3 (5.1.5.2.2)	Program unit decision	The program unit removed the clause, “...and the statement For Autologous Use Only,” from standard 5.1.5.2.2 and moved it to new standard 5.1.5.2.3. New standard 5.1.5.2.3 also includes a statement requiring that labeling of products conform to all FDA regulations, including barcode labeling, as applicable. This requirement was included in response to feedback from the FDA indicating that any perioperative products that are stored in a blood bank refrigerator would be required to conform to the new bar code labeling rule issued on February 26, 2004. The standard also requires that, when applicable, perioperative products be labeled, “Donor Untested.”
5.1.7	Program unit decision	The program unit elected to remove the term “distribution” from both the title of the standard and from the body of the standard itself.
5.2.2	Change based on public comment	Comment: It seems that this standard is projecting processes that take place for preoperative donation and does not account for the intraoperative environment where the “order” would not necessarily be needed when the attending

		<p>MD is standing over the patient.</p> <p>Outcome: The standard was rewritten in response to this comment. The language is now broader and simply requires that each facility define how physician orders are communicated and documented. Verbal orders are acceptable if this is reflected in the facility's policies, processes, and procedures. There should always be a record of verbal agreements.</p>
5.2.3 (since removed)	Change based on public comment	<p>Comment: Can the program unit define what 21 CFR 610.40 (d)(4) requires somewhere in the document? I can guarantee that MDs other than blood bankers will have no idea what the code of federal regulations is.</p> <p>Outcome: The program unit elected to remove this standard and the associated reference from the document.</p>
5.3, #8 (New)	Program unit decision	<p>The program unit elected to add, "Centrifugation speeds, if applicable" to the collection parameters required by this standard.</p>
5.3.1 (New)	Change based on public comment	<p>Comment: What is green soap? Most operating rooms would have betadine or alcohol as a topical bacterial decontaminant.</p> <p>Outcome: This standard is new to the 2nd edition and was added before the comment period by the program unit. The program unit removed the sentence in question from the standard. Guidance will be provided on currently accepted arm preparation methodologies through Standards Source.</p>
5.3.1.1 (New)	Public comment submitted, no change made	<p>Comment: Blood donation can also take place through an arterial line. In fact, most advocates of ANH recommend this as the preferred route of donation.</p> <p>Outcome: This standard is new to the 2nd edition and was added by the program unit before the comment period. The program unit elected not to change the standard, which was intended to be general rather than prescriptive.</p>
5.3.1.1.1 (New)	Public comment submitted, no change made	<p>Comment: We feel this standard is too restrictive in requiring the use of only an unused port. Please consider modifying the standard to allow the discretionary use of previously used ports based on how the port was used (i.e., what was infused through the port prior to initiation of collection, etc.). Recommended wording: "Blood should be drawn as soon as possible following line placement through a previously unused port."</p> <p>Outcome: This standard is new to the 2nd edition and was added before the comment period by the program unit. The program unit elected to not change the standard, which was written to address the issue of bacterial contamination in the line.</p>
5.3.2 (New)	Program unit decision	<p>This standard is new to the 2nd edition and was added before the comment period by the program unit. The program unit added this standard to respond to queries received since the implementation of the 1st edition.</p>
5.4.2.1 (5.4.2)	Change based on public comment	<p>Comment: We agree with the Standard as written, however this Standard should include a reference to Chapter 7. Add "Chapter 7, Deviations, Nonconformances, and Complications, as applicable."</p> <p>Outcome: Based on this comment, the program unit elected to add the suggested language.</p>
5.4.4	Public comment submitted, no change	<p>Comment: This comes back to my comments regarding 0.9% saline for bladder irrigation. Practice of medicine does not necessitate these requirements.</p>

	made	Outcome: The program unit elected to make no change to this standard, but does plan to issue guidance.
5.4.5.1	Public comment submitted, no change made	Comment: 5.4.5.1 states that perioperative components intended for transfusion shall be transfused through a filter designed to retain particles potentially harmful to the donor-patient. This statement is vague in that basic blood administration sets on the market permit gross particulate emboli greater than 50 microns to enter the vascular system. The statement should provide a nominal or depth filtration limit in microns as to what filter should be used with each specific perioperative component. For example, autologous packed red blood cells produced by any of the perioperative autotransfusion machines should be filtered with at least a 40 micron filter to remove any particulate gross and micro emboli, but still allow gravitational flow or rapid infusion via pressure bag if acute volume resuscitation is required. Outcome: The program unit elected not to change the standard, but will issue guidance through Standards Source in the near future.
5.4.5.2 (New)	Program unit decision	This standard is new to the 2nd edition and was added before the comment period by the program unit. The standard reads, “For topically applied products, the patient’s medical record shall contain the date and time of application, the identification of the individual applying the perioperative product, and a record of application. Records of adverse reactions shall be maintained. Standard 5.1.5 applies.
5.1.7A, 5.1.7B	Program unit decision	The program unit elected to split Reference Standard 5.1.7A into two separate Reference Standards. Reference Standard 5.1.7A addresses all red cell products and Reference Standard 5.1.7B addresses non-red cell products.
5.1.7A	Change based on public comment	Comment: Because Platelet Rich and Platelet Poor Plasma for Topical use are often harvested and applied outside of an operating room, the wording should reflect that possibility. Many are using PRP and PPP topically for chronic wounds, burns, or in dental offices or outpatient offices. The current proposed wording appears to only allow these products to be harvested and used in an operating room. Perhaps the following wording could be used: “Shall be used prior to donor-patient leaving the operating room <i>or clinical donation site.</i> ” This way we are able to apply this technology to the patient at the clinical site of need without concern for transportation (separation from donor-patient), mixing or confusion of other products or increased chance of contamination. Outcome: The program unit elected to change the standard in response to the comment. The language reads, “Shall be used prior to donor-patient leaving the operating room or other clinical procedure area.”
5.1.7A	Public comment submitted, no change made	Comment: In Reference Standard 5.1.7A, Handling, Storage, and Expiration of Perioperative Autologous Blood Products, changes should be made with respect to: (1) Acute Normovolemic hemodilution: When kept at room temperature, expiration should be 4 hours from end of collection; Special Conditions should be with regular or continuous soft agitation or rocking. (2) Intraoperative blood recovered and shed blood with or without processing, plasma, platelet rich plasma, platelet

		<p>poor plasma, and cryoprecipitate: When kept at room temperature, expiration should be 4 hours from the end of collection.</p> <p>This time limitation relate to possible bacterial contamination of the component. Surgical operations that require four or more hours of procedure time should be considered highly complex and will possibly have a large amount of surgical instruments involved. This could also mean there could be an increased amount of instrumentation being brought to the surgical tables thus increasing the possibility of cross contamination. Those products that are collected into a reservoir via vacuum should be processed as soon as possible, as it has been demonstrated that vacuum collected shed blood has a bacterial count upon collection.</p> <p>Outcome: Because there is considerable variation in the length of collection time, the program unit elected to continue phrasing this requirement as a number of hours from the beginning of the collection rather than from the ending of collection. Therefore, no change was made.</p>
5.1.7A	Public comment submitted, no change made	<p>Comment: The current verbiage related to processing time for salvaged blood is vague. It does not take into account the concept incorporated into perioperative salvage devices. Such devices allow for both intraoperative and postoperative collection of shed blood. Given that these devices can continuously process the salvaged blood, and that some patients will have active or ongoing blood loss in the postoperative period, a different and more precise time limit would be helpful (e.g. 6 hours from the cessation or obvious diminution of bleeding postoperatively).</p> <p>Outcome: A new section on “Combined intraoperative and postoperative blood recovered with processing” was added; expiration times for the intraoperative and postoperative portions of the collection are defined.</p>
6.2.3	Program unit decision	<p>The program unit elected to add the clause, “...and to investigate adverse events manifested by the patient.” to the standard.</p>
6.2A	Change based on public comments	<p>Comment:</p> <ul style="list-style-type: none"> -3.6.2 - Change ambient to “room temperature” to be consistent with wording throughout Chapters 3 and 5. -5.4.2.1- Change wording to clarify requirement applies to non-conforming products (Physician approval for use of non-conforming perioperative product before transfusion). -Review 5 years versus 10 year retention requirements (5.4.5.1.1 vs. 5.1.6.1 vs. 5.1.5.1) to ensure consistency and traceability of records. Compare defined retention periods with <i>Standards for Blood Banks and Transfusion Services</i> to ensure compatibility. <p>Outcome:</p> <ul style="list-style-type: none"> 3.6.2 - The program unit elected not to make the requested change, however the requirement was modified from its original wording to focus on storage devices. 5.4.2.1 - The program unit made the change requested and the term “nonconforming” has been added to the retention requirement. -The time periods were reviewed and changes were made to the overall reference standard.

7.0	Program unit decision	The program unit elected to add the clause, "...and to outside agencies as required" to the standard.
7.1.3	Program unit decision	The program unit elected to rewrite standard 7.1.3 and has added the following requirements. The standard now requires that any of the following be notified in the case of a nonconforming perioperative product being released, the patient's physician, and the customer and the supplier as necessary.
8.1.1 (8.1.2)	Program unit decision	The program unit elected to rewrite standard 8.1.1 so that it more specifically states that any corrective or preventive action be taken in accordance with the standard set forth in chapter 9, Process Improvement.
Glossary	Change based on public comments	<p>Comment:</p> <ul style="list-style-type: none"> - I would like the definition of "Acute Normovolemic Hemodilution" as written in the Glossary to be changed. There have been many discussions of the established definition that include the process of cardiopulmonary bypass (CPB) as well as extracorporeal membrane oxygenation (ECMO). Many in the perfusion profession feel the current definition is extremely vague and should include a statement that would exclude CPB, ECMO, and any other use of an extra-corporeal circuit that provides support for cardiac and/or pulmonary functions. The reasoning is that although the procedures mentioned above do include the use of acute hemodilution, the patient's actual blood volume is not sequestered to another external source and/or replaced by normovolemic hemodilution. The patient's actual blood volume is kept in whole within the extra-corporeal circuit. We are actually improving the use of acute hemodilution of our patients by effectively lowering the amount of crystalloid hemodilution being used within the extra-corporeal circuits. These circuits are allowing perfusionists to reduce the hemodilution to range between 0 and 900 milliliters. -Add definitions for "start of collection" and "completion of processing" (based on Reference Standard 5.1.7 A). -Based on 4.2.1, Agreement review is performed prior to signing an agreement and when changes are incorporated. The definition should correspond to the wording 4.2.1: Agreement Review: "Systematic activities carried out to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable." <p>Outcome:</p> <ul style="list-style-type: none"> -The committee elected to change the wording of the definition to acute normovolemic hemodilution, although not with the exact wording suggested by the commenter. -"Start of collection" has been added to the glossary. -The definition of "agreement review" has been changed in accordance with the comment submitted.