

Significant Changes and Response to Comments Received to the 12th edition of *Standards for Perioperative Autologous Blood Collection and Administration*

Please note that public comments that were submitted address the proposed 12th edition of *Standards for Perioperative Autologous Blood Collection and Administration (Perioperative Standards)*, and not the final version. The Perioperative Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 12th 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 appear below.

Standard	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome
1.1.1	SC	NA	NA	The committee added the new final sentence to the standard to ensure that the communication between the medical director and executive management (which in a perioperative setting is not a guarantee), occurs at set times. The sentence reads as follows, “ The medical director shall be responsible for reporting to executive management at defined intervals. ”
1.1.1	RtC	It is suggested to provide a recommended minimum frequency for these reports to ensure global consistency across accredited facilities.	No	The committee reviewed this comment but did not feel that a change was appropriate at this time. The committee feels that it is necessary for programs to define the intervals in question to best reflect what best fits their program.
1.1.1.1	SC	NA	NA	The committee added a crossreference to standard 1.3.1 to the standard. Standard 1.3.1 focuses on the need for medical directors and their designees (as appropriate) to review all policies, processes, and procedures. This crossreference was added for completeness.
1.9 (New)	SC	NA	NA	Standard 1.9 is new to the 12 th edition and was added to mirror a new standard in every new set of Standards since the release of the 12 th edition of <i>Standards for Cellular Therapy Services</i> . This ensures that there is clear communication between AABB and

				all accredited laboratories in cases where an event has occurred that has impacted their accreditation status.
1.9.1 (New)	SC	NA	NA	Standard 1.9.1 is new to the 12th edition and was added to mirror a new standard in every new set of Standards since the release of the 12th edition of <i>Standards for Cellular Therapy Services</i>. This standard now requires accredited programs contact AABB if they are under investigation by their relevant Competent Authority. This ensures AABB accreditation's department is aware of all issues that could potentially impact the program or AABB as an accreditation organization. The standard reads as follows: 1.9.1 If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, the organization shall notify AABB within 7 days in electronic or written format. The committee also added a new definition to the Glossary for "Regulatory Enforcement Action" for clarity which reads as follows: Regulatory Enforcement Action: Measures taken by a Competent Authority that include, but are not limited to, progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues; deficiencies in risk management systems).
2.1.3.2 (New)	SC	NA	NA	The committee added new standard 2.1.3.2 to the edition for completeness. This requirement is implied in chapter 4, however the committee felt it important to affirm that third party providers ensure that their staff is trained against the standards for which they are to be held accountable.

2.1.7.1	SC	NA	NA	The committee added new standard 2.1.7.1 to ensure that programs review the workload of all personnel to ensure that the workload is at a level that does not affect patient safety in a negative fashion.
2.1.7.1	RtC	In practical terms, workload assessment is often difficult to standardize. It may be helpful to specify whether indicators such as procedure volume, staff-to-case ratio, emergency coverage, or adverse event trends should be considered as part of this evaluation.	No	The committee reviewed this comment but did not feel that a change was needed at this time. This would be defined by each facility based on their case load to reflect the needs of their staff and patients. The standard does include a list of examples including, “eg, procedure volume, staff-to-case ratio, emergency coverage, or adverse event trends, quality assessment trends, etc.”
3.3.1	SC	NA	NA	The committee edited standard 3.3.1 for clarity. The committee felt that the edits ensure that the focus of the standard is on the actual functionality of the device. The standard reads as follows: 3.3.1 The organization shall verify that devices and equipment function as intended at defined intervals.* Standards 4.1.4 and 4.2.4 apply.
3.5.4.1 (New)	SC	NA	NA	The committee created new standard 3.5.4.1 for clarity. This new standard clarifies that not all equipment has to be reviewed when it is known that one piece of equipment is at the root of the nonconformance.
3.5.4.1 (New)	RtC	The phrase “all potentially affected” maybe open to variable interpretation between institutions. It may be helpful to further clarify whether the determination of “potentially affected” should be based on predefined risk assessment criteria, shared equipment characteristics, or involvement in the same procedural workflow.	No	The committee noted this comment but did not feel that a change was needed at this time. The suggestion provided reads as guidance and not a requirement.
3.6 (deleted)	SC	NA	NA	Based on a review of chapter 3, it was deemed that this standard is redundant to many standards in chapter 3, specifically the 3.5

				thread. This standard was also deemed redundant per standard 6.2.2.
3.7 (New)	SC	NA	NA	The committee created new standard 3.7 to ensure that facilities monitor their critical technology infrastructure and that they function as expected. This standard requires that there are defined checks to monitor that technology is working as intended and expected.
3.8	RtC	I suggest the addition of the following standards to the edition: 3.8 Selection, Specifications, and Monitoring of Blood Storage Devices and Containers 3.8.1 Selection and Specifications Blood storage devices (eg, refrigerators, freezers, platelet incubators) and storage containers (eg, portable coolers) shall be selected based on their ability to maintain required storage temperatures for blood components. Devices and containers shall meet defined specifications, including corrosion-resistant and cleanable materials, structural integrity, adequate insulation, secure seals or closures, and temperature monitoring capability, as applicable. Storage devices shall include alarm systems. Manufacturer documentation or validation shall demonstrate suitability for intended use. 3.8.2 Qualification Storage devices and storage containers shall be qualified prior to use and requalified at defined intervals or after repair, relocation, or modification to confirm maintenance of required temperature conditions under intended use. 3.8.3 Temperature Monitoring Storage devices shall have continuous or automated temperature monitoring. Storage containers shall have temperature recorded at defined intervals to ensure compliance with required storage conditions during storage and transport. 3.8.4 Alarm Systems Storage devices shall have alarm systems to detect temperature excursions and initiate	No	The committee reviewed this comment and appreciated the content. However the intent of the change was merely a reorganization and not a substantive change and would constitute change for changes sake.

		immediate investigation and corrective action. 3.8.5 Maintenance Storage devices shall be maintained under a documented program including calibration, preventive maintenance, and periodic performance review.		
3.8	RtC	Perhaps some clarity could be added here on the intent of when these standards become applicable. For example, at what point does the collection device become a storage device? I noticed in Reference Standard 5.1.9A, "storage" is used when cooling the blood, "collection" is used when the blood is at room temperature.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that in the case of these standards, storage is the focus of those cited.
3.8.1	SC	NA	NA	The committee added a crossreference to reference standards 5.1.9A – 5.1.9C for clarity and completeness. This closes a loop on the need to monitor the temperature, as well as ensuring that storage devices are maintained at the appropriate temperature. This mirrors changes to similar edits made to the 35 th ed of BB/TS and 14 th ed of IRL Standards.
3.8.4	SC	NA	NA	The committee added a crossreference to reference standards 5.1.9A – 5.1.9C for clarity and completeness. This closes a loop on the need to monitor the temperature, as well as ensuring that storage devices are maintained at the appropriate temperature. This mirrors changes to similar edits made to the 35 th ed of BB/TS and 14 th ed of IRL Standards.
4.1.4	SC	NA	NA	The committee added a crossreference to standard 2.1.3.2 for completeness. Standard 2.1.3.2 is focused on ensuring that third party providers are trained to perform critical tasks related to these <i>Standards</i> .
4.1.4	RtC	There are centers that indicate cell salvage choice. Then the patient finds out the	No	The committee reviewed this comment but did not think a change

		institution does not have the equipment or outside group that is available to bring equipment, with trained personnel that is responsible.		would be appropriate at this time. The committee does not feel that it would be for the Standards to determine what each program do and do not have, more that the program should have adequate resources and services to meet the needs of their patient population.
4.3.1.1	SC	NA	NA	The committee added the term “blood” to this standard for completeness. This change has been made throughout the edition for parallel construction.
5.1.1.1.1	SC	NA	NA	The committee elected to replace the term “components” with “products” for clarity.
5.1.7.1	SC	NA	NA	The committee elected to edit standard 5.1.7.1 by including the clause “administration or reinfusion” in place of “issue or delivery.” Where appropriate, the clause “or reinfusion” has been added to the <i>Standards</i> throughout.
5.1.8.1	SC	NA	NA	The committee added the clause, “or reinfusion” to the standard for parallel construction with the rest of the edition.
5.1.8.2, 5.1.8.4 (deleted)	SC	NA	NA	The committee added the clause, “with unique identifiers”, to the standard which previously appeared as former standard 5.1.8.4 for completeness. This allowed for the deletion of standard 5.1.8.4.
5.1.8.2.4 (New)	SC	NA	NA	The committee created new standard 5.1.8.2.4 to ensure that all accredited perioperative programs are labeling products for perioperative administration are labeled accordingly and in clear manner.
5.1.9	RtC	In these standards, room temperature collections are good for 8 hours, cooled collections are good for 24hrs. Is there a reference or more information that could be added that provides context to how these cutoffs were set? This would help readers understand what considerations affect if they need to reinfuse the blood sooner or discard.	No	The committee noted this comment but did not feel that a change was needed at this time. The time period defined was based on the length of time that blood can remain viable before infusion.

		In “AABB Guide to Blood Recovery and Reinfusion in Surgery and Trauma”, there is a reference for the “use within 8hrs” recommendation, but it is just the standard being reviewed.		
5.1.9.1	SC	NA	NA	The committee added the elements, “defined policies and processes regarding the performance of perioperative procedures for patients who are known to have infectious agents that are transmissible” to ensure that programs have defined policies and processes to ensure that patients that are known to have infectious agents are recognized and treated accordingly.
5.1.9.1.1 (New)	SC	NA	NA	In conjunction with the addition of the clause cited to standard 5.1.9.1, the committee added new standard 5.1.9.1.1 to the edition. The standard was added to ensure that programs are labeling and segregating products that contain infectious agents appropriately.
5.1.10	SC	NA	NA	The committee elected to add three elements to standard 5.1.10 for completeness. Adding the requirements, included below, are the minimum of what should be included as an element of defined criteria for pharmaceutical, solutions and reagents. The elements included read as follow: 1) Date and time of preparation of the product. 2) Individual preparing the product. 3) Expiration date and time of the product.
5.2	SC	NA	NA	The committee elected to edits standard 5.2 to mirror other changes made to the edition by include the clause “...perioperative blood and blood...”. A crossreference to standard 1.1.1 was also added to the standard for completenss. Standard 1.1.1 focuses on medical director responsibilities.

5.2.2	SC	NA	NA	The committee elected to edit standard 5.2.2 to mirror other changes made to the edition by include the clause "...perioperative blood and blood...", as well as the clause "...or reinfusion..."
5.3 (5.2.3)	SC	NA	NA	The committee elected to make former standard 5.2.3 a "parent standard" as new standard 5.3, as it was determined that it did not fit exactly in the consent section. New standard 5.3 has added a title "Perioperative Procedure Documentation". For parallel construction, the standard was edited to include the clause, "...perioperative blood and blood component."
5.3.1 (5.2.3.1)	SC	NA	NA	For parallel construction, the standard was edited to include the clause, "...perioperative blood and blood component."
5.4.1, #8 (New)	SC	NA	NA	The committee added new #8 to standard 5.4.1 to focus on "Vacuum pressures" for completeness. This is an element that is a part of intraoperative blood recovery.
5.4.1.2 (5.3.1.2)	SC	NA	NA	The committee added a new title to standard 5.4.1.2, "Ultrafiltration." The content and intent of the standard has not changed.
5.4.2, #2 (5.3.2, #2)	SC	NA	NA	The committee edited subnumber 2 for clarity. The entry now reads: 2) Volume <u>to be</u> collected based on patient characteristics.
5.4.2.3 (5.3.2.3)	SC	NA	NA	The committee edited the order of the content standard 5.4.2.3 for consistency, but the intent of the standard has not changed.
5.5 (5.4)	SC	NA	NA	The committee elected to edit standard 5.2 to mirror other changes made to the edition by include the clause "...perioperative blood and blood...", as well as the clause "...or reinfusion..." These terms

				were also included in the title of the standard.
5.5.1 (5.4.1)	SC	NA	NA	The committee elected to edit standard 5.5.1 to mirror other changes made to the edition by include the clause "...perioperative blood and blood...", as well as the clause "...or reinfusion..."
5.5.1.1 (5.4.1.1)	SC	NA	NA	The committee edited standard 5.5.1.1 for clarity. The replaced the term "component" with "product" and added the clause, "...or reinfusion.." and finally replaced "clinical procedure" with "clinical operating/procedural area." These edits were made to ensure parallel construction.
5.5.2 #1 (5.4.2 #1)	SC	NA	NA	The committee updated subnumber 1 for clarity and parallel construction with language in AABB's Standards for Blood Banks and Transfusion Services. The edit replaces the term "appearance" with "visual inspection of the product." The intent of the standard has not changed.
5.5.2, #3 (New)	SC	NA	NA	The committee added #3 for completeness, recognizing that this element, "integrity of the bag" is key element of inspection criteria.
5.5.2, #4 (5.4.2, #3)	SC	NA	NA	The committee edited subnumber 4 to include the clause, "as applicable" recognizing that there are times where blood is not stored and kept at room temperature.
5.5.2.2 (5.4.2.2)	SC	NA	NA	The committee replaced the term "component" with the clause "blood and blood component" for clarity and parallel construction.
5.5.2.2.1 (5.4.2.2.1)	SC	NA	NA	The committee added the term "nonconforming" to the standard for clarity, recognizing that in this case a "conforming product" would not require a physician's approval. The standard has also been updated for clarity and parallel construction by adding the clause "...or reinfusion."

5.5.3 (5.4.3)	SC	NA	NA	The committee edited standard 5.5.3 in terms of the order of the opening sentence, but the intent of the standard has not changed.
5.5.3.1 (New)	SC	NA	NA	The committee created new standard 5.5.3.1 recognizing that programs in the field are using these types of wash fluid (eg, plasmalyte) for intravenous infusion in place of 0.9% sodium chloride. The standard reads as follows: 5.5.3.1 When an alternative biocompatible physiological wash fluid is utilized by the perioperative program, the organization shall have policies, processes, and procedures for its use, and shall ensure that such use is reviewed and approved by the responsible medical director or designee.
5.5.3.1 (New)	RtC	After further review of the new proposed standard 5.5.3.1 for the 12th Edition, I do not understand its intent to qualify alternate wash solutions for the use of cell salvage. The standards and safety are clearly stated under standard 5.4.5.3, which state alternate solutions must be approved for such use by the FDA AND/OR documentation must be available to demonstrate the solution is safe and does not adversely affect the blood. Plasmalyte solution is FDA approved for use with blood and blood components, and there are several peer reviewed studies showing that is more biocompatible and physiological than Normal Saline. To my knowledge, Normal Saline had never been clinically compared to other physiological wash solutions before being grandfathered into FDA standards for use with blood. Therefore it appears that it has never undergone the New Drug Application Process. Plasmalyte A has undergone the New Drug application Process and has been studied against other solutions for biocompatibility with blood. To my knowledge, there was only one study conducted that examined Potassium levels in	Yes	As submitted initially, the standard did not contain the clause, “biocompatible” and based on this comment, the committee agreed to including it. Of note, the committee notes they are not questioning compatibility as a part of the standard, but more that certain manufacturer’s instructions do not include their use beyond normal saline.

		cell saver blood (after wash and 24 hours after wash) between Plasmalyte and Normal Saline (Colette JM et al:J ExtraCorp Technology 2021, 53(3):214-19). The study found Potassium levels elevated in both groups at 24 hours, with the Potassium group being higher than the Saline group. However, the potassium values were normal after 24 hours in both groups. The wording of the new standard 5.5.3.1, tends to add confusion to the existing standard 5.4.5.3. It does not add any further safety or clarity the existing standards. Plasmalyte should be included as an alternative wash solution to Normal Saline under the existing standard 5.4.5.3.		
5.5.4 (5.4.4)	SC	NA	NA	The committee edited standard 5.5.4 for parallel construction with other changes throughout the edition. The clause "...or reinfusion" has been added to the standard in both the title and body. The clause, "...perioperative blood and blood components" has been added to the standard for completeness.
5.5.4.2, #1 (5.4.4.2, #1)	SC	NA	NA	The committee added the clause "...or reinfusion" for completeness and parallel construction with other edits to the standards in this edition.
5.5.4.3 #1 (5.4.4.2, #1)	SC	NA	NA	The committee added the clause "...or reinfusion" for completeness and parallel construction with other edits to the standards in this edition.
5.5.5 (5.4.5)	SC	NA	NA	The committee added the clause "...or reinfusion" for completeness and parallel construction with other edits to the standards in this edition.
5.6 (New)	SC	NA	NA	The committee created new standard 5.6 which is focused on organ procurement recognizing that there are perioperative programs that are engaging in this space and the addition of this standard ensures that the <i>Perioperative Standards</i> are future proofed. The committee also added a definition of "normothermic machine perfusion" to the Glossary for completeness.

				The glossary entry reads as follows: Normothermic Machine Perfusion (NMP)/Normothermic Regional Perfusion (NRP): An adopted organ procurement and transport technique approved by the appropriate Competent Authority to maintain physiologic conditions that can enhance organ quality, enable extended transport times, and reduce postoperative complications.
5.1.9A, #6	SC	NA	NA	The committee edited the entry in the “special conditions” column replacing “None” with “To be maintained at the patient’s bedside” for entry #6. This recognizes that this product will be at the patient’s bedside and not stored in a storage device or storage container.
6.2.6.1	SC	NA	NA	The committee added the clause “...in the perioperative setting.” to ensure that the standard is focused on perioperative programs.
7.1.3	SC	NA	NA	The committee added the clause “...perioperative blood and blood component” to the standard as well as the clause “...administration or reinfusion” for completeness. These changes mirror other changes made throughout the edition.
7.2.4.2	SC	NA	NA	The committee edited the standard for clarity by including the clause, “...applicable Competent Authority...”, mirroring the language throughout the edition and other sets of AABB Standards.
7.3	RtC	Consider adding a requirement for mandatory communication and structured clinical information sharing between perioperative staff and the transfusion service/blood bank during the investigation of suspected transfusion or reinfusion adverse events. Suggested elements may include: - Medications administered concurrently. - Other IV fluids or products infused at the same time. - Route and line used for administration. - Intraoperative events or interventions.	No	The committee noted this comment but did not feel that a change was needed at this time. The committee feels that the language of the standard as slightly more broad allows for perioperative programs to meet the standard in the fashion that best meets their needs.

		- Nursing and physician clinical observations. - Timeline of symptom onset relative to administration. Rationale: Adverse reactions occurring during perioperative transfusion or reinfusion may have multifactorial causes. Improved interdisciplinary communication and standardized clinical documentation would strengthen hemovigilance practices, support more accurate root cause analysis, and reduce the risk of prematurely attributing adverse events solely to blood products without complete clinical context.		
7.3.3.1	SC	NA	NA	The committee added the clause "...perioperative blood and blood component" to the standard as well as the clause "...administration or reinfusion" for completeness. These changes mirror other changes made throughout the edition.
7.3.3.3	SC	NA	NA	The committee edited standard 7.3.3.3 for completeness and parallel structure with the rest of the edition. The committee included the clause, "perioperative blood and blood component" as well as the clause "ensure accurate" for clarity.
7.3.3.4				The committee added the clause "...perioperative blood and blood component" to the standard as well as the clause "...or reinfusion" for completeness. These changes mirror other changes made throughout the edition.
7.3.3.3, 7.3.3.4	RtC	I suggest the following additions to the Standards: 7.3.3.3 The labels on perioperative blood and blood component containers, together with all associated records, shall be compared and verified to confirm accurate patient identification, product identification, and traceability. 7.3.3.4	No	The committee noted this comment but did not feel that a change was needed at this time. The committee feels that the suggestions already are covered in the flow of the document already.

		Collection, administration, or reinfusion of perioperative blood and blood components shall be discontinued immediately if evidence of a nonconformance (eg, equipment malfunction, improper storage conditions, labeling discrepancy, or suspected bacterial contamination) is identified. Standard 3.5.4 applies.		
7.3.4	SC	NA	NA	The committee added the clause "...perioperative blood and blood component" to the standard as well as the clause "...or reinfusion" for completeness. These changes mirror other changes made throughout the edition.
7.3.6	SC	NA	NA	The committee added the clause "...or reinfusion..." for completeness and parallel construction with other edits to the Standards.
8.4.2, #1	SC	NA	NA	The committee added the clause "...and utilization review." for completeness. This entry now mirrors the same standard in the <i>Standards for Blood Banks and Transfusion Services</i> .
8.4.2 #2 (New)	SC	NA	NA	The committee added new subnumber 2 which reads, "Program's impact on patient blood management: to the edition for completeness and this mirrors a similar addition to the <i>Standards for a Patient Blood Management Program</i> .
Glossary – Patient Blood Management	SC	NA	NA	The committee added this definition to the glossary for completeness. Patient Blood Management (PBM): An evidence-based, patient-centered, systematic, multidisciplinary approach to caring for patients who might require a blood transfusion. PBM is meant to improve patient outcomes by preserving a patient's own blood through diagnosis- and etiology-specific treatment of anemia and bleeding.

Glossary – PBM Program	SC	NA	NA	The committee added this definition to the glossary for completeness. PBM Program: A program within an organization that provides the services outlined in the current edition of AABB’s Standards for a Patient Blood Management Program.
Glossary - Reinfusion	SC	NA	NA	The committee added this definition to the glossary for completeness. Reinfusion: For the purposes of these Perioperative Standards, the intravenous administration of an autologous component to the patient from whom it was collected. (See also Transfusion.)