PROPOSED Standards for Perioperative Autologus Blood Collection and Administration
9th edition

Effective Date: January 1, 2021

A Note to Readers

Individuals not familiar with the standards-setting practices of AABB should be aware of the following:

• Requirements, once stated, are not repeated. For example, standard 5.0 requires that all processes and procedures be validated. Therefore, it is not necessary to require in other areas that a specific process or procedure be validated.

• Words or phrases used in a way different from their usual meaning are defined in the glossary.

• The term “specified requirements” is defined broadly to include accreditation requirements, national, state, or local laws, and any other applicable requirement.

• Please note, that the Summary of Significant Changes to the proposed 9th edition begins on page 2 and runs through page 11. The proposed 9th edition begins on page 11 and runs through page 54.
Significant Changes to the Proposed 9th edition Standards for Perioperative Autologous Blood Collection and Administration

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 and components obtained during intraoperative and postoperative autologous blood recovery; and perioperative autologous component production. Blood and components covered under these activities include but are not limited to red blood cells, plasma for reinfusion, injection, or 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.

The committee added the term “red blood cells” to the Standards because the Standards do encapsulate RBCs and felt that this was needed for accuracy and completeness.

1.1.1 Medical Director Responsibilities
The perioperative program shall have a medical director who is a licensed physician and who is qualified by education, training and/or experience. The medical director shall have responsibility and authority for all policies, processes, and procedures.

The committee added the term “education” to match the language in other sets of AABB Standards.

1.4 Operational Continuity
Executive management shall ensure that the facility has policies, processes and procedures that address continuity for potential events that put operations at risk.

This committee added this standard to match the inclusion of it in all sets of AABB Standards as a new element to the quality template.

3.3 Use of Equipment
All equipment that is qualified to collect, prepare, process, test, store, or administer perioperative blood components shall be used in accordance with the manufacturers’ written instructions or facility-defined procedures. The perioperative program shall validate devices and equipment, including Food and Drug Administration (FDA)-cleared or -approved devices, for their intended use.*

*21 CFR 211.68

PROPOSED Standards for Perioperative Autologous Blood Collection and Administration, 9th Edition
FOR COMMENT PURPOSES ONLY
FEBRUARY 21, 2020 – APRIL 21, 2020
3.5.2 Investigation and Follow-up
Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include the following:
1) Assessment of the conformance of components provided when equipment is found to be out of calibration.
2) Assessment of the effect on the donor/patient.
3) Steps to ensure that the equipment is removed from service.
4) Investigation of malfunction, failure, or adverse event.
5) Steps for requalification of equipment.
6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer and/or regulatory agencies, when indicated.*

* 21 CFR Part 803.30

3.8.1 Information Systems Records
Records of the following shall be maintained:
1) Validation of system software, hardware, databases, user-defined tables, electronic data transfer, and/or electronic data receipt.^
2) Fulfillment of applicable life-cycle requirements for internally developed software.*
3) Numerical designation of system versions, if applicable, with inclusive dates of use.
4) Monitoring of data integrity for critical data elements.

^21 CFR 211.68

* 21 CFR 820.30.


CFR references were included in standards 3.3, 3.5.2 and 3.8.1 for completeness.

3.7 Warming Devices
Warming devices for perioperative blood components prepared for transfusion shall be cleared or approved by the FDA or Competent Authority and shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to perioperative blood components. Standard 3.5 applies.
The committee added this clause for completeness. The language was taken from the most recent version of BB/TS Standards.

3.8.2 An alternative system that ensures continuous operation shall be available in the event that computerized data and computer-assisted functions are unavailable. The alternative system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and recovery plans.

The clause in strikethrough was removed from the standard as the committee felt that it would best fit in Guidance and was redundant.

4.2 Agreements

Agreements, or changes to agreements, to obtain or provide critical materials and services for perioperative collection, processing, storage, and administration transfusion services shall define supplier and customer expectations. The agreement shall reflect that both parties have accepted the terms therein.

The committee added the terms “services”, “processing” and “administration” for completeness. Transfusion services was removed based on the additions of the new terms to the standard.

5.1.2.1 Quality control results shall be reviewed and evaluated against acceptance criteria. Quality control failures shall be investigated. Standard 8.2, #5 applies.

The committee added a cross reference to standard 8.2, #5 which requires that quality control results be monitored as a part of a perioperative program’s utilization review. The addition was made for completeness.

5.1.5 Prevention of Contamination Sterility

The perioperative program shall employ methods that provide assurance of a pyrogen-free product. Standard 5.3.1 applies. Single-use materials, sterile, and pyrogen-free pharmaceuticals, solutions, and reagents shall be used.

The committee re-titled the standard to better match the content of the standard, and the subsequent substandards.
5.1.6.2 General Labeling Requirements
The perioperative program shall have a labeling process for perioperative blood components, **including review of patient identification before the label is applied.** This process shall include steps taken to:

The committee added the elements in bold for completeness. This matches current practice.

５.２.１ At a minimum, elements of consent shall include all of the following:
1) A description of the procedure, risks, benefits, and treatment alternatives.
2) The opportunity to ask and receive answers to questions.
3) The right to accept or refuse treatment.

The committee added the term “procedure” for completeness.

５.２.２ The medical director shall participate in the development of policies, processes, and procedures regarding the collection and administration of perioperative blood components, including patient selection and preparation of the patient for surgery the use of perioperative blood components.

The committee replaced the term “surgery” with the clause, “the use of perioperative blood components” for clarity. Surgery is not an accurate representation of what occurs in all situations covered by these Standards.

５.４.１ Patient Identification
Perioperative blood components shall be administered only to the patient who donated them. There shall be positive identification of the patient and the component.

５.４.１.１ There shall be positive identification of the patient by the transfusionist and one other qualified individual (or an electronic identification system) using two independent identifiers, eg, patient name and identification number, whenever the component is separated from the patient or if administration occurs outside of the operating suite or clinical procedure area.

The committee removed the term “positive” from standards 5.4.1 and 5.4.1.1 as they did not feel that it was necessary. The term “qualified” was added to standard 5.4.1.1 for completeness.

５.４.３.１ If a direct patient requires a direct connection to the processing device is required, additional measures shall be taken to detect and prevent air embolism.
The committee edited the standard for clarity.

5.4.4 **Addition of Drugs and Solutions**
With the exception of 0.9% sodium chloride, USP, drugs or medications shall not be added to perioperative blood components intended for transfusion unless one of the following applies:
1) They have been approved for this use by the FDA or Competent Authority.

The committee edited the standard for completeness.

6.1.3 Review and approval **by an authorized individual** of new and revised documents before use.

The committee added the clause in bold for completeness.

6.2.1 **Facility Records**
The perioperative program shall have a process to ensure that records are complete, retrievable in a period of time appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.

The committee edited the standard to better match the wording throughout the document concerning the need for processes.

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 component, or an employee, approval from an individual qualified to evaluate the deviation shall be obtained before final release of the component. This approval shall be made by the medical director and/or the patient’s physician/licensed provider, depending upon the circumstances.

The committee added record retention requirements to standards 7.1.1 – 7.1.3 to ensure users knew that a record was required in each instance. The cascading pen symbol from 7.1 was not something the committee wanted to assume users understood.

7.2.2 **Nonconforming perioperative blood components and critical materials shall be retrieved**, quarantined, and recalled. The perioperative program shall have a process for
the quarantine, retrieval, and recall of noneconforming perioperative blood components and critical materials.

The committee edited this standard to match the style of standards 7.2.1 and 7.2.3. The intent of the standard has not changed.

7.3.1 When an adverse event is suspected, the following steps shall be performed immediately:

7.3.1.1 **Discontinue the administration of any perioperative blood components.**

7.3.1.2 **Compare and verify** the label on the perioperative blood component containers and all other records shall be compared to the patient identification.

7.3.1.3 The perioperative program shall **discontinue the use of any processing devices and materials** involved in immediate complication and shall examine them for evidence of nonconformance(s) (eg, malfunction or bacterial contamination). Standard 3.5.2 applies.

7.3.1.4 **Assess the need for additional testing, including collection of specimens, materials, and/or supplies, if applicable.** The perioperative program shall have a process for indicating the circumstances under which additional testing will be performed and what will be tested. Standard 4.1.2 applies.

The committee edited the standards below standard 7.3.1 to ensure that the presentation matched the use of the colon in the parent standard.

Standard 7.3.1.1 is new and was included as it is the first step one would take in the case of an adverse event occurring.

Standards 7.3.1.2 and 7.3.1.3 have been edited for flow purposes, the intent of the standard has not changed.

Standard 7.3.1.4 has been edited for flow and has been expanded to match current practice was assessing need for additional testing.

7.3.3.1 Fatalities associated with perioperative services shall be reported to **internal and external** appropriate outside authorities.*

*21 CFR 606.170
The committee edited standard 7.3.3.1 for accuracy. The term “appropriate” was deleted as it is difficult to assess.

8.0 Assessments: Internal and External
The perioperative program shall have a process to ensure that external assessments (ie, inspections and surveys) are conducted at defined intervals and that internal assessments of operations and the quality system are scheduled and conducted.

The committee felt that the terms in strikethrough did not provide any value to the standard and are already covered in guidance.

8.2 Monitoring of the Perioperative Program
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) Sample and product collection and labeling.

Subnumber 3 was edited for completeness.

8.3.1 The perioperative program shall provide all data generated to the personnel who have responsibility for the quality indicator data collected including third party providers.

This standard is new to this edition and was taken from the PBM Standards.

9.2.1 The review of appropriate sources of information, including assessment results, quality control records, and complaints, to detect and analyze potential causes of nonconforming components and materials. Standard 8.3.1 applies.

The committee added a crossreference to new standard 8.3.1 focused on data collection for completeness.

Glossary

Contamination Mitigation: A process or method to reduce the growth of pathogens.

Modified Component: A component that has been altered through processing. It may or may not be considered the final component.

Process (verb): To perform a series of steps or actions to produce or modify a perioperative component.
**Service:** A result of a process or procedure.

**Topical Application:** Nonparenteral administration of a perioperative component to a surface (e.g., skin, mucous membrane, operative site).

*These terms were added to the Glossary for completeness.*

### List of Perioperative Blood Components and Processing Methods

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>DESCRIPTION</th>
<th>PROCESS/METHOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood and red cell components:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole blood (WB)</td>
<td>Whole blood is collected in an anticoagulant/preservative solution and is not processed further</td>
<td>Collected by Acute Normovolemic Hemodilution (ANH). ANH involves the removal of whole blood (usually immediately before surgery) with the simultaneous replacement of intraoperative volume (colloids and crystalloids). WB stored at room temperature (up to 8 hours) will contain viable platelets and clotting factors. After 8 hours and when stored at refrigerated temperature (up to 24 hours) both labile clotting factors (FV and FVIII) and platelet viability begin to decline.</td>
</tr>
<tr>
<td>Red blood cells prepared by apheresis and intended for reinfusion</td>
<td>Red blood cells in anticoagulant that have been prepared by centrifugal separation of whole blood and sequestration</td>
<td>Using product sequestration via a direct or indirect technique, whole blood is anticoagulated and then processed in a blood recovery device. The effluent line of the centrifuge bowl is fashioned with a Y line to direct components to transfer bags. Centrifugation separates the whole blood into RBCs, platelet-rich plasma (PRP), and platelet-poor plasma (PPP). Once the PPP reaches the top of the bowl the revolutions per minute (RPMs) are slowed; the Y line is opened; and the PPP, PRP, and RBCs are collected in separate bags.</td>
</tr>
<tr>
<td>Plasma and platelet components:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Plasma intended for reinfusion

Plasma in anticoagulant that has been collected by centrifugal separation of whole blood and sequestration

Using product sequestration via a direct or indirect technique, whole blood is anticoagulated and then processed in a blood recovery device. The effluent line of the centrifuge bowl is fashioned with a Y line to direct components to transfer bags. Centrifugation separates the whole blood into RBCs, PRP, and PPP. Once the PPP reaches the top of the bowl the RPMs are slowed; the Y line is opened; and the PPP, PRP, and RBCs are collected in separate bags.

Platelet-Rich plasma (PRP) intended for reinfusion

Plasma containing platelets

Using product sequestration via a direct or indirect technique, whole blood is anticoagulated and then processed in a blood recovery device. The effluent line of the centrifuge bowl is fashioned with a Y line to direct components to transfer bags. Centrifugation separates the whole blood into RBCs, PRP, and PPP. Once the plasma reaches the top of the bowl the RPMs are slowed, the Y line is opened, and the plasma is collected. Once the PRP begins to show RBCs the process is stopped.

The term “blood recovery” was removed from these entries as it was deemed redundant.

List of Perioperative Blood Components and Processing Methods

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<tr>
<th>COMPONENT</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Topical or injectable applications:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelet-rich plasma (PRP) intended for use as platelet gel for topical application</td>
<td>Concentrated platelets within a limited volume of plasma</td>
<td>Whole blood is centrifuged into layers. The concentrated PRP is sequestered into a syringe. This PRP is then combined with calcium chloride and thrombin. When dispensed, these components combine to form a viscous coagulum gel used for hemostasis and wound healing. The platelet concentrate releases several growth factors from the alpha granules of the platelets.</td>
</tr>
</tbody>
</table>

The committee removed the elements in strikethrough as they were deemed “Guidance” and would be added to the Guidance doc when published.
1. ORGANIZATION

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 and components obtained during intraoperative and postoperative autologous blood recovery; and perioperative autologous component production. Blood and components covered under these activities include but are not limited to red blood cells, plasma for reinfusion, injection, or 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.

1.1 Executive Management
The perioperative program shall have a defined executive management. Executive management shall have the following:
1) Responsibility and authority for the perioperative program’s operations.
2) The authority to establish or make changes to the perioperative program’s quality system.
3) The responsibility for compliance with these Perioperative Standards and applicable laws and regulations.
4) Participation in management review of the quality system.

1.1.1 Medical Director Responsibilities
The perioperative program shall have a medical director who is a licensed physician and who is qualified by education, training and/or experience. The medical director shall have responsibility and authority for all policies, processes, and procedures.

1.1.1.1 Medical Director Designee
The medical director may delegate these responsibilities to another qualified individual; however, the medical director shall retain ultimate responsibility.

1.2 Quality System
A quality system shall be defined, documented, implemented, and maintained. All personnel shall be trained in its application.

1.2.1 Quality Representative
The quality system shall be under the supervision of a designated person who reports to executive management.
1.2.2 Management Reviews
Management shall assess the effectiveness of the quality system through scheduled management reviews.

1.3 Policies, Processes, and Procedures
Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these Perioperative Standards are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

1.3.1 Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and prior approval by the medical director or medical director designee on a case-by-case basis. Chapter 7, Deviations, Nonconforming Components or Materials, and Adverse Events, applies.

1.4 Operational Continuity
Executive management shall ensure that the facility has policies, processes and procedures that address continuity for potential events that put operations at risk.

1.5 Emergency Preparedness
The perioperative program shall have emergency operation policies, processes, and procedures to respond to the effects of internal and external disasters.

1.5.1 The emergency management plan, including emergency communication systems, shall be tested at defined intervals.

1.6 Communication of Concerns
The perioperative program shall have a process for personnel to anonymously communicate concerns about quality or safety. Personnel shall be given the option to communicate such concerns either to their facility’s executive management, AABB, or both. AABB’s contact information shall be readily available to all personnel. Standards 6.1.5 and 9.1 apply.

1.7 Customer Focus
The perioperative program leadership shall identify its customers and their needs and expectations for components and services. Standard 4.2 applies.
2. RESOURCES

2.0 Resources
The perioperative program shall have policies, processes, and procedures to ensure the provision of adequate resources to perform, verify, and manage all activities in the perioperative program.

2.1 Human Resources
The perioperative program shall have a process to ensure the employment of an adequate number of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualifications for each job or position.

2.1.1 Qualification
Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training, and/or experience.

2.1.2 Training
The perioperative program shall have a process for identifying training needs and shall provide for the training of personnel to perform critical tasks. The program shall define the qualifications required for trainers.

2.1.3 Competence
Evaluations of competence shall be performed before independent performance of assigned activities and at least annually thereafter.

2.1.3.1 Action shall be taken when competence has not been demonstrated.

2.1.4 Continuing Education
The perioperative program shall define continuing education requirements for all personnel and ensure that these requirements are met.

2.1.5 Workload
Perioperative program personnel shall have time to perform their duties.

2.1.6 Personnel Records
Personnel records for each employee shall be maintained.

2.1.6.1 For those authorized to perform or review critical processing steps, records of names, signatures, initials or identification codes, and inclusive dates of
employment shall be maintained.
3. EQUIPMENT

3.0 Equipment
The perioperative program shall identify the equipment that is critical to the provision of perioperative blood components. The perioperative program shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conform to these Perioperative Standards and other specified requirements.

3.1 Selection of Equipment
The perioperative program shall have a process to define the selection criteria for equipment.

3.2 Equipment Qualification
Equipment shall be qualified for its intended use.

3.2.1 Installation Qualification
Equipment shall be installed per manufacturer’s specifications.

3.2.2 Operational Qualification
The functionality of each piece of equipment and each component of a computer system shall be verified before actual use, and shall meet the manufacturer’s operational specifications.

3.2.3 Performance Qualification
The perioperative program shall demonstrate that equipment performs as expected for its intended use in the perioperative program’s work processes. Standard 5.1.1 applies.

3.2.3.1 Performance specifications shall be established and met for all equipment.

3.3 Use of Equipment
All equipment that is qualified to collect, prepare, process, test, store, or administer perioperative blood components shall be used in accordance with the manufacturers’ written instructions or facility-defined procedures. The perioperative program shall validate devices and equipment, including Food and Drug Administration (FDA)-cleared or -approved devices, for their intended use.*

*21 CFR 211.68
3.4 Unique Identification of Equipment
Equipment shall have unique identification. Standard 5.1.6 applies.

3.5 Equipment Monitoring and Maintenance
The perioperative program shall have a process for scheduled monitoring and maintenance of equipment. The process shall include: frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.

3.5.1 Calibration of Equipment
Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be performed as follows:
1) Before use.
2) After activities that may affect the calibration.
3) At prescribed intervals.

3.5.1.1 There shall be safeguards to prevent equipment adjustments that would invalidate the calibrated setting. Standard 5.1.2 applies.

3.5.1.2 Calibration procedures shall follow manufacturer’s written instructions and shall include:
1) Instructions for performing calibrations.
2) Acceptance criteria.
3) Actions to be taken when unsatisfactory results are obtained.

3.5.2 Investigation and Follow-up
Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include the following:
3) Assessment of the conformance of components provided when equipment is found to be out of calibration.
4) Assessment of the effect on the donor/patient.
3) Steps to ensure that the equipment is removed from service.
4) Investigation of malfunction, failure, or adverse event.
5) Steps for requalification of equipment.
6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer and/or regulatory agencies, when indicated.*

* 21 CFR Part 803.30

Chapter 7, Deviations, Nonconforming Components or Materials, and Adverse Events, applies.
3.6 Storage Devices and Storage Containers for Perioperative Blood Components

The perioperative program shall have storage devices and/or storage containers (eg, portable coolers) for collected perioperative blood components, if applicable.

3.6.1 Storage devices and/or containers for perioperative blood components shall have the capacity and design to ensure that the proper temperature is maintained.

3.6.2 Storage devices shall have a system to monitor the temperature continuously or to record the temperature at least every 4 hours.

3.6.3 Storage devices shall have alarm systems.

3.6.3.1 The alarm shall be set to activate at a temperature that will allow proper action to be taken before the perioperative blood components reach unacceptable temperatures.

3.6.3.2 Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective action.

3.6.4 Storage containers shall be qualified for their intended use and requalified at defined intervals.

3.7 Warming Devices

Warming devices for perioperative blood components prepared for transfusion shall be cleared or approved by the FDA or Competent Authority and shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to perioperative blood components. Standard 3.5 applies.

3.8 Information Systems

The perioperative program shall have processes to support the implementation and modification of software, hardware, and databases relating to the requirements of these Standards. Standard 5.1.1 applies. These processes shall include the following:

1) Risk analysis, training, validation, implementation, and evaluation of postimplementation performance.
2) System maintenance and operation.
3) Documentation written in language understandable to the user.
4) Display and verification before final acceptance, when data are added, or when data are amended.
5) Evaluation, authorization, and documentation of modifications to the system.

3.8.1 Information Systems Records

Records of the following shall be maintained:

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1) Validation of system software, hardware, databases, user-defined tables, electronic data transfer, and/or electronic data receipt.\(^\text{^1}\)
2) Fulfillment of applicable life-cycle requirements for internally developed software.\(^*\)
3) Numerical designation of system versions, if applicable, with inclusive dates of use.
4) Monitoring of data integrity for critical data elements.

\(^{21}\) CFR 211.68

\(^*\) 21 CFR 820.30.


3.8.2 An alternative system that ensures continuous operation shall be available in the event that computerized data and computer-assisted functions are unavailable. The alternative system shall be tested at defined intervals.

3.8.3 Personnel responsible for the management of information systems shall be responsible for compliance with the regulations that affect their use.

3.8.4 There shall be processes and procedures to support the management of information systems.

3.8.5 A system designed to prevent unauthorized access to computers and electronic records shall be established and followed.
4. SUPPLIER AND CUSTOMER ISSUES

4.0 Supplier and Customer Issues
The perioperative program shall have policies, processes, and procedures to evaluate the ability of suppliers of perioperative blood and blood components, critical materials, equipment, and services to consistently meet agreed-upon requirements.

4.1 Supplier Qualification
The perioperative program shall evaluate and participate in the selection of suppliers, when possible, before acceptance of an agreement.

4.1.1 When a supplier fails to meet specified requirements, that failure shall be reported to the management with contracting authority.

4.1.2 Testing or services required by these Perioperative Standards shall be performed in a facility accredited by AABB or an equivalent accrediting body.

4.1.2.1 Testing shall be performed in a facility certified by the Centers for Medicare & Medicaid Services (CMS) or other regulatory agencies.

4.1.2.2 Testing by facilities outside of the US shall be performed by a laboratory authorized as a testing center by the Competent Authority.

4.1.3 The perioperative program shall define the qualifications required for third party provider staff. Standard 2.1 applies.

4.2 Agreements
Agreements, or changes to agreements, to obtain or provide critical materials and services for perioperative collection, processing, storage, and administration shall define supplier and customer expectations. The agreement shall reflect that both parties have accepted the terms therein.

4.2.1 Agreement Review
Agreements shall be reviewed at defined intervals, and changes shall be incorporated as needed.

4.2.2 The responsibilities for activities covered by these Perioperative Standards when more than one entity is involved shall be specified by agreement.
4.3 Receipt, Inspection, and Testing of Incoming Critical Materials

Incoming critical materials shall be received, inspected, and tested, as necessary, before acceptance or use.

4.3.1 Critical materials shall meet facility-specified requirements.

4.3.1.1 All containers and solutions used for collection, preparation, preservation, and storage of perioperative blood, components and all reagents used for required tests on blood samples shall meet or exceed applicable FDA or Competent Authority criteria.*

*21 CFR 606.65
5. PROCESS CONTROL

5.0 Process Control
The perioperative program shall have policies and validated processes and procedures that ensure the quality of the perioperative blood components. The perioperative program shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

5.1 General Elements

5.1.1 Change Control
The perioperative program shall have a process to develop and implement new processes and procedures or to change existing processes and procedures. This process shall include:
1) Identification of specifications.
2) Verification that specifications have been met.
3) Validation of new or changed processes and procedures before implementation.
4) Postimplementation assessment.
Standards 2.1.2 and 2.1.3 apply.

5.1.1.1 The perioperative program shall have a process to introduce new or novel uses of existing or new perioperative methods and components.

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.

5.1.2.1 Quality control results shall be reviewed and evaluated against acceptance criteria. Quality control failures shall be investigated. Standard 8.2, #5 applies.

5.1.2.2 The validity of test results and methods and the acceptability of components or services provided shall be evaluated when quality control failures occur.

5.1.3 Use of Materials
All materials that are used to collect, prepare, process, test, store, or administer perioperative blood components shall be used in accordance with the manufacturers’ written instructions and shall meet specified requirements.

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5.1.4 Facility-Prepared Pharmaceuticals, Solutions, and Reagents
The facility shall have defined criteria for pharmaceuticals, solutions, and reagents that are prepared in-house.

5.1.5 Prevention of Contamination
The perioperative program shall employ methods that provide assurance of a pyrogen-free product. Standard 5.3.1 applies. Single-use materials, sterile, and pyrogen-free pharmaceuticals, solutions, and reagents shall be used.

5.1.5.1 Single-patient-use materials intended to produce a postoperative component shall be used for no more than 24 hours after coming into contact with a patient’s blood at room temperature. Standard 1.3.1 and Reference Standards 5.1.8A–C apply.

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 Identification and Traceability
The perioperative program shall ensure that all perioperative blood components and critical materials used in their processing, as well as laboratory samples and patient records, are identified and traceable.

5.1.6.1 Process or Procedure Steps
The perioperative program shall have a process to identify the individuals performing each critical step in collection, processing, and administration of perioperative blood components and when each step was performed. Standard 6.2.4 applies.

5.1.6.2 General Labeling Requirements
The perioperative program shall have a labeling process for perioperative blood components, including review of patient identification before the label is applied. This process shall include steps taken to:
1) Identify the collection container, components, samples, and modified components.
2) Complete the required reviews.
3) Attach the appropriate labels.

5.1.6.2.1 The original label and added portions of the label shall be attached to the container and shall be in clear, eye-readable type. Handwritten additions or changes to the label shall be legible,
permanent, and traceable.

5.1.6.2.1 Intermediate components that may potentially be separated from the patient shall be labeled with two patient identifiers.

5.1.6.2.2 Final perioperative blood components for administration shall be labeled with the patient’s first name, last name, and 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.

5.1.6.2.2.1 When the final perioperative blood component enters the surgical field, labeling requirements shall be defined by the perioperative program.

5.1.6.2.3 Labeling of the final component for reinfusion shall conform to all Competent Authority regulations, including barcode labeling as applicable. Each unit shall be labeled “For Autologous Use Only”, “Donor Untested,” and “Biohazard”. Standard 5.1.8.1 applies.

5.1.6.3 The process shall ensure that patient identifiers are unique.

5.1.7 Inspection
The perioperative program shall have a process to ensure that perioperative blood components are inspected at facility-defined stages to verify that specified requirements are met.

5.1.7.1 Final Inspection
The perioperative program shall have a process to ensure that finished perioperative blood components are acceptable before issue or delivery. Standards 5.4.2.1 and 7.2.1 apply.

5.1.8 Handling, Storage, and Transportation
The perioperative program shall have a process to ensure that perioperative blood components are handled, stored, and transported in a manner that prevents damage, limits deterioration, and meets requirements contained in Reference Standards 5.1.8A, Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components, and 5.1.8B, Handling, Storage, and Expiration of Perioperative Autologous Platelet Components.

5.1.8.1 The perioperative program shall have a process for the collection, handling, labeling, and storage of perioperative blood components known to contain infectious agents.

5.2 Consents, Approvals, and Notifications
The perioperative program medical director shall participate in the development of policies, processes, and procedures regarding recipient consent for collection and use of perioperative blood components.

5.2.1 At a minimum, elements of consent shall include all of the following:
1) A description of the procedure, risks, benefits, and treatment alternatives.
2) The opportunity to ask and receive answers to questions.
3) The right to accept or refuse treatment.

5.2.2 The medical director shall participate in the development of policies, processes, and procedures regarding the collection and administration of perioperative blood components, including patient selection and preparation of the patient for the use of perioperative blood components.

5.2.3 There shall be an order from a licensed healthcare provider for collection, preparation, and administration/reinfusion of a perioperative blood component. There shall be a process to define the communication and recording of orders.

5.3 Perioperative Collection
The perioperative program shall define collection parameters that include, at a minimum, the following:
1) Clinical applications of the various perioperative methods (including contraindications).
2) Vacuum requirements.
3) Anticoagulant solutions.
4) Circuit configuration.
5) Filtration.
6) Wash volumes, if applicable.
7) Pump speeds, if applicable.
8) Centrifugation speeds, if applicable.
9) Flow rates and system pressures within the circuitry, if ultrafiltration is utilized for recovery of an autologous product off of cardiopulmonary bypass.
10) Minimum blood volume collected for processing.
5.3.1 For blood collection by venipuncture, the site shall be prepared so as to minimize the risk of bacterial contamination of the component.

5.3.2 For blood collection through a central or peripheral line, the line placement site shall be prepared so as to minimize the risk of bacterial contamination of the component.

5.3.3 Ratio of Blood to Anticoagulant-Preservative Solution
The volume of blood to be 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.

5.4 Conditions of Administration

5.4.1 Patient Identification
Perioperative blood components shall be administered only to the patient who donated them. There shall be identification of the patient and the component.

5.4.1.1 There shall be identification of the patient by the transfusionist and one other qualified individual (or an electronic identification system) using two independent identifiers, eg, patient name and identification number, whenever the component is separated from the patient or if administration occurs outside of the operating suite or clinical procedure area.

5.4.2 Inspection of Perioperative Blood Components Before Administration
Perioperative blood components shall be inspected immediately before administration.

5.4.2.1 Component inspection criteria shall include evaluation or verification of the following:
1) Appearance (as defined by the program).
2) Labeling.
3) Storage requirements have been met.
4) Volume.
5) Expiration date and time.
Standard 5.1.6.2.2 applies.

5.4.2.2 If the component does not meet program-defined criteria, it shall not be used. Chapter 7, Deviations, Nonconforming Components or Materials, and Adverse Events, applies.
5.4.2.2.1 If the patient’s clinical circumstances warrant administration of the component, a record of the treating physician’s approval shall be maintained.

5.4.3 Prevention of Air Embolism
Processes and procedures for the administration of perioperative blood components shall prevent air embolism, including the prohibition of direct patient connection to the autotransfusion processing device.

5.4.3.1 If a patient requires a direct connection to the processing device, additional measures shall be taken to detect and prevent air embolism.

5.4.4 Addition of Drugs and Solutions
With the exception of 0.9% sodium chloride, USP, drugs or medications shall not be added to perioperative blood components intended for transfusion unless one of the following applies:
1) They have been approved for this use by the FDA or Competent Authority.
2) There is documentation available to show that the addition is safe and that it does not adversely affect the perioperative blood component.

5.4.5 Administration Protocol
The perioperative program shall have a protocol for the administration of perioperative blood components, including the use of infusion devices and ancillary equipment. Standard 6.2.4 applies.

5.4.5.1 Perioperative blood components intended for reinfusion shall be reinfused through a filter designed to retain particles that are potentially harmful to the patient, and according to the manufacturer’s recommendations if applicable. Standard 3.3 applies.

5.4.5.2 For perioperative blood components intended for reinfusion, the patient’s medical record shall contain the date and time of administration, pre- and post-administration vital signs, volume administered, and the identification of the individual administering the perioperative blood component. For components 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.

5.4.5.3 For topically applied or injected components, the patient’s medical record shall contain the date and time of administration, the identification of the individual administering the perioperative blood component, and a record
of administration. For components 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.
### Reference Standard 5.1.8A—Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components*

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Collection Type</th>
<th>Storage Temperature</th>
<th>Time from the Start of Collection to Expiration‡</th>
<th>Time from Completion of Processing to Expiration‡</th>
<th>Special Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Acute normovolemic hemodilution (whole blood)</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>N/A</td>
<td>None</td>
</tr>
<tr>
<td>2.</td>
<td>Acute normovolemic hemodilution (whole blood)</td>
<td>1-6 C</td>
<td>24 hours</td>
<td>N/A</td>
<td>Storage at 1-6 C shall begin within 8 hours of start of collection</td>
</tr>
<tr>
<td>3.</td>
<td>Intraoperative blood recovery with processing (centrifugation and/or washing and/or ultrafiltration)</td>
<td>Room temperature</td>
<td>N/A</td>
<td>8 hours</td>
<td>None</td>
</tr>
<tr>
<td>4.</td>
<td>Intraoperative blood recovery with processing (centrifugation and/or washing and/or ultrafiltration)‡</td>
<td>1-6 C</td>
<td>N/A</td>
<td>24 hours</td>
<td>Storage at 1-6 C shall begin within 4 hours of completion of processing</td>
</tr>
<tr>
<td>5.</td>
<td>Intraoperative blood recovery without processing</td>
<td>Room temperature</td>
<td>N/A</td>
<td>8 hours</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Temperature</td>
<td>Timing</td>
<td>Storage/Cooling</td>
<td>Notes</td>
</tr>
<tr>
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<td>------------------------------------------------------------------------------</td>
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<td>--------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>6.</td>
<td>Shed blood under postoperative or posttraumatic conditions with or without processing</td>
<td>N/A</td>
<td>8 hours</td>
<td>N/A</td>
<td>None</td>
</tr>
<tr>
<td>7.</td>
<td>Combined intraoperative and postoperative blood recovery with processing</td>
<td>Room temperature</td>
<td>Postoperatively processed units: 8 hours from the start of postoperative collection</td>
<td>Intraoperatively processed units: 8 hours</td>
<td>None</td>
</tr>
<tr>
<td>8.</td>
<td>Red Blood Cells prepared by apheresis and intended for reinfusion</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>N/A</td>
<td>None</td>
</tr>
<tr>
<td>9.</td>
<td>Red Blood Cells prepared by apheresis and intended for reinfusion</td>
<td>1-6 C</td>
<td>24 hours</td>
<td>N/A</td>
<td>Storage at 1-6 C shall begin within 8 hours of collection</td>
</tr>
</tbody>
</table>

*Standard 1.3.1 applies.
†If manufacturer’s written instructions are more stringent than this requirement, they shall be followed. Standard 3.3 applies.
‡Can include blood recovered from surgical sponges.
### Reference Standard 5.1.8B—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Component Type</th>
<th>Storage Temperature</th>
<th>Expiration Time from Start of Collection</th>
<th>Special Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Platelet-rich plasma intended for reinfusion</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>None</td>
</tr>
<tr>
<td>2.</td>
<td>Platelet-rich plasma intended for reinfusion *</td>
<td>1-6 C</td>
<td>24 hours</td>
<td>Storage at 1–6 C shall begin within 8 hours of collection</td>
</tr>
<tr>
<td>3.</td>
<td>Plasma intended for reinfusion</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>None</td>
</tr>
<tr>
<td>4.</td>
<td>Plasma intended for reinfusion</td>
<td>1-6 C</td>
<td>24 hours</td>
<td>Storage at 1–6 C shall begin within 8 hours of collection</td>
</tr>
</tbody>
</table>

* The storage requirements herein apply only to components not intended for platelet activity.
<table>
<thead>
<tr>
<th>Item No.</th>
<th>Component Type</th>
<th>Storage Temperature</th>
<th>Expiration*</th>
<th>Special Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Platelet-rich plasma intended for topical use or injectable 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>
<tr>
<td>2.</td>
<td>Platelet-poor plasma intended for topical use or injectable 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>
<tr>
<td>3.</td>
<td>Thrombin intended for topical use</td>
<td>Room temperature</td>
<td>Within 8 hours after component preparation (or not to exceed device manufacturer’s recommendations)</td>
<td>Shall be used before the patient leaves the operating room or clinical procedure area</td>
</tr>
<tr>
<td>4.</td>
<td>Bone Marrow Aspirate Concentrate intended for topical or injectable 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>
</tbody>
</table>

* If manufacturer’s written instructions are more stringent than this requirement, they shall be followed. Standard 3.3 applies.
6. DOCUMENTS AND RECORDS

6.0 Documents and Records
The perioperative program shall have policies, processes, and procedures to ensure that documents are identified, reviewed, approved, and retained and that records are created, stored, and archived in accordance with record retention policies.

6.1 Documents
The perioperative program shall have a process for document control that includes the following elements:

6.1.1 A master list of documents, including policies, processes, procedures, labels, and forms that relate to the requirements of these Perioperative Standards.

6.1.2 Use of standardized formats for all policies, processes, and procedures. Additional procedures (such as those in an operator’s manual or published in the AABB Technical Manual) may be incorporated by reference.

6.1.3 Review and approval by an authorized individual of new and revised documents before use.

6.1.4 Review of each policy, process, and procedure shall be performed by an authorized individual at a minimum every two years.

6.1.5 Use of only current and valid documents. Documents shall be available at all locations where activities essential to meeting the requirements of these Perioperative Standards are performed.

6.1.6 Identification and archival of obsolete documents.

6.1.7 Storage in a manner that preserves legibility and protects from accidental or unauthorized access, destruction, or modification.

6.2 Records
The perioperative program shall ensure identification, collection, indexing, access, filing, storage, and disposition of records as required by Reference Standard 6.2A, Retention of Records.
6.2.1 Facility Records
The perioperative program shall have a process to ensure that records are complete, retrievable in a period of time appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.

6.2.1.1 Records shall be legible and indelible.

6.2.1.2 Copies
Before the destruction of the original records, the perioperative program shall have a process to ensure that copies of records are identified as such. Copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.

6.2.2 A system designed to prevent unauthorized access and ensure confidentiality of records shall be established and followed.

6.2.3 The record system shall make it possible to trace any perioperative blood component from its source to final disposition, to review the records applying to the specific perioperative blood component, and to investigate adverse events manifested by the patient.

6.2.4 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.

6.2.5 Records shall be created concurrently with performance of each critical activity.

6.2.6 Changes to Records
Changes to records shall be controlled.

6.2.6.1 The date of changes and the identity of the individual who changed the record shall be documented and this information shall be maintained for the retention period of the original record.

6.2.6.2 Record changes shall not obscure previously recorded information.
6.2.6.3 Changes to records (including electronic records) shall be verified for accuracy and completeness.

6.2.7 Laboratory Testing
The result of each laboratory test performed shall be recorded immediately and the final interpretation recorded upon completion of testing.

6.2.8 Electronic Records
There shall be processes and procedures to support the management of computer systems.

6.2.8.1 There shall be a process in place for routine backup of all critical data.

6.2.8.1.1 Procedures shall be in place to ensure that data are retrievable and usable.

6.2.8.1.2 Backup data shall be stored in an off-site location.

6.2.9 Storage of Records
Records shall be stored to:
1) Preserve record legibility and integrity for the entire retention period.
2) Protect from accidental or unauthorized access, destruction, or modification.
3) Allow retrieval.

6.2.10 Destruction of Records
Destruction of records shall be conducted in a manner that protects the confidential content of the records.
<table>
<thead>
<tr>
<th>Item No.</th>
<th>Standard No.</th>
<th>Record to Be Maintained</th>
<th>Minimum Retention Time (in years)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.2.2</td>
<td>Management review of the effectiveness of the quality system</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>1.3.1</td>
<td>Exceptions to policies, processes, and procedures</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>1.5.1</td>
<td>Emergency operation plan tested at defined intervals</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>2.1</td>
<td>Current job descriptions</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>2.1.1</td>
<td>Qualification of personnel performing activities affecting quality</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>2.1.2</td>
<td>Training records</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>2.1.3, 2.1.3.1</td>
<td>Evaluations of competence</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>2.1.4</td>
<td>Continuing education requirements</td>
<td>5</td>
</tr>
<tr>
<td>9</td>
<td>2.1.6</td>
<td>Personnel records of all employees</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>2.1.6.1</td>
<td>Signatures, initials, or identification codes for those authorized to perform or review critical processing steps</td>
<td>7</td>
</tr>
<tr>
<td>11</td>
<td>3.2</td>
<td>Equipment qualification</td>
<td>5</td>
</tr>
<tr>
<td>12</td>
<td>3.4</td>
<td>Unique identification of critical equipment</td>
<td>5</td>
</tr>
<tr>
<td>13</td>
<td>3.5.1</td>
<td>Monitoring and maintenance of equipment</td>
<td>5</td>
</tr>
<tr>
<td>14</td>
<td>3.5.2</td>
<td>Investigation and follow-up of equipment malfunctions</td>
<td>5</td>
</tr>
<tr>
<td>15</td>
<td>3.6.2</td>
<td>Storage device temperature</td>
<td>5</td>
</tr>
<tr>
<td>16</td>
<td>3.8</td>
<td>Implementation of new or modified software, hardware, or databases and modifications of existing software, hardware, or databases</td>
<td>2 years after retirement of the system</td>
</tr>
</tbody>
</table>
| 17 | 3.8.1 | 1) Validation of system software, hardware, databases, and user-defined tables  
2) Fulfillment of applicable life-cycle requirements  
3) Numerical designation of system versions, if applicable, with inclusive dates of use  
4) Monitoring of data integrity for critical data elements | 2 years after retirement of the system |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>4.1</td>
<td>Evaluation and participation in selection of suppliers</td>
<td>5</td>
</tr>
<tr>
<td>19</td>
<td>4.2</td>
<td>Agreements</td>
<td>5</td>
</tr>
<tr>
<td>20</td>
<td>4.2.1</td>
<td>Review of agreements</td>
<td>5</td>
</tr>
<tr>
<td>21</td>
<td>4.2.2</td>
<td>Responsibilities between more than one entity for activities specified by agreement</td>
<td>5</td>
</tr>
<tr>
<td>22</td>
<td>4.3</td>
<td>Inspection of incoming critical materials</td>
<td>5</td>
</tr>
<tr>
<td>23</td>
<td>5.1.1</td>
<td>Validation of new or changed processes and procedures</td>
<td>5</td>
</tr>
<tr>
<td>24</td>
<td>5.1.2</td>
<td>Review of quality control results for reagents, equipment, and methods</td>
<td>5</td>
</tr>
<tr>
<td>25</td>
<td>5.1.4</td>
<td>Pharmaceuticals, solutions, and reagents prepared by facility meet or exceed applicable criteria</td>
<td>5</td>
</tr>
<tr>
<td>26</td>
<td>5.1.6.1</td>
<td>Records of procedure, including identification of procedural steps, and identification of individuals performing critical steps in collection, processing, and reinfusion or application of perioperative blood components</td>
<td>7</td>
</tr>
<tr>
<td>27</td>
<td>5.1.7.1</td>
<td>Final inspection</td>
<td>5</td>
</tr>
<tr>
<td>28</td>
<td>5.2.1</td>
<td>Elements of consent</td>
<td>7</td>
</tr>
<tr>
<td>29</td>
<td>5.2.3</td>
<td>Physician orders</td>
<td>5</td>
</tr>
<tr>
<td>30</td>
<td>5.4.1</td>
<td>Patient Identification</td>
<td>5</td>
</tr>
<tr>
<td>31</td>
<td>5.4.2.1</td>
<td>Component inspection</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Physician approval of nonconforming perioperative blood components for use before administration</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>32</td>
<td>5.4.2.2, 5.4.2.2.1</td>
<td>Perioperative blood components intended for reinfusion administration records</td>
<td>7</td>
</tr>
<tr>
<td>33</td>
<td>5.4.5.2</td>
<td>Topical or injectable component administration records</td>
<td>7</td>
</tr>
<tr>
<td>34</td>
<td>5.4.5.3</td>
<td>Review and approval of new and revised documents before use</td>
<td>5</td>
</tr>
<tr>
<td>35</td>
<td>6.1.3</td>
<td>Biennial review of policies, processes, and procedures</td>
<td>5</td>
</tr>
<tr>
<td>36</td>
<td>6.1.4</td>
<td>Identification and appropriate archival of obsolete documents</td>
<td>5</td>
</tr>
<tr>
<td>37</td>
<td>6.1.6</td>
<td>Capture, investigation, assessment, and reporting of deviations</td>
<td>5</td>
</tr>
<tr>
<td>38</td>
<td>7.1, 7.1.1, 7.1.2, 7.1.3</td>
<td>Description, evaluation, and disposition of nonconforming components or materials</td>
<td>5</td>
</tr>
<tr>
<td>39</td>
<td>7.2</td>
<td>Quarantined or recalled perioperative blood components and critical materials</td>
<td>5</td>
</tr>
<tr>
<td>40</td>
<td>7.2.2</td>
<td>Notification and report of nonconforming components and materials discovered after release and subsequent actions taken, including acceptance for use</td>
<td>5</td>
</tr>
<tr>
<td>41</td>
<td>7.3</td>
<td>Evaluation of adverse reactions related to perioperative blood components</td>
<td>5</td>
</tr>
<tr>
<td>42</td>
<td>8.1.2</td>
<td>Executive management reviews of results of internal and external assessments and associated corrective and preventive action</td>
<td>5</td>
</tr>
<tr>
<td>43</td>
<td>8.2</td>
<td>Perioperative program monitors and reviews</td>
<td>5</td>
</tr>
<tr>
<td>44</td>
<td>9.0</td>
<td>Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Process for corrective action is documented and includes description of event, investigation, determination of cause, and implementation and monitoring of corrective action.</strong></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>9.1</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>9.2.3</td>
<td><strong>Initiation of preventive action and monitoring to ensure that it is effective</strong></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>10.3</td>
<td><strong>Discard of perioperative blood components</strong></td>
<td>7</td>
</tr>
</tbody>
</table>

*Applicable state or local law may exceed this period.*
7. DEVIATIONS, NONCONFORMING COMPONENTS OR MATERIALS, AND ADVERSE EVENTS

7.0 Deviations, Nonconforming Components or Materials, and Adverse Events
The perioperative program shall have policies, processes, and procedures to ensure the capture, assessment, investigation, and monitoring of failure to meet specified requirements. The responsibility for review and authority for the disposition of nonconforming perioperative blood components and critical materials shall be defined. Deviations, nonconforming components or materials, and adverse events shall be reported in accordance with specified requirements and to outside agencies as required.

7.1 Deviations
The perioperative program shall have a process to capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. 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 component, or an employee, approval from an individual qualified to evaluate the deviation shall be obtained before final release of the component. This approval shall be made by the medical director and/or the patient’s physician/licensed provider, depending upon the circumstances.

7.2 Nonconforming Components or Materials
Upon discovery, nonconforming perioperative blood components and critical materials shall be evaluated and their disposition determined.

7.2.1 Perioperative blood components and critical materials that do not conform to specified requirements shall be prevented from being unintentionally distributed or used.

7.2.2 Nonconforming perioperative blood components and critical materials shall be retrieved, quarantined, and recalled.

7.2.3 Perioperative blood components and critical materials that are determined after
release not to conform to specified requirements shall be reported to the patient’s
physician/licensed provider and, if applicable, the supplier and regulatory agencies.

7.2.3.1 Records shall include the disposition of the component or service, the
rationale, and the name(s) of the individual(s) responsible for the decision.

7.3 Adverse Events
The perioperative program shall have processes and procedures for the evaluation and
reporting of adverse events related to perioperative blood component 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. Standard 8.2 applies.

7.3.1 When an adverse event is suspected, the following steps shall be performed
immediately:

7.3.1.1 Discontinue the administration of perioperative blood components.

7.3.1.2 Compare and verify the label on the perioperative blood component
containers and all other records to the patient identification.

7.3.1.3 Discontinue the use of processing devices and materials involved in
immediate complication and examine for evidence of nonconformance(s) (eg, malfunction or bacterial contamination). Standard 3.5.2 applies.

7.3.1.4 Assess the need for additional testing, including collection of specimens,
materials, and/or supplies, if applicable.

7.3.2 The perioperative program shall have a process for indicating the circumstances
under which additional testing will be performed and what will be tested. Standard
4.1.2 applies.

7.3.3 Interpretation of the evaluation shall be recorded in the patient’s medical record and,
if the interpretation suggests a hemolytic reaction, bacterial contamination, or other
serious complication of administration, that interpretation shall be reported immediately to the medical director and/or patient’s physician/licensed healthcare
provider.

7.3.3.1 Fatalities associated with perioperative services shall be reported internally
and to external authorities.*
*21 CFR 606.170 and 21 CFR 803.30
8. ASSESSMENTS: INTERNAL AND EXTERNAL

8.0 Assessments: Internal and External
The perioperative program shall have a process to ensure that external assessments are conducted at defined intervals and that internal assessments of operations and the quality system are scheduled and conducted.

8.1 Management of Assessment Results
The results of internal and external assessments shall be reviewed by personnel who have responsibility for the area being assessed.

8.1.1 When corrective and/or preventive action is taken, it shall be developed, implemented, and evaluated in accordance with Chapter 9, Process Improvement.

8.1.2 The results of internal and external assessments and the associated corrective and/or preventive actions shall be reviewed by executive management.

8.2 Monitoring of the Perioperative Program
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:
1) Ordering practices.
2) Patient identification.
3) Sample and product collection and labeling.
4) Appropriateness of use.
5) Quality control results.
6) Adverse events.
7) Near-miss events.
8) Usage, discard, and cause(s) of waste.
9) Ability of services to meet customer needs.
10) Overall program effectiveness and opportunities for improvement.

8.3 Quality Indicators
The perioperative program shall have a process to collect and evaluate quality indicator data on a scheduled basis.

8.3.1 The perioperative program shall provide all data generated to the personnel who have responsibility for the quality indicator data collected including third party providers.

PROPOSED Standards for Perioperative Autologous Blood Collection and Administration, 9th Edition
FOR COMMENT PURPOSES ONLY
FEBRUARY 21, 2020 – APRIL 21, 2020
9. PROCESS IMPROVEMENT

9.0 Process Improvement Through Corrective and Preventive Action
The perioperative program shall have policies, processes, and procedures for data collection and analysis and for follow-up of issues requiring corrective and preventive action, including near-miss events. Process improvement activities shall be reviewed and approved by executive management at defined intervals.

9.1 Corrective Action
The perioperative program shall have a process for corrective action with regard to deviations, nonconforming components and materials, and complaints relating to perioperative blood components, critical materials, and services, which includes the following elements:
1) Description of the event
2) Investigation of the event.
3) Determination of the cause.
4) Implementation of corrective action.
5) Monitoring to ensure that corrective action is complete and effective.

9.2 Preventive Action
The perioperative program shall have a process for preventive action that includes the following elements:

9.2.1 The review of appropriate sources of information, including assessment results, quality control records, and complaints, to detect and analyze potential causes of nonconforming components and materials. Standard 8.3.1 applies.

9.2.2 Determination of steps needed to respond to any potential problems requiring preventive action.

9.2.3 Initiation of preventive action and monitoring to ensure that it is effective.
10. FACILITIES AND SAFETY

10.0 Facilities and Safety
The perioperative program shall have policies, processes, and procedures to ensure the provision of safe environmental conditions. The facility shall be suitable for the activities performed. Safety programs shall meet local, state, and federal regulations, where applicable.

10.1 Safe Environment
The perioperative program shall have a process to minimize and respond to environmentally related risks to the health and safety of health-care workers, third-party providers, and patients. Programs shall meet local, state, and federal regulations, where applicable. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

10.2 Biological, Chemical, and Radiation Safety
The perioperative program shall have a process for monitoring adherence to biological, chemical, and radiation safety standards and regulations.

10.3 Discard of Perioperative Blood Components
Perioperative blood components shall be handled and discarded in a manner that minimizes human exposure to biohazards.
GLOSSARY

**Acute Normovolemic Hemodilution:** The removal of whole blood (usually immediately before surgery) into a standard blood bag containing anticoagulant with the simultaneous replacement of intravascular volume using acellular fluids. The product is reinfused to the patient during the intra- or post-operative period. Does not include the hemodilution that occurs as a result of extracorporeal circulation or fluid replacement.

**Administration:** The act of injecting, reinfusing, or topically applying a perioperative blood component to the patient from whom it was collected.

**Adverse Event:** An unintended or undesirable occurrence that may or may not have caused a complication in the patient temporally related to the collection or administration of perioperative blood components.

**Agreement:** A contract, order, or understanding between two or more parties, such as between a facility and one of its customers.

**Agreement Review:** Systematic activities carried out to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.

**Assessment:** A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments usually include a comparison of actual results with expected results. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.

**Autologous:** In relation to blood, when an individual serves as both the donor and the recipient.

**Blood Recovery:** Collection of blood lost during or after a procedure with the intent to return that blood to the patient. This may include the recovery of residual blood in the extracorporeal circuit.

**Calibrate:** To set measurement equipment against a known standard.

**Certified by the Centers for Medicare & Medicaid Services (CMS):** Having met the requirements of the Clinical Laboratory Improvement Amendments of 1988 for nonwaived testing through inspection by the CMS, a deemed organization, or an exempt state agency.

**Circuit Configuration:** The connections by which the supplies for blood recovery are provided to the surgical field, the blood recovery instrument, and the patient.

**Competence:** The ability of a person to perform a specific task according to procedures.

**Competent Authority:** The agency responsible under its national law for regulations applicable to perioperative programs.
Completion of Processing: The time at which processed blood enters the reinfusion bag.

Compliance: See Conformance.

Component: A biologic compound created from donor or patient blood through a process that involves nothing more than physical separation of the different parts of blood (eg, by centrifugation). Whole blood is not technically a component, but it should be handled in the same manner as red-cell-containing components for the purposes of these Perioperative Standards. (See also Product.)

Conformance: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.

Corrective Action: An activity performed to eliminate the cause of an existing nonconformance or other undesirable situation and to prevent recurrence.

Critical Equipment/Materials/Services/Tasks: A piece of equipment, material, service, or task that can affect the quality of the facility’s components or services.

Customer: The receiver of a product or service. A customer may be internal (ie, another department within the same organization) or external (ie, another organization).

Deviation(s): A departure from policies, processes, procedures, applicable regulations, standards, or specifications. Deviations can be planned or unplanned. Not all deviations result in an unacceptable product or result.

Disaster: An event (internal, local, or national) that can affect the activities of the perioperative program or the safety of staff and patients.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

Document (verb): To capture information through writing or electronic media.

Equipment: A durable item, instrument, or device used in a process or procedure.

Establish: To define, document, and implement.

Executive Management: The highest level of personnel within an organization, including employees and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization’s quality policy. Executive management may be an individual or a group of individuals.

Facility: A location or operational area within an organization. The part of the organization that is assessed by the AABB and receives AABB accreditation for its specific activities.

Final Inspection: The process of measuring, examining, or testing one or more characteristics of a material, component, or service and comparing the results with specified requirements to establish whether conformance is achieved for each characteristic.
Hemoconcentration: See Ultrafiltration.

Inspect: To measure, examine, or test one or more characteristics of a component or service and to compare the results with specific requirements.

Intermediate Component: A component that is not meant to be a final component for reinfusion or other application, but a step in the process of creating a final component. (See also Component.)

Intraoperative: During a surgical procedure.

Label: An inscription affixed to a component for identification.

Maintain: To keep in the current state.

Material: A good or supply item used in a process or procedure to prepare the final component or service. Reagents are a type of material.

Modified Component: A component that has been altered through processing. It may or may not be considered the final component.

Near-Miss Event: An unexpected occurrence that did not adversely affect the outcome, but could have resulted in a serious adverse event.

New Perioperative Methods: As opposed to a novel method, a new method is a change to an existing method already used in perioperative blood management. This might involve the new application or indication of an existing perioperative blood component, or simply the introduction of a new technique or component that has not been previously used by the perioperative program.

Nonconformance: Failure to meet requirements.

Novel Perioperative Method(s): A procedure or technique that has not been peer reviewed.

Organization: An institution, or part thereof, that has its own functions and executive management.

Perioperative: The timeframe before, during, and after a surgical procedure. For these Perioperative Standards, the perioperative period typically includes the day of surgery and the first day after surgery.

Perioperative Blood Component: Whole blood, blood components, or recovered blood collected during the perioperative period. See the List of Perioperative Blood Components and Processing Methods.

Perioperative Program: A location or operational area within an organization that provides the perioperative autologous blood services outlined in these Perioperative Standards.
**Pharmaceutical(s):** Drug(s) used during the delivery of therapies covered under these *Perioperative Standards*. These may include, but are not limited to, drugs such as heparin, acid-citrate-dextrose, citrate-phosphate-dextrose, calcium chloride, and bovine thrombin.

**Policy:** A documented general principle that guides present and future decisions.

**Postoperative:** The timeframe following a surgical procedure.

**Preoperative:** The timeframe preceding a surgical procedure.

**Preventive Action:** An action taken to reduce the potential for nonconformance or other undesirable situation.

**Procedure:** A series of tasks usually performed by one person according to instructions.

**Process (noun):** A set of related tasks and activities that accomplish a work goal.

**Process (verb):** To perform a series of steps or actions to produce or modify a perioperative component.

**Process Control:** Efforts made to standardize and direct processes to produce predictable output.

**Product:** A tangible result of a process or procedure; in this case, a biologic material. (See also Component.)

**Qualification:** With respect to individuals, the aspects of an individual’s education, training, and experience that are necessary to successfully meet the requirements of a position. With respect to equipment, verification that specified attributes required to accomplish the desired task have been met.

**Quality:** Characteristics of a product or service that bear on its ability to meet requirements, including those defined during the agreement review.

**Quality Control:** Testing routinely performed on materials and equipment to ensure their proper function.

**Quality Indicator Data:** Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by executive management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

**Quality System:** The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

**Reagent:** A substance used to perform an analytical procedure. A substance used (as in detecting or measuring a component or preparing a component) because of its biological or chemical activity.
Record *(noun)*: Information captured in writing or through an electronically generated medium that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Record *(verb)*: To capture information for use in records through writing or electronic media.

Recovery: The collection and reinfusion of blood lost during and immediately after surgery. The use of perioperative blood recovery can reduce or eliminate the patient’s need for allogeneic blood transfusion.

Reference Standards: Specified requirements defined by AABB (see Specified Requirements). Reference standards define how or within what parameters an activity shall be performed, and they are more detailed than quality system requirements.

Regulations: Rules promulgated by federal, state, or local authorities to implement laws enacted by legislative bodies.

Reinfusion: For the purposes of these *Perioperative Standards*, the intravenous administration of an autologous perioperative blood component to the patient from whom it was collected. See also transfusion.

Separated: With respect to perioperative blood components that are removed from the presence of the patient; eg, taken out of the room.

Service: A result of a process or procedure.

Shall: A verb used to indicate a requirement.

Specified Requirements: Any requirements in these *Perioperative Standards* and including, but not limited to, Competent Authority requirements; requirements of a facility’s internal policies, processes, and procedures; manufacturers’ written instructions; customer agreements; practice standards; and requirements of accrediting organizations such as AABB.

Start of Collection: The first introduction of blood into the collection container or processing system.

Storage Container: A vessel (eg, a cooler) that has been validated to maintain a controlled temperature in which perioperative blood components are held at a controlled temperature before administration.

Storage Device: A piece of equipment (eg, a refrigerator) used to maintain perioperative blood components at a controlled temperature.

Supplier: An entity that provides an input product or service.
Supplier Qualification: An evaluation method designed to ensure that input materials and services (e.g., disposable materials, reagents, blood components, and patient blood samples) obtained from a supplier meet specified requirements.

System: A subgroup of related activities performed by a particular organization. Activities dealing with maintaining product and service quality are organized into a quality system.

Third-Party Provider: An entity that contracts with a hospital or other medical facility to provide on-site perioperative services.

Topical Application: Nonparenteral administration of a perioperative component to a surface (e.g., skin, mucous membrane, operative site).

Traceability: The ability to follow the history of a component or service by means of recorded identification.

Transfusion: The intravenous administration of any blood component to a patient. (See also reinfusion.)

Ultrafiltration: A process of whole blood concentration through a microporous membrane filter that removes noncellular water and low-molecular-weight solutes from anticoagulated blood recovered in reservoirs and/or in extracorporeal circuits.

User-Defined Tables: Data maintained in tables and used by computer programs to direct their operations. Typically, user-defined tables contain data that are unique to a specific installation, and thus they may change from system to system.

Validation: Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.

Whole Blood Sequestration: A collection procedure where Whole Blood is removed and separated into components.
## List of Perioperative Blood Components and Processing Methods

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>DESCRIPTION</th>
<th>PROCESS/METHOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood and red cell components:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole blood (WB)</td>
<td>Whole blood is collected in an anticoagulant/preservative solution and is not processed further</td>
<td>Collected by Acute Normovolemic Hemodilution (ANH). ANH involves the removal of whole blood (usually immediately before surgery) with the simultaneous replacement of intraoperative volume (colloids and crystalloids).</td>
</tr>
<tr>
<td>Red blood cells (RBCs)</td>
<td>Red blood cells concentrated by the removal of most of the plasma from sedimented or centrifuged whole blood</td>
<td>Whole blood collected by acute normovolemic hemodilution is later processed and separated into red blood cells and plasma.</td>
</tr>
<tr>
<td>Red blood cells prepared by apheresis and intended for reinfusion</td>
<td>Red blood cells in anticoagulant that have been prepared by centrifugal separation of whole blood and sequestration</td>
<td>Using product sequestration via a direct or indirect technique, whole blood is anticoagulated and then processed in a device. The effluent line of the centrifuge bowl is fashioned with a Y line to direct components to transfer bags. Centrifugation separates the whole blood into RBCs, platelet-rich plasma (PRP), and platelet-poor plasma (PPP). Once the PPP reaches the top of the bowl the revolutions per minute (RPMs) are slowed; the Y line is opened; and the PPP, PRP, and RBCs are collected in separate bags.</td>
</tr>
<tr>
<td>Plasma and platelet components:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma intended for reinfusion</td>
<td>Plasma in anticoagulant that has been collected by centrifugal separation of whole blood and sequestration</td>
<td>Using product sequestration via a direct or indirect technique, whole blood is anticoagulated and then processed in a device. The effluent line of the centrifuge bowl is fashioned with a Y line to direct components to transfer bags. Centrifugation separates the whole blood into RBCs, PRP, and PPP. Once the PPP reaches the top of the bowl the RPMs are slowed; the Y line is opened; and the PPP, PRP, and RBCs are collected in separate bags.</td>
</tr>
<tr>
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</tr>
<tr>
<td>Platelet-Rich plasma (PRP) intended for reinfusion</td>
<td>Plasma containing platelets</td>
<td>Using product sequestration via a direct or indirect technique, whole blood is anticoagulated and then processed in a device. The effluent line of the centrifuge bowl is fashioned with a Y line to direct components to transfer bags. Centrifugation separates the whole blood into RBCs, PRP, and PPP. Once the plasma reaches the top of the bowl the RPMs are slowed, the Y line is opened, and the plasma is collected. Once the PRP begins to show RBCs the process is stopped.</td>
</tr>
</tbody>
</table>

### Recovery and reinfusion:

| Intraoperative blood recovery with washing | Use of a collection system and cell washing device to remove contaminants and wash recovered red blood cells from surgical site/wounds | Shed blood from the surgical site is recovered, mixed with an anticoagulant, and stored in a sterile reservoir. When enough blood has been collected it is then processed by centrifugation to separate components. Plasma, platelets, red cell stroma, and debris are lighter and are eliminated. Wash solution (0.9% normal saline) is added to the washing chamber to wash the red cells and results in further removal of debris, anticoagulant, and other components. This results in a concentrated washed red cell component. |
| Intraoperative blood recovery: Hemoconcentration by ultrafiltration | Use of an Ultrafiltration device to remove noncellular plasma water from whole blood | A process that removes noncellular plasma, water, and low-molecular-weight solutes from anticoagulated whole blood flowing through a microporous membrane filter. The fluid removal rate is dependent on blood flow rate, membrane pore size, and the transmembrane pressure gradient. The result is a concentrated whole blood. |
| Intraoperative blood recovery without processing | Shed blood that has not undergone hemoconcentration or washing | A process where shed blood is collected and then reinfused to the patient without centrifugation/hemoconcentration or washing. Shed blood is typically filtered to remove clots and tissue debris, but its final composition is similar to that of the shed blood itself. |
Shed blood under postoperative or posttraumatic conditions with or without processing

Shed blood collected through drains or suction

Shed blood without processing involves collection of postoperative blood from a drain into a device where it is filtered. Once a sufficient amount has been collected, the blood is then transferred to an infusion bag. Shed blood with processing involves collection of blood from drains and/or wounds and further processed by washing once a minimal amount has been recovered. The washed product is then transferred to a bag for reinfusion.

### Topical or injectable applications:

<table>
<thead>
<tr>
<th>Platelet-poor plasma (PPP) intended for topical application</th>
<th>Plasma without platelets</th>
<th>Using sequestration and centrifugation, the blood is fractionated into RBCs, PRP, and PPP. The PPP is collected into a syringe. Using dual syringe technique, the PPP is combined with calcium chloride and thrombin rapidly forming a viscous coagulum gel.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet-rich plasma (PRP) intended for use as platelet gel for topical application</td>
<td>Concentrated platelets within a limited volume of plasma</td>
<td>Whole blood is centrifuged into layers. The concentrated PRP is sequestered into a syringe. This PRP is then combined with calcium chloride and thrombin. When dispensed, these components combine to form a viscous coagulum gel used for hemostasis and wound healing.</td>
</tr>
<tr>
<td>Platelet-poor plasma (PPP) intended for injection</td>
<td>Plasma without Platelets</td>
<td>Using sequestration and centrifugation, the blood is fractionated into RBCs, PRP, and PPP. The PPP is collected into a syringe and injected into tissue.</td>
</tr>
<tr>
<td>Platelet-rich plasma (PRP) intended for injection</td>
<td>Concentrated platelets as a source of growth factors in a small volume of plasma</td>
<td>Whole blood is collected via syringe with a small amount of anticoagulant. Whole blood then undergoes two stages of centrifugation to separate the PRP layer from the PPP and RBCs. The final PRP product, which is transferred to a syringe for injection, contains a concentrated amount of platelets. Depending on the equipment and technique used, the concentration of the platelets in the final PRP product can vary.</td>
</tr>
<tr>
<td>Thrombin intended for topical application</td>
<td>Thrombin is an enzyme that plays a role in hemostasis, inflammation, and cell signaling</td>
<td>Thrombin is acquired from three sources, bovine, human, and recombinant. Thrombin is then used alone or with cryoprecipitate, PPP, and/or PRP to enhance clot formation.</td>
</tr>
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<td>----------------------------------------</td>
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</tr>
<tr>
<td>Autologous thrombin prepared from whole blood phlebotomy</td>
<td>Autologous thrombin prepared from the PPP portion of whole blood after separation</td>
<td>Using sequestration and centrifugation the blood is fractionated into RBCs, PRP, and PPP. The PPP is collected into a syringe containing reagents. Following a period of time a clot is formed. Autologous thrombin can then be expressed from the syringe for clinical use.</td>
</tr>
<tr>
<td>Bone marrow aspirate concentrate for topical application or injection</td>
<td>Autologous bone marrow nucleated cells that have been aspirated from bone for a primary purpose of tissue regeneration</td>
<td>Bone marrow aspirate is centrifuged into layers. Concentrated nucleated cells are separated and sequestered into a syringe for clinical use. It may be combined with other perioperative blood components.</td>
</tr>
</tbody>
</table>