PROPOSED Standards for Perioperative Autologous Blood Collection and Administration, 10th Edition

Effective January 1, 2023

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 10th edition begins on page 2 and runs through page 10. The proposed 10th edition begins on page 11 and runs through page 68.
Significant Changes to the Proposed 10th edition of 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. Whole blood and perioperative autologous blood components (hereinafter referred to as 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.

For consistency, the committee has modified the Standards to use the term “components” as a catch all for all products and components that are included in this edition.

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.

The committee felt it was important to add a record retention requirement for the standards concerning the medical director designee ensuring that the individual is documented in this role.

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. Standard 1.3 applies.
The committee added a cross reference to standard 1.3 which focuses on programs having policies, processes and procedures for completeness.

1.7 Assessment of Risk

The perioperative program shall have a process in place to perform risk assessments for defined activities at defined intervals.

This standard is new to the edition and is a part of the Quality Systems Framework. Other sets of Standards (RT and CT) have begun implementing this requirement into their editions as well.

2.1.1 Qualification

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

The committee edited the standard for clarity, the intent has not changed however.

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 perioperative program shall define the qualifications required for trainers.

2.1.2.1 The perioperative program shall define the qualifications required for trainers.

The committee created new standard 2.1.2.1, removing the second sentence from standard 2.1.2 as it was deemed a separate concept for a separate individual from the individuals noted in standard 2.1.2.

2.1.3.1 Corrective Action shall be taken when a lack of competence has not been demonstrated.
The committee elected to edit this standard for clarity, focusing the requirement on corrective action to be taken.

3.3 **Use of Equipment**
All equipment that is qualified to collect, prepare, process, test, store, or administer components shall be used in accordance with the manufacturer’s *written* instructions for use 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.

The committee elected to replace the clause “manufacturer’s written instructions” with “manufacturer’s instructions for use.” The committee notes that more and more instructions are appearing online and the term “written” could be limiting and antiquated. This change has been made throughout the standards where the term was included (3.5.1.2, 5.1.3, 5.1.5.2, 5.4.3, 5.1.8A, and 5.1.8C.)

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

The committee added the clause in bold at the end of the standard for completeness, putting the onus for determining what are and are not acceptable temperatures on the perioperative program itself.

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

The committee added a record retention requirement to this standard to ensure that programs document the initiation of the actions taken when an alarm sounds.
3.8.6 The perioperative program shall have a process in place to minimize the risk and impact of an internal or external data breach.

The committee added new standard 3.8.6 for completeness. This standard has been incorporated into all sets of AABB Standards to date.

4. SUPPLIERS AND CUSTOMERS ISSUES

4.0 Suppliers and Customers 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.

The committee has replaced the title of chapter 4 and standard 4.0 to reflect similar changes made in every other set of Standards.

4.3 Receipt, Inspection, and Testing of Incoming Critical Materials

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

The committee added the term “and” for clarity.

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 for use.

The committee added the term “for use” for completeness.

5.1.6.2.2 If the final component is separated from the recipient, 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.

The committee added the clause that begins the standard for clarity.

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

The committee added the clause “or medical director designee” to standard 5.2.2 for completeness.

5.3.1 Blood Collection

5.3.1.1 For blood collection by venipuncture, the site shall be prepared so as to minimize the risk of bacterial contamination of the component. Standard 5.1.5 applies.

5.3.1.2 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. Standard 5.1.5 applies.

The content of standard 5.3.1.1 previously appeared as the content of standard 5.3.1. The determination to create new standard 5.3.1.1 and move standard 5.3.2 to appear as standard 5.3.1.2 was made for clarity. Both standards cover
blood collection, however the standards should appear on the same “level” in terms of how they appear in the flow of the section. Standard 5.1.5 (which is referenced in both standards) requires programs to institute methods to prevent contamination of products.

5.4.3 Prevention of Air Embolism
Processes and procedures for the administration of components shall **follow manufacturer’s instructions for use to** prevent air embolism, including the prohibition of direct patient connection to the autotransfusion processing device.

The committee added the clause in bold for clarity and completeness.

🔗 5.4.5.2 For perioperative blood components intended for reinfusion, the patient’s medical record shall contain the **following information:**
1) Date and time of administration,  
2) Pre- and postadministration vital signs,  
3) Volume administered, and  
4) The identification of the individual administering the component.  
5) Records of adverse reactions

🔗 5.4.5.2.1 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.

Standard 5.4.5.2 has been edited for clarity by shifting the standards appearance from a paragraph to appear as a list. The committee also moved the second sentence of standard 5.4.5.2 to appear as new standard 5.4.5.2.1. New entry #5 in standard 5.4.5.2 has been moved from standard 5.4.5.2.1 to create this new entry, however the content has not changed.

🔗 5.4.5.3 For topically applied or injected components, the patient’s medical record shall contain the **following information:**
1) Date and time of administration,
2) The identification of the individual administering the component, and
3) A record of administration.
4) Records of adverse reactions

5.4.5.3.1 For **topically applied or injected** 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.

Standard 5.4.5.3 has been edited for clarity by shifting the standards appearance from a paragraph to appear as a list. The committee also moved the second sentence of standard 5.4.5.3 to appear as new standard 5.4.5.3.1. New entry #5 in standard 5.4.5.3 has been moved from standard 5.4.5.3.1 to create this new entry, however the content has not changed. In standard 5.4.5.3.1 has also included the clause “topically applied or injected” for parallel construction with standard 5.4.5.3.

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:

1) Verified as containing the original content,
2) Legible, **indelible**, complete and accessible, and
3) Identified as a copy

The committee edited this standard for legibility and to mirror the changes included in other sets of standards.

6.2.2 A system designed to prevent unauthorized access and ensure confidentiality of records shall be established and followed. **Standards 3.8.5 and 3.8.6 apply.**

The committee added crossreferences to standards 3.8.5 and 3.8.6 which focus on ensuring unauthorized access to information systems and managing the risk of internal and external data breaches. The committee added the crossreferences for completeness.
6.2.9 **Storage of Records**
Records shall be stored to:
1) **Stored in a manner to** preserve record legibility and integrity for the entire retention period.
2) Protected from accidental or unauthorized:
   a) access,
   b) destruction, or
   c) modification.
3) **Retrievable** Allow retrieval.

The committee edited the structure of this standard for clarity, the content has not changed.

6.2.10 **Destruction of Records**
Confidential content shall be protected during the destruction of records shall be conducted in a manner that protects the confidential content of the records.

The committee edited this standard to mirror other changes being put forth in other sets of AABB Standards. The intent of the standard has not changed.

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. **Standard 8.2 applies.**

The committee added a crossreference to standard 8.2 for completeness. Standard 8.2 ensures that certain elements of usage are monitored by the perioperative program.

Glossary

**Licensed Health Care Provider:** An individual licensed by a competent authority to provide health care services covered by these Perioperative Standards.
**Room Temperature:** Controlled room temperature is between 15 and 30°C (59 and 86°F), unless stated in manufacturer’s instructions for use.

The committee added these terms to the glossary based on their inclusion in the edition.
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. Whole blood and perioperative autologous blood components (hereinafter referred to as 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. Standard 1.3 applies.

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 Assessment of Risk
The perioperative program shall have a process in place to perform risk assessments for defined activities at defined intervals.

1.8 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 based on 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.

2.1.2.1 The perioperative 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 Corrective 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, the 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 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 an information system shall be verified before actual use with patients, 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 components shall be used in accordance with the manufacturers’ instructions for use 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 instructions for use 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:
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 803.30.

Chapter 7, Deviations, Nonconforming Components or Materials, and Adverse Events, applies.

3.6 Storage Devices and Storage Containers for Components
The perioperative program shall have storage devices and/or storage containers (eg, portable coolers) for collected components, if applicable.

3.6.1 Storage devices and/or containers for 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 components reach unacceptable temperatures as defined by the perioperative program.

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 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 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 Perioperative 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:

1) Validation of system software, hardware, databases, user-defined tables, electronic data transfer, and/or electronic data receipt.*

* 21 CFR 211.68

2) Fulfillment of applicable life-cycle requirements for internally developed software.†

† 21 CFR 820.30.

3) Numerical designation of system versions, if applicable, with inclusive dates of use.

4) Monitoring of data integrity for critical data elements.


3.8.2 An alternative system that ensures continuous operation shall be available in the event that computerized data and information system 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 information systems and electronic records shall be established and followed.

3.8.6 The perioperative program shall have a process in place to minimize the risk and impact of an internal or external data breach.
4. SUPPLIERS AND CUSTOMERS

4.0 Suppliers and Customers
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 and Medicaid Services (CMS) or other regulatory agencies.

4.1.2.2 Testing by facilities outside of the United States 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 and/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 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 components shall be used in accordance with the manufacturers’ instructions for use and shall meet specified requirements.

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 Standard 5.1.8A, Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components, Reference Standard 5.1.8B, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion, and Reference Standard 5.1.8C, Handling, Storage, and Expiration of Perioperative Autologous Non-
Red-Cell Blood Components for Topical Application or Injectable Application 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 for use.

5.1.6 Identification and Traceability
The perioperative program shall ensure that all 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 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 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.

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

5.1.6.2.2 All final 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, Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components, and 5.1.8B, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion apply.

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

5.1.6.2.2.2 If the final component is separated from the recipient, 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 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 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 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 Non-Red-Cell Blood Components for Reinfusion. Standard 1.3.1 applies.

5.1.8.1 The perioperative program shall have a process for the collection, handling, labeling, and storage of 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 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 or medical director designee shall participate in the development of policies, processes, and procedures regarding the collection and administration of components, including patient selection and preparation of the patient for the use of components.

5.2.3 There shall be an order from a licensed health-care provider for collection, preparation, and administration/reinfusion of a 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 Blood Collection**

**5.3.1.1** For blood collection by venipuncture, the site shall be prepared so as to minimize the risk of bacterial contamination of the component. Standard 5.1.5 applies.

**5.3.1.2** 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. Standard 5.1.5 applies.

**5.3.2 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**

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
Proposed Standards for Perioperative Autologous Blood Collection and Administration, 10th edition
FOR COMMENT PURPOSES ONLY
March 18 – May 18, 2022

5.4.2 **Inspection of Components Before Administration**
Components shall be inspected immediately before administration.

5.4.2.1 Component inspection criteria shall include evaluation or verification of the following elements:
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, Non-conforming 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 components shall follow manufacturer’s instructions for use to 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.

separated from the patient or if administration occurs outside of the operating suite or clinical procedure area.
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 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 component.

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

5.4.5.1 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 components intended for reinfusion, the patient’s medical record shall contain the following information:
1) date and time of administration,
2) pre- and post-administration vital signs,
3) volume administered, and
4) the identification of the individual administering the component.
5) Records of adverse reactions

5.4.5.2.1 For components that are not used, records of their disposition 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 following information:
1) date and time of administration,
2) the identification of the individual administering the component,
3) a record of administration, and
4) records of adverse reactions.

5.4.5.3.1 For topically applied or injected components that are not used, records of their disposition 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 the 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>
</tbody>
</table>

---

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34
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Temperature</th>
<th>Storage Time</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Intraoperative blood recovery with processing (centrifugation(^\text{‡}) and/or washing and/or ultrafiltration)</td>
<td>1-6 C</td>
<td>24 hours</td>
<td>Storage at 1-6 C shall begin within 4 hours of the completion of processing</td>
</tr>
<tr>
<td>5</td>
<td>Intraoperative blood recovery without processing</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>None</td>
</tr>
<tr>
<td>6</td>
<td>Shed blood under postoperative or post-traumatic conditions with or without processing</td>
<td>N/A</td>
<td>8 hours</td>
<td>N/A</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 post-operative collection</td>
<td>Intraoperatively processed units: 8 hours</td>
</tr>
<tr>
<td></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>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------------------------------</td>
<td>------------------</td>
<td>---------</td>
<td>-----</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>
</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>
</tr>
</tbody>
</table>

*Standard 1.3.1 applies.
†If the manufacturer’s instructions for use 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.*
Reference Standard 5.1.8C—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application

<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)</td>
<td>Shall be used before the patient leaves the operating room or clinical procedure area</td>
</tr>
<tr>
<td></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>
<tr>
<td>---</td>
<td>---------------------------------------------------------------------</td>
<td>------------------</td>
<td>-----</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>

*If the manufacturer’s instructions for use 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 2 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 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:

1) Verified as containing the original content,
2) Legible, indelible, complete and accessible, and
3) Identified as a copy.

6.2.2 A system designed to prevent unauthorized access and ensure confidentiality of records shall be established and followed. Standards 3.8.5 and 3.8.6 apply.

6.2.3 The record system shall make it possible to trace any component from its source to final disposition, to review the
records applying to the specific 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 information systems. Standard 3.9 applies.

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:
1) Stored in a manner to preserve record legibility and integrity for the entire retention period.
2) Protected from accidental or unauthorized:
   a) access,
   b) destruction, or
   c) modification.
3) Retrievable.

6.2.10 **Destruction of Records**
Confidential content shall be protected during the destruction of 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>1.1.1.1</td>
<td>Medical director designee identification and qualifications</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>1.2.2</td>
<td>Management review of the effectiveness of the quality system</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>1.3.1</td>
<td>Exceptions to policies, processes, and procedures</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>1.5.1</td>
<td>Emergency operation plan tested at defined intervals</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>1.7</td>
<td>Level of risk associated with laboratory activities</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>2.1</td>
<td>Current job descriptions</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>2.1.1</td>
<td>Qualification of the personnel performing activities affecting quality</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>2.1.2</td>
<td>Training records</td>
<td>5</td>
</tr>
<tr>
<td>9</td>
<td>2.1.3, 2.1.3.1</td>
<td>Evaluations of competence</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>2.1.4</td>
<td>Continuing education requirements</td>
<td>5</td>
</tr>
<tr>
<td>11</td>
<td>2.1.6</td>
<td>Personnel records of all employees</td>
<td>5</td>
</tr>
<tr>
<td>12</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>10</td>
</tr>
<tr>
<td>13</td>
<td>3.2</td>
<td>Equipment qualification</td>
<td>5</td>
</tr>
<tr>
<td>14</td>
<td>3.4</td>
<td>Unique identification of critical equipment</td>
<td>5</td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td>---</td>
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<td>--------------------------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>15</td>
<td>3.5.1</td>
<td>Monitoring and maintenance of equipment</td>
<td>5</td>
</tr>
<tr>
<td>16</td>
<td>3.5.2</td>
<td>Investigation and follow-up of equipment malfunctions</td>
<td>5</td>
</tr>
<tr>
<td>17</td>
<td>3.6.2</td>
<td>Storage device temperature</td>
<td>5</td>
</tr>
<tr>
<td>18</td>
<td>3.6.3.2</td>
<td>Investigation of alarm activation</td>
<td>5</td>
</tr>
<tr>
<td>19</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>
<tr>
<td>20</td>
<td>3.8.1</td>
<td>1) Validation of system software, hardware, databases, and user-defined tables</td>
<td>2 years after retirement of the system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2) Fulfillment of applicable life-cycle requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3) Numerical designation of system versions, if applicable, with inclusive dates of use</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4) Monitoring of data integrity for critical data elements</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>4.1</td>
<td>Evaluation and participation in selection of suppliers</td>
<td>5</td>
</tr>
<tr>
<td>22</td>
<td>4.2</td>
<td>Agreements</td>
<td>5</td>
</tr>
<tr>
<td>23</td>
<td>4.2.1</td>
<td>Review of agreements</td>
<td>5</td>
</tr>
<tr>
<td>24</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>25</td>
<td>4.3</td>
<td>Inspection of incoming critical materials</td>
<td>5</td>
</tr>
<tr>
<td>26</td>
<td>5.1.1</td>
<td>Validation of new or changed processes and procedures</td>
<td>5</td>
</tr>
<tr>
<td>27</td>
<td>5.1.2</td>
<td>Review of quality control results for reagents, equipment, and methods</td>
<td>5</td>
</tr>
<tr>
<td></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>---</td>
<td>-------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td></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 components</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>5.1.7.1</td>
<td>Final inspection</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>5.2.1</td>
<td>Elements of consent</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>5.2.3</td>
<td>Physician orders</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>5.4.1</td>
<td>Patient identification</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>5.4.2.1</td>
<td>Component inspection</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>5.4.2.2, 5.4.2.2.1</td>
<td>Physician approval for use of nonconforming components before administration</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>5.4.5.2</td>
<td>Administration records for components intended for reinfusion</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>5.4.5.2.1</td>
<td>Disposition of components not used.</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>5.4.5.3</td>
<td>Administration records for topical or injectable components</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>5.4.5.3.1</td>
<td>Disposition of topically applied or injected components that are not used.</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>6.1.3</td>
<td>Review and approval of new and revised documents before use</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>6.1.4</td>
<td>Biennial review of policies, processes, and procedures</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>6.1.6</td>
<td>Identification and appropriate archival of obsolete documents</td>
<td>5</td>
</tr>
<tr>
<td>Page</td>
<td>Standard Numbers</td>
<td>Description</td>
<td>Column 3</td>
</tr>
<tr>
<td>------</td>
<td>------------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td>43</td>
<td>7.1, 7.1.1, 7.1.2, 7.1.3</td>
<td>Capture, investigation, assessment, and reporting of deviations</td>
<td>5</td>
</tr>
<tr>
<td>44</td>
<td>7.2</td>
<td>Description, evaluation, and disposition of nonconforming components or materials</td>
<td>5</td>
</tr>
<tr>
<td>45</td>
<td>7.2.2</td>
<td>Quarantined or recalled components and critical materials</td>
<td>5</td>
</tr>
<tr>
<td>46</td>
<td>7.2.3, 7.2.3.1</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>47</td>
<td>7.3</td>
<td>Evaluation of adverse reactions related to components</td>
<td>5</td>
</tr>
<tr>
<td>48</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>49</td>
<td>8.2</td>
<td>Perioperative program monitors and reviews</td>
<td>5</td>
</tr>
<tr>
<td>50</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>51</td>
<td>9.1</td>
<td>Process for corrective action is documented and includes description of event, investigation, determination of cause, and implementation and monitoring of corrective action</td>
<td>5</td>
</tr>
<tr>
<td>52</td>
<td>9.2.3</td>
<td>Initiation of preventive action and monitoring to ensure that it is effective</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>10.3</td>
<td>Discard of components</td>
<td></td>
</tr>
<tr>
<td>---</td>
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<td>-----------------------</td>
<td>---</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 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. Standard 8.2 applies.
7.2 Nonconforming Components or Materials
Upon discovery, nonconforming components and critical materials shall be evaluated and their disposition determined.

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

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

7.2.3 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 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 components.

7.3.1.2 Compare and verify the label on the 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 health-care 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 quality indicator data to the personnel with responsibility for oversight including third-party providers.
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 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 healthcare 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 Components
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 postoperative period. The process 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 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 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 and 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 device, 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 is available for reinfusion or application.

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, national, or global) 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.

Licensed Health Care Provider: An individual licensed by a competent authority to provide health care services covered by these Perioperative Standards.

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 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 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 also 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 component to the patient from whom it was collected. (See also Transfusion.)

Room Temperature: Controlled room temperature is between 15 and 30 C (59 and 86 F), unless stated in manufacturer’s instructions for use.

Separated: With respect to components, those 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’ instructions for use; 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 components are held at a controlled temperature before administration.

Storage Device: A piece of equipment (eg, a refrigerator) used to maintain 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 (eg, 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 (eg, 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 split into components.
## List of Components and Processing Methods

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>DESCRIPTION</th>
<th>PROCESS/METHOD</th>
</tr>
</thead>
<tbody>
<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, processed and split into red blood cells and plasma/effluent.</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. Centrifugation splits the whole blood into RBCs, platelet-rich plasma (PRP), and platelet-poor plasma (PPP).</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. Centrifugation splits the whole blood into RBCs, PRP, and PPP.</td>
</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. Centrifugation splits the whole blood into RBCs, PRP, and PPP.</td>
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<td>-------------------------------------------------</td>
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</table>

### Recovery and reinfusion:

<table>
<thead>
<tr>
<th>Intraoperative blood recovery with washing</th>
<th>Use of a collection system and cell washing device to remove contaminants and wash recovered red blood cells from surgical site/wounds</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative blood recovery: Hemoconcentration by ultrafiltration</td>
<td>Use of an Ultrafiltration device to remove noncellular plasma water from whole blood</td>
<td>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.</td>
</tr>
<tr>
<td>Intraoperative blood recovery without processing</td>
<td>Shed blood that has not undergone hemoconcentration or washing</td>
<td>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.</td>
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<tr>
<td>Shed blood under postoperative or posttraumatic conditions with or without processing</td>
<td>Shed blood collected through drains or suction</td>
<td>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.</td>
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<tr>
<td><strong>Topical or injectable applications:</strong></td>
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<tr>
<td><strong>Platelet-poor plasma (PPP) intended for topical application</strong></td>
<td><strong>Plasma without platelets</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Platelet-rich plasma (PRP) intended for use as platelet gel for topical application</strong></td>
<td><strong>Concentrated platelets within a limited volume of plasma</strong></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><strong>Platelet-poor plasma (PPP) intended for injection</strong></td>
<td><strong>Plasma without Platelets</strong></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>
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<tr>
<td><strong>Platelet-rich plasma</strong></td>
<td><strong>Concentrated platelets as a source of growth factors in a small volume of plasma</strong></td>
<td>**Whole blood is collected via syringe with a small amount of anticoagulant. Whole</td>
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<td>(PRP) intended for</td>
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<td>blood then undergoes two stages of centrifugation to separate the PRP layer from the</td>
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<tr>
<td>injection</td>
<td></td>
<td>PPP and RBCs. The final PRP product, which is transferred to a syringe for injection,</td>
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<td></td>
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<td>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>
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<tr>
<td>**Thrombin intended</td>
<td><strong>Thrombin is an enzyme that plays a role in hemostasis, inflammation, and cell signaling</strong></td>
<td><strong>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.</strong></td>
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<td>for topical application</td>
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<tr>
<td>**Autologous thrombin</td>
<td><strong>Autologous thrombin prepared from the PPP portion of whole blood after separation</strong></td>
<td><strong>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.</strong></td>
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<td>prepared from whole</td>
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<td>blood phlebotomy</td>
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<tr>
<td>**Bone marrow aspirate</td>
<td><strong>Autologous bone marrow nucleated cells that have been aspirated from bone for a primary purpose of tissue regeneration</strong></td>
<td><strong>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 components.</strong></td>
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<tr>
<td>concentrate for topical</td>
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<tr>
<td>application or injection</td>
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