PROPOSED STANDARDS FOR PERIOEPERATIVE AUTOLOGOUS BLOOD COLLECTION AND ADMINISTRATION
12th Edition

Effective: January 1, 2027

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 12th edition begins on page 2 and runs through page 11. The proposed 35th edition begins on page 12 and runs through page 76.

Significant Changes to the Proposed 12th edition of Standards for Perioperative Autologous Blood Collection and Administration

1.1.1 Medical Director Responsibilities
The organization 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 medical director shall be responsible for reporting to executive management at defined intervals.**

The committee added the clause in bold to ensure that the communication between the medical director and executive management (which in a perioperative setting is not a guarantee), occurs at set times.

1.1.1.1 Medical Director Designee
The medical director may delegate these responsibilities to another individual who is qualified by education, training, and/or experience. However, the medical director shall retain ultimate responsibility. **Standard 1.3.1.1 applies.**

The committee added a crossreference to standard 1.3.1 which focuses on the need for medical directors and their designees (as appropriate) to review all policies, processes, and procedures. This was added for completeness.

1.9 Facility Status Changes
The facility shall communicate to AABB in electronic or written format within 30 days a change that directly or indirectly impacts a facility's accreditation status.

1.9.1 If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, they shall notify AABB in electronic or written format within 7 days.

The committee added new standards 1.9 and 1.9.1 to the proposed edition to mirror the addition of the same standards to all other AABB Standards, which include to date, the 12th edition of CT Standards, 17th edition of RT Standards, 14th edition of IRL Standards, and 35th edition of BB/TS Standards.

2.1.3.2 The organization shall ensure that personnel from third party providers are trained to perform critical tasks related to these *Perioperative Standards* and are capable of consistently ensuring the safety and quality of the delivered product.

The committee added new standard 2.1.3.2 to the proposed edition for completeness. This requirement is implied in chapter 4, however the committee felt it important to affirm that third party providers ensure that their staff is trained against the standards for which they are to be held accountable.

2.1.7.1 Organizations shall evaluate the workload of the program against staffing levels to ensure quality patient care at defined intervals.

The committee added new standard 2.1.7.1 to ensure that programs review the workload of all personnel to ensure that the workload is at a level that does not affect patient safety in a negative fashion.

3.3.1 The organization shall ~~validate~~ **verify that** devices and equipment **function as intended at defined intervals** ~~including Food and Drug Administration (FDA) cleared or approved devices, for their intended use~~.* **Standard 4.1.4 and 4.2.4 apply.**

*21 CFR 211.68.

The committee elected to edit standard 3.3.1 for clarity. The committee felt that the edits cited ensure that the focus of the standard is on the actual functionality of the device. The deletions, the committee felt that the terminology included was superfluous.

3.5.4.1 When a nonconformance cannot be attributed to a specific piece of equipment, all potentially affected pieces of equipment shall be systematically assessed for failures or malfunction to determine expected performance measures based on the manufacturer's written instructions.

The committee has added this new standard for clarity. This clarifies that not all equipment has to be reviewed when it is known that one piece of equipment is at the root of the nonconformance. Thus, saving the community time and effort. This addition has been made to other sets of AABB Standards.

~~***3.6 Equipment Traceability***~~

~~*The organization shall maintain records of equipment use in a manner that permits:*~~

~~*1) Equipment to be uniquely identified and traceable.*~~

~~*2) Tracing of any given product or service to all equipment associated with the procurement, processing, storage, distribution, and administration of the product or service.*~~

Based on a review of chapter 3, it was deemed that this standard is redundant to many standards in chapter 3, specifically the 3.5 thread and standard 6.2.2. While this is a QSE, it is causing issues for accredited facilities and will be struck from the other standards as they are being set.

3.7 Technology Infrastructure

The organization shall have an active program to ensure that critical technology infrastructure and communications infrastructure function as intended, including continuous monitoring or testing at facility defined intervals. Standards 1.4, 1.5, and 1.6 apply.

The committee added new standard 3.7 to the proposed edition to mirror the addition of the same standard to all other AABB Standards, which include to date, the 12th edition of CT Standards, 17th edition of RT Standards, 14th edition of IRL Standards, and 35th edition of BB/TS Standards.

3.8.1 Storage devices and/or containers for components shall have the capacity and design to ensure that the proper temperature is maintained. **Reference standards 5.1.9A – C apply**.

The committee added the element in bold for clarity and completeness. This closes a loop on the need to monitor the temperature, as well as ensuring that storage devices are maintained at the appropriate temperature. This mirrors changes to the 35th ed of BB/TS and 14th ed of IRL Standards.

3.8.4 Storage containers shall be qualified for their intended use and requalified at defined intervals. **Reference standards 5.1.9A – C apply**.

The committee edited this standard for clarity and completeness. This closes a loop on the need to monitor the temperature, as well as ensuring that storage containers are maintained at the appropriate temperature. This mirrors changes to the 35th ed of BB/TS and 14th ed of IRL Standards.

4.1.4 Third-Party Provider Qualification
The organization shall qualify third-party providers to ensure that contracted activities meet the requirements of these *Perioperative Standards*. **Standard 2.1.3.2 applies.**

The committee added a crossreference to new standard 2.1.3.2 for completeness.

4.3.1.1 All equipment, containers, and solutions used for collection, preparation, preservation, and storage of perioperative **blood**, 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.

The committee added the term "blood" to this standard for completeness. This change has been made throughout the edition for parallel construction. Note, in the 13th edition this term was removed, but the committee felt that this edit did not provide the benefit expected.

5.1.1.1.1 The organization shall have a process to introduce new or novel uses of existing or new perioperative methods and ~~components~~ **products**.

The committee replaced the term "components" with "products" for clarity.

5.1.7.1 Final Inspection
The organization shall ensure that **perioperative blood and blood** components are acceptable before ~~issue or delivery~~ **administration or reinfusion**. Standard 7.2.2 applies.

The committee edited standard 5.1.7.1 for clarity. The clause "or reinfusion" has been added throughout the Standards where appropriate.

5.1.8.2 General Labeling Requirements
The organization shall have a labeling process for components, including review of patient identification **with unique identifiers** ~~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.

~~**5.1.8.4** The patient identifiers shall be unique.~~

The committee added the elements in bold that previously appeared as former standard 5.1.8.4 for completeness. The elements in strikethrough were removed as they were deemed redundant to the title and content of the standard.

5.1.8.2.4 **Blood product and blood components collected, processed, or prepared within the perioperative setting shall have a label that clearly identifies them as intended for perioperative administration or reinfusion.**

The committee created new standard 5.1.8.2.4 to ensure that programs labeled products for perioperative administration are labeled accordingly and in clear manner.

5.1.9.1 The organization shall have **defined policies and processes regarding the performance of perioperative procedures for patients who are known to have infectious agents that are transmissible. This shall include** the collection, handling, labeling, and storage of components known to contain infectious agents.

The committee added the elements in bold to ensure that programs have defined policies processes to ensure that patients that have infectious are recognized and treated accordingly.

5.1.9.1.1 Storage of perioperative blood and blood components containing infectious agents shall be segregated from all other components and labeled accordingly. *

***21 CFR 606.40.**

In conjunction with the addition to standard 5.1.9.1, the committee added new standard 5.1.9.1.1 to ensure that programs are labeling and segregating products that contain infectious agents appropriately.

5.1.10 Facility-Prepared Pharmaceuticals, Solutions, and Reagents
The facility shall have defined criteria for pharmaceuticals, solutions, and reagents that are prepared ~~in house~~ **perioperatively**. **This shall include but not be limited to:**
1) Date and time of preparation of the product.
2) Individual preparing the product.
3) Expiration date and time of the product.

The committee added the elements in standard 5.1.10 for completeness. The committee felt that these minimum requirements should be in place for all accredit perioperative programs.

5.2 Consents, Approvals, and Notifications
The medical director shall participate in the development of policies, processes, and procedures regarding informed consent for collection and use of **perioperative blood and blood** components. **Standard 1.1.1 applies.**

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

The edits to standards 5.2 and 5.2.2 were done so to ensure parallel construction with edits made to the Standards cited above.

5.~~2.~~3 <u>Perioperative Procedure Documentation</u>

There shall be documentation from a licensed health-care provider for collection, preparation, and administration **<u>or</u>** reinfusion of a **<u>perioperative blood and blood component</u>**.

5.~~2.~~<u>3</u>.1 The organization shall define the information to be contained for the collection, preparation, and administration or reinfusion of a **<u>perioperative blood and blood</u>** component.

The committee moved former standard 5.2.3 to appear as new standard 5.3 as a parent standard as it did not fit in the consent section. The edits to standards 5.3 and 5.3.1 were also done so to ensure parallel construction with edits made to the Standards cited above.

5.~~3.~~<u>4</u>.1 Intraoperative Blood Recovery

The organization shall define the criteria for utilizing intraoperative blood recovery that include the following:

1) Patient inclusion and exclusion criteria.
2) Collection system used.
3) Anticoagulant used.
4) Volume collected/recovered and processed.
5) Circuit configuration.
6) Wash volumes.
7) Pump and centrifugation speeds.
<u>8) Vacuum pressures.</u>
9) Filtration.
10) Minimum blood volume collected for processing.
11) Labeling requirements.
12) Storage requirements.
13) Final inspection

The committee added new subnumber 8 for completeness.

5.4.1.2 <u>Ultrafiltration</u>

The organization shall have policies, processes, and procedures for ultrafiltration if used for recovery of an autologous product processed through an extracorporeal circuit or concentrating reservoir. The organization shall monitor flow rates and system pressures within the circuitry.

The committee added the title "ultrafiltration" to the standard for clarity.

5.<u>4</u>~~3~~.2 Acute Normovolemic Hemodilution (ANH)

The organization shall have policies, processes, and procedures that define the criteria for performing ANH and shall include the following:

2) Volume **<u>to be</u>** collected based on patient characteristics.

The committee edited subnumber 2 for clarity.

5.4.2.3 **Whole ~~B~~b**lood containers **shall be** used ~~for whole blood collection shall be used~~ per the manufacturer's written instructions.

The committee updated the standard for clarity, the intent of the standard has not changed.

5.54 Perioperative Blood and Blood Component Administration or Reinfusion

The organization shall define criteria for **perioperative blood and blood** component administration **or reinfusion**.

✎ **5.5.~~4~~.1 Patient Identification**

Perioperative blood and blood components shall be administered only to the patient from whom they were collected. There shall be positive identification of the patient and the **product** ~~component~~.

The edits to standards 5.5 and 5.5.1 were done so to ensure parallel construction with edits made to the Standards cited above.

5.5.~~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 **patient** ~~independent~~ identifiers ~~(eg, patient name and identification number)~~ whenever the **product** ~~component~~ is separated from the patient or if administration **or reinfusion** occurs outside of the operating suite or clinical ~~procedure~~ **operating/procedural** area. Standard 5.1.8.3 applies.

The committee edited standard 5.5.1.1 for clarity and parallel construction.

5.5.~~4~~.2 Inspection of Blood and Blood Components Before Administration or Reinfusion

Blood and blood components shall be inspected immediately before administration **or reinfusion**.

The committee edited standard 5.5.2 for clarity and parallel construction.

✎ **5.5.~~4~~.2.1** ~~Component~~ Inspection criteria shall include evaluation or verification of the following elements:

1) **Visual inspection of the product** ~~Appearance~~ (as defined by the organization).
2) Labeling.
3) Integrity of the bag.
4~~3~~) Storage requirements have been met, **as applicable**.
5~~4~~) Volume.
6~~5~~) Expiration date and time.

Standard 5.1.8.2.3 applies.

The committee updated subnumber 1 for clarity and parallel construction with language in the BB/TS Standards.
The committee added #3 for completeness, recognizing that this element is key element of inspection criteria.
Subnumber 4 has added the clause, "as applicable" recognizing that there are times where blood is not stored and kept at room temperature.

5.5.~~4~~.2.2 If the **blood and blood** ~~component~~ does not meet program-defined criteria, it shall not be used. Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

The committee edited standard 5.5.2.2 for clarity and parallel construction.

5.5.~~4~~.2.2.1 If the patient's clinical circumstances warrant administration **or reinfusion** of the **nonconforming product** ~~component~~, a record of the treating physician's approval shall be maintained.

The committee added the term "nonconforming" to the standard for clarity, recognizing that in this case a "conforming product" would not require a physician's approval. The standard has also been updated for clarity and parallel construction.

5.~~4~~.5.3 Addition of Drugs and Solutions

~~With the exception~~ **Except for** 0.9% sodium chloride, USP, **no** drugs or medications shall be added to components intended for ~~transfusion~~ **administration or reinfusion** 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.

The committee edited the content of standard 5.5.3 for clarity, the intent of the standard has not changed.

5.5.3.1 When an alternative physiological wash fluid is utilized by the perioperative program, the organization shall have policies, processes, and procedures for its use, and shall ensure that such use is reviewed and approved by the responsible medical director or designee.

The committee created new standard 5.5.3.1 recognizing that programs in the field are using these types of wash fluid (eg, plasmalyte) for intravenous infusion in place of 0.9% sodium chloride.

5.5.4 Administration or Reinfusion Protocol

The organization shall have a protocol for the administration **or reinfusion** of **perioperative blood and blood components**, including the use of reinfusion devices and ancillary equipment. Standard 6.2.2 applies.

5.5.4.2 For components intended for reinfusion, the patient's medical record shall contain the following information:

1) Date and time of administration **or reinfusion**.

5.5.4.3 For topically applied or injected components, the patient's medical record shall contain the following information:

1) Date and time of administration **or reinfusion**.

5.5.5 Prevention of Air Embolism

Processes and procedures for the administration **or reinfusion** of components shall follow the manufacturer's written instructions for use to prevent air embolism, including the prohibition of direct patient connection to the reinfusion device.

The committee edited the standards above for clarity and parallel construction.

5.6 Organ Procurement Using Normothermic Machine Perfusion/Normothermic Regional Perfusion (NRP)

The perioperative program shall have policies, processes and procedures for responding to blood and blood component requests for use with normothermic machine perfusion, including:

1) A mechanism to classify administration (perfusion vs transfusion),

2) Documentation of request and administration,

3) Special modification requests,

4) Traceability from collection to perfusion device to final disposition, adverse events, and lookback.*

*** 21 CFR 606.100 and 21 CFR 606.160**

Normothermic Machine Perfusion (NMP)/Normothermic Regional Perfusion (NRP): An adopted organ procurement and transport technique approved by the appropriate Competent Authority to maintain physiologic conditions that can enhance organ quality, enable extended transport times, and reduce postoperative complications.

The committee created new standard 5.6 focused on organ procurement recognizing that there are perioperative programs that are engaging in this space and the addition of this standard to the proposed edition ensures that the Standards are future proofed. The committee looks forward to feedback from the community regarding the intent of the standard and its uptake. The committee also added a definition of "normothermic machine perfusion" to the Glossary for completeness.

Reference Standard 5.1.9A—Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components*

Item No.	Collection Type	Storage Temperature	Time from Start of Collection to Expiration†	Time from Completion of Processing to Expiration†	Special Conditions
6	Shed blood under postoperative or posttraumatic conditions with or without processing	N/A	8 hours	N/A	**To be maintained at the patient's bedside** ~~None~~

The committee edited the special conditions entry for #6 recognizing that this product will be at the patient's bedside and not stored in a storage device or storage container.

6.2.6.1 The result of each laboratory test performed **in the perioperative setting** shall be recorded immediately and the final interpretation recorded upon completion of testing.

The committee edited the element in bold to standard 6.2.6.1 to ensure that the standard is focused on perioperative programs. This standard originally appeared in the BBTS Standards.

7.1.3 For deviations having the potential to adversely affect the safety, purity, or potency of **perioperative blood and blood** component**(s)**, approval from the medical director and/or the patient's physician/licensed provider shall be obtained before final release **for administration or reinfusion** of the **perioperative blood and blood** component(s).

The committee edited the standards above for clarity and parallel construction.

7.2.4.2 Released nonconforming products shall be reported to the patient's physician/licensed provider and, if applicable, the supplier and **applicable Competent Authority (eg,** regulatory agencies**)**.

The committee edited the standard for clarity, mirroring the language throughout the edition and other sets of AABB Standards.

7.3.3.1 Pause the collection procedure or administration **or reinfusion** of **perioperative blood and blood** components.

7.3.3.3 Compare **and verify** the label on the **perioperative blood and blood** component containers and all other records to **ensure accurate** ~~the~~ patient identification~~, and verify~~.

7.3.3.4 Discontinue the collection or administration or **reinfusion** of **perioperative blood and blood** components if evidence of nonconformance(s) (eg, malfunction or bacterial contamination) is observed. Standard 3.5.4 applies.

7.3.4 The organization shall have a policy for the resumption of collection, administration, **or reinfusion** of **perioperative blood and blood** components following the investigation of an adverse event, that shall include approval by the medical director or patient's physician/licensed provider.

7.3.6 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 **or reinfusion**, that interpretation shall be reported immediately to the medical director and/or patient's physician/licensed health-care provider.

The committee edited the standards above for clarity and parallel construction.

8.4.2 The organization shall have a process that monitors perioperative collection, administration or reinfusion 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 **and utilization review**.
2) Program's impact on patient blood management.

The committee edited subnumber 1 for completeness. This term is used by the BB/TS Standards as well. The committee added new subnumber 2 to the edition for completeness and this mirrors a similar addition to the PBM Standards.

Glossary

Normothermic Machine Perfusion (NMP)/Normothermic Regional Perfusion (NRP): An adopted organ procurement and transport technique approved by the appropriate Competent Authority to maintain physiologic conditions that can enhance organ quality, enable extended transport times, and reduce postoperative complications.

Patient Blood Management (PBM): An evidence-based, patient-centered, systematic, multidisciplinary approach to caring for patients who might require a blood transfusion. PBM is meant to improve patient outcomes by preserving a patient's own blood through diagnosis and etiology specific treatment of anemia and bleeding.

PBM Program: A program within an organization that provides the services outlined in the current edition of AABB's *Standards for a Patient Blood Management Program*.

Regulatory Enforcement Action: Measures taken by a Competent Authority that include but are not limited to progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues, deficiencies in risk management systems.)

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.)

The committee added these terms to the Glossary for completeness.

QSE 1 – Organization

Key Concepts:
This quality system essential (QSE) describes the responsibilities of executive management, the nature of the quality system, and the need for ongoing attention to operational and quality issues through demonstrated management commitment.

Key Terms:
Customer: The recipient of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

Emergency Management: Strategies and specific activities designed to manage situations in which there is a significant disruption to organization operations or a significantly increased demand for the organization's products or services.

Executive Management: The highest-level personnel within an organization, including employees, clinical leaders, 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.

Organization: An institution, or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

Policy: A set of basic principles or guidelines that direct or restrict the organization's plans, actions, and decisions.

Procedure: A defined series of tasks and instructions that specify how an activity is to be performed.

Process: A set of related activities that transform inputs into outputs.

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

Examples of Objective Evidence:
- Policies, processes, and procedures related to this chapter.
- Organizational charts or documents describing roles, responsibilities, and decision-making authority.
- Evidence of executive management review of a quality system.
- Applicable federal, national, state, and local laws and regulations, as well as copies of any required certificates.
- Defined quality system.
- Process for approving exceptions to policies, processes, and procedures, as well as documented examples, if applicable.
- Risk assessments and mitigation strategies.
- Emergency operation and disaster continuity plan(s).
- Executive management review of customer feedback.

1.0 Organization

The organization shall define the parties responsible for the provision of products or services.

1.1 Executive Management

The organization shall have a defined executive management. Executive management shall have:
1) Responsibility and authority for the quality system and operations.
2) Responsibility for compliance with these Standards and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
3) Authority to establish or make changes to the quality system.

1.1.1 Medical Director Responsibilities

The organization 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 medical director shall be responsible for reporting to executive management at defined intervals.

1.1.1.1 Medical Director Designee

The medical director may delegate these responsibilities to another individual who is qualified by education, training, and/or experience. However, the medical director shall retain ultimate responsibility. Standard 1.3.1.1 applies.

1.2 Quality System

The organization shall have a quality system. The organization's executive management shall ensure that this quality system is implemented and followed at all levels of the organization.

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 at defined intervals.

1.3 Policies, Processes, and Procedures

Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these Standards. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

1.3.1 The medical director and/or laboratory director (as applicable) shall approve all medical and technical policies, processes, and procedures.

1.3.1.1 Approval of all medical and technical policies, processes, and procedures shall not be delegated.

1.3.2 Any exceptions to medical and technical policies, processes, and procedures shall require justification and preapproval by the medical director and/or laboratory director, as applicable.

1.3.2.1 The medical director designee shall have the authority to approve any exceptions to medical and technical policies, processes, and procedures, as applicable. Standard 1.1.1.1 applies.

1.4 Risk Assessment

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

1.4.1 Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.

1.5 Operational Continuity

The organization shall address continuity in the event that operations are at risk.

1.6 Emergency Preparedness

The organization shall have an emergency operation plan(s) to respond to the effects of internal and external disasters.

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

1.7 Communication of Concerns

The organization 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 organization's executive management, AABB, or both. AABB's contact information shall be readily available to all personnel.

1.8 Customer Focus

Executive management shall identify the organization's customers and their needs and expectations for products or services.

1.9 Facility Status Changes

The facility shall communicate to AABB in electronic or written format within 30 days a change that directly or indirectly impacts a facility's accreditation status.

1.9.1 If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, they shall notify AABB in electronic or written format within 7 days.

Excerpt of Reference Standard 6.2.9A Relevant to Organization

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
1.1.1.1	Medical director designee identification and qualifications	5
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	10
1.3.2	Exceptions to policies, processes, and procedures	10
1.4	Risk assessment	5
1.6.1	Emergency operation plan tested at defined intervals	2 years, or two organizational testing intervals (whichever is longer)

[1]Applicable federal, state or local law may exceed this period.

QSE 2 – Resources

Key Concepts: This QSE describes the need for resources—human, financial, and otherwise—to support the work performed. It also describes personnel issues such as the qualification of staff, assessments of competence [including those performed under Clinical Laboratory Improvement Amendment (CLIA) regulations], and continuing education requirements.

Key Terms:
Competence: An individual's demonstrated ability to apply knowledge and skills needed to perform the job tasks and responsibilities.

Qualification (individuals): The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Current job descriptions.
- Evaluation of staffing levels and workload, if performed.
- Process for recruiting and hiring.
- Personnel records (eg, certifications, qualifications, competence assessments, diplomas, transcripts).
- Training records.
- Evaluations of competence records.
- Evidence that job qualifications are met.
- Continuing education records.

2.0 Resources

The organization shall have adequate resources to perform, verify, and manage all the activities described in these Standards.

2.1 Human Resources

The organization shall employ an adequate number of individuals qualified by education, training, and/or experience.

2.1.1 Job Descriptions

The organization shall establish and maintain job descriptions defining the roles and responsibilities for each job position related to the requirements of these Standards.

2.1.2 Qualification

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

2.1.3 Training

The organization shall provide training for personnel performing critical tasks.

2.1.3.1 The organization shall define the qualifications required for trainers.

2.1.3.2 The organization shall ensure that personnel from third party providers are trained to perform critical tasks related to these *Perioperative Standards* and are capable of consistently ensuring the safety and quality of the delivered product.

2.1.4 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.

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

2.1.4.2 The medical director or medical director designee shall verify at defined intervals that operators of perioperative collection equipment are trained and capable of delivering a safe product.

2.1.5 Personnel Records

Personnel records for each employee shall be maintained.

2.1.5.1 For those authorized to perform or review critical tasks, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

2.1.6 Continuing Education

The organization shall ensure that continuing education requirements applicable to these Standards are met when applicable.

2.1.7 Workload

Organization personnel shall have time to perform their duties.

2.1.7.1 Organizations shall evaluate the workload of the program against staffing levels to ensure quality patient care at defined intervals.

Excerpt of Reference Standard 6.2.9A Relevant to Resources

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
2.1.1	Job descriptions	5
2.1.2	Qualification of personnel performing critical tasks	5
2.1.3	Training records of personnel	5
2.1.4	Evaluations of competence	5
2.1.5	Personnel records of each employee	5 years following conclusion of employment period
2.1.5.1	Records of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
2.1.6	Continuing education requirements	5

[1]Applicable federal, state or local law may exceed this period.

QSE 3 – Equipment

Key Concepts: This QSE describes the selection, use, maintenance, and monitoring of equipment, including information systems. It also describes the use and testing of alternative systems when primary systems fail.

Key Terms:
Backup: Digital data and/or physical storage containing copies of relevant data.

Calibrate: To set or align measurement equipment against a known standard.

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Critical Equipment/Materials: A piece of equipment or material that can affect the quality of the organization's products.

Data Integrity: The accuracy, completeness, and consistency of information resources.

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

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and the manufacturer's recommendations in an environment suitable for its operation and use.

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

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

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Processes for equipment selection, qualification, and maintenance.
- List or tool used for critical equipment identification.
- Equipment calibration and maintenance records, if applicable.
- Equipment qualification records.
- Manufacturer's written instructions.
- Records of investigation of equipment malfunction, failure, repair, and requalification, if applicable.
- Alarm system testing and records of alarm management, if appropriate.
- Evidence of information system backup and records of testing.

3.0 Equipment

The organization shall define and control critical equipment.

3.1 Equipment Specifications

Equipment specifications shall be defined before purchase.

✎3.2 Qualification of Equipment

All critical equipment shall be qualified for its intended use. Equipment shall be requalified, as needed, after repairs and upgrades.

3.2.1 Installation Qualification

Equipment shall be installed per manufacturer specifications.

3.2.2 Operational Qualification

Each piece of equipment and component of an information system shall be verified before actual use.

3.2.3 Performance Qualification

Equipment shall perform as expected for its intended use.

3.3 Use of Equipment

Equipment shall be used in accordance with the manufacturer's written instructions.

3.3.1 The organization shall verify that devices and equipment function as intended at defined intervals.* Standard 4.1.4 and 4.2.4 apply.

*21 CFR 211.68.

✎3.4 Unique Identification of Equipment

Equipment shall have unique identification.

3.5 Equipment Monitoring and Maintenance

Equipment shall be monitored and maintained in accordance with the manufacturer's written instructions.

✎ 3.5.1 Calibration and Accuracy 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 confirmed as described below unless otherwise indicated by the manufacturer:

1) Before use.
2) After activities that may affect the calibration.
3) At prescribed intervals.

3.5.1.1 Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and specified limitations.

3.5.1.2 Equipment used for calibration, inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards exist, the basis for calibration shall be described and recorded.

3.5.1.3 Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.

3.5.2 When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of potential affected products or services (including those that have already been released or delivered) shall be verified.

3.5.3 The organization shall:

1) Define cleaning and sanitization methods and intervals for equipment.
2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out.
3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel.
4) Monitor equipment to ensure that defined parameters are maintained.
5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use.
6) Ensure that all equipment maintenance and repairs are performed by qualified individuals and in accordance with the manufacturer's recommendations.

3.5.4 Investigation and Follow-up

Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

1) Assessment of products or services provided since the equipment was last known to be functioning per the manufacturer's written instructions or organization-defined specifications.
2) Assessment of the effect on the safety of individuals affected.
3) Removal of equipment from service, if indicated.
4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable.
5) Requalification of the equipment.
6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.

3.5.4.1 When a nonconformance cannot be attributed to a specific piece of equipment, all potentially affected pieces of equipment shall be systematically assessed for failures or malfunction to determine expected performance measures based on the manufacturer's written instructions.

3.6 Information Systems

The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include:

1) Numeric designation of system versions with inclusive dates of use.
2) Validation/verification/qualification of system software, hardware, databases, and user-defined tables before implementation.
3) Fulfillment of life-cycle requirements for internally developed software.
4) Defined processes for system operation and maintenance.
5) Defined process for authorizing and documenting modifications to the system.
6) System security to prevent unauthorized access.
7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
8) Functionality that allows for display and verification of data before final acceptance of the additions or alterations.
9) Defined process for monitoring of data integrity for critical data elements.
10) System design that establishes and maintains unique identity of the donor, the product, or service, and the recipient (as applicable).
11) Training and competency of personnel who use information systems.
12) Procedures to ensure confidentiality of protected information.

3.6.1 Alternative Systems

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

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

3.6.3 The organization shall support the management of information systems.

3.6.4 A system designed to prevent unauthorized access to computers and electronic records shall be in place.

3.6.5 The organization shall have measures in place to minimize the risk of internal and external data breaches.

3.7 Technology Infrastructure

The organization shall have an active program to ensure that critical technology infrastructure and communications infrastructure function as intended, including continuous monitoring or testing at facility defined intervals. Standards 1.4, 1.5, and 1.6 apply.

3.8 Storage Devices and Storage Containers for Components

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

3.8.1 Storage devices and/or containers for components shall have the capacity and design to ensure that the proper temperature is maintained. Reference standards 5.1.9A – C apply.

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

3.8.3 Storage devices shall have alarm systems.

3.8.3.1 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 organization.

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

3.8.4 Storage containers shall be qualified for their intended use and requalified at defined intervals. Reference standards 5.1.9A – C apply.

3.8.4.1 Storage container temperature shall be recorded at least every 4 hours.

3.9 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 (eg, overheating) and prevent damage to components (eg, hemolysis). Standards 3.5 and 3.6 apply.

Excerpt of Reference Standard 6.2.9A Relevant to Equipment

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
3.2	Equipment qualification	10 years after retirement of the equipment
3.4	Unique identification of equipment	5
3.5.1	Equipment calibration activities	5 years after retirement of the equipment
3.5.2	Equipment found to be out of calibration	5
3.5.3	Equipment monitoring, maintenance, calibration, and repair	5 years after retirement of the equipment
3.6	Implementation and modification of software, hardware, or databases	2 years after retirement of system
3.8.2	Storage device temperature	10
3.8.3.2	Investigation of alarm activation	10
3.8.4	Storage container temperature	10

[1]Applicable federal, state or local law may exceed this period.

QSE 4 – Suppliers and Customers

Key Concepts: This QSE describes the need for agreements between the organization and its suppliers and customers. The agreements define expectations between both parties and measures taken when one entity fails to meet the expectations of an agreement.

Key Terms:
Agreement: A contract, order, or understanding between two or more parties, such as between an organization and one of its customers.

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

Customer: The receiver of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

Quality: Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.

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

Supplier: An entity that provides a material, product, or service.

Supplier Qualification: Evaluation of a supplier to assess its ability to consistently deliver products or services that meet specified requirements.

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Processes for defining and updating or changing agreements.
- Process for recording verbal agreements, if practiced.
- Agreement records.
- Agreement review records.
- Supplier qualification records.
- Supplier evaluation records.
- Supplier selection process.
- Evidence of action taken when a supplier fails to meet expectations, if applicable.
- Evidence of receipt of product(s) as stipulated in agreements.
- Records of inspection and testing.

4.0 Suppliers and Customers

The organization shall ensure that agreements to provide or receive products or services are reviewed, approved, and meet supplier and customer expectations.

✎4.1 Supplier Qualification

The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.

4.1.1 The organization shall evaluate and participate in the selection of suppliers. If executive management is not included in the selection process, there shall be a mechanism to provide feedback to management with contracting authority.

4.1.2 When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.

4.1.3 Laboratory testing required by these Perioperative Standards shall be performed in a facility accredited by AABB or an equivalent accrediting body.

4.1.3.1 Laboratory testing shall be performed in a facility certified by the Centers for Medicare and Medicaid Services (CMS) or other regulatory agencies.

4.1.3.2 Laboratory testing by facilities outside of the United States shall be performed by a laboratory authorized as a testing center by the Competent Authority.

4.1.4 Third-Party Provider Qualification

The organization shall qualify third-party providers to ensure that contracted activities meet the requirements of these Perioperative Standards. Standard 2.1.3.2 applies.

✎4.2 Agreements

Agreements and any incorporated changes shall be reviewed and communicated.

✎ **4.2.1** Agreements shall be reviewed at defined intervals to ensure that the terms of the agreement continue to meet requirements.

4.2.2 Changes to agreements shall be communicated to affected parties.

✎ **4.2.3** The responsibilities for activities covered by these Standards when more than one organization is involved shall be specified by agreement.

4.2.4 Third-Party Provider Agreements

The organization shall define the agreements required for third-party provider(s) for the contracted activities. Standard 2.1 applies.

✎4.3 Incoming Receipt, Inspection, and Testing

Incoming products or services, equipment, and materials shall be received, inspected, and tested, as necessary, before approval for use.

4.3.1 Critical materials shall meet facility-specified requirements.

4.3.1.1 All equipment, containers, and solutions used for collection, preparation, preservation, and storage of perioperative blood, 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.

Excerpt of Reference Standard 6.2.9A Relevant to Suppliers and Customers

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.3	Agreements concerning activities involving more than one organization	5
4.3	Inspection of incoming critical materials	10

[1]Applicable federal, state or local law may exceed this period.

QSE 5 – Process Control

Key Concepts: This QSE covers the organization's operations and production functions. It describes the need to ensure that this work is controlled, that processes function as expected, and that expected outcomes are met. This QSE encapsulates what occurs in each organization and forms the basis of its accreditation.

Key Terms:
Change Control: A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the quality of the organization's products.

Executive Management: The highest-level personnel within an organization, including employees, clinical leaders, 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.

Process Control: Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.

Product: A tangible output from a process.

Reference Standard: Specified requirements defined by the AABB. Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.

Service: An intangible output of a process.

Standard: A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

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

Examples of Objective Evidence:
- Policies, processes, and procedures related to this chapter.
- Implementation records.
- Records enabling traceability.
- Storage records.
- Quality control records.
- Process planning, process validation, and change control records.
- Records of material storage, handling, and use.
- Records of inspection of materials.
- Product inspection records.

- Testing records.

5.0 Process Control

The organization shall ensure the quality of products or services.

5.1 General Elements

The organization shall ensure that processes are carried out under controlled conditions.

5.1.1 Change Control

When the organization develops new processes or procedures or changes existing ones, they shall be validated before implementation.

5.1.1.1 This process shall include:

1) Identification and definition of the scope of the change.
2) Verification and validation of new or changed process(es) and/or procedure(s) before implementation.
3) Implementation of the new or changed process(es) and/or procedure(s).
4) Postimplementation assessment.

Standards 2.1.3 and 2.1.4 apply.

5.1.1.1.1 The organization shall have a process to introduce new or novel uses of existing or new perioperative methods and products.

5.1.2 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment, materials, and analytical functions perform as intended.

5.1.2.1 Quality control results shall be reviewed and evaluated against acceptance criteria.

5.1.2.2 Quality control failures shall be investigated before release of test results, products, or services.

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

5.1.3 Process Planning

Quality requirements shall be incorporated into new or changed processes, products, services, and novel methods. Planning and implementation activities shall include the following:

1) Evaluation of accreditation, regulatory, and legal requirements related to the new or changed process, product, or service.
2) Review of current available knowledge (eg, review of medical practice and/or literature).
3) Evaluation of risk.
4) Identification of affected internal and external parties and mechanism to communicate relevant information.

5) Identification of performance measures applicable to the new or changed process, product, or service.
6) Evaluation of resource requirements.
7) Evaluation of the impact of the new or changed process, product, or service on other organization (or program) processes.
8) Evaluation of the need to create or revise documents for the new or changed process, product, or service.
9) Review and approval of the output of process development and design activities (eg, pilot or scale-up study results, process flow charts, procedures, data forms).
10) Evaluation of the extent and scope of process validation or revalidation depending on the level of risk and impact of the new or changed products or services.

5.1.4 Process Validation

Before implementation, the new or changed processes and procedures shall be validated.

5.1.4.1 Validation activities shall include the following:

1) Identification of objectives, individual(s) responsible, expected outcomes, and/or performance measures.
2) Criteria for review of outcomes.
3) Approval of validation plan.
4) Review and approval of actual results.
5) Actions to be taken if objectives are not met.

5.1.5 Process Implementation

The implementation of new or changed processes and procedures shall be planned and controlled.

5.1.5.1 Postimplementation evaluations of new or changed processes and procedures shall be performed.

5.1.6 Use of Materials

All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.

5.1.7 Inspection

The organization shall ensure that products or services are inspected at organization-defined stages.

5.1.7.1 Final Inspection

The organization shall ensure that perioperative blood and blood components are acceptable before administration or reinfusion. Standard 7.2.2 applies.

5.1.8 Identification and Traceability

The organization shall ensure that all products or services are identified and traceable.

5.1.8.1 Process or Procedure Steps

The organization shall have a process to identify the individuals performing each critical step in collection, processing, and administration or reinfusion of components and when each step was performed. Standard 6.2.2 applies.

5.1.8.2 General Labeling Requirements

The organization shall have a labeling process for components, including review of patient identification with unique identifiers. 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.

5.1.8.2.1 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.

5.1.8.2.2 Intermediate components that are separated from the patient shall be labeled with two patient identifiers.

5.1.8.2.3 All final components for administration or reinfusion shall be labeled with the following:

Reference Standard 5.1.9A, Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components, and Reference Standard 5.1.9B, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion, apply.

5.1.8.2.3.1 When the final component enters the surgical field immediately after collection, labeling requirements shall be defined by the organization.

5.1.8.2.3.2 If the final component is separated from the patient, labeling of the final component for reinfusion shall conform to all FDA or Competent Authority regulations, including bar code labeling, as applicable. Each unit shall be labeled “For Autologous Use Only,” “Donor Untested,” and “Biohazard.” Standard 5.1.9.1 applies.*

*21 CFR 606.121 and 21 CFR 610.40.

5.1.8.2.4 Blood product and blood components collected, processed, or prepared within the perioperative setting shall have a label that

clearly identifies them as intended for perioperative administration or reinfusion.

5.1.8.3 The labeling system shall ensure that any component can be traced from its source to final disposition.

5.1.9 Handling, Storage, and Transportation

The organization shall ensure that products or services are handled, stored, and transported in a manner that prevents damage, limits deterioration, and provides traceability.

5.1.9.1 The organization shall have defined policies and processes regarding the performance of perioperative procedures for patients who are known to have infectious agents that are transmissible. This shall include the collection, handling, labeling, and storage of components known to contain infectious agents.

5.1.9.1.1 Storage of perioperative blood and blood components containing infectious agents shall be segregated from all other components and labeled accordingly. *

* 21 CFR 606.40.

5.1.10 Facility-Prepared Pharmaceuticals, Solutions, and Reagents

The facility shall have defined criteria for pharmaceuticals, solutions, and reagents that are prepared perioperatively. This shall include but not be limited to:
1) Date and time of preparation of the product.
2) Individual preparing the product.
3) Expiration date and time of the product.

5.1.11 Prevention of Contamination

The organization shall employ methods that provide assurance of a pyrogen-free product. Standard 5.3 applies. Single use materials,-sterile and pyrogen-free pharmaceuticals, solutions, and reagents shall be used.

5.1.11.1 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 1.3.2; Reference Standard 5.1.9A, Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components; Reference Standard 5.1.9B, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion; and Reference Standard 5.1.9C, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application, apply.

5.1.11.2 The organization shall define the length of time disposables may be opened and set up before use. Time frames shall be consistent with the manufacturer's instructions for use.

5.2 Consents, Approvals, and Notifications

The medical director shall participate in the development of policies, processes, and procedures regarding informed consent for collection and use of perioperative blood and blood components. Standard 1.1.1 applies.

✎ **5.2.1** At a minimum, elements of consent shall include all of the following:
1) A description of the procedure and risks and benefits.
2) Discussion of treatment alternatives.
3) The opportunity for patients to ask questions and receive answers from a knowledgeable health-care professional.
4) 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 or reinfusion of perioperative blood and blood components, including patient selection and preparation of the patient for the use of components.

✎ **5.3 Perioperative Procedure Documentation**

There shall be documentation from a licensed health-care provider for collection, preparation, and administration or reinfusion of a perioperative blood and blood component.

5.3.1 The organization shall define the information to be contained for the collection, preparation, and administration or reinfusion of a perioperative blood and blood component.

5.4 Perioperative Collection

The organization shall have technical policies, processes, and procedures to ensure safe and effective delivery of these services, as well as the safety and quality of the collected perioperative product. Standard 5.1.2 applies.

5.4.1 Intraoperative Blood Recovery

The organization shall define the criteria for utilizing intraoperative blood recovery that include the following:
1) Patient inclusion and exclusion criteria.
2) Collection system used.
3) Anticoagulant used.
4) Volume collected/recovered and processed.
5) Circuit configuration.
6) Wash volumes.
7) Pump and centrifugation speeds.
8) Vacuum pressures.
9) Filtration.
10) Minimum blood volume collected for processing.
11) Labeling requirements.
12) Storage requirements.
13) Final inspection.

5.4.1.1 Cell washing devices for intraoperative blood collection shall be used in accordance with the manufacturer's written instructions.

5.4.1.2 Ultrafiltration

The organization shall have policies, processes, and procedures for ultrafiltration if used for recovery of an autologous product processed through an extracorporeal circuit or concentrating reservoir. The organization shall monitor flow rates and system pressures within the circuitry.

5.4.2 Acute Normovolemic Hemodilution (ANH)

The organization shall have policies, processes, and procedures that define the criteria for performing ANH and shall include the following:

1) Patient inclusion and exclusion criteria.
2) Volume to be collected based on patient characteristics.
3) Collection procedure.
4) Anticoagulant used.
5) Product and quality determination.
6) Storage requirements.
7) Labeling requirements.
8) Final inspection.

5.4.2.1 For blood collection by venipuncture, the site shall be prepared so as to minimize the risk of bacterial contamination of the component. Standard 5.1.11 applies.

5.4.2.2 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 5.1.11 applies.

5.4.2.3 Whole blood collection containers shall be used per the manufacturer's written instructions.

5.4.2.4 The organization shall use qualified scales to measure the amount of whole blood collected to provide proper whole-blood-to-anticoagulant ratio. Standard 3.5.1 applies.

5.4.3 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.

5.4.4 Platelet-Rich Plasma (PRP)

The organization shall have policies, processes, and procedures for the collection and administration of PRP, which shall include:

1) Patient inclusion and exclusion criteria.
2) Volume collected.
3) Collection and processing procedures.
4) Infusion, injection, or topical administration, as applicable.
5) Labeling requirements.
6) Storage requirements.
7) Final inspection.

Reference Standard 5.1.9B, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion, and Reference Standard 5.1.9C, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application, apply.

5.4.5 Other Topical or Injectable Products

The organization shall have processes and procedures for the collection and safe administration of components for topical or injectable application. Reference Standard 5.1.9C, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application, applies.

5.5 Perioperative Blood and Blood Component Administration or Reinfusion

The organization shall define criteria for perioperative blood and blood component administration or reinfusion.

5.5.1 Patient Identification

Perioperative blood and blood components shall be administered only to the patient from whom they were collected. There shall be positive identification of the patient and the product.

5.5.1.1 There shall be positive identification of the patient by the transfusionist and one other qualified individual (or an electronic identification system) using two patient identifiers whenever the product is separated from the patient or if administration or reinfusion occurs outside of the operating suite or clinical operating/procedural area. Standard 5.1.8.3 applies.

5.5.2 Inspection of Blood and Blood Components Before Administration or Reinfusion

Blood and blood components shall be inspected immediately before administration or reinfusion.

5.5.2.1 Inspection criteria shall include evaluation or verification of the following elements:

1) Visual inspection of the product (as defined by the organization).
2) Labeling.
3) Integrity of the bag.
4) Storage requirements have been met, as applicable.
5) Volume.
6) Expiration date and time.

Standard 5.1.8.2.3 applies.

5.5.2.2 If the blood and blood component does not meet program-defined criteria, it shall not be used. Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

5.5.2.2.1 If the patient's clinical circumstances warrant administration or reinfusion of the nonconforming product, a record of the treating physician's approval shall be maintained.

5.5.3 Addition of Drugs and Solutions

Except for 0.9% sodium chloride, USP, no drugs or medications shall be added to components intended for administration or reinfusion 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.

5.5.3.1 When an alternative physiological wash fluid is utilized by the perioperative program, the organization shall have policies, processes, and procedures for its use, and shall ensure that such use is reviewed and approved by the responsible medical director or designee.

5.5.4 Administration or Reinfusion Protocol

The organization shall have a protocol for the administration or reinfusion of perioperative blood and blood components, including the use of reinfusion devices and ancillary equipment. Standard 6.2.2 applies.

5.5.4.1 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.

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

Standard 5.2 applies.

5.5.4.2.1 For components that are not used, records of their disposition shall be maintained. Standards 5.1.8.3, and 10.3 apply.

5.5.4.3 For topically applied or injected components, the patient's medical record shall contain the following information:
1) Date and time of administration or reinfusion.
2) Identification of the individual administering the component.
3) Records of adverse reactions.

Standard 5.2 applies.

5.5.4.3.1 For topically applied or injected components that are not used, records of their disposition shall be maintained. Standards 5.1.8.3, and 10.3 apply.

5.5.5 Prevention of Air Embolism

Processes and procedures for the administration or reinfusion of components shall follow the manufacturer's written instructions for use to prevent air embolism, including the prohibition of direct patient connection to the reinfusion device.

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

5.6 Organ Procurement Using Normothermic Machine Perfusion/Normothermic Regional Perfusion (NRP)

The perioperative program shall have policies, processes and procedures for responding to blood and blood component requests for use with normothermic machine perfusion, including:
1) A mechanism to classify administration (perfusion vs transfusion),
2) Documentation of request and administration,
3) Special modification requests,
4) Traceability from collection to perfusion device to final disposition, adverse events, and lookback.*

* 21 CFR 606.100 and 21 CFR 606.160

Reference Standard 5.1.9A—Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components*

Item No.	Collection Type	Storage Temperature	Time from the Start of Collection to Expiration†	Time from Completion of Processing to Expiration†	Special Conditions
1	Acute normovolemic hemodilution (whole blood)	Room temperature	8 hours	N/A	None
2	Acute normovolemic hemodilution (whole blood)	1-6 C	24 hours	N/A	Storage at 1-6 C shall begin within 8 hours of the start of collection
3	Intraoperative blood recovery with processing (centrifugation‡ and/or washing and/or ultrafiltration)	Room temperature	N/A	8 hours	None
4	Intraoperative blood recovery with processing (centrifugation‡ and/or washing and/or ultrafiltration)	1-6 C	N/A	24 hours	Storage at 1-6 C shall begin within 8 hours of the completion of processing
5	Intraoperative blood recovery without processing	Room temperature	N/A	8 hours	None
6	Shed blood under postoperative or posttraumatic conditions with or without processing	N/A	8 hours	N/A	To be maintained at the patient's bedside

7	Combined intraoperative and postoperative blood recovery with processing	Room temperature	Postoperatively processed units: 8 hours from the start of postoperative collection	Intraoperatively processed units: 8 hours	None
8	Red Blood Cells prepared by apheresis and intended for reinfusion	Room temperature	8 hours	N/A	None
9	Red Blood Cells prepared by apheresis and intended for reinfusion	1-6 C	24 hours	N/A	Storage at 1-6 C shall begin within 8 hours of collection

*Standard 1.3.2 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 5.1.9B—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion

Item No.	Component Type	Storage Temperature	Expiration Time from Start of Collection	Special Conditions
1	Platelet-rich plasma intended for reinfusion	Room temperature	8 hours	None
2	Plasma intended for reinfusion	Room temperature	8 hours	None
3	Plasma intended for reinfusion	1-6 C	24 hours	Storage at 1-6 C shall begin within 8 hours of collection

Reference Standard 5.1.9C—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application

Item No.	Component Type	Storage Temperature	Expiration*	Special Conditions
1	Platelet-rich plasma intended for topical use or injectable use	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area
2	Platelet-poor plasma intended for topical use or injectable use	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area
3	Thrombin intended for topical use	Room temperature	Within 8 hours after component preparation (or not to exceed device manufacturer's instructions for use)	Shall be used before the patient leaves the operating room or clinical procedure area
4	Marrow aspirate concentrate intended for topical or injectable use	Room temperature	N/A	Shall be used before the patient leaves the operating room or clinical procedure area

*If the manufacturer's instructions for use are more stringent than this requirement, they shall be followed. Standard 3.3 applies.

Excerpt of Reference Standard 6.2.9A Relevant to Process Control

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	10
5.1.7.1	Final inspection	5
5.1.8	Identification and traceability of products	5
5.1.8.1	Records of procedures, including identification of procedural steps, and identification of individuals performing critical steps in collection, processing, and reinfusion or application of components	10
5.1.10	Pharmaceuticals, solutions, and reagents prepared by facility meet or exceed applicable criteria	5
5.2.1	Elements of consent	5
5.3	Perioperative procedure documentation	5
5.5.1	Patient identification	5
5.5.2.1	Component inspection	10
5.5.2.2, 5.5.2.2.1	Physician approval for use of nonconforming components before administration	10
5.5.4.2	Administration records for components intended for reinfusion	10
5.5.4.2.1	Disposition of components not used	10
5.5.4.3	Administration records for topical or injectable components	10
5.5.4.3.1	Disposition of topical or injectable components that are not used	10

[1]Applicable federal, state or local law may exceed this period.

QSE 6 – Documents and Records

Key Concepts: This QSE focuses on the need to maintain all documents and records in a manner that ensures their confidentiality, traceability, completeness, uniformity, and ability to be retrieved and located in a time deemed adequate. This QSE also includes the need to ensure data integrity and that all data can be backed up and retrieved.

Key Terms:
Backup: Digital data and/or physical storage containing copies of relevant data.

Confidentiality: The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure.

Data Integrity: The accuracy, completeness, and consistency of information resources.

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.

Label: An inscription affixed or attached to a product for identification.

Labeling: Information that is required or selected to accompany a product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

Master List of Documents: A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the Standards, including information for document control.

Record (noun): Information captured in writing or through electronically generated media 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.

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Records of activities performed.
- Record system.
- Master list of documents.
- An electronic record system, if applicable.
- Uniform storage media and ability to track newer technologies to older ones as needed.
- Evidence of document and record review.
- Evidence of standardized formats for all documents and records.
- Record retention periods.
- Record traceability.
- Data backup plans.
- Record change process.
- Obsolescence of records and disposition.

- Record destruction.

6.0 Documents and Records

The organization shall ensure that documents and records are created, stored, and archived in accordance with record retention policies.

6.1 Document Control

The organization shall control all documents that relate to the requirements of these Standards. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.

6.1.1 Format

Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual or published in the AABB Technical Manual) may be incorporated by reference.

6.1.2 Document Review, Approval, and Distribution

The document control process shall ensure that documents:

1) Are reviewed by personnel trained and/or qualified in the subject area.
2) Are approved by an authorized individual.
3) Are identified with the current version and effective date.
4) Are available at all locations where operations covered by these Standards are performed.
5) Are not used when deemed invalid or obsolete.
6) Are identified as archived or obsolete when appropriate.

6.1.3 Document Changes

Changes to documents shall be reviewed and approved by an authorized individual.

6.1.3.1 The organization shall track changes to documents.

6.1.4 Master List of Documents

The organization shall maintain complete lists of all active policies, processes, procedures, labels, forms, and other documents that relate to the requirements of these Standards.

6.1.5 Review of Policies, Processes, and Procedures

Review of each policy, process, and procedure shall be performed by an authorized individual at a minimum of every 2 years.

6.1.6 Document Retention

The organization shall determine which documents shall be archived, destroyed, or made obsolete.

6.1.7 Document Storage

Documents shall be stored in a manner that preserves integrity and legibility; protects

from accidental or unauthorized access, loss, destruction, or modification; and ensures accessibility and retrievability.

6.1.8 Document Retrieval

The organization shall ensure that documents are retrievable in a timely manner.

6.1.9 The organization shall use only current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these Standards are performed.

6.2 Record Control

The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.

6.2.1 Records

Records shall be complete, retrievable in a period appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.

6.2.2 Record Traceability

The records system shall ensure traceability of:

1) Critical activities performed.
2) The individual who performed the activity.
3) Date the activity was performed.
4) Time the activity was performed, if applicable.
5) Results obtained.
6) Method(s) used.
7) Equipment used.
8) Critical materials used.
9) The organization where the activity was performed.

6.2.3 Information to Be Retained

Records shall demonstrate that a material, product, or service conforms to specified requirements and that the quality system is operating effectively.

6.2.4 Legibility

All records shall be legible and indelible.

6.2.5 Record Change

The organization shall establish processes for changing records. The date and identity of the person making the change shall be recorded. Record changes shall not obscure previously recorded information.

6.2.5.1 Changes to records (including electronic records) shall be verified for accuracy and completeness.

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

6.2.6.1 The result of each laboratory test performed in the perioperative setting shall be recorded immediately and the final interpretation recorded upon completion of testing.

6.2.7 Copies

Before destruction of original records, copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.

6.2.8 Confidentiality

The organization shall ensure the confidentiality of records.

6.2.9 Retention

Records required by these Standards shall be retained for a period indicated in the record retention table at the end of each chapter.

6.2.10 Record Review

Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.

6.2.11 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, loss, deterioration, damage, destruction, mix-up, or modification.
3) Permit ready identification.
4) Allow retrieval in a defined time frame.

6.2.12 Destruction of Records

Destruction of records shall be conducted in a manner that protects the confidential content of the records.

6.3 Electronic Records

The organization shall support the management of information systems.

6.3.1 Access to Data and Information

Access to data and information shall be controlled.

6.3.1.1 The authorization to access and release data and information shall be defined, and individuals authorized to enter, change, and release results shall be identified.

6.3.1.1.1 Electronic records shall include the date and identity of the person making a change.

6.3.2 Data Integrity

Data integrity shall ensure that data are retrievable and usable.

6.3.2.1 Data shall be accurately, reliably, and securely sent from the point of entry to final destination.

6.3.2.2 Data shall be retrievable for the entire retention period.

6.3.2.2.1 The organization shall archive records or data from media and platforms no longer in use.

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

6.3.3 Storage Media

Data storage media shall be protected from damage or unintended access and destruction.

6.3.4 Backup Data

The organization shall back up all critical data.

6.3.4.1 Backup data shall be stored in a secure off-site location.

6.3.4.2 Backup data shall be protected from unauthorized access, loss, or modification.

6.3.4.3 The ability to retrieve data from the backup system shall be tested at defined intervals.

Excerpt of Reference Standard 6.2.9A Relevant to Documents and Records

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
6.1.2	Document control, including review and approval of all documents before use	5
6.1.3	Review and approval of changes to documents	5
6.1.4	List of all active policies, processes, procedures, labels, and forms	5
6.1.5	Biennial review of each policy, process, or procedure	5
6.1.6	Documents that are archived, destroyed, or made obsolete	5
6.2.5	Record change	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	5
6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	5
6.3	Electronic records	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	5

[1]Applicable federal, state or local law may exceed this period.

Reference Standard 6.2.9A—Retention of Records

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
1.1.1.1	Medical director designee identification and qualifications	5
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	10
1.3.2	Exceptions to policies, processes, and procedures	10
1.4	Risk assessment	5
1.6.1	Emergency operation plan tested at defined intervals	2 years, or two organizational testing intervals (whichever is longer)
2.1.1	Job descriptions	5
2.1.2	Qualification of personnel performing critical tasks	5
2.1.3	Training records of personnel	5
2.1.4	Evaluations of competence	5
2.1.5	Personnel records of each employee	5 years following conclusion of employment period
2.1.5.1	Records of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
2.1.6	Continuing education requirements	5
3.2	Equipment qualification	10 years after retirement of the equipment
3.4	Unique identification of equipment	5
3.5.1	Equipment calibration activities	5 years after retirement of the equipment
3.5.2	Equipment found to be out of calibration	5
3.5.3	Equipment monitoring, maintenance, calibration, and repair	5 years after retirement of the equipment
3.6	Implementation and modification of software, hardware, or databases	2 years after retirement of system
3.8.2	Storage device temperature	10
3.8.3.2	Investigation of alarm activation	10
3.8.4	Storage container temperature	10
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.3	Agreements concerning activities involving more than one organization	5

4.3	Inspection of incoming critical materials	10
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	10
5.1.7.1	Final inspection	5
5.1.8	Identification and traceability of products	5
5.1.8.1	Records of procedures, including identification of procedural steps, and identification of individuals performing critical steps in collection, processing, and reinfusion or application of components	10
5.1.10	Pharmaceuticals, solutions, and reagents prepared by facility meet or exceed applicable criteria	5
5.2.1	Elements of consent	5
5.3	Perioperative procedure documentation	5
5.5.1	Patient identification	5
5.5.2.1	Component inspection	10
5.5.2.2, 5.5.2.2.1	Physician approval for use of nonconforming components before administration	10
5.5.4.2	Administration records for components intended for reinfusion	10
5.5.4.2.1	Disposition of components not used	10
5.5.4.3	Administration records for topical or injectable components	10
5.5.4.3.1	Disposition of topical or injectable components that are not used	10
6.1.2	Document control, including review and approval of all documents before use	5
6.1.3	Review and approval of changes to documents	5
6.1.4	List of all active policies, processes, procedures, labels, and forms	5
6.1.5	Biennial review of each policy, process, or procedure	5
6.1.6	Documents that are archived, destroyed, or made obsolete	5
6.2.5	Record change	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	5
6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	5
6.3	Electronic records	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	5

7.1	Deviations	10 years after any impacted product is used or discarded
7.1.1, 7.1.2, 7.1.3	Capture, investigation, assessment, and reporting of deviations	5
7.2	Nonconforming products or services	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10
7.2.4.1	Disposition of the nonconforming product or service	10
7.2.4.2	Notification and report of nonconforming components and materials discovered after release and subsequent actions taken, including acceptance for use	10
7.3.4	Approval for the resumption of administration of components	10
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5
8.4.2	Perioperative program monitors and reviews	5
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10

[1]Applicable federal, state or local law may exceed this period.

QSE 7 – Deviations, Nonconformances, and Adverse Events

Key Concepts: This QSE focuses on the need to ensure capture of, management of, and response to deviations, nonconformances, or adverse events. This also includes the need to maintain records of resolution.

Key Terms:
Adverse Event: A complication. Adverse events may occur in relation to organization-defined activities.

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

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Disaster: An event (internal, local, or national) that can affect the safety and availability of the organization's products or the safety of individuals.

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

Nonconformance: Failure to meet requirements.

Root Cause(s): The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Traceability: The ability to follow the history of a product or service from source to final distribution or disposition using records.

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Records and evaluation of deviations, nonconformances, and adverse events.
- Notification to customer(s) following investigation, if appropriate.
- Records of evidence that measures were taken to ensure deviations, nonconformances, and adverse events do not recur.
- Planned deviation records, if any.
- Records of deviation reporting to appropriate parties [eg, Food and Drug Administration (FDA)].

7.0 Deviations, Nonconformances, and Adverse Events

The organization shall capture, assess, investigate, and monitor failures to meet specified requirements. The responsibility for review and authority for the disposition of nonconformances shall be defined. These events shall be reported in accordance with specified requirements and to outside agencies as required.

7.1 Deviations

The organization shall capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. The assessment shall ensure timely and appropriate clinical management of the recipient, if applicable.

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, purity, or potency of perioperative blood and blood component(s), approval from the medical director and/or the patient's physician/licensed provider shall be obtained before final release for administration or reinfusion of the perioperative blood and blood component(s).

7.2 Nonconformances

Upon discovery, nonconforming products or services shall be evaluated and their disposition determined.

7.2.1 Nonconforming products or services shall be quarantined and/or destroyed.

7.2.2 The unintended distribution or use of products or services that do not conform to specified requirements shall be prevented.

7.2.3 The organization shall:

1) Identify, quarantine, retrieve, recall, and determine the disposition of nonconforming products or services.
2) Identify and manage nonconforming products or services.

7.2.4 Released Nonconforming Products or Services

Products or services that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality and/or safety of the product or service.

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

7.2.4.2 Released nonconforming products shall be reported to the patient's physician/licensed provider and, if applicable, the supplier and applicable Competent Authority (eg, regulatory agencies).

7.3 Adverse Events

The organization shall detect, monitor, evaluate, manage, and report adverse events related to safety and quality.

7.3.1 Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.

7.3.2 Investigation results and analysis shall be communicated among all facilities involved, if applicable.

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

7.3.3.1 Pause the collection procedure or administration or reinfusion of perioperative blood and blood components.

7.3.3.2 Evaluate the adverse event while concurrently managing the patient's clinical needs.

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

7.3.3.4 Discontinue the collection or administration or reinfusion of perioperative blood and blood components if evidence of nonconformance(s) (eg, malfunction or bacterial contamination) is observed. Standard 3.5.4 applies.

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

7.3.4 The organization shall have a policy for the resumption of collection, administration, or reinfusion of perioperative blood and blood components following the investigation of an adverse event, that shall include approval by the medical director or patient's physician/licensed provider.

7.3.5 The organization shall have a process for indicating the circumstances under which additional testing will be performed and what will be tested. Standard 4.1.3 applies.

7.3.6 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 or reinfusion, that interpretation shall be reported immediately to the medical director and/or patient's physician/licensed health-care provider.

7.3.6.1 Fatalities associated with perioperative services shall be reported internally and to external authorities.*

*21 CFR 606.170 and 21 CFR 803.30.

Excerpt of Reference Standard 6.2.9A Relevant to Deviations, Nonconformances, and Adverse Events

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
7.1	Deviations	10 years after any impacted product is used or discarded
7.1.1, 7.1.2, 7.1.3	Capture, investigation, assessment, and reporting of deviations	5
7.2	Nonconforming products or services	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10
7.2.4.1	Disposition of the nonconforming product or service	10
7.2.4.2	Notification and report of nonconforming components and materials discovered after release and subsequent actions taken, including acceptance for use	10
7.3.4	Approval for the resumption of administration of components	10

[1]Applicable federal, state or local law may exceed this period.

QSE 8 – Internal and External Assessments

Key Concepts: This QSE addresses the organization's internal quality assessment functions as well as processes to support external assessments by accreditors, health authorities, and regulators This chapter also describes the need for the organization to engage in ongoing quality monitoring and utilization review.

Key Terms:
Adverse Event: A complication. Adverse events may occur in relation to organization-defined activities.

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

Competent Authority: The agency responsible under its national law for regulations applicable to the organization.

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

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Nonconformance: Failure to meet requirements.

Preventive Action: An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances, or other undesirable situations.

Quality Indicator Data: Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top 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.

Root Cause(s): The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Records of internal assessments scheduled and conducted.
- Records of evidence that deficiencies discovered during assessments and inspections have been addressed, including changes to quality or operational functions.
- Records of external assessments being conducted.
- Quality indicator data collection and review.

8.0 Internal and External Assessments

The organization shall conduct assessments of operations and quality systems.

8.1 Internal Assessments

The organization shall conduct internal assessments. Internal assessments shall be performed by personnel independent of those having direct responsibility for the activity being assessed.

8.2 External Assessments

The organization shall participate in an external assessment program applicable to the activities performed in the organization.

8.3 Management of Assessment Results

The results of assessments shall be:

1) Reviewed by the personnel having responsibility for the area assessed.
2) Evaluated to determine the need for corrective and preventive action.
3) Communicated to the appropriate staff.
4) Reported to executive management.

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

8.4 Quality Monitoring

The organization shall collect and evaluate quality indicator data on a scheduled basis, including adverse events.

8.4.1 The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.

8.4.2 The organization shall have a process that monitors perioperative collection, administration or reinfusion 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 and utilization review.
2) Program's impact on patient blood management.
3) Patient identification.
4) Sample and component collection.
5) Labeling.
6) Appropriateness of use.
7) Quality control.
8) Adverse events.
9) Near-miss events.
10) Usage, discard, and cause(s) of waste.
11) Ability of services to meet customer needs.
12) Overall program effectiveness and opportunities for improvement.

Excerpt of Reference Standard 6.2.9A Relevant to Internal and External Assessments

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5
8.4.2	Monitors and reviews	5

[1]Applicable federal, state or local law may exceed this period.

QSE 9 – Process Improvement

Key Concepts: This QSE focuses on the use of corrective and preventive actions to drive process improvement. It describes measures to ensure that the root causes of nonconformances are effectively addressed.

Key Terms:
Adverse Event: A complication. Adverse events may occur in relation to organization defined activities.

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

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

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

Nonconformance: Failure to meet requirements.

Preventive Action: An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances, or other undesirable situations.

Root Cause(s): The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Records of collected data analysis and corrective action taken when near-misses, deviations, or adverse events are discovered.
- Tracking of relevant data that affect the organization's current and future operations.
- Records indicating that corrective and preventive action was taken.
- Records indicating that corrective and preventive action taken was effective and is being monitored.
- Documentation that process improvement data are included in executive management review.

✎9.0 Process Improvement

The organization shall collect data, perform analysis, and follow up on issues requiring corrective and preventive action, including near-miss events.

✎9.1 Corrective Action

The organization shall have a process for corrective action that includes:

1) Description of the event.
2) Investigation of the root cause(s) of nonconformances relating to the product or service, the process, and the quality system.
3) Determination of the corrective action needed to eliminate the cause of nonconformances, as applicable.
4) Ensuring that corrective action is reviewed and found to be effective.

9.1.1 Investigation and corrective action shall include consideration of deviations, nonconformances, and complaints.

✎9.2 Preventive Action

The organization shall have a process for preventive action that includes:

1) Analysis of appropriate sources of information to detect, analyze, and eliminate potential causes of nonconformances.
2) Determination of steps needed to address any problems requiring preventive action.
3) Initiation of preventive action and application of controls to ensure that it is effective.

9.3 Performance Improvement

The organization shall track and identify trends in information related to its operational and quality system performance to identify opportunities for improvement.

Excerpt of Reference Standard 6.2.9A Relevant to Process Improvement

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5

[1]Applicable federal, state or local law may exceed this period.

QSE 10 – Facilities and Safety

Key Concepts: This QSE addresses the safety and adequacy of areas where the work required by these Standards is performed. This includes occupational safety, biohazardous material disposal, environmental monitoring, and compliance with applicable local and national regulations.

Key Terms:
Environmental Monitoring: Policies, processes, and procedures used for monitoring any or all of the following: temperature, humidity, particulates, and microbial contamination in a specific area. Where appropriate, the program shall include sampling sites, frequency of sampling, and investigative and corrective actions that should be followed when specified limits are exceeded.

Executive Management: The highest-level personnel within an organization, including employees, clinical leaders, 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.

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

Examples of Objective Evidence:
- Policies, processes, and procedures related to this chapter.
- Safe environmental conditions for all individuals in the organization.
- Local, state, and national regulations being followed.
- Proper discard of hazardous and potentially hazardous materials.
- Personal protective equipment (PPE) is available and in use.

10.0 Facilities and Safety

The organization shall ensure safe environmental conditions. The work area shall be suitable for the activities performed. Safety programs shall meet local, state, and national regulations.

10.1 Safe Environment

The organization shall minimize and respond to environmentally related risks to the health and safety of all individuals and products or services. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

✎10.2 Biological, Chemical, and Radiation Safety

The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.

✎10.3 Handling and Discarding of Biological Materials

Biological materials shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

Excerpt of Reference Standard 6.2.9A Relevant to Facilities and Safety

Standard	Record to Be Maintained	Minimum Retention Time (in years)[1]
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10

[1]Applicable federal, state or local law may exceed this period.

LIST OF COMPONENTS AND PROCESSING METHODS

Component	Description	Process/Method
Whole blood and red cell components:		
Whole Blood	Whole Blood is collected in an anticoagulant/ preservative solution and is not processed further	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).
Red Blood Cells (RBCs)	Red cells concentrated by the removal of most of the plasma from sedimented or centrifuged whole blood	Whole blood collected, processed, and split into RBCs and plasma/effluent.
Red Blood Cells prepared by apheresis and intended for reinfusion	Red cells in anticoagulant that have been prepared 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 device. Centrifugation splits the whole blood into RBCs, platelet-rich plasma (PRP), or platelet-poor plasma (PPP).
Plasma and platelet components:		
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 device. Centrifugation splits the whole blood into RBCs, PRP, or PPP.
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 device. Centrifugation splits the whole blood into RBCs, PRP, or PPP.

Recovery and reinfusion:		
Intraoperative blood recovery with washing	Use of a collection system and cell washing device to remove contaminants and wash recovered red cells from surgical sites/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 is then added to the centrifuge 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 is 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:		
Platelet-poor plasma (PPP) intended for topical application	Plasma without platelets	Using sequestration and centrifugation, the blood is fractionated into RBCs, PRP, or 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.
Platelet-rich plasma (PRP) intended for use as platelet gel for topical application	Concentrated platelets within a limited volume of plasma	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.
Platelet-poor plasma (PPP) intended for injection	Plasma without platelets	Using sequestration and centrifugation, the blood is fractionated into RBCs, PRP, or PPP. The PPP is collected into a syringe and injected into tissue.

Platelet-rich plasma (PRP) intended for injection	Concentrated platelets as a source of growth factors in a small volume of plasma	Whole blood is collected via syringe with a small amount of anticoagulant that 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.
Thrombin intended for topical application	Thrombin is an enzyme that plays a role in hemostasis, inflammation, and cell signaling	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.
Autologous thrombin prepared from whole blood phlebotomy	Autologous thrombin prepared from the PPP portion of whole blood after separation	Using sequestration and centrifugation, the blood is fractionated into RBCs, PRP, or PPP. The PPP is collected into a syringe containing reagents. After some time, a clot is formed. Autologous thrombin can then be expressed from the syringe for clinical use.
Marrow aspirate concentrate for topical application or injection	Autologous marrow nucleated cells that have been aspirated from bone for the primary purpose of tissue regeneration	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.

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.

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

Adverse Event: A complication. Adverse events may occur in relation to organization-defined activities.

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

Agreement Review: Systematic activities carried out before finalizing the agreement 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. 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.

Backup: Digital data and/or physical storage containing copies of relevant data.

Calibrate: To set or align 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.

Change Control: A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.

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: An individual's demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities.

Competent Authority: The agency responsible under its national law for regulations applicable to the organization.

Completion of Processing: The time at which a processed component 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.)

Confidentiality: The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure.

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

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the quality of the organization's products or services.

Customer: The recipient of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

Data Integrity: The accuracy, completeness, and consistency of information.

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Disaster: An event (internal, local, or national) that can affect the safety and availability of the organization's products or the safety of individuals.

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.

Emergency Management: Strategies and specific activities designed to manage situations in which there is a significant disruption to organization operations or a significantly increased demand for the organization's products or services.

Environmental Monitoring: Policies, processes, and procedures used for monitoring any or all of the following: temperature, humidity, particulates, and microbial contamination in a specific area. Where appropriate, the program shall include sampling sites, frequency of sampling, and investigative and corrective actions that should be followed when specified limits are exceeded.

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

Establish: To perform all of the activities required to plan, validate, and implement a system or process.

Executive Management: The highest-level personnel within an organization, including employees,

clinical leaders, 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 product or service and compare results with specific requirements.

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and the manufacturer's recommendations in an environment suitable for its operation and use.

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.

Key Quality Functions: Essential job functions that affect the services provided by the organization.

Label: An inscription affixed or attached to a product for identification.

Labeling: Information that is required or selected to accompany the product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

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; to preserve or retain; to keep in a state of validity.

Master List of Documents: A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the Standards, including information for document control.

Material: A supply item used in a process or procedure.

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 Method(s): A change to an existing method that is considered standard practice in the perioperative setting. 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 organization.

Nonconformance: Failure to meet requirements.

Normothermic Machine Perfusion (NMP)/Normothermic Regional Perfusion (NRP): An adopted organ procurement and transport technique approved by the appropriate Competent Authority to maintain physiologic conditions that can enhance organ quality, enable extended transport times, and reduce postoperative complications.

Novel Perioperative Method(s): A procedure or technique that is not considered standard practice but has proven to be effective.

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Operational Systems: Processes, resources, and activities that work together to result in a product or service.

Organization: An institution, or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

Patient Blood Management (PBM): An evidence-based, patient-centered, systematic, multidisciplinary approach to caring for patients who might require a blood transfusion. PBM is meant to improve patient outcomes by preserving a patient's own blood through diagnosis and etiology specific treatment of anemia and bleeding.

PBM Program: A program within an organization that provides the services outlined in the current edition of AABB's *Standards for a Patient Blood Management Program*.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

Perioperative: The time frame 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 List of Components and Processing Methods before the Glossary.

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 set of basic principles or guidelines that direct or restrict the organization's plans, actions, and decisions.

Postoperative: The time frame following a surgical procedure.

Preoperative: The time frame preceding a surgical procedure.

Preventive Action: An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances, or other undesirable situations.

Procedure: A defined series of tasks and instructions that specify how an activity is to be performed.

Process: A set of related activities that transform inputs into outputs.

Process Control: Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.

Processing: As it relates to perioperative blood and blood components, the modification of collected blood for reinfusion, administration, or topical application.

Product: A tangible output from a process.

Qualification (individuals): The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.

Qualification (materials): For materials that come into contact with the product, verification that the materials are sterile, the appropriate grade and suitability for the intended use, and, whenever possible, approved for human use by the US Food and Drug Administration (FDA) or relevant Competent Authority.

Quality: Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.

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 Management 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 electronically generated media 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 eventual reinfusion of blood lost during and immediately after surgery. The use of recovered perioperative blood can reduce or eliminate the patient's need for allogeneic blood transfusion.

Reference Standard: Specified requirements defined by the AABB. Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.

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

Regulatory Enforcement Action: Measures taken by a Competent Authority that include but are not limited to progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues, deficiencies in risk management systems.)

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.)

Release: Removal of a product from quarantine or in-process status for the purpose of distribution.

Risk: The threat of quantifiable damage or any other negative occurrence that is caused by external or internal vulnerabilities and that may be avoided through preemptive action.

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

Root Cause(s): The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Separated: With respect to components, those that are removed from the patient; for example, taken out of the room, placed in a cooler in the operating room, etc.

Service (noun): An intangible output of a process.

Service (verb): An action that leads to the creation of a product or a result that can affect donors, patients, and/or recipients.

Shall: A term used to indicate a requirement.

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

Standard: A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.

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

Storage Container: A vessel (eg, a portable cooler) that has been validated to maintain a controlled temperature in which components are held temporarily 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 a material, product, or service.

Supplier Qualification: Evaluation of a potential supplier to assess its ability to consistently deliver products or services that 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: Non parenteral administration of a perioperative component to a surface (eg, skin, mucous membrane, operative site).

Traceability: The ability to follow the history of a product or service from source to final distribution or disposition using records.

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.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

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