Guidance for Standards for Perioperative Autologous Blood Collection and Administration

12th Edition

Effective Date January 1, 2027

Efforts are made to have publications of the AABB consistent in regard to acceptable practices. However, they may not be. As new developments in the field of standards occur, changes may be recommended to the AABB ***Perioperative Standards***. It is not possible, however, to revise each publication as soon as such a change may be made. Thus, it is essential that the most recent edition of the ***Perioperative Standards*** be consulted as a reference in regard to current acceptable practices.

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GENERAL POLICIES

The following guidance is intended to assist in the understanding and practical application of the 12th edition of *Standards for Perioperative Autologous Blood Collection and Administration (Perioperative Standards)*. The document contains guidance on both the quality concepts that provide the framework for the *Perioperative Standards* and many of the technical elements contained therein.

It is important to note that the standards in the *Perioperative Standards* contain the imperative "shall." The majority of the information in this document, on the other hand, is termed "guidance," which is intended to serve as helpful advice or to provide examples of how to implement a specific standard; guidance is often characterized by use of the word "should."

This document includes verbatim requirements from the *Perioperative Standards* interspersed with guidance. Language from the standards is presented; when there is appropriate guidance for that standard, the guidance language follows the standard with the heading "Guidance." This format allows the reader to see both the requirement and the associated guidance side by side. Due to the interrelated nature of this guidance document and the standards, readers are encouraged to become familiar with the *Perioperative Standards* and its format. The Introduction and Preface to the *Perioperative Standards* contain information that is applicable to this document as well.

Please note that there is no guidance for some standards. The Perioperative Standards Committee has chosen to focus this guidance document on those issues that may require additional context and/or examples to assist in attaining compliance with the *Perioperative Standards*.

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. Organization

1.0 Organization

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

G u i d a n c e

The primary purpose of this chapter is to ensure that an organization has statements of quality goals or objectives and that all parties (including contracted services) involved in activities that affect quality understand these goals and objectives of the organization and their responsibility in fulfilling them. Another purpose is to ensure that management at the highest level of the program is ultimately responsible and accountable for quality in the activities covered by the *Perioperative Standards*.

The organization's area of focus could include the following: intraoperative acute normovolemic hemodilution; collection, storage, and administration of autologous blood products and components obtained during intraoperative and postoperative autologous blood recovery; and perioperative autologous component production. Whole blood and perioperative autologous blood components covered under these activities include, but are not limited to, red cells, platelets, and plasma for reinfusion, injection, or topical application; thrombin for topical application; and marrow aspirate concentrate for topical application.

Standard 1.0 requires that there be a structure that clearly identifies the parties who are responsible for providing perioperative autologous components and services covered by the *Perioperative Standards*. It also requires that the relationship of individuals who are responsible for key quality functions be defined. Each program must evaluate and identify key quality functions within its own organization. An organizational chart would be one example of meeting this standard.

The purpose in limiting the requirement to parties responsible for providing perioperative components and services is to exclude personnel who serve in peripheral support functions within the program, such as accounting. As a general principle, the program should include within this requirement any person whose job affects the quality of perioperative components or services provided by the organization. The standard does not define which individuals are responsible for "key quality functions."

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 Perioperative 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.

G u i d a n c e

Standard 1.1 requires that the organization have a defined executive management. Executive management is further defined as the individual or individuals who have responsibility or authority for the organization's operations, the authority to make changes in the quality system, and the ultimate responsibility for compliance with *Perioperative Standards* and applicable regulations. Executive management is also required to participate in management review of the quality system. Executive management may be lim-

ited to the medical director. It may also include an executive team with representation from nursing, surgery, etc. Alternatively, the executive management structure may include input from these key groups through their representation on an advisory committee.

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.

Guidance

The medical director, or designee, is required to participate in the development of policies, processes, and procedures related to the organization. The responsibilities of the transfusion service and the perioperative service should be defined. The medical director should have direct responsibility for medically related issues, such as patient selection and rejection criteria, and monitoring of patients who undergo blood recovery and are at risk for complications, such as hemolysis or infection.

When perioperative procedures are outsourced, the hospital medical director is not likely to have much control over the policies, processes, and procedures for the employees of an outside organization. However, at a minimum, the medical director should have a copy of the outsourced perioperative service's policies, processes, and procedures, be aware of them, and be invited to provide input.

When a third party provides perioperative services, the medical director for the organization may be an employee of the facility or the third-party supplier. If the medical director is an employee of a third-party provider, he or she should be available to the contracting medical facility as needed. The contract between the facility and the third-party provider should define the role of the third party's medical director as it applies to that facility. If more than one medical director exists, the responsibilities of each medical director should be defined.

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.

Guidance

Standard 1.2 requires that each organization have a quality system. Implicit in this requirement are development, documentation, and ongoing maintenance of the quality system. The quality system must, at a minimum, address the elements identified in Chapters 1 through 10 of the *Perioperative Standards*. A quality system is composed of the policies, processes, and procedures that affect the quality of perioperative components or services, storage, or infusion/administration services. All requirements contained in the *Perioperative Standards* can be assumed to affect quality.

If the organization is a stand-alone program (ie, functions independently from a hospital), it would be expected to have its own quality system. If the organization is one of several operating departments or divisions in an AABB-accredited organization, such as a blood center, there is often a quality system that applies to all services, which would include the organization. Facilities currently implementing a quality system that satisfies AABB requirements can be assured that the requirements of this section are met.

1.2.1 Quality Representative

The quality system shall be under the supervision of a designated person who reports to executive management.

Guidance

Standard 1.2.1 requires that there be a designated individual within the organization who actively oversees the quality system and confirms that the program is in compliance with these *Perioperative Standards* and all applicable federal, state, and local regulations. The designated individual may have other responsibilities, and ideally they will not assess activities for which they are responsible. The individual designated to oversee the quality function must report to the medical director. The medical director can involve executive management as necessary; exercise oversight of all matters relating to compliance of the program with the written policies, processes, and procedures; and direct or recommend preventive/corrective action when it is appropriate.

1.2.2 Management Reviews

Management shall assess the effectiveness of the quality system at defined intervals.

Guidance

Standard 1.2.2 requires that management regularly review the organization's quality system to determine whether it is working as intended. For Standard 1.2.2, executive management is required to participate in the reviews (see Standard 1.1); however, this review should not be limited to that group. Other managers who may provide important input include nurses, department/program managers, quality assurance managers, and risk assessment managers.

Each program should determine how frequently management reviews will occur. For example, if a program has had a quality system in place for 10 years and it operates smoothly, an annual meeting may suffice. For a program with a new quality system, however, it is recommended that reviews take place three or four times a year. Once management is satisfied that the quality system is working as intended, fewer management review meetings can be scheduled.

Discussion of the status of the organization's quality system and implementation of each quality system essential should occur at the management reviews. In addition, particular attention should be focused on results of internal and external assessments and resulting follow-up action, as well as issues requiring corrective action and preventive action. This review also presents an opportunity to discuss the cost of implementing the quality system, marketing efforts to customers regarding the existence of the program's quality system, and customer response to the quality system.

Records of management reviews are required, as represented by the pen icon to the left of the standard. This requirement may be met through a form designed to track management meetings or a set of meeting minutes.

1.3 Policies, Processes, and Procedures

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

Guidance

Standard 1.3 requires that the organization develop and implement written quality and operational policies, processes, and procedures.

A **policy** is a documented general principle that guides present and future decisions. Policies are often generated as a result of standards, regulations, or a company's "rules." A mission statement is generally understood to be at the level of a policy. A policy might also be a generally articulated "rule," such as a no-smoking policy.

A **process** is a description of a specific work goal and defines what is done and who does it. Processes are larger and more complicated activities than procedures. Processes usually involve more than one person, and often more than one department or work area within a program. The responsibility of a particular person within a process may or may not involve performing a specific procedure. Intraoperative blood recovery is an example of a process. Within the process of intraoperative blood recovery, there are several procedures. For example, the procedures may include selection of patients for perioperative autologous blood recovery, ordering and consent for perioperative autologous blood components, collection and processing of intraoperative autologous blood, labeling of perioperative autologous blood components, reinfusion of recovered blood components, maintenance of equipment used in intraoperative blood recovery, and documentation and recordkeeping for perioperative autologous blood recovery. Although most facilities have documented their procedures, documentation of processes is less prevalent. A common way to describe a process in writing is by using a flow diagram with interconnected steps and branch points. Processes may also be described in tables or a narrative format. An example of a table format for outlining a process may include 1) what happens, 2) who is responsible, and 3) applicable documents (eg, titles of procedures and forms) for each major step or group of steps in the process. Documentation of all processes is required by Standard 1.3.

A **procedure** is a series of simple tasks that complete one piece of work. When written down, the procedure serves as a set of work instructions. Procedures are usually performed by one person, from beginning to end. Instructions for collection of blood for acute normovolemic hemodilution and storage of blood obtained by acute normovolemic hemodilution are examples of procedures. There may be policies that relate to some of the steps in a procedure (eg, "storage parameters and labeling policies").

A way to think about the distinctions among a policy, a process, and a procedure is that:

- Policies are **rules**.
- Processes are **what we do**.
- Procedures are **how we do things**.

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.

Guidance

The medical director has the authority to approve exceptions from existing policies, processes, and procedures, given the clinical situation of a specific patient. Recurring exceptions should be evaluated for incorporation into existing policies, processes, and procedures. The standard requires that the medical director's approval be obtained before the event's occurrence. The incident should be handled in conformance with Chapter 7, Deviations, Nonconformances, and Adverse Events.

In circumstances where a medical director is not available, the medical director designee does have the authority to approve exceptions from existing policies, processes, and procedures; however, the medical director will retain the responsibility for the actions taken by the medical director designee.

An example of when it may be appropriate to vary from the standard operating procedure (SOP) might be in the situation of a critically injured trauma patient with massive bleeding where time does not permit completion of washing of shed blood collected in the reservoir. A medical decision may be made to suspend washing and return the blood after centrifugation and microaggregate filtering. The decision to suspend washing should be documented. Another example might be to extend the expiration time on a perioperatively collected acute normovolemic hemodilution whole blood unit stored at room temperature to 8.5 hours to allow its administration when the surgical case has gone longer than expected.

1.4 Risk Assessment

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

Guidance

The purpose of this standard is to ensure that any new or changed policy, process, or procedure is evaluated prospectively for associated risks to the purity, potency, efficacy, or safety of the product. Risk assessment evaluates the probability of occurrence and the severity of impact. Identified risks with a higher probability of harm or unexpected outcome can be mitigated by the implementation of an administrative control (policy or procedure) or an engineering control (clean room or biological safety cabinet for open product manipulations).

Documentation of the risk assessment and mitigation strategies could be included in the validation program or a more formalized risk assessment tool. The outcome should be shared with executive management for acceptance. This standard is closely aligned with other standards designed to ensure that risk assessment and risk mitigation are integral elements of process or change control planning and that mitigation strategies are validated or verified for effectiveness before implementation.

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.

Guidance

"Operational continuity" refers to the means of ensuring critical functions continue in settings that may hamper the ability to carry out those functions. This element of review is a key aspect of resolution and planning for individual organizations. The situations that would be covered by each facility would be different based on size, location, and scope of work. It should be noted that operational continuity would occur not only in the setting of a "disaster." For example, if 1) a key employee left a facility without notice and there was no immediate backup to perform their functions, 2) a critical piece of equipment were to fail, or 3) a facility was sold to another entity, there should be policies, processes, and procedures in place to ensure critical operations are designed to function at a level needed to maintain key quality metrics. It is not expected that a facility can anticipate every possible risk; however, SOPs can be developed to address known common risks as well as procedures for unspecified, more unusual situations.

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.

Guidance

The organization should determine its plan for responding to disasters, both internal and external. Such a plan may be part of a larger institutional plan or be specifically for the organization. The following items should be addressed in terms of who does what and when: communication and notification procedures, assessment of service needs and capabilities, decision-making, and service expectations. Ideally, there is redundancy in the communication systems. Cell phones are an obvious good first choice, but in the time of disaster, cell towers are not always a reliable form of communication; therefore, secondary and tertiary systems such as UHF/VHF and HAM radios are important and valuable. Because these types of systems are not used daily, testing on a predetermined schedule becomes very important. There are other backup systems that could also be used. Paper communication systems should be periodically tested to ensure that all current forms are available and that instructions for completion and delivery of the forms are clear. Regardless of the system used, there should be scheduled testing. Records of testing of the emergency communications system should be available for review.

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.

Guidance

The facility shall develop a process whereby personnel can communicate their concerns directly or anonymously to the facility's executive management or the AABB. This process shall allow the employee to voice concerns without fear of reprisal. Corrective action plans shall be developed to address communicated problems. All communications to the AABB can be sent to the Accreditation Department at the AABB National Office by mail (4550 Montgomery Avenue, Suite 700, North Tower, Bethesda, MD, 20814), by fax (301-657-0957), or by email (accreditation@aabb.org) with attached files.

1.8 Customer Focus

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

Guidance

The facility should not only identify or know its customers, but more importantly assess their needs and expectations. Customers typically would be defined as the patients who receive perioperative services, but other customers also exist for the program. For example, doctors who order the services and/or receive the components produced, central supply employees who deliver supplies and materials for the program, or staff who schedule procedures that use perioperative services might all be considered customers. It is up to each program to define its customer base and be ready to respond to customer needs and expectations. This may be accomplished by a variety of methods (eg, customer focus groups, customer surveys, a complaint comment handling process, open customer phone lines, etc).

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, the organization shall notify AABB in electronic or written format within 7 days.

Guidance

Standard 1.9 was added to the edition to inform member facilities of AABB accreditation guidelines, which can be found on the AABB website under AABB Accredited Member Tools. AABB accreditation guidelines require member facilities who are AABB accredited to provide timely notification in writing of changes that may impact the facility's accreditation status:

1. Changes to AABB-accredited activities. Examples include adding or discontinuing acute normovolemic hemodilution.
2. Changes in premises, location, or contact information. Examples include facility official address or physical location changes, and changes in primary and alternate contacts with AABB.
3. Organizational structure and management changes, including mergers or consolidations with other facilities.
4. Changes in laboratory leadership (ie, medical director, director, or director designee). A current curriculum vitae (CV) and evidence of qualifications as defined in the current standards must be submitted to AABB. Standard 1.1.1 applies. The relevant accreditation committees will ensure the new directors meet the requirements for the position.
5. Change in the facility personnel designated as responsible for AABB accreditation activities.

In Standard 1.9.1, the notification time frame to AABB is within 7 days if the organization is the subject of regulatory enforcement action. For example, if the transfusion service is under investigation by the Department of Health, notification shall be provided to AABB. The transfusion service shall not wait for the outcome of the investigation to notify AABB. In maintaining a communication pathway with AABB, facilities have the opportunity to address any regulatory concerns with AABB.

Notification of facility status changes can be made in writing:

- Mail: AABB Accreditation Department at the AABB National Office, 4500 Montgomery Avenue, Suite 700, North Tower, Bethesda, MD, 20814
- Electronic: accreditation@aabb.org

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. Resources

2.0 Resources

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

G u i d a n c e

Standard 2.0 requires that the organization have adequate resources. In the setting of perioperative services, having adequate human resources can be challenging, especially in facilities that perform significant emergency surgeries such as trauma centers. The staffing plan should address how to ensure adequate personnel in emergency situations and at times of increased workload.

2.1 Human Resources

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

G u i d a n c e

This chapter requires that an appropriate number of qualified personnel be hired. Individuals may be qualified by education, experience, or both. When defining qualifications, one should consider technical knowledge, level of decision-making needed (technical vs medical), and amount of supervision required or available. This chapter also requires that these individuals be trained, initially and at defined intervals, and that the organization assess their competence before independent performance of assigned activities and at least annually thereafter. In addition, staff must have adequate time and training to perform their jobs.

The purpose of this standard is to ensure that only qualified individuals perform activities in the organization. Implicit in this standard is the requirement that the organization define qualifications for each job function, define and meet appropriate training needs, and assess staff competence. Records of qualification, training, and competence assessments must be maintained.

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 *Perioperative 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.

G u i d a n c e

The organization's personnel should have the qualification(s) required for the subject, by education, by training in/on the subject academically, theoretically, and/or practically by hands-on methods (techniques).

For qualifying staff/personnel, each facility needs to define:

1. Minimum qualifications required. For example, for personnel performing perioperative blood collection for intraoperative blood recovery, qualifications may include training or certificates in operating specified equipment (eg, in-service review by the manufacturer) and a review of any other critical materials.
2. Hours of training required. For example, to qualify the personnel for performing blood administration after intraoperative collection, 6 hours of training must have been documented.
3. Experience in years required. For example, to qualify personnel to train new staff, the facility might require 1 year of experience successfully completing independent processing of intraoperatively collected blood units.
4. Competency required for the task. For example, the staff may have been assessed for competency in processing of intraoperatively collected units and have been found competent and qualified to process units independently.

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.

G u i d a n c e

The intent of this standard is to ensure that if third-party providers are utilized for the collection and/or administration of perioperative blood components, there is an available record indicating that the personnel are also expected to be trained and capable in the same way that an organization's own personnel would be qualified, as described above.

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.

G u i d a n c e

Personnel performing critical tasks who fail a competency assessment for any or all of the tasks should be retrained and reevaluated for performance of those tasks before they are permitted to perform testing. If retraining fails, the person should be removed from the tasks and a performance improvement plan should be developed. If the person is unable to be retrained and cannot demonstrate competence, the person may be subject to reassignment of duties, or other action as deemed appropriate by the facility.

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.

Guidance

Training is only one aspect of competency and typically involves the teaching of a set of skills (eg, operation of a piece of equipment or performance of a specific work task) by a trainer to a trainee. The organization must identify the specific training needs for all staff who perform the various activities of the program. Qualification for those assigned as trainers needs to be defined and documented. Competency assesses the ability of a specific individual to independently perform a specific task according to procedures and effectively apply the knowledge and skills they have learned to different case scenarios. Competency assessment is completed before the individual performs the task independently and at least annually thereafter. When procedures or processes are revised, retraining and/or competency assessment may need to be conducted for the staff who will be performing the new/revised procedure. For those training needs identified by the program, completion of training and competency assessment must be documented on paper (eg, training checklist) or electronically in the institution's computer-based training applications software.

Competency assessment for any laboratory testing is dependent on the type of testing being performed (ie, waived, moderate complexity, or high complexity) as defined by the *Code of Federal Regulations*, 42 CFR 493 (493.5 and 493.17), and must be conducted in compliance with the CFR and the facility's accrediting agency. Accrediting agencies may include, but are not limited to, the AABB, the College of American Pathologists, the Centers for Medicare and Medicaid Services (re: CLIA), and the state. The websites for the various accrediting and regulatory agencies provide information regarding their requirements for competency assessment.

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 *Perioperative Standards* are met when applicable.

Guidance

Certain state licensure and national accreditation organizations have minimum continuing education requirements for personnel. The purpose of this standard is for the organization to define the minimum continuing education requirements and ensure that these requirements are being met by the staff performing perioperative activities. Although attendance at national conferences may be one means of acquiring continuing education, other means may include internal training sessions, presentations by staff, or competency training. The standard does not define continuing educational activities with which the program must comply; the program should evaluate its state requirements, facility accreditations, personnel credentialing needs, and operations and budget, and make an individualized determination.

2.1.7 Workload

Organization personnel shall have time to perform their duties.

Guidance

The intent of this standard is to ensure that personnel with multiple responsibilities have adequate time to perform/monitor their perioperative activities even in hectic clinical situations. Workload planning provides a process of forecasting, planning, distributing, scheduling, and monitoring staff workload on the projects they are required to perform and complete. This standard may help ensure adequate staffing of the organization's program.

2.1.7.1 At defined intervals, organizations shall evaluate the workload of the program against staffing levels to ensure quality patient care (eg, procedure volume, staff-to-case ratio, emergency coverage, or adverse event trends, quality assessment trends, etc).

Guidance

Staffing levels and duties should be assessed in an ongoing fashion to ensure that workload is evenly balanced, especially in times of short staffing coverage. If the workload is inappropriate for existing staff, additional positions or reorganization of duties may need to be considered to achieve a stable program.

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. Equipment

3.0 Equipment

The organization shall define and control critical equipment.

Guidance

This standard requires that the organization have a process for identification, calibration, maintenance, and monitoring of equipment that is critical to the perioperative setting.

3.1 Equipment Specifications

Equipment specifications shall be defined before purchase.

Guidance

Before the actual selection of equipment for use in the organization, criteria must be developed that reflect consideration of the types of procedures to be performed, the expected quality of the autologous components to be prepared, the intended instrument operators, the type of environment in which the equipment will be used, the expected production time, and other facility- or practice-specific needs. These criteria can then be used to assess the various equipment options and determine which best meet the program's needs (qualification).

When purchasing equipment, the facility should consider the following guidance:

- Identify suitable equipment and exclude devices that do not meet requirements.
- Approve the purchase agreement, as required in Chapter 4, Suppliers and Customers.
- Obtain the equipment.
- Inspect equipment upon arrival, give it a unique identification code, and install it in a suitable working environment.
- Qualify the equipment and maintain records of the qualification.
- Set the date for implementation after training has been conducted for all users.
- Use the equipment.
- Maintain the equipment.

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.

Guidance

The intent of Standard 3.2 is to provide assurance that a device and the associated processes that employ the device are operating as designed and as intended. An important element of qualification is to provide assurance not only that the manufacturer's specifications are met but also that the equipment will work in the user's environment. This includes the physical environment as well as variables such as procedures and staff. Multiple factors can influence how a piece of equipment performs. These include hardware, software, individual equipment components, device design, manufacturing process, shipping, installation,

etc. Robust installation, operational, and performance qualification (IQ, OQ, and PQ) processes will give the facility confidence that the equipment functions as designed and intended in the environment in which it is installed and using the facility-developed procedures and facility-trained operators.

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.

G u i d a n c e

After selection, the equipment should then be validated to ensure that it operates as expected and that an appropriate component can be made before putting it into use for patient care. For example, one may select a device to make platelet-rich plasma (PRP) for use as platelet gel. The performance qualification portion of the validation could consist of collecting blood from a volunteer, processing it to make PRP, and then measuring the volume and the increase in platelet concentration to determine if the manufacturer's specifications are met. The validation protocol and criteria for acceptability should be defined before the actual performance of the validation.

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.* Standards 4.1.4 and 4.2.4 apply.

G u i d a n c e

If one chooses to deviate from the manufacturer's written instructions, evaluation of the impact of that deviation should be part of the initial validation protocol and at defined intervals thereafter. Risk assessments may be useful to evaluate use outside of the manufacturer's written instructions.

3.4 Unique Identification of Equipment
Equipment shall have unique identification.

G u i d a n c e

This standard places an affirmative obligation on the facility to uniquely identify the pieces of critical equipment that can affect the quality of test results or products collected. The facility is required to assign a unique identification to each piece of critical equipment. To assist in calibration and maintenance, the facility should maintain a list of all critical equipment. A serial number can serve as the identification number.

*21 CFR 211.68.

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.
7) Ensure that all critical equipment is stored in accordance with the manufacturer's written instructions.

Guidance

When equipment or systems undergo preventive maintenance, calibration, or repairs, the facility should verify that the person performing the maintenance work is trained and qualified to perform the task. The facility should verify that there is a record or report about the type of work performed. The maintenance work performed should match the expectations of the facility, the agreement with the service provider, and the specifications and frequency described in the manufacturer's/operator's manual.

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.

Guidance

Appropriate calibration and maintenance include several concepts. All equipment must be properly installed and calibrated before use, with appropriate records maintained of any problems encountered and corrected. The organization must develop appropriate processes and schedules for ongoing calibration, preventive maintenance, and quality control. Such maintenance/quality control activities and schedules should follow the manufacturer's instructions. Records of calibration, preventive maintenance, and repairs must be maintained. Defective equipment must be identified, controlled, and managed to ensure that it is not used. If defective equipment is identified, it is important to assess whether the quality, potency, or purity of the components prepared was affected and whether there was any impact on patient safety. The assessment should determine if there has been any impact since the device/equipment was last known to be properly functioning (ie, per the manufacturer's instructions or as defined in the facility's SOPs). Examples may include assessing the equipment since the last successful preventive maintenance, calibration, or validation activity, as applicable. A system for reporting adverse events to the manufacturer must also be in place. After a defective piece of equipment is repaired, the steps needed to again allow its use, including calibration, maintenance, and/or validation, must also be documented.

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.

Guidance

If a nonconformance cannot be attributed or linked to a specific piece of equipment, SOPs should define how any piece of equipment potentially involved will be evaluated. The facility should evaluate and then determine if other pieces of similar equipment are potentially affected as well (eg, same make and model number as the device in question or devices using the same version of software). The facility SOPs should also define the criteria for evaluation and review of equipment malfunctions and for documenting the rationale for determining impact on other pieces of equipment, as this applies to how they may affect the quality, potency, or purity of the components prepared.

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.

G u i d a n c e

This section applies to the organization, if the program uses any computer system to document or manage the policies, processes, procedures, and/or records required by the standards. This might include recording and tracking any perioperative products prepared by the program. In Standard 1.4, the term "risk assessment" represents an introductory step where a comprehensive evaluation of the purchase or modification of computer software and its associated impact are considered. It is a method of analyzing loss potential. The fundamental questions in risk assessment are *What can go wrong?* and *If something does go wrong, what is the probability of it happening again, and what are the consequences?* For example, if software is purchased that will detect patient identification discrepancies, a risk analysis might evaluate what would happen if the patient identification discrepancies were not detected.

The purchase of computer software, hardware, or databases should involve adequate supplier qualifications. For example, if the laboratory/facility is purchasing computer software that will be used by the entire laboratory/facility, the organization should request an opportunity to provide input to ensure that it meets program needs. Similarly, if the organization places an order for software, hardware, or databases to be used in its department, it should identify necessary requirements and ensure that the software, hardware, or databases to be obtained or modified will be capable of meeting those requirements. It should ensure that the Information Systems department can provide adequate technical support.

Once the system is obtained, training of applicable staff must be provided, and the equipment and software must be validated to ensure that it does what it was intended to do. It must be tested in a "live" environment, and once it has been functioning for a few days or weeks, the organization should determine whether the system is operating as anticipated and generating expected results.

Whether software is developed in-house or is purchased and then modified, software that involves critical processes must go through the same rigorous stages of risk analysis, training, validation, implementation, and postimplementation evaluation of effectiveness.

Standard 3.6, #3 requires records of the fulfillment of life-cycle requirements for internally developed software. The term "fulfillment of life-cycle requirements" refers to the completion of the series of stages that computer software is required to go through from its time of inception to retirement. These stages are defined by the software developer and depend on the product and the organization.

The typical development phase for internally developed software, including purchased software that is subsequently modified, includes:

- Management of software.
- Identification of requirements.
- Design.
- Coding.
- Integration and testing.

Typical stages of software during and following implementation are:

- Installation.
- Acceptance testing.
- Operation and support.
- Maintenance.

For modifications that will be made during or after implementation, the development phase should be revisited.

Based on the system, the organization will incorporate the life-cycle requirements into its processes and procedures. Records are required to be maintained throughout the life cycle of the software.

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.

Guidance

The organization should consider the program's processes and procedures for instances when the computer system is down. In order to do so, the program may want to define "continuous operation" by identifying its critical activities. Programs are free to define the nature of their "continuous operation." Implicit in this concept is that the program should define whether it will continue to operate in the absence of the computer system.

If a program does not wish to cease operation when the computer system is unavailable, it must have an alternate system (eg, paper, backup computer) to ensure patient safety and compliance with these *Perioperative Standards*. An example of an alternate process in the event of a computer power outage is the following:

- When the computers are not operational, the employees write results on worksheets.
- When the computers are restored, the results are entered in the computer system.
- Second employees (different from those who initially entered the information in the computer) verify accurate transfer of the information. The paper records may then be destroyed because the computer results become the official records—in accordance with the program's processes and procedures.

The facility-defined alternate system for continuous operation must be periodically checked to ensure that all staff are competent in the process to be used and that the performance of activities maintains quality and safe perioperative components. The interval to test the alternate system is defined by the program, and these "checks" must be documented.

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.

G u i d a n c e

Information systems typically are maintained by designated employees other than those who provide direct patient services. Standard 3.6.2 states that those employees who maintain the information system for the organization need to take on the responsibility of ensuring the information system is in compliance with these *Perioperative Standards* as well as any applicable regulations. Recognizing that such maintenance takes time, Standard 3.6.3 requires that the program provide adequate support for such activities. Similar to requirements for other information systems used in the health-care environment, Standard 3.6.4 describes the need for security with regard to access to the information system.

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

G u i d a n c e

Organizations store a great deal of donor- and patient-specific confidential data. As for any organization in today's world, it is the facility's responsibility to protect the data from an internal or external breach. Policies and procedures aimed at this are often determined at the highest level of an organization.

For example:

- Information security policies are in place and being followed.
- Compliance is audited (eg, people change passwords frequently enough and keep them secure).
- Appropriate data are encrypted.
- All reports and other materials carrying sensitive/confidential information are controlled and disposed of securely.
- Data extraction is controlled (eg, prohibiting staff from running a query on the database and generating a spreadsheet kept on their laptops without proper security controls).
- All hardware to be disposed of has been appropriately cleansed of all data.
- Staff have been trained in the basics (eg, training documentation should show that they were instructed not to open a suspicious attachment in an email, click on links in emails from unknown senders, or navigate to websites that are questionable).
- Computer screens containing confidential information do not face areas where an unauthorized individual could view.

Management staff should have knowledge of and be able to explain, at least at a general level, how data are protected within the organization.

Levels of security must be instituted to ensure that only those with verified skills to enter results or edit data (corrected reports) will have access to these applications. Background programs are required that will identify users and access and will capture intrusion. Appropriate Information Systems support or trained supervisory staff will ensure that any intrusions are identified and reported for further investigation. Staff are trained to ensure that no password sharing occurs and terminals are logged off when not in use.

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.

Guidance

Multiple blood collection organizations and health-care facilities have been targets of significant operation-disrupting cyberattacks over the past several years against their critical technology and communication infrastructures. Therefore, it is not a matter of *if* but rather *when* an organization may be the target of such an attempt. AABB has added this standard to its existing standards covering "Risk Assessment" (Standard 1.4), "Operational Continuity" (Standard 1.5), and "Emergency Preparedness" (Standard 1.6) to emphasize the need to incorporate critical technology and communication infrastructures in the activities performed under Standards 1.4 to 1.6. The intention of this standard is to ensure the organization has processes in place to help safeguard the confidentiality, availability, and integrity of electronic data, including protected health information (PHI) of patients.

Critical technology infrastructures include, but are not limited to, interfaced perioperative blood collection equipment, interfaced billing and coding systems, and interfaced laboratory testing instrumentation. Critical communication infrastructures include organizational intranet, external Internet access, email, telephone, and fax (as applicable). Such programs are often executed at the institutional/enterprise level.

Examples of monitoring and testing activities within such ongoing programs include (but are not limited to):

- Employee education programs on cybersecurity best practices and testing of employee knowledge about and/or ability to identify potentially unsafe situations.
- Routine penetration testing to determine whether the software possesses any security gaps.
- Data backup and recovery process testing in regard to potential infrastructure outage.
- Cybersecurity incident response plans and testing of the activities for effectiveness and to identify vulnerabilities.

Testing frequencies for these critical infrastructures should be defined by the organization. A process for addressing any problems identified with such testing should also be defined and supporting documentation created to document its execution, results, and any corrective or preventive actions taken in response to those results.

Reference:

Health Insurance Portability and Accountability Act: Privacy Rule and Security Rule. Washington, DC: US Department of Health and Human Services Office for Civil Rights, 2025. [Available at https://www.hhs.gov/hipaa/index.html (accessed December 26, 2025).]

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 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.

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.

Guidance

In most circumstances, perioperative components will either be stored at room temperature for a limited time or be administered immediately. If the facility has a policy that allows for storage of perioperative components at refrigerator temperatures, these standards are applicable. If devices are used, procedures that define their appropriate use should be in place. Alternative procedures should also be available to provide instructions for what to do if the usual storage devices are not available.

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

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

Guidance

Before being put into use, storage devices (eg, monitored refrigerators or platelet environments) or storage containers (eg, coolers) must be qualified to ensure that they can maintain the required temperature range for the intended component and, if applicable, for a reasonable period (eg, for coolers, typically validated for 8 or 12 hours to maintain appropriate temperature range). This predefined time limit for

storage containers must be periodically requalified, either by the organization if containers are owned by the program, or another appropriate department (eg, transfusion service). The interval for requalification is defined by the program. An example of such interval is annually, but this may be dependent on the extent of use and/or handling of the container. Records of the periodic qualification for the containers used by the program must be maintained. Storage containers should not be in use for a period longer than that for which they are qualified. If the procedure extends beyond this time, the container must be either repacked or exchanged for a newly packed container so as to maintain the components at the required temperature range.

3.9 Warming Devices

Warming devices for components prepared for transfusion shall be cleared or approved by the Food and Drug Administration (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.

G u i d a n c e

The organization should have a process in place to define acceptable temperature limits for warming devices, including action to be taken when the device is not within acceptable temperature ranges. Facilities should have documented review of maintenance of blood warming devices.

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. Suppliers and Customers

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.

Guidance

A supplier is an individual or organization that provides critical materials or services to the perioperative program. A material is considered "critical" if it can affect the quality and/or safety of the product made or service rendered. Suppliers of critical materials and services must be qualified. Suppliers are qualified when it can be demonstrated that they can consistently meet the organization's requirements.

The program should determine the type and extent of control that it expects to exercise over the supplier and identify what criteria will be used for evaluating supplier acceptability.

The standard does not define which materials are critical; the program should evaluate its operations and make that determination.

Examples of supplier qualification factors include:

- Licensure, certification, or accreditation by a reputable organization.
- Product requirements.
- Review of a supplier's relevant quality documents.
- Review of the program's experience with the supplier.
- Cost of products or services.
- Delivery arrangements.
- Financial security, market position, and customer satisfaction.
- Postsales support.

4.1 Supplier Qualification

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

Guidance

Some organizations are part of a larger corporate entity in which a purchasing department makes purchasing decisions for the entire facility. In these situations, the program should educate the administration with contracting authority on the importance of qualifying suppliers. The program must participate in the evaluation and selection of suppliers.

Suppliers of critical materials and services are required to be qualified by the program. For example, the program should qualify a reagent supplier, but it would not need to be so careful with a supplier of office materials because these are not critical materials. The standard does not define which materials are critical; the program should evaluate its operations and make this determination. Suppliers are qualified when it is demonstrated that they can consistently meet the program's requirements.

The program should define appropriate criteria (characteristics or functional requirements) for all critical materials and services and maintain a list of suppliers capable of meeting those criteria. A copy of the

qualified suppliers should be provided to personnel who make purchasing requisitions. Further, the program should have a policy mandating the purchase of materials and services only from qualified providers. The program should determine the type and extent of control that it expects to exercise over the supplier and identify what criteria will be used for evaluating supplier acceptability.

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.

Guidance

Once a supplier has been qualified, there should be periodic evaluation of each supplier's performance or ability to provide products as well as a review of the agreement with the supplier (eg, once a year or every 3 years). The organization may also consider a separate quality record for each supplier.

It is important to track deviations, rejections, and complaints because all these factors reflect a supplier's performance. Quality problems should be recorded and brought to the attention of management with contracting authority and to the suppliers. It is required that corrective action plans be developed to address problems. In addition, deviations, rejections, and complaints should be brought to the attention of the supplier for its corrective action, and to management with contracting authority. It is important to remember that supplier qualification does not eliminate the need to validate a particular critical material or service for use in the program's processes and procedures.

In situations where the purchasing decisions for the entire organization are made at a higher level, it is recommended that individual departments educate the administration with contracting authority on the importance of qualifying suppliers. Reporting the failures of suppliers to meet requirements and recording these initiatives will provide evidence that the department is striving to meet this standard. During a management review of the quality system, these failures will be revealed and may give the department more leverage in the supplier selection/qualification process.

Purchasing documents should maintain information that clearly describes the material or service being purchased. The organization should establish effective working relationships and feedback systems with all suppliers. Often, the agreement or contract contains the conditions agreed to and serves as evidence that both parties agreed. If a supplier is unable to meet requirements or experiences a less-than-expected compliance rate, the program will report this to the vendor or contracting authority and request an action plan on how the trading partner/supplier will get back to a minimum compliance level.

After an extended period of unresolved compliance issues or after the transmission of documents that results in unreliable integration, the program may request a halt to all supplier transmissions until which time the issues are adequately addressed.

It is acceptable to "grandfather in" some current suppliers who are known to perform satisfactorily. However, the program should have a process in place that continues to evaluate the qualifications of the supplier.

Standard 4.1.3 applies to those tests that are sent to another accredited testing laboratory. Standard 4.1.3.2 was added to emphasize that testing at a facility outside of the United States must be conducted by a laboratory that undergoes some sort of external assessment to determine its competence to perform such testing.

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.

G u i d a n c e

Although the organization is not responsible for the hiring or training of third-party provider staff who provide services to it, it may (and should) define expectations for the appropriate level of performance for those staff members.

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.

G u i d a n c e

Agreements, in some form, between the perioperative service and the supplier of critical equipment or a critical material or service should exist. Agreements include written contracts, purchase orders, and oral commitments. The facility should determine which agreements should be in writing or in the form of a legal contract. Agreements to provide materials or services must be reviewed to ensure that each party's expectations are defined. Agreements can be between two separate organizations or individuals or between separate departments within a single organization. This standard does not require that all agreements be in writing. It does, however, require that there be a system in place to verify a customer's requirements.

4.2.2 Changes to agreements shall be communicated to affected parties.

4.2.3 The responsibilities for activities covered by these *Perioperative 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.

G u i d a n c e

In some cases, perioperative services within a hospital are performed by third-party providers (entities that contract with a hospital to provide on-site perioperative services). Under these circumstances, care should be taken to ensure that the responsibility for conformance to all standards is explicitly defined in agreements between the hospital and the third-party provider, paying particular attention to "hand-off" points between the third-party provider and hospital personnel. For example, a third-party provider may not have control over such activities as patient selection or component administration, but a definition of the responsible parties should be included in the agreement.

In the case of a third-party provider seeking accreditation, the third-party provider would be responsible for making sure all the requirements of the *Perioperative Standards* are defined in its agreement with the hospital(s). Even though the third-party provider may not be responsible for all activities of the program, that entity should still be introducing and discussing the requirements of the *Perioperative Standards* with the hospital customer(s) and establishing responsibility in order to ensure that the entirety of the *Perioperative Standards* is addressed.

From an accreditation standpoint, agreements and implementation of agreements fall under at least three categories when third-party providers are involved:

1. A hospital wishes to be accredited and contracts with a third-party provider for perioperative services. In this scenario, agreements should define the responsibilities of each party and should ensure that all areas of *Perioperative Standards* are addressed. The hospital (as the accredited entity) is held responsible to ensure that the contract is implemented as written.
2. A third-party provider wishes to be accredited as an independent entity. In this scenario, agreements should define the responsibilities of each party and should ensure that all areas of *Perioperative Standards* are addressed. The third-party provider is held responsible to ensure that all areas under its control conform to the *Perioperative Standards*, that the areas not under its control (eg, patient selection) are defined, and that there is evidence that the provider has given input, regarding standards not under the provider's control, to the hospital.
3. A third-party provider and hospital wish to be accredited jointly. In this scenario, as in the others, agreements should define the responsibilities of each party and should ensure that all areas of *Perioperative Standards* are addressed. Both the hospital and the third-party provider are held responsible to ensure that the contract is implemented as written and that there is conformance to all standards.

An example of how any of these goals could be accomplished would involve meeting with the parties involved in the program, drafting a table that lists the standards (number only) in one column, identifying which party is responsible for each standard in a second column, and adding a brief description of how that standard is met in a third column. The completed table would then be appended to the formal agreement.

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.

Guidance

The organization is required to ensure that critical materials acquired and incorporated into its perioperative components are acceptable. Acquired components include those that are purchased, donated, or otherwise acquired. They include, but are not limited to, instruments, disposables, and anticoagulant solutions. Examples of services include equipment calibration and preventive maintenance.

Another step in ensuring that intended materials meet the qualifications specified by the perioperative program's processes is to verify upon delivery that the expected products and services are received and acceptable. The inspection can take place when the products or services are delivered, or it may take place later but before use. Although inspection may occur outside of the control of the perioperative program, organization management should ensure that inspection is being performed properly.

There are many ways to perform an incoming inspection. Examples include visual inspection of packages and/or documentation from the supplier verifying that the product was conforming at critical points in the supplier's processes. An example of when the incoming receipt process can help prevent a product from becoming nonconforming is the situation where the usual red cell recovery 3-L saline wash solution approved for intravenous use is not available. The vendor or materials management department may have substituted a 3-L normal saline for irrigation that is not approved for intravenous use. It is ideal to recognize this before starting to wash recovered red cells in the operating room. The package insert contains this type of information. Review of the package insert should be part of the receipt process to make sure that there have not been changes in the product or the use of the product. This can be accomplished by documenting the package insert version and/or date and verifying with each shipment that it is the package insert currently on file.

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. Process Control

5.0 Process Control

The organization shall ensure the quality of products or services.

G u i d a n c e

"Process control" refers to the management of processes and procedures that affect the quality of products and services. Process control ensures that processes and procedures will be performed consistently and as they were intended to be performed. The program activities will include some or all of the following: collection, preparation, processing, storage, administration, or disposal. To manage these processes and procedures, the program will develop and document processes and procedures for those activities that directly affect the quality of perioperative components. In most programs, these processes and procedures will already exist, but they have to be identified and documented. When all processes and procedures conform to established requirements, their output should result in acceptable components and services.

Implicit in general process control are the following concepts:

Critical processes in the collection, storage, preparation, processing, or reinfusion of components should be validated (tested to ensure that the process consistently delivers perioperative components that meet previously defined requirements) before their initial use and after modification or change. There must be a defined mechanism to ensure that validation of new or changed processes occurs.

To implement process control, programs may consider the following guidelines:

1. Identify the processes and procedures that need to be followed to fulfill the requirements for perioperative components.
2. Capture all processes and procedures in writing, as required in Standard 1.3.
3. Before implementation, validate all new processes and procedures to ensure they function as designed and meet or exceed the outcome(s) intended. An example of a validation method would be running saline through a blood recovery device to validate new computer program driver controls, ensuring that all the pumps and valves work as expected before using outdated blood components to validate that the new program produces components acceptable to the manufacturer's specifications and performs according to the facility's acceptance criteria.
4. Review and approve processes and procedures, as required in Chapter 6, Documents and Records.
5. Train staff to comply with processes and procedures, as required in Chapter 2, Resources.
6. Use validation requirements that are specific for equipment, as outlined in Chapter 3, Equipment.

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.

Guidance

Standard 5.1.1.1 requires change control documentation and validation of new or changed processes and procedures before implementation. When developing a new process, participation by representatives from all of the involved departments and work areas ensures that the planned activities fit and work within each environment. The same departments and work areas should participate in the validation. A validation plan should include documentation of the following:

- Installation qualification (IQ)/initial design verification.
- Operational qualification (OQ)/initial design validation.
- Performance qualification (PQ)/design validation.
- Implementation plan.

After implementation, a postimplementation assessment should be documented with process improvements and/or process control/quality control monitoring parameters, if appropriate. Validation confirms both of the following:

- The design allows the work to be performed consistently to achieve the intended results.
- The work instructions are clear, complete, and easy to use.

Even when validation has been performed carefully, it is still possible to find errors and omissions after implementation. If errors occur, authorized and controlled changes to the way work is performed and to the corresponding processes and procedures need to be made without delay and monitored for effective process control.

The intent of Standard 5.1.1 is not for programs to perform validation on processes and procedures that have been in place for years. For these processes and procedures, retrospective validation is acceptable, which could include a review of historical records that serve as the documented evidence of a controlled process or procedure. For example, if a program has been performing blood recovery for many years, the program's procedure and quality control records can provide evidence that the expected results are consistently achieved. It is recommended that the program have a statement on file to this effect to serve as the record of validation. It should be noted, however, that if problems in current processes and procedures have been identified, or if there is no active mechanism to identify problems, validation of all processes and procedures in Chapter 5 is recommended.

Processes and procedures are required to be controlled because they relate most directly to the quality of the perioperative components. When processes and procedures are validated, and competent trained staff perform them the same way each time, the program can be confident that the controlled conditions will consistently result in the intended perioperative component.

Because the *Perioperative Standards* represents minimum requirements, programs are encouraged to implement additional measures that are appropriate for their program. For example, programs should consider validating safety processes, documenting control processes, and ensuring that the event reporting process works, or that the competency assessment, internal audit tool, or any written procedure can be understood and executed.

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.

G u i d a n c e

The organization must have in place a program of quality control to ensure that reagents, personnel, equipment, and processes function as expected. The scope of the program can vary based on the medical device and the manufacturer's recommendations; however, it must be defined by each organization. At a minimum, the organization should monitor the effectiveness of the operator and device and the quality of materials used and produced. Quality control could include correlation with the patient's condition regarding appropriate use of components and/or chart review of documentation requirements. Records of these reviews must be maintained.

The purpose of a quality control program for perioperative collection activities is to ensure that a perioperative component of consistent quality is made. In general, perioperative activities that simply collect and reinfuse whole blood or recovered blood without modification (other than simple filtration) are difficult to assess by testing because patient characteristics determine the nature of the end product; appropriate patient selection and adherence to procedural techniques/controls are critical in ensuring a quality perioperative component. If the collected material is altered by some procedure, then periodic measurements of a component's quality are useful to monitor ongoing processes. All perioperative components should be measured for volume and appropriately labeled. The final quality assessment should include visual inspection at the end of processing and before administration.

The quality control program should specify the type and frequency of testing, and the tolerance limits for each assay or test performed. For example, an organization that performs only red cell recovery may elect to test one red cell component collected on each device in use once per month. Hematocrit may be the defined measure for routine testing, with an established acceptance range of 40% to 60%. (The acceptance range, though, should be determined by the institution or based on the manufacturer's specifications because it can vary with the type of instrument used, the analyzer or method used to measure the hematocrit, and other variables.) The hematocrit results should be reviewed and assessed by the acceptance criteria defined. For example, the hematocrit values can be charted per device over time to demonstrate continuous process control to investigate trends and failures. Any failures should have a documented investigation as well as chart review of the recipient's chart for possible adverse events. A root cause analysis may reveal the cause to be a partially filled bowl, inadequate pump speeds, dirty optics, excessive hemolysis or premature wash cycle, unexpected events during the surgical case, operator error, or the need for recalibration and revalidation of the device before use for a patient. Depending on the cause of the outlier, the corrective action may be to perform more frequent quality control testing

or possibly additional testing of components made from that particular device to ensure the consistency of the components produced. Effective quality monitoring should identify problems early to prevent possible harm to the patient.

Acute Normovolemic Hemodilution

This technique is used to collect autologous whole blood unit(s) in the operating room immediately preceding anesthesia induction or during the early stages of the proposed surgical procedure, where significant blood loss (20%-50% of patient's blood volume) is expected, while maintaining the patient's normal circulating blood volume and oxygen delivery as a blood management strategy.

This technique reduces the red cell mass by removing whole blood so that blood shed during surgery has a lower concentration of red cells, followed by infusion of colloid or crystalloid to maintain blood volume and oxygen delivery through increases in tissue extraction, increases in cardiac output, and decreased blood viscosity. The whole blood is collected with either heparin or a citrate-based anticoagulant solution. The volume should be measured for each unit to ensure a proper ratio of anticoagulant to whole blood. Volume can be calculated from the weight using the specific gravity of whole blood as 1.05 g/mL. The whole blood removed is labeled sequentially with the collection time to identify and trace individual units collected. The whole blood should remain at room temperature to preserve platelet function for 8 hours. The unit(s) can be readministered during or at the end the surgical procedure, transfusing them in the reverse order of collection to allow the freshest unit to be transfused last, to ensure that clotting factors and platelets are restored when most needed. Any units not transfused during the procedure can be placed into refrigerated storage within 8 hours from the start of collection until 24 hours after the start of collection if the container label fulfills the requirements for distribution.*

Perioperative Blood Recovery Using a Cell Washer

In this procedure, shed blood from the surgical wound is collected and then processed before reinfusion. The component is typically red cells suspended in 0.9% NaCl. Most of these instruments have two mechanisms of operation: concentration and washing. Supernatant removal is achieved through both mechanisms. Periodic quality control must be performed to assess instrument function and operator competency.

Concentration of the red cells can be checked by measuring the hematocrit of the component. A range of acceptable results should be established for each type of instrument, either as a result of testing or based on the manufacturer's specifications.

The ability of the device to remove supernatant materials may be assessed in the following ways:

1. Color of the waste line: A clear color in the waste line suggests that little free hemoglobin is still being removed during the saline wash. However, this qualitative assessment does not reflect the actual amounts of residual free hemoglobin or heparin in the final blood component or the overall efficiency of supernatant removal.
2. Heparin concentration: If heparin is used as the anticoagulant in the collection reservoir, heparin levels in the final unit of blood component may be measured and should be very low or undetectable. The choice of a heparin assay is critical—only those test systems that do not rely on the presence of normal plasma in the sample are acceptable for use.
3. Albumin removal: The extent of removal of supernatant albumin is another way of evaluating instrument function. In this circumstance, samples need to be taken from both the collection reservoir (before processing) and the final blood component. The concentration of albumin in the final blood component depends on the initial concentration in the recovered blood; therefore, percent removal should be calculated (typically, it is greater than 95%). A sensitive albumin (microalbumin)

*21 CFR 610 applies.

assay may be necessary to get accurate results.

4. Free hemoglobin removal: The recommended indicator for this parameter is also percent removal (see above discussion on albumin). Residual free hemoglobin concentrations may be quite high (500-1000 mg/dL) despite greater than 90% removal, particularly in orthopedic surgery cases. The removal of free hemoglobin is typically lower than removal of albumin; the reasons for this difference are unclear. The facility may also want to define a maximum allowable plasma free hemoglobin level in the final component.
5. Potassium removal: The recommended indicator for this parameter is also percent removal (see above discussion on albumin).

Quality control could include correlation with the patient's condition regarding appropriate use of components and/or chart review of documentation requirements.

Perioperative Blood Recovery with Processing (Hemoconcentration by Ultrafiltration)

In this procedure, remaining heparinized whole blood from extracorporeal circuits or blood collected in reservoirs is circulated by a pump through a hemoconcentrator (a semipermeable microporous membrane filter; also known as ultrafiltration) in a closed loop to remove noncellular plasma, water, and solutes of 55 kD or less, producing a concentrated whole blood for reinfusion. The starting volume and the final amount reinfused should be recorded. Periodic quality control, such as hematocrit and coagulation testing (eg, thromboelastography) should be monitored to ensure consistency of components produced. Visual inspection for air/clot/debris is important.

Perioperative Blood Recovery without Processing

In this approach, shed blood is collected and then reinfused to the patient without hemoconcentration or washing. These devices should ensure the blood is filtered to remove clots and tissue debris. Anticoagulant may be used as ordered by the physician. The ratio of anticoagulant to whole blood depends on the amount collected. The amount collected and volume reinfused should be measured and documented. Periodic hematocrit determinations on the final component for reinfusion may be useful for ongoing assessment of clinical utility. Visual inspection for clot/debris is important. As with any other form of transfusion, this blood should be infused through a standard 40-micron filter.

Perioperative Component Preparation

Components containing platelets, plasma, cryoprecipitate, and/or red cells may be prepared by apheresis during the perioperative period. Autologous PRP is typically prepared from fresh whole blood using differential centrifugation techniques. PRP may be further separated by additional centrifugation into platelet concentrate and platelet-poor plasma (PPP). PRP may also be highly concentrated using hemofiltration procedures. Autologous conditioned plasma (ACP) is typically prepared from fresh whole blood using differential centrifugation techniques at lower rpm levels and for shorter periods. ACP has lower levels of white and red cells than PRP.

Marrow aspirate concentrate is typically prepared from fresh marrow aspirate using differential centrifugation techniques. The concentrated aspirate may be combined with autologous, allogeneic, or synthetic materials for topical application. The addition of thrombin to PRP, ACP, or marrow aspirate concentrate or platelet concentrate results in a gelled component, such as platelet gel, that is administered topically. PRP (without added thrombin) may be given intravenously, topically, or via injection into soft tissue or joints. When thrombin is added to PPP, topical fibrin sealant is produced.

Because whole blood is being manipulated to make a therapeutic component with specific characteristics, periodic quality control to ensure consistency is reasonable. The quality control indicators should be

selected based on the type of component being made and the manufacturer's specifications. Examples of indicators that might be used are shown in the table below.

Component	Example of Indicator(s)
Platelet-rich plasma/platelet gel	Platelet count Fibrinogen
Platelet-poor plasma/fibrin sealant	Fibrinogen
Autologous conditioned plasma	Platelet count White cell count
Marrow aspirate concentrate	White cell and differential count to determine mononuclear cell count
Apheresis Red Blood Cells	Hemoglobin or hematocrit

Note: Organizations should perform their own study of average or "acceptable" platelet or fibrinogen concentrations in the plasma components prepared. In this event, the program should maintain records and data. The acceptable criteria for these indicators should be determined by the program.

One example of a quality indicator for PRP could be the percent recovery of platelets or efficiency of the platelet concentration (ie, platelet count of PRP patient's baseline platelet count), a value that would be monitored against the manufacturer's stated claim or one's own established "acceptable" range.

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.

Guidance

Validation should be performed in-house. For example, an affiliated department within a facility could validate an autologous blood recovery/salvage system so long as validation activities are designed to ensure that the equipment operates as intended in the environment in which it will be used by the relevant staff. However, a validation of the autologous blood recovery/salvage system performed off-site by a vendor would not meet this standard.

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.

Guidance

Before performing the validation, there should a written validation plan that includes objectives, persons responsible for performing the validation, criteria, and expected outcomes and/or performance. The plan should be reviewed and approved by the medical director before performance of validation. The actual results of the validation should be reviewed and approved by the medical director before implementation. If the validation objectives are not met, there should be a documented action plan.

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.

Guidance

There should be a change control process for the implementation of new or changed processes or procedures, including approval of procedures or policies; staff training and competency, if applicable; and communication to all affected parties. Any new or changed processes and procedures must be evaluated for effectiveness. Methods to perform effectiveness evaluation could include observations or audits with established thresholds or criteria for acceptability; review of records; review of customer comments; or stakeholder interviews.

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.

Guidance

The manufacturer's written instructions are also known as Information for Use (IFU). Program leaders should carefully examine the documents and verify that the instructions have not changed. Many manufacturers are using document control; therefore, a traceable number (ie, tracking number for a piece of equipment) may appear on the IFU document. If IFU is not included with the materials on receipt, the manufacturer should be consulted for instructions. These are often on the manufacturer's website or available through a company representative. Use of materials not according to IFU may be considered "off-label use."

5.1.7 Inspection

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

Guidance

This standard is intended to ensure that facilities define how often and what to inspect as products move through the system. For example, the "organization-defined stages" could include the following: after collection from the patient (shed blood suctioned from the surgical field), after centrifugation and washing, and before reinfusion. The "specified requirements" for inspection could include an examination to verify that the product is visually acceptable (eg, no container damage, hemolysis, discoloration, lipemia, clots, cloudiness, etc), that the label is accurate and legible (eg, no smearing, no print off the label), that the label adheres completely to the bag, and that the container is intact (eg, no leakage, etc). The inspections should be defined procedurally, including any requirements for documentation.

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.

Guidance

Inspection and testing ensure that only those perioperative components that meet defined criteria are transferred to the next stage. Implicit in inspection and testing is that the organization defines appropriate inspection and testing requirements. Inspection and testing can include visual inspection, review of labeling or records of performance, or individual or periodic testing of perioperative components. Perioperative components provided by the organization must be controlled to ensure that those components that do not meet requirements are not inadvertently given back to the patient.

Inspection/testing at facility-defined stages might be applicable in the production of autologous PRP for use as platelet gel. It may be important to determine the patient's preprocedure platelet count in order to calculate how much whole blood should be processed to make the PRP. Once the PRP is obtained, a platelet count on the product may be useful to determine its adequacy for clinical use.

If the inspection/testing does not meet the predetermined requirements at any stage, policies regarding component use/disposition should exist and be followed.

5.1.8 Identification and Traceability

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

Guidance

This section requires that there be a method to ensure the traceability of critical materials and perioperative components throughout the process. Traceability does not require that all relevant information about blood or a component be located on the label of the blood or product itself. Traceability requires that there be a system in place to identify the source, location, and disposition of perioperative components and critical materials. Accordingly, the organization must have in place a process to ensure that all perioperative products, and critical materials used in the blood or components, are both identified and traceable to final disposition.

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.

Guidance

The intent of Standard 5.1.8.1 is that there be a mechanism to allow one to trace the identity of the individuals who perform critical steps so that errors or discrepancies may be investigated if they occur. This standard does not mandate maintenance of a signature file. There are several mechanisms that can be used to identify the person who performs the perioperative service. In some programs, each employee has an identification number that is written on the procedure record, and that number serves as the defining identifier of the person who performed the procedure or specific step in the procedure. In other programs, the information is recorded electronically. These practices also meet the intent of the standard.

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.

Guidance

Patient identification information on the label is particularly important when there is the possibility that the patient and perioperative component(s) will be separated. The final component for those perioperative components intended for infusion (eg, whole blood or washed recovered blood) must be labeled with two patient identifiers (ie, patient name and hospital identification number), date and time of initiation of collection, date and time of expiration, and "For Autologous Use Only," as well as "Donor Untested" and "Biohazard" if the infectious disease status of the patient is unknown. If infectious disease testing has been performed in conformance with the FDA regulations and the patient is found to be nonreactive, labeling of the product "Donor Untested" and "Biohazard" is not necessary. Because infectious disease status is often unknown in most, if not all, patients who have perioperative autologous components processed/prepared, the organization should consider routine inclusion of highly visible "Donor

Untested" and "Biohazard" indications on its labels. The organization should have policies in the event that the infectious disease status of the patient is known.

The following comes from the FDA's "Guidance for Industry: Bar Code Label Requirements Questions and Answers" (dated August 2011, at https://www.fda.gov/media/81277/download):

Q23: Do the bar code regulations apply to routine intraoperative or postoperative blood collection from surgical drains ("salvaged blood") followed by reinfusion on the nursing unit or other location within the hospital?

A23: No. In a 1989 memorandum to all registered blood establishments, CBER delineated its policies on autologous blood. That memorandum stated that the quarantine, storage, recordkeeping, and labeling requirements of 21 CFR part 606 are generally not applicable to salvaged blood collected for proximate transfusion to the patient as part of the patient's treatment. Because bar code requirements fall under the category of label requirements contained in 21 CFR part 606, the requirements would not be applicable to salvaged blood. However, the intent of FDA's bar code rule is to reduce medication errors, including transfusion errors. To help reduce transfusion errors for salvaged blood, some hospitals may voluntarily implement the use of machine-readable information, including bar codes, blood bank computer systems, and bedside readers.

If recovered blood is stored in the hospital blood bank, the requirements under 21 CFR 606.121(c)(13) apply.

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.

Guidance

Handwritten labels can be used to meet this standard, provided that they contain the information as required. Any changes made to a label after it is applied to the container should follow good manufacturing practice regulations. The information should be clear and legible. The recording of the changes and identification of the individual adding the information should follow Standard 6.2.6. The term "intermediate component" refers to a blood component at a step in the process for creating a final component for reinfusion or application. An example of an intermediate component might be a container or syringe that will undergo a second centrifugation step to concentrate the autologous platelets into a small amount of plasma for the final PRP component. There are circumstances where components may be separated from the patient, and in those cases, the container or syringe must be labeled with, at a minimum, two patient identifiers.

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

1) Patient's first and last name.
2) Patient identification number.
3) Component name.
4) Date and time of expiration.
5) The identification of the individual collecting the component.

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.

Guidance

For components that do not have a defined expiration time, the labeling should clearly indicate that the component is to be considered expired upon removal from the clinical procedure area. If any portion of the component is not used, it should be properly discarded in the clinical procedure area, such as the operating room. Records of discard should be retained. The clinical procedure area includes the area in which intermediate components are altered. For example, if the centrifuge for producing PRP is located within the substerile area adjacent to the operating room, transfer of intermediate and final components between this location and the operating room does not constitute removal from the clinical procedure area. Standard 5.1.8.2.1 applies.

For components intended for topical application, labeling requirements for the final component (typically before handoff to the sterile field) need to include, at a minimum, patient name and hospital identification number; date and time of collection; and time of, or condition for, expiration. For topical components prepared in a surgical suite or sterile procedure area, patient identification should be verified by two staff members participating in the care of the patient, before transfer of the component to the sterile operating field.

When a final perioperative component will need to enter the sterile field for application, such as when applying PRP to exposed tissue or bone, the organization must define the required elements for labeling. Standard surgical practice regarding the labeling of sterile containers for their contents should be followed.

Identification of the correct product for the correct recipient is essential. The components created perioperatively are usually not tested for infectious agents. Therefore, it is critical to label all components to maintain traceability from patient through processing to administration. This may be accomplished by a tie tag or sticker attached to the end of a syringe or a neon-green autologous blood label for a container. Verification of the product with the recipient must be completed before administration according to the same process used for blood administration with two-person verification of patient and autologous component.

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 barcode labeling, as applicable. Each unit shall be labeled "For Autologous Use Only," "Donor Untested," and "Biohazard." Standard 5.1.9.1 applies.*

5.1.8.2.4 Blood products 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.

*21 CFR 606.121 and 21 CFR 610.40.

Guidance

Blood products and blood components collected within the perioperative setting should be labeled to clearly distinguish them from allogeneic blood components and identify them as intended only for perioperative administration or reinfusion to the intended patient. The label should include clear designation: for example, "For Perioperative Reinfusion Only," "Autologous Blood," or equivalent wording.

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.

Guidance

The purpose of this requirement is to ensure that there exists a process to minimize the possibility of damage and/or deterioration of blood and component(s) during processing, storage, distribution, and transport. It requires that the organization specify any storage requirements for blood or components. Specific requirements for storage and expiration are included in charts at the end of the chapter.

It may be noted that storage temperatures for components, such as platelet-rich plasma, are listed as room temperature, which aligns with the practice of whole blood collection cooling to room temperature before platelet products are created. Platelet components have historically been stored at 20 to 24 C with continuous agitation; however, cold-stored platelet products with approved additive solution can be stored at 1 to 6 C. The cold-stored platelet products should be used to treat actively bleeding patients.

Refer to the FDA document "Exceptions and Alternative Procedures Approved Under 21 CFR 640.120(a)" (dated February 14, 2023), which states, regarding 21 CFR 606.65(e) and 21 CFR 610.53(c):

a. To store apheresis platelets at refrigerator temperature (1-6 C) without agitation for up to 3 days. The cold stored platelets will only be used in the resuscitation of actively bleeding patients. The new storage conditions will be reflected in Circular of Information.
b. To store apheresis platelet products at 1-6 C for up to 14 days without agitation. The cold stored platelet products will be used to treat actively bleeding patients when conventional platelet products are not available, or their use is not practical.

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.

Guidance

To meet the intent of this standard, the organization should define policies and processes regarding the performance of perioperative procedures for patients who are known to have viral, bacterial, or parasitic infections. For example, a program may set a policy that blood recovery will be performed for patients with a known infectious agent. All products must be labeled as "Biohazard" and the infectious agent identified on the product and to all staff in perioperative services. Storage of components containing infectious agents must be segregated from all other components and labeled per 21 CFR 606.121.

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.*

Guidance

Perioperative blood and blood components identified as containing, or suspected of containing, infectious agents should be stored separately from all other blood and blood components to prevent them being inadvertently taken back to the blood bank for administration. The unit(s) should stay with the patient in the perioperative setting, clearly designated and conspicuously labeled to indicate their infectious status.

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.

Guidance

Pharmaceuticals such as topical hemostatic agents, and solutions such as anticoagulant and washing solutions should be prepared in accordance with facility-defined policies and pharmacy practice guidelines. These pharmaceuticals, solutions, and reagents should be properly labeled to include preparation and expiration. Testing reagents such as those used for component quality control should be prepared in accordance with facility-defined laboratory procedures. Sterile saline for infusion is the accepted wash solution, unless otherwise stated by the pharmacy practice guidelines. Sterile saline for irrigation is not FDA approved for intravenous infusion.

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.

*21 CFR 606.40.

Guidance

Throughout the process, from beginning to end, the organization must ensure that aseptic methods are used. See "Guidelines for the Prevention of Intravascular Catheter-Related Infections" (CDC, 2002; http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm).

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.

Guidance

In order to have an autotransfusion device readily available for emergent cases and/or unexpected massive bleeding, the disposables may be installed (partially or completely) on the device ahead of time. The intent of this standard is for the program to define the allowable time for open disposables to be installed on the device. The policy and processes related to this standard should ensure that any component subsequently processed with such a device with open disposables still conforms to the program's specifications and does not result in an increased risk of contamination in the component or possible harm to the patient. The program should follow any manufacturer's instructions regarding open disposables. This does not include the connection of solutions to the disposables.

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.

Guidance

The issue of informed consent for patients should be considered, and decisions regarding specific need for consent should be reflected in the organization's policies. The consent for perioperative components need not be a separate consent but can be incorporated into the institution's consent for transfusion of blood components or surgical consent. Ideally, the consent for collection and reinfusion of autologous perioperative components could be part of the total consent process for treatment and services offered in a patient blood management program.

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 perioperative blood or a perioperative blood component.

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

Guidance

Best practice dictates that there be a process for documentation of each order in the patient's medical record. Standing orders based on certain procedures, verbal orders if documented and signed later, surgical listings/schedules, procedure records, and/or documentation on the anesthesia record are examples of acceptable documentation.

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 to ensure the safety and quality of the collected perioperative product. Standard 5.1.2 applies.

Guidance

The organization should establish criteria for patient selection, taking into account the medical procedure to be performed and the potentially applicable perioperative techniques. Collection parameters need to be established for each collection method and should be based on the manufacturer's specifications, where appropriate. The organization should also define handling of partially filled bowls in a blood recovery device, which should include the minimum volume to be collected to allow processing, because this can lead to inadequately washed components. If ultrafiltration is used, flow rates (ie, speed of the roller pump in mL/minute) and system pressure [ie, pressure in the circuit that is generated by the flow rate and resistance to the blood viscosity (hematocrit) flowing through an ultrafilter] should be defined to provide consistent, reproducible components.

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.

Guidance

For organizations that perform intraoperative blood recovery, the list included in Standard 5.4.1 is comprehensive and required to be followed; however, additionally defined criteria determined by the organization can be added.

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.

Guidance

For organizations that perform acute normovolemic hemodilution, the list included in Standard 5.4.2 is comprehensive and required to be followed; however, additionally defined criteria determined by the organization can be added. When developing these criteria, organizations should consider factors that support the effectiveness of ANH, including the collection and reinfusion of a clinically meaningful blood volume sufficient to achieve the intended therapeutic benefit. These criteria should be supported by current evidence-based medicine [for example, see: Acute normovolemic hemodilution in cardiac surgery. N Engl J Med 2025;393(19):1963-4. https://doi.org/10.1056/NEJMc2513087].

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.

Guidance

The intent of Standards 5.4.2.1 and 5.4.2.2 is to minimize the risk of bacterial contamination of the collected blood. Materials used for site preparation must follow the manufacturer's instructions for veni-

puncture site preparation. Site preparation for placement of a central or peripheral line should minimize the risk of bacterial contamination. Processes such as "scrub the hub" should be used to access the port of such venous access. The likelihood of risk of bacterial contamination increases with the duration of the catheter placement and the repeated use of access ports.

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 a 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.

G u i d a n c e

The intent of Standard 5.4.3 is to ensure that collected blood is adequately anticoagulated to prevent formation of clots and an inferior component. The ratio of anticoagulant to blood should be regulated based on the volume of blood collected, whether by intraoperative blood recovery (wound suction) or acute normovolemic hemodilution (ANH). Anticoagulants approved for whole blood collection and storage are typically supplied in fixed amounts of CPD and CPDA-1 in blood collection bags for use in ANH. Although other anticoagulants may be used for ANH, platelet-rich plasma, or marrow aspirate concentrate, the organization should ensure the appropriate ratio of anticoagulant to blood for collection and ensure that storage in these anticoagulants for an extended period does not adversely affect the viability or function of the desired blood components intended for reinfusion/application. Some bag manufacturers supply smaller collection bags (ie, 250 mL) for whole blood collection in pediatric patients. It is also important to ensure adequate mixing while collecting blood into anticoagulant to prevent clotting.

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 the following:

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.

Guidance

For organizations that collect or administer platelet-rich plasma, the list included in Standard 5.4.4 is comprehensive and required to be followed; however, additionally defined criteria determined by the organization can be added.

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.

Guidance

Best practice dictates that before any component administration, the recipient must be conclusively identified by either two appropriate staff members or an electronic patient identification device that may substitute for the second person. Per The Joint Commission, the transfusionist should be one of the individuals performing the patient identification process, and the other must be a qualified person involved with the patient's care at the time of patient identification/verification with the blood component transfusion tag verification. In addition, two patient identifiers (eg, patient name and medical record number or birth date) must be used in the patient verification process, and this information is matched to the component. For topical components, patient identification should be verified by two staff members before transfer of the component to the sterile operating field.

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.

Guidance

For red cell components, abnormal appearance can include clots, discoloration, a high fat content, particulate matter, hemolysis, or any fluid interface irregularity. For hemoconcentrated whole blood, abnormal appearance can include discoloration, presence of air bubbles, high fat content, or clots. For plasma or platelet components, abnormal appearance can include discoloration, evidence of fat, or particulate matter.

The labeling of the component should be verified against the patient identifier(s), as well as reviewed for expiration date and time to ensure component viability and safety. If the facility uses colored labels (eg, green labels to designate an autologous component), the colored label affixed to the component should be inspected to confirm it is correct.

5.5.2.2 If the blood or 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.

Guidance

The physician approval can be documented in the patient's medical chart and include medical justification.

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.

Guidance

Normal saline USP for irrigation may not be used for recovered blood processing unless the package insert states that it can be used for cell washing and intravenous use, or the manufacturer has provided documentation indicating it is safe to use for this purpose.

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

Guidance

When an alternative biocompatible physiological wash fluid is used in place of normal saline, the perioperative program should define the clinical indications and circumstances under which the alternative solution may be used. Approval by the medical director should be based on evidence-based medicine, clinical considerations, and available data supporting the safety and effectiveness of the alternative solution for its intended clinical application [for example, see: Myers GJ. What is the ideal solution for washing salvaged red blood cells using a cell saver for autotransfusion during surgery? Perfusion 2025 (online ahead of print). https://doi.org/10.1177/02676591251413495].

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.

Guidance

Other than gravity reinfusion, other methods may be employed to reinfuse the component, such as syringes, in-line squeezable bulbs, pressure bags, infusion pumps, and rapid infusion devices.

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.

Guidance

The information required by Standard 5.5.4.2 may be captured in the anesthesia or perfusionist's notes or in the blood management technologist's notes.

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.

Guidance

Air embolism is one of the most significant and fatal risks associated with infusion of blood components and is defined by CMS as a "never event." Interventions to prevent air embolism are simple and easily implemented. Methods to prevent the risk of air embolism include, but are not limited to:

- Transferring blood into a separate bag.
- Disconnecting the bag from equipment.
- Ensuring that air has been completely removed from the bag before transfer and the initiation of infusion, particularly if a pressure infusion device is to be used.
- Use of Buretrol.
- Use of an air detector when a direct connection is required.

5.6 Organ Procurement Using Normothermic Machine Perfusion/Normothermic Regional Perfusion

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

1) A mechanism to classify administration (perfusion vs transfusion).
2) Documentation of the request and administration.
3) Special modification requests.
4) Traceability from collection to perfusion device to final disposition, as well as regarding any adverse events and look-back investigations.*

*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

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

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.

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. Documents and Records

6.0 Documents and Records

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

Guidance

This standard sets forth requirements for two separate types of written or electronically captured materials: documents and records. Because the integrity of a quality system is dependent on its documents and records, a whole section of the standards is dedicated to ensuring that the program has processes and procedures for controlling both its documents and records.

6.1 Document Control

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

Guidance

Documents are written or electronically captured materials that define how or what is to be accomplished. Documents include policies, processes (descriptions of activities that involve two or more individuals), and procedures (descriptions of activities that are performed by one individual, such as standard operating procedures).

Forms are documents that are designed to capture outcomes. Forms must be controlled in the same manner as all other documents. Forms must be accompanied by appropriate instructions to ensure that they are correctly utilized. A completed form becomes a record.

Documents may be in printed or electronic form. It is not necessary to maintain a hard copy of the text of all policies, processes, and procedures if the facility maintains accessible electronic copies of all documents.

Below, each concept of the document control process is considered in more detail.

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.

Guidance

Document control requires a standardized format for documents and a system that describes how policies, processes, procedures, labels, and forms are linked. Additional procedures developed by manufacturers or other organizations (eg, operator's manual or the AABB *Technical Manual*) that may be incorporated by reference need not be recreated in the standardized format. The standardized format for procedures should include the purpose, materials, equipment needed, and identified endpoints.

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 *Perioperative Standards* are performed.
5) Are not used when deemed invalid or obsolete.
6) Are identified as archived or obsolete when appropriate.

Guidance

Before distribution, it is required that all documents relating to the requirements of the quality system and the *Perioperative Standards* be reviewed and approved by authorized individuals.

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.

Guidance

Document control requires that documents be changed or corrected in the same manner in which they were created. When revisions to existing documents are submitted for approval, those making decisions should have the appropriate information to make the decision. Any significant changes in a procedure itself shall be given to the laboratory director to review and approve. Once changes to documents are made, personnel must be trained on the new processes or procedures.

Each program should 1) identify who will review the documents and how they will be reviewed, including manner and scope, and 2) define what level of authority will approve the final documents. The same person may perform both functions.

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 *Perioperative Standards*.

Guidance

All programs are required to maintain a master list of current policies, processes, procedures, labels, and forms. It is recommended that a master list include the following information: title of document, holder of the document (ie, person responsible for maintaining it), current revision number, the location of the document, and date of implementation. This list may be an effective tool in preventing obsolete documents from being used. It is acceptable for separate departments within an organization to control documents differently; however, there should be a system that links related documents.

Programs may organize a master list by linking a policy with related processes, related procedures, and related forms. Alternatively, there may be a comprehensive list of all of policies, another list of processes,

a list of procedures, and a list of forms. It is important to identify the individuals who control the master list. For example, the department director's assistant might control the master list on his/her computer.

It is acceptable to have multiple master lists as long as this is defined in the document control system. This ensures that updates to the list are controlled. Regardless of who controls the master list, executive management should always have a list of all departmental master lists or access to all departmental master lists.

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.

Guidance

There should be a schedule that indicates when processes and procedures are reviewed. At a minimum, all processes and procedures are required to be reviewed every 2 years by the medical director or designee as defined by the organization.

6.1.6 Document Retention

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

Guidance

When revised documents are distributed, obsolete documents must be identified. If old copies are maintained for historical purposes, they should be stamped or labeled "obsolete" to indicate their status.

The standard requires the program to determine which, if any, documents are to be archived. The intent of the standard is to physically remove obsolete documents so that staff do not inadvertently use outdated processes and procedures. It should be clear which documents are intended for archival (eg, placed in a computer file or notebook of archived documents). It might be helpful to indicate on archived documents the date of archival and the reason for archival, although this is not required.

According to Reference Standard 6.2.9A, Retention of Records (published in the *Perioperative Standards* and not reproduced here), documents are required to be archived for a minimum of 5 to 10 years depending on the document, or in accordance with applicable federal, state, or local laws. The more stringent applicable rule is the rule that should be followed.

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.

Guidance

The intention of storing documents is to have them available at a later date, for example, to recreate the circumstances surrounding an event that happened in the past. Assessors might want to know which procedure was in use at the time that a particular record was created to be sure that the correct proce-

dure was followed. For this to be possible, retained documents must be in a condition that makes them legible when they are retrieved from storage.

Security procedures must be in place to prevent unauthorized modification of documents while they are in storage. Storage of documents must be done in such a way that even accidental destruction or modification will reasonably be prevented.

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 *Perioperative Standards* are performed.

G u i d a n c e

Once approved, the documents are required to be available at all locations where they are used. A distribution list may help to direct where the new or revised documents should be delivered. The program should consider whether to store the most current documents on paper copies or in electronic files. This standard also requires the use of only current documents, which implies that outdated (archived, obsolete) documents are removed from circulation in a controlled way to prevent their use after new documents have been put into use.

When revised documents are distributed, it may be helpful to provide a cover sheet that summarizes the changes or to highlight changes through formatting (eg, underline and strike-out) so that employees do not have to perform a line-by-line comparison. If an errata sheet is distributed and employees make corrections to paper copies, they should be written in ink. Unless authorized, no written changes should be made to documents. Further, handwritten notes or "stickers" on documents should be avoided because they are "uncontrolled," which means that they add new information that is not authorized, controlled, or equally available on all authorized copies of the document.

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

G u i d a n c e

A record is information (captured in writing or in an electronically generated medium) that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or assessment results. Records do not exist until the activity has been performed and documented. Records prove that:

- A product or service conforms to specified requirements.
- Each step of the quality system is being performed.

Records may be maintained in any format; however, their security must be ensured.

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.

Guidance

Similar to what is stated in Standard 6.1.7, records must be retained in a way that would allow them to be read at a later date. This standard also states that they must be retrievable in a reasonable amount of time. Retrieval of paper records from storage is expected to take longer than retrieval of electronically stored records. The institution's policies should indicate how long it might take to retrieve various types of records. Record retrieval is not typically done under emergency circumstances and should be done as workload permits.

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.

Guidance

The facility must determine how these records are captured and maintained. In total, the information captured (as outlined in Standard 6.2.3) should support the intent of Standard 6.2.2, making it possible to trace every perioperative component from source to final disposition. The facility is also responsible for defining which materials and activities are critical and how methods, equipment, and individuals are identified. For example, are staff members identified by their initials or by an employee identification number?

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.

Guidance

As required by Standard 6.2.1, unauthorized changes to records must not be allowed. For this reason, all changes to records must be controlled and traceable. The intent of this standard is to be sure that the original information recorded, which would be the information that was concurrently recorded as required in Standard 6.2.6, is still able to be read after changes are made. It is also important to be able to understand why changes were made to a record, who made the change, and when it was made.

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.

Guidance

Recording of results must be performed in such a manner that the accuracy and integrity of the results is upheld during record creation. The intent of this standard as well as Standard 6.2.6 is to be sure that information is recorded in the most accurate and timely way, before distractions and the passage of time interfere with the best possible recording of information. The circumstances for recording laboratory results should follow the same rules as those for the creation of any other type of record.

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.

Guidance

The responsibility for each program is to determine what is the "official" record. Some programs prefer to use paper copies as the official record. In other organizations, the paper worksheets serve as the official copy, although the information is still entered into a computer system and is used by billing departments or as patient records. This practice is acceptable if it is defined in the program's processes and procedures. In this instance, worksheets serve as the official record. Later, if there are questions about the results, employees would know to refer to the information on the worksheet. These worksheets are subject to record retention requirements. A computer record may also serve as the official record. This practice is also acceptable as long as it is defined in the organization's processes and procedures. In this case, employees enter data straight into the computer and no paper is used. Issues to keep in mind when computer records serve as the official records are the security of the computer system, trackability of changes, backup tapes, protection against adulteration, and proper record retention.

Transfer of Information from Paper Source to Computer

An original record might be destroyed when information from worksheets is entered into a computer. Before it is destroyed, however, the program must ensure that all necessary information on the record is accurately transferred to an alternate source (eg, the computer system). Because the worksheet is the original record, verification of accurate transfer of the information is required before any "source" documentation is destroyed. The program should consider how it will verify that information has been transferred accurately.

Storage Media

Another instance when records may be destroyed is when copies of original records are placed on storage media (eg, microfiche and videodisc) or scanned in a portable document format (PDF). Because these storage media are exact copies of original records, the original records could be destroyed, while the microfiche/videodiscs or computer files are retained according to record retention requirements. Depending on the storage media used, it is important to retain the appropriate technology to ensure there is a method to read the records in the future. This might include retaining a particular software program that would allow reading of the stored document files. The standard requires that the program verify that copies of records contain all of the original content. Vendor qualification may be one method of satisfying this requirement. During agreement review with the storage media company, the organization can require that the vendor state how it will verify that complete and appropriate records are transferred to the other storage media. The official records must be maintained for the appropriate length of time—in accordance with specified requirements of both state and local law, where applicable.

6.2.8 Confidentiality

The organization shall ensure the confidentiality of records.

G u i d a n c e

Ensuring confidentiality of records requires that access to the record systems (physical or virtual) is controlled. This may be accomplished with physical barriers to access (eg, who has keys to a locked office/file cabinet) and/or electronic barriers to access (eg, login credentials for information systems).

6.2.9 Retention

Records required by these *Perioperative 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.

G u i d a n c e

See the Guidance for Standards 6.2.1 and 6.2.2.

6.2.12 Destruction of Records

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

Guidance

Because records might contain protected health information, the method that is utilized for destruction of records must ensure that all such protected information is not inadvertently disclosed to unauthorized individuals.

✎ **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.

Guidance

Minimum retention times for records are defined in Reference Standard 6.2.9A, Retention of Records (published in the *Perioperative Standards* and not reproduced here).

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.

Guidance

All facilities should have off-site storage for backup. Disastrous loss of data and functionality may occur due to a variety of reasons, such as natural disasters or construction accidents. Many facilities already have off-site storage for patient files, administrative files, and financial records. The use of similar storage facilities for files regarding perioperative components should be explored through the administrative group at the facility. Off-site storage could also be at a sister facility, with each storing the other's backup data. The off-site location should also meet all security requirements for the level of data being stored to prevent tampering or violation of requirements contained in the Health Insurance Portability and Accountability Act (HIPAA).

The off-site storage should meet the temperature and other environmental requirements for the media to be stored (eg, heat/cold/humidity, magnetic influences, and security).

If, for some reason, there is no off-site storage already established, it should be done immediately. This backup data would be necessary during disaster recovery, and off-site storage will be well worth any costs, should the need arise.

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.

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, FDA).

7. Deviations, Nonconformances, and Adverse Events

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.

Guidance

Standard 7.0 requires that the organization establish a process to capture, assess, investigate, and monitor events that deviate from the requirements. Deviations, nonconforming components, and adverse reactions should be considered as adverse events. Implicit in this standard is the expectation that the program has defined its "specified requirements" as well as the expectation that the perioperative program has a standardized approach to reacting to these events. That approach should include problem identification, investigation, classification, and the application of data collection and analysis tools. The organization should have a method for tracking and trending these events. In the absence of a defined individual responsible for review of these activities, the program's medical director is responsible for such review, including ensuring that reports are made to outside agencies as appropriate.

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.

Guidance

Procedures involved with recovery of blood and further processing, such as washing, performed at the bedside during surgery are not considered manufacturing. These procedures occur under the direction of a surgeon, during surgery, and are considered to be the practice of medicine; therefore, there is no requirement to report deviations associated with perioperative procedures to the FDA via its established process for biological product deviation (BPD); however, fatalities associated with the reinfusion of blood products are reportable in accordance with 21 CFR 606.170(b). This information was verified per communication with staff in the Office of Compliance and Biologics Quality, CBER, FDA. The majority of perioperative events require only internal reporting and evaluation.

The process for documenting deviations (eg, completing a form) should include an indication of whether or not the patient was affected and whether any steps needed to be taken to manage the patient after the deviation. Of course, such documentation should wait until after the patient is properly assessed and provided with any necessary support.

7.1.1 Deviations shall be reported as soon as possible after detection.

Guidance

In a nonpunitive atmosphere, to foster a culture of reporting deviations, employees should be encouraged to submit event reports. If management views these reports as an opportunity to improve processes rather than as punishment, employees will be more likely to embrace the concept.

7.1.2 Deviations shall be evaluated to determine the need for corrective and preventive action. Standards 9.1 and 9.2 apply.

Guidance

Appropriate evaluation of deviations using quality improvement tools (such as root cause analysis, process mapping, or failure mode and effects analysis) should be used to identify process failures and redesign processes to be as error-proof as possible. Analysis is most successfully conducted when the evaluation focuses on the processes involved and not on "human failure." The process or procedure for controlling nonconforming components or services should be followed even when the nonconformance appears to be minimal or insignificant. The following actions may be acceptable options in the disposition of nonconforming components:

1. Reprocessing, retesting, or reworking.
2. Acceptance for administration, with appropriate documentation and disclosure of the nonconformance.
3. Relabeling.
4. Destruction.

Appropriate action may be documentation of the circumstances or nonconforming component. Components that are reprocessed, reworked, or relabeled must be reinspected before use. Reinspected components should be evaluated against all applicable requirements. It is important that descriptions and records of the nonconforming component be maintained so that the program can accurately assess corrective and preventive actions (Chapter 9, Process Improvement). Identifying trends in nonconforming components may provide insight into process or procedure problems.

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 or blood component(s).

Guidance

The organization's policies, processes, and procedures need to define how deviations are handled, especially those deviations that could pose a risk to patients or employees. The program must have a defined mechanism for obtaining approval from authorized individuals to proceed under such circumstances. The program should define whether the medical director alone or both the medical director and the care provider using a nonconforming perioperative component would have authority over its final disposition. How such approval is documented also needs to be defined.

It is important that the individuals provided with decision-making authority over the disposition of nonconforming components be qualified (Chapter 2, Resources).

The fact that a component has already been distributed should not preclude the investigation of a deviation as described above. Actions taken immediately after a component is distributed could still prevent harm. If nothing else, an investigation after the release of a component could prevent harm in future similar cases.

7.2 Nonconformances

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

Guidance

Each facility should establish criteria defining an acceptable component. Failure to meet these criteria may result in a nonconforming component or service. Such criteria can be case-specific: depending on the clinical circumstances, a component that is nonconforming for one type of case may be appropriate for a different type of case. It should be recognized that nonconforming components or services can occur even when processes and procedures are followed and performed correctly. For example, nonconforming components could be a consequence of the condition of the patient or the results of the surgery. The goal of inspections/tests is to identify nonconforming components and services before administration of the component. The program should indicate in its processes and procedures those nonconformances that are considered to affect the safety, purity, and efficacy of components (ie, whether the nonconformance precludes use of the component because the component can be replaced with an allogeneic unit or is too dangerous to use). In some cases, the program may intentionally use a nonconforming product because it is considered to be the best product for a particular patient. In such cases, the factors that contributed to the decision to use the component should be clearly documented in the patient's record.

The following examples are used to illustrate the practical implications of this standard in the perioperative setting:

1. During acute normovolemic hemodilution, only 100 mL of whole blood is collected into a bag containing anticoagulant intended for 350 to 500 mL of whole blood.
2. The final processed component from a blood recovery procedure has a hematocrit of 25%, when the procedure has a known acceptable range for final component hematocrit of 45% to 65%.
3. The final processed component from a blood recovery procedure has a residual heparin concentration of 1.3 units/mL. The acceptance criteria for residual heparin in final components is ≤0.5 unit/mL.

For these and related examples, the organization is required to determine whether that component can be used or should be discarded, and to investigate and correct the potential reasons for the nonconformance. Processes and procedures should indicate how nonconforming components are managed.

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.

Guidance

The program's policies, processes, and procedures must clearly designate what is done with nonconforming components or materials. If such components or materials are placed in quarantine, it should be done in a way that would prevent their inadvertent release and use.

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.

Guidance

After being placed in quarantine, a component or material might be found to be acceptable for use, in which case processes need to be in place to put it back into use. For components not found to be acceptable, processes need to guide their final disposition (eg, discarded, returned to the vendor, or sent to a laboratory for additional testing). Policies, processes, and procedures for retrieval and recall may require the inclusion of supply chain and/or risk management personnel. If the nonconformance(s) affected a component that was transfused, then notification and documentation of all responsible parties should be included.

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.

Guidance

If the nonconforming material was provided by a vendor, it might be necessary to report the incident to the vendor. Anything that might affect patient safety must be reported to the patient's physician. Policies, processes, and procedures for each of these possibilities should be defined by the organization. For what needs to be reported to the FDA, refer to the Guidance for Standard 7.1.

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.

Guidance

In cases where safety and efficacy are affected, acceptance by the intended recipient's physician and informed consent of the intended recipient should be considered; however, all individuals responsible for such decisions must be included in the records. The organization is required to determine whether a component should be used or discarded and to investigate and correct the potential reasons for the nonconformance. Processes and procedures should indicate how nonconforming components are managed.

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.

Guidance

The organization must identify an approach to evaluate complications of perioperative component collection and administration. The symptoms would be similar to those for transfusion reactions, such as changes in vital sign values, respiratory rate, and urine output, as well as rash or signs of hemolysis. The goal of such a process is to identify the underlying cause of the adverse event and to potentially prevent it from occurring in other patients. The initial response should focus on limiting further component administration, limiting further use of implicated equipment, ruling out clerical errors, and ruling out hemolysis in the component and/or the patient. Subsequently, the program should outline the steps for additional investigation, including further testing.

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.

Guidance

Although two different patients would not likely be in the room at the same time, it is possible that a component could be mislabeled. Verification of patient identification and unit/label identification can very quickly identify a problem that might cause harm to more than one patient.

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.

Guidance

The program's processes and procedures should define how implicated equipment is investigated, removed from service, and returned to service. Acceptance criteria for "return to service" should be defined. Standard 3.5.4 describes the investigation and follow-up of equipment malfunctions. Immediate cessation of administration of a component that is suspected to be causing an adverse event is the first step that should be taken when an adverse event is identified. A delay in cessation of administration may worsen the adverse event and potentially cause additional harm to the patient.

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

Guidance

If the patient's care providers have reason to believe that the patient is hemolyzing as a result of collection or administration of a perioperative component, laboratory testing can help to clarify whether the hemolysis is due to immune-mediated mechanisms or mechanical mechanisms. A standard investigation for hemolytic events, including which laboratory testing should be performed, should be included in the program's processes and may be under the purview of the facility's transfusion service.

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.

Guidance

Additional testing might also be appropriate for other situations (eg, Gram stain, culture, and sensitivity if bacterial contamination is suspected). This type of testing should also be specified by the program. Standard 4.1.3 specifies that testing must be performed by an accredited laboratory.

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.

Guidance

Adverse reactions to perioperative components could be due to something other than hemolysis. An appropriate investigation, including laboratory testing, might be outlined based on the patient's clinical signs and symptoms. Alternatively, a standard investigation might be defined for all adverse reactions, and then additional investigation and testing might be included as optional actions based on the initial findings. If all reactions are investigated in an identical way, the program might have a policy to state that

additional testing is not undertaken unless requested by an authorized individual (eg, the patient's physician or the program's medical director). The program should define whether the medical director or both the medical director and the patient's care provider would be notified and how they would be notified. The program's processes and procedures should also define who is responsible for reporting the results of such investigations to the patient's care provider, if they are not originally notified, and how such reporting is documented.

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

Guidance

A fatality attributed to, or suspected to be related to, a perioperatively processed blood component needs to be reported both internally through defined procedures as well as externally to the FDA per "Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion" (Final Guidance, August 2021). For example, fatalities that would be reportable include an improperly washed unit that had enough hemolysis to cause acute renal failure and subsequent death. Another example might be fatal air embolism from failure to use a transfer pack properly. If there is a device malfunction or failure, reporting might be required or appropriate according to the FDA MedWatch program.

*21 CFR 606.170 and 21 CFR 803.30.

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. Internal and External Assessments

8.0 Internal and External Assessments

The organization shall conduct assessments of operations and quality systems.

Guidance

Chapter 8 aims to ensure that the quality management system is effective and provides an opportunity for improvement. The organization has two obligations under the requirements in this chapter.

External Assessments

The program must ensure that external assessments, such as inspections and/or surveys, are obtained at appropriately defined intervals. External assessments may be provided by organizations such as AABB, The Joint Commission, Det Norske Veritas Healthcare (DNVHC), and/or the College of American Pathologists (CAP), based on the accreditation(s) of the facility. The results of the external assessments should be reviewed by executive management.

Internal Assessments

Internal assessments should be scheduled on the basis of the significance of the activity to be assessed. The *Perioperative Standards* do not establish a specific schedule; the organization should review its operations and determine what schedule is appropriate. It is recommended that all activities that constitute the quality system be assessed at least once a year. During the first 2 to 3 years of implementation of a quality management system, however, it is recommended that the quality system be assessed more frequently (eg, at 3- to 6-month intervals). As a general rule, critical activities should be assessed frequently, and areas with consistent problems should be assessed often until there is clear resolution of the problems.

These internal assessments should evaluate both operational and quality system activities. It is acceptable to use the AABB Assessment Tools (eg, Perioperative Assessment Tool, available to members) as a guide for these assessments.

Ideally, individuals who assess specific activities should be independent from those having direct responsibility for the activity. In an era of limited resources, however, this independence may not always be possible. Accordingly, independence may be interpreted as employees from the same department who assess one another's work. The organization should determine how often specific departments will be assessed and identify when they will be assessed.

When the internal assessors have been identified, they need to be trained. External courses provide a training option, or a large organization may choose to provide internal training for a group of assessors. Regardless of where it takes place, assessment training should focus on the general structure of the quality system, an understanding of auditing techniques, and good communication skills.

Assessors should use a systems approach rather than depending on a predictable checklist of standard questions. Assessors can assess all departments at one time or may choose to develop a schedule where departments are assessed, one at a time, throughout the year. A "life of a component" assessment is another option. All procedures involved in the creation and administration of a specific perioperative component are audited, from the initial assessment/scheduling of the patient (eg, informed consent process) to the collection, preparation, labeling, any storage, and final disposition of the component. This

audit includes review of records related to quality assessments of personnel, reagents, and equipment used in the procedures. The program's policies, processes, and procedures should describe the internal assessment process.

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.

Guidance

The results of all assessments are required to be brought to the attention of management for review and sign-off, and to individuals who have responsibility for the activity. Management personnel are responsible for implementing timely corrective and preventive actions for each identified nonconformance, in conjunction with Chapter 9, Process Improvement.

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.

Guidance

Executive management should define quality objectives on an ongoing basis. Quality indicator data should be collected and provided to executive management to ensure that the quality objectives are met. Periodic review of the data should be shared with the applicable quality review committee. Options for presenting and reviewing the quality indicator data can include a blood utilization review committee, a patient blood management committee, or a surgical services quality committee. In addition, if the organization activities are performed by a third-party service, the quality indicator results and any related comments should be shared with them for continued improvement.

Examples of data that can be used as quality indicators may include some of those listed under Standard 8.4.2. Additional examples of quality indicators for perioperative services may include:

1. **Component preparation and quality of components.** For example, are there policies related to processing of partial bowls? Is the percentage of processed partial bowls tracked? Are infusion times of washed recovered blood tracked, and is the start time of the infusion within the designated expiration time/time frame from completion of processing?
2. **Physician practices in ordering perioperative services.** For example, are surgeons who perform high-blood-loss procedures consistent in their ordering practices for usage of cell recovery for the same procedure?
3. **Patient selection criteria for use of perioperative services.** For example, has each department established criteria? Are contraindications for use of cell recovery established? Are the criteria consistently followed? Are outlier cases reviewed? Are cases tracked where cell recovery is set up but insufficient recovered blood is collected for processing?
4. **Blood and blood component usage during surgery other than that collected perioperatively.** For example, are allogeneic and/or directed donor components used in addition to perioperatively collected components? Are both types of components (eg, perioperative autologous blood and allogeneic blood) tracked for certain surgical procedures (eg, open-heart surgery, liver transplantation) to monitor effectiveness of cell recovery on reduction of allogeneic blood use and potential cost savings, and to identify potential areas for improvement?

8.4.2 The organization shall have a process that monitors perioperative collection and 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.

Guidance

Each program should define its expected utilization review and criteria for the review based on the type and extent of perioperative activities performed within the facility. The selected metrics and process for utilization monitoring may be overseen by the institutional transfusion committee or patient blood management committee, or any committee overseeing blood utilization. Examples for possible utilization review and assessment may include, but are not limited to, the following:

Requirement	Examples of Utilization Metrics and/or Areas to Review and Assess:
1) Ordering practices	• Number of procedures the cell recovery device is set up for, both overall and by case type (eg, cardiac, vascular, orthopedic/spine, liver transplant) • Number of procedures where standby option was used and percentage of time converted to collecting and processing

Requirement	Examples of Utilization Metrics and/or Areas to Review and Assess:
2) Patient identification	• Proper use of patient armbands (or other identification technique used by the facility) • Correct designation on the surgery schedule of patients who have perioperative procedures requested, including exactly which procedure is expected
3) Sample and component collection	• Correct information on specimen labels, including, at a minimum, two patient identifiers, date and time of collection, identification of the person collecting the specimen • Proper technique in collecting specimens, for example, proper syringes for whole blood collection for PRP, or tubes with the proper additive for laboratory testing
4) Labeling	• Audit that the labeling of products prepared meets program-defined requirements
5) Appropriateness of use	• Percentage of cases with sufficient blood collected for processing and reinfusion • Percentage of cancellations
6) Quality control	• Summary of quarterly hematocrit results (mean + SD) performed on all cell recovery devices
7) Adverse events	• Summary of all adverse events and near misses associated with perioperative blood collection and/or reinfusion that occurred over a defined period. Depending on the number of events, they might be categorized with regard to seriousness or the process affected.
8) Near-miss events	• "Near miss" is defined as an occurrence that was caught and corrected before an adverse event could occur
9) Usage, discard, and cause of waste	• Mean volume of blood processed and volume of blood returned to patient, overall and by case type • Number of components wasted and reason • Number of allogeneic units saved based on volume of blood returned to patient, overall and by case type
10) Ability of services to meet customer needs	• Any complaints from patients, surgeons, or members of the anesthesia department • Ability of technicians to meet established timelines for emergent procedures • If the program uses a contracted service for perioperative autologous collection, the ability to meet previously agreed-upon expectations
11) Overall program effectiveness and opportunities for improvement	• All internal and external assessment reports

AABB supports the use of a comprehensive patient blood management program encompassing tools, techniques, and processes that can reduce the patient's exposure to allogeneic blood components. Blood usage for the organization should be incorporated into the facility's overall blood utilization review. If review of certain surgical procedures indicates consistently high blood loss and usage of allogeneic blood without use of cell recovery, a process improvement project may help increase awareness of this blood conservation strategy. Utilization review of both the equivalent units of cell recovery blood reinfused and number of allogeneic units reinfused for a specific surgical procedure may provide opportunity for improved use of cell recovery or auto-reinfusion.

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. Process Improvement

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.

Guidance

This chapter requires that the organization identify corrective and preventive actions that might be required in the program, collect data about these actions, analyze the necessary actions, and follow up on any corrective or preventive action. The difference between corrective and preventive action is that corrective action is taken in response to an event (including a near-miss event) that already happened, exposing a possible nonconformance or deficiency in the program, and preventive action is taken when data reveal a potential nonconformance or deficiency in the program that has not yet resulted in any type of event.

This standard requires a process for managing corrective and preventive action. Corrective action, at a minimum, must include: effective handling of error and accident reports that relate to nonconformances, investigation of the cause of the nonconformance, records of the investigation, a determination of the corrective action needed to eliminate the nonconformance, and evaluation to ensure that corrective action is taken and that it is effective.

Preventive action must include the review of appropriate sources of information to detect and analyze potential causes of nonconformances. Information such as internal and external assessment results, customer complaints, quality control records, and proficiency testing results are suggested as potential sources of information.

The goal of Chapter 7, Deviations, Nonconformances, and Adverse Events, was to control nonconforming components or materials to prevent their unintended administration. Chapter 9 requires an organization to have processes and procedures for implementing corrective and preventive action plans to prevent nonconformances from happening again. Periodic management review of these plans and their implementation is also required.

Although most organizations deal well with immediate problems, a thorough investigation of the cause is often overlooked. Quality improvement tools such as root cause analysis or failure mode and effects analysis may need to be initiated for nonconformances and near-miss events. This critical step is an important aspect of a quality system. The time spent on corrective and preventive actions should be proportional to the magnitude of the problem or potential problem so that valuable time is not spent on issues unnecessarily. Likewise, if a significant problem arises, appropriate resources should be allocated, including a multidisciplinary review of transfusion medicine physicians and nursing, laboratory, and quality staff whenever necessary. The standards do not specifically define the nature, extent, or scope of appropriate corrective or preventive actions; the program needs to determine these actions.

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.

Guidance

Complaints regarding perioperative blood collection can come from any customer that uses the program's services. Customers can include hospitals, clinicians, patients, contract services, and other departments.

Corrective action processes and procedures should include:

- A clear description of the event to help best determine the cause and contributing factors, as well as identify any potential corrective action.
- Effective handling of nonconformance reports to aid in the accurate description of the event.
- Investigation of the cause of, and contributing factors to, component or service nonconformances.
- Review of current processes and procedures and determination of whether any corrective action is necessary. This review might also include review of pertinent literature to determine the current standard of care and how that compares to the facility's processes and procedures.
- The initiation of corrective action(s) and verification that those actions were effective. Monitoring for effectiveness is most likely to be in the form of audits, but other forms of monitoring (eg, quality indicator data) might also be appropriate.

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.

Guidance

The steps taken for preventive action do not necessarily have to be markedly different from those used for corrective action. The main difference should be the focus of preventing potentially harmful situations rather than responding to an event that has already happened. Preventive action processes and procedures should include:

- The use of appropriate information to identify potential problems.
- Determination of the steps necessary to prevent potential problems.
- Review of current processes and procedures and determination of the preventive action necessary.
- Initiation of preventive action and knowledge that it is effective.

Sources of information that may be used to improve processes include assessment results, quality records, and customer complaints. Preventive actions may be initiated in response to minor observations, but in combination and over time, the organization may discover trends that depict system-wide problems. Standard 2.1.7 requires that staff have adequate time to perform their duties. Preventive

action (and corrective action) should be considered part of the staff's routine responsibilities, and sufficient time should be allowed for them to perform these activities.

Although preventive action is intended to avoid potential problems, it can also be a process improvement tool to assist the organization in operating more effectively and efficiently.

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.

QSE 10 – Facilities and Safety

Key Concepts

This QSE addresses the safety and adequacy of areas where the work required by these *Perioperative 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. Facilities and Safety

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.

G u i d a n c e

These *Perioperative Standards* require that the organization ensure safe and adequate environmental conditions in the workplace. Specifically, they require that the organization be designed to minimize risks to the health and safety of its employees, volunteers, and patients. The point of these *Perioperative Standards* is that safe and adequate facilities must be thoughtfully considered as part of the design of the program.

There must be documentation available to show that all of the aspects of safety listed above have been considered. For example, if there is no risk of radiation exposure for any aspect of the organization, that should be specifically stated and not simply implied. Third-party providers should establish policies in conjunction with the hospital and train their staff accordingly. The ability of staff to perform their duties safely includes proper training and proper personal protective equipment, as well as having adequate time. (See Standards 2.1.3 and 2.1.7.) Staff should be trained as to what to do during emergency situations as part of working in a safe environment. (See Standard 1.6.)

The *Perioperative Standards* also requires that perioperative components be handled and disposed of in a manner that is designed to prevent the potential for human exposure to infectious agents. Documentation of disposal of unused components should be maintained, and such disposal must follow all requirements, including regulations, applicable to the facility.

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.

(Continued)

List of Components and Processing Methods (Continued)

Component	Description	Process/Method
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.
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 *Perioperative 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 action based on 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 *Perioperative 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: Nonparenteral 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.