PROPOSED Standards for Blood Banks and Transfusion Services, 35th Edition

Effective April 1, 2026

A Note to Readers

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

• Requirements, once stated, are not repeated. For example, standard 5.0 requires that all processes and procedures be validated. Therefore, it is not necessary to require in other areas that a specific process or procedure be validated.
• Words or phrases used in a way different from their usual meaning are defined in the glossary.
• The term "specified requirements" is defined broadly to include accreditation requirements, national, state, or local laws, and any other applicable requirement.
• Please note that the Summary of Significant Changes to the proposed 35th edition begins on page 2 and runs through page 22. The proposed 35th edition begins on page 23 and runs through page 218.

Significant Changes to the Proposed 35th edition of Standards for Blood Banks and Transfusion Services

General
Where appropriate, the following phrase was added to all applicable standards that are related CMS regulations:
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

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 BB/TS 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.
~~4) A participatory role in management review of the quality system.~~

The committee deleted subnumber 4 (an addition to QSE 1.1 in the 34th) as it was deemed redundant to standard 1.2.2.

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

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

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

1.9.2 Staffing Changes
The organization shall communicate to AABB in electronic or written format all initial appointments and changes for the medical director within 30 days of appointment.

The committee took the concept of standard 1.9.2 from the Standards for Molecular Testing Laboratories for Red Cells, Platelets, and Neutrophil Antigens. The committee along with the BB/TS Accreditation Committee feel that this addition will be beneficial.

1.10 Unanticipated Event Notification
Within 30 days, the organization shall notify AABB of the discovery of an event that has, is, or is likely to cause serious injury, harm, or death to an individual resulting from deviation(s) related to the scope of these *BB/TS Standards*.

Unanticipated Event: Unplanned occurrences that can cause serious injury or harm, or death, to an individual resulting from a deviation(s).

This standard is new to the edition and has been included for completeness. This requirement mirrors requirements set forth by AABB's Accreditation Department. The committee also added a new definition to the Glossary for "Unanticipated Event" for clarity.

2.1.3.1 The organization shall ensure that personnel are evaluated following training to demonstrate the skills necessary to perform critical tasks and are deemed competent.

The committee created new standard 2.1.3.1 for completeness. This ensures that personnel are evaluated once they have completed their training to ensure they are competent.

2.1.6.1 The organization shall establish minimum continuing education requirements for employees performing or overseeing critical tasks.

The committee created new standard 2.1.6.1to ensure that facilities have continuing education for certain employees as an addition to standard 2.1.6. This closes a potential loophole that could exist in the Standards.

3.5.4.1 When a nonconformance cannot be attributed to a specific piece of equipment, all potentially involved pieces of equipment shall be evaluated to determine expected performance criteria are met based on the manufacturer's written instructions.

The committee created new standard for clarity. This clarifies that not all equipment has to be reviewed when it is known that one piece of equipment is at the root of the nonconformance. Thus, saving the community time and effort.

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

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

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

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

Based on a review of chapter 3, it was deemed that this standard is redundant to many standards in chapter 3, specifically the 3.5 thread.

3.7 Technology Infrastructure

The organization shall have an ongoing program to ensure that critical technology and communication infrastructures function as intended, including risk-based monitoring or testing at organization defined intervals. Standards 1.4, 1.5, and 1.6 apply.

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

3.8.2.1 The organization shall perform quality control testing of automated temperature recording devices at facility defined intervals to verify accuracy of recordings. Standards 3.5.1 and 5.1.2 apply.

The committee added new standard 3.8.2.1 for completeness, reflecting a gap in the standards where assessors did not have the ability to cite a specific standard related to the expected quality control testing needed of temperature recording devices.

3.9 Storage Device Alarm Systems

Storage devices for blood, blood components, tissue, derivatives, and reagents shall have alarms and shall conform to the following standards:

The committee added the term "Storage device" to the title of the standard for clarity, recognizing that the focus of this section is on storage devices.

3.9.1.1 The organization shall perform quality control testing of alarm activations at facility defined intervals to verify alarms are activated when the temperature sensing device/probe detects an unacceptable temperature. Standards 3.5.1 and 5.1.2 apply.

In conjunction with the addition of standard 3.8.2.1, standard 3.9.1.1 has been added for parallel construction and completeness.

3.10 Bedside Warming Devices for Blood and Blood Components

The committee added the term "Bedside" to the title of the standard for clarity, recognizing that the focus of this section is on where the warming devices are used and in place.

3.10.1 The organization shall perform quality control testing of the warning system at facility defined intervals to verify warnings are activated when the temperature sensing device detects an unacceptable temperature. Standards 3.5.1 and 5.1.2 apply.

In conjunction with the addition of standards 3.8.2.1 and 3.9.1.1, standard 3.10.1 has been added for parallel construction and completeness.

5.1.1.1 This shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated. Standard 2.1.3 applies.*

***42 CFR 493.1253**

For completeness, the CFR has been added.

5.1.8.4 Donor Identification
Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.*

***21 CFR 606.160(b)(l)(vii)**
21 CFR 630.10(g)(1)

For completeness, the CFRs have been added.

~~**5.1.9.1 Inventory Management**~~

The committee elected to delete standard 5.1.9.1 as it appeared as merely as a title with no purpose.

5.1.9.3 Storage areas and devices for blood and blood components shall be monitored:

5.1.9.~~1~~.3.1 **Electronic** storage **devices** for blood and blood components ~~the temperature~~ shall be monitored continuously and **the temperature** recorded at least every 4 hours. **Standard 1.5 applies.**

5.1.9.3.2 **Temporary storage containers shall be qualified and validated to store blood, and blood components to ensure that they maintain temperature within the acceptable range for the defined duration of storage.**

The committee revised standard 5.1.9.3 to focus on storage devices with electronic capabilities that do allow for continuous monitoring for clarity. With that, new standard 5.1.9.3.2 has been added to the proposed edition to cover the requirements around temporary storage containers and what is expected with regard to the maintenance of viability of blood and blood components.

5.1.9.5.1 Containers (eg, portable coolers) shall be qualified **and validated** to transport blood, blood components, tissues, and derivatives to ensure that they maintain temperatures within the acceptable range for the **defined** ~~expected~~ duration of transport or shipping.

The committee edited this standard for clarity and completeness.

5.1.10 Proficiency Testing Program
The BB/TS shall participate in a proficiency testing program, if available, for testing regulated by the Clinical Laboratory Improvement Amendments and performed by the facility.† Results shall be reviewed, and when expected results are not achieved, investigation and corrective action shall be taken

where appropriate.

†42 CFR 493.1236.
42 CFR 493.857
42 CFR 493.959
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

For completeness, the CFRs have been added.

5.3.3 Postphlebotomy Instructions
The collection facility shall provide the donor with written instructions for postphlebotomy care, and actions to take concerning adverse events that may occur after donation. Standard 7.3.3. applies.

~~**5.3.3.1** The collection facility shall provide the donor with written instructions about postphlebotomy care.~~

~~**5.3.3.2** The collection facility shall provide the donor with written instructions, including actions to take, about adverse events that may occur after donation.~~

The committee elected to merge standards 5.3.3.1 and 5.3.3.2 into standard 5.3.3 which previously only appeared as a title, noting that both standards were virtually identical.

5.4.1.3~~2~~ Donors implicated in a transfusion-related acute lung injury (TRALI) event or associated with multiple events of TRALI shall be evaluated regarding their continued eligibility to donate.

Standard 5.4.1.3 is not new to the edition but previously appeared as standard 5.4.1.2 and was rearranged for proper workflow.

5.4.2.1 If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, this information shall be obtained **per FDA or relevant Competent Authority regulations or** within ~~24~~ **72** hours of collection.

~~*21 CFR 630.10(c).~~

The committee edited standard 5.4.2.1 to allow the requirements to appear as more applicable to facilities in and out of the United States. The 72 hour timeframe is supported by current FDA enforcement discretion for the 24 hour requirement and is in line with community expectations.

5.6.5.2.1 If the apheresis product intended for cold storage without pathogen reduction will arrive at the processing facility within 4 hours of collection, the product may be transported in a manner intended to cool the ~~blood and~~ Apheresis Platelets toward a temperature range of 20 to 24 C.

The committee removed the clause "blood and" as the standard is strictly focused on apheresis platelets.

5.7.3.2.1 **The dose delivery shall be evaluated in accordance with the collection set manufacturer's written instructions concerning irradiation of products and modifications made to expiration date based on the**

dosimetry results.

The committee added standard 5.7.3.2.1 for completeness. Standards 5.7.3.2 and 5.7.3.2.1 (now 5.7.3.2.2) receive many queries and this standard addresses the most prevalent issue.

5.7.4.20 PATHOGEN REDUCED CRYOPRECIPITATED FIBRINOGEN COMPLEX
Pathogen Reduced Cryoprecipitated Fibrinogen Complex shall be prepared as per the manufacturer's written instructions.

The committee added new standard 5.7.4.20 for completeness. The product appeared in previous editions as a part of reference standard 5.1.9A.

✎ **5.8.2 Determination of Rh Type for All Collections**
The Rh type shall be determined for each collection with anti-D reagent. If the initial test with anti-D is negative, **further testing shall be performed to detect** ~~the blood shall be tested using a method designed to detect weak~~ **variant expression of** D. When either test is positive, the label shall read "Rh POSITIVE." When **initial and indirect antiglobulin tests (IAT) for D are** ~~the tests for both D and weak D are~~ **both** negative, the label shall read "Rh NEGATIVE."

The committee edited this standard (and other subsequent standards related to D) for clarity and to mirror language in the community currently. The intent of the standard has not changed.

✎ **5.12 Serologic Confirmation of Donor Blood ABO/Rh (including autologous units)**
Before transfusion, the ABO group of each unit of Whole Blood, Red Blood Cell, and Granulocyte component and the Rh type of such units labeled as Rh negative shall be confirmed by a serologic test from an integrally attached segment. Confirmatory testing for **serologic** weak D is not required.

The committee added the term "serologic" to the standard to mirror the title of the standard. The intent of the standard has not changed.

✎ **5.14.2 Rh Type**

Rh type shall be determined with anti-D reagent. The test for **serologic** weak D is optional when testing the patient. If a discrepancy is detected and transfusion is necessary before resolution, only Rh-negative Red Blood Cells shall be issued to patients of childbearing potential. Standard 5.30 applies.

The committee added the term "serologic" to the standard to mirror edits to other standards. The intent of the standard has not changed.

5.16.2.3 A **validated interface shall be used to transfer ABO/Rh and antibody screen data from an instrument to the information system, or a facility defined** method exists to verify correct entry of data before release of blood or blood components.

The committee added the elements in standard 5.16.2.3 for completeness and to ensure that the standard focused on both an electronic system or a facility defined method.

5.19.7 Specially Selected Platelets

The BB/TS shall have a policy regarding indications for specially selected platelet requirements, where applicable, including but not limited to:

1) HLA-matched, crossmatch-compatible, HLA antigen-negative, and HPA antigen-negative platelets.
2) The use of cold stored platelets.*

***FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding When Conventional Platelets**

Are Not Available or Their Use Is Not Practical (June 2023).

The committee added the reference to the FDA guidance surrounding the use of cold stored platelets for completeness.

5.30 Rh Immune Globulin

The transfusion service shall have a policy for Rh Immune Globulin prophylaxis for Rh-negative patients who have been exposed to Rh-positive red cells. The results of **serologic** weak D testing and/or *RHD* genotyping, if performed, shall be evaluated when determining Rh Immune Globulin prophylaxis.

The committee added the term "serologic" to the standard to mirror edits to other standards. The intent of the standard has not changed.

5.30.2 Individuals who are pregnant or who have been pregnant recently shall be considered for Rh Immune Globulin administration when all of the following apply:

1) The individual's test for D antigen is negative. A **serologic** test for weak Dis optional.
2) The individual is not known to be actively immunized to the D antigen.
3) The RhD type of the fetus/neonate is unknown, or the type of the fetus/neonate is positive when tested for D or **serologic** weak D. **Serologic** weak D testing is required when the **initial** test for D is negative.

The committee added the term "serologic" to the standard to mirror edits to other standards. The intent of the standard has not changed.

~~**Reference Standard 5.1.9A—Requirements for Storage, Transportation, and Expiration1**~~

Reference Standard 5.1.9A—Requirements for Storage, Transportation, and Expiration of Cellular Components[1]

Reference Standard 5.1.9B—Requirements for Storage, Transportation, and Expiration of Acellular Components[1, 2]

Reference Standard 5.1.9C—Requirements for Storage, Transportation, and Expiration of Recovered Plasma, Tissue, and Derivatives[1]

The committee elected to divide Reference Standard 5.1.9A into three separate reference standards to allow for readability and to ensure that all like products are maintained on the same row with expanded columns.

The edit of the original reference standard also included a division of the reference standard into three new reference standards, new 5.1.9A focused on cellular components (whole blood, RBCs, platelets, etc.), new reference standard 5.1.9B focused on acellular components (fresh frozen plasma, thawed plasma, plasma pathogen reduced, etc.) and reference standard 5.1.9C (recovered plasma, tissue and derivatives). Along with the changes cited above, reference standards 5.1.8A and 5.1.8B includes columns expanded beyond storage, transport and expiration. These columns still exist, however specific entries within expiration to include leukoreduction, and irradiation recognizing the specific components that previously had appeared as separate rows. The changes to the reference standards are included below.

Reference Standard 5.1.9A—Requirements for Storage, Transportation, and Expiration of Cellular Components[1]

Item #	Component	Storage	Transport[2]	Expiration[3, 4]			Modifications			
					Leukoreduced	Irradiated	Expiration[5]	Storage	Transport	Additional Criteria
2	Red Blood Cells (RBCs)	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-	Same	Original expiration or 28 days from date of irradiation, whichever is sooner **ACD-A/ADSOL**	Washed: 24 hours **Rejuvenated:** CPD, CPDA-1: 24 hours **Deglycer**	1-6 C	1-10 C	AS-1: freeze after rejuvenated

				1: 35 days Additive solution: 42 days Open system: 24		**units irradiated at ≥3000cGY, 28 days from date of collection**	**olize dand Rejuvenated Deglycerolized:** Open system: 24 hours Closed system: 14 days			

				hours						

The addition in bold has been included to mirror the addition of standard 5.7.3.2.1.

Reference Standard 5.1.9A—Requirements for Storage, Transportation, and Expiration of Cellular Components[1]

Item #	Component	Storage	Transport[2]	Expiration[3, 4]			Modifications			
					Leukoreduced	Irradiated	Expiration[5]	Storage	Transport	Additional Criteria
4	**Pooled Platelets (in a closed system using the buffy coat method)**	**20-24 C with continuous gentle agitation[8]**	**As close as possible to 20-24 C[9] Maximum time witho**	**7 days**		**No change from original expiration date**				

			ut agitation: 30 hours							

Entry #4 is new to this edition and is given its own row due to the fact that it is new and to highlight the addition. Following the comment period, if the membership approves of its inclusion, it will be potentially included in row 3.
The addition of buffy coat platelets was included for completeness and in recognition of the fact that many member facilities are using these products and that the requirements surrounding them exist and are being followed.

Reference Standard 5.1.9A—Requirements for Storage, Transportation, and Expiration of Cellular Components[1]

[4] As defined by the FDA or relevant Competent Authority

The committee added the footnote (which has been applied to the expiration columns) understanding that the majority of the times are set by the FDA, however, recognizing that there are relevant Competent Authorities (Ministries of Health etc) that may have different expiration times.

Reference Standard 5.1.9B—Requirements for Storage, Transportation, and Expiration of Acellular Components[1, 2]

[2] Convalescent plasma product storage, transport, and expiration times conform to manufacturer's written instructions

Convalescent Plasma: Therapeutic convalescent plasma units contain high levels of specific viral/microbe neutralization antibodies sufficient for severe disease reduction. Therapeutic convalescent plasma needs to be distinguished from nontherapeutic plasma, which, while still protective for the donor, will not protect antibody naïve recipients after the 10-to-20-fold dilution that occurs when transfused into a recipient.

The committee added the footnote related to convalescent plasma recognizing that there are future uses of plasma products and should those emerge after the Standards become effective, having a requirement to follow the manufacturers written instructions that emerge with the product.

Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period
8) Platelet Count	**For plateletpheresis collections, the donor platelet count, if available, shall be > 150,000/µL Standard 5.5.3.4.3 applies.**	

As an element of donor qualification appearing in the Standards, the committee felt it appropriate to reproduce the content in the specific donor qualification reference standard for completeness.

Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period
14) Immunizations and Vaccinations	• Receipt of live attenuated viral and bacterial vaccines [German measles (rubella), **Trivalent measles-mumps-rubella (MMR) vaccine quadrivalent MMRV**, Chicken pox/Shingles (varicella zoster), Chikungunya (IXCHIQ)]	- 4 weeks

The committee added the elements in bold to address the trivalent MMR

vaccine to the deferral period associated with measles based on a request from AABB's Transfusion Transmitted Diseases Committee.

Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period
14) Immunizations and Vaccinations	• **Ebola Vaccine**	- **6 weeks**

The committee added the deferral period for the Ebola vaccine for completeness. This was based on a member request.

Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period
15) Relevant Transfusion-Transmitted Infections[7]	Contact with blood of another individual through percutaneous inoculation such as a needlestick or through contact with ~~a donor's~~ **an** open wound or mucous membranes	3 months
	Have had more than one sexual partner in the past 3 months and have had **anal** sex in the past 3 months	3 months[4]

The committee updated the entries to row 15 for clarity. The intents of the standards have not changed.

6.0 Documents and Records

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

***21 CFR 606.160, 42 CFR 493.1105**

For completeness, the CFRs have been added.

7.3.4.2 When the transfusion is discontinued, the following shall be performed immediately:

2) The recipient's physician **or authorized health professional** shall be notified.

7.3.5.3 Interpretation of the evaluation shall be recorded in the patient's medical record and, if suggestive of hemolysis, bacterial contamination, pulmonary reactions, or other serious adverse event related to transfusion, the interpretation shall be reported to the patient's physician **or authorized health professional** immediately. Standard 7.3.5.4 applies.

7.3.6 Delayed Transfusion Reactions (Antigen-Antibody Reactions)

If a delayed transfusion reaction is suspected or detected, tests shall be performed to determine the cause. The results of the evaluation shall be reported to the patient's physician **or authorized health professional** and recorded in the patient's medical record. Standard 7.3.5.4 applies.

For completeness, the committee added the clause in bold to these standards recognizing that there are instances where an individual contacted that is not the recipient's physician due to the need to contact an individual immediately.

8.5 Utilization Review

Transfusing facilities shall have a peer-review program that monitors and addresses transfusion practices for all categories of blood and blood components. The following shall be monitored:

7) Appropriateness of use, including the use of group O **Rh(D)–**

positive and Rh(D)-negative **Whole Blood**, RBCs, and group AB plasma.

The committee edited the standard for completeness.

QSE 1 – Organization

Key Concepts

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

Key Terms

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

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

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

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

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

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

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

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

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.

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

1. Organization

1.0 Organization

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

1.1 Executive Management

The organization shall have a defined executive management. Executive management shall have:

1) Responsibility and authority for the quality system and operations.
2) Responsibility for compliance with these BB/TS Standards and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
3) Authority to establish or make changes to the quality system.

1.1.1 Medical Director Qualifications and Responsibilities

The blood bank or transfusion service (hereinafter referred to as the BB/TS) shall have a medical director who is a licensed physician, qualified by training, experience, and facility-defined relevant continuing education in activities required by these *BB/TS Standards* for which the facility is accredited. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedures—including those that pertain to laboratory personnel, operations, quality, and test performance—and for the consultative and support services that relate to the care and safety of donors and/or transfusion recipients. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.*

*21 CFR 630.3(i), 42 CFR 493.1251, 42 CFR 493.1407, and 42 CFR 493.1445.

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

1.2 Quality System

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

1.2.1 Quality Representative

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

1.2.2 Management Reviews

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

1.3 Policies, Processes, and Procedures

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

1.3.1 The medical director and/or laboratory director (as applicable) shall approve all medical and technical policies, processes, and procedures. Standard 1.1.1 applies.*

*42 CFR 493.1251(d), 42 CFR 493.1407, and 42 CFR 493.1445.

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

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. Standard 1.1.1 applies.*

*42 CFR 493.1251(d), 42 CFR 493.1407, and 42 CFR 493.1445.

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

1.4 Risk Assessment

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

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

1.5 Operational Continuity

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

1.5.1 The BB/TS shall have a policy to address product inventory shortages.

1.6 Emergency Preparedness

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

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

1.7 Communication of Concerns

The organization shall have a process for personnel to anonymously communicate concerns about quality or safety. Personnel shall be given the option to communicate such concerns either to their organization's executive management, AABB, or both. AABB's contact information shall be readily available to all personnel. Standards 6.1.9 and 9.1 apply.

1.8 Customer Focus

Executive management shall identify the organization's customers and their needs and expectations for products or services. Standard 4.2 applies.

1.9 Facility Status Changes

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

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

1.9.2 Staffing Changes

The organization shall communicate to AABB in electronic or written format all initial appointments and changes for the medical director within 30 days of appointment.

1.10 Unanticipated Event Notification

Within 30 days, the organization shall notify AABB of the discovery of an event that has, is, or is likely to cause serious injury, harm, or death to an individual resulting from deviation(s) related to the scope of these *BB/TS Standards*.

Excerpt of Reference Standard 6.2.9A Relevant to Organization

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

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

QSE 2 – Resources

Key Concepts

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

Key Terms

Competence: An individual's demonstrated ability to apply knowledge and skills needed to perform 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 BB/TS Standards.

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

*21 CFR 606.20(b).

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 BB/TS 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.†

†42 CFR 493.1403, 42 CFR 493.1405, 42 CFR 493.1407(a), 42 CFR 493.1421, 42 CFR 493.1441, and 42 CFR 493.1487.

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

2.1.3 Training
The organization shall provide training for personnel performing critical tasks.

2.1.3.1 The organization shall ensure that personnel are evaluated following training to demonstrate the skills necessary to perform

critical tasks and are deemed competent.

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

‡42 CFR 493.1235 and 42 CFR 493.1451(b)(8)(9).

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

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

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. Standard 2.1.2 applies.

2.1.6 Continuing Education
The organization shall ensure that continuing education requirements applicable to these BB/TS Standards are met when applicable.

2.1.6.1 The organization shall establish minimum continuing education requirements for employees performing or overseeing critical tasks.

Excerpt of Record Retention Standard 6.2.9A Relevant to Resources

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

	review critical tasks					
2.1.6	Continuing education requirements	X	X	X	X	5

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

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

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.

3.1 Equipment Specifications
Equipment specifications shall be defined before purchase.

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

3.2.1 Installation Qualification
Equipment shall be installed per manufacturer specifications.

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

*FDA Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility (April 2013).

3.2.3 Performance Qualification
Equipment shall perform as expected for its intended use.

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

✎3.4 Unique Identification of Equipment
Equipment shall have unique identification. Standard 5.1.8.2 applies.

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. Standard 5.1.2 applies.

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

3.5.3 The organization shall:

1) Define cleaning and sanitization methods and intervals for equipment.
2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out.
3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel.

4) Monitor equipment to ensure that defined parameters are maintained.
5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use.
6) Ensure that all equipment maintenance and repairs are performed by qualified individuals and in accordance with the manufacturer's recommendations.

3.5.4 Investigation and Follow-up

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

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

Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

*21 CFR 803.30.

3.5.4.1 When a nonconformance cannot be attributed to a specific piece of equipment, all potentially involved pieces of equipment shall be evaluated to determine if expected performance criteria are met based on the manufacturer's written instructions.

✎3.6 Information Systems

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

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

†21 CFR 820.30.
FDA Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Device Software Functions (June, 2023).

FDA Final Guidance for Industry and FDA Staff: General Principles of Software Validation (January 11, 2002).

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

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

3.6.3 The organization shall support the management of information systems.

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

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

3.7 Technology Infrastructure
The organization shall have an ongoing program to ensure that critical technology and communication infrastructures function as intended, including risk-based monitoring or testing at organization defined intervals. Standards 1.4, 1.5, and 1.6 apply.

3.8 Storage Devices for Blood, Blood Components, Reagents, Tissue, and Derivatives

3.8.1 Storage devices shall have the capacity and design to ensure that the proper temperature is maintained.

3.8.2 Storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored. Standard 5.1.9.1.3 applies.

3.8.2.1 The organization shall perform quality control testing

of automated temperature recording devices at facility defined intervals to verify accuracy of recordings. Standards 3.5.1 and 5.1.2 apply.

✎ **3.8.3** If storage devices utilize liquid nitrogen, either liquid nitrogen levels or temperature shall be monitored.

✎**3.9 Storage Device Alarm Systems**
Storage devices for blood, blood components, tissue, derivatives, and reagents shall have alarms and shall conform to the following standards:

3.9.1 The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, tissue, derivatives, or reagents reach unacceptable conditions.

3.9.1.1 The organization shall perform quality control testing of alarm activations at facility defined intervals to verify alarms are activated when the temperature sensing device/probe detects an unacceptable temperature. Standards 3.5.1 and 5.1.2 apply.

3.9.2 The alarm system in liquid nitrogen freezers shall be activated before the contained liquid nitrogen reaches an unacceptable level.

3.9.3 Activation of the alarm shall initiate a process for immediate action, investigation, and appropriate corrective action. Standard 5.1.2 applies.

✎**3.10 Bedside Warming Devices for Blood and Blood Components**
Warming devices shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to blood or blood components.

3.10.1 The organization shall perform quality control testing of the warning system at facility defined intervals to verify warnings

are activated when the temperature sensing device detects an unacceptable temperature. Standards 3.5.1 and 5.1.2 apply.

Excerpt of Record Retention Standard 6.2.9A Relevant to Equipment

Standard	Record to Be Maintained	Donor/ Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years)[1]
3.2	Equipment qualification	X	X	X	X	10 years after retirement of the equipment
3.4	Unique identification of equipment	X	X	X	X	5
3.5.1	Equipment calibration activities	X	X	X	X	5
3.5.2	Equipment found to be out of calibration	X	X	X	X	5
3.5.3	Equipment monitoring, maintenance, calibration, and repair	X	X	X	X	5
3.6	Implementation and modification of software, hardware, or databases	X	X	X	X	2 years after retirement of system

3.7	Monitoring or technology infrastructure	X	X	X	X	10
3.8.2	Temperature monitoring of refrigerators, freezers, and platelet incubators	X	X	X	X	10
3.8.3	Monitoring of liquid nitrogen levels or temperature	X	X	X	N/A	10
3.9	Alarm system check	X	X	X	X	10
3.10	Warming devices shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to blood or blood components.	X	X	N/A	N/A	10

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

QSE 4 – Suppliers and Customers

Key Concepts

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

Key Terms

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

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

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

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.

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.

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, are approved, and meet supplier and customer expectations. Standard 1.8 applies.

✎ **4.1 Supplier Qualification**
The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.

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

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

4.1.3 Testing or services required by these *BB/TS Standards* shall be performed in a laboratory accredited by the AABB or equivalent accrediting body.

4.1.3.1 Laboratory testing shall be performed in a laboratory certified by the Centers for Medicare and Medicaid Services (CMS) and registered with the Food and Drug Administration (FDA), if indicated by 21 CFR 610.40(f).

4.1.3.2 Testing performed by facilities outside the United States shall be carried out by a laboratory authorized as a testing center by the Competent Authority.

✎ **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 agreement continue to meet requirements.

4.2.2 Changes to agreements shall be communicated to affected parties.

4.2.3 The responsibilities for activities covered by these BB/TS Standards when more than one organization is involved shall be specified by 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 Each container used for collection, preservation, and storage of blood and blood components shall be inspected to ensure that it is intact. The label shall be complete, affixed, and legible.

4.3.2 Critical materials shall meet specified requirements.

4.3.2.1 All containers and solutions used for collection, processing, preservation, and storage and all reagents used for required tests on blood samples shall meet or exceed applicable FDA or relevant Competent Authority
criteria.*

*21 CFR 660, 21 CFR 606.65, 21 CFR 640.2(b), and 21 CFR 640.4(d).

Excerpt of Record Retention Standard 6.2.9A Relevant to Suppliers and Customers

Standard	Record to Be Maintained	Donor/ Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years)[1]
4.1	Evaluation and participation in selection of suppliers	X	X	X	X	5
4.2	Agreements	X	X	X	X	5
4.2.1	Agreement review	X	X	X	X	5
4.2.3	Agreements concerning activities involving more than one organization	X	X	X	X	5
4.3	Inspection of incoming critical materials	X	X	X	X	10
4.3.2.1	Incoming containers, solutions, and reagents meet or exceed applicable FDA criteria	X	X	X	X	10

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

QSE 5 – Process Control

Key Concepts

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

Key Terms

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

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

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 (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.

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.

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 shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated. Standard 2.1.3 applies.*

*42 CFR 493.1253

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. Standard 2.1.2 applies.

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

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

5.1.2.4 The laboratory shall evaluate the comparability of test

results obtained using different methods, instruments, and if applicable, testing sites. This shall be performed twice annually.*

*42 CFR 493.1281.

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.3 Process Planning

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

1) Evaluation of accreditation, regulatory, and legal requirements related to the new or changed process, product, or service.
2) Review of current available knowledge (eg, review of medical practice and/or literature).
3) Evaluation of risk.
4) Identification of affected internal and external parties and mechanism to communicate relevant information.
5) Identification of performance measures applicable to the new or changed process, product, or service.
6) Evaluation of resource requirements.
7) Evaluation of the impact of the new or changed process, product, or service on other organization (or program) processes.
8) Evaluation of the need to create or revise documents for the new or changed process, product, or service.
9) Review and approval of the output of process development and design activities (eg, pilot or scale-up study results, process flow charts, procedures, data forms).

10) Evaluation of the extent and scope of process validation or revalidation depending on the level of risk and impact of the new or changed products or services.

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

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

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

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

5.1.6 Use of Materials
All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements. Standard 4.3 applies.

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

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

5.1.8.1 Process or Procedure Steps

For each critical step in collection, processing, compatibility testing, and transportation of blood, blood components, tissue, and derivatives, there shall be a mechanism to identify who performed the step and when it was performed. Standard 6.2.2 applies.

5.1.8.2 Traceability

The BB/TS shall ensure that all blood, blood components, tissue, derivatives, and critical materials used in their processing, as well as laboratory samples and donor and patient records, are identified and traceable.

5.1.8.3 General Labeling Requirements

The BB/TS shall have a labeling process. This process shall include all steps taken to:

1) Identify the original unit, any components, and any component modifications.
2) Complete the required reviews.
3) Attach the appropriate labels.

Standard 5.9 applies.

5.1.8.3.1 The following requirements shall apply:

1) Labeling of blood and blood component containers shall be in conformance with the most recent version of the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128.*

*FDA Guidance for Industry: Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels (April 2024).

United States Industry Consensus

Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128 (current published version).

2) The original label and added portions of the label shall be affixed or attached to the container and shall be in clear, eye-readable type. Additionally, the ABO/Rh, donation identification number, product code, and facility identification shall be in machine-readable format.† The label shall include the applicable items required in Reference Standard 5.1.8A, Requirements for Labeling Blood and Blood Components.
†21 CFR 606.121(c)(13).

3) Handwritten additions or changes shall be legible and applied with permanent, moisture-proof ink.

4) All modifications to component labels shall follow policies, processes, and procedures.

5) If a component is modified and new labels are applied, the labeling process shall include a method to ensure the accuracy of all labels, including the donation identification number, ABO/Rh, expiration date (as appropriate), and product name and code.‡
‡21 CFR 606.121(b).

6) The labeling process shall include a second check to ensure the accuracy of affixed labels, including the correct donation identification number, ABO/Rh, expiration date, and product name and code.

5.1.8.4 Donor Identification

Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.*

*21 CFR 606.160(b)(l)(vii)
21 CFR 630.10(g)(1)

5.1.8.5 Unit or Tissue Identification

The labeling system shall make it possible to trace any unit of blood, blood component (including those in a pool), or tissue from source to final disposition. The system shall allow recheck of records applying to the specific unit or tissue, including investigation of reported adverse events.

5.1.8.5.1 A unique identification shall be affixed by the collecting or pooling facility to each unit of blood, blood component, and attached container, or a tissue or lot. This identification shall not be obscured, altered, or removed by facilities that subsequently handle the unit.

5.1.8.5.2 If a transfusing facility or an intermediate shipping facility receives blood or a blood component labeled with a non-ISBT-128 donation identification number, an ISBT 128 Donation Identification Number shall be assigned. The label shall be affixed to the container and shall identify the facility assigning the identification. Standard 5.1.8.2 applies.

5.1.8.5.3 A maximum of two donation identification numbers, one of which being that of the original collecting facility, may be visible on a blood or product container. All other donation identification numbers shall be removed, obscured, or obliterated. This requirement does not preclude the use of a

patient identification number.

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. Reference Standards 5.1.9A, Requirements for Storage, Transportation, and Expiration of Cellular Components, 5.1.9B, Requirements for Storage, Transportation, and Expiration of Acellular Components, and Reference Standard 5.1.9C, Requirements for Storage, Transportation, and Expiration of Recovered Plasma, Tissue and Derivatives apply.

5.1.9.1 The BB/TS shall ensure the appropriate segregation of all stored products, including autologous units.

5.1.9.2 Tissue, derivatives, and reagents shall be stored in accordance with the manufacturer's written instructions.

5.1.9.3 Storage areas and devices for blood and blood components shall be monitored:

5.1.9.3.1 Electronic storage devices for blood and blood components shall be monitored continuously and the temperature recorded at least every 4 hours. Standard 1.5 applies.

5.1.9.3.2 Temporary storage containers shall be qualified and validated to store blood, and blood components to ensure that they maintain temperature within the acceptable range for the defined duration of storage.

5.1.9.3.3 For open storage areas, the ambient temperature shall be monitored and recorded at least every 4 hours.

5.1.9.4 Access to storage areas and authorization to remove contents shall be controlled.

5.1.9.5 Transportation
Blood, blood components, tissue,* and derivatives shall be inspected immediately before packing for shipment, and shipped for transfusion or transplantation only if specified requirements are met.

*21 CFR 1271.3(b), 21 CFR 1271.3(bb), and 21 CFR 1271.15(d).

5.1.9.5.1 Containers (eg, portable coolers) shall be qualified and validated to transport blood, blood components, tissues, and derivatives to ensure that they maintain temperatures within the acceptable range for the defined duration of transport or shipping.

5.1.10 Proficiency Testing Program
The BB/TS shall participate in a proficiency testing program, if available, for testing regulated by the Clinical Laboratory Improvement Amendments and performed by the facility.† Results shall be reviewed, and when expected results are not achieved, investigation and corrective action shall be taken where appropriate.

†42 CFR 493.1236.
42 CFR 493.857
42 CFR 493.959

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.10.1 Laboratories shall ensure that no interlaboratory communications pertaining to proficiency test events

occur until after the submission deadline.‡

‡42 CFR 493.801(b)(4).

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.10.2 The laboratory shall ensure that no portion of a proficiency testing sample is sent to another laboratory for analysis.*

*42 CFR 493.801(b)(5).

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.10.3 Any laboratory that receives a proficiency testing sample from another laboratory for testing shall notify CMS of the receipt of the sample.*

*42 CFR 493.801(b)(5).

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.10.4 When a CMS-approved program is not available, there shall be a system for determining the accuracy and reliability of test results.

5.1.10.5 Proficiency Testing for Facilities Not Subject to US

Regulation
Facilities not subject to US regulation shall participate in an external proficiency testing program, if available, for each analyte.

5.1.10.5.1 When an external proficiency testing program is not available, there shall be a system for determining the accuracy and reliability of test results.

5.1.10.5.2 Proficiency testing shall include comparison of test results from an outside laboratory.

5.1.11 Sterility
Aseptic methods shall be employed to minimize the risk of microbial contamination of blood and blood components. Equipment and solutions that come into direct contact with blood or blood components shall be sterile and pyrogen-free. Single-use equipment and a closed system of product processing shall be used whenever possible.

5.1.11.1 The BB/TS shall have methods to limit introduction of bacteria during collection, processing, and sampling. Standard 5.6.2 applies.

5.1.11.2 The BB/TS shall have methods to detect bacteria or use pathogen reduction technology in all platelet components stored at 20 to 24 C.†

†21 CFR 606.145.

FDA Guidance for Industry: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (updated December 2020).

5.1.11.2.1 Detection methods shall use devices cleared or approved by the FDA or

relevant Competent Authority.

5.1.11.2.2 Pathogen reduction technologies shall be cleared or approved by the FDA or relevant Competent Authority.

5.1.11.3 When a true-positive culture result is obtained and a sample is available, additional testing to identify the organism shall be performed. Additional testing and follow-up shall be defined. Standards 5.2.4 and 7.2 to 7.2.4.2 apply.

Collection and Production of Components

5.2 Information, Consents, and Notifications

5.2.1 Donor Education

The blood bank shall ensure that the following requirements are met for all donors before donation:

1) Donors are given educational materials regarding the donation process.
2) Donors are given educational materials regarding relevant transfusion-transmitted infections.*
   *21 CFR 630.10.
   FDA Guidance for Industry: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (May 2023).
3) Donors are informed of the importance of providing accurate information.
4) Donors are informed that they should not donate blood in order to obtain infectious disease testing services and that there are circumstances in which testing is not performed.
5) Donors are given educational materials regarding the risks of postdonation iron deficiency and mitigation strategies.
6) Donors are informed of the importance of withdrawing themselves from the donation process if

they believe that their blood is not suitable for transfusion.†

†FDA Guidance for Industry: Recommendations for Assessment of Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus (January 2017).

7) Donors acknowledge that the educational materials have been read.

5.2.2 When parental permission is required, the collection facility shall ensure information is provided to parent(s) or legally authorized representative(s) of the donor concerning the donation process and potential adverse effects related to the donation. Standard 5.2.1, #5 applies.

5.2.3 Donor Consent

The consent of all donors shall be obtained on the day of donation and before collection. Elements of the donation procedure shall be explained to the prospective donor in understandable terms. The explanation shall include information about risks of the procedure, tests performed to reduce the risks of relevant transfusion-transmitted infections to the allogeneic recipient, and requirements to report donor information, including test results, to state or local health departments. The donor shall have an opportunity to ask questions and have them answered and to give or refuse consent for donation. In the case of a minor or a legally incompetent adult, consent shall be addressed in accordance with applicable law.

5.2.4 Donor Notification of Abnormal Findings and Test Results

The medical director shall ensure notification to all donors (including autologous donors) of any medically significant abnormality detected during the predonation evaluation or as a result of laboratory testing or recipient follow-up. In the case of autologous donors, the referring physician shall also be notified. Appropriate education, counseling, and referral shall be offered.*

*21 CFR 630.40 and 21 CFR 630.10(g)(1).

5.3 Care of Donors

5.3.1 The collection facility shall ensure that the donor qualification process is private† and confidential.

†21 CFR 606.40(a)(1).

5.3.2 The donor shall be observed during the donation and for a length of time, thereafter, as defined by the facility's policies and procedures.

5.3.2.1 The collection facility shall treat donor adverse events and provide emergency medical care as necessary.

5.3.2.1.1 Immediate assistance and the necessary equipment and supplies shall be available. Standard 7.3.3 applies.

5.3.3 Postphlebotomy Instructions
The collection facility shall provide the donor with written instructions for postphlebotomy care, and actions to take concerning adverse events that may occur after donation. Standard 7.3.3. applies.

5.3.4 Postdonation Information
The collection facility shall provide donors with written instructions on how to notify the collection facility with information relevant to the safety of the donation.

5.3.4.1 The facility shall manage postdonation information about a donor's eligibility received from the donor or a third party.

5.4 Donor Qualification

5.4.1 Allogeneic Donor Qualification

The prospective donor shall meet the donor qualification requirements contained in Reference Standard 5.4.1A, Requirements for Allogeneic Donor Qualification.

5.4.1.1 If the donor is deferred or if the donation is determined to be unsuitable, the donor's record will identify the donor as ineligible to donate and the donor will be notified of the reason for deferral.

5.4.1.2 Plasma, Apheresis Platelets, and Whole Blood for allogeneic transfusion shall be from donors who have not been pregnant, or who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.

5.4.1.3 Donors implicated in a transfusion-related acute lung injury (TRALI) event or associated with multiple events of TRALI shall be evaluated regarding their continued eligibility to donate.

5.4.2 Protection of the Recipient

On the day of donation and before collection, the prospective donor's history shall be evaluated and the donor examined to exclude donation by a person with evidence of disease transmissible by blood transfusion or other conditions thought to compromise the suitability of the blood or blood component. Reference Standard 5.4.1A, Requirements for Allogeneic Donor Qualification, applies.

5.4.2.1 If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, this information shall be obtained per FDA or relevant Competent Authority regulations or within 72 hours of collection.

5.4.3 Protection of the Donor

The collection facility shall minimize the adverse effects of donation.

5.4.3.1 On the day of donation and before collection, the

prospective donor's history shall be evaluated and the donor examined to minimize the risk of harm to the donor.†

†21 CFR 630.10(a).

5.4.3.2 The collection facility shall mitigate the risk of adverse reactions in young donors.

5.4.3.3 The collection facility shall ensure that donor red cell losses for all donations and samples collected during any rolling 12-month period do not exceed the loss of red cells permitted for whole blood collections.‡

‡FDA Memorandum to All Registered Blood and Source Plasma Establishments: Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis (December 4, 1995).

FDA Guidance for Industry: Technical Correction: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods (February 2001).

FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).

5.4.4 Autologous Donor Qualification

Because of the special circumstances related to autologous blood transfusion, rigid criteria for donor selection are not required. In situations where requirements for allogeneic donor selection or collection are not applied, alternate requirements shall be defined and documented by the medical director. Standard 1.3.2 applies. Autologous donor qualification requirements shall include:

5.4.4.1 A medical order from the patient's physician or other authorized health professional to collect blood for

autologous use.

5.4.4.2 The hemoglobin concentration of the autologous donor's blood shall be ≥11 g/dL, or the hematocrit shall be ≥33%.

5.4.4.3 All blood collections from the autologous donor shall be completed more than 72 hours before the time of anticipated surgery or transfusion.

5.4.4.4 Autologous donors shall be deferred when they have a clinical condition for which there is a risk of bacteremia.

5.4.4.5 The unit shall be reserved for autologous transfusion.

5.5 Additional Apheresis Donor Qualification Requirements

5.5.1 Selection of Donors

With the exception of the donation interval, the standards that apply to allogeneic donor qualification shall apply to the selection of apheresis donors. Donors who do not meet allogeneic donor requirements shall undergo apheresis only when the components are expected to be of particular value to an intended recipient and only when approved by the medical director.

5.5.2 Automated Plasmapheresis Donation

5.5.2.1 Infrequent Plasmapheresis Program

In an "infrequent" plasmapheresis program, donors shall undergo plasmapheresis no more frequently than once every 4 weeks.*

*21 CFR 630.3(e).

5.5.2.2 Frequent Plasmapheresis Program

In a "frequent" plasmapheresis program, in which plasma is donated more frequently than once every 4

weeks, the FDA requirements for donor testing and evaluation by a physical exam shall be followed.† †21 CFR 630.10, 21 CFR 630.15(b), and 21 CFR 640.65.

5.5.2.2.1 Collection shall occur a maximum of two times in a 7-day period, and the interval between two collections shall be at least 2 days.*

*FDA Memorandum to All Registered Blood Establishments: Volume Limits for Automated Collection of Source Plasma (November 4, 1992).

5.5.2.3 Plasmapheresis donors shall be weighed at each donation.

5.5.2.4 A plasma product derived from collection of a platelet product stored in platelet additive solution is not considered a concurrently collected plasma product, and therefore shall not affect the determination of plasmapheresis frequency, when the plasma volume derived from the collection is equivalent to the volume of additive solution added.

5.5.3 Automated Cytapheresis Donations

5.5.3.1 The interval between procedures for platelet, granulocyte, and leukocyte donors shall be at least 2 days, and the total volume of plasma collected shall not exceed the volume of plasma cleared by the FDA for the instrument. A donor shall undergo the procedure a maximum of two times in a 7-day period. When greater than or equal to 6×10^{11} platelet collection is performed, the donor shall undergo the procedure a maximum of once in 7 days. Procedures shall not exceed 24 times in a rolling 12-month period, except in unusual circumstances as determined

by the medical director. Standard 5.4.3.3 applies.†

†21 CFR 640.21(e). FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).

5.5.3.2 The interval between a Whole Blood donation and a subsequent cytapheresis procedure shall be at least 8 weeks, unless the extracorporeal red cell volume of the apheresis machine is less than 100 mL, in which case the interval shall be at least 2 calendar days. Standards 5.4.3.3 and 5.5.3.1 apply.

5.5.3.3 If it becomes impossible to return the donor's red cells during apheresis, at least 8 weeks shall elapse before a subsequent apheresis procedure, unless the red cell loss was <200 mL. Standards 5.4.3.3 and 5.5.3.1 apply.*

*FDA Guidance for Industry: Technical Correction: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods (January 2001, Technical Correction February 2001).

5.5.3.4 Plateletpheresis Donors
A blood sample shall be collected before each procedure for the determination of the donor's platelet count. If the result is available, it shall be used as the platelet count to qualify the donor.

5.5.3.4.1 If the result of the predonation platelet count is not available, the donor's most recent platelet count may be used to qualify the donor. 9.0×10^{11} or more platelets may not be collected from first-time donors unless a qualifying platelet count is obtained or confirmed from a sample collected before donation.†

†21 CFR 640.21.

5.5.3.4.2 The results of platelet counts performed before or after a procedure may be used to qualify the donor for the next procedure.

5.5.3.4.3 Plateletpheresis donors with a platelet count of <150,000/µL shall be deferred from plateletpheresis donation until a subsequent platelet count is at least 150,000/µL.‡

‡FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).

5.5.3.5 2-Unit Red Blood Cell Apheresis Donors The donor of a 2-unit Red Blood Cell apheresis collection shall meet specific hemoglobin/hematocrit and weight requirements for the device cleared by the FDA.§

§FDA Guidance for Industry: Technical Correction: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods (January 2001; technical correction February 13, 2001).

5.5.3.5.1 The donor shall be deferred from all donations for 16 weeks following a 2-unit Red Blood Cell apheresis collection.

5.5.3.5.2 2-Unit Red Blood Cell Collection

The volume of red cells removed from apheresis donors shall not exceed a volume predicted to result in a donor hematocrit of <30% or a hemoglobin <10 g/dL after volume replacement.

5.5.4 Multiple Concurrent Apheresis Collection
The donor eligibility criteria and interval between donations shall meet FDA or relevant Competent Authority criteria. The combined volume limits of red cells and plasma removed from the donor shall follow criteria for the FDA-cleared or relevant Competent-Authority-approved device used.

5.6 Blood Collection

5.6.1 Methods
Blood shall be collected into a sterile closed system.

5.6.2 Protection against Contamination
The venipuncture site shall be prepared so as to minimize risk of bacterial contamination.

5.6.2.1 Blood collection containers with draw line (inlet) diversion pouches shall be used for any collection of platelets, including whole blood from which platelets are made.

5.6.3 Samples for Laboratory Tests

5.6.3.1 At the time of collection or component preparation, the integral donor tubing shall be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent compatibility testing.

5.6.3.1.1 The integral donor tubing segments shall be separable from the container

without breaking the sterility of the container.

5.6.3.2 Tubes for laboratory tests shall be properly labeled before the donation begins, shall accompany the blood container, and shall be reidentified with the blood container during or after filling and before the tubes and container(s) are separated.

5.6.3.3 Storage of samples before testing shall meet the requirements stated in the manufacturer's written instructions for the tests being performed.

5.6.4 Ratio of Blood to Anticoagulant/Preservative Solution
The volume of blood to be collected shall be proportional to the amount of anticoagulant/preservative solution for the collection.

5.6.5 Temperature during Transport from Collection Site to Processing Site
If blood is to be transported from the collection site, it shall be placed in a qualified container having sufficient refrigeration capacity to cool the blood continuously toward a temperature range of 1 to 10 C until it arrives at the processing site.

5.6.5.1 Whole Blood and Apheresis Platelets intended for room temperature processing shall be transported in a manner intended to cool the blood and Apheresis Platelets toward a temperature range of 20 to 24 C.

5.6.5.2 Apheresis platelets intended for cold storage without pathogen reduction shall be placed at 1 to 6 C within 4 hours from the end of collection.*

*FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding When Conventional Platelets Are Not Available or Their

Use Is Not Practical (June 2023).

5.6.5.2.1 If the apheresis product intended for cold storage without pathogen reduction will arrive at the processing facility within 4 hours of collection, the product may be transported in a manner intended to cool the Apheresis Platelets toward a temperature range of 20 to 24 C.

5.6.5.2.2 If the apheresis product intended for cold storage without pathogen reduction will not arrive at the processing facility within 4 hours of collection, the product shall be placed at 1 to 6 C within 4 hours from the end of collection.

5.6.5.2.2.1 If the apheresis product intended for cold storage without pathogen reduction has been placed at 1 to 6 C, it shall be transported in a qualified container having sufficient refrigeration capacity to maintain a temperature range of 1 to 10 C.

5.6.6 Additional Apheresis Collection Requirements

5.6.6.1 The process used in performing a phlebotomy and processing the blood shall be designed to ensure the safety of any reinfusion to the donor.

5.6.6.2 Leukapheresis Collection
The collection facility shall have criteria for the administration and dose of any ancillary agents used.

5.6.6.2.1 Drugs to facilitate leukapheresis shall not be used for donors whose medical history suggests that such drugs may exacerbate a medical condition. The collection facility shall have a policy defining the maximal cumulative dose of any sedimenting agent that will be administered to a donor within a given time.

5.6.7 Therapeutic Phlebotomy and Apheresis
Therapeutic phlebotomy and apheresis shall be performed only when ordered by an authorized health professional.

5.6.7.1 Units drawn as therapeutic phlebotomies shall not be used for allogeneic transfusion unless the individual undergoing the therapeutic phlebotomy meets all allogeneic donor criteria with the exception of donation interval.

5.6.7.1.1 The container label shall conspicuously state the disease or condition of the donor that necessitated phlebotomy. However, labeling for the disease or condition is not required if both of the following conditions are met:

1) The phlebotomy is for hereditary hemochromatosis or for a condition for which the collection procedure has been approved by the FDA or relevant Competent Authority.*
*21 CFR 630.15(a)(2).
2) The phlebotomy is performed for no charge for all individuals with that disease or condition.

5.7 Preparation and Processing of Components

Methods that ensure the quality and safety of components, including aliquots and pooled components, shall be employed.

5.7.1 Seal

If the seal is broken during processing, components shall be considered to have been prepared in an open system, and expiration times specified for such components in Reference Standards 5.1.9A, Requirements for Storage, Transportation, and Expiration of Cellular Components, 5.1.9B, Requirements for Storage, Transportation, and Expiration of Acellular Components, and Reference Standard 5.1.9C, Requirements for Storage, Transportation, and Expiration of Recovered Plasma, Tissue and Derivatives apply.

5.7.2 Weld

If a sterile connection device is used to produce sterile welds between two pieces of compatible tubing, the following requirements shall apply:

5.7.2.1 The weld shall be inspected for completeness.

5.7.2.1.1 If the integrity of the weld is complete, and the container in use is approved for storage of the specific blood component by the FDA or relevant Competent Authority, then the expiration date/time before welding shall apply. Standard 5.1.6 applies.

5.7.2.1.1.1 If the container in use is not approved for storage of the component by the FDA or relevant Competent Authority, the component shall have an expiration time of

4 hours or as defined and validated by the facility.

5.7.2.1.2 If the integrity of the weld is incomplete, the container shall be considered an open system and may be sealed and used with a component expiration as indicated in Reference Standard 5.1.9A, Requirements for Storage, Transportation, and Expiration of Cellular Components, 5.1.9B, Requirements for Storage, Transportation, and Expiration of Acellular Components, and Reference Standard 5.1.9C, Requirements for Storage, Transportation, and Expiration of Recovered Plasma, Tissue and Derivatives.

5.7.3 Methods

5.7.3.1 Leukocyte Reduction

Leukocyte-reduced blood and blood components shall be prepared by a method known to reduce the leukocyte number to $<5 \times 10^6$ for Red Blood Cells and Apheresis or Pooled Platelets and to $<8.3 \times 10^5$ for whole-blood-derived Platelets. Validation and quality control shall demonstrate that >95% of units sampled meet this criterion.*

*FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).

FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012).

5.7.3.2 Irradiation

Irradiated blood and blood components shall be prepared by a method known to ensure that irradiation has occurred. A method shall be used to indicate that irradiation has occurred with each batch. The intended dose of irradiation shall be a minimum of 25 Gy (2500 cGy) delivered to the central portion of the container. The minimum dose at any point in the components shall be 15 Gy (1500 cGy).† Alternate methods shall be demonstrated to be equivalent.

†FDA Memorandum: Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products (July 22, 1993).

5.7.3.2.1 The dose delivery shall be evaluated in accordance with the collection set manufacturer's written instructions concerning irradiation of products and modifications made to expiration date based on the dosimetry results.

5.7.3.2.2 Verification of dose delivery shall be performed using a fully loaded canister as follows:

1) Annually for cesium-137 as a radiation source.
2) Semiannually for cobalt-60 as a radiation source.
3) As recommended by the manufacturer for alternate sources of radiation.
4) Upon installation, major repairs, or relocation of the irradiator.

5.7.3.3 Pooling

For pooled components, the preparing facility shall maintain records of the ABO/Rh, donation

identification number, and collecting facility for each unit in the pool. Standards 5.1.8.5.1, 5.1.8.5.2, and Reference Standard 5.1.8A, Requirements for Labeling Blood and Blood Components, apply.

5.7.4 Preparation of Blood and Blood Components
Reference Standard 5.1.9A, Requirements for Storage, Transportation, and Expiration of Cellular Components, 5.1.9B, Requirements for Storage, Transportation, and Expiration of Acellular Components, and Reference Standard 5.1.9C, Requirements for Storage, Transportation, and Expiration of Recovered Plasma, Tissue and Derivatives applies.

5.7.4.1 WHOLE BLOOD LEUKOCYTES REDUCED
Whole Blood Leukocytes Reduced shall be prepared by a method known to retain at least 85% of the original whole blood content. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. FDA criteria apply.* Standard 5.7.3.1 applies.

*FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012).

5.7.4.2 RED BLOOD CELLS
Red Blood Cells shall be prepared by separating the red cells from the plasma portion of blood.

5.7.4.2.1 Red Blood Cells without additive solutions shall be prepared using a method known to result in a final hematocrit of $\leq$80%.

5.7.4.3 FROZEN RED BLOOD CELLS
Frozen Red Blood Cells shall be prepared by a method known to minimize post-thaw hemolysis.

5.7.4.3.1 Red Blood Cells shall be frozen within 6 days of collection, except when rejuvenated. Rare units may be frozen without

rejuvenation up to the date of expiration.

5.7.4.4 REJUVENATED RED BLOOD CELLS
Rejuvenated Red Blood Cells shall be prepared by following the manufacturer's written instructions. Rejuvenated Red Blood Cells shall be prepared by a method known to restore 2,3-diphosphoglycerate and adenosine triphosphate to normal levels or above. Reference Standard 5.1.9A, Requirements for Storage, Transportation, and Expiration of Cellular Components, applies.

5.7.4.5 DEGLYCEROLIZED RED BLOOD CELLS
Deglycerolized Red Blood Cells shall be prepared by a method known to ensure adequate removal of cryoprotective agents, result in minimal free hemoglobin in the supernatant solution, and yield a mean recovery of $\geq$80% of the preglycerolization red cells following the deglycerolization process.

5.7.4.6 WASHED RED BLOOD CELLS
Washed Red Blood Cells shall be prepared by a method known to ensure that the red cells are washed with a volume of compatible solution that will remove almost all of the plasma.

5.7.4.7 RED BLOOD CELLS LEUKOCYTES REDUCED
Red Blood Cells Leukocytes Reduced shall be prepared by a method known to retain at least 85% of the original red cells. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. FDA criteria apply.* Standard 5.7.3.1 applies.

*FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012).

5.7.4.8 RED BLOOD CELLS LOW VOLUME

When 300 to 404 mL of whole blood is collected into an anticoagulant volume calculated for 450 ± 45 mL or when 333 to 449 mL of whole blood is collected into an anticoagulant volume calculated for 500 ± 50 mL, red cells prepared from the resulting unit shall be labeled Red Blood Cells Low Volume. No other components shall be made from a low volume collection.

5.7.4.9 APHERESIS RED BLOOD CELLS

Apheresis Red Blood Cells shall be prepared by a method known to ensure a mean collection of $\geq$60 g of hemoglobin (or 180 mL red cell volume) per unit. At least 95% of the units sampled shall have >50 g of hemoglobin (or 150 mL red cell volume) per unit. Validation and quality control shall demonstrate that these criteria or the criteria specified in the operator's manual are met.

5.7.4.9.1 APHERESIS RED BLOOD CELLS LEUKOCYTES REDUCED

Apheresis Red Blood Cells Leukocytes Reduced shall be prepared by a method known to ensure a final component containing a mean hemoglobin of $\geq$51 g (or 153 mL cell volume). The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. At least 95% of units sampled shall have >42.5 g of hemoglobin (or 128 mL red cell volume). Validation and quality control shall demonstrate that these criteria or the criteria specified in the operator's manual are met. FDA criteria apply.* Standards 3.3 and 5.7.3.1 apply.

*FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and

Blood Components Intended for Transfusion (September 2012).

5.7.4.10 FRESH FROZEN PLASMA

Fresh Frozen Plasma shall be prepared from a whole blood or apheresis collection and placed at –18 C or colder within the time frame required for the collection, processing, and storage system.

5.7.4.11 PLASMA FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY

Plasma Frozen Within 24 Hours After Phlebotomy shall be prepared from whole blood or apheresis collection. The product prepared from a whole blood collection must be separated and placed at –18 C or colder within 24 hours from whole blood collection. When prepared from an apheresis collection, the product is stored at 1 to 6 C within 8 hours of collection and placed at –18 C or colder within 24 hours of collection.

5.7.4.12 PLASMA FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY HELD AT ROOM TEMPERATURE UP TO 24 HOURS AFTER PHLEBOTOMY

Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy shall be prepared from whole blood or an apheresis collection. The product can be held at room temperature for up to 24 hours after collection and then placed at –18 C or colder.

5.7.4.13 LIQUID PLASMA

Liquid Plasma shall be prepared by a method known to separate the plasma from the cellular components of the blood.

5.7.4.14 THAWED PLASMA

Thawed Plasma shall be prepared from Fresh Frozen Plasma, Plasma Frozen Within 24 Hours After

Phlebotomy, or Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy that has been collected in a closed system.

5.7.4.15 RECOVERED PLASMA

Recovered Plasma shall be prepared from donations originally intended for transfusion.

5.7.4.16 PATHOGEN-REDUCED PLASMA

Pathogen-reduced plasma shall be prepared as per the manufacturer's written instructions.

5.7.4.16.1 Components prepared from pathogen-reduced plasma (including, but not limited to, thawed plasma, cryoprecipitated fibrinogen complex, plasma cryoprecipitate reduced) shall be processed and stored per the manufacturer's written instructions.

5.7.4.17 CRYOPRECIPITATED AHF

Cryoprecipitated AHF shall be prepared from frozen plasma derived from whole blood or apheresis by a method known to separate the cold insoluble precipitate. Validation and quality control shall demonstrate an average content of at least 150 mg of fibrinogen and 80 IU of coagulation Factor VIII per container or unit. In tests performed on prestorage pooled components, the pool shall contain at least 150 mg of fibrinogen and 80 IU of coagulation Factor VIII per component in the pool.*

*21 CFR 606.122, 21 CFR 640.50, 21 CFR 640.54, and 21 CFR 640.56.

5.7.4.18 PLASMA CRYOPRECIPITATE REDUCED

Plasma Cryoprecipitate Reduced that has been collected in a closed system shall be prepared by refreezing the supernatant plasma that has been used to prepare Cryoprecipitated AHF.

5.7.4.19 THAWED PLASMA CRYOPRECIPITATE REDUCED

Thawed Plasma Cryoprecipitate Reduced shall be prepared from Plasma Cryoprecipitate Reduced.

5.7.4.20 PATHOGEN REDUCED CRYOPRECIPITATED FIBRINOGEN COMPLEX

Pathogen Reduced Cryoprecipitated Fibrinogen Complex shall be prepared as per the manufacturer's written instructions.

5.7.4.21 PLATELETS

Validation and quality control of Platelets prepared from Whole Blood shall demonstrate that at least 90% of units sampled contain $\geq 5.5 \times 10^{10}$ platelets and have a pH ≥ 6.2 at the end of allowable storage. FDA criteria apply.*

*21 CFR 640.25(b).

5.7.4.22 PLATELETS LEUKOCYTES REDUCED

Validation and quality control of Platelets Leukocytes Reduced shall demonstrate that at least 75% of units sampled contain $\geq 5.5 \times 10^{10}$ platelets and at least 90% of units sampled have a pH ≥ 6.2 at the end of allowable storage. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $< 8.3 \times 10^{5}$ leukocytes. FDA criteria apply.†

†21 CFR 640.25(b).
FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012).

5.7.4.23 POOLED PLATELETS LEUKOCYTES REDUCED

Pooled Platelets Leukocytes Reduced shall be prepared by a method known to result in a 95% confidence that more than 95% of units contain $< 5 \times$

10^6 leukocytes and at least 90% of units sampled have a pH $\geq$6.2 at the end of allowable storage. Standard 5.7.4.22 applies.

5.7.4.24 APHERESIS PLATELETS

Validation and quality control of Apheresis Platelets shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that greater than 95% of units have a pH $\geq$6.2 at the time of issue or within 12 hours after expiration. FDA criteria apply.‡

‡21 CFR 640.25(b).
FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).

5.7.4.24.1 Apheresis Platelets containing $<3.0 \times 10^{11}$ platelets shall have the platelet content included on the label.

5.7.4.25 APHERESIS PLATELETS LEUKOCYTES REDUCED

Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that greater than 95% of units have a pH $\geq$6.2 at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. FDA criteria apply.*

*21 CFR 640.25(b).
FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).
FDA Guidance for Industry: Pre-Storage Leukocyte

Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012).

5.7.4.25.1 Apheresis Platelets Leukocytes Reduced containing $<3.0 \times 10^{11}$ platelets shall have the platelet content included on the label.

5.7.4.26 APHERESIS PLATELETS PLATELET ADDITIVE SOLUTION ADDED LEUKOCYTES REDUCED

Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced shall be collected by apheresis and suspended in variable amounts of plasma and an approved platelet additive solution. Validation and quality control shall demonstrate with 95% confidence that greater than 75% of units contain $\geq 3.0 \times 10^{11}$ platelets and shall demonstrate with 95% confidence that 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration. The sampling plan shall confirm with 95% confidence that more than 95% of units contain $<5 \times 10^6$ leukocytes. FDA criteria apply.†

†FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).
FDA Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012).

5.7.4.26.1 Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced containing $<3.0 \times 10^{11}$ platelets shall have the platelet content included on the label.

5.7.4.27 PATHOGEN-REDUCED PLATELETS

Pathogen-reduced platelets shall be prepared as per the manufacturer's written instructions.

5.7.4.27.1 Pathogen-Reduced Platelets containing $<3.0 \times 10^{11}$ platelets shall have the platelet content included on the label. Standards 5.7.4.24 and 5.7.4.26 apply.*

*FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).

5.7.4.28 APHERESIS PLATELETS COLD STORED

Apheresis Platelets Cold Stored shall be placed at 1 to 6 C within 4 hours from either the end of collection or completion of the pathogen reduction process. Validation shall demonstrate with 95% confidence that greater than 75% of the platelets stored at 1 to 6 C maintain a pH >6.2 at the end of the allowable storage period, up to 14 days.† Platelet and leukocyte content before storage shall meet the requirements for Apheresis Platelets maintained at room temperature. Quality control shall demonstrate with 95% confidence that greater than 95% of units have a pH >6.2 at the time of issue or within 12 hours after expiration.

†FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).

5.7.4.28.1 The number of Apheresis Platelets Cold Stored components included in the overall monthly quality control

testing plan shall represent the proportion of Apheresis Platelets Cold Stored in the total platelet inventory.†

†FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).

5.7.4.29 APHERESIS GRANULOCYTES

Unless prepared for neonates, Apheresis Granulocytes shall be prepared by a method known to yield a minimum of 1.0×10^{10} granulocytes in at least 75% of the units tested. Product requirements for neonates shall be defined by the medical director.

5.8 Testing of Donor Blood

5.8.1 Determination of ABO Group for All Collections

The ABO group shall be determined for each collection by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma for expected antibodies with A_1 and B reagent red cells.

5.8.2 Determination of Rh Type for All Collections

The Rh type shall be determined for each collection with anti-D reagent. If the initial test with anti-D is negative, further testing shall be performed to detect variant expression of D. When either test is positive, the label shall read "Rh POSITIVE." When initial and indirect antiglobulin tests (IAT) for D are both
negative, the label shall read "Rh NEGATIVE."

5.8.3 Detection of Unexpected Antibodies to Red Cell Antigens for Allogeneic Donors

5.8.3.1 Serum or plasma from donors shall be tested for unexpected antibodies to red cell antigens.

5.8.3.2 Methods for testing shall be those that demonstrate clinically significant red cell antibodies.*

*21 CFR 606.151(d).

5.8.3.3 A control system appropriate to the method of testing shall be used. Standard 5.1.2 applies.

5.8.4 Red Cell Antigens Other than ABO and RhD

Units may be labeled as antigen negative, without testing the current donation, if units from two previous separate donations were tested by the collection facility and found to be concordant.†

†FDA Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen Typing Results (December 2018).

5.8.5 Tests Intended to Prevent Disease Transmission by Allogeneic Donations

A sample of blood from each allogeneic donation shall be tested for HBV DNA, HBsAg, anti-HBc, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, and syphilis by a serologic test. Donations collected in states in the United States specified by FDA guidance shall undergo nucleic acid testing for *Babesia* spp.* Each donor shall be tested at least once for antibodies to *Trypanosoma cruzi (T. cruzi).* Blood and blood components shall not be distributed or issued for transfusion unless the results of these tests are negative, except in the case of a test for syphilis that has been shown to have a biological false-positive result. Units with biological false-positive results shall be labeled in accordance with FDA requirements.† Standards 4.3.2.1 and 5.2.4 apply.

*FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

†21 CFR 610.40 and 21 CFR 630.3(h).

FDA Memorandum to All Registered Blood Establishments: Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc) (September 10, 1991).

FDA Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion (November 2009).

FDA Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis (December 2020).

FDA Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry (December 2017).

FDA Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus (October 2012).

FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV-I/II) (February 2020).

FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components (December 2017).

FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

5.8.5.1 Testing for *Babesia* spp. is not required if all transfusable components from the donation are prepared using FDA-approved pathogen reduction technology.‡

‡FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

5.8.5.2 If blood or blood components are distributed or issued before completion of these tests due to urgent need, a notation that testing is not completed shall appear conspicuously on an attached label or tie tag. Required tests shall be completed and results reported to the transfusion service as soon as possible.

5.8.5.3 For a cytapheresis donor dedicated to the support of a specific patient, testing required by Standard 5.8.5 shall be performed at the first donation and at least every 30 days thereafter.*

*21 CFR 610.40(c)(1).

5.8.6 Tests Intended to Prevent Disease Transmission by Autologous Donations

Autologous blood or components that will be transfused outside the collection facility shall be tested for HBV DNA, HbsAg, anti-HBc, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, and syphilis by a serologic test. Donations collected in states in the United States specified by FDA guidance shall undergo nucleic acid testing for *Babesia* spp. These tests shall be performed before shipping on at least the first unit collected during each 30-day period.† Each donor shall be tested at least once for antibodies to *T. cruzi*. Standard 4.3.2.1 applies.

†21 CFR 610.40(d).

FDA Guidance for Industry: Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use—Compliance Policy (August 2016). For other relevant FDA Guidance concerning testing of donor blood, see footnote for Standard 5.8.5.

5.8.6.1 Testing for *Babesia* spp. is not required if all transfusable components from the donation are prepared using FDA-approved pathogen reduction technology.‡

‡FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

5.8.6.2 The patient's physician and the donor-patient shall be informed of any medically significant abnormalities discovered. Standard 5.2.4 applies.§

§21 CFR 630.40(d).

5.8.7 Quarantine and Disposition of Units from Prior Collections

The BB/TS shall have a process that is in accordance with FDA requirements and recommendations for quarantine and disposition of prior collections when a repeat donor has a reactive screening test for anti-HBc, HbsAg, HBV DNA, anti-HCV, HCV RNA, anti-HIV-1/2, HIV-1 RNA, anti-HTLV-I/II, WNV RNA, *T. Cruzi* antibodies, or *Babesia* spp. DNA.*

*21 CFR 610.40(h)(1), 21 CFR 610.46, and 21 CFR 610.47.

FDA Memorandum to All Registered Blood and Plasma Establishments: Recommendations for the Quarantine and Disposition of Units from Prior Collection from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and

Human T-Lymphotropic Virus Type I (HTLV-I) (July 19, 1996).

FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV-I/II) (February 2020).

FDA Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion (November 2009).

FDA Guidance for Industry: "Lookback" for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV (December 2010).

FDA Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry (December 2017).

FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components (December 2017).

FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

5.9 Final Labeling

The BB/TS shall ensure that all specified requirements have been met at final labeling.

5.9.1 Testing and acceptability criteria shall be defined, and there shall be evidence that all records relating to testing and acceptability criteria for the current donation, and the facility's deferral registry, have been reviewed.

5.9.2 The component shall be physically inspected for container integrity and normality of appearance.

5.9.3 ABO/Rh typing shall be compared to a historical type, if available. Discrepancies shall be resolved before release.

✎ **5.9.4** The facility shall ensure that blood and blood components from ineligible donors are quarantined and are not issued for transfusion.

5.9.5 After the final label(s) has been affixed/attached to the units, there shall be a process to verify that the correct information is captured on the label.

5.9.5.1 When an information system is used, it shall be validated to prevent the release of mislabeled components.

5.9.5.2 The confirmation process shall be completed before release.

5.10 Final Inspection

The BB/TS shall ensure that blood, blood components, tissue, derivatives, or services meet specified requirements, including appearance before distribution or issue.

5.10.1 The current *Circular of Information for the Use of Human Blood and Blood Components* shall be available.

Transfusion-Service-Related Activities

5.11 Samples and Requests

Identifying information for the patient and the sample shall correspond and be confirmed at the time of collection using two independent identifiers.

✎ **5.11.1 Requests**

Requests for blood, blood components, tests, tissue, derivatives, and records accompanying samples from the patient shall contain sufficient information to uniquely

identify the patient, including two independent identifiers. The transfusion service shall accept only complete, accurate, and legible requests.

5.11.1.1 A physician or other authorized health professional shall order blood, blood components, tests, tissue, and derivatives.

5.11.2 Patient Samples

Patient samples shall be identified with an affixed label bearing sufficient information for unique identification of the patient, including two independent identifiers.

5.11.2.1 The completed label shall be affixed to the sample container before the person who obtained the sample leaves the side of the patient.

5.11.2.2 There shall be a mechanism to identify the date and time of sample collection and the individual(s) who collected the sample from the patient.

5.11.2.3 The transfusion service shall accept only those samples that are completely, accurately, and legibly labeled.

5.11.2.4 The transfusion service shall have a policy to reduce the risk of misidentification of patient pretransfusion samples.

5.11.3 Identifying Information

The transfusion service shall confirm that all identifying information on the request is in agreement with that on the sample label. In case of discrepancy or doubt, another sample shall be obtained.

5.11.4 Retention of Blood Samples

Patient samples and a segment from any red-cell-containing component(s) shall be stored at refrigerated temperatures for at least 7 days after transfusion.

5.12 Serologic Confirmation of Donor Blood ABO/Rh (including autologous units)

Before transfusion, the ABO group of each unit of Whole Blood, Red Blood Cell, and Granulocyte component and the Rh type of such units labeled as Rh negative shall be confirmed by a serologic test from an integrally attached segment. Confirmatory testing for serologic weak D is not required.

5.12.1 Discrepancies shall be reported to the collecting facility and shall be resolved before issue of the blood for transfusion. Standards 7.2.1 and 7.2.2 apply.

5.13 Serologic Confirmation of Donor Blood Red Cell Antigens Other than ABO/Rh

Red Blood Cell products labeled as negative for red cell antigens other than ABO and RhD do not require repeat testing for the labeled antigens.

5.14 Pretransfusion Testing of Patient Blood

Pretransfusion tests for allogeneic transfusion shall include ABO group and Rh type. In addition, for Whole Blood, Red Blood Cell, and Granulocyte components, pretransfusion testing for unexpected antibodies to red cell antigens shall be performed.

5.14.1 ABO Group

The ABO group shall be determined by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma for expected antibodies with A_1 and B reagent red cells. If a discrepancy is detected and transfusion is necessary before resolution, only group O Red Blood Cells shall be issued.

5.14.2 Rh Type

Rh type shall be determined with anti-D reagent. The test for serologic weak D is optional when testing the patient. If a discrepancy is detected and transfusion is necessary before resolution, only Rh-negative Red Blood Cells shall be issued to patients of childbearing potential. Standard 5.30 applies.

5.14.3 Unexpected Antibodies to Red Cell Antigens

Methods of testing shall be those that demonstrate clinically significant antibodies. They shall include incubation at 37 C preceding an antiglobulin test using reagent red cells that are not pooled.

5.14.3.1 When antibodies are detected, additional testing shall be performed to identify antibodies of clinical significance.

5.14.4 A new sample shall be obtained from the patient within 3 days prior to transfusion in the following situations:

1) If the patient has been transfused in the preceding 3 months with blood or a blood component containing allogeneic red cells.
2) If the patient has been pregnant within the preceding 3 months.
3) If the history is uncertain or unavailable.

Day 0 is the day of draw.

5.14.5 In patients with a history of previously identified antibodies, testing shall be capable of detecting and identifying the presence of newly formed clinically significant antibodies. Standard 5.14.3.1 applies.

5.14.6 A control system appropriate to the method of testing shall be used. Standard 5.1.2 applies.

5.14.7 Pretransfusion Testing for Autologous Transfusion
Pretransfusion testing for autologous transfusion shall include ABO group and Rh type on the patient sample. Standard 5.11 applies.

5.14.8 Pretransfusion Testing for Allogeneic Transfusion of Whole Blood, Red Blood Cell, and Granulocyte Components
There shall be two determinations of the recipient's ABO group as specified in Standard 5.14.1. The first determination shall be performed on a current sample, and the second determination by one of the following methods:

1) Comparison with previous records.
2) Testing a second sample collected at a time different from the first sample, including a new verification of patient identification.
3) Retesting the same sample if patient identification was verified at the time of sample collection using an electronic identification system.

Standards 3.2, 5.11, and 5.27.1 apply.

5.14.9 Comparison with Previous Records

The organization shall ensure that the historical records for the following have been reviewed:

1) ABO group and Rh type.
2) Difficulty in blood typing.
3) Clinically significant antibodies.
4) Significant adverse events to transfusion.
5) Special transfusion requirements.

5.14.9.1 These records shall be compared to current results, and any discrepancies shall be investigated and appropriate action taken before a unit is issued for transfusion.

5.15 Selection of Compatible Blood and Blood Components for Transfusion

5.15.1 Recipients shall receive ABO group-compatible Red Blood Cell components, or ABO group-specific Whole Blood. Standard 5.15.4 applies.

5.15.2 Rh-negative recipients shall receive Rh-negative Whole Blood or Red Blood Cell components.

5.15.2.1 The transfusion service shall have a policy for the use of Rh-positive red-cell-containing components in Rh-negative recipients, including during times of critical inventory levels. Standards 1.5 and 1.5.1

apply.

5.15.3 When clinically significant red cell antibodies are detected or the recipient has a history of such antibodies, Whole Blood or Red Blood Cell components shall be prepared for transfusion that do not contain the corresponding antigen and are serologically crossmatch-compatible. Standard 5.27.5 applies.

5.15.4 The transfusion service shall have a policy concerning transfusion of significant volumes of plasma containing incompatible ABO antibodies or unexpected red cell antibodies.

5.15.5 The red cells in Apheresis Granulocytes shall be ABO-compatible with the recipient's plasma and be crossmatched as in Standard 5.16. The donor blood cells for the crossmatch may be obtained from a sample collected at the time of donation.

5.15.6 The red cells in Platelets shall be ABO-compatible with the recipient's plasma and be crossmatched as in Standard 5.16 unless the component is prepared by a method known to result in a component containing <2 mL of red cells. The donor blood cells for the crossmatch may be obtained from a sample collected at the time of donation.

5.16 Crossmatch

5.16.1 Serologic Crossmatch
Before issue, a sample of the recipient's serum or plasma shall be crossmatched against a sample of donor cells from an integrally attached Whole Blood or Red Blood Cell segment. The crossmatch shall use methods that demonstrate ABO incompatibility and clinically significant antibodies to red cell antigens and shall include an antiglobulin test as described in Standard 5.14.3.

5.16.1.1 If no clinically significant antibodies were detected in tests performed in Standard 5.14.3 and there is no record of previous detection of such antibodies, at a

minimum, detection of ABO incompatibility shall be performed.

5.16.2 Use of an Information System to Detect ABO Incompatibility

If an information system is used as a method to detect ABO incompatibility, the following requirements shall be met:

5.16.2.1 The information system has been validated on-site to ensure that only ABO-compatible Whole Blood or Red Blood Cell components have been selected for transfusion.

5.16.2.1.1 For facilities subject to United States laws and regulations, the information system shall be an FDA 510(k)-cleared medical device.*

*FDA Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility (April 2013).

5.16.2.2 The system contains the donation identification number, component name, ABO group, and Rh type of the component; the confirmed unit ABO group; the two unique recipient identifiers; recipient ABO group, Rh type, and antibody screen results; and interpretation of compatibility.

5.16.2.3 A validated interface shall be used to transfer ABO/Rh and antibody screen data from an instrument to the information system, or a facility defined method exists to verify correct entry of data before release of blood or blood components. **5.16.2.4** The system contains logic to alert the user to discrepancies between the donor ABO group and Rh type on the unit label and those determined by blood group confirmatory tests, and to ABO incompatibility between the recipient and the donor unit.†

†FDA Guidance for Industry: "Computer

Crossmatch" (Computerized Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type) (April 2011).

5.17 Special Considerations for Neonates

5.17.1 An initial pretransfusion sample shall be tested to determine ABO group and Rh type. For ABO, only anti-A and anti-B reagents are required. The Rh type shall be determined as in Standard 5.14.2. The serum or plasma of either the neonate or the mother may be used to perform the initial test for unexpected antibodies as in Standard 5.14.3.

5.17.1.1 Repeat ABO grouping and Rh typing may be omitted for the remainder of the neonate's hospital admission or until the neonate reaches the age of 4 months, whichever is sooner.

5.17.1.2 If the initial screen for red cell antibodies is negative, it is unnecessary to crossmatch donor red cells for the initial or subsequent transfusions. Repeat testing may be omitted for the remainder of the neonate's hospital admission or until the neonate reaches the age of 4 months, whichever is sooner.

5.17.1.2.1 If the neonate is discharged and readmitted, pretransfusion testing shall be performed using the neonate's serum or plasma. Standards 5.14 and 5.17.2 apply.

5.17.1.3 If the initial antibody screen demonstrates clinically significant unexpected red cell antibodies, units shall be prepared for transfusion that either do not contain the corresponding antigen or are compatible by antiglobulin crossmatch until the antibody is no longer demonstrable in the neonate's serum or plasma.

5.17.2 If a non-group-O neonate is to receive non-group-O Red

Blood Cells that are not compatible with the maternal ABO group, the neonate's serum or plasma shall be tested for anti-A or anti-B.

5.17.2.1 Test methods shall include an antiglobulin phase using either donor or reagent A_1 or B red cells. Standard 5.14.6 applies.

5.17.2.2 If anti-A or anti-B is detected, Red Blood Cells lacking the corresponding ABO antigen shall be transfused.

5.18 Special Considerations for Intrauterine Transfusion

The BB/TS shall have a policy regarding intrauterine transfusion, including a mechanism to ensure that when fetal transfusion is performed, the fetal blood type is differentiated from that of the mother.

5.19 Selection of Blood and Blood Components in Special Circumstances

Once it has been determined that a patient has special transfusion requirements, there shall be a mechanism to ensure that all future blood or blood components for that patient meet the special transfusion requirements for as long as clinically indicated.

5.19.1 Leukocyte-Reduced Components

The BB/TS shall have a policy regarding transfusion of leukocyte-reduced components.

5.19.2 Cytomegalovirus

The BB/TS shall have a policy regarding transfusion of cellular components selected or processed to reduce the risk of cytomegalovirus (CMV) transmission.

5.19.3 Washed Red Blood Cells and Platelets

The BB/TS shall have a policy regarding the use of washed cellular products.

5.19.4 Prevention of Transfusion-Associated Graft-vs-Host Disease

The BB/TS shall have a policy regarding the prevention of transfusion-associated graft-vs-host disease.

5.19.4.1 Methods known to prevent transfusion-associated graft-vs-host disease shall be used and include either irradiation or the use of a pathogen reduction technology that is known to inactivate residual leukocytes and is cleared or approved by the FDA or relevant Competent Authority.

5.19.4.2 At a minimum, cellular components shall be prepared by a method known to prevent transfusion-associated graft-vs-host disease when:

5.19.4.2.1 A patient is identified as being at risk for transfusion-associated graft-vs-host disease.

5.19.4.2.2 The donor of the component is a blood relative of the recipient.

5.19.4.2.3 The donor is selected for HLA compatibility, by typing or crossmatching.

5.19.5 Hemoglobin S

The BB/TS shall have a policy regarding indications for the transfusion of Red Blood Cells or Whole Blood known to lack hemoglobin S.

5.19.6 Massive Transfusion

The BB/TS shall have a policy regarding compatibility testing when, within 24 hours, a patient has received an amount of blood approximating or greater than the patient's total blood volume.

5.19.7 Specially Selected Platelets

The BB/TS shall have a policy regarding indications for specially selected platelet requirements, where applicable, including but not limited to:

1) HLA-matched, crossmatch-compatible, HLA antigen-negative, and HPA antigen-negative platelets.
2) The use of cold stored platelets.*

*FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding When Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).

5.19.8 Patients at Increased Risk for Transfusion-Associated Circulatory Overload (TACO)

The BB/TS shall respond to requests for products for patients identified by the ordering physician or other authorized health professional as being at increased risk for TACO.

5.20 Preparation of Tissue

The facility shall ensure that any preparation steps performed in the facility before dispensing tissue are in accordance with the manufacturer's written instructions. The following information shall be maintained:

1) Type of tissue.
2) Numeric or alphanumeric identifier.
3) Quantity.
4) Expiration date and, if applicable, time.
5) Identity of personnel who prepared the tissue and the date of preparation.

5.21 Preparation of Derivatives

The facility shall ensure that any preparation steps performed in the facility before dispensing derivatives are in accordance with the manufacturer's written instructions. The following information shall be maintained:

1) Type of derivative.
2) Lot number.
3) Quantity.
4) Expiration date and, if applicable, time.
5) Identity of personnel who prepared the derivative and the date of preparation.

5.22 Final Inspection Before Issue

The BB/TS shall have a policy for visual inspection of blood, blood components, tissue, and derivatives at the time of issue.

5.22.1 Transfusion Recipient Blood Container Identification

A blood container shall have an attached label or tie tag indicating:

1) The intended recipient's two independent identifiers.
2) Donation identification number or pool number.
3) Interpretation of compatibility tests, if performed.

5.23 Issue of Blood and Blood Components

At the time a unit is issued, there shall be a final check of transfusion service records and each unit of blood or blood component. Verification shall include:

1) The intended recipient's two independent identifiers, ABO group, and Rh type.
2) The donation identification number, the donor ABO group, and, if required, the Rh type.
3) The interpretation of crossmatch tests, if performed.
4) Special transfusion requirements, if applicable.
5) The expiration date and, if applicable, time.
6) The date and time of issue.
7) Final visual inspection of the product.

5.24 Issue of Tissue and Derivatives

The following information shall be verified:

1) The manufacturer's package insert documents are issued with the product or listed on the product contents list.
2) The product quantity and name are consistent with the request.
3) The record of final inspection of the product.
4) If tissue or derivatives are issued for a specific patient, the intended recipient's two independent identifiers.
5) The expiration date and, if applicable, time.
6) The date and time of issue.

5.25 Discrepancy Resolution

The BB/TS shall confirm agreement of the identifying information, the records, the blood or blood component, and the order. Discrepancies shall be resolved before issue.

5.26 Reissue of Blood, Blood Components, Tissue, and Derivatives

Blood, blood components, tissue, or derivatives that have been returned to the BB/TS shall be accepted into inventory for reissue only if the following conditions have been met:

1) The container closure has not been disturbed.
2) The appropriate temperature has been maintained.*
3) For Red Blood Cell components, at least one sealed segment of integral donor tubing remains attached to the container. Removed segments shall be reattached only after confirming that the tubing identification numbers on both the removed segment(s) and the container are identical.
4) The records indicate that the blood, blood component, tissue, or derivatives have been visually inspected and that they are acceptable for reissue.

*21 CFR 606.160(b)(3)(iv).

5.27 Urgent Requirement for Blood and Blood Components

The BB/TS shall have a defined process to provide blood and blood components before completion of tests listed in Standards 5.8.4, 5.14, 5.14.1, 5.14.2, 5.14.3, 5.14.8, and 5.16 when a delay in transfusion could be detrimental to the patient. Standards 5.8.5.3, 5.12, 5.22.1, and 7.0 to 7.3 apply.

5.27.1 Recipients whose ABO group is not known or has not been confirmed shall receive group O Red Blood Cells or low-titer group O Whole Blood. Standards 5.14.1 and 5.14.8 apply.

5.27.2 If low-titer group O Whole Blood is used, the BB/TS shall have policies, processes, and procedures to define:

1) Low-titer threshold.
2) Use of low-titer group O Whole Blood.
3) Maximum volume/units allowed per event.

Standard 5.15.4 applies.

5.27.3 If blood is issued before completion of compatibility testing, recipients whose ABO group has been determined as in Standard 5.14.1 by the transfusing facility shall receive only ABO group-specific Whole Blood, low-titer group O Whole Blood, or ABO group-compatible Red Blood Cell components. Standards 5.15.4 and 5.27.2 apply.

5.27.4 The container tie tag or label shall indicate in a conspicuous fashion that compatibility and/or infectious disease testing was not completed at the time of issue. Standard 5.22.1 applies.

5.27.5 Compatibility testing shall be completed expeditiously using a patient sample collected before the beginning of the transfusion sequence, when possible. Standard 5.19.6 applies.

5.27.6 The records shall contain a signed statement from the requesting physician indicating that the clinical situation was sufficiently urgent to require release of blood before completion of compatibility testing or infectious disease testing. The signature can occur before or after the release/issue of the blood.*

*21 CFR 606.160(b)(3)(v) and 21 CFR 606.151(e).

5.27.6.1 The transfusion service medical director and the recipient's physician shall be notified immediately of abnormal test results that may affect patient safety.

5.28 Administration of Blood and Blood Components

There shall be a protocol for the administration of blood and blood components that includes the use of infusion devices and ancillary equipment, and the identification, evaluation, and reporting of adverse events related to transfusion. The medical director shall participate in the development of these protocols. The protocol shall be consistent with the *Circular of Information for the Use of Human Blood and Blood Components*. Standard 7.3.4 applies.

5.28.1 Recipient Consent
The BB/TS medical director shall participate in the development of policies, processes, and procedures regarding recipient consent for transfusion.

5.28.1.1 At a minimum, elements of consent shall include all of the following:

1) A description of the risks, benefits, and treatment alternatives (including nontreatment).
2) The opportunity to ask questions.
3) The right to accept or refuse transfusion.

5.28.2 Transfusions shall be prescribed and administered under medical direction by an authorized health professional.

5.28.3 In the presence of the recipient, and before initiating transfusion, the following information shall be verified:

1) The intended recipient's two independent identifiers, ABO group, and Rh type.
2) The donation identification number, the donor ABO group, and, if required, the Rh type.
3) The interpretation of crossmatch tests, if performed.
4) Special transfusion requirements are met, if applicable.
5) The unit has not expired.

5.28.4 In the presence of the recipient, and before initiating transfusion, the transfusionist and one other individual (or an electronic identification system) shall positively identify the recipient and match the blood component to the recipient through the use of two independent identifiers.

5.28.5 All identification attached to the container shall remain attached until the transfusion has been terminated.

5.28.6 The patient shall be monitored for potential adverse events during the transfusion and for an appropriate time after transfusion. Standard 7.3.4 applies.

5.28.7 Specific written instructions concerning possible adverse events, including emergency medical care contacts, shall be provided to the patient or a responsible caregiver when direct medical observation or monitoring of the patient will not be available after transfusion.

5.28.8 Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.

5.28.9 Addition of Drugs and Solutions
With the exception of 0.9% sodium chloride (USP), drugs or medications shall not be added to blood or blood components unless one of the following conditions is met:

1) They have been approved for this use by the FDA.
2) There is documentation available to show that the addition is safe and does not adversely affect the blood or blood component.

5.28.10 Granulocytes
Leukocyte reduction filters or microaggregate filters shall not be used. Standard 5.28.8 applies.

5.29 Medical Record Documentation

5.29.1 The patient's medical record shall include the transfusion order; documentation of patient consent; the component name; the donation identification number; the donor ABO/Rh type; the date and time of transfusion; vital signs taken at facility-defined intervals including before, during, and after transfusion; the amount transfused; the identification of the transfusionist; and, if applicable, transfusion-related adverse events.

5.29.2 For recipients of tissue, the recipient's medical record shall include the type of tissue, the numeric or alphanumeric identifier, the quantity, the expiration date and the date of use, personnel responsible for the clinical application of the tissue, and, if applicable, related adverse events.

5.29.3 For recipients of derivatives, the recipient's medical record shall include the product name, the lot number, the quantity, the date and time of administration, individuals administering the derivative, and, if applicable, related adverse events.

5.30 Rh Immune Globulin

The transfusion service shall have a policy for Rh Immune Globulin prophylaxis for Rh-negative patients who have been exposed to Rh-positive red cells. The results of serologic weak D testing and/or *RHD* genotyping, if performed, shall be evaluated when determining Rh Immune Globulin prophylaxis.

5.30.1 Interpretation criteria shall be established to prevent the mistyping of an Rh-negative patient as Rh positive due to exposure to Rh-positive red cells.

5.30.2 Individuals who are pregnant or who have been pregnant recently shall be considered for Rh Immune Globulin administration when all of the following apply:

1) The individual's test for D antigen is negative. A serologic test for weak Dis optional.
2) The individual is not known to be actively immunized to the D antigen.
3) The RhD type of the fetus/neonate is unknown, or the type of the fetus/neonate is positive when tested for Dor serologic weak D. Serologic weak D testing is required when the initial test for D is negative.

5.30.3 If the transfusion service is responsible for issue of Rh Immune Globulin, the transfusion service shall recommend the appropriate dose.

5.30.3.1 Rh Immune Globulin shall be administered as soon as possible after exposure.

Reference Standard 5.1.8A—Requirements for Labeling Blood and Blood Components

Item No.	Labeling Item	Collection or Prepara-tion	Final Compo-nent	Pooled
1	Name of blood component or intended component[1]	NR	R	R
2	Donation identification number[1]	R	R	R
3	Identity of anticoagulant[2] or other preservative solution	R	R	R
4	Identity of sedimenting agent, if applicable	NR	R	NA
5	Approximate volume[3]	NR	R	R, total
6	Facility collecting component[1]	NR	R	NR
7	Facility modifying component[4]	NA	R, if leaves the facility	R[1]
8	Storage temperature	NA	R	R
9	Expiration date and, when appropriate, time[5]	NA	R	R
10	ABO group and Rh type[1,6]	NA	R	See line 19
11	Specificity of unexpected red cell antibodies[7-9]	NA	R[2]	R
12	For whole-blood-derived platelets, name of drug taken by donor that adversely affects platelet function[10]	NR	R	NR

13	Instructions to the transfusionist[11]: 1. See *Circular of Information for the Use of Human Blood and Blood Components* for indications, contraindications, cautions, and methods of infusion 2. Properly identify intended recipient 3.This product may transmit infectious agents 4. Rx only	NR	R	R
14	Phrase: "Volunteer Donor," if applicable	NR	R	R
15	Phrase: "Paid Donor," if applicable	R	R	R
16	Phrase: "Autologous Donor," if applicable	R[7]	R	R
17	CMV seronegative, if applicable	NR	R	R
18	Indication that the unit is low volume, if applicable	NR	R	NA
19	Number of units in pool[7]	NA	NA	R
20	ABO and Rh of units in pool[6,12]	NA	NA	R
21	Red cell antigens other than ABO or RhD, if applicable[13]	NA	R	NA
22	Actual platelet content for apheresis platelets containing $<3.0 \times 10^{11}$	NA	R	NA
Additional Autologous Labeling Requirements				
23	Phrase: "For autologous use only"[11]	R	R	R

24	Date of donation	NR	R	NR
25	Recipient name, identification number, and, if available, name of facility where patient is to be transfused[7]	R	R	R
26	Biohazard label, if applicable[14]	NR	R	R
27	Phrase: "Donor untested," if applicable[11,15]	NR	R	R
28	Phrase: "Donor tested within the last 30 days," if applicable[11,16]	NR	R	R
Additional Dedicated Donor Labeling Requirements				
29	Intended recipient information label[7]	R	R	R
30	Phrase: "Donor tested within the last 30 days," if applicable[16]	NR	R	R
31	Biohazard label, if applicable[14]	NR	R	R
Additional Labeling Requirements for Recovered Plasma[17]				
32	Phrase: "Caution: For Manufacturing Use Only" or "Caution: For Use in Manufacturing Noninjectable Products Only" based on intended use[11]	NA	R	R
33	Biohazard label, if applicable	NR	R	R

34	Phrase: “Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act” (applicable to plasma not meeting requirements for manufacture into licensable products)	NA	R	R
35	In lieu of expiration date, the date of collection of the oldest material in the container	R	R	R

R = required; NR = not required; NA = not applicable.
[1]Must be machine-readable (see Standard 5.1.8.3.1).
[2]Not required for Cryoprecipitated AHF; pathogen-reduced cryoprecipitated fibrinogen complex; or frozen, deglycerolized, rejuvenated, or washed Red Blood Cells.
[3]For platelets, low-volume Red Blood Cells, plasma, pooled components, and components prepared by apheresis, the approximate volume in the container.
[4]Includes irradiation, if applicable.
[5]21 CFR 606.121(c)(4)(i).
[6]Rh type not required for single or pooled Cryoprecipitated AHF, or pathogen-reduced cryoprecipitated fibrinogen complex.
[7]The facility has the option of placing information on a tie tag or label.
[8]Specificity of antibodies is not required for autologous units.
[9]Not required for Cryoprecipitated AHF or pathogen-reduced cryoprecipitated fibrinogen complex.
[10]21 CFR 640.21(c).
[11]Wording may be different outside of the United States.
[12]For pooled Cryoprecipitated AHF, pathogen-reduced cryoprecipitated fibrinogen complex, plasma, or platelets of mixed types, a pooled type label is acceptable. The specific ABO group and Rh types of units in the pool may be put on a tie tag. Standard 5.7.3.3 applies.
[13]For facilities subject to US laws and regulations, FDA Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen Typing Results (December 2018) applies. For facilities not subject to US laws and regulations, follow Competent Authority, where applicable.

[14]Biohazard labels for autologous units or allogeneic units from a dedicated donor shall be used for the following test results:

Test	Test Result
HBsAg	Repeatedly reactive
Anti-HBc	Repeatedly reactive
HBV NAT	Positive or reactive
Anti-HCV	Repeatedly reactive
HCV NAT	Positive or reactive
Anti-HIV-1/2	Repeatedly reactive
HIV-1 NAT	Positive or reactive
Anti-HTLV-I/II	Repeatedly reactive
WNV NAT	Positive or reactive
Syphilis	Reactive screening test*
When performed:	
T. cruzi antibody screening	Repeatedly reactive
Babesia NAT	Positive or reactive†

*21 CFR 610.40(e)(2) applies.

†FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

[15]Donor not tested for evidence of relevant transfusion-transmitted infections.
[16]When the first unit has been tested but any unit collected within 30 days after the first collection has not been tested.
[17]Labeling of Recovered Plasma shall conform to 21 CFR 606.121(c)(10), 21 CFR 606.121(c)(11), and 21 CFR 606.121(e)(4).

Reference Standard 5.1.9A—Requirements for Storage, Transportation, and Expiration of Cellular Components[1]

Item #	Component	Storage	Transport[2]	Expiration[3, 4]			
					Leukoreduced	Irradiated	Ex ati

1	Whole Blood	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days Open system: 24 hours	Same	Original expiration or 28 days from date of irradiation, whichever is sooner	
2	Red Blood Cells (RBCs)	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days Additive solution: 42 days Open system: 24 hours	Same	Original expiration or 28 days from date of irradiation, whichever is sooner ACD-A/ADSOL units irradiated at ≥3000cGY, 28 days from date of collection	Wa ed: 24 hou **Rej ver ed:** CP CP A-1 24 hou **De cer zed nd Rej ver ed De cer zed**

							Op sys m: 24 hou Clo d sys m: 14 day
3	Platelets [5-7] (whole-blood derived)	20-24 with continuous gentle agitation[8]	As close as possible to 20-24 C[9] Maximum time without agitation: 30 hours	Up to 5 days, depending on collection system and bacterial testing strategy used	Open system: 4 hours Closed system: Up to 5 days, depending on collection system and bacterial testing strategy used	No change from original expiration date	Poo d: 4 hou in a ope sys m c afte poo ng or 5 - day foll wir col tio of t old uni in t poo

							dep din on col tion sys m a bac ial test g stra gy use as spe ied inst ctio for use by sys m app ved or clea d b FD or con ete aut rity

4	Pooled Platelets (in a closed system using the buffy coat method)	20-24 C with continuous gentle agitation[8]	As close as possible to 20-24 C[9] Maximum time without agitation: 30 hours	7 days		No change from original expiration date	
5	Apheresis Platelets [4-6]	20-24 C with continuous gentle agitation[8]	As close as possible to 20-24 C[9] Maximum time without agitation: 30 hours	5 days or up to 7 days, depending on the collection system and bacterial testing strategy used	Open system: within 4 hours of opening system Closed system: 5 days or up to 7 days depending on the collection system and bacterial testing strategy used	No change from original expiration date	**Pat oge Rec ced** 5 - day
6	Apheresis Granulocytes	20-24 C without agitation	As close as possible to 20-24 C without agitation	24 hours	N/A	No change from original expiration date	

7	Liquid Plasma	1-6 C	1-10 C	CPD or CP2D: 26 days CPDA-1: 40 days		No change to expiration date	
8	Apheresis Platelets Cold Stored[10]	1-6 C (agitation optional)	1-10 C	14 days	No change	No change in expiration date	**Pat oge Rec ced** 14 day 5
9	Whole-Blood Derived Platelets Cold Stored	1-6 C (agitation optional)	1-10 C	As specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by	No change	No change in expiration date	

				FDA or Relevant Competent Authority			
10	Frozen RBCs 40% Glycerol	-65 C or colder if 40% glycerol or as FDA approved	Maintain frozen state	10 years (A policy shall be developed if rare frozen units are retained beyond this time)			
11	Frozen Rejuvenated RBCs	-65 C or colder	Maintain frozen state	CPD, CPDA-1: 10 years AS-1: 3 years			

[1]Products may be pathogen reduced if approved by the FDA or relevant Competent Authority.
[2]For products being transported between the collection and processing site, Standards 5.6.5 and 5.6.5.1 apply.
[3]If the seal is broken during processing, components stored at 1 to 6 C shall

have an expiration time of 24 hours, and components stored at 20 to 24 C shall have an expiration time of 4 hours, unless otherwise indicated. This expiration shall not exceed the original expiration date or time.
[4] As defined by the FDA or relevant Competent Authority
[5]The platelet storage system shall be FDA-cleared or -approved for the conditions specified.
[6]One of the following storage temperatures shall be used continuously: 1) 20 to 24 C or 2) 1 to 6 C. 21 CFR 640.24(d).
[7]FDA Guidance for Industry: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance Safety and Availability of Platelets for Transfusion (December 2020).
[8]21 CFR 610.53(b) and 21 CFR 640.25(a).
[9]21 CFR 600.15.
[10]FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding When Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).
[11]These lines could apply to apheresis plasma or whole-blood-derived plasma.

Reference Standard 5.1.9B—Requirements for Storage, Transportation, and Expiration of Acellular Components[1, 2]

Item #	Component	Storage	Transport	Expiration	Additional Criteria	Expiration
	Frozen					
1	Fresh Frozen Plasma (FFP)[, 3]	-18 C or colder or -65 C or colder	Maintain frozen state	-18 C or colder: 12 months from collection -65 C or colder: 7	Placed in freezer within 8 hours of collection or as stated in FDA-cleared operator's manuals/package inserts	If issue as FFP, 24 hou

				years from collection	Storage at –65 C or colder requires FDA approval if product is stored for longer than 12 months	
2	Plasma Frozen Within 24 Hours After Phlebotomy (PF24)[3] Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24) Plasma Cryoprecip	-18 C or colder	Maintain frozen state	12 months from collection	Shall be refrozen within 24 hours of thawing the FFP from which it was derived	If issue as labeled 24 hou

	itate Reduced					
3	Thawed Plasma Thawed Plasma Cryoprecipitate Reduced	1-6 C	1-10 C	5 days from date product was thawed or original expiration, whichever is sooner	Shall have been collected and processed in a closed system	
4	Plasma Pathogen Reduced	-18 C or colder	Maintain frozen state	12 months from original collection	Placed in a -18 C freezer within 24 hours for pooled whole blood derived plasma or within 8 hours of apheresis collection	24 hour
5	Cryoprecipitated AHF	-18 C or colder	Maintain frozen state	12 months from original collection **Pooled** (before freezing): 12 months from earliest collection date of product in pool	Thaw the FFP at 1-6 C Place cryoprecipitate in the freezer within 1 hour after removal from refrigerated centrifuge	Single unit: 6 hours Pooled an oper system: 4 hours Pooled using a sterile connec n devic 6 hours

6	Pathogen Reduced Cryoprecipitated Fibrinogen Complex	-18 C or colder	Maintain frozen state	Up to 12 months from date of collection of the first donation in the input plasma pool		5 days after thawing

[1] Products maybe pathogen reduced if approved by the FDA or relevant Competent Authority

[2] Convalescent plasma product storage, transport, and expiration times conform to manufacturer's written instructions

[3]These lines could apply to apheresis plasma or whole-blood-derived plasma.

Reference Standard 5.1.9C—Requirements for Storage, Transportation, and Expiration of Recovered Plasma, Tissue, and Derivatives[1]

Item #	Component	Storage	Transport	Exp
1	Recovered Plasma (Liquid or frozen)	Refer to short supply agreement	Refer to short supply agreement	Refer to supply
2	Tissue	Conform to source manufacturer's written instructions	Conform to source manufacturer's written instructions	Conform source manufa written instruct
3	Derivatives	Conform to source manufacturer's written instructions	Conform to source manufacturer's written instructions	Conform source manufa written instruct

[1] Products maybe pathogen reduced if approved by the FDA or relevant Competent Authority
[2] 21 CFR 601.22.

Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period
1) Age	• Conform to applicable state law, relevant Competent Authority or • ≥16 years	
2) Blood Pressure[1]	• 90-180 mm Hg systolic • 50-100 mm Hg diastolic	
3) Pulse[1]	• 50-100 beats per minute, without pathologic irregularities	
4) Whole Blood Volume Collected	• Maximum of 10.5 mL/kg of donor weight, including samples	
5) Donation Interval	• 8 weeks after whole blood donation (Standards 5.5.1-5.5.4 and 5.6.7.1 apply) • 16 weeks after 2-unit Red Blood Cell collection • 4 weeks after infrequent plasmapheresis • ≥2 days after plasma-, single platelet-, or leukapheresis • ≥7 days after double or triple platelet apheresis[2]	
6) Temperature	• ≤37.5 C (99.5 F) if measured orally, or equivalent if measured by another method	
7) Hemoglobin/ Hematocrit	• ≥12.5 g/dL, ≥38% women; ≥13.0 g/dL, ≥39% men • For double Red Blood Cell collections, follow instrument operator's manual	21 CFR 630.10(f)(3)

8) Platelet Count	• For plateletpheresis collections, the donor platelet count, if available, shall be > 150,000/μL Standard 5.5.3.4.3 applies.	
9) Weight	• All donors shall weigh a minimum of 50 kg (110 lb) • For plasmapheresis collections, the donor shall be weighed • For all other product collections, self-reported weight is acceptable	
10) Drug Therapy[3]	• The facility shall use the current version of the Medication Deferral List within 6 months of the list's effective date (https://www.aabb.org/news-resources/resources/donor-history-questionnaires/blood-donor-history-questionnaires)	Defer according to the current version of the Medication Deferral List
	• Other medications	As defined by the facility's medical director
	• Taken any medication by mouth (oral) to prevent HIV infection [ie, PrEP (preexposure prophylaxis) or PEP (postexposure prophylaxis)]	3 months[4]
	• Received any medication by injection to prevent HIV infection (ie, long-acting antiviral PrEP or PEP)	2 years[4]
	• Taken any medication to treat HIV infection	Permanent [4]

10) Medical History and General Health	• The prospective donor shall appear to be in good health and shall be free of major organ disease (eg, heart, liver, lungs), cancer, or abnormal bleeding tendency, unless determined suitable by the medical director • The venipuncture site shall be evaluated for lesions on the skin and shall be free from infectious skin disease and any disease that might create a risk of contaminating the blood	
	• For donors previously deferred for family genetic history of Creutzfeldt-Jakob disease (CJD)[5]	Defer in accordance with FDA Guidance
11) Pregnancy	• Defer if pregnant within the last 6 weeks	21 CFR 630.10(e)(v)
12) Receipt of Blood, Blood Component, or Human Tissue	• Receipt of human cadaveric (allogeneic) dura mater transplant • Donors previously deferred for human growth hormone • Receipt of allogeneic blood, components, or human tissue	Permanent Permanent in accordance with FDA Guidance 3 months
13) Xenotransplantation	• Receipt of live cells, live tissues, or live organs from a nonhuman animal source • Note: Nonliving biological products or materials from nonhuman animals, such as porcine or bovine heart valves and porcine insulin, are acceptable	Indefinite

14) Immunizations and Vaccinations	• Receipt of toxoids, or synthetic or killed viral, bacterial, or rickettsial vaccines if donor is symptom-free and afebrile [Anthrax, Cholera (inactivated), Diphtheria, Hepatitis A, Hepatitis B, Influenza, Lyme disease, Paratyphoid, Pertussis, Plague, Pneumococcal polysaccharide, Polio (Salk/injection), Rabies, Rocky Mountain spotted fever, Tetanus, Typhoid (by injection)] • Receipt of recombinant vaccine [eg, RSV, HPV and Zoster Recombinant, Adjuvanted (Shingrix) Vaccine] • Receipt of intranasal live attenuated flu vaccine • Receipt of Vaxchora (live attenuated, nonsystemically absorbed, oral cholera vaccine)	None
	• Receipt of live attenuated viral and bacterial vaccines [Measles (rubeola), Mumps, Polio (Sabin/oral), Typhoid (oral), Yellow fever]	2 weeks
	• Receipt of live attenuated viral and bacterial vaccines [German measles (rubella), Trivalent measles-mumps-rubella (MMR) vaccine quadrivalent MMRV, Chicken pox/Shingles (varicella zoster), Chikungunya (IXCHIQ)]	4 weeks
	• Receipt of Jynneos vaccine for smallpox and monkeypox (attenuated, live, nonreplicating vaccine)	None

	• Receipt of Smallpox Vaccinia Vaccine (live virus vaccine composed of vaccinia virus—"replication competent" vaccine)	Refer to FDA Guidance[6]
	• SARS-CoV-2 – Individuals who received a nonreplicating, inactivated, or mRNA-based vaccine – Individuals who received a live attenuated viral COVID-19 vaccine – Individuals who are uncertain about which COVID-19 vaccine was administered	– None – 14 days – 14 days
	• Ebola Vaccine	- 6 weeks
	• Receipt of other vaccines, including unlicensed vaccines	As determined by the medical director or defer according to the current version of the Medication Deferral List
15) Relevant Transfusion-Transmitted Infections[7]	• Confirmed positive test for HBsAg[8]	Permanent
	• Repeatedly reactive test for anti-HBc on more than one occasion[9] • Positive HBV NAT result	Indefinite Indefinite[10]

	• Repeatedly reactive test for anti-HTLV on more than one occasion	Indefinite[1] [1]
	• Present or past clinical or laboratory evidence of infection with HIV, HCV,[12] HTLV, or *T. cruzi* [13]	Indefinite
	• Present or past confirmed positive test result for HIV infection[4]	Permanent
	• Evidence or obvious stigmata of parenteral drug use	Indefinite
	• Use of a needle to inject drugs, steroids, or anything not prescribed by a doctor	3 months
	• Contact with blood of another individual through percutaneous inoculation such as a needlestick or through contact with an open wound or mucous membranes	3 months
	• Tattoo, ear or body piercing – For tattoos, no deferral if the tattoo was applied by a state-regulated entity with sterile needles and non-reused ink – For ear or body piercings, no deferral if the piercing was done using single-use equipment	3 months
	• Sexual contact or lived with an individual who: – Has acute or chronic hepatitis B (positive HBsAg test, HBV NAT) – Has symptomatic hepatitis C	3 months
	• Sexual contact with an individual who ever had a positive test result for HIV infection	3 months[4]

	• Sexual contact with an individual who, in the past 3 months: – Has received money, drugs, or other payment for sex – Has used needles to inject drugs, steroids, or anything not prescribed by a doctor	3 months[4]
	• Received money, drugs, or other payment for sex	3 months[4]
	• Have had a new sexual partner in the past 3 months and have had anal sex in the past 3 months	3 months[4]
	• Have had more than one sexual partner in the past 3 months and have had anal sex in the past 3 months	3 months[4]
	• Incarceration in a correctional institution (including juvenile detention, lockup, jail, or prison) for 72 or more consecutive hours[14]	12 months
	• Syphilis or gonorrhea – Following the diagnosis of syphilis or gonorrhea; must have completed treatment – Donor who has a reactive screening test for syphilis[15]	– 3 months[15] – Indefinite; donor reentry in accordance with FDA Guidance
	• West Nile virus	In accordance with FDA

		Guidance[1] 6
	• Malaria[17] These deferral periods apply *in non-malaria-endemic countries*, irrespective of the receipt of antimalarial prophylaxis:	
	– Prospective donors who have had a diagnosis of malaria	– 3 years after becoming asymptomatic while residing in a non malaria-endemic country for the same 3-year period
	– Individuals who have lived longer than 5 consecutive years in countries considered malaria-endemic by the Malarial Branch, Centers for Disease Control and Prevention, US Department of Health and Human Services	– 3 years after departure from malaria-endemic country(ies) lived in
	– Individuals who have lived longer than 5 consecutive years in countries considered malaria-endemic by the Malarial Branch,	– 3 years after departure from

	Centers for Disease Control and Prevention, US Department of Health and Human Services, who have traveled to an area where malaria is endemic before living at least 3 consecutive years in non-malaria-endemic country(ies)	malaria-endemic area(s) traveled to
	– Individuals who meet either of the following criteria: – Traveled to an area where malaria is endemic – Lived longer than 5 consecutive years in countries considered malaria-endemic by the Malarial Branch, Centers for Disease Control and Prevention, US Department of Health and Human Services, who have traveled to an area where malaria is endemic after having lived at least 3 consecutive years in non-malaria-endemic country(ies)[17]	– Defer for 3 months from most recent date of departure from malaria-endemic area(s) (deferral not required for platelets or plasma processed with an FDA- or relevant Competent-Authority-approved pathogen reduction device)

	• Reactive test for *Babesia* spp.	At least 2 years; donor reentry in accordance with FDA Guidance[18]
16) Travel	• The prospective donor's travel history shall be evaluated for potential risks[17,19,20]	
	• Donors recommended for deferral for risk of vCJD, as defined in most recent FDA Guidance[5]	In accordance with FDA Guidance

[1]For blood pressure, see 21 CFR 630.10(f)(2); for pulse, see 21 CFR 630.10(f)(4), FDA Guidance for Industry: Blood Pressure and Pulse Donor Eligibility Requirements – Compliance Policy (July 2024).
[2]FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007).
[3]Medication Deferral List current version at https://www.aabb.org/news-resources/resources/donor-history-questionnaires/blood-donor-history-questionnaires.
[4]FDA Guidance for Industry: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (May 2023).
[5]FDA Guidance for Industry: Recommendations to Reduce the Possible Risk

of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components (May 2022).
[6]FDA Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients (December 2002).
[7]21 CFR 610.40.
[8]FDA Memorandum: Recommendations for the Management of Donors and Units That Are Initially Reactive for Hepatitis B Surface Antigen (December 1987).
FDA Guidance for Industry: Requalification Method for Reentry of Donors Who Test Hepatitis B Surface Antigen (HBsAg) Positive Following a Recent Vaccination against Hepatitis B Virus Infection (November 2011).
[9]21 CFR 640.21.
FDA Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc) (May 2010).
[10]FDA Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus (October 2012).
[11]FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Type I and II (HTLV-I/II) (February 2020).
[12]FDA Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry (December 2017).
[13]FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components (December 2017).
[14]21 CFR 630.10(e)(1)(iv).
[15]FDA Guidance for Industry: Recommendations for Screening, Testing and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis (updated December 2020).
[16]FDA Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion (November 2009).
[17]FDA Guidance for Industry: Revised Recommendations to Reduce the Risk

of Transfusion-Transmitted Malaria (December 2022).
[18]FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).
[19] http://www.cdc.gov/travel.
[20]FDA Guidance for Industry: Recommendations for Assessment of Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus (January 2017).

Excerpt of Record Retention Standard 6.2.9A Relevant to Process Control

Standard	Record to Be Maintained	Donor /Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years)[1]
5.1.1	Validation of new or changed processes and procedures	X	X	X	X	5
5.1.2	Quality control records and review of quality control results	X	X	X	X	10
5.1.8	Identification and traceability of products	X	X	X	X	5
5.1.8.1	Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components	X	NA	NA	NA	10
5.1.8.2	Traceability of blood, blood components, tissue, derivatives, and critical materials	X	X	X	X	10
5.1.8.5	Source to final disposition of each unit of blood or	X	X	X	NA	10

	blood component and, if issued by the facility for transfusion, identification of the recipient					
5.1.8.5.1, 5.1.8.5.2	Unique identification of each unit	X	X	X	X	10
5.1.9.3	Records of storage temperatures for blood products	X	X	X	X	10
5.1.9.3.2	Ambient temperature recorded every 4 hours when components are stored in open storage area	X	X	X	X	10
5.1.9.5	Inspection before shipping	X	X	X	X	10
5.1.9.5.1	Container qualification and process validation records	X	X	X	X	10
5.1.10	Participation in proficiency testing program	X	X	X	X	5
5.2.1 #7	Donor acknowledgment that educational materials have been read	X	NA	NA	NA	10
5.2.3	Consent of donors	X	NA	NA	NA	10

5.2.4	Notification to donor of significant abnormal findings	X	NA	NA	NA	10
5.4.1, 5.4.1.1, 5.4.2, 5.5.2.3	Donor information, including address, medical history, physical examination, health history, or other conditions thought to compromise suitability of blood or blood component	X	NA	NA	NA	10
5.4.4.1	A medical order from the patient's physician is required to collect blood for autologous use	X	NA	NA	NA	10
5.5.3.4	Platelet count for frequent plateletpheresis donors	X	NA	NA	NA	10
5.6.6.2	Cytapheresis record, including anticoagulant drugs given, duration of procedure, volume of components, drugs used, lot number of disposables, and replacement fluids	X	NA	NA	NA	10
5.6.6.2.1	Maximal cumulative dose of sedimenting agent administered	X	NA	NA	NA	10

	to donor in a given time					
5.6.7	Therapeutic apheresis: physician request or other authorized health professional, patient identification, diagnosis, type of therapeutic procedure performed, method used, vital signs before and after the procedure, extracorporeal blood volume if applicable, nature and volume of component removed, nature and volume of replacement fluids, any occurrence of adverse events, and medication administered Therapeutic phlebotomy: physician or other authorized health professional request, patient identification, diagnosis, vital signs before the procedure, volume removed, and any	X	X	NA	NA	5

	occurrence of adverse events					
5.7.2.1	Inspection of weld for completeness and identification numbers of blood or blood components and of lot numbers of disposables used during component preparation	X	NA	NA	NA	10
5.7.3.2.1	Verification of irradiation dose delivery	X	NA	NA	NA	10
5.7.3.3	Donation identification number and collecting facility for each unit in pooled components	X	NA	NA	NA	10
5.7.4	Preparation of specific components	X	NA	NA	NA	10
5.8.1, 5.8.2	ABO group and Rh type for all collections	X	NA	NA	NA	10
5.8.3.1	Allogeneic donor testing to detect unexpected antibodies to red cell antigens	X	NA	NA	NA	10
5.8.3.3	Control system results appropriate to the method of testing	X	NA	NA	NA	10
5.8.5	Interpretations of disease marker testing for allogeneic testing	X	NA	NA	NA	10
5.8.5.3	Distribution or issue of units before completion of tests	X	NA	NA	NA	10
5.8.7	Quarantine of units from prior	X	NA	NA	NA	10

	collections when a repeat donor has a reactive disease marker screening test					
5.9.1	Final review of records relating to testing and acceptability criteria	X	NA	NA	NA	10
5.9.4	Review of donor records to ensure any units from an ineligible donor are quarantined	X	NA	NA	NA	10
5.11.1	Requests for blood and blood components, tissues and derivatives	NA	X	X	X	5
5.11.1.1	Order for blood, blood components, tests, and derivatives	NA	X	X	X	5
5.12	Serologic confirmation of donor blood ABO/Rh	X	NA	NA	NA	10
5.12.1	Reporting and resolution of ABO/Rh labeling discrepancies to collecting facility	X	NA	NA	NA	10
5.14.1 5.14.2	Test results and interpretation of patient's ABO group and Rh type	NA	X	NA	NA	10
5.14.3	Patient testing to detect unexpected antibodies to red cell antigens	NA	X	NA	NA	10
5.14.3.1	Additional testing to detect clinically significant antibodies	NA	X	NA	NA	10

5.14.6	Control system results appropriate to the method of testing	NA	X	NA	NA	10
5.14.7	Pretransfusion testing for autologous transfusion	NA	X	NA	NA	10
5.14.8	Two determinations of the recipient's ABO group	NA	X	NA	NA	10
5.14.9(1)	ABO group and Rh type	NA	X	NA	NA	10
5.14.9(3)	Difficulty in blood typing, clinically significant antibodies, significant adverse events to transfusion, and special transfusion requirements	NA	X	NA	NA	Indefinite
5.16.1	Test results and interpretation of serologic crossmatch	NA	X	NA	NA	10
5.16.1.1	Detection of ABO incompatibility when no clinically significant antibodies are detected	NA	X	NA	NA	10
5.16.2.2	Computer detection of ABO incompatibility	NA	X	NA	NA	10
5.17.1	ABO/Rh of neonatal recipients	NA	X	NA	NA	10
5.17.1.3	Selection of compatible units when initial antibody screen for neonates demonstrates clinically significant antibodies	NA	X	NA	NA	10
5.17.2	Testing of the neonate's serum or	NA	X	NA	NA	10

	plasma for anti-A or anti-B if a non-group-O neonate is to receive non-group-O Red Blood Cells that are not compatible with the maternal ABO group					
5.18	Intrauterine transfusion policy	NA	X	NA	NA	10
5.19.4.2	Irradiation of cellular components, if applicable	NA	X	NA	NA	10
5.20	Preparation of tissue including: 1. Type of tissue 2. Numeric or alphanumeric identifier 3. Quantity 4. Expiration date and, if applicable, time 5. Personnel who prepared tissue	NA	NA	X	NA	10
5.21	Preparation of derivatives to include: 1. Type of derivative 2. Lot number 3. Quantity 4. Expiration date and, if applicable, time 5. Personnel who prepared the derivative	NA	NA	NA	X	10
5.22	Final inspection of blood and blood	NA	X	NA	NA	10

	components before issue; if the container is not intact or components are abnormal in appearance, maintain record of medical director approval					
5.23	Verification at issue of blood and blood components 1. The intended recipient's two independent identifiers, ABO group, and Rh type 2. The donation identification number, the donor ABO group, and, if required, the Rh type 3. The interpretation of crossmatch tests, if performed 4. Special transfusion requirements, if applicable 5. The expiration date and, if applicable, time 6. The date and time of issue 7. Personnel issuing and accepting blood components	NA	X	NA	NA	10
5.24	Issue of tissue and derivatives, including:	NA	NA	X	X	10

	1. The manufacturer's package insert documents are present and are issued 2. Product quantity and name matches request 3. Final inspection 4. Personnel dispensing tissues or derivative 5. Personnel accepting tissues or derivative for use 6. If issued for a particular patient, the intended recipient's two independent identifiers 7. The date and time of issue					
5.26	If a unit is returned for reissue, confirmation that the blood or blood components have been inspected and are suitable for reissue. If a tissue or derivative is returned for reissue, confirmation that the tissue or derivative is suitable for reissue	X	NA	X	X	10
5.27	A signed statement from the requesting physician indicating	X	X	NA	NA	10

	that the clinical situation was sufficiently urgent to require release of blood before completion of compatibility testing or infectious disease testing					
5.27.6.1	Notification of abnormal test results	NA	X	NA	NA	10
5.28.1	Recipient consent Participation in development of policies, processes, and procedures regarding recipient consent for transfusion	NA	X	NA	NA	5
5.28.3	Verification of the following information before transfusion: 1. The intended recipient's two independent identifiers, ABO group, and Rh type 2. The donation identification number, the donor ABO group, and, if required, the Rh type 3. The interpretation of cross-match tests, if performed	NA	X	NA	NA	5

	4. Special transfusion requirements are met, when applicable The expiration date (or time) of the unit and that it has not expired					
5.28.4	Verification of patient identification before transfusion	NA	X	NA	NA	5
5.28.6	Potential adverse events during the transfusion and for an appropriate time after transfusion	NA	X	NA	NA	5
5.29.1, 7.5	Patient's medical record: transfusion order, documentation of patient consent, component name, donation identification number, date and time of transfusion, pre- and posttransfusion vital signs, the amount transfused, identification of the transfusionist, and, if applicable, transfusion-related adverse events	NA	X	NA	NA	5
5.29.2	Patient's medical record for receipt of tissue to include type of tissue, numeric or alphanumeric	NA	NA	X	NA	10 beyond the date of final dispositio n

	identifier, quantity, expiration date and date of use, personnel using the tissue, and, if applicable, related adverse events					
5.29.3	Patient's medical record for receipt of derivatives to include product name, lot number, quantity, administration date and time, individuals administering the derivative, and, if applicable, related adverse events	NA	NA	NA	X	10 beyond the date of distribution, date of infusion, date of disposition, or date of expiration, whichever is the latest date

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

QSE 6 – Documents and Records

Key Concepts

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

Key Terms

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

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

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

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 *BB/TS 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.*

*21 CFR 606.160, 42 CFR 493.1105

6.1 Document Control

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

6.1.1 Format

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

✎ **6.1.2 Document Review, Approval, and Distribution**

The document control process shall ensure that documents:

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

6.1.2.1 The organization shall ensure all new and revised documents are reviewed and approved before use. Standard 1.3.1 applies.

✎ **6.1.3 Document Changes**

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

6.1.3.1 The organization shall track changes to documents.

6.1.4 Master List of Documents
The organization shall maintain complete lists of all active policies, processes, procedures, labels, forms, and other documents that relate to the requirements of these BB/TS Standards.

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

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

6.1.7 Document Storage
Documents shall be stored in a manner that preserves integrity and legibility; protects from accidental or unauthorized access, loss, destruction, or modification; and ensures accessibility and retrievability.

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

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

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

6.2.1 Records

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

6.2.1.1 The record system shall make it possible to trace any unit of blood, blood component, tissue, or derivative from its source to final disposition; to review the records applying to the specific component; and to investigate adverse events manifested by the recipient.

6.2.1.2 The system shall ensure that the donor and patient identifiers are unique.

6.2.2 Record Traceability

The records system shall ensure traceability of:

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

6.2.3 Information to Be Retained

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

6.2.4 Legibility

All records shall be legible and indelible.

6.2.5 Record Change

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

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

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

6.2.6.1 The actual result of each test performed shall be recorded immediately, and the final interpretation shall be recorded upon completion of testing.

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

6.2.8 Confidentiality
The organization shall ensure the confidentiality of records.

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

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

6.2.11 Storage of Records
Records shall be stored to:

1) Preserve record legibility and integrity for the entire retention period.
2) Protect from accidental or unauthorized access, loss, deterioration, damage, destruction, mix-up, or modification.
3) Permit ready identification.
4) Allow retrieval in a defined time frame.

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

6.3 Electronic Records

The organization shall support the management of information systems.

6.3.1 Access to Data and Information

Access to data and information shall be controlled.

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

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

6.3.2 Data Integrity

Data integrity shall ensure that data are retrievable and usable.

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

6.3.2.2 Data shall be retrievable for the entire retention period.

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

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

6.3.3 Storage Media

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

6.3.4 Backup Data

The organization shall back up all critical data.

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

location.

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

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

Excerpt of Record Retention Standard 6.2.9A Relevant to Documents and Records

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

6.3.1.1.1	Date and identity of person making change(s) to electronic records	X	X	X	X	5

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

Reference Standard 6.2.9A – Retention of Records

Standard	Record to Be Maintained	Donor /Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years)[1]
1.2.2	Management review of effectiveness of the quality system	X	X	X	X	5
1.3	Policies, processes, and procedures	X	X	X	X	10
1.3.2	Exceptions to policies, processes, and procedures	X	X	X	X	10
1.4	Risk assessment	X	X	X	X	5
1.6.1	Emergency operation plan tested at defined intervals	X	X	X	X	2 years, or two organizational testing intervals (whichever is longer)
2.1.1	Job descriptions	X	X	X	X	5
2.1.2	Qualification of personnel performing critical tasks	X	X	X	X	5
2.1.3	Training records of personnel	X	X	X	X	5

2.1.3.1	Training evaluation of personnel	X	X	X	X	5
2.1.4	Evaluations of competence	X	X	X	X	5
2.1.5	Personnel records of each employee	X	X	X	X	5 years following conclusion of employment period
2.1.5.1	Records of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	X	X	X	X	10
2.1.6	Continuing education requirements	X	X	X	X	5
3.2	Equipment qualification	X	X	X	X	10 years after retirement of the equipment
3.4	Unique identification of equipment	X	X	X	X	5
3.5.1	Equipment calibration activities	X	X	X	X	5

3.5.2	Equipment found to be out of calibration	X	X	X	X	5
3.5.3	Equipment monitoring, maintenance, calibration, and repair	X	X	X	X	5
3.6	Implementation and modification of software, hardware, or databases	X	X	X	X	2 years after retirement of system
3.7	Monitoring or technology infrastructure	X	X	X	X	10
3.8.2	Temperature monitoring of refrigerators, freezers, and platelet incubators	X	X	X	X	10
3.8.3	Monitoring of liquid nitrogen levels or temperature	X	X	X	N/A	10
3.9	Alarm system check	X	X	X	X	10
3.10	Warming devices shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and	X	X	N/A	N/A	10

	prevent hemolysis or other damage to blood or blood components.					
4.1	Evaluation and participation in selection of suppliers	X	X	X	X	5
4.2	Agreements	X	X	X	X	5
4.2.1	Agreement review	X	X	X	X	5
4.2.3	Agreements concerning activities involving more than one organization	X	X	X	X	5
4.3	Inspection of incoming critical materials	X	X	X	X	10
4.3.2.1	Incoming containers, solutions, and reagents meet or exceed applicable FDA criteria	X	X	X	X	10
5.1.1	Validation of new or changed processes and procedures	X	X	X	X	5
5.1.2	Quality control records and review of quality control results	X	X	X	X	10

5.1.8	Identification and traceability of products	X	X	X	X	5
5.1.8.1	Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components	X	NA	NA	NA	10
5.1.8.2	Traceability of blood, blood components, tissue, derivatives, and critical materials	X	X	X	X	10
5.1.8.5	Source to final disposition of each unit of blood or blood component and, if issued by the facility for transfusion, identification of the recipient	X	X	X	NA	10
5.1.8.5.1, 5.1.8.5.2	Unique identification of each unit	X	X	X	X	10
5.1.9.3	Records of storage	X	X	X	X	10

	temperatures for blood products					
5.1.9.3.2	Ambient temperature recorded every 4 hours when components are stored in open storage area	X	X	X	X	10
5.1.9.5	Inspection before shipping	X	X	X	X	10
5.1.9.5.1	Container qualification and process validation records	X	X	X	X	10
5.1.10	Participation in proficiency testing program	X	X	X	X	5
5.2.1 #7	Donor acknowledgment that educational materials have been read	X	NA	NA	NA	10
5.2.3	Consent of donors	X	NA	NA	NA	10
5.2.4	Notification to donor of significant abnormal findings	X	NA	NA	NA	10
5.2.4	Donors placed on permanent deferral, and indefinite deferral for protection of recipient	X	NA	NA	NA	Indefinite

5.4.1, 5.4.1.1, 5.4.2, 5.5.2.3	Donor information, including address, medical history, physical examination, health history, or other conditions thought to compromise suitability of blood or blood component	X	NA	NA	NA	10
5.4.4.1	A medical order from the patient's physician is required to collect blood for autologous use	X	NA	NA	NA	10
5.5.3.4	Platelet count for frequent plateletpheresis donors	X	NA	NA	NA	10
5.6.6.2	Cytapheresis record, including anticoagulant drugs given, duration of procedure, volume of components, drugs used, lot number of disposables, and replacement fluids	X	NA	NA	NA	10

5.6.6.2.1	Maximal cumulative dose of sedimenting agent administered to donor in a given time	X	NA	NA	NA	10
5.6.7	Therapeutic apheresis: physician request or other authorized health professional, patient identification, diagnosis, type of therapeutic procedure performed, method used, vital signs before and after the procedure, extracorporeal blood volume if applicable, nature and volume of component removed, nature and volume of replacement fluids, any occurrence of adverse events, and medication administered Therapeutic phlebotomy: physician or other	X	X	NA	NA	5

	authorized health professional request, patient identification, diagnosis, vital signs before the procedure, volume removed, and any occurrence of adverse events					
5.7.2.1	Inspection of weld for completeness and identification numbers of blood or blood components and of lot numbers of disposables used during component preparation	X	NA	NA	NA	10
5.7.3.2.1	Verification of irradiation dose delivery	X	NA	NA	NA	10
5.7.3.3	Donation identification number and collecting facility for each unit in pooled components	X	NA	NA	NA	10
5.7.4	Preparation of specific components	X	NA	NA	NA	10
5.8.1 5.8.2	ABO group and Rh type for all collections	X	NA	NA	NA	10
5.8.3.1	Allogeneic donor testing to detect	X	NA	NA	NA	10

	unexpected antibodies to red cell antigens					
5.8.3.3	Control system results appropriate to the method of testing	X	NA	NA	NA	10
5.8.5	Interpretations of disease marker testing for allogeneic testing	X	NA	NA	NA	10
5.8.5.3	Distribution or issue of units before completion of tests	X	NA	NA	NA	10
5.8.7	Quarantine of units from prior collections when a repeat donor has a reactive disease marker screening test	X	NA	NA	NA	10
5.9.1	Final review of records relating to testing and acceptability criteria	X	NA	NA	NA	10
5.9.4	Review of donor records to ensure any units from an ineligible donor are quarantined	X	NA	NA	NA	10
5.11.1	Requests for blood and blood components, tissues and derivatives	NA	X	X	X	5
5.11.1.1	Order for blood, blood components, tests, and derivatives	NA	X	X	X	5

5.12	Serologic confirmation of donor blood ABO/Rh	X	NA	NA	NA	10
5.12.1	Reporting and resolution of ABO/Rh labeling discrepancies to collecting facility	X	NA	NA	NA	10
5.14.1 5.14.2	Test results and interpretation of patient's ABO group and Rh type	NA	X	NA	NA	10
5.14.3	Patient testing to detect unexpected antibodies to red cell antigens	NA	X	NA	NA	10
5.14.3.1	Additional testing to detect clinically significant antibodies	NA	X	NA	NA	10
5.14.6	Control system results appropriate to the method of testing	NA	X	NA	NA	10
5.14.7	Pretransfusion testing for autologous transfusion	NA	X	NA	NA	10
5.14.8	Two determinations of the recipient's ABO group	NA	X	NA	NA	10
5.14.9(1)	ABO group and Rh type	NA	X	NA	NA	10
5.14.9(3)	Difficulty in blood typing, clinically significant antibodies, significant	NA	X	NA	NA	Indefinite

	adverse events to transfusion, and special transfusion requirements					
5.16.1	Test results and interpretation of serologic crossmatch	NA	X	NA	NA	10
5.16.1.1	Detection of ABO incompatibility when no clinically significant antibodies are detected	NA	X	NA	NA	10
5.16.2.2	Computer detection of ABO incompatibility	NA	X	NA	NA	10
5.17.1	ABO/Rh of neonatal recipients	NA	X	NA	NA	10
5.17.1.3	Selection of compatible units when initial antibody screen for neonates demonstrates clinically significant antibodies	NA	X	NA	NA	10
5.17.2	Testing of the neonate's serum or plasma for anti-A or anti-B if a non-group-O neonate is to receive non-group-O Red Blood Cells that are not compatible	NA	X	NA	NA	10

	with the maternal ABO group					
5.18	Intrauterine transfusion policy	NA	X	NA	NA	10
5.19.4.2	Irradiation of cellular components, if applicable	NA	X	NA	NA	10
5.20	Preparation of tissue including: 1. Type of tissue 2. Numeric or alphanumeric identifier 3. Quantity 4. Expiration date and, if applicable, time 5. Personnel who prepared tissue	NA	NA	X	NA	10
5.21	Preparation of derivatives to include: 1. Type of derivative 2. Lot number 3. Quantity 4. Expiration date and, if applicable, time 5. Personnel who prepared the derivative	NA	NA	NA	X	10
5.22	Final inspection of blood and blood components before issue; if the container is not intact or components are abnormal in	NA	X	NA	NA	10

	appearance, maintain record of medical director approval					
5.23	Verification at issue of blood and blood components 1. The intended recipient's two independent identifiers, ABO group, and Rh type 2. The donation identification number, the donor ABO group, and, if required, the Rh type 3. The interpretation of crossmatch tests, if performed 4. Special transfusion requirements, if applicable 5. The expiration date and, if applicable, time 6. The date and time of issue 7. Personnel issuing and accepting blood components	NA	X	NA	NA	10
5.24	Issue of tissue and derivatives, including: 1. The manufacturer's package insert documents	NA	NA	X	X	10

	are present and are issued 2. Product quantity and name matches request 3. Final inspection 4. Personnel dispensing tissues or derivative 5. Personnel accepting tissues or derivative for use 6. If issued for a particular patient, the intended recipient's two independent identifiers 7. The date and time of issue					
5.26	If a unit is returned for reissue, confirmation that the blood or blood components have been inspected and are suitable for reissue. If a tissue or derivative is returned for reissue, confirmation that the tissue or derivative is suitable for reissue.	X	NA	X	X	10

5.27	A signed statement from the requesting physician indicating that the clinical situation was sufficiently urgent to require release of blood before completion of compatibility testing or infectious disease testing.	X	X	NA	NA	10
5.27.6.1	Notification of abnormal test results	NA	X	NA	NA	10
5.28.1	Recipient consent Participation in development of policies, processes, and procedures regarding recipient consent for transfusion	NA	X	NA	NA	5
5.28.3	Verification of the following information before transfusion: 5. The intended recipient's two independent identifiers, ABO group, and Rh type	NA	X	NA	NA	5

	6. The donation identification number, the donor ABO group, and, if required, the Rh type 7. The interpretation of cross-match tests, if performed 8. Special transfusion requirements are met, when applicable The expiration date (or time) of the unit and that it has not expired					
5.28.4	Verification of patient identification before transfusion	NA	X	NA	NA	5
5.28.6	Potential adverse events during the transfusion and for an appropriate time after transfusion	NA	X	NA	NA	5
5.29.1, 7.5	Patient's medical record: transfusion order, documentation of patient consent, component name, donation identification number, date and time of transfusion, pre-	NA	X	NA	NA	5

	and posttransfusion vital signs, the amount transfused, identification of the transfusionist, and, if applicable, transfusion-related adverse events					
5.29.2	Patient's medical record for receipt of tissue to include type of tissue, numeric or alphanumeric identifier, quantity, expiration date and date of use, personnel using the tissue, and, if applicable, related adverse events	NA	NA	X	NA	10 beyond the date of final disposition
5.29.3	Patient's medical record for receipt of derivatives to include product name, lot number, quantity, administration date and time, individuals administering the derivative, and, if applicable, related adverse events	NA	NA	NA	X	10 beyond the date of distribution, date of infusion, date of disposition, or date of expirat

						ion, whichever is the latest date
6.1.2	Document control, including review and approval of all documents before use	X	X	X	X	5
6.1.3	Review and approval of changes to documents	X	X	X	X	5
6.1.4	List of all active policies, processes, procedures, labels, and forms	X	X	X	X	5
6.1.5	Biennial review of each policy, process, or procedure	X	X	X	X	5
6.1.6	Documents that are archived, destroyed, or made obsolete	X	X	X	X	5
6.2.5	Record change	X	X	X	X	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	X	X	X	X	5

6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	X	X	X	X	5
6.3	Electronic records	X	X	X	X	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	X	X	X	X	5
7.1	Deviations	X	X	X	X	10 years after any impacted product is used or discarded
7.2	Nonconforming products or services	X	X	X	X	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after	X	X	X	X	10

	release and subsequent actions taken, including acceptance for use					
7.2.4.1	Disposition of the nonconforming product or service	X	X	X	X	10
7.3.3	Adverse events related to donation	X	NA	NA	NA	10
7.3.4	Adverse events related to transfusion	NA	X	NA	NA	10
7.3.4.2	Evaluation of suspected transfusion reactions	NA	X	NA	NA	10
7.3.5	Laboratory evaluation and review of clerical information related to suspected hemolytic reactions	NA	X	NA	NA	10
7.3.5.1	Interpretation of the evaluation of suspected transfusion adverse events	NA	X	NA	NA	10
7.3.5.3	Evaluation and interpretation of delayed transfusion adverse events	NA	X	NA	NA	10
7.3.5.4	Look-back to identify recipients who may have been infected with HCV or HIV	X	X	NA	NA	10

7.3.6	Evaluation and interpretation of delayed transfusion adverse events	NA	X	NA	NA	10
7.3.7.1	Transfusion service evaluation and reporting of transmissible diseases	X	X	X	X	10
7.3.7.2	Collection facility's investigation of transmissible diseases	X	NA	NA	NA	10
7.3.8	Look back investigation	X	NA	NA	NA	10
7.3.8.1	Look-back to identify recipients who may have been infected with HCV or HIV	NA	X	NA	NA	10
7.3.10	Investigation of adverse effects, disease transmission, or other suspected adverse events of tissue and derivatives and reporting of such cases to the tissue supplier or manufacturer, and outside agencies as required	NA	X	X	X	10
7.4	Fatality reports	X	X	X	X	10
7.5	Classification of adverse events	X	X	X	X	10
8.1	Internal assessments	X	X	X	X	5

8.2	External assessments	X	X	X	X	5
8.3	Management of assessment results	X	X	X	X	5
8.5	Peer-review assessment of blood utilization	X	X	X	X	5
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	X	X	X	X	5
9.1	Corrective action	X	X	X	X	5
9.2	Preventive action	X	X	X	X	5
10.1.1.1.1	Alarm investigation	X	X	X	X	5
10.2	Monitoring of biological, chemical, and radiation safety	X	X	X	X	5
10.3	Appropriate discard of products	X	X	X	X	10

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

QSE 7 – Deviations, Nonconformances, and Adverse Events

Key Concepts

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

Key Terms

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

Examples of Objective Evidence

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

*21 CFR 606.171, 21 CFR 1271.350, and 42 CFR 493.1103(d).
For accredited facilities that are assessed for CLIA conformance by AABB, refer to the Verification of CLIA Compliance Form before on site assessment.

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

7.1.1 The investigation shall, when applicable, include an assessment of the effect of the deviation on donor eligibility and donor and patient safety.

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

7.2.1 Nonconforming products shall be quarantined and/or destroyed.

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

7.2.3 The organization shall:
1) Identify, quarantine, retrieve, recall, and determine the disposition of nonconforming products or services.

2) Identify and manage nonconforming products or services.
3) Notify users, suppliers, and outside agencies as required.

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. Standard 9.1 applies.†

†21 CFR 606.171.

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

7.2.4.1.1 The records shall include a description of nonconformances and any subsequent actions taken.

7.2.4.2 In cases where quality may have been affected, the nonconformance shall be reported to the customer.

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

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

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

7.3.3 Adverse Events Related to Donation
Adverse events related to the blood donation process shall be assessed, investigated, and monitored.

7.3.4 Adverse Events Related to Transfusion

There shall be a process for the administration of blood and blood components that includes the recognition, evaluation, and reporting of suspected transfusion-related adverse events.

7.3.4.1 Recognition of and Response to Transfusion Reactions

There shall be processes and procedures for the transfusing staff for the recognition of and response to transfusion reactions and for the recording of relevant information in the patient's medical record.

7.3.4.1.1 The process shall include:

1) Definition of signs and symptoms of suspected transfusion reactions.
2) Indications for interruption or discontinuation of the transfusion.
3) Evaluation and the timely clinical management of the patient.

7.3.4.2 When the transfusion is discontinued, the following shall be performed immediately:

1) The label on the blood containers and records shall be examined to detect errors in identifying the patient, blood, or blood component.
2) The recipient's physician or authorized health professional shall be notified.
3) Except in the cases of signs and symptoms suggestive of mild allergic reactions (eg, urticaria):
   a) The BB/TS shall be notified.
   b) The blood container (whether or not it contains any blood) shall be sent to the BB/TS with the attached transfusion set and intravenous solutions, when possible.

c) A posttransfusion sample shall be obtained from the patient and sent to the BB/TS.

✎ **7.3.5 Laboratory Evaluation and Reporting of Transfusion Reactions**

The BB/TS shall have policies, processes, and procedures for the evaluation and reporting of suspected transfusion reactions, including evaluation, review of clerical information by the BB/TS, and notification of the BB/TS medical director.

✎ **7.3.5.1** For suspected hemolytic transfusion reactions, the evaluation shall include the following:

1) The patient's posttransfusion reaction serum or plasma shall be inspected for evidence of hemolysis. Pretransfusion samples shall be used for comparison.
2) A repeat ABO group determination shall be performed on the posttransfusion sample.
3) A direct antiglobulin test shall be performed on the posttransfusion sample. If the result is positive, the most recent pretransfusion sample shall be used for comparison.
4) The BB/TS shall determine under what circumstances additional testing shall be performed and what that testing shall be.
5) Review and interpretation by the medical director.

7.3.5.2 The BB/TS shall have a defined procedure for evaluation of suspected nonhemolytic transfusion reactions including, but not limited to, febrile reactions, possible bacterial contamination, and pulmonary reactions (including TRALI and TACO).

✎ **7.3.5.3** Interpretation of the evaluation shall be recorded in the patient's medical record and, if suggestive of hemolysis, bacterial contamination, pulmonary reactions, or other serious adverse event related to

transfusion, the interpretation shall be reported to the patient's physician or authorized health professional immediately. Standard 7.3.5.4 applies.

7.3.5.4 When a transfusion fatality or other serious, unexpected adverse event occurs that is suspected to be related to an attribute of a donor or a unit, the collecting facility shall be notified immediately and subsequently in writing.

7.3.6 Delayed Transfusion Reactions (Antigen-Antibody Reactions)

If a delayed transfusion reaction is suspected or detected, tests shall be performed to determine the cause. The results of the evaluation shall be reported to the patient's physician or authorized health professional and recorded in the patient's medical record. Standard 7.3.5.4 applies.

7.3.7 Transmissible Diseases

7.3.7.1 Transfusion Service Reporting of Diseases Transmitted by Blood, Tissue, or Derivatives

The transfusion service shall have a defined process to evaluate and report diseases transmissible by blood, blood components, tissue, or derivatives. The process shall include the following:

7.3.7.1.1 Prompt investigation of each event by the medical director.

7.3.7.1.2 If transmission is confirmed or not ruled out, the identity of the implicated blood, blood component(s), tissue, or derivative shall be reported to the collecting facility, tissue supplier, or manufacturer.

7.3.7.2 Collection Facility Investigation of Transmissible Diseases

The collection facility shall have policies, processes, and procedures for:

1) Investigating reports of diseases transmissible by blood, tissue, or derivatives.
2) Deferral of donors.
3) Communicating findings to the reporting facility.

7.3.8 Look-Back

7.3.8.1 Collection Facility

The collection facility shall have a defined process to notify consignees of blood or blood components from donors subsequently found to have, or be at risk for, relevant transmissible diseases.*

*21 CFR 610.46 and 21 CFR 610.47.

7.3.8.2 Transfusion Services

The transfusion service shall have a defined process to:

7.3.8.2.1 Identify recipients, if appropriate, of blood or blood components from donors subsequently found to have, or to be at risk for, relevant transmissible infections.

7.3.8.2.2 Notify, if appropriate, the recipient's physician and/or recipient as specified in FDA regulations and recommendations.†

†21 CFR 610.46, 21 CFR 610.47, and 42 CFR 482.27(b) and (c).

FDA Guidance for Industry: Nucleic Acid Testing (NAT) for Human

Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry (December 2017).

7.3.9 Adverse Events Related to Tissue or Derivatives
The BB/TS shall have a process for investigating adverse effects, disease transmission, or other suspected adverse events related to the use of tissue and derivatives and for promptly reporting such cases to the supplier, manufacturer, and outside agencies as required.

7.4 Fatality Reporting
Fatalities confirmed to be caused by blood donation or blood transfusion shall be reported to outside agencies as required.‡

‡21 CFR 606.170(b).
FDA Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion (updated August 2021).

7.5 Classifying Adverse Events
The BB/TS shall use nationally recognized classifications for donor and patient adverse events. The medical director shall participate in the development of protocols used by the staff to identify, evaluate, and report adverse events.

7.5.1 Internationally recognized classifications shall be used when no national classifications exist.

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

Standard	Record to Be Maintained	Donor/Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years)[1]
7.1	Deviations	X	X	X	X	10 years after any impacted product is used or discarded
7.2	Nonconforming products or services	X	X	X	X	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	X	X	X	X	10
7.2.4.1	Disposition of the nonconforming product or service	X	X	X	X	10
7.3.3	Adverse events related to donation	X	NA	NA	NA	10
7.3.4	Adverse events related to transfusion	NA	X	NA	NA	10
7.3.4.2	Evaluation of suspected transfusion reactions	NA	X	NA	NA	10

7.3.5	Laboratory evaluation and review of clerical information related to suspected hemolytic reactions	NA	X	NA	NA	10
7.3.5.1	Interpretation of the evaluation of suspected transfusion adverse events	NA	X	NA	NA	10
7.3.5.3	Evaluation and interpretation of delayed transfusion adverse events	NA	X	NA	NA	10
7.3.5.4	Look-back to identify recipients who may have been infected with HCV or HIV	X	X	NA	NA	10
7.3.6	Evaluation and interpretation of delayed transfusion adverse events	NA	X	NA	NA	10
7.3.7.1	Transfusion service evaluation and reporting of transmissible diseases	X	X	X	X	10
7.3.7.2	Collection facility's investigation of transmissible diseases	X	NA	NA	NA	10

7.3.8	Look back investigation	X	NA	NA	NA	10
7.3.8.1	Look-back to identify recipients who may have been infected with HCV or HIV	NA	X	NA	NA	10
7.3.9	Investigation of adverse effects, disease transmission, or other suspected adverse events of tissue and derivatives and reporting of such cases to the tissue supplier or manufacturer, and outside agencies as required	NA	X	X	X	10
7.4	Fatality reports	X	X	X	X	10
7.5	Classification of adverse events	X	X	X	X	10

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

QSE 8 – Internal and External Assessments

Key Concepts

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

Key Terms

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

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

✎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. Standards 9.1 and 9.2 apply.
3) Communicated to the appropriate staff.
4) Reported to executive management.

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

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

✎8.5 Utilization Review
Transfusing facilities shall have a peer-review program that monitors and addresses transfusion practices for all categories of blood and blood components. The following shall be monitored:
1) Ordering practices.
2) Patient identification.

3) Sample collection and labeling.
4) Infectious and noninfectious adverse events.
5) Near-miss events.
6) Usage and discard.
7) Appropriateness of use, including the use of group O Rh(D)–positive and Rh(D)-negative Whole Blood, RBCs, and group AB plasma.
8) Blood administration policies.
9) The ability of services to meet patient needs.
10) Compliance with peer-review recommendations.
11) Clinically relevant laboratory results.

Chapter 9, Process Improvement, applies.

Excerpt of Record Retention Standard 6.2.9A Relevant to Internal and External Assessments

Standard	Record to Be Maintained	Donor/ Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years)[1]
8.1	Internal assessments	X	X	X	X	5
8.2	External assessments	X	X	X	X	5
8.3	Management of assessment results	X	X	X	X	5
8.5	Peer-review assessment of blood utilization	X	X	X	X	5

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

QSE 9 – Process Improvement

Key Concepts

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

Key Terms

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Records of collected data analysis and corrective action taken when near-misses, deviations, or adverse events are discovered.
- Tracking of relevant data that affect the organization's current and future operations.
- Records indicating that corrective and preventive action was taken.

- Records indicating that corrective and preventive action taken was effective and is being monitored.
- Documentation that process improvement data are included in executive management review.

9. 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.

9.1 Corrective Action

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

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

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

9.2 Preventive Action

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

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

9.3 Performance Improvement

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

Excerpt of Record Retention Standard 6.2.9A Relevant to Process Improvement

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

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

QSE 10 – Facilities and Safety

Key Concepts

This QSE addresses the safety and adequacy of areas where the work required by these *BB/TS 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 a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

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.

10.1.1 Where liquid nitrogen is stored, specific hazards shall be addressed.

10.1.1.1 Facilities with liquid nitrogen tanks shall have a system in place to monitor oxygen levels and an alarm system set to activate under conditions that will allow action to be taken.

✎ **10.1.1.1.1** Oxygen alarm activation shall require personnel to investigate and document the condition activating the alarm and to take immediate corrective action as necessary.

✎**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 Products**
Products shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

Excerpt of Record Retention Standard 6.2.9A Relevant to Facilities and Safety

Standard	Record to Be Maintained	Donor/ Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years)[1]
10.1.1.1.1	Alarm investigation	X	X	X	X	5
10.2	Monitoring of biological, chemical, and radiation safety	X	X	X	X	5
10.3	Appropriate discard of products	X	X	X	X	10

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

GLOSSARY

ABO Incompatibility Detection: Use of a method (eg, serologic or computer-based) to determine incompatibility of ABO group between donor and recipient.

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.

Allogeneic Donor: An individual from whom products intended for another person are collected.

Antibody Screen: A serologic method to detect the presence of clinically significant antibodies in recipients and/or donors.

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.

Authorized Health Professional: A person permitted to perform certain tasks in accordance with regulations and based on their credentials, qualification, education, training, and experience.

Autologous Donor: A person who acts as his or her own product donor.

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

Blood Bank: A facility that performs, or is responsible for the performance of, the collection, processing, storage, and/or distribution of human blood and/or blood components intended for transfusion and transplantation.

Blood Components: Products prepared from a Whole Blood collection or produced through an automated collection (eg, red cells, plasma, and platelets).

Blood-Group-Compatible: When there is no anticipated harm to the recipient due to identity of the donor antigens or absence of an alloimmune response (eg, a patient of unknown blood type receives group O RBCs or AB plasma,

and a group A patient receives group A or O RBCs and group A or AB plasma).

Blood-Group-Specific: When the component is blood group identical (eg, a group A patient receives group A RBCs and group A plasma).

By a Method Known to: Use of published data to demonstrate the acceptability of a process or procedure, particularly for component preparation.

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.

Clinically Significant Antibody: An antibody that is capable of causing shortened cell survival.

Closed System: A system, the contents of which are not exposed to air or outside elements during collection, preparation, and separation of components.

Collection Facility: A facility that collects blood and/or blood components from a donor.

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.

Compliance: See Conformance.

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.

Convalescent Plasma: Therapeutic convalescent plasma units contain high levels of specific viral/microbe neutralization antibodies sufficient for severe disease reduction. Therapeutic convalescent plasma needs to be distinguished from nontherapeutic plasma, which, while still protective for the donor, will not

protect antibody naïve recipients after the 10-to-20-fold dilution that occurs when transfused into a recipient.

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.

Crossmatch: A method (eg, serologic or computer-based) to detect incompatibility between donor and recipient.

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).

Cytapheresis: A collection procedure where whole blood is removed and separated into components. One or more of the cellular components may be retained, while the remaining elements are combined and returned to the donor or patient.

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

Dedicated Donor: An individual who donates blood components intended for and used solely by a single identified recipient.

Defined Process: A delineated set of steps to perform the contents of the process.

Derivatives: Sterile solutions of a specific protein(s) derived from blood or by recombinant technology (eg, albumin, plasma protein fraction, immune globulin, and factor concentrates).

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.

Expiration: The last day or time that the blood, blood component, tissue, derivative, or material(s) is considered suitable for use.

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: To measure, examine, or test one or more characteristics of a unit of blood or a blood component, a tissue, or a service and compare results with specified requirements in order to establish whether conformance is achieved before distribution or issue.

Guidelines: Documented recommendations.

Health Professional: An individual employed by a facility qualified by education, training, and experience to perform the duties assigned.

Indefinite Deferral: A deferral applied to a donor who is not eligible to donate blood for someone else for an unspecified period.

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 Facility: A facility that imports a product and then ships it to another facility.

Irradiated: Exposure of blood components to x-rays or gamma rays at a minimum dose of 25 Gy (2500 cGy) targeted to the central portion of the irradiation canister or irradiation field to prevent the proliferation of T lymphocytes.

ISBT 128: A standard for the identification, terminology, coding, and labeling of blood, cellular therapy, and tissue products. When linear bar codes are used, Code 128 symbology is utilized.

Issue: To release for clinical use (transfusion or transplantation).

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.

Lived with: Resided in the same dwelling (eg, home, dormitory room, or apartment).

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 BB/TS Standards, including information for document control.

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

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

Neonate: A child less than 4 months of age.

Nonconformance: Failure to meet requirements.

Open System: A system, the contents of which are exposed to air and outside elements during preparation and separation of components.

Operational Continuity: The ability of an organization to maintain essential functions and services during and after a disruption, aiming to minimize impact on its operations and customers. It involves proactive measures to ensure that critical processes can continue functioning, even if faced with unexpected events.

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.

Pathogen Reduction: Exposure of blood components to a system designed to reduce the risk of transfusion-transmitted infections.

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.

Permanent Deferral: A deferral applied to a donor who will never be eligible to donate blood for someone else.

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

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.

Product: A tangible output from a process.

Proficiency Testing: The structured evaluation of laboratory methods that assesses the suitability of processes, procedures, equipment, materials, and personnel.

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.

Quarantine: To isolate nonconforming blood, blood components, tissue, derivatives, or materials to prevent their distribution or use.

Reagent: A substance used to perform an analytical procedure. A substance used (as in detecting or measuring a component or preparing a product) because of its biological or chemical activity.

Record (noun): Information captproiured 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.

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

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

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

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

Relevant Transfusion-Transmitted Infection: A transfusion-transmitted infection defined in FDA regulations [21 CFR 630.3(h)] as any of the following: human immunodeficiency virus, types 1 and 2; hepatitis B virus; hepatitis C virus; human T-lymphotropic virus, types I and II; Treponema pallidum; West Nile virus; Trypanosoma cruzi; Creutzfeldt-Jakob disease; variant Creutzfeldt-Jakob disease; Plasmodium species; babesiosis; and any other transfusion-transmitted infections identified by the FDA as having both of the following:

1. Appropriate screening measure(s) and/or an FDA-licensed, -approved, or -cleared screening test available.
2. Significant incidence and/or prevalence to affect the potential donor population, including agents accidentally or intentionally released.

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.

Risk Assessment: An analysis of risk includes predictable kinds of negative occurrences, severity, and the probability of their happening.

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

Segregate: To separate or isolate products by a method known to clearly identify them and to minimize the possibility of their unintended distribution or use.

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.

Sexual Contact: Any of the following activities (whether or not a condom or other protection was used): vaginal sex (contact between penis and vagina); oral sex (mouth or tongue on someone's vagina, penis, or anus); or anal sex (contact between penis and anus).

Shall: A term used to indicate a requirement.

Special Transfusion Requirements: Refers to a patient's medical need for components that have been modified, such as components that are irradiated, washed, or leukocyte reduced; components from special sources, such as autologous or directed sources; components that need special handling (eg, being subjected to the heat of a blood warming device); or components that contain special attributes (eg, CMV-seronegative or antigen-negative).

Specified Requirements: Any requirements in these BB/TS 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.

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.

Temporary Deferral: A deferral placed on a donor who is not eligible to donate for a specified period.

Tissue: A group of functional cells and/or intercellular matrix intended for implantation, transplantation, or other therapy (eg, cornea, ligaments, bone). Cellular therapy products covered by the AABB's Standards for Cellular Therapy Services are not included herein. A cellular therapy product is defined by the Standards for Cellular Therapy Services as somatic cell-based products (eg, mobilized hematopoietic progenitor cells, cord blood, pancreatic islets) that are procured from a donor and intended for manipulation and/or administration.

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

Transfusion-Associated Circulatory Overload (TACO): Adverse signs and symptoms related to an infusion volume that cannot be effectively processed due to high infusion rate and/or volume.

Transfusion-Related Acute Lung Injury (TRALI): A new acute lung injury within 6 hours of a completed transfusion.

Transfusion Service: A facility that performs one or more of the following activities: compatibility testing, storage, selection, and issuing of blood and blood components to intended recipients. Transfusion services do not routinely collect blood or process Whole Blood into components (except Red Blood Cells and Recovered Plasma).

Transfusionist: The individual(s) in the presence of the recipient who positively identifies and matches the blood component to the recipient through the use of two independent identifiers. This individual may also be responsible for physically initiating and/or maintaining a transfusion of blood or blood products.

True Positive: A positive result on both the initial test and the confirmatory test. Specifically for bacteria detection, a confirmatory test is a culture-based test performed on a different sample than the blood culture bottle or other sample used for the initial test. For example, a sample source for the confirmatory test could be the original platelet component. A subculture of the initial positive culture is not an adequate sample for this purpose. If initial testing was culture-based, the confirmatory test can use the same method applied to the alternate sample source.

Unanticipated Event: Unplanned occurrences that can cause serious injury or harm, or death, to an individual resulting from a deviation(s).

Unit: A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.

Urticaria Reaction: The development of hives, maculopapular rash, or similar allergic manifestation.

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

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.

Xenotransplantation: Any procedure that involves the transplantation, implantation, or infusion into a human recipient of live cells, live tissues, or live organs from a nonhuman animal source.