

## **PROPOSED 34<sup>th</sup> edition of Standards for Blood Banks and Transfusion Services**

**Effective April 1, 2024**

### **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 34th edition begins on page 2 and runs through page 14. The proposed 34th edition begins on page 15 and runs through page 140.

## Updated Quality System Essentials

The proposed 34<sup>th</sup> edition of Standards for Blood Banks and Transfusion Services has incorporated the updated quality system essentials (QSE) template for this edition. This includes a number of updates to the chapters and the tone and flow of the edition.

### Highlights of the updated QSEs include:

- All standards written in the active voice.
- Once a requirement has been stated, it is not repeated.
- Each chapter begins with a description of what the standards therein cover.
- Each chapter contains a list of examples of key terms that mirror the content of the chapter and that should be kept in mind when reviewing the standards.
- Each chapter contains a list of examples of key objectives that an assessor could look for during an onsite assessment, however, this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only.
- Each chapter now concludes with the record retention table for that chapter. Note a comprehensive record retention table still exists at the end of chapter 6.

### Driving factors behind the revisions to the updated QSEs:

- Deliver a streamlined template that mirrors current quality concepts.
- Make it user-friendly to shorten learning curves.
- A top-to-bottom reworking of tone, formatting, language, and style.
- Preserve chapter headings and overall structure, to make it easier for users to follow and understand the core quality concepts.
- Maintain the exact same standards numerology for all core quality standards across all sets of AABB Standards.
  - Incorporate activity-based standards into that structure
- Responding to member needs and requests.
- Beneficial to facilities with multiple accreditations (uniformity of language and numbering).

## Significant Changes to the Proposed 34<sup>th</sup> Edition of Standards for Blood Banks and Transfusion Services

### **4.10.3 Medical Director Qualifications and Responsibilities**

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**

*The committee added the terms, “operations and quality” along with additional references to CLIA requirements for laboratory director responsibilities for completeness.*

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

*✎* **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.**

*The committee added cross-references to standard 1.1.1 in both 1.3.1 and 1.3.2 for completeness. Standard 1.1.1 details the qualifications needed to serve in the capacity of a medical director and who must approve all medical and technical policies, processes and procedures.*

### **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)**

*The committee added a reference to the CFRs concerning personnel requirements for completeness.*

#### *✎* **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, and 42 CFR 493.144.1, and 42 CFR 493.1487**

*The committee added the content in bold to the standard for completeness, understanding that there are*

qualification requirements for personnel in the United States, and the CFRs are applicable, while also recognizing that the CFRs would not apply to facilities outside the US which should follow the applicable laws and regulations to their country.

**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.**

*The committee added a cross-reference to standard 2.1.2 concerning personnel qualification for completeness.*

**5.1.2.1** Quality control results shall be reviewed and evaluated against acceptance criteria.  
**Standard 2.1.2 applies.**

*The committee added a cross-reference to standard 2.1.2 concerning personnel qualification for completeness.*

#### **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.**

*The committee added a cross-reference to standard 4.3, concerning the inspection of incoming receipt, inspection and testing of incoming products.*

#### **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.\* ~~When a CMS approved program is not available, there shall be a system for determining the accuracy and reliability of test results.~~ Results shall be reviewed and when expected results are not achieved, investigation and corrective action shall be taken where appropriate.

\*42 CFR 493.1236.

**5.1.10.1 Laboratories shall ensure that no inter-laboratory communications pertaining to proficiency test events occur until after the submission deadline.\***

**\*42 CFR 493.801(b)(3)**

*The Ie added new standard 5.1.10.1 to address requirements set forth by CMS in July 2022 with an effective date of 2024. This mostly focuses on waived testing, however, the new requirement also addresses proficiency testing referrals and what is and is not allowed until the results of proficiency testing are complete and submitted. The CLIA memo detailing this CFR can be found [here](#).*

**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)(4)**

*The committee added new standard 5.1.10.1.2 in conjunction with the addition of the CFR cited, which requires that laboratories perform proficiency testing to show that they can successfully perform the tests. Laboratories outsource their proficiency testing would not meet the requirements in the CFR. The CLIA memo detailing this CFR can be found [here](#).*

**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)(4)**

*The committee added new standard 5.1.10.1.3 in conjunction with the addition of the CFR cited, which requires that if a laboratory receives samples for proficiency testing from an outside source that they immediately contact CMS who will instruct them on how to move forward. The CLIA memo detailing this CFR can be found [here](#).*

**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.**

*The committee created new standard 5.1.10.4 which was previously the second sentence of standard 5.1.10. The rationale being that this concept did not really fit within the content of the standard. The content or intent of this standard has not changed.*

**5.2.1 Donor Education**

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

- 2) Donors are given educational materials regarding relevant transfusion-transmitted infections.\*

**\*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)**

*The committee, in line with the updated quality template, has removed “have procedures to” for consistency.*

*#2, The committee also added a cross-reference to the new FDA HIV Guidance which requires donor educational materials related to the risk of HIV transmission.*

-  **5.2.2** When parental permission is required, the collection facility shall **ensure information is provided** ~~have a process to provide information~~ 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.

*The committee has edited this standard to mirror the style of the update quality template, for consistency.*

✍ **5.2.4 Donor Notification of Abnormal Findings and Test Results**

The medical director shall **ensure notification to** ~~establish a process to notify~~ 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).

*The committee has edited this standard to mirror the style of the updated quality template, for consistency.*

**5.3.1** The collection facility shall ~~have a policy to~~ ensure that the donor qualification process is private\* and confidential.

\*21 CFR 606.40(a)(1).

*The committee has edited this standard to mirror the style of the updated quality template, for consistency.*

✍ **5.3.2.1** The collection facility shall ~~have a process for treating~~ donor adverse events and ~~providing for~~ emergency medical care as necessary.

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

*The committee has edited standard 5.3.2.1 to mirror the style of the updated quality template, for consistency. New standard 5.3.2.2 previously appeared as the second sentence of standard 5.3.2.1. The intent of standard has not changed.*

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

*The committee has edited this standard to mirror the style of the updated quality template, for consistency.*

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

*The committee removed any gender related terms from standard 5.4.1.3. This ensures that the standards are in line with edits made to the Donor History Questionnaire version 4.0.*

**5.4.3 Protection of the Donor**

The collection facility shall ~~have processes to~~ minimize the adverse effects of donation.

*The committee has edited this standard to mirror the style of the update quality template, for consistency.*

**5.4.3.2** The collection facility ~~shall have a process to reduce~~ **mitigate** the risk of adverse reactions in young donors.

*The committee has edited this standard to mirror the style of the updated quality template, for consistency. The committee also replaced the term “reduce” with “mitigate” for consistency with other standards.*

**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 of the nonretained components to~~ **the donor.**

*The committee edited this standard for clarity. Replacing the elements in strikethrough with “any” does not change the intent of the standard.*

~~**5.7.4.10.1** If a liquid freezing bath is used, the container shall be protected from chemical exposure.~~

~~**5.7.4.11.1** If a liquid freezing bath is used, the container shall be protected from chemical exposure.~~

~~**5.7.4.12.1** If a liquid freezing bath is used, the container shall be protected from chemical exposure.~~

*The committee elected to delete these standards related to liquid freezing baths that followed requirements for FFP, Plasma Frozen Within 24 hours after Phlebotomy, and Plasma Frozen within 24 Hours After Phlebotomy Held at Room Temperature up to 24 Hours After Phlebotomy as the committee has not seen any evidence that this method is currently utilized. The committee will add this for historical context into the guidance.*

## **5.9 Final Labeling**

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

*The committee has edited this standard to mirror the style of the updated quality template, for consistency.*

## **5.10 Final Inspection**

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

*The committee has edited this standard to mirror the style of the updated quality template, for consistency.*

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

*The committee elected to add new standard 5.10.1 to ensure that the COI would be available for provision to the receiving facility or transfusionist, as the COI is considered to be the extended labeling (e.g, package insert) for blood components.*

✍ **5.14.9 Comparison with Previous Records**

The organization shall ~~be a process to 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.

*The content of standard 5.14.9.1 previously appeared as an element of standard 5.14.9. The committee felt that the content better fit as a substandard than as a part of the parent standard. The intent and content of the standard has not changed.*

**5.15.5** The red cells in Apheresis Granulocytes ~~and 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 know to result in a component containing < 2mL of red cells.~~. 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.

*The committee created new standard 5.15.6 by removing platelets from standard 5.15.5 and mirroring the tone and style of standard 5.15.5. The committee felt that the standards for granulocytes and platelets should be separated because the red cell content of Apheresis Granulocytes is expected to exceed 2 mL of red cells.*

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

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

*The committee has edited this standard to mirror the style of the updated quality template, for consistency.*

✍ **5.20 Preparation of Tissue**

The facility shall ~~have policies, processes and procedures to 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:

✍ **5.21 Preparation of Derivatives**

The facility shall ~~have policies, processes and procedures~~ to 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:

*The committee has edited this standard to mirror the style of the updated quality template, for consistency. "In the facility" was added to clarify that the BB/TS's responsibility related to preparatory steps applies to the processes that it performs.*

#### **5.25 Discrepancy Resolution**

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

*The committee has edited this standard to mirror the style of the updated quality template, for consistency.*

#### **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:

- 2) The appropriate temperature has been maintained.\*

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

*The committee added a cross-reference to the CFR cited which requires that any reissue of products contain temperature records for completeness.*

- 5.28.3 In the presence of the recipient, and before initiating** ~~after issue and immediately before transfusion,~~ the following information shall be verified:  
Standard 5.23 applies.

*The committee added the clause in bold for accuracy and reflecting common practice and to mirror the content of standard 5.28.4. The committee elected to delete the cross-reference to standard 5.23 regarding the issuance of blood and components as it did not appear relevant to this process.*

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

*The committee edited this standard for clarity and consistency.*

#### **5.30.2 Individuals** ~~Women~~ 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** ~~woman's~~ test for D antigen is negative. A test for weak D is optional.
- 2) The **individual** ~~woman~~ is not known to be actively immunized to the D antigen.

- 3) The Rh type of the fetus/neonate is unknown, or the type of the fetus/neonate is positive when tested for D or weak D. Weak D testing is required when the test for D is negative.

*The committee removed any gender-related terms from standard. This change ensures that the standards are in line with edits made to the Donor History Questionnaire version 4.0.*

**5.30.3** The **transfusion service** shall **recommend** ~~ensure that the adequate~~ the appropriate dose of Rh Immune Globulin ~~is administered~~

*The committee edited this standard for clarity and to match current practice.*

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

Item No.	Labeling Item	Collection or Preparation	Final Component	Pooled
16	Phrase: “Autologous Donor,” if applicable	NR	R	<del>R</del> NR

*The committee edited the labeling requirement for Pooled components from an autologous donor from “Not Required” to “Required” to address a possible scenario in which autologous components are pooled.*

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

Item No.	Labeling Item	Collection or Preparation	Final Component	Pooled
<i>Additional Autologous Labeling Requirements</i>				
27	Phrase: “Donor untested,” if applicable <sup>11,15</sup>	NR	R	<del>R</del> NA
28	Phrase: “Donor tested within the last 30 days,” if applicable <sup>11,16</sup>	NR	R	<del>R</del> NA
<i>Additional Autologous Labeling Requirements</i>				
29	Intended recipient information label <sup>7</sup>	R	R	<del>R</del> NA
30	Donor tested within the last 30 days, if applicable <sup>16</sup>	NR	R	<del>R</del> NA

*The committee edited the labeling requirements of the Pooled components from “Not Applicable” to “Required” to address a possible scenario in which autologous components are pooled.*

**Reference Standard 5.1.9A – Requirements for Storage, Transportation, and Expiration**

<i>Plasma Components</i>					
27	Cryoprecipitated AHF (after thawing)	20-24 C	As close as possible to 20-24 C	Single unit: 6 hours	Thaw at 30-37 C <b>or in an FDA-cleared</b>

					<b><u>Cryoprecipitate thawing device.</u></b>
29	Pooled Cryoprecipitated AHF (after thawing)	20-24 C	As close as possible to 20-24 C	Pooled in an open system: 4 hours If pooled using a sterile connection device: 6 hours	Thaw at 30-37 C <b><u>or in an FDA-cleared Cryoprecipitate thawing device.</u></b>

The committee added these clarifications to the entries concerning cryo products allowing for the use of FDA cleared cryoprecipitate thawing device. The intent of the entries have not changed.

#### Reference Standard 5.1.9A – Requirements for Storage, Transportation, and Expiration

<i>Plasma Components</i>					
33	FFP (after thawing) <sup>10</sup>	1-6 C	1-10 C	If issued as FFP: 24 hours	Thaw at 30-37 C or by using an FDA-cleared <b><u>plasma thawing device</u></b>
35	Plasma Frozen Within 24 Hours After Phlebotomy (after thawing) <sup>10</sup>	1-6 C	1-10 C	If issued as PF24: 24 hours	Thaw at 30-37 C or by using an FDA-cleared <b><u>plasma thawing device</u></b>
37	Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up to 24 Hours After Phlebotomy (after thawing)	1-6 C	1-10 C	If issued as PF24RT24: 24 hours	Thaw at 30-37 C or by using an FDA-cleared <b><u>plasma thawing device</u></b>
40	Plasma Cryoprecipitate Reduced (after thawing)	1-6 C	1-10 C	If issued as Plasma Cryoprecipitate Reduced: 24 hours	Thaw at 30-37 C <b><u>or in an FDA-cleared plasma thawing device.</u></b>

The committee added these clarifications to the entries concerning plasma products allowing for the use of FDA cleared plasma thawing device. The intent of the entries has not changed.

#### Reference Standard 5.1.9A – Requirements for Storage, Transportation, and Expiration

~~<sup>4</sup>If a liquid freezing bath is used, the container shall be protected from chemical alteration.~~

Footnote 4 was removed to mirror the deletions of standards 5.7.4.10.1, 5.7.4.11.1, and 5.7.4.12.1.

Reference Standard 5.4.1A Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period
9) Drug Therapy	<ul style="list-style-type: none"> <li>• <u>Taken any medication by mouth (oral) to prevent HIV infection (i.e., PrEP or PEP)</u></li> </ul>	<u>3 months</u> <sup>4</sup>
	<ul style="list-style-type: none"> <li>• <u>Received any medication by injection to prevent HIV infection (i.e., long-acting antiviral PrEP or PEP)</u></li> </ul>	<u>2 years</u> <sup>4</sup>
	<ul style="list-style-type: none"> <li>• <u>Taken any medication to treat HIV infection</u></li> </ul>	<u>Permanent</u> <sup>4</sup>

Category	Criteria/Description/Examples	Deferral Period
15) Relevant Transfusion-Transmitted Infections <sup>7</sup>	<ul style="list-style-type: none"> <li>• Present or past clinical or laboratory evidence of infection with HIV, HCV,<sup>12</sup> HTLV, or <i>T. cruzi</i> <del>or as excluded by current FDA regulations and recommendations for the prevention of HIV transmission by blood and components</del><sup>13</sup></li> </ul>	Indefinite
	<ul style="list-style-type: none"> <li>• <u>Ever had a confirmed positive test result for HIV infection</u><sup>4</sup></li> </ul>	<u>Permanent</u>
	<ul style="list-style-type: none"> <li>• Use of a needle to administer <u>inject</u> drugs, <u>steroids or anything not prescribed by their doctor</u></li> </ul>	3 months
	<ul style="list-style-type: none"> <li>• <u>Contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open wound or</u> mucous membranes <del>exposure to blood.</del></li> </ul>	3 months
	<ul style="list-style-type: none"> <li>• <u>Nonsterile skin penetration</u> <ul style="list-style-type: none"> <li>— <u>With instruments or equipment contaminated with blood or body fluids other than the donor's own</u></li> </ul> </li> </ul>	3 months

	<ul style="list-style-type: none"> <li>- Includes tattoos or permanent make-up unless applied by a state-regulated entity with sterile needles and ink that has not been reused</li> <li>• Tattoo, ear or body piercing <ul style="list-style-type: none"> <li>- For tattoos, no deferral if the tattoo was applied by a state-regulated entity with sterile needles and non-reused ink.</li> <li>- <b><u>For ear or body piercings, no deferral if the piercing was done using single-use equipment.</u></b></li> </ul> </li> </ul>	
	<ul style="list-style-type: none"> <li>• Sexual contact with an individual with <b><u>who ever had a positive test result for HIV infection or at high risk of HIV infection</u></b></li> </ul>	3 months <sup>4</sup>
	<ul style="list-style-type: none"> <li>• <b><u>Sexual contact with an individual who in the past 3 months:</u></b> <ul style="list-style-type: none"> <li>-<b><u>has received money, drugs, or other payment for sex.</u></b></li> <li>-<b><u>has used needles to inject drugs, steroids or anything not prescribed by their doctor.</u></b></li> </ul> </li> </ul>	<b><u>3 months<sup>4</sup></u></b>
	<ul style="list-style-type: none"> <li>• <b><u>Received money, drugs, or other payment for sex.</u></b></li> </ul>	<b><u>3 months<sup>4</sup></u></b>
	<ul style="list-style-type: none"> <li>• <b><u>Have had a new sexual partner in the past 3 months and have had anal sex in the past 3 months.</u></b></li> </ul>	<b><u>3 months<sup>4</sup></u></b>
	<ul style="list-style-type: none"> <li>• <b><u>Have had more than one sexual partner in the past 3 months and have had anal sex in the past 3 months.</u></b></li> </ul>	<b><u>3 months<sup>4</sup></u></b>

<sup>4</sup> [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-Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products \(May 2023 August 2020\)](#)

Based on the new FDA guidance and verbiage changes to the FDA-accepted donor history questionnaire, the committee has made the above additions and edits. These changes are being presented as emergent standards to the 33<sup>rd</sup> edition of BBTS Standards.

**Reference Standard 6.2.9A – Retention of Records**

Standard	Record to be Maintained	Donor/ Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years) <sup>1</sup>
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In previous editions of the BB/TS Standards there existed 5 different record retention tables, 6.2A focused on donor/unit records, 6.2B focused on patient records, 6.2C focused on quality records, 6.2D focused on tissue records and 6.2E focused on records of derivatives. The committee has elected to create one complete table that can exist in sequential order with all record retention requirements consolidated with columns for each previous table appearing in the newly consolidated record retention table.

 **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 (~~including TRALI and TACO~~), or other serious adverse event related to transfusion, the interpretation shall be reported to the patient’s physician immediately. Standard 7.3.5.4 applies.

The committee removed the clause in parentheses as it was deemed guidance and unnecessary. Note, there are two separate standards for TRALI and TACO in chapter 5.

**9.1.1 Investigation and corrective action shall include deviations, nonconformances, and complaints relating to blood, blood components, tissue, derivatives, critical materials, and services.**

The committee created new standard 9.1.1 to supplement the revised quality template and standard 9.0 for completeness.

## Chapter 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, local laws, regulations as well as copies of any required certificates
- Defined quality system
- Process for approving exceptions to policies, processes, 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

DRAFT

## 1.0 Organization

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

### 1.1 Executive Management

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

- 1) Responsibility and authority for the quality system and operations.
- 2) Responsibility for compliance with these Standards and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
- 3) Authority to establish or make changes to the quality system.
- 4) Participate in management review of the quality system.

#### 1.1.1 Medical Director Qualifications and Responsibilities

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

## 1.2 Quality System

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

### 1.2.1 Quality Representative

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

### 1.2.2 Management Reviews

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

### 1.3 Policies, Processes, and Procedures

Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these Standards.

**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.

 **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.

### 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. Standard 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.

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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)

<sup>1</sup>Applicable state or local law may exceed this period.

## Chapter 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 his/her 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 (e.g., certifications, qualifications, competence assessments, diplomas, transcripts)
- Training records
- Evaluations of competence records
- Evidence that job qualifications are met
- Continuing education records

## 2.0 Resources

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

## 2.1 Human Resources

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

\*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 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

### 2.1.3 Training

The organization shall provide training for personnel performing critical tasks.

### 2.1.4 Competence

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

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

### 2.1.5 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 *Standards* are met when applicable.

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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
2.1.4	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

<sup>1</sup>Applicable state or local law may exceed this period.

## Chapter 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

### **3.0 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's 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 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 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. \*

\*21 CFR 803.30.

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

#### **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.

### **3.7 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 dated May 11, 2005, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

FDA Final Guidance for Industry and FDA Staff dated January 11, 2002, "General Principles of Software Validation."

#### **3.7.1 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.

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

**3.7.3** The organization shall support the management of information systems.

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

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

### **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. Standard 5.1.9.1.3 applies.

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

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

### **3.9 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.

**3.9.2** 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 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. Standard 3.5 applies.

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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	Equipment traceability	X	X	X	X	5
3.7	Implementation and modification of software, hardware, or databases	X	X	X	X	2 years after retirement of system
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
3.10	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

<sup>1</sup>Applicable state or local law may exceed this period.

## Chapter 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 United States 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

## 4.0 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. 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 *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 Competent Authority criteria.\*

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

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<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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

<sup>1</sup>Applicable state or local law may exceed this period.

## Chapter 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

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## **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 change 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.

### **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.

### **5.1.3 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.\*
- 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.
- 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.
- 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.

\*FDA Guidance for Industry: Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels (June 2014).

United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128, Current Published Version.

†21 CFR 606.121(c)(13).

#### **5.1.8.4 Donor Identification**

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



#### **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 Standard 5.1.9A, Requirements for Storage, Transportation, and Expiration apply.

##### **5.1.9.1 Inventory Management**

###### **5.1.9.1.1**

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

###### **5.1.9.1.2**

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



###### **5.1.9.1.3**

For storage of blood and blood components, the temperature shall

be monitored continuously and recorded at least every 4 hours.



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

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



**5.1.9.2 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).



**5.1.9.2.1** Containers (eg, portable coolers) shall be qualified to transport blood, blood components, tissues, and derivatives to ensure that they maintain temperatures within the acceptable range for the expected 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.

**5.1.10.1** Laboratories shall ensure that no inter-laboratory communications pertaining to proficiency test events occur until after the submission deadline.\*

\*42 CFR 493.801(b)(3)

**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)(4)

**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)(4)

**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 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 20-24 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 17, 2020).

**5.1.11.2.1** Detection methods shall use devices cleared or approved by the FDA or Competent Authority.

**5.1.11.2.2** Pathogen reduction technologies shall be cleared or approved by the FDA or 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.\*

- 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 education 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.<sup>†</sup>
- 7) Donors acknowledge that the educational materials have been read.

\*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)

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

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.

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

**5.3.3 Postphlebotomy Instructions**

**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.

**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** 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.

**5.4.1.3** 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.

**5.4.2 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 within 24 hours of collection. \*

\*21 CFR 630.10(c).

### **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 13, 2001).

FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 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  $\geq 11$  g/dL, or the hematocrit shall be  $\geq 33\%$ .

**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 630.25.

#### **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  $6 \times 10^{11}$  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 17, 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 (February 13, 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.  $9.0 \times 10^{11}$  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/ $\mu$ L shall be deferred from plateletpheresis donation until a subsequent platelet count is at least 150,000/ $\mu$ L. †

†FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 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 (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 Competent Authority criteria. The combined volume limits of red cells and plasma removed from the donor shall follow criteria for the FDA-cleared or 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 intended for room temperature processing and Apheresis Platelets shall be transported and stored in a manner intended to cool the blood and Apheresis Platelets toward a temperature range of 20 to 24 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 Competent Authority. \*
- 2) The phlebotomy is performed for no charge for all individuals with that disease or condition.

\*21 CFR 630.15(a)(2).

## 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 Standard 5.1.9A, Requirements for Storage, Transportation, and Expiration, 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 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 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.

### 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).<sup>†</sup> Alternate methods shall be demonstrated to be equivalent.

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



- 5.7.3.2.1** 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, 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, 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 deglycerolized 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  $450 \pm 45$  mL or when 333 to 449 mL of whole blood is collected into an anticoagulant volume calculated for  $500 \pm 50$  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.

#### **5.7.4.15RECOVERED PLASMA**

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

#### **5.7.4.16PATHOGEN-REDUCED PLASMA**

Pathogen-reduced plasma shall be collected and processed 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.

#### **5.7.4.17CRYOPRECIPITATED AHF**

Cryoprecipitated AHF shall be prepared by a method known to separate the cold insoluble portion from Fresh Frozen Plasma and result in 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 640.54, and 21 CFR 640.56.

#### **5.7.4.18PLASMA 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.

#### **5.7.4.19THAWED PLASMA CRYOPRECIPITATE REDUCED**

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

#### **5.7.4.20PLATELETS**

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  $\geq 6.2$  at the end of allowable storage. FDA criteria apply.\*

\*21 CFR 640.25(b).

#### **5.7.4.21PLATELETS 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  $\geq 6.2$  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).

**5.7.4.22 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 5.7.4.21 applies.

**5.7.4.23 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 17, 2007).

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

**5.7.4.24 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 17, 2007).

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

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

**5.7.4.25 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  $\geq 6.2$  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. \*

\*FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 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 Platelet Additive Solution Added Leukocytes Reduced containing  $<3.0 \times 10^{11}$  platelets shall have the platelet content included on the label.

#### **5.7.4.26 PATHOGEN-REDUCED PLATELETS**

Pathogen-reduced platelets shall be collected and processed as per the manufacturer's written instructions.

**5.7.4.26.1** 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 5.7.4.25 apply.\*

\*FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007).

#### **5.7.4.27 APHERESIS GRANULOCYTES**

Unless prepared for neonates, Apheresis Granulocytes shall be prepared by a method known to yield a minimum of  $1.0 \times 10^{10}$  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<sub>1</sub> 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, the blood shall be tested using a method designed to detect weak D. When either test is positive, the label shall read "Rh POSITIVE." When the tests for both D and weak D are 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 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 610.40I(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.<sup>†</sup>

<sup>†</sup>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.<sup>‡</sup>

<sup>‡</sup>21 CFR 610.40(a)(4), 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 6, 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.

-  **5.11.1.1A** 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 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<sub>1</sub> 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 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 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<sub>1</sub> 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 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.

**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. Standard 5.27.2 applies.

**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 the 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 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 test for weak D is optional.
  - 2) The individual is not known to be actively immunized to the D antigen.
  - 3) The Rh type of the fetus/neonate is unknown, or the type of the fetus/neonate is positive when tested for D or weak D. Weak D testing is required when the test for D is negative.
- 5.30.3 The transfusion service shall recommend the appropriate dose of Rh Immune Globulin.
  - 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 Preparation	Final Component	Pooled
1	Name of blood component or intended component <sup>1</sup>	NR	R	R
2	Donation identification number <sup>1</sup>	R	R	R
3	Identity of anticoagulant <sup>2</sup> or other preservative solution	R	R	R
4	Identity of sedimenting agent, if applicable	NR	R	NA
5	Approximate volume <sup>3</sup>	NR	R	R, total
6	Facility collecting component <sup>1</sup>	NR	R	NR
7	Facility modifying component <sup>4</sup>	NA	R, if leaves the facility	R <sup>1</sup>
8	Storage temperature	NA	R	R
9	Expiration date and, when appropriate, time <sup>5</sup>	NA	R	R
10	ABO group and Rh type <sup>1,6</sup>	NA	R	See line 19
11	Specificity of unexpected red cell antibodies <sup>7-9</sup>	NA	R <sup>2</sup>	R
12	For whole-blood-derived platelets, name of drug taken by donor that adversely affects platelet function <sup>10</sup>	NR	R	NR
13	Instructions to the transfusionist <sup>11</sup> : 1. See <i>Circular of Information for the Use of Human Blood and Blood Components</i> 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	NR	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 <sup>7</sup>	NA	NA	R
20	ABO and Rh of units in pool <sup>6,12</sup>	NA	NA	R

21	Red cell antigens other than ABO or RhD, if applicable <sup>13</sup>	NA	R	NA
22	Actual platelet content for apheresis platelets containing <math><3.0 \times 10^{11}</math>	NA	R	NA
<b><i>Additional Autologous Labeling Requirements</i></b>				
23	Phrase: “For autologous use only” <sup>11</sup>	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 <sup>7</sup>	R	R	R
26	Biohazard label, if applicable <sup>14</sup>	NR	R	R
27	Phrase: “Donor untested,” if applicable <sup>11,15</sup>	NR	R	R
28	Phrase: “Donor tested within the last 30 days,” if applicable <sup>11,16</sup>	NR	R	R
<b><i>Additional Dedicated Donor Labeling Requirements</i></b>				
29	Intended recipient information label <sup>7</sup>	R	R	R
30	Donor tested within the last 30 days, if applicable <sup>16</sup>	NR	R	R
31	Biohazard label, if applicable <sup>14</sup>	NR	R	R
<b><i>Additional Labeling Requirements for Recovered Plasma<sup>16</sup></i></b>				
32	“Caution: For Manufacturing Use Only” or “Caution: For Use in Manufacturing Noninjectable Products Only” based on intended use <sup>11</sup>	NA	R	R
33	Biohazard label, if applicable	NR	R	R
34	“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.

<sup>1</sup>Must be machine-readable (see Standard 5.1.6.3.1).

<sup>2</sup>Not required for Cryoprecipitated AHF; pathogen-reduced cryoprecipitated fibrinogen complex; frozen, deglycerolized, rejuvenated, or washed Red Blood Cells.

<sup>3</sup>For platelets, low-volume Red Blood Cells, plasma, pooled components, and components prepared by apheresis, the approximate volume in the container.

<sup>4</sup>Includes irradiation, if applicable.

<sup>5</sup>21 CFR 606.121 c, 4, i.

<sup>6</sup>Rh type not required for single or pooled Cryoprecipitated AHF, or pathogen-reduced cryoprecipitated fibrinogen complex.

<sup>7</sup>The facility has the option of placing information on a tie tag or label.

<sup>8</sup>Specificity of antibodies is not required for autologous units.

<sup>9</sup>Not required for Cryoprecipitated AHF or pathogen-reduced cryoprecipitated fibrinogen complex.

<sup>10</sup>21 CFR 640.21 (c).

<sup>11</sup>Wording may be different outside of the United States.

<sup>12</sup>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.

<sup>13</sup>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.

<sup>14</sup>Biohazard labels for autologous units or allogeneic units from a dedicated donor shall be used for the following test results:

<u>Test</u>	<u>Test Result</u>
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:	
<i>T. cruzi</i> antibody screening	Repeatedly reactive
<i>Babesia</i> NAT	Positive or reactive†

\*21 CFR 610.40(h)(2), applies.

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

<sup>15</sup>Donor not tested for evidence of relevant transfusion-transmitted infections.

<sup>16</sup>When the first unit has been tested but any unit collected within 30 days after the first collection has not been tested.

<sup>17</sup>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<sup>1</sup>**

<b>Item No.</b>	<b>Component</b>	<b>Storage</b>	<b>Transport<sup>2</sup></b>	<b>Expiration<sup>3</sup></b>	<b>Additional Criteria</b>
<i>Whole Blood Components</i>					
1	Whole Blood	1-6 C	1-10 C	CPD/CP2D: 21 days CPDA-1: 35 days	
2	Whole Blood Irradiated	1-6 C	1-10 C	Original expiration or 28 days from date of irradiation, whichever is sooner	
3	Whole Blood Leukocytes Reduced	1-6 C	1-10 C	CPD/CP2D: 21 days CPDA-1: 35 days Open system: 24 hours	
<i>Red Blood Cell Components, Whole-Blood-Derived or Apheresis-Derived</i>					
4	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	
5	Deglycerolized RBCs	1-6 C	1-10 C	Open system: 24 hours Closed system: 14 days	
6	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 to be retained beyond this time)	Frozen within 6 days of collection unless rejuvenated Frozen before Red Blood Cell expiration if rare unit
7	RBCs Irradiated	1-6 C	1-10 C	Original expiration or 28 days from date of irradiation, whichever is sooner	
8	RBCs Leukocytes Reduced	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days Additive solution: 42 days	

				Open system: 24 hours	
9	Rejuvenated RBCs	1-6 C	1-10 C	CPD, CPDA-1: 24 hours	AS-1: freeze after rejuvenation
10	Deglycerolized Rejuvenated RBCs	1-6 C	1-10 C	Open system: 24 hours Closed system: 14 days	
11	Frozen Rejuvenated RBCs	-65 C or colder	Maintain frozen state	CPD, CPDA-1: 10 years AS-1: 3 years (A policy shall be developed if rare frozen units are to be retained beyond this time)	
12	Washed RBCs	1-6 C	1-10 C	24 hours	
<b>Platelet Components<sup>4-6</sup></b>					
13	Platelets (whole-blood-derived)	20-24 C with continuous gentle agitation <sup>8</sup>	As close as possible to 20-24 C <sup>8</sup> Maximum time without agitation: 30 hours	Up to 5 days, depending on collection system and bacterial testing strategy used	
14	Platelets Cold Stored <sup>9</sup>	1-6 C (agitation optional)	1-10 C	According to manufacturer's written instructions	
15	Platelets Irradiated	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20-24 C <sup>8</sup> Maximum time without agitation: 30 hours	No change from original expiration date	
16	Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20-24 C <sup>8</sup> Maximum time without agitation: 30 hours	Open system: 4 hours Closed system: No change in expiration	

17	Pooled Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20- 24 C <sup>8</sup> Maximum time without agitation: 30 hours	4 hours after pooling or 5 days following collection of the oldest unit in the pool	
18	Pooled Platelets (in open system)	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20- 24 C <sup>8</sup> Maximum time without agitation: 30 hours	Open system: 4 hours	
19	Apheresis Platelets	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20- 24 C <sup>8</sup> Maximum time without agitation: 30 hours	5 days or up to 7 days, depending on the collection system and bacterial testing strategy used	
20	Apheresis Platelets Irradiated	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20- 24 C <sup>8</sup> Maximum time without agitation: 30 hours	No change from original expiration date	
21	Apheresis Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20- 24 C <sup>8</sup> Maximum time without agitation: 30 hours	Open system: within 4 hours of opening the system Closed system: 5 days or up to 7 days depending on the collection system and bacterial testing strategy used	
22	Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20- 24 C <sup>8</sup> Maximum time without agitation: 30 hours	Up to 5 days depending on the collection system and bacterial testing strategy used	

23	Apheresis Platelets Pathogen Reduced	20-24 C with continuous gentle agitation <sup>7</sup>	As close as possible to 20- 24 C <sup>8</sup> Maximum time without agitation: 30 hours	5 days	
<b><i>Granulocyte Components</i></b>					
24	Apheresis Granulocytes	20-24 C without agitation	As close as possible to 20- 24 C without agitation	24 hours	Transfuse as soon as possible; Standard 5.28.10 applies
25	Apheresis Granulocytes Irradiated	20-24 C without agitation	As close as possible to 20- 24 C without agitation	No change from original expiration date	Transfuse as soon as possible; Standard 5.28.10 applies
<b><i>Plasma Components</i></b>					
26	Cryoprecipitated AHF	-18 C or colder	Maintain frozen state	12 months from original collection	Thaw the FFP at 1-6 C Place cryoprecipitate in the freezer within 1 hour after removal from refrigerated centrifuge
27	Cryoprecipitated AHF (after thawing)	20-24 C	As close as possible to 20- 24 C	Single unit: 6 hours	Thaw at 30-37 C or in an FDA-cleared Cryoprecipitate thawing device.
28	Pooled Cryoprecipitated AHF (pooled before freezing)	-18 C or colder	Maintain frozen state	12 months from earliest date of collection of product in pool	Thaw the FFP at 1-6 C Place cryoprecipitate in the freezer within 1 hour after removal from refrigerated centrifuge
29	Pooled Cryoprecipitated AHF (after thawing)	20-24 C	As close as possible to 20- 24 C	Pooled in an open system: 4 hours If pooled using a sterile connection device: 6 hours	Thaw at 30-37 C or in an FDA-cleared Cryoprecipitate thawing device.

30	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	Thaw according to institutional procedures.
31	Pathogen Reduced Cryoprecipitated Fibrinogen Complex (after thawing)	20-24 C	As close as possible to 20-24 C	5 days after thawing	
32	Fresh Frozen Plasma (FFP) <sup>9</sup>	-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 years from collection	Placed in freezer within 8 hours of collection or as stated in FDA-cleared operator's manuals/package inserts Storage at -65 C or colder requires FDA approval if product is stored for longer than 12 months
33	FFP (after thawing) <sup>10</sup>	1-6 C	1-10 C	If issued as FFP: 24 hours	Thaw at 30-37 C or by using an FDA-cleared plasma thawing device
34	Plasma Frozen Within 24 Hours After Phlebotomy (PF24) <sup>10</sup>	-18 C or colder	Maintain frozen state	12 months from collection	
35	Plasma Frozen Within 24 Hours After Phlebotomy (after thawing) <sup>10</sup>	1-6 C	1-10 C	If issued as PF24: 24 hours	Thaw at 30-37 C or by using an FDA-cleared plasma thawing device
36	Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up to 24 Hours After Phlebotomy (PF24RT24)	-18 C or colder	Maintain frozen state	12 months from collection	

37	Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up to 24 Hours After Phlebotomy (after thawing)	1-6 C	1-10 C	If issued as PF24RT24: 24 hours	Thaw at 30-37 C or by using an FDA-cleared plasma thawing device
38	Thawed Plasma <sup>10</sup>	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
39	Plasma Cryoprecipitate Reduced	-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
40	Plasma Cryoprecipitate Reduced (after thawing)	1-6 C	1-10 C	If issued as Plasma Cryoprecipitate Reduced: 24 hours	Thaw at 30-37 C or in an FDA-cleared plasma thawing device.
41	Thawed Plasma Cryoprecipitate Reduced	1-6 C	1-10 C	If issued as Thawed Plasma Cryoprecipitate Reduced: 5 days from date product was thawed or original expiration, whichever is sooner	Shall have been collected and processed in a closed system
42	Liquid Plasma	1-6 C	1-10 C	CPD or CP2D, the expiration for Liquid Plasma is 26 days. If whole blood is stored in CPDA-1, the Liquid Plasma expiration date is 40 days	21 CFR 610.53(b)
43	Recovered Plasma (liquid or frozen)	Refer to short supply agreement	Refer to short supply agreement	Refer to short supply agreement	Requires a short supply agreement <sup>11</sup>
44	Plasma Pathogen Reduced	-18 C or colder	Maintain frozen state	12 months from original collection	
<i>Tissue and Derivatives</i>					

45	Tissue	Conform to source manufacturer's written instructions	Conform to manufacturer's written instructions	Conform to manufacturer's written instructions	21 CFR 1271.3(b), 21 CFR 1271.3(bb), and 21 CFR 1271.15(d)
46	Derivatives	Conform to manufacturer's written instructions	Conform to manufacturer's written instructions	Conform to manufacturer's written instructions	

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<sup>1</sup>Products may be pathogen reduced if approved by the FDA.

<sup>2</sup>For products being transported between the collection and processing site, Standards 5.6.5 and 5.6.5.1 apply.

<sup>3</sup>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.

<sup>4</sup>The platelet storage system shall be FDA-cleared or -approved for the conditions specified.

<sup>5</sup>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).

<sup>6</sup>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).

<sup>7</sup>21 CFR 600.15(a), 21 CFR 640.25(a).

<sup>8</sup>21 CFR 610.53(b).

<sup>9</sup>Applies to modified, unmodified, apheresis, and whole-blood-derived platelet products.

<sup>10</sup>These lines could apply to apheresis plasma or whole-blood-derived plasma.

<sup>11</sup>21 CFR 601.22.

**Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification**

Category	Criteria/Description/Examples	Deferral Period
1) Age	<ul style="list-style-type: none"> <li>• Conform to applicable state law or</li> <li>• ≥16 years</li> </ul>	
2) Blood Pressure <sup>1</sup>	<ul style="list-style-type: none"> <li>• 90-180 mm Hg systolic</li> <li>• 50-100 mm Hg diastolic</li> </ul>	
3) Pulse <sup>1</sup>	<ul style="list-style-type: none"> <li>• 50-100 beats per minute, without pathologic irregularities</li> </ul>	
4) Whole Blood Volume Collected	<ul style="list-style-type: none"> <li>• Maximum of 10.5 mL/kg of donor weight, including samples</li> </ul>	
5) Donation Interval	<ul style="list-style-type: none"> <li>• 8 weeks after whole blood donation (Standards 5.5.1-5.5.4 and 5.6.7.1 apply)</li> <li>• 16 weeks after 2-unit Red Blood Cell collection</li> <li>• 4 weeks after infrequent plasmapheresis</li> <li>• ≥2 days after plasma-, single platelet-, or leukapheresis</li> <li>• ≥7 days after double or triple platelet apheresis<sup>2</sup></li> </ul>	
6) Temperature	<ul style="list-style-type: none"> <li>• ≤37.5 C (99.5 F) if measured orally, or equivalent if measured by another method</li> </ul>	
7) Hemoglobin/ Hematocrit	<ul style="list-style-type: none"> <li>• ≥12.5 g/dL, ≥38% women; ≥13.0 g/dL, ≥39% men</li> <li>• For double Red Blood Cell collections, follow instrument operator’s manual</li> </ul>	<a href="#">21 CFR 630.10(f)(3)</a>
8) Weight	<ul style="list-style-type: none"> <li>• All donors shall weigh a minimum of 50 kg (110 lb)</li> <li>• For plasmapheresis collections, the donor shall be weighed</li> <li>• For all other product collections, self-reported weight is acceptable</li> </ul>	
9) Drug Therapy <sup>3</sup>	<ul style="list-style-type: none"> <li>• The facility shall use the current version of the Medication Deferral List within 6 months of the list’s effective date</li> <li>• (<a href="http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx">http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx</a>)</li> </ul>	Defer according to the current version of the Medication Deferral List
	<ul style="list-style-type: none"> <li>• Other medications</li> </ul>	As defined by the facility’s medical director
	<ul style="list-style-type: none"> <li>• Taken any medication by mouth (oral) to prevent HIV infection (i.e., PrEP or PEP)</li> </ul>	3 months <sup>4</sup>
	<ul style="list-style-type: none"> <li>• Received any medication by injection to prevent HIV infection (i.e., long-acting antiviral PrEP or PEP)</li> </ul>	2 years <sup>4</sup>
	<ul style="list-style-type: none"> <li>• Taken any medication to treat HIV infection</li> </ul>	Permanent <sup>4</sup>

10) Medical History and General Health	<ul style="list-style-type: none"> <li>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</li> <li>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</li> </ul>	
	<ul style="list-style-type: none"> <li>For donors previously deferred for family genetic history of Creutzfeldt-Jakob disease (CJD)<sup>5</sup></li> </ul>	Defer in accordance with FDA Guidance
11) Pregnancy	<ul style="list-style-type: none"> <li>Defer if pregnant within the last 6 weeks</li> </ul>	21 CFR 630.10(e)(v)
12) Receipt of Blood, Blood Component, or Human Tissue	<ul style="list-style-type: none"> <li>Receipt of human cadaveric (allogeneic) dura mater transplant</li> <li>Donors previously deferred for human growth hormone</li> <li>Receipt of blood, components, or human tissue</li> </ul>	<p>Permanent</p> <p>Permanent in accordance with FDA Guidance</p> <p>3 months</p>
13) Xenotransplantation	<ul style="list-style-type: none"> <li>Receipt of live cells, live tissues, or live organs from a nonhuman animal source</li> </ul> <p>Note: Nonliving biological products or materials from nonhuman animals, such as porcine or bovine heart valves and porcine insulin, are acceptable</p>	Indefinite
14) Immunizations and Vaccinations	<ul style="list-style-type: none"> <li>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)]</li> <li>Receipt of recombinant vaccine [eg, HPV and Zoster Recombinant, Adjuvanted (Shingrix) Vaccine]</li> <li>Receipt of intranasal live attenuated flu vaccine</li> </ul>	None
	<ul style="list-style-type: none"> <li>Receipt of Vaxchora (live attenuated, nonsystemically absorbed, oral Cholera vaccine)</li> </ul>	None
	<ul style="list-style-type: none"> <li>Receipt of live attenuated viral and bacterial vaccines [Measles (rubeola), Mumps, Polio (Sabin/oral), Typhoid (oral), Yellow fever]</li> </ul>	2 weeks
	<ul style="list-style-type: none"> <li>Receipt of live attenuated viral and bacterial vaccines [German measles (rubella), chicken pox/shingles (varicella zoster)]</li> </ul>	4 weeks
	<ul style="list-style-type: none"> <li>Receipt of Jynneos vaccine for Smallpox and Monkeypox (Attenuated, live, nonreplicating vaccine).</li> </ul>	None

	<ul style="list-style-type: none"> <li>• Smallpox Vaccinia Vaccine (Live virus vaccine comprised of Vaccinia Virus – “replication competent” vaccine)</li> </ul>	Refer to FDA Guidance <sup>6</sup>
	<ul style="list-style-type: none"> <li>• SARS – CoV-2 <ul style="list-style-type: none"> <li>– Individuals who received a nonreplicating, inactivated, or mRNA-based vaccine</li> <li>– Individuals who received a live-attenuated viral COVID-19 vaccine</li> <li>– Individuals who are uncertain about which COVID-19 vaccine was administered</li> </ul> </li> </ul>	None 14 days 14 days
	<ul style="list-style-type: none"> <li>• Receipt of other vaccines, including unlicensed vaccines</li> </ul>	As determined by the medical director or defer according to the current version of the Medication Deferral List
15) Relevant Transfusion-Transmitted Infections <sup>7</sup>	<ul style="list-style-type: none"> <li>• Confirmed positive test for HBsAg<sup>8</sup></li> </ul>	Permanent
	<ul style="list-style-type: none"> <li>• Repeatedly reactive test for anti-HBc on more than one occasion<sup>9</sup></li> <li>• Positive HBV NAT result</li> </ul>	Indefinite Indefinite <sup>10</sup>
	<ul style="list-style-type: none"> <li>• Repeatedly reactive test for anti-HTLV on more than one occasion</li> </ul>	Indefinite <sup>11</sup>
	<ul style="list-style-type: none"> <li>• Present or past clinical or laboratory evidence of infection with HIV, HCV,<sup>12</sup> HTLV, or <i>T. cruzi</i><sup>13</sup></li> </ul>	Indefinite
	<ul style="list-style-type: none"> <li>• Ever had a confirmed positive test result for HIV infection<sup>4</sup></li> </ul>	Permanent
	<ul style="list-style-type: none"> <li>• Evidence or obvious stigmata of parenteral drug use</li> </ul>	Indefinite
	<ul style="list-style-type: none"> <li>• Use of a needle to inject drugs, steroids or anything not prescribed by their doctor</li> </ul>	3 months
	<ul style="list-style-type: none"> <li>• Contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor’s open wound or mucous membranes.</li> </ul>	3 months
	<ul style="list-style-type: none"> <li>• Tattoo, ear or body piercing</li> <li>-For tattoos, no deferral if the tattoo was applied by a state regulated entity with sterile needles and non-reused ink.</li> <li>-For ear or body piercings, no deferral if the piercing was done using single-use equipment.</li> </ul>	3 months

	<ul style="list-style-type: none"> <li>• Sexual contact or lived with an individual who: <ul style="list-style-type: none"> <li>- Has acute or chronic hepatitis B (positive HBsAg test, HBV NAT)</li> <li>- Has symptomatic hepatitis C</li> </ul> </li> </ul>	3 months
	<ul style="list-style-type: none"> <li>• Sexual contact with an individual who ever had a positive test result for HIV infection</li> </ul>	3 months <sup>4</sup>
	<ul style="list-style-type: none"> <li>• Sexual contact with an individual who, in the past 3 months: <ul style="list-style-type: none"> <li>- Has received money, drugs, or other payment for sex.</li> <li>- Has used needles to inject drugs, steroids or anything not prescribed by their doctor.</li> </ul> </li> </ul>	3 months <sup>4</sup>
	<ul style="list-style-type: none"> <li>• Received money, drugs, or other payment for sex.</li> </ul>	3 months <sup>4</sup>
	<ul style="list-style-type: none"> <li>• Have had a new sexual partner in the past 3 months <b>and</b> have had anal sex in the past 3 months.</li> </ul>	3 months <sup>4</sup>
	<ul style="list-style-type: none"> <li>• Have had more than one sexual partner in the past 3 months <b>and</b> have had anal sex in the past 3 months.</li> </ul>	3 months <sup>4</sup>
	<ul style="list-style-type: none"> <li>• Incarceration in a correctional institution (including juvenile detention, lockup, jail, or prison) for 72 or more consecutive hours<sup>15</sup></li> </ul>	12 months
	<ul style="list-style-type: none"> <li>• Syphilis or gonorrhea <ul style="list-style-type: none"> <li>- Following the diagnosis of syphilis or gonorrhea; must have completed treatment</li> <li>- Donor who has a reactive screening test for syphilis<sup>16</sup></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- 3 months<sup>16</sup></li> <li>- Indefinite; donor re-entry in accordance with FDA Guidance</li> </ul>
	<ul style="list-style-type: none"> <li>• West Nile virus</li> </ul>	In accordance with FDA Guidance <sup>17</sup>
	<ul style="list-style-type: none"> <li>• Malaria<sup>18</sup> These deferral periods apply <i>in non-malaria-endemic countries</i>, irrespective of the receipt of antimalarial prophylaxis: <ul style="list-style-type: none"> <li>- Prospective donors who have had a diagnosis of malaria</li> </ul> </li> </ul>	3 years after becoming asymptomatic while residing in a non-malaria-endemic country for the same 3-year period

	<ul style="list-style-type: none"> <li>- 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</li> <li>- 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 who have traveled to an area where malaria is endemic before living at least 3 consecutive years in non-malaria-endemic country(ies)</li> <li>- Individuals who meet either of the following criteria: <ul style="list-style-type: none"> <li>o Traveled to an area where malaria is endemic</li> <li>o 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)<sup>18</sup></li> </ul> </li> </ul>	<p>3 years after departure from malaria-endemic country(ies) lived in</p> <p>3 years after departure from malaria-endemic area(s) traveled to</p> <p>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 Competent Authority approved pathogen reduction device)</p>
	Reactive test for <i>Babesia</i> spp.	At least 2 years; donor re-entry in accordance with FDA Guidance <sup>13</sup>
16) Travel	<ul style="list-style-type: none"> <li>• The prospective donor’s travel history shall be evaluated for potential risks<sup>18-20</sup></li> </ul>	
	<ul style="list-style-type: none"> <li>• Donors recommended for deferral for risk of vCJD, as defined in most recent FDA Guidance<sup>4</sup></li> </ul>	In accordance with FDA Guidance

<sup>1</sup>For blood pressure, see 21 CFR 630.10(f)(2); for pulse, see 21 CFR 630.10(f)(4).

<sup>2</sup>FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007).

<sup>3</sup>Medication Deferral List current version at <http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx>.

<sup>4</sup>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)

<sup>5</sup>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 (August 2020).

<sup>6</sup>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 30, 2002).

<sup>7</sup>21 CFR 610.40.

<sup>8</sup>FDA Memorandum: Recommendations for the Management of Donors and Units that are Initially Reactive for Hepatitis B Surface Antigen (December 2, 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).

<sup>9</sup>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 30, 2010).

<sup>10</sup>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).

<sup>11</sup>FDA Guidance for Industry: Donor Screening for Antibodies to HTLV-I/II (February 2020).

<sup>12</sup>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).

<sup>13</sup>FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components Intended for Transfusion (December 2010).

<sup>14</sup>FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis (May 2019).

<sup>15</sup>21 CFR 630.10(e)(1)(iv).

<sup>16</sup>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 17, 2020).

<sup>17</sup>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 6, 2009).

<sup>18</sup>FDA Guidance for Industry: Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria (December 2022).

<sup>19</sup>[www.cdc.gov/travel](http://www.cdc.gov/travel).

<sup>20</sup>FDA Guidance for Industry: Recommendations for Assessment of Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus (January 2017).

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
5.1.1	Validation of new or changed processes and procedures	X	X	X	X	5
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
5.1.9.1.3	Records of storage temperatures for blood products	X	X	X	X	10
5.1.9.1.3.1	Ambient temperature recorded every 4 hours when components are stored in open storage area	X	X	X	X	10
5.1.9.2	Inspection before shipping	X	X	X	X	10
5.1.9.2.1	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

<b>Standard</b>	<b>Record to be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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	Cytopheresis 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 authorized health professional request, patient identification, diagnosis, vital signs before the procedure, volume	X	X	NA	NA	5

	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 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 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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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 with the maternal ABO group	NA	X	NA	NA	10
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 appearance, maintain record of medical director approval	NA	X	NA	NA	10

Standard	Record to Be Maintained	Donor/ Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years) <sup>1</sup>
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 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	NA	NA	X	X	10

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
5.26	<p>If a unit is returned for reissue, confirmation that the blood or blood components have been inspected and are suitable for reissue.</p> <p>If a tissue or derivative is returned for reissue, confirmation that the tissue or derivative is suitable for reissue</p>	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	<p>Recipient consent</p> <p>Participation in development of policies, processes, and procedures regarding recipient consent for transfusion</p>	NA	X	NA	NA	5

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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 crossmatch tests, if performed 4. Special transfusion requirements are met, when applicable The expiration date (or time) of the unit and that it has not expired	NA	X	NA	NA	5
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 identifier, quantity, expiration date and	NA	NA	X	NA	10 beyond the date of final disposition

	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

<sup>1</sup>Applicable state or local law may exceed this period.

## Chapter 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 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 back up plans

- Record change process
- Obsolescence of records and disposition
- Record destruction

DRAFT

## **6.0 Documents and Records**

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

### **6.1 Document Control**

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

#### **6.1.1 Format**

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

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

The document control process shall ensure that documents:

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

**6.1.2.1** 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 *Standards*.

#### **6.1.5 Review of Policies, Processes, and Procedures**

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

#### **6.1.6 Document Retention**

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

### **6.1.7 Document Storage**

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

### **6.1.8 Document Retrieval**

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

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

## **6.2 Record Control**

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

### **6.2.1 Records**

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

**6.2.1.1** 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 *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.

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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

<sup>1</sup>Applicable state or local law may exceed this period.

**Reference Standard 6.2.9A – Retention of Records**

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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
2.1.4	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	Equipment traceability	X	X	X	X	5

3.7	Implementation and modification of software, hardware, or databases	X	X	X	X	2 years after retirement of system
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
3.10	Warning 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
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
5.1.8	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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
5.1.9.1.3	Records of storage temperatures for blood products	X	X	X	X	10
5.1.9.1.3.1	Ambient temperature recorded every 4 hours when components are stored in open storage area	X	X	X	X	10
5.1.9.2	Inspection before shipping	X	X	X	X	10
5.1.9.2.1	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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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 occurrence of adverse events	X	X	NA	NA	5
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 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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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 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	NA	X	NA	NA	10
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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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 appearance, maintain record of medical director approval	NA	X	NA	NA	10
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

Standard	Record to Be Maintained	Donor/ Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years) <sup>1</sup>
5.24	Issue of tissue and derivatives, including: 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	NA	NA	X	X	10
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

Standard	Record to Be Maintained	Donor/ Unit	Patient	Tissue	Derivative	Minimum Retention Time (in years) <sup>1</sup>
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 6. The donation identification number, the donor ABO group, and, if required, the Rh type 7. The interpretation of crossmatch 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	NA	X	NA	NA	5
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	NA	X	NA	NA	5

	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 expiration, 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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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 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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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	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

<sup>1</sup>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, Food and Drug Administration (FDA)]

## **7.0 Deviations, Nonconformances, and Adverse Events**

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

\*21 CFR 606.171 and 21 CFR 1271.350

### **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 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 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 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.

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<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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

<sup>1</sup>Applicable state or local law may exceed this period.

## Chapter 8 – Assessments: Internal and External

**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 data or multiple-source data, as long as it is clear how the data will come together to define the indicator.*

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

### Examples of Objective Evidence:

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

## **8.0 Internal and External Assessments**

The organization shall conduct assessments of operations and quality systems.

### **✎ 8.1 Internal Assessments**

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

### **✎ 8.2 External Assessments**

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

### **✎ 8.3 Management of Assessment Results**

The results of assessments shall be:

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

## **8.4 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 and group O Rh(D)-negative RBCs and 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.

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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

<sup>1</sup>Applicable state or local law may exceed this period.

## Chapter 9 – Process Improvement

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

**Key Terms:**

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

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

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

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

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

**Nonconformance:** Failure to meet requirements.

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

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

**Examples of Objective Evidence:**

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

## **9.0 Process Improvement**

The organization shall collect data, perform analysis, and followup 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 relating to blood, blood components, tissue, derivatives, critical materials, and services.

## **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.

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
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

<sup>1</sup>Applicable state or local law may exceed this period.

## Chapter 10 – Facilities and Safety

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

### Key Terms:

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

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

**Organization:** *An institution, or 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

## **10.0 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.

<b>Standard</b>	<b>Record to Be Maintained</b>	<b>Donor/ Unit</b>	<b>Patient</b>	<b>Tissue</b>	<b>Derivative</b>	<b>Minimum Retention Time (in years)<sup>1</sup></b>
10.1.1.1	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

<sup>1</sup>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.

**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 is transfused with 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.

**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.

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

**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.

**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 for 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 *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 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 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.

**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.

**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 transfusion--transmitted infections: 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 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 *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.

**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.

**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).

**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.

**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.

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