

# Fundamental Standards for Blood Collection and Transfusion

1<sup>ST</sup> EDITION



Advancing Transfusion and  
Cellular Therapies Worldwide

# QUICK REFERENCE

## 1st Edition Chapters

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| 1.0  | Organization                                    |
| 2.0  | Resources                                       |
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| 4.0  | Supplier and Customer Issues                    |
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| 8.0  | Assessments: Internal and External              |
| 9.0  | Process Improvement Through Corrective Action   |
| 10.0 | Facilities and Safety                           |

**Fundamental Standards for Blood Banks  
and Transfusion Services**  
1st Edition



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## PREFACE

**T**he Standards Program Committee (SPC) and the Global Transfusion Services Standards Committee (GS SC) are pleased to present this 1st edition of *Fundamental Standards for Blood Banks and Transfusion Services (Fundamentals)*.

The SPC is the umbrella committee whose primary role is to oversee the creation, development, and revision of all AABB standards to ensure harmonization and consistency in AABB's standard-setting activities. The SPC consists of a committee chair, the chair of the Standards Interpretation Committee, as well as the chairs of the seven specialty committees.

The GS SC developed this 1st edition of *Fundamentals* as a tool to assist users and facilities as a first step of incorporating quality concepts, and technical requirements in blood banking. This edition, unlike all other sets of AABB Standards, does not have an associated accreditation program. The purpose of this document is to serve as a resource only and introduction to AABB standards setting.

The process of developing the requirements in *Fundamentals* requires that the final publication reflects the concerns and priorities of several different aspects of the discipline, including the input of recognized experts in the field and the best interests of their donors and patients. In addition, *Fundamentals* was developed in the context of the global drive for quality in health care and internationally recognized principles of quality management. To this end, the GS SC also consulted the scientific literature on blood bank and transfusion service techniques and applications. Accordingly, the *Fundamentals* are based on input from a variety of sources, including member and public comments. In an effort to harmonize AABB publications, like the AABB standards, the *Fundamentals* have incorporated the AABB Quality System Essentials (first identified in Association Bulletin #97-4) as the foundation of the standards.

This effort was truly an international collaborative effort to bring tools to regions currently without minimum standards for blood transfusion. Representatives from international blood banking organizations contributed over many years to try to create a set of standards that are achievable with limited resources, at the same time ensuring safe blood transfused in a safe fashion. These standards are not intended to replace or substitute for Standards and guidelines currently in existence. Specifically, for those institutions able to achieve accreditation conforming with current AABB Standards (including those with variances for international sites that need not adhere to FDA requirements) we continue to encourage assessment and accreditation through the current pathway. For institutions eligible to use the Stepwise Standards co-developed by the African Society for Blood Transfusion and the AABB, these Standards do not replace and are not a substitute for the current standards. Rather, this effort is to provide a first step for institutions that are not eligible to use the stepwise standards to help ensure quality by embarking on a process improvement journey. We look forward to dialogue with various international groups and organizations as to what the next steps should be, such as developing an intermediate and more advanced international version. Similarly, for those organizations hoping to move towards some sort of accreditation process, how can organizations work together to establish affordable yet robust assessment process that results in some sort of regionally recognized accreditation. Thanks to AABB staff for their dauntless pursuit of this international goal and to the myriad contributing individuals and organizations.

Jed Gorlin, MD, MPH  
Chair, Global Standards Committee

## INTRODUCTION

**T**he *Fundamental Standards for Blood Banks and Transfusion Services (Fundamentals)* was prepared by the Global Standards Committee (GS SC) and the Standards Program Committee of AABB. The goal of the *Fundamentals* is to maintain and enhance the quality and safety of services provided by blood banks and transfusion services.

The following frequently asked questions will help users of this publication better understand the 1st edition of *Fundamentals*:

### **Are the standards requirements or recommendations?**

The *Fundamentals* contains requirements that can be implemented by interested blood banks and transfusion services. A requirement contains the word “shall,” which indicates that the statement is mandatory. There are rare instances in which a standard uses the term “may.” A statement that uses “may” is not a requirement.

### **How does this publication relate to other laws and regulations?**

The *Fundamentals* was developed on the basis of good medical practice and, when available, scientific and evidence-based data. The requirements in this publication can be followed by a blood bank or transfusion service located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. The *Fundamentals* are not intended as a substitute for legal advice, and the content should not be relied upon for legal purposes. Users therefore must make their own determinations as to how best to ensure compliance with all applicable laws and requirements, including consulting legal counsel familiar with these issues.

**Does this publication require me to follow my own local laws and regulations?**

Yes. In many standards, the GS SC chose to use the term “specified requirements.” This phrase is defined in the glossary to include any applicable requirement under which a service might operate. These could include, but are not limited to, a federal regulation, a customer agreement, a practice standard, the instructions for the intended use of a device, or a requirement of an accrediting organization.

**What does the pen symbol (  ) mean?**

When the pen symbol precedes a standard, users have to maintain a record of that activity in order to meet the standard. Readers should refer to the reference standard at the end of Chapter 6 to determine what that record must contain and the length of record retention.

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# 1. Organization

## 1.0 Organization

The blood bank or transfusion service (hereinafter referred to as the BB/TS) shall have a structure that clearly defines and documents the parties responsible for the provision of blood, blood components, and services and the relationship of individuals responsible for key quality functions.

### 1.1 Executive Management

The BB/TS shall have a defined executive management. Executive management shall have:

- 1) Responsibility and authority for the blood bank's or transfusion service's operations.
- 2) The authority to establish or make changes to the blood bank's or transfusion service's quality system.
- 3) The responsibility for compliance with these *Fundamental Standards for BB/TS (Fundamentals)* and applicable local laws and regulations.

**1.1.1** The BB/TS shall have a director who is a licensed physician/scientist who is qualified by appropriate education, training, and/or experience. The director shall have responsibility and authority for all policies, processes, and procedures—including those that pertain to laboratory personnel and test performance. The director may delegate these responsibilities to another qualified individual; however, the director shall retain ultimate responsibility for director duties.

**1.1.2** The BB/TS shall have a licensed physician who is qualified by appropriate education, training, and/or experience. The physician shall have responsibility

for all medical issues and the support services that relate to the medical care and safety of transfusion recipients or donors.

### 1.2 **Quality System**

A quality system shall be defined, documented, implemented, and maintained. All personnel shall be trained in its application.



#### 1.2.1 **Management Reviews**

Management shall assess the effectiveness of the quality system through scheduled management reviews at planned intervals.

### 1.3 **Policies, Processes, and Procedures**

Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these *Fundamentals* are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

**1.3.1** All policies, processes, and procedures shall be approved by the director; the BB/TS licensed physician shall approve medically related policies, processes, and procedures.



**1.3.2** Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and preapproval by the BB/TS licensed physician. Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

### 1.4 **Emergency Preparedness**

The BB/TS shall have emergency operation policies, processes, and procedures to respond to the effects of internal and external disasters.



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## 2. RESOURCES

### 2.0 Resources

The BB/TS shall have policies, processes, and procedures to ensure the provision of adequate resources to perform, verify, and manage all activities in the BB/TS.

### 2.1 Human Resources

The BB/TS shall have a process to ensure the employment of an adequate number of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.

#### 2.1.1 Qualification

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

#### 2.1.2 Training

The BB/TS shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.

#### 2.1.3 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals at a minimum of every two years.

#### 2.1.4 Personnel Records

Personnel records for each employee shall be maintained.

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## 3. EQUIPMENT

### 3.0 Equipment

The BB/TS shall identify the equipment that is critical to the provision of blood, blood components, and/or services. The BB/TS shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conforms to these *Fundamentals* and other specified requirements.

#### 3.1 Selection of Equipment

The BB/TS shall have a process to define the selection criteria for equipment.

#### 3.2 Qualification of Equipment

All equipment shall be qualified for its intended use. Equipment repairs and upgrades shall be evaluated and equipment re-qualified, as appropriate, based on the facility's policies and manufacturer recommendations.

##### 3.2.1 Installation Qualification

Equipment shall be installed per the manufacturer's specifications.

##### 3.2.2 Operational Qualification

The functionality of each piece of equipment and each component of a computer system shall be verified before actual use and shall meet the manufacturer's operational specifications.

##### 3.2.3 Performance Qualification

The BB/TS shall demonstrate that equipment performs as expected for its intended use. Performance specifications established by the manufacturer shall be met.

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### 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 5.1.4.3 applies.

 **3.5 Equipment Monitoring and Maintenance**

The BB/TS shall have a process for scheduled monitoring and maintenance of equipment that at a minimum is in accordance with the manufacturer's written instructions

### 3.6 Storage Devices for Blood, Blood Components, and Reagents

**3.6.1** Storage devices shall have the capacity and design to ensure that the proper temperature is maintained. Standard 5.1.6.1.2 applies.

 **3.6.2** Storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored.

### 3.7 Alarm Systems

Storage devices for blood and blood components shall have alarms and shall conform to the following standards (Standard 5.1.1 applies):

**3.7.1** The alarm shall be set to activate under conditions that will allow proper action to be taken before blood and blood components reach unacceptable conditions.

**3.7.2** In the absence of automated alarms, regular temperature monitoring shall be in place. Standard 5.1.6.1.2 applies.

**3.8 Warming Devices for Blood and Blood Components**

Warming devices shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to blood or blood components.

 **3.9 Information Systems**

The BB/TS shall have processes to support the implementation and modification of software, hardware, and databases relating to the requirements of these *Fundamentals*. Standard 5.1.1 applies. These processes shall include:

- 1) Risk analysis, training, validation, implementation, and evaluation of post-implementation performance.
- 2) System maintenance and operation.
- 3) Documentation written in language understandable to the user.
- 4) Display and verification of data before final acceptance, when data are added, or when data are amended.
- 5) Evaluation, authorization, and documentation of modifications to the system.

 **3.9.1 Information Systems Records**

Records of the following shall be maintained:

- 1) Validation of system software, hardware, databases, user-defined tables, electronic data transfer, and/or electronic data receipt.
- 2) Fulfillment of applicable life-cycle requirements for internally developed software.
- 3) Numerical designation of system versions, if applicable, with inclusive dates of use.
- 4) Monitoring of data integrity for critical data elements.

- 3.9.2** An alternate (manual or computer-based) 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.
- 3.9.3** Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect their use. Standard 1.1, #3 applies.
- 3.9.4** There shall be processes and procedures to support the management of information systems.
- 3.9.5** A system designed to prevent unauthorized access to computers and electronic records shall be established and followed.

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## 4. SUPPLIER AND CUSTOMER ISSUES

### 4.0 Supplier and Customer Issues

The BB/TS shall have policies, processes, and procedures to evaluate the ability of suppliers of critical materials, equipment, and services to consistently meet specified requirements.



### 4.1 Incoming Receipt, Inspection, and Testing

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

**4.1.1** When a supplier fails to meet specified requirements, it shall be reported to the Competent Authority, Contracting Authority, or both.

**4.1.2** 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.

**4.1.3** Critical materials shall meet specified requirements.



**4.1.3.1** All containers and solutions used for collection, preservation, and storage and all reagents used for required tests on blood samples shall meet or exceed applicable Competent Authority's criteria.

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## 5. PROCESS CONTROL

### 5.0 Process Control

The BB/TS shall have policies and validated processes and procedures that ensure the quality of the blood, blood components, and services. The BB/TS shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

### 5.1 General Elements



#### 5.1.1 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods perform as expected. Chapter 9, Process Improvement Through Corrective and Preventive Action, applies.

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

#### 5.1.2 Use of Materials

All materials (including containers and solutions used for collection, processing, preservation, and storage of blood and blood components, and all reagents used for tests) shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements. Standards 3.6 and 4.1.3.1 apply.

**5.1.3 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.

**5.1.4 Identification and Traceability**

**5.1.4.1 Use of Materials**

All materials (including containers and solutions used for collection, processing, preservation, and storage of blood and blood components, and all reagents used for tests) shall be stored and used in accordance with the manufacturer’s written instructions and shall meet specified requirements.



**5.1.4.2 Process or Procedure Steps**

For each critical step in collection, processing, compatibility testing, and transportation of blood and blood components, there shall be a mechanism to identify who performed the step and when it was performed. Standard 6.2.4 applies.



**5.1.4.3 Traceability**

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



**5.1.4.4 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 labels.

**5.1.4.4.1** The following requirements shall apply:

- 1) Labeling of blood and blood component containers shall be standardized.
- 2) The original label and added portions of the label shall be affixed or attached to the container, and shall include the applicable items required in Reference Standard 5.1.4A, 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 be specified and controlled.
- 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.
- 6) The labeling process shall include a second check to ensure the accu-

racy of affixed labels, including the correct donation identification number, ABO/Rh, expiration date (as appropriate), and product name.



**5.1.4.5 Unit Identification**

The labeling system shall make it possible to trace any unit of blood or blood component from source to final disposition. The system shall allow recheck of records applying to the specific unit including investigation of reported adverse events.



**5.1.4.5.1** A unique identification shall be affixed by the collection or pooling facility to each unit of blood, blood component, and attached container. This identification shall not be obscured, altered, or removed by facilities that subsequently handle the unit.

**5.1.4.5.2** 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.

**5.1.5 Inspection**

The BB/TS shall have a process to ensure that blood, blood components, and services are inspected at facility-defined stages to verify that specified requirements are met.

**5.1.6 Handling, Storage, and Transportation**

The BB/TS shall have a process to ensure that blood, blood components, samples, and critical materials (including reagents)

are handled, stored, and transported in a manner that prevents damage, limits deterioration, and meets requirements contained in Reference Standard 5.1.6A, Requirements for Storage, Transportation, and Expiration.

### **5.1.6.1 Inventory Management**

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



**5.1.6.1.2** For storage of blood or blood components, the temperature shall be recorded and monitored every eight hours.

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



### **5.1.6.2 Transportation**

Blood and blood components shall be inspected immediately before packing for shipment, and/or shipped for transfusion only if specified requirements are met.



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

**Collection and Production of Components**

**5.2 Information, Consents, and Notifications**



**5.2.1 Donor Education**

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

- 1) Donors are given educational information regarding:
  - the donation process.
  - infectious diseases transmitted by blood transfusion.
  - the risks of postdonation iron deficiency.
- 2) Donors are informed of the importance of providing accurate information.
- 3) 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.
- 4) Donors are informed of the importance of withdrawing themselves from the donation process if they believe that their blood is not suitable for transfusion.
- 5) Donors acknowledge that the educational materials have been provided.



**5.2.2**

When parental permission is required, the collection facility shall have a process to provide information concerning the donation process to parents or the legally authorized representative of the donor.



**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 transmission of infectious diseases to the allogeneic recipient, and requirements to report donor information, including test results, to the local health authority. 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 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.

### **5.3 Care of Donors**

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

**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 have a process for mitigating, detecting and treating, donor

adverse events and providing for emergency medical care as necessary. Immediate assistance and the necessary equipment and supplies shall be available. Standard 7.2 applies.

**5.3.3 Postphlebotomy Instructions**

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

**5.3.3.2** The collection facility shall provide the donor with 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 instructions on how to notify the collection facility with information relevant to the safety of the donation.

**5.3.4.1** The facility shall have a process for managing 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.



**5.4.2 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.

**5.4.3 Protection of the Donor**

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.

**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 BB/TS licensed physician.

## **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 for a minimum of 30 seconds or per manufacturer specifications to minimize risk of bacterial contamination.

### **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 re-identified with the blood container after filling.

**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**

If blood is to be transported from the collection site to the component processing laboratory, 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 laboratory.

- 5.6.5.1** Whole Blood intended for room temperature, component preparation, 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.

**5.7 Preparation/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 5.1.6A, 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, the component shall retain original expiration dates or have storage times approved by the Competent Authority.

**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 5.1.6A, Requirements for Storage, Transportation, and Expiration.



**5.7.3 Preparation of Products and Specific Components**

Reference Standard 5.1.6A, Requirements for Storage, Transportation, and Expiration, applies.

**5.7.3.1 WHOLE BLOOD**

Whole Blood shall be collected and stored based on manufacturer specifications. Reference Standard 5.1.6A, Requirements for Storage, Transport and Expiration applies.

**5.7.3.2 RED BLOOD CELLS**

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

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

**5.7.3.3 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 and contain  $< 5 \times 10^6$  residual leukocytes per unit.

**5.7.3.4 FROZEN PLASMA**  
Frozen Plasma shall be prepared from a whole blood or apheresis collection and placed at  $-18\text{ C}$  or colder within the time frame required for the collection, processing, and storage system.

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

**5.7.3.6 APHERESIS PLATELETS**  
Validation and quality control of Apheresis Platelets shall demonstrate that at least 90% of units sampled contain  $\geq 3.0 \times 10^{11}$  platelets and, at the end of allowable storage or at the time of issue, have a pH  $\geq 6.2$ .

**5.7.3.7 APHERESIS PLATELETS LEUKOCYTES REDUCED**  
Validation and quality control shall demonstrate that 90% of units sampled contain

$\geq 3.0 \times 10^{11}$  platelets and, at the end of allowable storage or at the time of issue, have a pH  $\geq 6.2$ . At a minimum, 95% of units sampled shall contain a residual leukocyte count  $< 5 \times 10^6$ .

## 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 A1 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 Tests Intended to Prevent Disease Transmission by Allogeneic Donations

A sample of blood from each allogeneic donation shall be tested for, HBsAg, anti-HIV-1/2, anti-HCV, syphilis, and any other requirements by the Competent Authority. Standard 5.2.4 applies.



**5.8.3.1** If, due to urgent need, blood or blood components are distributed or issued before completion of these tests, a notation that testing is not completed shall appear con-

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spicuously on an attached label or tie tag. Required tests shall be completed and results reported to the transfusion service as soon as possible.

#### **5.8.4 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 HBsAg, anti-HIV-1/2, anti-HCV, syphilis, and any other requirements by the Competent Authority.

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

#### **5.8.5 Testing High Titer for Group O Donations**

When Group O Whole Blood is transfused, donations shall be tested for high titer ABO antibodies. Whole Blood units found to contain high titer antibodies shall be labeled and issued only to group O patients. High titer shall be defined by the facility.



#### **5.8.6 Quarantine and Disposition of Units from Prior Collections**

The BB/TS shall have a process that is in accordance with the Competent Authority and recommendations for quarantine and disposition of prior collections when a repeat donor has a reactive screening test for HBsAg, anti-HIV-1/2, anti-HCV, syphilis, and test requirements by the Competent Authority.

**5.9 Final Labeling**

The BB/TS shall have a process to 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.

**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 have a process to ensure that blood, blood components, or services meet specified requirements, including appearance before distribution or issue.

## **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, and records accompanying samples from the patient shall contain sufficient information to uniquely identify the patient, including two independent identifiers. The transfusion service shall accept only complete, accurate, and legible requests.



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

#### **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 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.

**5.11.2.5** The transfusion service shall have policies, processes, and procedures that minimize blood volume collected for laboratory testing.

### **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 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. Standard 7.1.1 applies.



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## 5.13 Pretransfusion Testing of Patient Blood

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



### 5.13.1 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 A1 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.



### 5.13.2 Rh Type

Rh type shall be determined with anti-D reagent. The test for weak D is optional when testing the patient.



### 5.13.3 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.



**5.13.3.1** When clinically significant antibodies are detected, additional testing shall be performed.

**5.13.3.2** A sample shall be obtained from the patient within 3 days of the scheduled transfusion in the following situations. Day 0 is the day of draw:

- 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.

**5.13.3.3** In patients with previously identified clinically significant antibodies, methods of testing shall be those that detect additional clinically significant antibodies.



**5.13.3.4** A control system appropriate to the method of testing shall be used. Standard 5.1.1 applies.



**5.13.4 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.



**5.13.5 Comparison with Previous Records**

There 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.

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.

## **5.14 Selection of Compatible Blood and Blood Components for Transfusion**

- 5.14.1** Recipients shall receive ABO group-specific Whole Blood, low-titer group O Whole Blood (for non-group-O recipients or for recipients whose ABO group is unknown), or ABO group-compatible Red Blood Cell components.
- 5.14.2** Rh-negative recipients shall receive Rh-negative Whole Blood or Red Blood Cell components. The BB/TS shall document the exception.
- 5.14.2.1** The transfusion service shall have a policy for the use of Rh-positive red-cell-containing components in Rh-negative recipients.
- 5.14.3** 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/or are serologically crossmatch-compatible to include anti-globulin testing.
- 5.14.4** The transfusion service shall have a policy concerning transfusion of components containing significant amounts of incompatible ABO antibodies or unexpected red cell antibodies.
- 5.14.5** The red cells in Apheresis Platelets shall be ABO-compatible with the recipient's plasma and be crossmatched as in Standard 5.15 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.

## 5.15 Crossmatch



### 5.15.1 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 5.13.3.



**5.15.1.1** If no clinically significant antibodies were detected in tests performed in Standard 5.13.3 and there is no record of previous detection of such antibodies, at a minimum, detection of ABO incompatibility shall be performed.

## 5.16 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.

### 5.16.1 Hemoglobin S

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

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 **5.17 Final Inspection Before Issue**

Blood and blood components shall be inspected at the time of issue.

**5.17.1 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.

 **5.18 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.

**5.19 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 request. Discrepancies shall be resolved before issue.

 **5.20 Urgent Requirement for Blood and Blood Components**


The BB/TS shall have a process for the provision of blood and blood components before completion of tests listed in Standards 5.13, 5.13.1, 5.13.3, 5.13.4, and 5.16 when a delay in transfusion could be detrimental to the patient. Standards 5.12 and 7.0 to 7.2 apply.

**5.20.1** Recipients whose ABO group is not known shall receive group O Red Blood Cells or low-titer group O Whole Blood. Standard 5.13.1 applies.

**5.20.2** If blood is issued before completion of compatibility testing recipients whose ABO group has been determined as in Standard 5.13.1 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.

**5.20.3** 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.

**5.20.4** Compatibility testing shall be completed expeditiously using a patient sample collected as early as possible in the transfusion sequence.

 **5.20.5** 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.



**5.20.5.1** The BB/TS licensed physician and the recipient's physician shall be notified immediately of abnormal test results that may affect patient safety.

## **5.21 Administration of Blood and Blood Components**

There shall be a protocol for the administration of blood and blood components, including the use of infusion devices and ancillary equipment, and the identification, evaluation, and reporting of adverse events related to transfusion. The BB/TS licensed physician shall participate in the development of these protocols.



### **5.21.1 Recipient Consent**

The BB/TS licensed physician shall participate in the development of policies, processes, and procedures regarding recipient consent for transfusion.



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

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

**5.21.2** Transfusions shall be prescribed and administered under medical direction.



**5.21.3** After issue and immediately before transfusion, the following information shall be verified:

- 1) The intended recipient's two independent identifiers, ABO group, and if required, the Rh type.

### 5.21.3

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- 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.



**5.21.4** 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.

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

**5.21.6** The patient shall be observed for potential adverse events during the transfusion and for an appropriate time thereafter. Standard 7.3 applies.

**5.21.7** Specific written instructions concerning possible adverse events 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.

**5.21.8** 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.



**5.21.9 Addition of Drugs and Solutions**

With the exception of 0.9% sodium chloride, 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 Competent Authority.
- 2) There is documentation available to show that the addition is safe and does not adversely affect the blood or blood component.

**5.22 Medical Record Documentation**

**5.22.1** The patient's medical record shall include the transfusion order, documentation of patient consent, the name of the component, the donation identification number, the date and time of transfusion, pre- and posttransfusion vital signs, the amount transfused, the identification of the transfusionist, the patient ABO/Rh and the donor ABO/Rh, and if applicable, transfusion-related adverse events.

### Reference Standard 5.1.4A—Requirements for Labeling Blood and Blood Components\*

| Item No. | Labeling Item  | Collection or Preparation | Final Component           |
|----------|--|---------------------------|---------------------------|
| 1        | Name of blood component or intended component            | NR                        | R                         |
| 2        | Donation identification number                           | R                         | R                         |
| 3        | Identity of anticoagulant or other preservative solution | R                         | R                         |
| 4        | Approximate volume                                       | NR                        | R                         |
| 5        | Facility collecting component                            | NR                        | R                         |
| 6        | Facility modifying component                             | NA                        | R, if leaves the facility |
| 7        | Storage temperature                                      | NA                        | R                         |
| 8        | Expiration date and, when appropriate, time              | NA                        | R                         |
| 9        | ABO group and Rh type                                    | NA                        | R                         |
| 10       | Specificity of unexpected red cell antibodies            | NA                        | R                         |
| 11       | Indication that the unit is low volume, if applicable    | NR                        | R                         |
| 12       | Red cell antigens other than ABO or RhD, if applicable   | NA                        | R                         |
| 13       | Phrase: "For autologous use only"                        | R                         | R                         |

|    |  |    |   |
|----|--|----|---|
| 14 | Recipient name, identification number, and, if available, name of facility where patient is to be transfused | R  | R |
| 15 | Biohazard label, if applicable <sup>†</sup>  | NR | R |
| 16 | Phrase: “Donor untested,” if applicable  | NR | R |
| 17 | Donor tested within the last 30 days, if applicable  | NR | R |
| 18 | “Caution: For Manufacturing Use Only”  | NA | R |
| 19 | In lieu of expiration date, the date of collection of the oldest material in the container                   | R  | R |

\*Competent Authority requirements apply.

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

| <b><u>Test</u></b> | <b><u>Test Result</u></b>  |
|--------------------|--|
| HbsAg              | Repeatedly reactive  |
| Anti-HCV           | Repeatedly reactive  |
| Anti-HIV-1/2       | Repeatdly reactive   |
| Syphilis           | Reactive Screening Test with a Positive Confirmatory Test or No Confirmatory |

NA = Not Applicable, R = Required, NR = Not Required.

## Reference Standard 5.1.6A—Requirements for Storage, Transportation, and Expiration<sub>+</sub>

| Item No.                         | Component                                | Storage   | Transport  | Expiration <sup>1</sup>  | Additional Criteria   |
|----------------------------------|--|---|--|--|---|
| <b>Whole Blood Components</b>    |  |   |  |  |   |
| 1                                | Whole Blood                              | 1-6 C<br>If intended for room temperature components, then store at 1-6 C within 8 hours after collection | Cooling toward 1-10 C<br>If intended for room temperature components, cooling toward 20-24 C | ACD/CPD/CP2D:<br>21 days<br>CPDA-1: 35 days  | May be leukodepleted. All requirements apply if leukodepleted |
| <b>Red Blood Cell Components</b> |  |   |  |  |   |
| 2                                | Red Blood Cells (RBCs)                   | 1-6 C   | 1-10 C   | ACD/CPD/CP2D:<br>21 days<br>CPDA-1: 35 days<br>Additive solution:<br>42 days<br>Open system:<br>24 hours | May be leukodepleted. All requirements apply if leukodepleted |
| <b>Plasma Components</b>         |  |   |  |  |   |
| 3                                | Fresh Frozen Plasma (FFP) <sup>2,3</sup> | -18 C or colder or -65 C or colder  | Maintain frozen state  | -18 C or colder:<br>12 months from collection<br>-65 C or colder: 7 years from collection                |   |

|   |                                 |       |        |   |  |
|---|---------------------------------|-------|--------|---|--|
| 4 | FP (after thawing) <sup>3</sup> | 1-6 C | 1-10 C | If issued as FP:<br>24 hours  |  |
| 5 | Thawed Plasma                   | 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 |

### Platelet Components

|   |                     |  |   |  |   |
|---|---------------------|--|---|--|---|
| 6 | Platelets           | 20-24 C with continuous gentle agitation | As close as possible to 20-24 C<br>Maximum time without agitation: 30 hours | 24 hours to 5 days, depending on collection system | May be leukodepleted. All requirements apply if leukodepleted |
| 7 | Apheresis Platelets | 20-24 C with continuous gentle agitation | As close as possible to 20-24 C<br>Maximum time without agitation: 30 hours | 24 hours to 5 days, depending on collection system | May be leukodepleted. All requirements apply if leukodepleted |

\*Competent authority requirements apply.

<sup>1</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>2</sup>If a liquid freezing bath is used, the container shall be protected from chemical alteration.

<sup>3</sup>These lines could apply to apheresis plasma or whole-blood-derived plasma.

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

| Category                        | Criteria/Description/Examples   | Deferral Period   |
|---------------------------------|---|---|
| 1) Age                          | Conform to applicable local law and $\geq 16$ years   |   |
| 2) Whole Blood Volume Collected | Maximum of 10.5 mL per kilogram of donor weight, including samples  |   |
| 3) Donation Interval            | 8 weeks after whole blood donation (Standard 5.5.1 applies)   |   |
| 4) Temperature                  | $\leq 37.5$ C if measured orally, or equivalent if measured by another method   |   |
| 5) Hemoglobin/ Hematocrit       | To meet hemoglobin screening method, conform to national guidelines; if not defined, then lower limit shall be 12.5 g/dL.   |   |
| 6) Weight                       | Maximum of 10.5 mL per kilogram of donor weight, including samples (self-reported weight is acceptable)   |   |
| 7) Drug Therapy                 | Generic medication name   |   |
|                                 | <ul style="list-style-type: none"> <li>• Finasteride</li> <li>• Isotretinoin</li> <li>• Dutasteride</li> <li>• Vismodegib</li> <li>• Acitretin</li> <li>• Etretinate</li> </ul> | <p>1 month after last dose</p> <p>6 months after last dose</p> <p>24 months after last dose</p> <p>3 years after last dose</p> <p>Permanent</p> |

|   |  |
|---|--|
| • Bovine insulin manufactured in the UK   | Indefinite   |
| • Medications that irreversibly inhibit platelet function preclude use of the donor as sole source of platelets |  |
| a. Aspirin, aspirin-containing medications, and piroxicam (eg, Feldene)   | 2 full days (>48 hours) after last dose  |
| b. Prasugrel (Effient) and ticagrelor (Brilinta)  | 7 days   |
| c. Clopidogrel (eg, Plavix), Ticlopidine (eg, Ticlid) and Vorapaxar (eg, Zontivity)                             | 14 days after last dose  |
| • Warfarin (eg, Coumadin, Warfilone, Jantoven)  | For plasma products for transfusion: 7 days after last dose  |
| • Heparin and derivatives   | For plasma products for transfusion: 7 days after last dose or as defined by the facility's BB/TS licensed physician |
| • Direct thrombin inhibitors (eg, Dabigatran)   | 2 days after last dose or as defined by the facility's BB/TS licensed physician                                      |
| • Direct Xa inhibitors (eg, Rivaroxaban)  |  |
| • Receipt of Hepatitis B Immune Globulin  | 12 Months  |
| • Other medications, such as antibiotics  | As defined by the facility's BB/TS licensed physician  |

(Continued)

## Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification\* (Continued)

| Category   | Criteria/Description/Examples  | Deferral Period                     |
|--|--|-------------------------------------|
| 8) 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. The venipuncture site shall be free from infectious skin disease and any disease that might create a risk of contaminating the blood</li> <li>Family history of Creutzfeldt-Jakob disease (CJD)</li> </ul> | Indefinite deferral for risk of CJD |
| 9) Pregnancy and lactation                             | <ul style="list-style-type: none"> <li>Defer if pregnant within the last 6 months or lactating</li> </ul>  |                                     |
| 10) Receipt of Blood, Blood Component, or Human Tissue | <ul style="list-style-type: none"> <li>Receipt of allogeneic dura mater or pituitary growth hormone of human origin</li> <li>Receipt of blood, components, or human tissue</li> </ul>  | Permanent<br>12 months              |



|                                    |  |                                     |
|------------------------------------|--|-------------------------------------|
| 11) Xenotransplantation            | <ul style="list-style-type: none"><li>Receipt of live cells, tissues or live organs from a nonhuman animal source.<br/>Note: Nonliving biological products or materials from nonhuman animals, such as porcine or bovine heart valves and porcine insulin, are acceptable.</li></ul>   | Permanent                           |
| 12) 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<br/>[Anthrax, Cholera, 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<br/>[eg, HPV Vaccine]</li><li>Receipt of intranasal live attenuated flu vaccine</li><li>Receipt of live attenuated viral and bacterial vaccines<br/>[Measles (rubeola), Mumps, Polio (Sabin/oral), Typhoid (oral), Yellow fever]</li></ul> | None<br><br><br><br><br><br>2 weeks |

(Continued)

### Reference Standard 5.4.1A—Requirements for Allogeneic Donor Qualification\* (Continued)

| Category  | Criteria/Description/Examples   | Deferral Period  |
|---|---|--|
| 13) Infectious Diseases   | <ul style="list-style-type: none"> <li>Receipt of live attenuated viral and bacterial vaccines<br/>[German measles (rubella), chicken pox/shingles (varicella zoster)]</li> </ul> | 4 weeks  |
|   | <ul style="list-style-type: none"> <li>Receipt of other vaccines</li> </ul>   | 12 months unless otherwise indicated by licensed physician |
|   | <ul style="list-style-type: none"> <li>Confirmed positive test for HBsAg</li> </ul>   | Permanent  |
|   | <ul style="list-style-type: none"> <li>Present or past clinical or laboratory evidence of infection with HIV, HCV</li> </ul>  | Indefinite   |
|   | <ul style="list-style-type: none"> <li>A history of babesiosis</li> </ul>   | Indefinite   |
|   | <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 administer nonprescription drugs</li> </ul>   | Indefinite   |
| <ul style="list-style-type: none"> <li>Mucous membrane exposure to blood</li> </ul> | 12 Months   |  |

14) Travel

- Nonsterile skin penetration with instruments or equipment contaminated with blood or body fluids other than the donor's own. 12 Months
- Sexual contact or lived with an individual who: 12 Months
  - a. Has acute or chronic hepatitis B
  - b. Has symptomatic hepatitis C
- Sexual contact with an individual with HIV infection or at high risk of HIV infection 12 Months
- Incarceration in a correctional institution (including lockup, jail, or prison) for more than 72 consecutive hours 12 Months
- Syphilis or gonorrhea 12 months
  - a. Following the diagnosis of syphilis or gonorrhea. Must have completed treatment
  - b. Donor who has a reactive screening test for syphilis where no confirmatory testing was performed
  - c. A confirmed positive test for syphilis
- The prospective donor's travel history shall be evaluated for potential risks

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\*Competent Authority requirements apply.

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## 6. DOCUMENTS AND RECORDS

### 6.0 Documents and Records

The BB/TS shall have policies, processes, and procedures to ensure that documents are identified, reviewed, approved, and retained and that records are created, stored, and archived in accordance with record retention policies.

### 6.1 Documents

The BB/TS shall have a process for document control that includes the following elements:

**6.1.1** Master list(s) of documents, including policies, processes, procedures, labels, and forms that relate to the requirements of these *Fundamentals*.



**6.1.2** Review and approval of new and revised documents before use.



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

**6.1.4** Use of only current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these *Fundamentals* are performed.

### 6.2 Records

The BB/TS shall ensure identification, collection, indexing, access, filing, storage, and disposition of records as required by Reference Standard 6.2A, Retention of Donor/Unit Records. Records shall be complete; retrievable in a period of time appropriate to the circumstances; protected

from accidental or unauthorized disclosure, destruction, or modification; and retained for a minimum of 5 years, except as noted in Reference Standard 6.2A.

**6.2.1 Facility Records**

Records shall be complete.

**6.2.1.1** Records shall be legible and indelible.

**6.2.1.2 Copies**

Before the destruction of the original records, the BB/TS shall have a process to ensure that copies of records are:

- 1) Verified as containing the original content.
- 2) Legible, complete, and accessible.

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

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

**6.2.4** Records shall be created and maintained to include:

- 1) Critical activities performed.
- 2) The individual who performed the activity.
- 3) When the activity was performed.
- 4) Results obtained.

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

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

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

**6.2.6 Changes to Records**

Changes to records shall be controlled.

**6.2.6.1** The date of changes and the identity of the individual who changed the record shall be documented, and this information shall be maintained for the retention period of the original record.

**6.2.6.2** Record changes shall not obscure previously recorded information.

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

**6.2.7 Electronic Records**

There shall be processes and procedures to support the management of computer systems.

**6.2.8 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, destruction, or modification.
- 3) Allow retrieval.

**6.2.9 Destruction of Records**

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

## 6.2A

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### Reference Standard 6.2A—Retention of Donor/Unit Records\*

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| Item No. | Standard | Record to Be Maintained  |
|----------|----------|--|
| 1        | 1.2.1    | Management review of effectiveness of the quality system   |
| 2        | 1.3.2    | Exceptions to policies, processes, and procedures  |
| 3        | 2.1      | Job descriptions   |
| 4        | 2.1.1    | Qualification of personnel performing critical tasks   |
| 5        | 2.1.2    | Training records of personnel  |
| 6        | 2.1.3    | Evaluations of competence of personnel   |
| 7        | 2.1.4    | Personnel records of each employee   |
| 8        | 3.2      | Equipment qualification  |
| 9        | 3.4      | Unique identification of equipment   |
| 10       | 3.5      | Monitoring and maintenance of equipment  |
| 11       | 3.6.2    | Temperature monitoring of refrigerators, freezers, and platelet incubators   |
| 12       | 3.9      | Implementation of new or modified software, hardware, or databases and modifications of existing software, hardware, or databases.   |
| 13       | 3.9.1    | Validation of computer system software, hardware, data-bases, and user-defined tables; fulfillment of life-cycle requirements for internally developed software; numeric designation of system versions, if applicable with inclusive dates of use; monitoring of data integrity for critical data elements. |
| 14       | 4.1      | Inspection of incoming critical materials and containers   |
| 15       | 4.1.3.1  | Incoming containers, solutions, and reagents meet or exceed applicable Competent Authority criteria  |
| 16       | 5.1.1    | Quality control records and review of quality control results for reagents, equipment, and methods   |
| 17       | 5.1.4.2  | Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components  |
| 18       | 5.1.4.3  | Traceability of blood, blood components, and critical materials  |



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**Reference Standard 6.2A—Retention of Donor/Unit Records\***  
**(Continued)**


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| <b>Item No.</b> | <b>Standard</b> | <b>Record to Be Maintained</b>   |
|-----------------|-----------------|--|
| 19              | 5.1.4.5         | Source to final disposition of each unit of blood or blood component and, if issued by the facility for transfusion, identification of the recipient                                       |
| 20              | 5.1.4.5.1       | Unique identification of each unit   |
| 21              | 5.1.6.1.2       | Records of storage temperatures for blood products   |
| 22              | 5.1.6.2         | Inspection before shipping   |
| 23              | 5.1.6.2.1       | Container qualification and process validation records   |
| 24              | 5.2.1, #5       | Donor acknowledgment that educational materials have been provided   |
| 25              | 5.2.2           | Parental permission for donation   |
| 26              | 5.2.3           | Consent of donors  |
| 27              | 5.2.4           | Notification to donor of significant abnormal findings   |
| 28              | 5.4.1,<br>5.4.2 | Donor information, including contact information, medical history, physical examination, health history, or other conditions thought to compromise suitability of blood or blood component |
| 29              | 5.7.2.1         | Inspection of weld for completeness and identification numbers of blood or blood components and of lot numbers or disposables used during component preparation                            |
| 30              | 5.7.3           | Preparation of specific components   |
| 31              | 5.8.1,<br>5.8.2 | ABO group and Rh type for all collections  |
| 32              | 5.8.3           | Interpretations of disease marker testing for allogeneic testing   |
| 33              | 5.8.3.1         | Distribution or issue of units before completion of tests  |
| 34              | 5.8.6           | Quarantine of units from prior collections when a repeat donor has a reactive disease marker screening test  |
| 35              | 5.9.1           | Final review of records relating to testing and acceptability criteria   |

(Continued)

**Reference Standard 6.2A—Retention of Donor/Unit Records\*  
(Continued)**

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| <b>Item No.</b> | <b>Standard</b>   | <b>Record to Be Maintained</b>   |
|-----------------|-------------------|--|
| 36              | 5.9.4             | Review of donor records to ensure any units from an ineligible donor are quarantined   |
| 37              | 5.11.1            | Requests for blood and blood components  |
| 38              | 5.11.1.1          | Order for blood, blood components, and tests   |
| 39              | 5.12              | Serologic confirmation of donor blood ABO/Rh   |
| 40              | 5.12.1            | Reporting and resolution of ABO/Rh labeling discrepancies to collecting facility   |
| 41              | 5.13.1,<br>5.13.2 | Test results and interpretation of patient's ABO group and Rh type   |
| 42              | 5.13.3            | Patient testing to detect unexpected antibodies to red blood cell antigens   |
| 43              | 5.13.3.1          | Additional testing to detect clinically significant antibodies   |
| 44              | 5.13.3.4          | Control system results appropriate to the method of testing  |
| 45              | 5.13.4            | Pretransfusion testing for autologous transfusion  |
| 46              | 5.13.5            | There shall be a process to ensure that the historical records for the following have been reviewed:<br>1) ABO group and Rh type.<br>2) Difficulty in blood typing.<br>3) Clinically significant antibodies.<br>4) Significant adverse events to transfusion.<br>5) Special transfusion requirements.<br>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. |
| 47              | 5.15.1            | Test results and interpretation of serologic crossmatch  |
| 48              | 5.15.1.1          | Detection of ABO incompatibility when no clinically significant antibodies are detected  |
| 49              | 5.17              | Final inspection of blood and blood components before issue; if the container is not intact or components are abnormal in appearance, maintain record of BB/TS licensed physician approval   |

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**Reference Standard 6.2A—Retention of Donor/Unit Records\***  
**(Continued)**


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| <b>Item No.</b> | <b>Standard</b> | <b>Record to Be Maintained</b>   |
|-----------------|-----------------|--|
| 50              | 5.18            | Verification shall include: <ol style="list-style-type: none"> <li>1) The intended recipient's two independent identifiers, ABO group, and Rh type.</li> <li>2) The donation identification number, the donor ABO group, and, if required, the Rh type.</li> <li>3) The interpretation of crossmatch tests, if performed.</li> <li>4) Special transfusion requirements, if applicable.</li> <li>5) The expiration date and, if applicable, time.</li> <li>6) The date and time of issue.</li> </ol>                                |
| 51              | 5.20            | Verification of patient identification before transfusion  |
| 52              | 5.20.5          | 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   |
| 53              | 5.20.5.1        | Notification of abnormal test results  |
| 54              | 5.21.1          | Recipient consent  |
| 55              | 5.21.1.1        | Elements of consent shall include all of the following: <ol style="list-style-type: none"> <li>1) A description of the risks, benefits, and treatment alternatives (including nontreatment).</li> <li>2) The opportunity to ask questions.</li> <li>3) The right to accept or refuse transfusion.</li> </ol>   |
| 56              | 5.21.3          | The following information shall be verified before transfusion: <ol style="list-style-type: none"> <li>1) The intended recipient's two independent identifiers, ABO group, and Rh type.</li> <li>2) The donation identification number, the donor ABO group, and, if required, the Rh type.</li> <li>3) The interpretation of crossmatch tests, if performed.</li> <li>4) Special transfusion requirements are met, when applicable.</li> <li>5) The expiration date (or time) of the unit and that it has not expired.</li> </ol> |
| 57              | 5.21.4          | Verification of patient identification before transfusion  |

(Continued)

**Reference Standard 6.2A—Retention of Donor/Unit Records\*  
(Continued)**

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| <b>Item No.</b> | <b>Standard</b> | <b>Record to Be Maintained</b>   |
|-----------------|-----------------|--|
| 58              | 5.22.1          | 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 |
| 59              | 6.1.2           | Review and approval of new and revised documents before use  |
| 60              | 6.1.3           | Biennial review of policies, processes, and procedures   |
| 61              | 7.0, 7.1        | Description and evaluation of nonconforming blood, blood components, critical materials, and services  |
| 62              | 7.1.2           | Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use  |
| 63              | 7.2             | Adverse events related to the blood donation process shall be assessed, investigated, and monitored.   |
| 64              | 7.3             | Adverse events related to the transfusion process shall be evaluated and reported  |
| 65              | 7.3.2           | Laboratory evaluation and review of clerical information related to suspected hemolytic reactions  |
| 66              | 7.3.3.1         | Transfusion service evaluation and reporting of transmissible diseases   |
| 67              | 7.3.3.2         | Collection facility's investigation of transmissible diseases  |
| 68              | 7.3.4           | Look-back investigation  |
| 69              | 8.2             | Utilization review   |
| 70              | 9.0             | Implementation of changes to policies, processes, and procedures resulting from corrective action  |
| 71              | 9.1             | Corrective action  |
| 72              | 10.2            | Appropriate discard of blood and blood components  |

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\*Applicable local law applies.

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## 7. DEVIATIONS, NONCONFORMANCES, AND ADVERSE EVENTS

### 7.0 Deviations, Nonconformances, and Adverse Events

The BB/TS shall have policies, processes, and procedures to ensure the capture, assessment, investigation, and monitoring of deviations from, or of failure to meet, specified requirements.

### 7.1 Nonconformances

Upon discovery, nonconforming blood, blood components, critical materials, and services shall be evaluated and their disposition determined.

**7.1.1** Nonconforming blood and blood components shall be quarantined.

### 7.1.2 Released Nonconforming Blood or Blood Components

Blood or blood components that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality of the product and recipient safety. In cases where quality may have been affected, the nonconformance shall be reported to the customer. Records of the nature of nonconformances and subsequent actions taken, including acceptance for use, shall be maintained. Standard 9.1 applies.

### 7.2 Adverse Events Related to Donation

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

 **7.3 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.

**7.3.1 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.

**7.3.1.1** 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.
- 4) Preventive measures for future transfusions.

 **7.3.2 Laboratory Evaluation and Reporting of Immediate Transfusion Reactions**

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

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### 7.3.3 Transmissible Diseases



#### 7.3.3.1 Transfusion Service Reporting of Diseases Transmitted by Blood

The transfusion service shall have policies, processes, and procedures to evaluate and report diseases transmissible by blood or blood components. The policies, processes, and procedures shall include the following:

**7.3.3.1.1** Prompt investigation of each event by the BB/TS licensed physician.

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



#### 7.3.3.2 Collection Facility Investigation of Transmissible Diseases

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

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



### 7.3.4 Look-Back

#### 7.3.4.1 Collection Facility

The collection facility shall have policies, processes, and procedures to notify consignees of blood or blood components from donors subsequently found to have, or be at risk for, relevant transmissible diseases.

**7.3.4.2 Transfusion Services**

The transfusion service shall have policies, processes, and procedures to:

- 7.3.4.2.1** Identify recipients, if appropriate, of blood or blood components from donors subsequently found to have, or to be at risk for, relevant transmissible infections.
  
- 7.3.4.2.2** Notify, if appropriate, the recipient's physician and/or recipient as specified in Competent Authority regulations and recommendations.



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## 8. ASSESSMENTS: INTERNAL AND EXTERNAL

### 8.0 Assessments: Internal and External

The BB/TS shall have policies, processes, and procedures to ensure that internal and external assessments of operations and quality systems are scheduled and conducted.

### 8.1 Management of Assessment Results

The results of internal and external assessments shall be reviewed by personnel having responsibility for the area being assessed.



### 8.2 Utilization Review

Transfusing facilities shall monitor and evaluate transfusion practices for all categories of blood and blood components.

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## 9. PROCESS IMPROVEMENT THROUGH CORRECTIVE ACTION

### 9.0 Process Improvement Through Corrective Action

The BB/TS shall have policies, processes, and procedures for data collection, analysis, and follow-up of issues requiring corrective action, including near-miss events.

### 9.1 Corrective Action

The BB/TS shall have a process for corrective action of deviations, nonconformances, and complaints relating to blood, blood components, critical materials, and services, which includes the following elements, as applicable:

- 1) Description of the event.
- 2) Investigation of the event.
- 3) Determination of the cause(s).
- 4) Implementation of the corrective action(s).
- 5) Evaluation to ensure that corrective action is taken and that it is effective.

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## 10. FACILITIES AND SAFETY

### 10.0 Facilities and Safety

The BB/TS shall have policies, processes, and procedures to ensure the provision of safe environmental conditions. The facility shall be suitable for the activities performed. Safety programs shall meet local, state, and federal regulations, where applicable. Standard 1.4 applies.

### 10.1 Safe Environment

The BB/TS shall have processes to minimize and respond to environmentally related risks to the health and safety of employees, donors, volunteers, patients, and visitors. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

### 10.2 Discard of Blood and Components

Blood and blood components shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

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## GLOSSARY

| <b>Term</b>                          | <b>Definition</b>   |
|--------------------------------------|---|
| <b>ABO Incompatibility Detection</b> | Use of a method (eg, serological or computer-based) to determine incompatibility of ABO group between donor and recipient.  |
| <b>Adverse Event</b>                 | A complication in a donor or patient. Adverse events may occur in relation to a donation, a transfusion, or a diagnostic or therapeutic procedure.  |
| <b>Agreement</b>                     | A contract, order, or understanding between two or more parties, such as between a facility and one of its customers.   |
| <b>Agreement Review</b>              | Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.  |
| <b>Allogeneic Donor</b>              | An individual from whom products intended for another person are collected.   |
| <b>Antibody Screen</b>               | A serologic method to detect the presence of clinically significant antibodies in recipients and/or donors.   |
| <b>Assessment</b>                    | A systematic, independent examination that is performed at defined intervals and at sufficient frequency to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments usually include comparison of actual results to expected results. Types of assessments include external assessments, internal assessments, quality assessments, peer-review assessments, and self-assessments. |

# Glossary

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| <b>Term</b>                            | <b>Definition</b>   |
|--|---|
| <b>Autologous Donor</b>                | A person who acts as his or her own product donor.  |
| <b>Backup</b>                          | Digital data storage media (magnetic tape, flash drive, CD, etc) containing copies of computer data.  |
| <b>Blood Bank</b>                      | 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. . |
| <b>Blood Components</b>                | Products prepared from a Whole Blood collection or produced through an automated collection, eg, red blood cells, plasma, and platelets.  |
| <b>By a Method Known to</b>            | Use of published data to demonstrate the acceptability of a process or procedure, particularly for component preparation.   |
| <b>Change Control</b>                  | A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.                            |
| <b>Clinically Significant Antibody</b> | An antibody that is capable of causing shortened cell survival.   |
| <b>Closed System</b>                   | A system, the contents of which are not exposed to air or outside elements during collection, preparation, and separation of components.  |
| <b>Collection Facility</b>             | A facility that collects blood and/or blood components from a donor.  |
| <b>Competence</b>                      | Ability of an individual to perform a specific task according to procedures.  |
| <b>Competent Authority</b>             | The agency responsible under its national law for regulations applicable to blood banks or transfusion services.  |

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| Term   | Definition  |
|--|---|
| <b>Compliance</b>                              | <i>See Conformance.</i>   |
| <b>Conformance</b>                             | Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.   |
| <b>Corrective Action</b>                       | An activity performed to eliminate the cause of an existing nonconformance or other undesirable situation in order to prevent recurrence.                         |
| <b>Critical Equipment/<br/>Materials/Tasks</b> | A piece of equipment, material, service, or task that can affect the quality of the facility's products or services.  |
| <b>Crossmatch</b>                              | A method (eg, serological or computer-based) to detect incompatibility between donor and recipient.   |
| <b>Customer</b>                                | The receiver of a product or service. A customer may be internal (eg, another department within the same organization) or external (eg, another organization).    |
| <b>Dedicated Donor</b>                         | An individual who donates blood components intended for and used solely by a single identified recipient.   |
| <b>Deviation</b>                               | A departure from policies, processes, procedures, applicable regulations, standards, or specifications.   |
| <b>Disaster</b>                                | An event (internal, local, or national) that can affect the safety and availability of the blood supply or the safety of staff, patients, volunteers, and donors. |
| <b>Document (noun)</b>                         | Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.                       |
| <b>Document (verb)</b>                         | To capture information through writing or electronic media.   |
| <b>Equipment</b>                               | A durable item, instrument, or device used in a process or procedure.   |

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## Glossary

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| <b>Term</b>                 | <b>Definition</b>   |
|-----------------------------|---|
| <b>Event</b>                | A generic term used to encompass the terms “incident,” “error,” and “accident.”   |
| <b>Executive Management</b> | The highest level personnel within an organization, including employees and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization’s quality policy. Executive management may be an individual or a group of individuals. |
| <b>Expiration</b>           | The last day or time that the blood, blood component, or material(s) is considered suitable for use.  |
| <b>Facility</b>             | 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.   |
| <b>Final Inspection</b>     | To measure, examine, or test one or more characteristics of a unit of blood, a blood component, or a service and compare results with specified requirements in order to establish whether conformance is achieved before distribution or issue.  |
| <b>Guidelines</b>           | Documented recommendations.   |
| <b>Indefinite Deferral</b>  | A deferral applied to a donor who is not eligible to donate blood for someone else for an unspecified period of time.   |
| <b>Inspect</b>              | To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements.  |
| <b>Irradiated</b>           | 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.  |

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| Term                            | Definition  |
|---------------------------------|---|
| <b>Issue</b>                    | To release for clinical use (transfusion or transplantation).   |
| <b>Label</b>                    | An inscription affixed or attached to a unit of blood or a blood component, or a sample for identification.   |
| <b>Labeling</b>                 | Information that is required or selected to accompany a unit of blood, a blood component, or a sample, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use. |
| <b>Lived with</b>               | Resided in the same dwelling (eg, home, dormitory room, or apartment).  |
| <b>Maintain</b>                 | To keep in the current state.   |
| <b>Master List of Documents</b> | A reference list, record, or repository of a facility's policies, processes, procedures, forms, and labels related to the <i>Fundamentals</i> which includes information for document control.  |
| <b>Material</b>                 | A good or supply item used in the manufacturing process. Materials are a type of input product. Reagents are a type of material.  |
| <b>Near-Miss Event</b>          | An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.  |
| <b>Nonconformance</b>           | Failure to meet requirements.   |
| <b>Open System</b>              | A system, the contents of which are exposed to air and outside elements during preparation and separation of components.  |
| <b>Organization</b>             | An institution, or part thereof, that has its own functions and executive management.   |

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## Glossary

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| <b>Term</b>                      | <b>Definition</b>   |
|----------------------------------|---|
| <b>Permanent Deferral Policy</b> | A deferral applied to a donor who will never be eligible to donate blood for someone else.  |
| <b>Preventive Action</b>         | A documented general principle that guides present and future decisions.  |
| <b>Procedure</b>                 | An action taken to reduce the potential for nonconformances or other undesirable situations.  |
| <b>Process</b>                   | A series of tasks usually performed by one person according to instructions.  |
| <b>Process Control</b>           | A set of related tasks and activities that accomplish a work goal.  |
| <b>Product</b>                   | The efforts to standardize and control processes in order to produce predictable output.  |
| <b>Proficiency Testing</b>       | A tangible result of a process or procedure.  |
| <b>Qualification</b>             | The structured evaluation of laboratory methods that assesses the suitability of processes, procedures, equipment, materials, and personnel.  |
| <b>Quality</b>                   | With respect to individuals, the aspects of an individual's education, training, and experience that are necessary to successfully meet the requirements of a position. Specifically for equipment, verification that specified attributes required to accomplish the desired task have been met. |
| <b>Quality Control</b>           | Characteristics of a unit of blood or a blood component, a sample, a critical material, or a service that bear on its ability to meet requirements, including those defined during agreement review.  |
| <b>Quality System</b>            | Testing routinely performed on materials and equipment to ensure their proper function.   |
|                                  | The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.  |

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| <b>Term</b>                | <b>Definition</b>   |
|----------------------------|---|
| <b>Quarantine</b>          | To isolate nonconforming blood, blood components, or materials to prevent their distribution or use.  |
| <b>Reagent</b>             | 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.   |
| <b>Record (noun)</b>       | 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. |
| <b>Record (verb)</b>       | To capture information for use in records through writing or electronic media.  |
| <b>Reference Standards</b> | Specified requirements defined by the AABB (see <i>Specified Requirements</i> ). Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.  |
| <b>Regulations</b>         | Rules promulgated by federal, state, or local authorities to implement laws enacted by legislative bodies.  |
| <b>Release</b>             | Removal of product from quarantine or in-process status for distribution.   |
| <b>Segregate</b>           | To separate or isolate products by a method known to clearly identify them and to minimize the possibility of their unintended distribution or use.   |
| <b>Service</b>             | An intangible result of a process or procedure.   |

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## Glossary

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| <b>Term</b>                             | <b>Definition</b>  |
|---|--|
| <b>Sexual Contact</b>                   | 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).   |
| <b>Shall</b>                            | A term used to indicate a requirement.   |
| <b>Special Transfusion Requirements</b> | 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). |
| <b>Specified Requirements</b>           | Any requirements in these <i>Fundamentals</i> , including, but not limited to, Competent Authority 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.  |
| <b>Supplier</b>                         | An entity that provides an input material or service.  |
| <b>Supplier Qualification</b>           | An evaluation method designed to ensure that input materials and services (eg, materials, blood, blood components, patient blood samples) obtained from a supplier meet specified requirements.  |
| <b>Temporary Deferral</b>               | A deferral placed on a donor who is not eligible to donate for a specified period of time.   |

| <b>Term</b>                  | <b>Definition</b>  |
|------------------------------|--|
| <b>Titer (High)</b>          | Anti-A and/or anti-B in plasma or serum, which when diluted to a specified titer in normal saline, agglutinates red cells containing the corresponding antigens (ie, A1, B or A1B).  |
| <b>Titer (Low)</b>           | The reciprocal value of the highest serum dilution causing agglutination.  |
| <b>Traceability</b>          | The ability to follow the history of a product or service by means of recorded identification.   |
| <b>Transfusionist</b>        | 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.             |
| <b>Transfusion Service</b>   | 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). |
| <b>Transmissible Disease</b> | A disease or condition caused by a virus, bacteria, fungus, parasite, or agent of transmissible spongiform encephalopathy that may be transmitted by transfusion of blood or blood components.   |
| <b>Unit</b>                  | A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.  |
| <b>Urticaria Reaction</b>    | The development of hives, maculopapular rash, or similar allergic manifestation.   |

## Glossary

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| <b>Term</b>                | <b>Definition</b>   |
|----------------------------|---|
| <b>User-Defined Tables</b> | 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. |
| <b>Validation</b>          | Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.     |
| <b>Verification</b>        | Confirmation by examination and provision of objective evidence that specified requirements have been met.  |
| <b>Xenotransplantation</b> | Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either live cells or live organs from a nonhuman animal source.                                      |

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