PROPOSED Fundamental Standards for Blood Collection and Transfusion

2nd Edition

A Note to Readers

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

- Requirements, once stated, are not repeated. For example, standard 5.0 requires that all processes and procedures be validated. Therefore, it is not necessary to require in other areas that a specific process or procedure be validated.

- Words or phrases used in a way different from their usual meaning are defined in the glossary.

- The term "specified requirements" is defined broadly to include accreditation requirements, national, state, or local laws, and any other applicable requirement.

- Please note, that the Summary of Significant Changes to the proposed 2nd edition begins on page 2 and runs through page 19. The proposed 2nd edition begins on page 20 and runs through page 87.

Significant Changes to the Proposed 2nd edition of Fundamental Standards for Blood Collection and Transfusion

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, **and the quality management system**.

3) The responsibility for compliance with these *Fundamental Standards for BB/TS (Fundamentals)* and applicable **Competent Authority requirements**, local laws and regulations.

4) Responsibility to support appropriate use of blood, safe transfusion practices, and working towards implementation of a formal patient blood management program.

The committee elected to edit subnumber 1 to ensure that users recognize the responsibility of executive management to have authority over the quality management system.
Subnumber 4 is new to the proposed edition and was included as a means of ensuring that users of the Fundamentals begin to implement elements of a patient blood management program.

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, **referred to as a designee**; however, the director shall retain ultimate responsibility for director duties.

The committee edited standard 1.1.1 for clarity, the intent of the standard has not changed.

1.2 Quality Management System

The facility shall have a quality **management** system in place.

The committee added the term "management" to quality system to read "quality management system." This change has been made throughout the edition.

1.2.1 **The quality management system shall be documented, implemented and maintained.**

The committee created this standard for completeness, reflecting the need for the quality management system be maintained by the facility for review and implementation.

1.2.2 All personnel shall be educated and trained in its application.

This standard is not new, it previously appeared as a part of standard 1.2. The committee felt it should appear as a standalone.

1.3.1 All policies, processes, and procedures shall be approved by the director **(or qualified designee)**; the BB/TS licensed physician **(or qualified designee)** 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 **(or qualified designee)**. Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

The committee edited the content of standard 1.3.1 and 1.3.2 to run parallel to the updates made to standard 1.1.1.

1.5 **Sufficiency of the Blood Supply**
The facility shall have plans (including policies, processes and procedures) to ensure the availability of blood donors, blood, blood products and critical materials for the scope of operations conducted.

1.5.1 **The facility shall have processes to address shortages of product and materials, including the identification of alternate available suppliers.**

1.5.2 The facility shall have a continuity plan to address disruptive events (eg, disasters, pandemics, etc.) which may affect supply chain and product inventory that could place operations at risk.

The committee added new standards 1.5 – 1.5.2 to ensure facilities have plans in place to ensure the continuity of their supply. These standards are based on requirements in the 34th edition of BB/TS Standards but adjusted for the global audience.

2.1.2 Education and Training

The BB/TS shall have a process for identifying education **and training** needs and shall provide education **and training for** personnel performing critical tasks **at facility defined intervals**.

The committee elected to expand standard 2.1.2 to include training as well as education, while ensuring that the bb/ts defines when this education and training occurs.

2.1.2.1 The BB/TS shall have a process for working towards identifying education and training needs regarding support for implementation of PBM concepts (such as those found in the AABB *Standards for a Patient Blood Management Program* and the ability to provide training where identified.

The committee would like to expand the scope of the Fundamentals to include initial requirements to have facilities begin the implementation of patient blood management principles.

2.1.3 Competence

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

These evaluations can include:

1) Direct observation of individuals performing daily job functions,
2) Internal or external quality review of employee job performance, or
3) Review of proficiency testing.

The committee elected to expand the requirements for 2.1.3 to provide elements of what evaluations of competence would include.

2.1.4 Personnel Records

Personnel records for each employee shall be maintained. **These records shall include employee education, training, work experience, and evidence of continuing education**.

The committee added the new requirement in standard 2.1.4 to provide evidence of what personnel records should include.

3.4.1 The BB/TS shall have a process to identify which pieces of specific equipment was used in the collection, component preparation (manufacturing) or storage, for lot/batch processing and investigation in the event of a failure.

The committee created new standard 3.4.1 to ensure that facilities have a means of identifying equipment to ensure that if an investigation was needed in case of failure. Similar standards exist in other sets of AABB Standards.

3.8.1 Cell Salvage Devices

To ensure reinfusion of non-contaminated and non-hemolyzed red cells, cell salvage devices shall be operated and maintained by competent personnel and according to the manufacturer instructions for use and facility procedures.

The committee created new standard 3.8.1 focused on the use and maintenance of cell salvage devices by appropriately identified personnel.

4. SUPPLIERS AND CUSTOMERS ~~ISSUES~~

4.0 Suppliers and Customers ~~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.

The committee updated the title of chapter 4 and standard 4.0 to mirror the title of the chapter and standard in the 34th edition of BB/TS Standards.

4.1 Incoming Receipt, Inspection, and Testing

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

The committee added the term "equipment" for completeness.

4.1.4 The facility shall ensure that benchmarking and blood product utilization data are shared between the supplier and the customer on a scheduled basis. This data shall be used as a basis for determination of appropriateness of use and tracking compliance to PBM principles.

As a part of the committee's desire to ensure that facilities are implementing PBM principles, the committee created new standard 4.1.4 to focus on the collection of data that forms the backbone of PBM programs and the data that support its implementation.

5.1.1.1 Results of quality control testing shall be reviewed to ensure that specifications are met and expected outcomes obtained.

The committee created new standard 5.1.1.1 for completeness. This ensures that the facility reviews the quality control testing results and records that they are gathering per the standards cited above.

5.6.2 Protection Against Contamination

The **phlebotomy skin area shall be exposed and thoroughly cleaned to minimize risk of bacterial contamination as per facility's validated protocol or standard operating procedure** ~~venipuncture site shall be prepared for a minimum of 30 seconds or per manufacturer specifications to minimize risk of bacterial contamination~~.

The committee edited the standard for clarity. The committee feels that the proposed language is clearer and more comprehensive.

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 ~~90~~**75**% of the original red cells and contain <5 x 10^6 residual leukocytes per unit.

The committee edited the percentage for retention from 90% to 75% reflecting what was more achievable by the committee members.

5.7.3.5 PLATELETS

Validation and quality control of Platelets prepared from Whole Blood shall demonstrate that at least ~~90~~**75**% of units sampled contain ≥5.5 x 10^{10} platelets and have a pH ≥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~~**75**% of units sampled contain ≥3.0 x 10^{11} platelets and, at the end of allowable storage or at the time of issue, have a pH ≥6.2.

The committee edited the percentage of units sampled from 90% to 75% recognizing that this was more achievable by the committee members.

5.7.3.8 THAWED PLASMA

Thawed Plasma shall be prepared from Plasma Frozen Within 24 Hours After Phlebotomy, that has been collected in a closed system.

5.7.3.9 CRYOPRECIPITATED AHF

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

5.7.3.10 PLASMA CRYOPRECIPITATE REDUCED

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

5.7.3.11 PLASMA FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY

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

5.7.3.12 WASHED RED BLOOD CELLS AND PLATELETS

Washed Red Blood Cells and Platelets shall be prepared by a method known to ensure that the red cells or platelets are washed with a volume of compatible solution that will remove almost all of the plasma.

The committee added the standards focused on the components above for completeness. They are based on similar standards in the 34th edition of BB/TS Standards.

5.8.7 **A minimum target of 1% (or as defined by the Competent Authority) of the total number of all blood components and blood products routinely prepared or 4 units per month, whichever is higher, shall be tested and at least 75% of products tested should comply with the specifications set. Reference Standard 5.1.6A, Requirements for Storage, Transportation, and Expiration applies.**

The committee elected to add standard 5.8.7 to this edition ensuring that facilities are testing units to ensure that components are meeting requirements set forth in the reference standard cited.

5.8.8 **A test for sterility shall be done on a minimum of 4 units (or as defined by the Competent Authority) of each type of platelet product per method. The microbiological test shall be done by a method that maintains a closed system.**

The committee added new standard 5.8.8 to ensure facilities are performing sterility testing on all types of platelet products collected and dispensed by the facility.

5.13.4 Pretransfusion Testing for Autologous Transfusion
Where this is offered, pretransfusion testing for autologous transfusion shall include ABO group and Rh type on the patient sample. Standard 5.11 applies.

The committee added the clause in bold to ensure that facilities that are not performing autologous transfusion are not held to the standard.

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. **Standard 1.1.1 applies.**

The committee added a crossreference to standard 1.1.1 for completeness. The standard in question is focused on the responsibilities of the medical director.

5.16 Selection of Blood and Blood Components in Special Circumstances
For patients with clinically indicated special transfusion requirements, there shall be a mechanism to ensure that all future **transfusions meet these** requirements for as long as clinically indicated.

The committee added the clause in bold for completeness. The requirement will ensure that there is documentation to confirm that the patient in question is able to undergo the transfusion.

5.20.1 Recipients whose ABO group is not known shall receive group O Red Blood Cells or low-titer group O Whole Blood. Standards 5.13.1 **and 5.14.2.1** apply.

The committee added a crossreference to standard 5.14.2.1 for completeness. Standard 5.14.2.1 focuses on the requirement that transfusion services have policies for the use of Rh positive red cell containing components in Rh negative recipients.

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 nontreatment), **in terms understandable to the recipient**.

The committee added the clause in bold for completeness. This addition mirrors

language in other sets of AABB Standards.

5.23 Patient Blood Management
The facility shall have policies, processes, and procedures to support appropriate use of blood, and work towards implementation of a formal patient blood management program.

The committee created new standard 5.23 as a means of promoting the concept of facilities implementing the Fundamentals are beginning to embrace patient blood management without setting forth a requirement to have a patient blood management program.

Reference Standard 5.1.4A – Requirements for Labeling Blood and Blood Components

Item No.	Labeling Item	Collection or Preparation	Final Component
6	Facility modifying component	NA	R~~, if leaves the facility~~

The committee removed the clause in strikethrough as it was deemed guidance and not a standard.

Item No.	Labeling Item	Collection or Preparation	Final Component
Additional Autologous Labeling Requirements			

The committee added this title into the reference standard to mirror the style of the 34th edition of BB/TS Standards.

Item No.	Labeling Item	Collection or Preparation	Final Component
Additional Dedicated Labeling Requirements			

18	**Intended recipient information label**	**R**	**R**
19	**Donor tested within the last 30 days, if applicable**	**NR**	**R**
20	**Biohazard label, 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~~

The committee added a new section for a labeling section for dedicated donor units. 18 – 20 are pulled from the 34th edition of BB/TS Standards.
The committee removed entries 18 and 19 noting that these labeling requirements would not be appropriate for the global audience.

Reference Standard 5.1.6A – Requirements for Storage, Transportation, and Expiration

Item No.	Component	Storage	Transport	Expiration[1]	Additional Criteria	Recommended QC Parameters
3	~~Fresh~~ Frozen Plasma ~~(FFP)~~[2,3]	–18 C or colder or –65 C or colder	Maintain frozen state	–18 C or colder: 12 months from collection –65 C or colder: 7 years from collection		Volume: ± 10% of stated vol. Factor VIII:C: ≥ 0.7 IU/ml

The committee edited subnumber 3 recognizing that access to fresh frozen plasma is not universal.

Reference Standard 5.4.1A – Requirements for Allogeneic Donor Qualification

Category	Criteria/Description/Examples	Deferral Period*
7) Drug Therapy	Generic medication name **(including, but not limited to):^**	

^ Note: this list is not exhaustive. Other medications, as determined by Competent Authority regulations and/or medical director, and their associated deferral periods can be implemented on a case by case basis with due consideration of the risk to either the recipient or the donor.

The committee included the clause in parentheses to ensure that users were aware that the list included below are not comprehensive.

The committee also included a new footnote to row 7 to ensure that facilities are aware of the medication and deferral periods that could be applicable based on what is required by each facility's Competent Authority.

Category	Criteria/Description/Examples	Deferral Period*
7) Drug Therapy **Known Teratogens**	• Finasteride • Isotretinoin • Dutasteride • Vismodegib • Acitretin • Etretinate	• 1 month after last dose • 6 months after last dose • 24 months after last dose • 3 years after last dose • Permanent

The committee added the clause "known teratogens" as a title for the row for completeness.

Category	Criteria/Description/Examples	Deferral Period*
7) Drug Therapy **Infectious Diseases**		

The committee added the clause "infectious diseases" as a title for the row for completeness.

Category	Criteria/Description/Examples	Deferral Period*
7) Drug Therapy **Medications that irreversibly inhibit platelet function preclude use of the donor as sole source of platelets**	~~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) b. Prasugrel (Effient) and ticagrelor (Brilinta) c. Clopidogrel (eg, Plavix), Ticlopidine (eg, Ticlid) and Vorapaxar (eg, Zontivity)	• 2 full days (>48 hours) after last dose • ~~7~~**3** days • 14 days after last dose

In line with the changes above, the committee moved the clause in strikethrough to appear as a title to the row. The content has not changed.

Category	Criteria/Description/Examples	Deferral Period*
7) Drug Therapy **Medication that impact product efficacy**	• Warfarin (eg, Coumadin, Warfilone, Jantoven) • Heparin and derivatives • Direct thrombin inhibitors (eg, Dabigatran) • Direct Xa inhibitors (eg, Rivaroxaban)	• For plasma products for transfusion: 7 days after last dose) • For plasma products for transfusion: 7 days after last dose or as defined by the BB/TS licensed physician • 2 days after last dose or as defined by the facility's BB/TS licensed physician

Mirroring the changes above, the committee added a title to the row for completeness.

Category	Criteria/Description/Examples	Deferral Period*
7) Drug Therapy **Plasma Derivatives**		

Mirroring the changes above, the committee added a title to the row for completeness

Category	Criteria/Description/Examples	Deferral Period*
10) Receipt of Blood, Blood - Component, or Human Tissue	• Receipt of allogeneic dura mater or pituitary growth hormone of human origin • Receipt of **allogeneic** blood, components, or human -tissue	Permanent 3 months **(If NAT is performed)** **12 months (If NAT is not performed)**

The committee updated row 10 to provide to create the two scenarios in which testing is performed either via NAT or not.

6.1.1 A document management system.

The committee added new standard 6.1.1 for completeness.

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

The committee edited the standard for clarity, updating the language that is more

easily understood. The intent of the standard has not changed.

6.2.7 Management of Electronic Data ~~Electronic Records~~

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

The committee edited this standard for clarity. This change ensures that the scope of the standard could be interpreted more broadly beyond electronic records.

6.2.10 Backup Data

The organization shall back up all critical data.

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

The committee added new standards 6.2.10 and 6.2.10.1 for completeness. These standards currently appear in all sets of AABB Standards.

7.3.3.1.1 Prompt investigation of each event by the BB/TS licensed physician, **as required by applicable regulations**.

The committee added the clause in bold for completeness. The requirement ensures that facilities are aware of the regulations in the country as well.

7.3.4.1 Collection Facility

The collection facility shall have policies, processes, and procedures to notify consignees **and/or prescribers** of blood or blood components from donors subsequently found to have, or be at risk for, relevant transmissible diseases. **Notification shall be in accordance with applicable regulations.**

The committee added the clause "and/or prescribers" for completeness recognizing there are instances where these individuals are a part of the lookback process. The sentence in bold ensures that facilities are aware of the regulations in the country as well.

8.2 Quality Monitoring and Evaluation
The BB/TS shall have a process to collect and evaluate quality indicator data at least annually.

The committee added new standard 8.2 to ensure that facilities collect quality indicator data annually in line with other changes made throughout the edition. This standard exists in the BB/TS Standards as well.

8.3~~2~~ Utilization Review

Transfusion **services** shall monitor and evaluate transfusion practices for all categories of blood and blood components**, e.g. patient blood management. This shall include, if applicable:**
1) Blood and blood component discard and cause(s) of waste.
2) Use and effectiveness of the emergency/massive transfusion processes and protocols.

The committee expanded the scope of standard 8.3 along with the concept of including patient blood management principles as a part of their utilization review policies. The content of this standard is similar those in the BB/TS and PBM Standards.

8.3.1 Wastage
The facility shall monitor blood component wastage across the blood supply chain, including the cause of wastage.

The committee included new standard 8.3.1 for facility monitoring as a part of adopting patient blood management program principles.

8.4 Clinical Interface

8.4.1 A facility that transfuses blood shall have access to timely consultation for clinical personnel.

8.4.2 The facility shall develop or adopt clinical guidelines on the appropriate use of blood and blood products and promote the implementation of patient blood management program.

The committee included new standards 8.4 – 8.4.2 for completeness. This addition as a part of adopting patient blood management program principles for users of the Fundamentals.

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 **and preventive** action, including near-miss events.

The committee edited the title of chapter 9 and standard 9.0 to mirror the language in the BB/TS Standards. The committee also included the concept of "preventive" in chapter 9 for completeness.

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

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

The committee elected to add new proposed standard 9.2 to the edition based on the addition to standard 9.0 of the concept of preventive action. The language of the standard is based on a similar standard in other AABB Standards.

Glossary

Consignee: A transfusionist or transfusing facility to whom the blood or blood products is to be delivered to.

Quality Indicator Data: Information that is collected and used to determine whether an organization is meeting its quality objectives.

The committee added the proposed entries above to the glossary for completeness.

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, and the quality management system.

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 Competent Authority requirements, local laws and regulations.

4) Responsibility to support appropriate use of blood, safe transfusion practices, and working towards implementation of a formal patient blood management program.

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, referred to as a designee; 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 Management System

The facility shall have a quality management system in place.

1.2.1 The quality management system shall be documented, implemented and maintained.

1.2.2 All personnel shall be educated and trained in its application.

1.2.3 Management Reviews

Management shall assess the effectiveness of the quality management 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 (or qualified designee); the BB/TS licensed physician (or qualified designee) 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 (or qualified designee). 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.

1.5 Sufficiency of the Blood Supply

The facility shall have plans (including policies, processes and procedures) to ensure the availability of blood donors, blood, blood products and critical materials for the scope of operations conducted.

1.5.1 The facility shall have processes to address shortages of product and materials, including the identification of alternate available suppliers.

1.5.2 The facility shall have a continuity plan to address disruptive events (eg, disasters, pandemics, etc.) which may affect supply chain and product inventory that could place operations at risk.

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, 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 Education and Training

The BB/TS shall have a process for identifying education and training needs and shall provide education and training for personnel performing critical tasks at facility-defined intervals.

2.1.2.1 The BB/TS shall have a process for working towards identifying education and training needs regarding support for implementation of PBM concepts (such as those found in the AABB *Standards for a Patient Blood Management Program* and the ability to provide training where identified.

2.1.3 Competence

Formal assessments and evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals at a minimum of every two years. These evaluations can include:

1) Direct observation of individuals performing daily job functions,

2) Internal or external quality review of employee job performance, or

3) Review of proficiency testing.

2.1.4 Personnel Records

Personnel records for each employee shall be maintained. These records shall include employee education, training, work experience, and evidence of continuing education.

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.

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 5.1.5.3 applies.

3.4.1 The BB/TS shall have a process to identify which pieces of specific equipment was used in the collection, component preparation (manufacturing) or storage, for lot/batch processing

and investigation in the event of a failure.

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 5.1.7.1.2 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 5.1.7.1.2 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.

3.8.1 Cell Salvage Devices
To ensure reinfusion of non-contaminated and non-hemolyzed red cells, cell salvage devices shall be operated and maintained by competent personnel and according to the manufacturer instructions for use and facility procedures.

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.

4. SUPPLIERS AND CUSTOMERS

4.0 Suppliers and Customers
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, equipment, 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 the 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 the applicable Competent Authority's criteria.

4.1.4 The facility shall ensure that benchmarking and blood product utilization data are shared between the supplier and the customer on a scheduled basis. This data shall be used as a basis for determination of appropriateness of use and tracking compliance to PBM principles.

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 and to drive the implementation of PBM and the appropriate use of such products. 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, applies.

5.1.1.1 Results of quality control testing shall be reviewed to ensure that specifications are met and expected outcomes obtained.

5.1.1.2 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 accuracy 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 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 phlebotomy skin area shall be exposed and thoroughly cleaned to minimize risk of bacterial contamination as per facility's validated protocol or standard operating procedure.

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 <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 75% 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 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 75% of units sampled contain >5.5 x 10^{10} platelets and have a pH >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 75% of units sampled contain >3.0 x 10^{11} platelets and, at the end of allowable storage or at the time of issue, have a pH >6.2.

5.7.3.7 APHERESIS PLATELETS LEUKOCYTES REDUCED

Validation and quality control shall demonstrate that 75% of units sampled contain >3.0 x 10^{11} platelets and, at the end of allowable storage or at the time of issue, have a pH >6.2. At a minimum, 95% of units sampled shall contain a residual leukocyte count <5 x 10^{6}.

5.7.3.8 THAWED PLASMA

Thawed Plasma shall be prepared from Plasma Frozen Within 24 Hours After Phlebotomy, that has been collected in a closed system.

5.7.3.9 CRYOPRECIPITATED AHF

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

per component in the pool.

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

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

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

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

5.8.4 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 required by the Competent Authority.

5.8.7 A minimum target of 1% (or as defined by the Competent Authority) of the total number of all blood components and blood products routinely prepared or 4 units per month, whichever is higher, shall be tested and at least 75% of products tested should comply with the specifications set. Reference Standard 5.1.6A, Requirements for Storage, Transportation, and Expiration

applies.

5.8.8 A test for sterility shall be done on a minimum of 4 units (or as defined by the Competent Authority) of each type of platelet product per method. The microbiological test shall be done by a method that maintains a closed system.

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 an 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.

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
Where this is offered, 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.

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. The BB/TS shall document the exception.

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. Standard 1.1.1 applies.

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

For patients with clinically
indicated special transfusion requirements, there shall be a mechanism in place to ensure that all future transfusions meet these requirements for as long as clinically indicated.

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. Standards 5.13.1 and 5.14.2 apply.

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 nontreatment), in terms understandable to the recipient.

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.

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.

5.23 Patient Blood Management

The facility shall have policies, processes, and procedures to support appropriate use of blood, and work towards implementation of a formal patient blood management program.

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
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
Additional Autologous Labeling Requirements			

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†	NR	R
16	Phrase: “Donor untested,” if applicable	NR	R
17	Donor tested within the last 30 days, if applicable	NR	R
Additional Dedicated Labeling Requirements			
18	Intended recipient information label	R	R
19	Donor tested within the last 30 days, if applicable	NR	R
20	Biohazard label, if applicable†	NR	R

*Competent Authority requirements apply.

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

Test	Test Result
HbsAg	Repeatedly reactive
Anti-HCV	Repeatedly reactive
Anti-HIV-1/2	Repeatedly 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+

Item No.	Component	Storage	Transport	Expiration1	Additional Criteria	Recommended QC Parameters
Whole Blood Components						
1	Whole Blood	1-6 C If intended for room temperature components, then store at 1-6 C within 8 hours after collection	Cooling toward 1-10 C If intended for room temperature components, cooling toward 20-24 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days	May be leukodepleted. All requirements apply if leukodepleted	Volume: 450 ml ± 10% Hemoglobin: > 45 g/unit Hemolysis: < 0.8% of red cell mass (test at end of storage)
Red Blood Cell Components						
2	Red Blood Cells (RBCs)	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days Additive solution: 42 days Open system: 24 hours	May be leukodepleted. All requirements apply if leukodepleted	Volume: 280 ± 50 ml Hematocrit: 65% - 75% Hemoglobin: > 45 g/unit Hemolysis:< 0.8% of red cell mass If leucoreduced, Leukocytes: < 5 × 106 /unit

Plasma Components						
3	Frozen Plasma 2,3	–18 C or colder or –65 C or colder	Maintain frozen state	–18 C or colder: 12 months from collection –65 C or colder: 7 years from collection		Volume: ± 10% of stated vol. Factor VIII:C: ≥ 0.7 IU/ml
4	FP (after thawing)3	1-6 C	1-10 C	If issued as FP: 24 hours		N/A
5	Plasma Frozen Within 24 Hours After Phlebotomy (PF24)	–18 C or colder	Maintain frozen state	12 months from collection		N/A
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	N/A
Platelet Components						

6	Platelets	20-24 C with continuous gentle agitation	As close as possible to 20-24 C Maximum time without agitation: 30 hours	24 hours to 5 days, depending on collection system	May be leukodepleted. All requirements apply if leukodepleted	Volume: ≥ 40 ml Leukocytes: < 5.0 × 106 /unit Platelet count: ≥ 5.5 × 1010 /unit pH (at expiry): ≥ 6.0
7	Apheresis Platelets	20-24 C with continuous gentle agitation	As close as possible to 20-24 C Maximum time without agitation: 30 hours	24 hours to 5 days, depending on collection system	May be leukodepleted. All requirements apply if leukodepleted	Volume: 200 - 300 ml Leukocytes: < 1.0 × 106 / unit Platelet count: > 3 × 1011 /unit pH (at expiry): 6.4 to 7.4

*Competent authority requirements apply.
[1]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.
[2]If a liquid freezing bath is used, the container shall be protected from chemical alteration.
[3]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 ≥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	<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 (including, but not limited to):^	
Known Teratogens	Finasteride	1 month after last dose

	Isotretinoin Dutasteride Vismodegib Acitretin Etretinate	 6 months after last dose 24 months after last dose 3 years after last dose Permanent
Medications that irreversibly inhibit platelet function preclude use of the donor as sole source of platelets	Aspirin, aspirin-containing medications, and piroxicam (eg, Feldene) b. Prasugrel (Effient) and ticagrelor (Brilinta) c. Clopidogrel (eg, Plavix), Ticlopidine (eg, Ticlid) and Vorapaxar (eg, Zontivity)	2 full days (>48 hours) after last dose 3 days 14 days after last dose
Medication that impact product efficacy	Warfarin (eg, Coumadin, Warfilone, Jantoven) Heparin and derivatives Direct thrombin inhibitors (eg, Dabigatran) Direct Xa inhibitors (eg, Rivaroxaban)	For plasma products for transfusion: 7 days after last dose For plasma products for transfusion: 7 days after last dose or as defined by the facility's BB/TS licensed physician 2 days after last dose or as defined by the facility's BB/TS licensed physician
Plasma Derivatives		

	Other medications, such as antibiotics	As defined by the facility's BB/TS licensed physician
8) Medical History and General Health	The prospective donor shall appear to be in good health and shall be free of major organ disease (eg, heart, liver, lungs), cancer, or abnormal bleeding tendency, unless determined suitable by the medical director The venipuncture site shall be evaluated for lesions on the skin. The venipuncture site shall be free from infectious skin disease and any disease that might create a risk of contaminating the blood	
	Family history of Creutzfeldt-Jakob disease (CJD)	Indefinite deferral for risk of CJD
9) Pregnancy and lactation	Defer if pregnant within the last 6 months or lactating	
10) Receipt of Blood, Blood Component, or Human Tissue	Receipt of allogeneic dura mater or pituitary growth hormone of human origin Receipt of allogeneic blood, components, or human -tissue	Permanent 3 months (If NAT is per-formed) 12 months (If NAT is not performed)
11) Xenotransplanta-tion	Receipt of live cells, tissues or live organs from a nonhuman animal source. Note: Nonliving biological products or materials from nonhuman animals, such as porcine or bovine heart valves and porcine insulin, are	Permanent

	acceptable.	
12) Immunizations and Vaccinations	Receipt of toxoids, or synthetic or killed viral, bacterial, or rickettsial vaccines if donor is symptom-free and afebrile [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)] Receipt of recombinant vaccine [eg, HPV Vaccine] Receipt of intranasal live attenuated flu vaccine	None
	Receipt of live attenuated viral and bacterial vaccines [Measles (rubeola), Mumps, Polio (Sabin/oral), Typhoid (oral), Yellow fever]	2 weeks
	Receipt of live attenuated viral and bacterial vaccines [German measles (rubella), chicken pox/-shingles (varicella zoster)]	4 weeks
	Receipt of other vaccines	12 months unless other-wise indicated by licensed

		physician
13) Infectious Diseases	Confirmed positive test for HBsAg	Permanent
	Present or past clinical or laboratory evidence of infection with HIV, HCV	Indefinite
	A history of babesiosis	Indefinite
	Evidence or obvious stigmata of parenteral drug use	Indefinite
	Use of a needle to administer nonprescription drugs	Indefinite
	Mucous membrane exposure to blood	12 Months
	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: a. Has acute or chronic hepatitis B b. Has symptomatic hepatitis C	12 Months
	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 Following the diagnosis of syphilis or gonorrhea. Must have completed treatment Donor who has a reactive screening test for syphilis where no confirmatory testing was performed A confirmed positive test for syphilis	12 months
14) Travel	The prospective donor's travel history shall be evaluated for potential risks	
*Competent Authority requirements apply. ^ Note: this list is not exhaustive. Other medications, as determined by Competent Authority regulations and/or medical director, and their associated deferral periods can be implemented on a case by case basis with due consideration of the risk to either the recipient or the donor.		

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 A document management system.

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

6.1.3 Review and approval of new and revised documents before use.

6.1.4 Review of each policy, process, and procedure shall be performed by an authorized individual at least every two years.

6.1.5 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 Management of Electronic Data
There shall be processes and procedures to support the management of electronic data and 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.

6.2.10 Backup Data
The organization shall back up all critical data.

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

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

Item No.	Standard	Record to Be Maintained
1	1.2.3	Review of effectiveness of the quality management 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, databases, 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
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, 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, 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
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, 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: ABO group and Rh type. Difficulty in blood typing. Clinically significant antibodies. Significant adverse events to transfusion. 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.

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
50	5.18	Verification shall include: The intended recipient's two independent identifiers, ABO group, and Rh type. The donation identification number, the donor ABO group, and, if required, the Rh type. The interpretation of crossmatch tests, if performed. Special transfusion requirements, if applicable. The expiration date and, if applicable, time. The date and time of issue.
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: A description of the risks, benefits, and treatment alternatives (including nontreatment). The opportunity to ask questions. The right to accept or refuse transfusion.
56	5.21.3	The following information shall be verified before transfusion: The intended recipient's two independent identifiers, ABO group, and Rh type. The donation identification number, the donor ABO group, and, if required, the Rh type. The interpretation of crossmatch tests, if performed. Special transfusion requirements are met, when applicable. The expiration date (or time) of the unit and that it has not expired.
57	5.21.4	Verification of patient identification before transfusion
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	6.1.3	Review and approval of new and revised documents before use
60	6.1.4	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	8.1	Assessment results
70	8.2	Collection and evaluation of quality indicator data
71	8.3	Utilization review
72	9.0	Implementation of changes to policies, processes, and procedures resulting from corrective action
73	9.1	Corrective action
74	9.2	Preventive action

75	10.2	Appropriate discard of blood and blood components
*Applicable local law applies.		

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.

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, as required by applicable regulations.

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 and/or prescribers of blood or blood components from donors subsequently found to have, or be at risk for, relevant transmissible diseases. Notification shall be in accordance with applicable regulations.

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.

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 management 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 Quality Monitoring and Evaluation

The BB/TS shall have a process to collect and evaluate quality indicator data at least annually.

✎8.3 Utilization Review

Transfusion services shall monitor and evaluate transfusion practices for all categories of blood and blood components, e.g. patient blood management. This shall include, if applicable:

1) Blood and blood component discard and cause(s) of waste.

2) Use and effectiveness of the emergency/massive transfusion processes and protocols.

8.3.1 Wastage

The facility shall monitor blood component wastage across the blood supply chain, including the cause of wastage.

8.4 Clinical Interface

8.4.1 A facility that transfuses blood shall have access to timely consultation for clinical personnel.

8.4.2 The facility shall develop or adopt clinical guidelines on the appropriate use of blood and blood products and promote the implementation of patient blood management program.

9. PROCESS IMPROVEMENT

9.0 Process Improvement

The BB/TS shall have policies, processes, and procedures for data collection, analysis, and follow-up of issues requiring corrective and preventive 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.

9.2 Preventive Action

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

1) Analysis of sources of information to detect, analyze, and eliminate potential causes of nonconformances.

2) Determination of steps needed to address any problems requiring preventive action.

3) Initiation of preventive action and application of controls to ensure that it is effective.

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.

GLOSSARY

ABO Incompatibility Detection: Use of a method (eg, serological or computer-based) to determine incompatibility of ABO group between donor and recipient.

Adverse Event: A complication in a donor or patient. Adverse events may occur in relation to a donation, a transfusion, or a diagnostic or therapeutic procedure.

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

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

Allogeneic Donor: An individual from whom products intended for another person are collected.

Antibody Screen: A serologic method to detect the presence of clinically significant antibodies in recipients and/or donors.

Assessment: A systematic, 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.

Autologous Donor: A person who acts as his or her own product donor.

Backup: Digital data storage media (magnetic tape, flash drive, CD, etc) containing copies of computer data.

Blood Bank: A facility that performs, or is responsible for the performance of, the collection, processing, storage, and/or distribution of human blood and/or blood components intended for transfusion.

Blood Components: Products prepared from a Whole Blood collection or produced through an automated collection, eg, red blood cells, plasma, and platelets.

Blood Products: See blood components.

By a Method Known to: Use of published data to demonstrate the acceptability of a process or procedure, particularly for component preparation.

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

Clinically Significant Antibody: An antibody that is capable of causing shortened cell survival.

Closed System: A system, the contents of which are not exposed to air or outside elements during collection, preparation, and separation of components.

Collection Facility: A facility that collects blood and/or blood components from a donor.

Competence: Ability of an individual to perform a specific task according to procedures.

Competent Authority: The agency responsible under its national law for regulations applicable to blood banks or transfusion services.

Compliance: See Conformance.

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

Consignee: An individual or facility that accepts delivery and responsibility for blood or blood components for transfusion

Corrective Action: An activity performed to eliminate the cause of an existing nonconformance or other undesirable situation in order to prevent recurrence.

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

Crossmatch: A method (eg, serological or computer-based) to detect incompatibility between donor and recipient.

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

Dedicated Donor: An individual who donates blood components intended for and used solely by a single identified recipient.

Derivative: Sterile solutions of a specific protein(s) derived from blood or by recombinant technology (eg, albumin, plasma protein fraction, immune globulin, and factor concentrates).

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

Disaster: An event (internal, local, or national) that can affect the safety and availability of the blood supply or the safety of staff, patients, volunteers, and donors.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

Document (verb): To capture information through writing or electronic media.

Document Management System: A paper or computerized system that stores, manages, and shares documents.

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

Event: A generic term used to encompass the terms "incident," "error," and "accident."

Executive Management: 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.

Expiration: The last day or time that the blood, blood component, or material(s) is considered suitable for use.

Facility: A location or operational area within an organization. The part of the organization that is assessed by the AABB and receives AABB accreditation for its specific activities.

Final Inspection: To measure, examine, or test one or more characteristics of a unit of blood, a blood component, or a service and compare results with specified requirements in order to establish whether conformance is achieved before

distribution or issue.

Guidelines: Documented recommendations.

Indefinite Deferral: A deferral applied to a donor who is not eligible to donate blood for someone else for an unspecified period of time.

Inspect: To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements.

Irradiated: Exposure of blood components to x-rays or gamma rays at a minimum dose of 25 Gy (2500 cGy) targeted to the central portion of the irradiation canister or irradiation field to prevent the proliferation of T lymphocytes.

Issue: To release for clinical use (transfusion or transplantation).

Label: An inscription affixed or attached to a unit of blood or a blood component, or a sample for identification.

Labeling: 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.

Lived with: Resided in the same dwelling (eg, home, dormitory room, or apartment).

Maintain: To keep in the current state.

Master List of Documents: A reference list, record, or repository of a facility's policies, processes, procedures, forms, and labels related to the Fundamentals which includes information for document control.

Material: A good or supply item used in the manufacturing process. Materials are a type of input product. Reagents are a type of material.

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

Nonconformance: Failure to meet requirements.

Open System: A system, the contents of which are exposed to air and outside elements during preparation and separation of components.

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

Permanent Deferral: A deferral applied to a donor who will never be eligible to donate blood for someone else.

Policy: A documented general principle that guides present and future decisions.

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

Procedure: A series of tasks usually performed by one person according to instructions.

Process: A set of related tasks and activities that accomplish a work goal.

Process Control: The efforts to standardize and control processes in order to produce predictable output.

Product: A tangible result of a process or procedure.

Proficiency Testing: The structured evaluation of laboratory methods that assesses the suitability of processes, procedures, equipment, materials, and personnel.

Qualification: 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.

Quality: 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.

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

Quality Indicator Data: Information that is collected and used to determine whether an organization is meeting its quality objectives.

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

Quarantine: To isolate nonconforming blood, blood components, or materials to

prevent their distribution or use.

Reagent: A substance used to perform an analytical procedure. A substance used (as in detecting or measuring a component or preparing a product) because of its biological or chemical activity.

Record (noun): Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Record (verb): To capture information for use in records through writing or electronic media.

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

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

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

Segregate: To separate or isolate products by a method known to clearly identify them and to minimize the possibility of their unintended distribution or use.

Service: An intangible result of a process or procedure.

Sexual Contact: Any of the following activities (whether or not a condom or other protection was used) vaginal sex (contact between penis and vagina); oral sex (mouth or tongue on someone's vagina, penis, or anus); or anal sex (contact between penis and anus).

Shall: A term used to indicate a requirement.

Special Transfusion Requirements: Refers to a patient's medical need for components that have been modified, such as components that are irradiated, washed, or leukocyte reduced; components from special sources, such as autologous or directed sources; components that need special handling (eg, being subjected to the heat of a blood warming device); or components that contain special attributes (eg, CMV-seronegative or antigen-negative).

Specified Requirements: Any requirements in these Fundamentals, 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.

Supplier: An entity that provides an input material or service.

Supplier Qualification: 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.

Temporary Deferral: A deferral placed on a donor who is not eligible to donate for a specified period of time.

Titer (High): 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).

Titer (Low): The reciprocal value of the highest serum dilution causing agglutination.

Traceability: The ability to follow the history of a product or service by means of recorded identification.

Transfusionist: The individual(s) in the presence of the recipient who positively identifies and matches the blood component to the recipient through the use of two independent identifiers. This individual may also be responsible for physically initiating and/or maintaining a transfusion of blood or blood products.

Transfusion Service: A facility that performs one or more of the following activities: compatibility testing, storage, selection, and issuing of blood and blood components to intended recipients. Transfusion services do not routinely collect blood or process Whole Blood into components (except Red Blood Cells and Recovered Plasma).

Transmissible Disease: 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.

Unit: A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.

Urticaria Reaction: The development of hives, maculopapular rash, or similar allergic manifestation.

User-Defined Tables: Tables containing data used by computer programs to direct their operations. Typically, user-defined tables contain data that are unique to a specific installation and may change from system to system.

Validation: Establishing 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.

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

Xenotransplantation: Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either live cells or live organs from a nonhuman animal source.

Quick Reference

Abbreviations Used

✎	Record Required
ACD	Acid Citrate Dextrose
BBTS	Blood Banks and Transfusion Services
CPD	Citrate Phosphate Dextrose
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
PBM	Patient Blood Management
QC	Quality Control
QMS	Quality Management System
vCJD	Variant Creutzfeldt-Jakob disease