1st Edition of Standards for Standards for Out of Hospital and Prehospital Transfusion Administration Services

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 1st edition begins on page 2 and runs through page 17. The proposed 1st edition begins on page 18 and runs through page 82.

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Updated Quality System Essentials

The proposed 1st edition of Standards for Out of Hospital and Prehospital Transfusion Administration Services has incorporated the updated quality system essentials (QSE) template for this edition. This includes a number of updates to the chapters and the tone and flow of the edition.

Highlights of the updated QSEs include:

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

Driving factors behind the revisions to the updated QSEs:

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

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Significant Changes to the 1st edition of Standards for Out of Hospital and Prehospital Transfusion Administration Services

1.1.2 The TAS shall have a structure that clearly defines and documents the parties responsible for the activities described in these TAS Standards and the relationship of individuals responsible for key quality functions.

The committee added this standard to the first edition to provide the description of the structure of the transfusion administration services. This standard is parallel to requirements included in other sets of AABB Standards. This standard applies to both disciplines.

✎ **4.3.1 The TAS shall verify that two ABO blood group tests have been performed on whole blood or red blood cells by the blood provider before issue. ***

***21 CFR 640.5(b)**

The committee created new standard 4.3.1 to ensure that two ABO tests are performed to mirror the requirements set forth in the CFR cited. This standard applies to both disciplines.

4.3.2 The TAS shall return blood and blood components as defined in agreements.

The committee created this standard to ensure that when blood can be returned to a supplier that it be done so based on parameters defined each party. This standard applies to both disciplines.

✎ **5.1.9.1 The TAS shall ensure all containers are validated for the handling, storage and transport of blood and blood components to ensure that temperatures are maintained within the acceptable range for the expected duration of transport, storage, or shipping.**

The committee created standard 5.1.9.1 to ensure that blood and blood components maintain the appropriate temperature during storage and transport. The committee intends to provide examples of the types of validation potentially included in this set of Standards. This standard applies to both disciplines.

5.1.9.2 The TAS shall ensure blood and blood components remain within the acceptable temperature range during storage and transport. Reference Standard 5.1.9A applies.

The committee created standard 5.1.9.2 to ensure that programs that transport blood and blood components maintain the temperatures defined in reference standard 5.1.9A. This standard applies to both disciplines.

5.1.9.3 For storage of blood and blood components, the temperature shall be monitored continuously and recorded at least every 4 hours.

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The committee created included standard 5.1.9.3 in this edition. This standard also exists in the Standards for Blood Banks and Transfusion Services. This standard applies to both disciplines.

OUT OF HOSPITAL ACTIVITIES

The committee elected to divide chapter 5 into two sections, one focused on out of hospital activities and one on prehospital activities. This division is similar to the breakdown in chapter 5 of the 34th edition of BB/TS Standards.

5.3 Sample Collection and Labeling

The individual collecting the sample shall ensure that, immediately before sample collection, the identity of the patient **is confirmed using two independent identifiers** ~~is confirmed by two sources~~.

The committee expanded the content of standard 5.3 for clarity. This edit mirrors the requirements in standard 5.4 and those contained in the 34th edition of BB/TS Standards.

5.4.4 There shall be two determinations of the recipient's ABO group. The first determination shall be performed on a current sample, and the second determination by one of the following methods:

1) Comparison with previous records.

2) Testing a second sample collected at a time different from the first sample, including a new verification of patient identification.

3) Retesting the same sample if patient identification was verified at the time of sample collection using an electronic identification system.

The committee included new standard 5.4.4 to the out of hospital section which also exists in the 34th edition of BB/TS Standards. This addition reflects current practice.

5.5 Requests for Compatibility Testing

The TAS shall ~~deliver the request for blood~~ **provide** the facility performing **pretransfusion and** compatibility testing **the patient sample, accompanied records and the blood product order, as defined in the facility agreement**.

The committee updated the standard for clarity, ensuring that the scope of the standard reflects updates.

5.6 Receipt of Blood and Blood Components

~~The blood and blood components shall be removed from the container by the individual(s) administering the transfusion.~~

~~**5.6.1**~~ The **blood and blood components** ~~individual administering~~ shall be inspected **each** ~~at the~~ time ~~it is~~ **they are** removed from the **transport** container **and/or storage device and** verified that the following **conditions are met**:

1) The unit has arrived to the destination within the validated time period for the transport container.
2) Unit appearance meets visual inspection criteria.
3) The unit has remained in a validated container or storage device. Standard 5.1.9.1 applies.

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The committee elected to merge standards 5.6 and 5.6.1 as the concepts were deemed redundant to one another. As such the opening sentence was adjusted and expanded to include the concepts of "transport" and the use of "storage devices." This expansion reflects the current scope of the work conducted by out of hospital programs.

5.7.2 All identification attached to the container shall remain attached until the transfusion has been completed.

This standard has not changed, but has been moved from where it previously appeared as standard 5.8.3.

5.8.2.1 The patient identifier shall remain attached to the patient for the duration of the transfusion process. In the case where the patient identifier is not attached, the transfusion shall not be initiated.

The committee has added new standard 5.8.2.1to reflect that there are instances where a patient can lose their identification band, and in those instances the transfusion should not proceed, which does reflect current practice.

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

The committee added new standard 5.8.7 to the edition reflecting the need for the COI to be available for use by the out of hospital programs. This standard mirrors standards in the BB/TS and CT Standards.

5.9 Medical Record Documentation

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

The committee updated the wording as it related to when vital signs are taken to mirror language similar to how they are written in the 34th edition of BB/TS Standards.

PREHOSPITAL ACTIVITIES

The committee elected to divide chapter 5 into two sections, one focused on out of hospital activities and one on prehospital activities. This division is similar to the breakdown in chapter 5 of the 34th edition of BB/TS Standards.

5.11 Receipt of Blood and Blood Components

The blood and blood components shall be inspected at the time of removal from the transport container and/or storage device and verified that the following conditions are met:

1) The unit has remained in a validated container or storage device within the validated time period for transport.

2) The unit appearance meets visual inspection criteria.

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Standard 5.1.9 applies.

The committee created this new standard to ensure that the program receiving blood and blood components are inspected for appropriateness of use.

5.12 Inspection Immediately Before Transfusion
Blood and blood components shall be visually inspected before transfusion.

In line with the creation of standard 5.11, this standard has been created to ensure that blood and blood components are inspected before they are transfused to a potential patient.

5.12.1 Blood and Blood Component Identification
The blood or blood components shall have an attached label or tie tag indicating the donation identification number, and that compatibility testing has not been performed.

The committee created new standard 5.12.1 to ensure that all blood and blood components are labeled appropriately included the DIN (Donation Identification Number).

5.12.2 All identification attached to the container shall remain attached until the transfusion has been completed.

The committee added new standard 5.12.2 to ensure that identification of the blood and blood component is attached to the until through the end of transfusion.

5.13 Administration of Blood
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 medical director shall participate in the development of these protocols. The protocol shall be consistent with the *Circular of Information for the Use of Human Blood and Blood Components*. Standard 7.3.3 applies.

The committee added standard 5.13 to this edition. This standard was modeled off of standard 5.28 from the 34th edition of BB/TS Standards and the language is parallel.

5.13.1 Immediately before transfusion, the following information shall be verified:
1) The intended unit for transfusion meets the ordering criterion and has not expired.
2) Unit ABO group.
3) Unit appearance meets visual inspection criteria.
4) The unit has remained in compliance with temperature requirements during storage/transport.
5) The informed and/or implied consent has been obtained.

The committee created new standard 5.13.1 to ensure that the 5 sub-numbers are covered before a unit is transfused in a prehospital setting.

5.13.2 The patient shall be observed for potential adverse events during the transfusion until the time of handoff. Standard 7.3.3 applies.

The committee created new standard 5.13.2 to ensure that patients are observed during the transfusion of blood products until the patient is transferred to the receiving hospital for treatment.

5.13.3 The TAS shall have a process to notify the receiving hospital and/or other prehospital care providers of the patient's transfusion status through the continuum of care.

The committee created new standard 5.13.3 to ensure that the prehospital providers are in communication with the receiving hospital to ensure that they are aware of the patient's status during transport.

5.13.3.1 The TAS shall provide materials related to prehospital transfusion (e.g., patient samples, empty bags, and segments) for follow up testing, as applicable. Standard 4.1.3.1 applies.

The committee created new standard 5.13.3.1 to ensure that (when possible) prehospital transfusion providers shall provide materials related to the transfusion to the receiving hospital for testing and follow-up as required.

5.13.4 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.

The committee added standard 5.13.4 to this edition. This standard was modeled off of standard 5.28.8 from the 34th edition of BB/TS Standards and the language is parallel.

5.13.5 Addition of Drugs and Solutions

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

1) The additions have been approved for this use by the FDA or Competent Authority.

2) There is documentation available to show that the addition is safe and does not adversely affect the blood or blood component.

The committee added standard 5.13.4 to this edition. This standard was modeled off of standard 5.28.9 from the 34th edition of BB/TS Standards and the language is parallel.

5.13.6 The TAS shall monitor patient vital signs at defined intervals including before, during, and after transfusion, as applicable. Standard 5.11 applies.

The committee created new standard 5.13.6 to ensure that patients are monitored during transfusion.

5.13.7 The TAS shall have defined criteria for adult and pediatric transfusion.

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The committee created new standard 5.13.7 to ensure that prehospital programs define how adult and pediatric patients are treated during transfusion.

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

The committee created new standard 5.13.8 in accordance with the creation of standard 5.13 ensuring that the current Circular of Information for the Use of Human Blood and Blood Components is available when blood at the time of administration of blood.

5.14 Requirements for Uncrossmatched Blood and Blood Components
The TAS medical director shall determine the appropriate ABO - RhD component selection for uncrossmatched units of blood and blood components issued as well as the maximum quantity of blood products that can be transfused to each patient in an emergency setting.

The committee created new standard 5.14, ensuring that in urgent cases the medical director determines the appropriate conditions for transfusion to each transfusion in emergent situations.

5.14.1 The TAS shall have a policy concerning the selection of the RhD type of blood products for transfusion of blood to patients of childbearing potential.

The committee created new standard 5.14.1 to ensure that prehospital programs have policies in place to determine what RhD products are given to patients of childbearing potential.

5.14.2 The TAS shall have a policy for the transfusion of pediatric patients in emergent situations.

The committee created new standard 5.14.2 to ensure that prehospital programs have policies in place for the transfusion of pediatric patients in emergent situations.

5.14.3 Records shall contain a signed statement from the ordering physician indicating that the clinical situation was sufficiently urgent to require release of uncrossmatched emergency released blood before completion of compatibility testing can be done. The signature could occur before or after the release/transfusion of the blood.*

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

The committee created new standard 5.14.3 in recognition of the need to issue uncrossmatched blood in urgent situations. The standard as described mirrors current practice of prehospital programs.

5.14.3.1 The TAS medical director and the patient's physician shall be notified of abnormal test results that may affect patient safety.

The committee created new standard 5.14.3.1 to ensure that there is communication between the medical

director and recipient's physician in the case of abnormal test results being found that could affect the patient's safety.

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

Item No.	Component	Storage	Transport	Expiration[2]	Additional Criteria
Whole Blood Components					
1	Whole Blood	1-6 C	1-10 C	CPD/CP2D: 21 days CPDA-1: 35 days	
2	Whole Blood Irradiated	1-6 C	1-10 C	Original expiration or 28 days from date of irradiation, whichever is sooner	
3	Whole Blood Leukocytes Reduced	1-6 C	1-10 C	CPD/CP2D: 21 days CPDA-1: 35 days Open system: 24 hours	
Red Blood Cell Components, Whole-Blood-Derived or Apheresis-Derived					
4	Red Blood Cells (RBCs)	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days Additive solution (AS): 42 days Open system: 24 hours	
5	Deglycerolized RBCs	1-6 C	1-10 C	Open system: 24 hours Closed system: 14 days	
6	RBCs Irradiated	1-6 C	1-10 C	Original expiration or 28 days from date of irradiation, whichever is sooner	
7	RBCs Leukocytes Reduced	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days Additive solution (AS): 42 days	

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				Open system: 24 hours	
8	Washed RBCs	1-6 C	1-10 C	24 hours	
Platelet Components[3-5]					
9	Platelets (whole-blood-derived)	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Up to 5 days, depending on collection system and bacterial testing strategy used	
10	Platelets Irradiated	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	No change from original expiration date	
11	Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Open system: 4 hours Closed system: No change in expiration	
12	Pooled Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	4 hours after pooling or 5 days following collection of the oldest unit in the pool	
13	Pooled Platelets (in open system)	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Open system: 4 hours	

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14	Apheresis Platelets	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	5 days or up to 7 days, depending on the collection system and bacterial testing strategy used	
15	Apheresis Platelets Irradiated	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	No change from original expiration date	
16	Apheresis Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Open system: within 4 hours of opening the system Closed system: 5 days or up to 7 days depending on the collection system and bacterial testing strategy used	
17	Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Up to 5 days depending on the collection system and bacterial testing strategy used	
18	Apheresis Platelets Pathogen Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	5 days	
19	Apheresis Platelets Cold Stored[8]	1-6 C (agitation optional)	1-10 C	14 days	Suspended in 100% Plasma or platelet additive solution
20	Apheresis Platelets Pathogen	1-6 C (agitation optional)	1-10 C	14 days	

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	Reduced Cold Stored[8]				
21	Whole Blood Derived Platelets Cold Stored	1-6 C (agitation optional)	1-10 C	As specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA or Competent Authority	
Plasma Components					
22	Cryoprecipitated AHF (after thawing)	20-24 C	As close as possible to 20-24 C	Single unit: 6 hours	
23	Pooled Cryoprecipitated AHF (after thawing)	20-24 C	As close as possible to 20-24 C	Pooled in an open system: 4 hours If pooled using a sterile connection device: 6 hours	
24	Pathogen Reduced Cryoprecipitated Fibrinogen Complex	20-24 C	As close as possible to 20-24 C	5 days	
25	FFP (after thawing)[9]	1-6 C	1-10 C	If issued as FFP: 24 hours	
26	Plasma Frozen Within 24 Hours After Phlebotomy (after thawing)[9]	1-6 C	1-10 C	If issued as PF24: 24 hours	
27	Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (after thawing)	1-6 C	1-10 C	If issued as PF24RT24: 24 hours	

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28	Thawed Plasma[9]	1-6 C	1-10 C	5 days from date product was thawed or original expiration, whichever is sooner	
29	Liquid Plasma	1-6 C	1-10 C	CPD or CP2D: The expiration for Liquid Plasma is 26 days If whole blood is stored in CPDA-1, the Liquid Plasma expiration date is 40 days	21 CFR 610.53(b)

[1]Products may be pathogen reduced if approved by the FDA.
[2]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.
[3]The platelet storage system shall be FDA-cleared or -approved for the conditions specified.
[4]One of the following storage temperatures shall be used continuously: 1) 20 to 24 C or 2) 1 to 6 C. 21 CFR 640.24(d).
[5]FDA Guidance for Industry: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance Safety and Availability of Platelets for Transfusion (December 2020).
[6]21 CFR 600.15(a) and 21 CFR 640.25(a).
[7]21 CFR 610.53(b).
[8]FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding When Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).
[9]These lines could apply to apheresis plasma or whole-blood-derived plasma.

Reference standard 5.1.9A is new to the edition and applies to both out of hospital and prehospital disciplines. The table is similar to reference standard 5.1.9A of the 34th edition of[3]4th edition of BB/TS Standards.

7.0 Deviations, Nonconformances, and Adverse Events

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

***21 CFR 606.171**

FDA Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments (March 2020).

The committee added the CFR and FDA Guidance for completeness. This is similar to the 34th edition of BB/TS Standards.

✎ **7.3.3 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.

The committee edited this standard for clarity and to mirror the language included in the 34th edition of BB/TS Standards. This standard applies to both disciplines.

7.3.3.1 Recognition of and Response to Immediate Transfusion Reactions

There shall be processes and procedures for the transfusing staff ~~for the recognition~~ **to recognize** of and respon**d**~~se~~ to ~~immediate~~ transfusion reactions and for the recording of relevant information in the patient's medical record.

The committee edited this standard by removing the term "immediate" as it was deemed difficult to assess. This allows for the standard to mirror the language included in the 34th edition of BB/TS Standards. This standard applies to both disciplines.

✎ **7.3.3.3** When the transfusion is discontinued, the following shall be performed ~~immediately~~:

1) The label on the blood ~~containers~~ **product** and records shall be examined to detect errors in identifying the patient, blood, or blood component.
2) The **ordering provider** ~~recipient's physician~~ or **TAS medical director** shall be notified.
3) The **unit** ~~container~~ (whether or not it contains any blood) shall be sent to the ~~blood supplier~~ **transfusion service or receiving hospital** with, whenever possible, the attached transfusion set and intravenous solutions.
4) A posttransfusion sample shall be obtained **as soon as possible** from the patient and sent to the ~~blood supplier~~ **transfusion service or receiving hospital**.

The committee edited standard 7.3.3.3 to reflect the expanded content of the Standards, recognizing the prehospital requirements and how the standards have to be adjusted to accommodate both disciplines. This standard applies to both disciplines.

✎ **7.3.4 ~~Delayed~~ Transfusion Reactions ~~(Antigen Antibody Reactions)~~**

The TAS shall provide **clear instructions to the patient's responsible caregivers and/or healthcare personnel regarding post-transfusion instructions** ~~the transfusion site with instructions for the~~ **including** recognition **and steps for managing suspected** ~~of delayed~~ transfusion reactions. **Standard 5.8.4 applies.**

The committee edited this standard to reflect the expanded content of the Standards recognizing the

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prehospital requirements and how the standards have to be adjusted to accommodate both disciplines. This standard applies to both disciplines.

7.3.4.1 If a ~~delayed~~ transfusion reaction is suspected or detected, the TAS shall be notified.

Based on the changes to standard 7.3.4, standard 7.3.4.1 was edited accordingly. This standard applies to both disciplines.

7.3.4.2 The TAS shall have a process to notify the **transfusion service or receiving hospital** ~~blood supplier~~.

The committee edited this standard to reflect the expanded content of the Standards recognizing the prehospital requirements and how the standards have to be adjusted to accommodate both disciplines. This standard applies to both disciplines.

7.3.5 Look-Back
the TAS shall have a process for providing relevant unit and/or patient information as requested when notified by the blood collection facility and/or transfusion service.*

***21 CFR 610.46 and 21 CFR 610.47 apply.**

This standard is new to this edition and was created based on a similar standard in the 34th edition of BB/TS Standards. This standard applies to both disciplines.

7.4 Fatality Investigation and Notification
The transfusion service and/or collection facility shall be notified of fatalities suspected to have resulted from transfusion.

The committee created standard 7.4 recognizing the need to notify the transfusion service or collection facility in the case of a patient fatality as a result of transfusion. This standard applies to both disciplines.

7.4.1 If a fatality is suspected to have occurred as a result of a blood transfusion, the TAS shall report this event to the transfusion service and/or collection facility for investigation.

In conjunction with the creation of standard 7.4, new standard 7.4.1 has been developed to ensure that an investigation takes place accordingly. This standard applies to both disciplines.

7.4.2 If a fatality is confirmed to have occurred as a result of a transfusion, the transfusion service and/or collection facility shall notify the FDA.*

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

The committee created new standard 7.4.2 to ensure that out of hospital and prehospital services notify the

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FDA in the case where a fatality is confirmed to have occurred as a result of transfusion. The CFR and Guidance for Industry are included for completeness. This standard applies to both disciplines.

8.5 The TAS shall have a process for the monitoring of blood utilization and wastage ~~provide the information requested by the blood supplier's utilization review committee~~.

The committee edited this standard to reflect the expanded content of the Standards recognizing the prehospital requirements and how the standards have to be adjusted to accommodate both disciplines. This standard applies to both disciplines.

Glossary

The following terms have been added to the glossary for completeness.

Hospital: A licensed establishment staffed by at least one physician, a nursing staff, can offer inpatient accommodation with active medical and nursing care.

Home Medical Care: Medical care or procedures that take place in a patient's home or residence.

Laboratory Director: A role defined by CLIA as the responsible party for all aspects of testing performed by a CLIA qualified laboratory.

Prehospital Setting: Urgent or emergent care provided to a patient before arrival at a hospital including but not limited to at the point of injury, in a road ambulance, or helicopter.

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).

Transfusion Administration Service (TAS): A service provider responsible for receiving and transmitting orders of blood for transfusion, transporting blood to the transfusion site, performing the transfusion, monitoring the patient during transfusion, reporting outcomes, and ensuring the traceability of the unit is maintained.

Transfusion Reactions: An adverse reaction to a transfusion that can be acute (i.e., occurring within 24 hours from the end of the transfusion) or delayed (i.e., occurring beyond 24 hours from the end of the transfusion).

Transfusion Service: A facility that performs one or more of the following activities: compatibility testing, ABO/Rh confirmatory testing of whole blood and/or red blood cells prior to issue 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).

Transfusion Site: The patient care area where a transfusion is performed.

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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.

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QSE 1 – Organization

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

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

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

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

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

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

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

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

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

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

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1.0 Organization

The organization shall define the parties responsible for the provision of products or services.**1.1 Executive Management**

The organization shall have a defined executive management. Executive management shall have:
1) Responsibility and authority for the quality system and operations.
2) Responsibility for compliance with these *Standards* and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
3) Authority to establish or make changes to the quality system.

1.1.1 Medical Director Qualifications and Responsibilities

The Transfusion Administration Service (TAS) shall have a medical director who is a licensed physician and qualified by education, training, and/or experience. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedures and for the consultative and support services that relate to the care and safety of the transfusion recipients. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.

1.1.2 The TAS shall have a structure that clearly defines and documents the parties responsible for the activities described in these TAS Standards and the relationship of individuals responsible for key quality functions.

1.2 Quality System

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

1.2.1 Quality Representative

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

1.2.2 Management Reviews

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

1.3 Policies, Processes, and Procedures

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

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

✎ **1.3.2** Any exceptions to medical and technical policies, processes, and procedures shall require justification and preapproval by the medical director and/or laboratory director, as applicable.

✎ **1.4 Risk Assessment**

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

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

1.5 Operational Continuity

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

1.6 Emergency Preparedness

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

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

1.7 Communication of Concerns

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

1.8 Customer Focus

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

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

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

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QSE 2 – Resources

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

Key Terms:
Competence: An individual's demonstrated ability to apply knowledge and skills needed to perform the job tasks and responsibilities.

Qualification (individuals): The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Current job descriptions.
- Evaluation of staffing levels and workload, if performed.
- Process for recruiting and hiring.
- Personnel records (eg, certifications, qualifications, competence assessments, diplomas, transcripts).
- Training records.
- Evaluations of competence records.
- Evidence that job qualifications are met.
- Continuing education records.

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2.0 Resources

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

2.1 Human Resources

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

2.1.1 Job Descriptions

The organization shall establish and maintain job descriptions defining the roles and responsibilities for each job position related to the requirements of these *Standards*.

2.1.2 Qualification

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

2.1.3 Training

The organization shall provide training for personnel performing critical tasks.

2.1.4 Competence

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

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

2.1.5 Personnel Records

Personnel records for each employee shall be maintained.

2.1.5.1 For those authorized to perform or review critical tasks, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

2.1.6 Continuing Education

The organization shall ensure that continuing education requirements applicable to these *Standards* are met when applicable.

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Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
2.1.1	Job descriptions	5
2.1.2	Qualification of personnel performing critical tasks	5
2.1.3	Training records of personnel	5
2.1.4	Evaluations of competence	5
2.1.5	Personnel records of each employee	5 years following conclusion of employment period
2.1.6	Continuing education requirements	5

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

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QSE 3 – Equipment

Key Concepts: This QSE describes the selection, use, maintenance, and monitoring of equipment, including information systems. It also describes the use and testing of alternative systems when primary systems fail.

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

Calibrate: To set or align measurement equipment against a known standard.

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

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

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

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

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and the manufacturer's recommendations in an environment suitable for its operation and use.

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

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

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Processes for equipment selection, qualification, and maintenance.
- List or tool used for critical equipment identification.
- Equipment calibration and maintenance records, if applicable.
- Equipment qualification records.
- Manufacturer's written instructions.
- Records of investigation of equipment malfunction, failure, repair, and requalification, if applicable.
- Alarm system testing and records of alarm management, if appropriate.

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- Evidence of information system backup and records of testing.

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3.0 Equipment

The organization shall define and control critical equipment.

3.1 Equipment Specifications

Equipment specifications shall be defined before purchase.

✎3.2 Qualification of Equipment

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

3.2.1 Installation Qualification

Equipment shall be installed per manufacturer specifications.

3.2.2 Operational Qualification

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

3.2.3 Performance Qualification

Equipment shall perform as expected for its intended use.

3.3 Use of Equipment

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

✎3.4 Unique Identification of Equipment

Equipment shall have unique identification.

3.5 Equipment Monitoring and Maintenance

Equipment shall be monitored and maintained in accordance with the manufacturer's written instructions.

✎ 3.5.1 Calibration and Accuracy of Equipment

Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be confirmed as described below unless otherwise indicated by the manufacturer:

1) Before use.
2) After activities that may affect the calibration.
3) At prescribed intervals.

3.5.1.1 Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and specified limitations.

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3.5.1.2 Equipment used for calibration, inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards exist, the basis for calibration shall be described and recorded.

3.5.1.3 Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.

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

3.5.3 The organization shall:

1) Define cleaning and sanitization methods and intervals for equipment.
2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out.
3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel.
4) Monitor equipment to ensure that defined parameters are maintained.
5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use.
6) Ensure that all equipment maintenance and repairs are performed by qualified individuals and in accordance with the manufacturer's recommendations.

3.5.4 Investigation and Follow-up

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

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

3.6 Equipment Traceability

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

1) Equipment to be uniquely identified and traceable.

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

✎3.7 Information Systems

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

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

3.7.1 Alternative Systems

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

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

3.7.3 The organization shall support the management of information systems.

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

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

3.8 Storage and Transport Devices for Blood and Blood Components

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

3.9 Warming Devices for Blood and Blood Components

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

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

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

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QSE 4 – Suppliers and Customers

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

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

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

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

Quality: Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.

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

Supplier: An entity that provides a material, product, or service.

Supplier Qualification: Evaluation of a supplier to assess its ability to consistently deliver products or services that meet specified requirements.

Examples of Objective Evidence:
- Policies, processes, and procedures related to this chapter.
- Processes for defining and updating or changing agreements.
- Process for recording verbal agreements, if practiced.
- Agreement records.
- Agreement review records.
- Supplier qualification records.
- Supplier evaluation records.
- Supplier selection process.
- Evidence of action taken when a supplier fails to meet expectations, if applicable.
- Evidence of receipt of product(s) as stipulated in agreements.
- Records of inspection and testing.

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4.0 Suppliers and Customers

The organization shall ensure that agreements to provide or receive products or services are reviewed, approved, and meet supplier and customer expectations.

4.1 Supplier Qualification

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

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

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

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

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

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

4.2 Agreements

Agreements and any incorporated changes shall be reviewed and communicated.

4.2.1 Agreements shall be reviewed at defined intervals to ensure that the terms of the agreement continue to meet requirements.

4.2.2 Changes to agreements shall be communicated to affected parties.

4.2.3 The responsibilities for activities covered by these *Standards* when more than one organization is involved shall be specified by agreement.

4.3 Incoming Receipt, Inspection, and Testing

Incoming products or services, equipment, and materials shall be received, inspected, and tested, as necessary, before approval for use.

4.3.1 The TAS shall verify that two ABO blood group tests have been performed on whole blood or red blood cells by the blood provider before issue. *

*21 CFR 640.5(b)

4.3.2 The TAS shall return blood and blood components as defined in agreements.

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Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.3	Agreements concerning activities involving more than one organization	5
4.3	Inspection of incoming critical materials	10
4.3.1	ABO group confirmation	10

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

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QSE 5 – Process Control

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

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

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

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

Process Control: Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.

Product: A tangible output from a process.

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

Service: An intangible output of a process.

Standard: A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

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

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Implementation records.
- Records enabling traceability.
- Storage records.
- Quality control records.
- Process planning, process validation, and change control records.

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- Records of material storage, handling, and use.
- Records of inspection of materials.
- Product inspection records.
- Testing records.

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5.0 Process Control

The organization shall ensure the quality of products or services.

5.1 General Elements

The organization shall ensure that processes are carried out under controlled conditions.

5.1.1 Change Control

When the organization develops new processes or procedures or changes existing ones, they shall be validated before implementation.

5.1.2 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment, materials, and analytical functions perform as intended.

5.1.2.1 Quality control results shall be reviewed and evaluated against acceptance criteria.

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

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

5.1.3 Process Planning

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

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

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

5.1.4 Process Validation

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

5.1.4.1 Validation activities shall include the following:

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

5.1.5 Process Implementation

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

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

5.1.6 Use of Materials

All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.

5.1.7 Inspection

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

5.1.8 Identification and Traceability

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

5.1.8.1 Process or Procedure Steps

For each critical step in transportation, inspection, and administration 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.

5.1.8.2 Traceability

The TAS shall ensure that all blood, blood components, and critical materials used are identified and traceable from source to final disposition.

5.1.8.3 Final Disposition

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The TAS shall be responsible for recording the final disposition of blood or blood components.

5.1.9 Handling, Storage, and Transportation
The organization shall ensure that products or services are handled, stored, and transported in a manner that prevents damage, limits deterioration, and provides traceability. Reference Standard 5.1.9A applies.

✎ **5.1.9.1** The TAS shall ensure all containers are validated for the handling, storage and transport of blood and blood components to ensure that temperatures are maintained within the acceptable range for the expected duration of transport, storage, or shipping.

5.1.9.2 The TAS shall ensure blood and blood components remain within the acceptable temperature range during storage and transport. Reference Standard 5.1.9A applies.

5.1.9.3 For storage of blood and blood components, the temperature shall be monitored continuously and recorded at least every 4 hours.

OUT OF HOSPITAL ACTIVITIES

✎**5.2 Orders**
The order for blood or blood components shall be placed by the patient's physician or other authorized health professional.

5.2.1 Orders for blood and blood components shall contain sufficient information to uniquely identify the patient, including two independent identifiers.

5.2.1.1 The TAS shall accept only complete, accurate, and legible orders.

5.2.1.2 The order shall include a record of the patient's informed consent. If consent is not obtained before the order, it shall be obtained before the transfusion.

5.2.1.3 Special transfusion requirements shall be identified in the order.

5.3 Sample Collection and Labeling
The individual collecting the sample shall ensure that, immediately before sample collection, the identity of the patient is confirmed using two independent identifiers.

5.3.1 The individual collecting the sample shall attach an identifier to the patient after confirmation of patient identity and before sample collection.

5.3.2 The patient identifier shall remain attached to the patient for the duration of the transfusion process or until the order for the transfusion is canceled.

5.4 Patient Samples

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

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

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

5.4.3 The TAS shall have a policy to reduce the risk of misidentification of patient pretransfusion samples.

5.4.4 There shall be two determinations of the recipient's ABO group. The first determination shall be performed on a current sample, and the second determination by one of the following methods:

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

5.5 Requests for Compatibility Testing

The TAS shall provide the facility performing pretransfusion and compatibility testing the patient sample, accompanied records and the blood product order, as defined in the facility agreement.

5.6 Receipt of Blood and Blood Components

The blood and blood components shall be inspected each time they are removed from the transport container and/or storage device and verified that the following conditions are met:

1) The unit has arrived to the destination within the validated time period for the transport container.
2) The unit appearance meets visual inspection criteria.
3) The unit has remained in a validated container or storage device. Standard 5.1.9.1 applies.

5.7 Inspection Immediately Before Transfusion

Blood and blood components shall be inspected before transfusion.

5.7.1 Blood and Blood Component Identification

The blood or blood components shall have an attached label or tie tag indicating:

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

5.7.2 All identification attached to the container shall remain attached until the transfusion has

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been completed.

5.8 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 medical director shall participate in the development of these protocols. The protocol shall be consistent with the current Circular of Information for the Use of Human Blood and Blood Components. Standard 7.3.3 applies.

5.8.1 Immediately before transfusion, the following information shall be verified:

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

Standard 5.7.2 applies.

5.8.2 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.

5.8.2.1 The patient identifier shall remain attached to the patient for the duration of the transfusion process. In the case where the patient identifier is not attached, the transfusion shall not be initiated.

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

5.8.4 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.

5.8.5 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.

5.8.6 Addition of Drugs and Solutions

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

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

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

✎**5.9 Medical Record Documentation**

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

5.10 Final Disposition

The TAS shall have a process to ensure that the blood supplier is notified of the final disposition of the blood or blood component.

PREHOSPITAL ACTIVITIES

5.11 Receipt of Blood and Blood Components

The blood and blood components shall be inspected at the time of removal from the transport container and/or storage device and verified that the following conditions are met:

1) The unit has remained in a validated container or storage device within the validated time period for transport.
2) The unit appearance meets visual inspection criteria.

Standard 5.1.9 applies.

5.12 Inspection Immediately Before Transfusion

Blood and blood components shall be visually inspected before transfusion.

5.12.1 Blood and Blood Component Identification

The blood or blood components shall have an attached label or tie tag indicating the donation identification number, and that compatibility testing has not been performed.

5.12.2 All identification attached to the container shall remain attached until the transfusion has been completed.

5.13 Administration of Blood

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 Medical Director shall participate in the development of the protocols. The protocol shall be consistent with the Circular of Information for the Use of Human Blood and Blood Components. Standard 7.3.3 applies.

✎ **5.13.1** Immediately before transfusion, the following information shall be verified:

1) The intended unit for transfusion meets the ordering criterion and has not expired.
2) Unit ABO group.

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3) Unit appearance meets visual inspection criteria
4) The unit has remained in compliance with temperature requirements during storage/transport
5) The informed and/or implied consent has been obtained.

5.13.2 The patient shall be observed for potential transfusion related adverse events by the TAS until the time of transfer of care. Standard 7.3.3 applies.

5.13.3 The TAS shall have a process to notify the receiving hospital and/or other prehospital care providers of the patient's transfusion status including any transfusion related adverse reactions through the continuum of care.

5.13.3.1 The TAS shall provide materials related to prehospital transfusion (e.g., patient samples, empty bags, and segments) for follow up testing, as applicable. Standard 4.1.3.1 applies.

5.13.4 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.

5.13.5 Addition of Drugs and Solutions

With the exception of 0.9% sodium chloride (USP), drugs or medications shall not be added to blood or blood components unless one of the following conditions is met:
1) The additions have been approved for this use by the FDA or Competent Authority.
2) There is documentation available to show that the addition is safe and does not adversely affect the blood or blood component.

5.13.6 The TAS shall monitor patient vital signs at defined intervals including before, during, and after transfusion, as applicable. Standard 5.11 applies.

5.13.7 The TAS shall have defined criteria for adult and pediatric transfusion.

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

5.14 Requirements for Uncrossmatched Blood and Blood Components

The TAS medical director shall determine the appropriate ABO - RhD component selection for uncrossmatched units of blood and blood components issued as well as the maximum quantity of blood products that can be transfused to each patient in an emergency setting.

5.14.1 The TAS shall have a policy concerning the selection of the RhD type of blood products for transfusion of blood to patients of childbearing potential.

5.14.2 The TAS shall have a policy for the transfusion of pediatric patients in emergent situations.

5.14.3 Records shall contain a signed statement from the ordering physician indicating that the

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clinical situation was sufficiently urgent to require release of uncrossmatched emergency released blood before completion of compatibility testing can be done. The signature could occur before or after the release/transfusion of the blood.*

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

5.14.3.1 The TAS medical director and the patient's physician shall be notified of abnormal test results that may affect patient safety.

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

Item No.	Component	Storage	Transport	Expiration[2]	Additional Criteria
Whole Blood Components					
1	Whole Blood	1-6 C	1-10 C	CPD/CP2D: 21 days CPDA-1: 35 days	
2	Whole Blood Irradiated	1-6 C	1-10 C	Original expiration or 28 days from date of irradiation, whichever is sooner	
3	Whole Blood Leukocytes Reduced	1-6 C	1-10 C	CPD/CP2D: 21 days CPDA-1: 35 days Open system: 24 hours	
Red Blood Cell Components, Whole-Blood-Derived or Apheresis-Derived					
4	Red Blood Cells (RBCs)	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days Additive solution (AS): 42 days Open system: 24 hours	
5	Deglycerolized RBCs	1-6 C	1-10 C	Open system: 24 hours Closed system: 14 days	
6	RBCs Irradiated	1-6 C	1-10 C	Original expiration or 28 days from date of irradiation, whichever is sooner	
7	RBCs Leukocytes Reduced	1-6 C	1-10 C	ACD/CPD/CP2D: 21 days CPDA-1: 35 days Additive solution (AS): 42 days Open system: 24 hours	
8	Washed RBCs	1-6 C	1-10 C	24 hours	

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Platelet Components[3-5]					
9	Platelets (whole-blood-derived)	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Up to 5 days, depending on collection system and bacterial testing strategy used	
10	Platelets Irradiated	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	No change from original expiration date	
11	Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Open system: 4 hours Closed system: No change in expiration	
12	Pooled Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	4 hours after pooling or up to 7 days following collection of the oldest unit in the pool	
13	Pooled Platelets (in open system)	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Open system: 4 hours	
14	Apheresis Platelets	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without	5 days or up to 7 days, depending on the collection system and bacterial testing strategy used	

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			agitation: 30 hours		
15	Apheresis Platelets Irradiated	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	No change from original expiration date	
16	Apheresis Platelets Leukocytes Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Open system: within 4 hours of opening the system Closed system: 5 days or up to 7 days depending on the collection system and bacterial testing strategy used	
17	Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	Up to 5 days depending on the collection system and bacterial testing strategy used	
18	Apheresis Platelets Pathogen Reduced	20-24 C with continuous gentle agitation[6]	As close as possible to 20-24 C[7] Maximum time without agitation: 30 hours	5 days	
19	Apheresis Platelets Cold Stored[8]	1-6 C (agitation optional)	1-10 C	14 days	Suspended in 100% Plasma or platelet additive solution
20	Apheresis Platelets Pathogen Reduced Cold Stored[8]	1-6 C (agitation optional)	1-10 C	14 days	

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21	Whole Blood Derived Platelets Cold Stored	1-6 C (agitation optional)	1-10 C	As specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA or Competent Authority	
Plasma Components					
22	Cryoprecipitated AHF (after thawing)	20-24 C	As close as possible to 20-24 C	Single unit: 6 hours	
23	Pooled Cryoprecipitated AHF (after thawing)	20-24 C	As close as possible to 20-24 C	Pooled in an open system: 4 hours If pooled using a sterile connection device: 6 hours	
24	Pathogen Reduced Cryoprecipitated Fibrinogen Complex	20-24 C	As close as possible to 20-24 C	5 days	
25	FFP (after thawing)[9]	1-6 C	1-10 C	If issued as FFP: 24 hours	
26	Plasma Frozen Within 24 Hours After Phlebotomy (after thawing)[9]	1-6 C	1-10 C	If issued as PF24: 24 hours	
27	Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (after thawing)	1-6 C	1-10 C	If issued as PF24RT24: 24 hours	

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28	Thawed Plasma[9]	1-6 C	1-10 C	5 days from date product was thawed or original expiration, whichever is sooner	
29	Liquid Plasma	1-6 C	1-10 C	CPD or CP2D: The expiration for Liquid Plasma is 26 days If whole blood is stored in CPDA-1, the Liquid Plasma expiration date is 40 days	21 CFR 610.53(b)

[1]Products may be pathogen reduced if approved by the FDA.

[2]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.

[3]The platelet storage system shall be FDA-cleared or -approved for the conditions specified.

[4]One of the following storage temperatures shall be used continuously: 1) 20 to 24 C or 2) 1 to 6 C. 21 CFR 640.24(d).

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

[6]21 CFR 600.15(a) and 21 CFR 640.25(a).

[7]21 CFR 610.53(b).

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

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

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Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	10
5.1.8	Identification and traceability of products	5
5.1.8.1	Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components	10
5.1.8.2	Traceability of blood, blood components, and critical materials	10
5.2	Orders placed by the patient's physician or other authorized health professional	5
5.4	Labeling of patient samples	10
5.5	Compatibility testing requests	10
5.6	Receipt of blood and blood components	
5.6.1	Verification of the following information before transfusion: 1) The unit has remained within the appropriate time and temperature range defined for the container in use. 2) Identifying information is accurate. 3) Unit appearance is normal	10
5.8.1	Verification of the following information before transfusion: 1) The intended recipient's two independent identifiers, ABO group, and Rh type. 2) The donation identification number, the donor ABO group, and, if required, the Rh type. 3) The interpretation of crossmatch tests, if performed. 4) Special transfusion requirements are met, when applicable. 5) The expiration date (or time) of the unit and that it has not expired.	5
5.8.2	Verification of recipient identification before transfusion	5
5.9	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.	5
5.13.1	Verification of the following information before transfusion:	5

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	1) The intended recipient's two independent identifiers, ABO group, and Rh type. 2) The donation identification number, the donor ABO group, and Rh type. 3) The interpretation of crossmatch tests, if performed. 4) Special transfusion requirements are met, when applicable. 5) The expiration date (or time) of the unit and that is has not expired.	
5.13.2	Verification of patient identification before transfusion	5
5.14	Emergent use of uncrossmatched blood	10
5.14.3.7.1	Notification of abnormal test results	10

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

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QSE 6 – Documents and Records

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

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

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

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

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

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

Label: An inscription affixed or attached to a product for identification.

Labeling: Information that is required or selected to accompany a product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

Master List of Documents: A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the *Standards,* including information for document control.

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

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

Examples of Objective Evidence:

- Policies, processes, and procedures related to this chapter.
- Records of activities performed.
- Record system.
- Master list of documents.
- An electronic record system, if applicable.
- Uniform storage media and ability to track newer technologies to older ones as needed.
- Evidence of document and record review.
- Evidence of standardized formats for all documents and records.
- Record retention periods.

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- Record traceability.
- Data backup plans.
- Record change process.
- Obsolescence of records and disposition.
- Record destruction.

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6.0 Documents and Records

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

6.1 Document Control

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

6.1.1 Format

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

6.1.2 Document Review, Approval, and Distribution

The document control process shall ensure that documents:

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

6.1.3 Document Changes

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

6.1.3.1 The organization shall track changes to documents.

6.1.4 Master List of Documents

The organization shall maintain complete lists of all active policies, processes, procedures, labels, forms, and other documents that relate to the requirements of these *Standards*.

6.1.5 Review of Policies, Processes, and Procedures

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

6.1.6 Document Retention

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

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6.1.7 Document Storage

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

6.1.8 Document Retrieval

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

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

6.2 Record Control

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

6.2.1 Records

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

6.2.2 Record Traceability

The records system shall ensure traceability of:

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

6.2.2.1 The system shall ensure that patient identifiers are unique.

6.2.3 Information to Be Retained

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

6.2.4 Legibility

All records shall be legible and indelible.

6.2.5 Record Change

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

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

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

✎ **6.2.7 Copies**

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

6.2.8 Confidentiality

The organization shall ensure the confidentiality of records.

6.2.9 Retention

Records required by these *Standards* shall be retained for a period indicated in the record retention table at the end of each chapter.

✎ **6.2.10 Record Review**

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

6.2.11 Storage of Records

Records shall be stored to:

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

6.2.12 Destruction of Records

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

✎ **6.3 Electronic Records**

The organization shall support the management of information systems.

6.3.1 Access to Data and Information

Access to data and information shall be controlled.

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

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

6.3.2 Data Integrity

Data integrity shall ensure that data are retrievable and usable.

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

6.3.2.2 Data shall be retrievable for the entire retention period.

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

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

6.3.3 Storage Media

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

6.3.4 Backup Data

The organization shall back up all critical data.

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

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

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

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

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

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Reference Standard 6.2.9A – Retention of Records

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	10
1.3.2	Exceptions to policies, processes, and procedures	10
1.4	Risk assessment	5
1.6.1	Emergency operation plan tested at defined intervals	2 years, or two organizational testing intervals (whichever is longer)
2.1.1	Job descriptions	5
2.1.2	Qualification of personnel performing critical tasks	5
2.1.3	Training records of personnel	5
2.1.4	Evaluations of competence	5
2.1.5	Personnel records of each employee	5 years following conclusion of employment period
2.1.6	Continuing education requirements	5
3.2	Equipment qualification	10 years after retirement of the equipment
3.4	Unique identification of equipment	5
3.5.1	Equipment calibration activities	5
3.5.2	Equipment found to be out of calibration	5
3.5.3	Equipment monitoring, maintenance, calibration, and repair	5
3.6	Equipment traceability	5
3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of system
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.3	Agreements concerning activities involving more than one organization	5
4.3	Inspection of incoming critical materials	10
4.3.1	ABO group confirmation	10
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	10
5.1.8	Identification and traceability of products	5
5.1.8.1	Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components	10

5.1.8.2	Traceability of blood, blood components, and critical materials	10
5.2	Orders placed by the patient's physician or other authorized health professional	5
5.4	Labeling of patient samples	10
5.5	Compatibility testing requests	10
5.6	Receipt of blood and blood components	
5.6.1	Verification of the following information before transfusion: 4) The unit has remained within the appropriate time and temperature range defined for the container in use. 5) Identifying information is accurate. 6) Unit appearance is normal	10
5.8.1	Verification of the following information before transfusion: 6) The intended recipient's two independent identifiers, ABO group, and Rh type. 7) The donation identification number, the donor ABO group, and, if required, the Rh type. 8) The interpretation of crossmatch tests, if performed. 9) Special transfusion requirements are met, when applicable. 10) The expiration date (or time) of the unit and that it has not expired.	5
5.8.2	Verification of recipient identification before transfusion	5
5.9	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.	5
5.13.1	Verification of the following information before transfusion: 6) The intended recipient's two independent identifiers, ABO group, and Rh type. 7) The donation identification number, the donor ABO group, and Rh type. 8) The interpretation of crossmatch tests, if performed. 9) Special transfusion requirements are met, when applicable.	5

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	10) The expiration date (or time) of the unit and that is has not expired.	
5.13.2	Verification of patient identification before transfusion	5
5.14	Emergent use of uncrossmatched blood	10
5.14.2.7.1	Notification of abnormal test results	10
6.1.2	Document control, including review and approval of all documents before use	5
6.1.3	Review and approval of changes to documents	5
6.1.4	List of all active policies, processes, procedures, labels, and forms	5
6.1.5	Biennial review of each policy, process, or procedure	5
6.1.6	Documents that are archived, destroyed, or made obsolete	5
6.2.5	Record change	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	5
6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	5
6.3	Electronic records	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	5
7.1	Deviations	10 years after any impacted product is used or discarded
7.2	Nonconforming products or services	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10
7.2.4.1	Disposition of the nonconforming product or service	10
7.3.3	Adverse events related to transfusion	10
7.3.3.3	Evaluation of suspected transfusion reactions	10
7.3.4	Recognition of transfusion reactions	10
7.3.5	Look-back investigation	10
7.4	Fatality reports	10
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5
8.5	Peer-review assessment of blood utilization	5
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5

10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10

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

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QSE 7 – Deviations, Nonconformances, and Adverse Events

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

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

Examples of Objective Evidence:
- Policies, processes, and procedures related to this chapter.
- Records and evaluation of deviations, nonconformances, and adverse events.
- Notification to customer(s) following investigation, if appropriate.
- Records of evidence that measures were taken to ensure deviations, nonconformances, and adverse events do not recur.
- Planned deviation records, if any.
- Records of deviation reporting to appropriate parties [eg, Food and Drug Administration (FDA)].

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7.0 Deviations, Nonconformances, and Adverse Events

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

*21 CFR 606.171

FDA Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments (March 2020).

7.1 Deviations

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

7.2 Nonconformances

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

7.2.1 Nonconforming products or services shall be quarantined and/or destroyed.

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

7.2.3 The organization shall:

1) Identify, quarantine, retrieve, recall, and determine the disposition of nonconforming products or services.
2) Identify and manage nonconforming products or services.

7.2.4 Released Nonconforming Products or Services

Products or services that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality and/or safety of the product or service.

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

7.3 Adverse Events

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

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

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

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applicable.

7.3.3 Adverse Events Related to Transfusion

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

7.3.3.1 Recognition of and Response to Transfusion Reactions

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

7.3.3.2 The process shall include:

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

7.3.3.3 When the transfusion is discontinued, the following shall be performed:

1) The label on the blood product and records shall be examined to detect errors in identifying the patient, blood, or blood component.
2) The ordering provider or TAS medical director shall be notified.
3) The unit (whether or not it contains any blood) shall be sent to the transfusion service or receiving hospital with, whenever possible, the attached transfusion set and intravenous solutions.
4) A posttransfusion sample shall be obtained as soon as possible from the patient and sent to the transfusion service or receiving hospital.

7.3.4 Transfusion Reactions

The TAS shall provide clear instructions to the patient's responsible caregivers and/or health care personnel regarding post-transfusion instructions, including recognition and steps for managing a suspected transfusion reaction. Standard 5.8.4 applies.

7.3.4.1 If a transfusion reaction is suspected or detected, the TAS shall be notified.

7.3.4.2 The TAS shall have a process to notify the transfusion service or receiving hospital.

7.3.5 Look-Back

the TAS shall have a process for providing relevant unit and/or patient information as requested when notified by the blood collection facility and/or transfusion service.*

*21 CFR 610.46 and 21 CFR 610.47 apply.

7.4 Fatality Investigation and Notification

The transfusion service and/or collection facility shall be notified of fatalities suspected to have resulted from transfusion.

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7.4.1 If a fatality is suspected to have occurred as a result of a blood transfusion, the TAS shall report this event to the transfusion service and/or collection facility for investigation.

7.4.2 If a fatality is confirmed to have occurred as a result of a transfusion, the transfusion service and/or collection facility shall notify the FDA.*

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

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Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
7.1	Deviations	10 years after any impacted product is used or discarded
7.2	Nonconforming products or services	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10
7.2.4.1	Disposition of the nonconforming product or service	10
7.3.3	Adverse events related to transfusion	10
7.3.3.3	Evaluation of suspected transfusion reactions	10
7.3.4	Recognition of transfusion reactions	10
7.3.5	Look-back investigation	10
7.4	Fatality reports	10

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

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QSE 8 – Internal and External Assessments

Key Concepts: This QSE addresses the organization's internal quality assessment functions as well as processes to support external assessments by accreditors, health authorities, and regulators This chapter also describes the need for the organization to engage in ongoing quality monitoring and utilization review.

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

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

Competent Authority: The agency responsible under its national law for regulations applicable to the organization.

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

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

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

Nonconformance: Failure to meet requirements.

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

Quality Indicator Data: Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

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

Examples of Objective Evidence:

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

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8.0 Internal and External Assessments

The organization shall conduct assessments of operations and quality systems.

✎8.1 Internal Assessments

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

✎8.2 External Assessments

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

✎8.3 Management of Assessment Results

The results of assessments shall be:

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

8.4 Quality Monitoring

The organization shall collect and evaluate quality indicator data on a scheduled basis, including adverse events.

8.4.1 The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.

✎8.5 The TAS shall have a process for the monitoring of blood utilization and wastage.

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Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5
8.5	Peer-review assessment of blood utilization	5

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

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QSE 9 – Process Improvement

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

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

Examples of Objective Evidence:

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

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9.0 Process Improvement

The organization shall collect data, perform analysis, and follow up on issues requiring corrective and preventive action, including near-miss events.

9.1 Corrective Action

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

1) Description of the event.
2) Investigation of the root cause(s) of nonconformances relating to the product or service, the process, and the quality system.
3) Determination of the corrective action needed to eliminate the cause of nonconformances, as applicable.
4) Ensuring that corrective action is reviewed and found to be effective.

9.1.1 Investigation and corrective action shall include consideration of deviations, nonconformances, and complaints.

9.2 Preventive Action

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

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

9.3 Performance Improvement

The organization shall track and identify trends in information related to its operational and quality system performance to identify opportunities for improvement.

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Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5

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

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QSE 10 – Facilities and Safety

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

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

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

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

Examples of Objective Evidence:
- Policies, processes, and procedures related to this chapter.
- Safe environmental conditions for all individuals in the organization.
- Local, state, and national regulations being followed.
- Proper discard of hazardous and potentially hazardous materials.
- Personal protective equipment (PPE) is available and in use.

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10.0 Facilities and Safety

The organization shall ensure safe environmental conditions. The work area shall be suitable for the activities performed. Safety programs shall meet local, state, and national regulations.

10.1 Safe Environment

The organization shall minimize and respond to environmentally related risks to the health and safety of all individuals and products or services. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

10.2 Biological, Chemical, and Radiation Safety

The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.

10.3 Handling and Discarding of Biological Materials

Biological materials shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

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Standard	Record to Be Maintained	Minimum Retention Time[1]
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10

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

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Glossary

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

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

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

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

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

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

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

Blood-Group-Compatible: When there is no anticipated harm to the recipient due to identity of the donor antigens or absence of an alloimmune response (eg, a patient of unknown blood type receives group O RBCs or AB plasma, and a group A patient receives group A or O RBCs and group A or AB plasma).

Blood-Group-Specific: When the component or whole blood is ABO blood group identical to the recipient (eg, a group A patient receives group A RBCs and group A plasma).

Blood Supplier: A blood center or transfusion service providing a unit for transfusion.

Calibrate: To set or align measurement equipment against a known standard.

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.

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

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

Competence: An individual's demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities.

Competent Authority: The agency responsible under its national law for regulations applicable to the organization.

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Compliance: *See* Conformance.

Confidentiality: The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure.
Conformance: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.

Container: A receptacle used in the handling, storage and/or transport of blood.

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

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

Crossmatch: See *Compatibility Testing*.

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

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

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

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

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

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

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

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

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

Establish: To perform all of the activities required to plan, validate, and implement a system or process.

Executive Management: The highest-level personnel within an organization, including employees,

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clinical leaders, and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

Expiration: The last day and 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, issue, or transfusion.

Health Professional: An individual employed by a facility qualified by education, training, and experience to perform the duties assigned.

Hospital: A licensed establishment staffed by at least one physician, a nursing staff, can offer inpatient accommodation with active medical and nursing care.

Home Medical Care: Medical care or procedures that take place in a patient's home or residence. **Inspect:** To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements.

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and the manufacturer's recommendations in an environment suitable for its operation and use.

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).

Key Quality Functions: Essential job functions that affect the services provided by the organization.

Label: An inscription affixed or attached to a product for identification.

Labeling: Information that is required or selected to accompany the product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

Laboratory Director: A role defined by CLIA as the responsible party for all aspects of testing performed by a CLIA qualified laboratory.

Maintain: To keep in the current state; to preserve or retain; to keep in a state of validity.

Master List of Documents: A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the *Standards*, including information for document

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control.

Material: A supply item used in a process or procedure.

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

Neonate: A child less than 4 months of age.

Nonconformance: Failure to meet requirements.

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

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Operational Systems: Processes, resources, and activities that work together to result in a product or service.

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

Out of Hospital Setting: Typically not acute care provided to a patient in facilities including but not limited to, long term care facilities, hospice, infusion centers, or home care settings.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

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

Prehospital Setting: Urgent or emergent care provided to a patient before arrival at a hospital including but not limited to at the point of injury, in a road ambulance, or helicopter.

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

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

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

Process Control: Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.

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Product: A tangible output from a process.

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

Qualification (individuals): The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.

Qualification (materials): For materials that come into contact with the product, verification that the materials are sterile, the appropriate grade and suitability for the intended use, and, whenever possible, approved for human use by the US Food and Drug Administration (FDA) or relevant Competent Authority.

Quality: Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.

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

Quality Indicator Data: Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by executive management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

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

Quarantine: To isolate nonconforming blood, blood components, or materials to prevent their distribution or use.

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

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

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

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

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

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

Risk: The threat of quantifiable damage or any other negative occurrence that is caused by external or internal vulnerabilities and that may be avoided through preemptive action.

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

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

Service (noun): An intangible output of a process.

Service (verb): An action that leads to the creation of a product or a result that can affect donors, patients, and/or recipients.

Shall: A term used to indicate a requirement.

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

Specified Requirements: Any requirements in these *Standards*, including, but not limited to, FDA requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as the AABB.

Standard: A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.

Supplier: An entity that provides a material, product, or service.

Supplier Qualification: Evaluation of a potential supplier to assess its ability to consistently deliver products or services that meet specified requirements.

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

Transfusion Administration Service (TAS): A service provider responsible for receiving and transmitting orders of blood for transfusion, transporting blood to the transfusion site, performing the

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transfusion, monitoring the patient during transfusion, reporting outcomes, and ensuring the traceability of the unit is maintained.

Transfusion Reactions: An adverse reaction to a transfusion that can be acute (i.e., occurring within 24 hours from the end of the transfusion) or delayed (i.e., occurring beyond 24 hours from the end of the transfusion).

Transfusion Service: A facility that performs one or more of the following activities: compatibility testing, ABO/Rh confirmatory testing of whole blood and/or red blood cells prior to issue, 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).

Transfusion Site: The patient care area where a transfusion is performed.

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.

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.

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

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

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

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