

PROPOSED Standards for a Patient Blood Management Program, 6th Edition

Effective June 1, 2027

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 6th edition begins on page 2 and runs through page 15. The proposed 6th edition begins on page 16 and runs through page 72.

Significant Changes to the Proposed 6th edition of Standards for a Patient Blood Management Program

1.1.1 Medical Director Qualifications and Responsibilities

The program shall have a medical director who is a licensed provider/physician and qualified by education, training, and/or experience **and program-defined relevant continuing education in activities required by these PBM Standards for which the program is accredited.**

The committee elected to add the elements in bold to the edition to ensure that individuals serving in this role have the necessary continuing education in PBM to maintain the expected level of competence for this individual.

1.1.1.1 The medical director's responsibilities shall include, but not be limited to:

1) Leadership and oversight **including operations, clinical services, and program activities.**

3) **Pursuit** Identification of program resources needed to conform to these PBM Standards.

The committee edited subnumber 1 to ensure that the oversight required reflected what a medical director actually oversees from a PBM program perspective.

The committee edited subnumber 3 reflecting an actual attempt to secure and acquire resources for the PBM program versus making a list of nice to have.



1.1.1.2 The medical director may delegate **specific** these responsibilities to another qualified individual(s); however, the medical director shall retain ultimate responsibility.

The committee edited standard 1.1.1.2 recognizing that not all responsibilities can be delegated.

1.1.2 Executive management **in collaboration with the PBM program medical director** shall define the **objectives** activities of the PBM program tied to patient outcomes.

The committee edited standard 1.1.2 to ensure that the PBM medical director is included in any decision making for the PBM program in concert with executive management. The committee also replaced the term "activities" with "objectives" for clarity.

1.1.3-2.1 A PBM program can be designated as **either** a program activity Level 1, **or 2** ~~or 3~~ **program**. To be designated a specific activity level, the program shall be responsible for or have direct involvement with oversight and monitoring of the following activities:

Based on edits to the activity level table removing any level 3 activities, the committee updated standard 1.1.3 (formerly 1.1.2.1). More information is included below.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
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In their review of the items included in the activity level chart, the committee recognized that by editing

former entry #18 (now 17), there was no elements strictly activity level 3, and that all elements now fit into activity level 1 and 2.

Item	Responsibility	Activity Level 1	Activity Level 2
2	Data Metrics regarding transfusion appropriateness consistent with transfusion guidelines	X	X

The committee replaced the term “metrics” with “data” as this term is more encompassing of the information available to the PBM program.

Item	Responsibility	Activity Level 1	Activity Level 2
3	Appropriate patient evaluation before intervention	X	X

The committee added the term “Appropriate” in item 3 to ensure that the evaluation that takes place best mirrors the needs of the specific patient.

Item	Responsibility	Activity Level 1	Activity Level 2
4	Patient or Case-specific blood usage assessment	X	X

The committee deleted the term “patient” as the intent of entry #4 is to be focused on the case to be considered and not an assumption that the focus is the patient.

Item	Responsibility	Activity Level 1	Activity Level 2
5 11	Process to identify, before or upon admission, patients for whom blood is not an option	X	X
6 12	Process to include shared decision-making during documented patient consent for receipt or documented decline of blood and blood components	X	X

The elements appearing as 5 and 6 previously appeared as 11 and 12 and were moved up to better mirror the expected workflow of a PBM program. The content of the entries have not changed.

Item	Responsibility	Activity Level 1	Activity Level 2
9 7	Assessment and management of patient hemostasis coagulation status, as applicable	X	X

The committee edited the entry, replacing “coagulation” with “hemostasis” for accuracy purposes. Coagulation focuses specifically on clotting, while hemostasis is a process that focuses on the entire body.

Item	Responsibility	Activity Level 1	Activity Level 2
10 8	Monitoring and minimizing blood component	X	X

	wastage and cause		
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The committee edited the entry recognizing that monitoring is not sufficient and minimizing should be included as well. This would include the “cause” of the wastage of blood.

Item	Responsibility	Activity Level 1	Activity Level 2
12 13	Massive transfusion/massive hemorrhage protocol for all patient populations with documented and evaluation of activation and deactivation criteria , and protocol workflow effectiveness and monitoring evidence of its use	X	X

The committee edited the entry for clarity and to expand the requirement of the entry. The additions ensure that the scope of a massive transfusion protocol is all encompassing covering its activation and deactivation.

Item	Responsibility	Activity Level 1	Activity Level 2
14	<u>PBM care for patients with established obstetric care</u>	<u>X</u>	<u>X</u>

The committee created entry #14 for completeness, ensuring that care is specifically tailored for those individuals that fit into the obstetric category.

Item	Responsibility	Activity Level 1	Activity Level 2
15	PBM care for obstetric patients including postpartum hemorrhage protocol with evidence of its use, plan(s) for patients with known high bleeding risk (eg, placental abnormalities), and plans for patients for whom blood is not an option, including those who decline blood and blood components	X	X

The committee removed the term “postpartum” from the entry as it was deemed redundant.

Item	Responsibility	Activity Level 1	Activity Level 2
16	Single-unit transfusion strategies for defined clinical settings	X	X

The committee removed former entry #16 as it was deemed more guidance than a required standard.

Item	Responsibility	Activity Level 1	Activity Level 2
16 17	Management of acquired coagulopathy	X	X

The committee removed the element in strikethrough as it was deemed redundant.

Item	Responsibility	Activity Level 1	Activity Level 2
17 18	Blood conservation strategies for <u>all</u> service lines associated with high blood usage	X	X

The committee removed the elements in bold as it was deemed too restrictive.

Item	Responsibility	Activity Level 1	Activity Level 2
19	Evaluating and managing iron and micronutrient deficiencies in patients with Red Blood Cells ordered in the inpatient and outpatient populations	X	X

The committee removed the entry as it was deemed the responsibility of the transfusion service and not the PBM program.

Item	Responsibility	Activity Level 1	Activity Level 2
19 21	Established Evaluation and management of identified anemia <u>clinic</u> in patients	X	NA

The committee elected to edit the entry to make there be an action as opposed to an evaluation.

Item	Responsibility	Activity Level 1	Activity Level 2
20 22	<u>Identification and management of presurgical anemia</u> before elective procedures for patients at risk for Red Blood Cell transfusion and/or adverse consequences of postsurgical anemia	X	N/A

The committee removed the entry to place the elements in guidance as they do not fit in standards specifically.

Item	Responsibility	Activity Level 1	Activity Level 2
24	Program to care for patients undergoing cardiac surgical or structural heart procedures	X	N/A

The committee deleted entry #24 as it was deemed more the responsibility of the transfusion service.

1.1.4 Program Coordinator

The program shall have a ~~program~~ coordinator who is responsible for the operational aspects of the program.

The committee removed the term “program” as it was noted that not every PBM program refers to this individual as a program coordinator.

1.1.5 Program Members

The program shall include representatives responsible ~~from administration, transfusion medicine, informatics, quality assurance, pharmacy, nursing, laboratory, and other departments that regularly transfuse, recommend, and/or have programmatic responsibility~~ for the oversight of the transfusion of blood and blood components and patients requiring alternative therapies ~~the management of anemic and bleeding patients.~~

The committee removed the elements in bold as it was deemed a better fit for the guidance and will appear there once published. The elements in bold were added for clarity.

1.2.3 Quality Plan

A patient-centered quality plan shall be defined, documented, implemented, maintained, **and reviewed** to ensure reliability and reproducibility, and optimize patient outcomes. All program member representatives shall be aware of its content. The program medical director will review the quality plan biennially and when updates are made.

The committee added the clause in bold for completeness.

- 1.5.1** The program shall **have a process that** ~~define and~~ addresses critical supplies, equipment, and product inventory shortages.

The committee added the clause in bold replacing “define” as they felt that it would ensure a tangible outcome to be assessed.

- 1.6.2** These emergency management plans shall include all PBM operations and procedures ~~to include all ancillary services and support to this program.~~

The committee removed the elements in strikethrough as it was deemed a better fit for the guidance.

1.9 Facility Status Changes

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

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

The committee added new standards 1.9 and 1.9.1 to the proposed edition to mirror the addition of the same standards to all other AABB Standards, which include to date, the 12th edition of CT Standards, 17th edition of RT Standards, 14th edition of IRL Standards, 35th edition of BB/TS Standards, 12th edition of Perioperative Standards and 8th edition of MT Standards.

2.1.7 Facility-Defined Educational Requirements

Individuals involved in ~~clinical~~ PBM shall meet facility defined requirements for

education, including evidence-based approaches to improving outcomes focused on patient-centered care.

The committee removed the element in strikethrough as it was deemed unnecessary.

3.5.4.1 When a nonconformance cannot be attributed to a specific piece of equipment, all potentially affected pieces of equipment shall be assessed to determine expected performance measures based on the manufacturer's written instructions.

The committee created new standard for clarity. This clarifies that in the case where a malfunction cannot be attributed to one piece of equipment, all other equipment has to be assessed. Note this standard is being incorporated into all sets of AABB Standards.

✎ 3.6 Equipment Traceability

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

- ~~1) Equipment to be uniquely identified and traceable.~~
- ~~2) Tracing of any given product or service to all equipment associated with the procurement, processing, storage, distribution, and administration of the product or service.~~
- ~~3) Identification and recall of all cellular therapy products associated with a specific piece of equipment.~~

Based on a review of chapter 3, it was deemed that this standard is redundant to many standards in chapter 3, specifically the 3.5 thread and standard 6.2.2 in chapter 6. While this is a QSE, it is causing issues for accredited facilities and will be struck from the other standards as they are being set, starting with the proposed 17th ed of RT Standards. The committee did request to keep elements of 3.6 into standard 3.5.3

✎ 3.6 Technology Infrastructure

The organization shall have an active program to ensure that critical technology infrastructure and communications infrastructure function as intended, including continuous monitoring or testing at facility define intervals. Standards 1.4, 1.5, and 1.6 apply.

The committee added new standard 3.7 to the proposed edition to mirror the addition of the same standard to all other AABB Standards, which include to date, the 12th edition of CT Standards, 17th edition of RT Standards, 14th edition of IRL Standards, 35th edition of BB/TS Standards, 12th edition of Periop Stds, and 8th edition of MT Standards.

✎ 3.6.1 Artificial Intelligence Oversight

The organization shall establish and maintain a framework for the responsible use of Artificial Intelligence (AI) technologies. This framework shall apply to all PBM processes where AI influences policy development, critical decision making, or donor/patient/staff safety. The PBM program shall maintain documentation of intended use, validation of output, including evidence, and audit trails for AI-driven decisions.

✎ 3.6.2 Risk Management of AI Output(s)

The program shall:

1) Define roles and responsibilities of the individual(s) for the oversight and use of AI.

2) Determine the intended use of AI.

3) Perform risk assessments of the AI software before implementation.

4) Ensure compliance with ethical principles, privacy, and applicable regulations.

3.6.3 Verification of AI Output(s)

The program shall verify the AI fitness for the intended use, including bias checks, and performance metrics.

Standard 3.3 applies.

3.6.4 Monitoring of AI

The program shall monitor and manage the performance of AI models including inputs and outputs.

3.6.4.1 The program shall monitor AI performance on a scheduled basis to detect unintended outcomes. Standards 3.5.4 and 3.5.4.1 apply.

Recognizing that AABB members are using artificial intelligence as a part of their day to day activities, the committee felt that it was important to include standards that could apply to all AABB members with regard to implementation, risk management, verification of the output, and monitoring of AI as part of their usage of the tool. The impetus for this was a memo drafted by the SPC and APC to the Board, and their assent to the committees to spearhead this. Whatever the final language, the standards will be implemented across all AABB Standards in the future.

3.8.1 Equipment controlled by the blood bank, transfusion service, clinical laboratory, or perioperative program shall be operated in accordance with the manufacturer's written instructions for use, or a medical director approved variance for use ~~and/or AABB Standards for Blood Banks and Transfusion Services and AABB Standards for Perioperative Autologous Blood Collection and Administration~~ or the requirements of an equivalent accrediting body.

The committee removed the elements in strikethrough as it was deemed unnecessary. When the PBM Standards were first issued, the awareness of these Standards was not as known as they have become to the patient blood management community. With the maturation of the PBM Standards, including this clause was deemed unnecessary.

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

The committee removed the clause "of specifications" as it was deemed unnecessary. The sentence deleted was deemed redundant to standard 5.1.1.

5.1.10 The program shall ensure that:

1) Patients with **or at risk for** anemia are assessed and managed.

4) ~~Internal~~ Quality metrics are in place and reported.

The committee added the clause “or at risk for” to #1 to ensure that the full spectrum of patient populations were addressed and had steps taken to ensure that they were treated appropriately. The committee removed the term “Internal” from #4 as it was deemed unnecessary.

5.1.11 PBM Guidelines

The program shall utilize evidence-based PBM guidelines specific to the hospital’s inpatient and outpatient populations. These guidelines shall include practices to manage and maintain patient hemostasis. These guidelines shall include but are not limited to:

6) Managing appropriate platelet utilization.

~~In addition, guidelines from major patient groups within the facility (service lines, care pathways) shall be reviewed to ensure adherence to PBM practices.~~

The committee added new subnumber 6 for completeness, as the usage of platelets continues to rise and shortages occur.

The element in strikethrough was removed as it was deemed guidance and will appear therein.

5.1.13 Educational Materials

The program shall develop, review, and distribute educational materials, at defined intervals for hospital personnel and patients, that:

5) Review the alternatives to transfusion, including **the option to decline transfusion, and available** pharmacologic therapies.

The committee removed the term “hospital” feeling it was too limiting for the PBM program personnel most affected by these Standards.

Subnumber 5 has added “no transfusion” for completeness, recognizing not receiving blood or blood components is an option for all patients.

5.2 Phlebotomy

The program shall ~~review, revise, or create policies, processes, and procedures that~~ minimize blood volume collected for laboratory testing. **Standard 1.3 applies.**

The committee removed the elements in strikethrough to make the standard read as an active item to mirror the rest of the language in the Standards. The crossreference to standard 1.3 was added for completeness.

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

4) The right to ~~change the transfusion directive~~ **withdraw consent for transfusion or consent after declining at any time.**

The committee edited subnumber 4 for clarity. The committee felt that the term “transfusion directive” was not clear in terms of the requirement.

5.3.3 The program shall have a policy for obtaining consent for patients lacking decisional capacity, and for all minors.

The committee created new standard 5.3.3 for completeness recognizing that this element was missing to cover these potential patients as it pertained to a specific informed consent process.

- 5.4.1** The program shall ~~have policies~~ **review blood administration protocols** for blood **and blood** component transfusion volume and frequency when transfusion is indicated.

The committee edited standard 5.4.1 to mirror the active language of the Standards. The addition in bold to ensure that all PBM programs review their blood administration protocols as a part of the transfusion order set.

- 5.4.2** The program shall promote the use of single-unit, **red blood cells (RBC), and platelet** component transfusion strategies.

The committee added RBCs and platelets to the standard as most PBM programs now have single unit transfusion plans for the products cited.

- 5.5.1** The program shall review, revise, or create the pretransfusion testing policies, processes, and procedures. These policies shall be consistent with the **current edition of AABB Standards for Blood Banks and Transfusion Services**.

The committee added the clause in bold to ensure that it was clear that users have to be consistent with the current edition of BB/TS Standards and potentially not one of their choosing.

- 5.5.3.1** Data regarding adherence to these guidelines shall be reviewed ~~quarterly~~ **at defined intervals** and shared with the hospital administration and quality committees at least annually.

The committee replaced the timeframe of “quarterly” with “at defined intervals” recognizing that some programs will wish to review conformance with the guidelines at a timeframe more frequently than quarterly.

- 5.6.1** For elective procedural/surgical patients, the following shall be performed ~~sufficiently~~ in advance of the planned procedure to allow for successful treatment:
- ~~1) Assessment of physiologic ability to tolerate anemia, iron deficiency, and coagulation systems stress.~~
 - 1) Evaluation and management of preprocedure anemia and coagulopathy.
 - 2) Evaluation of safe and effective discontinuation of anticoagulants and/or platelet inhibitors.
 - 3) Assessment of bleeding risk, including review of the patient’s current medications.
 - 4) Assessment and plan for blood or blood component needs and alternatives.

The committee removed element #1 from the standard as it was deemed redundant per the activity level table.

- 5.6.2** For patients undergoing urgent or emergent procedures, there shall be processes and/or procedures for the following:
- ~~1) Management of the blood or blood component needs of unknown or unidentified~~

patients.

- 1) Assessment of bleeding risk, including review of the patient's current medications, if available.
- 2) Assessment of patients for preexisting anemia and physiologic ability to tolerate blood loss.
- 3) Interventions to stop bleeding, including:
 - a) Directed interventions, including hemostatic agents.
 - b) Protocols for rapid reversal of anticoagulants.
 - c) Assessment of recovering and reinfusing shed blood.
 - d) Utilization of program-defined rapid testing for coagulation management.
- 4) Timely delivery of blood components.

The committee deleted subnumber as it was noted that it is the responsibility of the transfusion service and not the PBM program.

Subnumber 2 was edited as it was deemed redundant to subnumber 1.

- 5.8.1** The program shall oversee and review compliance with established PBM guidelines.
Standard 5.1.11 applies.

The committee added the crossreference in bold for completeness.

5.9 Management of Patients Who Do Not Require Undergoing Minimally Invasive Procedures

The program shall oversee and review:

- 1) Processes to discuss with patients the availability of alternative therapies to transfusion.
- 2) The prescribing and ordering of blood and blood components or alternatives to transfusion.

The committee edited the title of the standard as it better reflected the content of the standard.

5.10 Anemia Care for Inpatients

Based on activity level, the program shall have policies, processes, and procedures in place to manage anemia in nonsurgical inpatients, including patients **with** ~~suffering from~~ iron and/ or micronutrient deficiency.

The committee edited standard 5.10 as the terminology previously included was deemed colloquial.

5.11 PBM for Obstetric Patients

The program shall oversee and review policies, processes, and procedures for obstetric patients, including:

- 1) Identification and management of pregnancies with known risk for hemolytic disease of the fetus and newborn or neonatal alloimmune thrombocytopenia.
- 2) Patients for whom blood is not an option ~~including those who decline blood and blood components.~~
- 3) Antepartum and postpartum anemia management.
- 4) Optimization of patient coagulation and fibrinogen status.

The committee edited standard 5.11 as it was deemed redundant.

5.11.1 Postpartum Hemorrhage Preparedness and Management

Postpartum hemorrhage preparedness and management shall include:

- 1) Quantitative ~~cumulative~~ assessment of maternal blood loss ~~for all patients~~.
- 2) Identification of patients with known high bleeding risk (eg, placental implantation abnormalities).
- 3) Proper use of antifibrinolytic agents (eg, tranexamic acid).
- 4) Consideration of point-of-care testing (eg, viscoelastic testing), **and** autotransfusion (eg, cell salvage), **as applicable**.
- 5) Postpartum hemorrhage protocol, including predelivery risk assessment, postdelivery patient identification with a stepwise process to manage bleeding, massive transfusion/massive hemorrhage protocol, and/or patient transfer.
- 6) Identification of patients for whom blood is not an option ~~including those who decline blood and blood components~~.

The committee edits subnumber 1 as the term “cumulative” was deemed redundant per “quantitative.” The clause “for all patients” was deleted as it was also deemed redundant.

Subnumber 4 was edited for clarity, recognizing that not all considerations will be included in each program.

Subnumber 6 was edited as the content was deemed redundant.

5.12 Massive Blood Loss and Emergent Care

The program shall ~~have policies, processes, and procedures for~~ **ensure compliance with the program’s massive transfusion/hemorrhage protocol** ~~the timely delivery of blood and blood components to manage~~ for patients experiencing massive bleeding and other emergent situations in. Standard 1.3 applies.

~~5.12.1 The program shall ensure compliance with the processes and procedures for managing and delivering blood and blood components for patients with emergency blood requirements, including massive blood loss.~~

The committee deleted standard 5.12.1 and included its content as a part of standard 5.12.

5.13 Reversal of Acquired Coagulopathy

The ~~facility program~~ shall have a plan in place to rapidly **identify and manage acquired coagulopathy including reversal when clinically indicated** ~~acquired coagulopathy~~. This plan shall include the dispensing of medications and/or blood and blood components as clinically indicated. The program shall ~~monitor~~ **review** the **facility’s** plan at defined intervals.

The committee edited standard 5.13 for clarity. The committee recognizes that this plan is usually in place with the facility and not the PBM program. As such the standard was edited.

5.15 PBM for Outpatients

The program shall oversee and review policies or processes to ensure ~~that~~:

- 1) Iron and/or micronutrient deficiency is considered, evaluated, and corrected in patients with RBC transfusion orders in the outpatient setting.

2) Monitoring platelet transfusion practices including feedback to clinical services.

Standard 5.1.11 applies.

The committee added subnumber 2 to standard 5.15 for completeness. Throughout the edition platelet monitoring and usage of these products has been added where appropriate. This addition reflects this update.

5.16 Performance Indicators

The program shall obtain and review the following data at least quarterly (unless noted):

- 1) **Work up and management of anemia in defined patient populations** ~~program utilization.~~
- 2) Iron and micronutrient deficiency identification and management in ~~the outpatient transfusion setting~~ **defined patient populations**.
- 3) ~~Biennial external assessment results (eg, AABB or equivalent accrediting body).~~
- 3) Bloodless program ~~enrollment~~ evaluation of effectiveness.
- 5) ~~Blood and blood component use.~~
- 4) Blood and blood component use appropriateness.
- 5) Single-unit RBC, **and platelet** transfusion practice performance metric.
- 6) Blood and blood component wastage and discard, including reasons for unused components.
- 9) ~~Transfusion index and transfusion probability.~~
- 7) Crossmatch-to-transfusion ratio.
- 11) ~~Blood administration policy compliance.~~
- 12) ~~Deviation from transfusion service procedures or protocols.~~
- 13) ~~Transfusion reactions by category.~~
- 8) Informed consent for blood transfusion.
- 15) ~~High usage service lines.~~
- 9) Massive transfusion/massive hemorrhage protocol use.
- 10) Prevalence of iatrogenic anemia.**
- 11) Use of intraoperative blood recovery equipment and quality control.
- 12) Blood infusion equipment ~~and warmer(s)~~ maintenance program (annually).

Standard 8.4 applies.

The committee edited subnumber 1 for clarity and to ensure specificity to better assist PBM programs in their implementation of the standards.

The committee edited subnumber 2 for clarity. This ensures that the standard is PBM specific, recognizing that this standard should be focused on the patient populations covered by these Standards.

The committee deleted former subnumber 3 as this was covered by chapter 8.

The committee edited subnumber 3 removing the clause “enrollment” as this is not the purview of the PBM program.

The committee deleted former subnumber 5 as that is covered by chapter 8.

The committee added the clause “and platelet” to subnumber 5 to mirror the addition of this product to this edition of PBM Standards.

The committee deleted former subnumber 9 as the committee did not feel that this addition was beneficial or truly understood by the implementers of the PBM Standards.

The committee deleted former subnumber 11 as it was deemed the responsibility of the transfusion service, specifically by nursing.

The committee deleted former subnumber 12 as this would be covered in chapter 7 and chapter 8.

The committee deleted former subnumber 13 as this would be covered by the transfusion service.

The committee deleted former subnumber 15 as it was deemed redundant as this is a part of all lines in

the PBM program and not specifically high usage, feeling that this would limit the standard.
The committee added subnumber 10 for completeness.
The committee edited subnumber 12 as a blood warmer would be considered part of the PBM program's equipment.

7.3.3 Characterization of Adverse Events

Adverse events shall be characterized using defined criteria and managed and reported in accordance with applicable regulations.

The committee added new standard 7.3.3 for completeness. This standard ensures that PBM programs use defined criteria to characterize adverse events.

7.4 Investigations of Deviations, Nonconformances, and Adverse Events

The investigation shall, when applicable, include a **documented** assessment of the effect of PBM program deviations on patient safety. The responsibility for review and authority for the disposition of nonconforming medications, blood, blood components, perioperative products, critical materials, and services shall be defined.

The committee added the term “documented” to ensure that these investigations are documented and can be shared as appropriate.

7.4.2 Trend Analysis

The organization shall analyze aggregated data on deviations, nonconformances, and adverse events to detect safety signals, trends, and clusters, and shall document resulting risk minimization actions at defined intervals.

The committee added new standard 7.4.2 for completeness. The addition ensures that the all data concerning any deviations, nonconformances and adverse events are used to determine if there are any potential trends that could lead to further nonconformances.

8.6 Reporting

The program shall report annually on its performance. The report shall include, but not be limited to, the following if required for the program's activity level:

- 2) Program's performance goals and other **resources** ~~needs~~ for next reporting period.

The committee replaced the term “needs” with “resources” for clarity.

9.1.2 As an element of corrective action, the program shall monitor:

- 5) ~~Employee~~ Knowledge gaps and assigned appropriate training or retraining, as applicable.

The committee removed the term “employee” as it was deemed too restrictive.

Glossary

Blood is Not an Option: Instances when individuals have religious or personal reasons to decline transfusion, instances when individuals have unusual blood types or alloimmunization for which components are not available, and circumstances of inadequate blood supply.

When Blood Is Not an Option: See “Blood is Not an Option” ~~Instances when individuals have religious or personal reasons to decline transfusion, instances when individuals have unusual blood types or alloimmunization for which components are not available, and circumstances of inadequate blood supply.~~

The committee added the term “Blood is Not an Option” and took the content of the definition “When Blood is Not an Option” for clarity.

Hospital Administration: The individual(s) who has responsibility for the patient blood management program, but that are not actively involved in patient care.

The term “hospital administration” has appeared in the PBM Standards previously but there was confusion about its meaning, as a result, the committee created this new definition.

Regulatory Enforcement Action: Measures taken by a Competent Authority that include but are not limited to progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues, deficiencies in risk management systems.)

The committee added this definition in conjunction with the creation of new standard 1.9.1.

QSE 1 – Organization

Key Concepts

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

Key Terms

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

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

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

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

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

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

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

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

Examples of Objective Evidence

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

1.0 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 *PBM Standards* and applicable laws and regulations, including all applicable current good manufacturing practice (CGMP) requirements.
- 3) Authority to establish or make changes to the quality system.
- 4) The responsibility for collecting and reviewing data on patient blood management (PBM), including patient outcomes and program performance metrics.
- 5) The responsibility to identify stakeholders and to communicate results to these stakeholders.

1.1.1 Medical Director Qualifications and Responsibilities

The program shall have a medical director who is a licensed provider/physician and qualified by education, training, and/or experience and program-defined relevant continuing education in activities required by these *PBM Standards* for which the program is accredited.

1.1.1.1 The medical director's responsibilities shall include, but not be limited to:

- 1) Leadership and oversight including operations, clinical services, and program activities.
- 2) Consultative and support services on PBM matters that relate to the care and safety of patients.
- 3) Pursuit of program resources needed to conform to these *PBM Standards*.
- 4) Communication of program results and opportunities for improvement to executive management and hospital staff at least annually.

1.1.1.2 The medical director may delegate specific responsibilities to another qualified individual(s); however, the medical director shall retain ultimate responsibility.

1.1.2 Executive management in collaboration with the PBM program medical director shall define the objectives of the PBM program tied to patient outcomes.

1.1.3 A PBM program can be designated as either a program activity Level 1, or 2. To be designated a specific activity level, the program shall be responsible for or have direct involvement with oversight and monitoring of the following activities:

Item	Responsibility	Activity Level 1	Activity Level 2
1	Evidence of institutional support for the PBM program at the hospital administration level	X	X
2	Data regarding transfusion appropriateness consistent with transfusion guidelines	X	X

3	Appropriate patient evaluation before intervention	X	X
4	Case-specific blood usage assessment	X	X
5	Process to identify, before or upon admission, patients for whom blood is not an option	X	X
6	Process to include shared decision-making during documented patient consent for receipt or documented decline of blood and blood components	X	X
7	Documentation of transfusion including patient consent, observation, adverse events, and outcomes	X	X
8	Preprocedure blood ordering including completion of type and antibody testing before procedure start time with a plan for antibody-positive patients	X	X
9	Assessment and management of patient hemostasis status, as applicable	X	X
10	Monitoring and minimizing blood wastage	X	X
11	Minimize blood loss due to laboratory testing (iatrogenic blood loss)	X	X
12	Massive transfusion/massive hemorrhage protocol for all patient populations with documented activation and deactivation criteria, workflow effectiveness and monitoring its use	X	X
13	PBM care for preterm, neonate, infant, and pediatric critical care patients, if applicable	X	X
14	PBM care for patients with established obstetric care	X	X
15	PBM care for obstetric patients including hemorrhage protocol with evidence of its use, plan(s) for patients with known high bleeding risk (eg, placental abnormalities), and plans for patients for whom blood is not an option, including those who decline blood and blood components	X	X
16	Management of coagulopathy	X	X
17	Blood conservation strategies for all service lines	X	X
18	Processes and equipment to facilitate rapid decision-making concerning anemia and coagulation management	X	N/A
19	Established anemia clinic	X	N/A
20	Identification and management of presurgical anemia	X	N/A
21	Program to care for patients who decline use of blood or blood derived components	X	N/A
22	Use of perioperative techniques consistent with current AABB <i>Standards for Perioperative Autologous Blood Collection and Administration</i>	X	N/A

1.1.4 Program Coordinator

The program shall have a coordinator who is responsible for the operational aspects of

the program.

1.1.5 Program Members

The program shall include representatives responsible for the oversight of the transfusion of blood and blood components and patients requiring alternative therapies.

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.

1.2.3 Quality Plan

A patient-centered quality plan shall be defined, documented, implemented, maintained, and reviewed to ensure reliability and reproducibility, and optimize patient outcomes. All program member representatives shall be aware of its content. The program medical director will review the quality plan biennially and when updates are made.

1.2.3.1 Scope

The quality plan shall encompass all the relevant policies, processes, procedures, protocols, and other work documents related to treating patients who may receive a blood transfusion, decline blood transfusion, or are managed per the activity level. Standard 1.1.3 applies.



1.3 Policies, Processes, and Procedures

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

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



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.

1.3.3 Policies, Processes, and Procedures Controlled by Other Departments

The program shall develop new policies and changes to existing policies, processes, and procedures that affect the quality of the program's activities, even when another department controls these documents.

- 1.3.3.1** The program shall ensure that responsibility for revision and changes to policies, processes, and procedures that affect the quality of the program's activities is defined. Standard 5.1.1 applies.

 1.4 Risk Assessment

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

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

1.5 Operational Continuity

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

- 1.5.1** The program shall have a process that addresses critical supplies, equipment, and product inventory shortages.

1.6 Emergency Preparedness

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

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

- 1.6.2** These emergency management plans shall include PBM operations and procedures.

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.

1.9 Facility Status Changes

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

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

Excerpt of Reference Standard 6.2.9A Relevant to Organization

Standard	Record to Be Maintained	Minimum Retention Time (Years)¹
1.1.1.2	Delegation of medical director responsibilities to another qualified individual(s)	5
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	5
1.3.2	Exceptions to policies, processes, and procedures	5
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)

¹Applicable state or local law may exceed this period.

QSE 2 – Resources

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

Key Terms

Competence: An individual’s demonstrated ability to apply knowledge and skills needed to perform 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.

2.0 Resources

The organization shall have adequate resources to perform, verify, and manage all the activities described in these *PBM 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 *PBM 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 *PBM Standards* are met when applicable.
- ✎ **2.1.7 Facility-Defined Educational Requirements**
Individuals involved in PBM shall meet facility defined requirements for education, including evidence-based approaches to improving outcomes focused on patient-centered care.

Excerpt of Reference Standard 6.2.9A Relevant to Resources

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
2.1.6	Continuing education requirements	5
2.1.7	Facility-defined educational requirements for individuals who order and/or transfuse blood	5

¹Applicable state or local law may exceed this period.

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.
- Evidence of information system backup and records of testing.

3.0 Equipment

The organization shall define and control critical equipment.

3.1 Equipment Specifications

Equipment specifications shall be defined before purchase.

✎ 3.2 Qualification of Equipment

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

3.2.1 Installation Qualification

Equipment shall be installed per manufacturer 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.

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.

3.5.4.1 When a nonconformance cannot be attributed to a specific piece of equipment, all potentially affected pieces of equipment shall be assessed to determine expected performance measures based on the manufacturer's written instructions.

✎ **3.6 Technology Infrastructure**

The organization shall have an active program to ensure that critical technology infrastructure and communications infrastructure function as intended, including continuous monitoring or testing at facility define intervals. Standards 1.4, 1.5, and 1.6 apply.

✍ **3.6.1 Artificial Intelligence Oversight**
The organization shall establish and maintain a framework for the responsible use of Artificial Intelligence (AI) technologies. This framework shall apply to all PBM processes where AI influences policy development, critical decision making, or donor/patient/staff safety. The PBM program shall maintain documentation of intended use, validation of output, including evidence, and audit trails for AI-driven decisions.

✍ **3.6.2 Risk Management of AI Output(s)**
The program shall:
1) Define roles and responsibilities of the individual(s) for the oversight and use of AI.
2) Determine the intended use of AI.
3) Perform risk assessments of the AI software before implementation.
4) Ensure compliance with ethical principles, privacy, and applicable regulations.

3.6.3 Verification of AI Output(s)
The program shall verify the AI fitness for the intended use, including bias checks, and performance metrics.

Standard 3.3 applies.

3.6.4 Monitoring of AI
The program shall monitor and manage the performance of AI models including inputs and outputs.

3.6.4.1 The program shall monitor AI performance on a scheduled basis to detect unintended outcomes. Standards 3.5.4 and 3.5.4.1 apply.

✍ **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 Equipment Controlled by Other Departments

The program shall ensure the responsibility for control of equipment critical to PBM-related activities is defined.

- 3.8.1** Equipment controlled by the blood bank, transfusion service, clinical laboratory, or perioperative program shall be operated in accordance with the manufacturer's written instructions for use, or a medical director approved variance for use.

Excerpt of Reference Standard 6.2.9A Relevant to Equipment

Standard	Record to Be Maintained	Minimum Retention Time (Years) ¹
3.2	Equipment qualification	5
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	2 years after retirement of the system
3.6	Monitoring of technology infrastructure	10
3.6.1	Artificial intelligence oversight	10
3.6.2	Artificial intelligence risk assessment	10
3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of the system

¹Applicable 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.

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.

✍ 4.2 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 *PBM Standards* when more than one organization is involved shall be specified by agreement.

4.2.4 Contract Services

The program shall review and evaluate agreements with suppliers responsible for providing any components or services critical to PBM. If a third-party provider performs PBM activities, the program shall be involved in the supplier qualification process.

✍ 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.

Excerpt of Reference Standard 6.2.9A Relevant to Suppliers and Customers

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	5

¹Applicable state or local law may exceed this period.

QSE 5 – Process Control

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

Key Terms

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

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

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.
- 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.

5.1.1.1 This process shall include the identification and verification that specifications have been met.

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).

- 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.

5.1.9 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.

5.1.10 The program shall ensure that:

- 1) Patients with or at risk for anemia are assessed and managed.
- 2) Patients who may need transfusion are evaluated and managed such that blood and blood components are given when clinically indicated.
- 3) Patients with or at risk for coagulopathy are evaluated and managed.
- 4) Quality metrics are in place and reported.

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5.1.11 PBM Guidelines

The program shall utilize evidence-based PBM guidelines specific to the hospital's inpatient and outpatient populations. These guidelines shall include practices to manage and maintain patient hemostasis. These guidelines shall include but are not limited to:

- 1) Managing anemia and coagulopathy.
- 2) Minimizing blood loss and promoting blood recovery.
- 3) Managing asymptomatic anemia without the use of blood components, according to activity level.
- 4) Administration of blood components, when indicated.
- 5) Avoiding unnecessary transfusions.
- 6) Managing appropriate platelet utilization.



5.1.12 Monitoring

The program shall have a process for ongoing review of PBM practices.

5.1.12.1 The program shall review all nonconformances, deviations from established procedures or protocol, and other incidents where PBM guidelines are not followed.

Chapter 7, Deviations, Nonconformances, and Adverse Events, and Chapter 9, Process Improvement, apply.



5.1.13 Educational Materials

The program shall develop, review, and distribute educational materials, at defined intervals for personnel and patients, that:

- 1) Describe PBM strategies in the facility.
- 2) Describe anemia management in patients.
- 3) Describe coagulopathy evaluation and management.
- 4) Discuss the risks and benefits of transfusion of blood components and transfusion avoidance.
- 5) Review the alternatives to transfusion, including the option to decline transfusion and available pharmacologic therapies.
- 6) Evaluate appropriate ordering of blood components based on clinical indicators.

5.2 Phlebotomy

The program shall minimize blood volume collected for laboratory testing. Standard 1.3 applies.



5.3 Consents, Approvals, and Notifications

The program shall participate in developing and revising policies, processes, and procedures regarding patient consent for transfusion and the right to decline transfusion.

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

- 1) A description of the risks, benefits, and treatment alternatives.
- 2) The opportunity to ask and receive answers to the questions.

- 3) The right to accept or decline treatment.
- 4) The right to withdraw consent for transfusion or to consent after declining at any time.

✍ **5.3.2** For patients who decline blood or blood components, alternative blood loss minimization, optimization of any coagulopathy, and anemia management strategies acceptable to the patient shall be documented in the medical record.

5.3.3 The program shall have a policy for obtaining consent for patients lacking decisional capacity, and for all minors.

5.4 Transfusion Orders

Transfusion orders shall include an indication(s) for transfusion, as determined by program-defined guidelines.

5.4.1 The program shall review blood administration protocols for blood and blood component transfusion volume and frequency when transfusion is indicated.

5.4.2 The program shall promote the use of single-unit, red blood cells (RBC), and platelet component transfusion strategies.

5.5 Pre- and Posttransfusion Patient Care

The program shall have guidelines for patient care in the pre and posttransfusion settings.

5.5.1 The program shall review, revise, or create the pretransfusion testing policies, processes, and procedures. These policies shall be consistent with the current edition of AABB *Standards for Blood Banks and Transfusion Services*.

5.5.2 The program shall create, review, and revise, as necessary, the policies, processes, and procedures to assess transfusion appropriateness and effectiveness.

5.5.3 The program shall implement transfusion guidelines and monitor adherence to these guidelines. Situation of over- or undertransfusion or failure to transfuse shall be identified and evaluated. Standard 9.0 applies.

5.5.3.1 Data regarding adherence to these guidelines shall be reviewed at defined intervals and shared with the hospital administration and quality committees at least annually.

5.6 Preoperative or Preintervention Patient Care

The program shall oversee and review:

- 1) Processes and procedures to identify and correct anemia and coagulopathy prior to procedure.
- 2) Processes to discuss with patients the availability of alternative therapies to transfusion.
- 3) Processes to document patient preferences for blood transfusion or alternatives, and communicate the decision taken with the patient's multidisciplinary care team.
- 4) Processes to ensure the availability of staff, equipment, and hemostatic medications, for blood-

sparing techniques.

5) Maximum surgical blood ordering schedule (MSBOS) or equivalent, including its review (at least biennially) and updating as needed.

6) The utilization of appropriate blood components or transfusion-related pharmaceuticals (eg, factor concentrates, antifibrinolytics, hemostatic agents).

5.6.1 For elective procedural/surgical patients, the following shall be performed in advance of the planned procedure to allow for successful treatment:

- 1) Evaluation and management of preprocedure anemia and coagulopathy.
- 2) Evaluation of safe and effective discontinuation of anticoagulants and/or platelet inhibitors.
- 3) Assessment of bleeding risk, including review of the patient's current medications.
- 4) Assessment and plan for blood or blood component needs and alternatives.

5.6.2 For patients undergoing urgent or emergent procedures, there shall be processes and/or procedures for the following:

- 1) Assessment of bleeding risk, including review of the patient's current medications, if available.
- 2) Assessment of patients for preexisting anemia.
- 3) Interventions to stop bleeding, including:
 - a) Directed interventions, including hemostatic agents.
 - b) Protocols for rapid reversal of anticoagulants.
 - c) Assessment of recovering and reinfusing shed blood.
 - d) Utilization of program-defined rapid testing for coagulation management.
- 4) Timely delivery of blood components.

5.7 Methods for PBM during Surgery and Invasive Procedures

The program shall define and review methods for managing blood loss during surgery or invasive procedures.

5.8 Postoperative or Postintervention Patient Care

The program shall ensure the monitoring, evaluation, and treatment of postoperative anemia and coagulopathy.

5.8.1 The program shall oversee and review compliance with established PBM guidelines. Standard 5.1.11 applies.

5.9 Management of Patients Undergoing Minimally Invasive Procedures

The program shall oversee and review:

- 1) Processes to discuss with patients the availability of alternative therapies to transfusion.
- 2) The prescribing and ordering of blood and blood components or alternatives to transfusion.

5.10 Anemia Care for Inpatients

Based on activity level, the program shall have policies, processes, and procedures in place to manage anemia in nonsurgical inpatients, including patients with iron and/or micronutrient deficiency.

5.11 PBM for Obstetric Patients

The program shall oversee and review policies, processes, and procedures for obstetric patients, including:

- 1) Identification and management of pregnancies with known risk for hemolytic disease of the fetus and newborn or neonatal alloimmune thrombocytopenia.
- 2) Patients for whom blood is not an option.
- 3) Antepartum and postpartum anemia management.
- 4) Optimization of patient coagulation and fibrinogen status.

5.11.1 Postpartum Hemorrhage Preparedness and Management

Postpartum hemorrhage preparedness and management shall include:

- 1) Quantitative assessment of maternal blood loss .
- 2) Identification of patients with known high bleeding risk (eg, placental implantation abnormalities).
- 3) Proper use of antifibrinolytic agents (eg, tranexamic acid).
- 4) Consideration of point-of-care testing (eg, viscoelastic testing), and autotransfusion (eg, cell salvage), as applicable.
- 5) Postpartum hemorrhage protocol, including predelivery risk assessment, postdelivery patient identification with a stepwise process to manage bleeding, massive transfusion/massive hemorrhage protocol, and/or patient transfer.
- 6) Identification of patients for whom blood is not an option.

5.12 Massive Blood Loss and Emergent Care

The program shall ensure compliance with the program's massive transfusion/hemorrhage protocol for patients experiencing massive bleeding and other emergent situations in. Standard 1.3 applies.

5.13 Reversal of Acquired Coagulopathy

The facility shall have a plan in place to rapidly identify and manage acquired coagulopathy including reversal when clinically indicated. This plan shall include the dispensing of medications and/or blood and blood components as clinically indicated. The program shall review the facility's plan at defined intervals.

5.14 PBM for Pediatric Patients

The program shall establish guidelines and plans for the care of preterm and term neonates, infants, and children.

5.15 PBM for Outpatients

The program shall oversee and review policies or processes to ensure:

- 1) Iron and/or micronutrient deficiency is considered, evaluated, and corrected in patients with RBC transfusion orders in the outpatient setting.
- 2) Monitoring platelet transfusion practices including feedback to clinical services.

Standard 5.1.11 applies.

5.16 Performance Indicators

The program shall obtain and review the following data at least quarterly (unless noted):

- 1) Work up and management of anemia in defined patient populations.
- 2) Iron and micronutrient deficiency identification and management in defined patient populations.
- 3) Bloodless program evaluation of effectiveness.
- 4) Blood and blood component use appropriateness.
- 5) Single-unit RBC, and platelet transfusion practice performance metric.
- 6) Blood and blood component wastage and discard, including reasons for unused components.
- 7) Crossmatch-to-transfusion ratio.
- 8) Informed consent for blood transfusion.
- 9) Massive transfusion/massive hemorrhage protocol use.
- 10) Prevalence of iatrogenic anemia.
- 11) Use of intraoperative blood recovery equipment and quality control.
- 12) Blood infusion equipment maintenance program (annually).

Standard 8.4 applies.

Excerpt of Reference Standard 6.2.9A Relevant to Process Control

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	5
5.1.8	Identification and traceability of products	5
5.1.11	Evidence based PBM guidelines	5
5.1.12	Review of blood management and utilization practices	5
5.1.13	Blood management educational materials	5
5.3	Patient consent	5
5.3.2	Alternative strategies acceptable to patients who decline blood	5

¹Applicable state or local law may exceed this period.

QSE 6 – Documents and Records

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

Key Terms

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

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

Data Integrity: The accuracy, completeness, and consistency of information 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 PBM Standards, including information for document control.

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

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

Examples of Objective Evidence

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

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

DRAFT

6.0 Documents and Records

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

6.1 Document Control

The organization shall control all documents that relate to the requirements of these *PBM 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 *PBM 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 *PBM Standards*.

6.1.5 Review of Policies, Processes, and Procedures

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

6.1.6 Document Retention

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

6.1.7 Document Storage

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

6.1.8 Document Retrieval

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

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

6.1.10 Documents and records related to transfusion medicine or perioperative programs records shall be created and controlled in accordance with the *AABB Standards for Blood Banks and Transfusion Services* and *AABB Standards for Perioperative Autologous Blood Collection and Administration* or the requirements of an equivalent accrediting body.

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.

6.2.3 Information to Be Retained

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

6.2.4 Legibility

All records shall be legible and indelible.



6.2.5 Record Change

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

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

6.2.6 Records shall be created concurrently with 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 *PBM 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.

6.2.11.1 The record storage system shall ensure compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations.

6.2.11.1.1

The program shall have access to patient records. Information in the record system shall allow the program to trace any patient from the preoperative/pretransfusion period to the postoperative/posttransfusion period, and the care and blood management services provided to the patient. In addition, the record system shall allow the evaluation of outcomes of specific interventions associated with blood management and investigate adverse events.

6.2.12 Destruction of Records

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

6.3 Electronic Records

The organization shall support the management of information systems.

6.3.1 Access to Data and Information

Access to data and information shall be controlled.

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



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

6.3.1.2 There shall be a process in place for linking patient records to those contained in the laboratory information system.

6.3.2 Data Integrity

Data integrity shall ensure that data are retrievable and usable.

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

6.3.2.2 Data shall be retrievable for the entire retention period.

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

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

6.3.3 Storage Media

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

6.3.4 Backup Data

The organization shall back up all critical data.

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

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

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

Excerpt of Reference Standard 6.2.9A Relevant to Documents and Records

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

¹Applicable state or local law may exceed this period.

Reference Standard 6.2.9A – Retention of Records

Standard	Record to Be Maintained	Minimum Retention Time (Years) ¹
1.1.1.2	Delegation of medical director responsibilities to another qualified individual(s)	5
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	5
1.3.2	Exceptions to policies, processes, and procedures	5
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
2.1.6	Continuing education requirements	5
2.1.7	Facility-defined educational requirements for individuals who order and/or transfuse blood	5
3.2	Equipment qualification	5
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	2 years after retirement of the system
3.6	Monitoring of technology infrastructure	10
3.6.1	Artificial intelligence oversight	10
3.6.2	Artificial intelligence risk assessment	10

3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of the 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	5
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	5
5.1.8	Identification and traceability of products	5
5.1.11	Evidence based PBM guidelines	5
5.1.12	Review of blood management and utilization practices	5
5.1.13	Blood management educational materials	5
5.3	Patient consent	5
5.3.2	Alternative strategies acceptable to patients who decline blood	5
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	5
7.2	Nonconforming products or services	5
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	5
7.2.4.1	Disposition of the nonconforming product or service	5

7.4	Investigations of Deviations, Nonconformances, and Adverse Events	5
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	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	5

¹Applicable state or local law may exceed this period.

QSE 7 – Deviations, Nonconformances, and Adverse Events

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

Key Terms

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

Examples of Objective Evidence

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

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

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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.

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 applicable.

7.3.3 Characterization of Adverse Events

Adverse events shall be characterized using defined criteria, managed and reported in accordance with applicable regulations.

7.4 Investigations of Deviations, Nonconformances, and Adverse Events

The investigation shall, when applicable, include a documented assessment of the effect of PBM program deviations on patient safety. The responsibility for review and authority for the disposition of nonconforming medications, blood, blood components, perioperative products, critical materials, and services shall be defined.

7.4.1 Deviations, nonconformances, and adverse events shall be reported in accordance with specified requirements.

7.4.2 Trend Analysis

The organization shall analyze aggregated data on deviations, nonconformances, and adverse events to detect safety signals, trends, and clusters, and shall document resulting risk minimization actions at defined intervals.

7.4.3 The program shall ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the *AABB Standards for Blood Banks and Transfusion Services* and *AABB Standards for Perioperative Autologous Blood Collection and Administration* or the requirements of an equivalent accrediting body.

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

Standard	Record to Be Maintained	Minimum Retention Time (Years)¹
7.1	Deviations	5
7.2	Nonconforming products or services	5
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	5
7.2.4.1	Disposition of the nonconforming product or service	5
7.4	Investigations of Deviations, Nonconformances, and Adverse Events	5

¹Applicable state or local law may exceed this period.

QSE 8 – Internal and External Assessments

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

Key Terms

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

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

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 Review Process

The program shall collect, tabulate, and analyze data at defined intervals and determine the number and type of nonconformances.

8.6 Reporting

The program shall report annually on its performance. The report shall include, but not be limited to, the following if required for the program's activity level:

- 1) Overall program effectiveness and opportunities for improvement.
- 2) Program's performance goals and other resources for next reporting period.
- 3) Program's financial impact.
- 4) Compliance with recommendations made by the PBM program.
- 5) Effectiveness of pretransfusion anemia management.
- 6) Use and efficacy of preoperative anemia management interventions.
- 7) Use of perioperative blood conservation techniques.
- 8) Use and effectiveness of the emergency/massive transfusion/ massive hemorrhage processes and protocols.
- 9) Allogeneic transfusion rates overall and by program defined high-blood-use service lines.
- 10) Appropriateness of allogeneic transfusion overall and by program-defined high-blood-use service lines.

- 11) Blood and blood component discard and cause(s) of waste.
- 12) Adverse events associated with PBM activities.

Excerpt of Reference Standard 6.2.9A Relevant to Internal and External Assessments

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

¹Applicable state or local law may exceed this period.

QSE 9 – Process Improvement

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

Key Terms

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

Examples of Objective Evidence

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

9.0 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.

9.1.2 As an element of corrective action, the program shall monitor:

- 1) Ordering practices.
- 2) Use of transfusion and/or alternatives.
- 3) Effectiveness of transfusions and/or alternatives.
- 4) Adverse events, including suspected transfusion reactions and other patient complications.
- 5) Knowledge gaps and assigned appropriate training or retraining, as applicable.

Standard 2.1.4 applies.

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.

9.4 Data Collection

The program shall provide all data generated from the utilization review process to the program members for review and analysis.

9.4.1 These data shall be analyzed for trends across the institution and within specific departments or services.

Excerpt of Reference Standard 6.2.9A Relevant to Process Improvement

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

¹Applicable state or local law may exceed this period.

QSE 10 – Facilities and Safety

Key Concepts This QSE addresses the safety and adequacy of areas where the work required by these PBM 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.

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.

Excerpt of Reference Standard 6.2.9A Relevant to Facilities and Safety

Standard	Record to Be Maintained	Minimum Retention Time¹
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	5

¹Applicable state or local law may exceed this period.

Glossary

Acute Normovolemic Hemodilution: The short-term removal of whole blood (usually immediately following induction of anesthesia) into a standard blood bag containing anticoagulant, with the simultaneous replacement of intravascular volume using acellular fluids. The product is reinfused to the patient during the perioperative period after anticipated significant blood loss has ended. It does not include the hemodilution that occurs due to extracorporeal circulation, or routine fluid replacement. Acute normovolemic hemodilution, for the purposes of these *PBM Standards*, does not include autologous blood donation.

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.

Anemia: The condition where a reduced healthy hemoglobin impairs the delivery of oxygen to body tissues.

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

Autologous: Concerning blood, involving a specific person as both the donor and the recipient.

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

Blood is Not an Option: Instances when individuals have religious or personal reasons to decline transfusion, instances when individuals have unusual blood types or alloimmunization for which components are not available, and circumstances of inadequate blood supply.

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.

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

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

Compliance: See Conformance.

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

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

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

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

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, 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.

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.

Hospital Administration: The individual(s) who has responsibility for the patient blood management program, but that are not actively involved in patient care.

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.

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.

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

Massive Hemorrhage: Blood loss exceeding the circulating volume within a 24-hour period. Programs develop protocol(s) to ensure rapid recognition, response, and intervention to care for those patients experiencing a massive hemorrhage event. This protocol is activated when the health-care provider anticipates the hemorrhage event will require massive transfusion support.

Massive Transfusion: The replacement of a patient's entire blood volume within a 24-hour period.

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

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

Maximum Surgical Blood Ordering Schedule: An institution-specific list of surgical procedures with the standard preoperative blood order for each procedure (ie, no blood order, type and screen, or type and crossmatch for a certain number of units) to optimize the availability of blood components for patients during the surgical procedure while limiting excessive ordering and wastage.

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.

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.

Patient Blood Management (PBM): An evidence-based, patient-centered, systematic, multidisciplinary approach to caring for patients who might require a blood transfusion. PBM is meant to improve patient outcomes by preserving a patient's own blood through diagnosis and etiology specific treatment of anemia and bleeding. PBM encompasses all aspects of the transfusion decision-making process, from the initial patient evaluation through all phases of clinical management. This approach is designed to promote optimal patient outcomes while maintaining the blood supply to help ensure that blood components are available when needed.

PBM Program: A program within an organization that provides the services outlined in these *PBM Standards*.

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.

Perioperative: During the time around a surgical procedure. For these *PBM Standards*, the perioperative period typically includes the day of surgery and the first day after surgery.

Perioperative Product: Whole blood, blood components, recovered blood, or blood component concentrates collected or administered during the perioperative period.

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

Postoperative: After a surgical procedure.

Preoperative: Before a surgical procedure.

Preterm Neonate: A premature infant born before 37 completed weeks of gestation.

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

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

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

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

Product: A tangible output from a process.

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.

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.

Regulatory Enforcement Action: Measures taken by a Competent Authority that include but are not limited to progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues, deficiencies in risk management systems.)

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.

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.

Specified Requirements: Any requirements in these PBM 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.

System: A subgroup of related activities performed by a particular organization. Activities dealing with maintaining product and service quality are organized into a quality system.

Third-Party Provider: An entity that contracts with a hospital or other medical facility to provide on-site PBM services.

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

Transfusion Index: A blood utilization metric that measures the number of units transfused compared to the number of patients crossmatched.

Transfusion Probability: A metric that measures how efficiently blood is used. Defined as the number of patients transfused divided by the number of patients crossmatched, multiplied by 100.

User-Defined Tables: Data maintained in tables and used by computer programs to direct their operations. Typically, user-defined tables contain data unique to a specific installation, and thus they 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.

When Blood Is Not an Option: See *"Blood is Not an Option"*