PROPOSED Standards for a Patient Blood Management Program

5th Edition

A Note to Readers

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

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

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

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

- Please note, that the Summary of Significant Changes to the proposed 5th edition begins on page 2 and runs through page 13. The proposed 1st edition begins on page 14 and runs through page 69.

Updated Quality System Essentials

The proposed 5th edition of Standards for a Patient Blood Management Program has incorporated the updated quality system essentials (QSE) template for this edition. This includes a number of updates to the chapters and the tone and flow of the edition.

Highlights of the updated QSEs include:

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

Driving factors behind the revisions to the updated QSEs:

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

Significant Changes to the Proposed 5th edition of Standards for a Patient Blood Management Program

1.1.2.1 A PBM program can be designated as a program activity Level 1, 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:

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
2.	Budgeting to the level of care required by implementing these *PBM Standards*	X	X	X

#2 previously appeared as #5 and was moved to mirror the proper workflow.

3.	~~Pretransfusion~~ Patient ~~testing~~ evaluation **for intervention**	X	X	X

#3 has been updated reflecting that the term "pretransfusion" implied a "transfusion" would always happen, which is not always the case. The elements in bold were included to ensure that the patient was evaluated to determine what actions would be taken based on the patient evaluation.

5.	Patient-or case-specific assessment of potential blood usage	X	X	X

#5 previously appeared as #7 and was moved to mirror the proper workflow.

~~7~~	~~Budgeting to the level of care required by implementing these *PBM Standards*~~	~~X~~	~~X~~	~~X~~

Former #7 was deleted as the committee wishes the focus of this edition of to be on patient care and not a question of financials.

8.	~~Preprocedure~~ Assessment and management of patient coagulation status, **as applicable**	X	X	X

#8 has been edited recognizing that the previous wording implied that a procedure is a guarantee. The addition of "as applicable" complements the edit made as noted above.

12.	Process to identify, before or upon admission, patients who may decline transfusion ~~with notification to the appropriate individuals (including providers) and noted in the patient's medical record~~	X	X	X

#12 has been edited recognizing that this would be a part of the consent process and that the notification element to each individual may not be possible in all instances due to the limitations of current EMRs.

13.	**Process to include shared decision-making during documented patient consent for receipt or**	**X**	**X**	**X**

	documented decline of blood and blood components			

#13 is new to the proposed edition and was included recognizing the need for programs to have a process to ensure that the patient and clinician can have a dialogue about whether to consent for transfusion or not.

15	**PBM care for** ~~Transfusion care and anemia management of~~ preterm, neonate, infant, and pediatric critical care patients, if applicable	X	X	X

#15 has been edited recognizing that transfusion and anemia care are a part of PBM care overall.

16	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	X

#16 has been edited for completeness and parallel construction.

21	Processes and equipment to facilitate rapid decision-making concerning anemia and coagulation management	X	**N/A** ~~X~~	N/A

#21 has been moved from a level 1 and 2 activity to just level1 recognizing that this requirement would not fit for all level 2 programs.

25	~~PBM~~ **Program to** care for patients undergoing cardiac surgical or structural heart procedures	X	N/A	N/A

#25 has been updated for clarity to focus on patient care, for as previously written the entry could be misread.

~~6.4~~ 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.

~~6.4.1~~ 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.

These standards previously appeared in chapter 6, however the committee felt that they would fit more appropriately in chapter 1. The content or intent of the standards have not changed.

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

The committee edited standard 1.6.2 to focus on PBM program with specific wording to that effect as opposed to the broad perspective from the previous edition that could have been read as a BB/TS focused standard.

5.1.10 The program shall ensure that:

1) Patients with anemia ~~who may or may not need a transfusion are also~~ are assessed and ~~for other means by which anemia may be~~ managed, ~~including by minimizing bleeding and treating anemia with medications.~~.
2) Patients who may need transfusion are evaluated and managed such that blood **and blood components are** ~~is~~ given when clinically indicated.
3) Patients with or at risk for coagulopathy are evaluated and managed.
4) **Internal quality metrics are in place and reported.**

#1 has been edited for clarity, recognizing that the elements in strikethrough better fit as guidance and the committee felt that providing a straight forward requirement was more appropriate.
#2 was edited for clarity.
#3 previously appeared as #4 and was reordered to follow proper workflow.
#4 previously appeared as #2 and was reordered to follow proper workflow.

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** ~~avoid unnecessary transfusion and ensure early and rapid delivery of blood components to those who need them~~. 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 transfusion.**

The committee edited the body of the second sentence to focus on managing the patient without the element in strikethrough which is focused on the giving of blood as opposed to patient management.

Subnumber 4 has been added to recognize that there are instances where blood is needed, with the caveat that blood be administered when appropriate.

Subnumber 5 has been added to recognize that steps should be taken to avoid, when possible, the administration of blood to a patient.

✎ **5.1.13 Educational Materials**

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

1) Describe PBM strategies in the facility ~~including, and as relevant to activity level, general PBM, and any or all PBM in surgical, pediatric, obstetric, and outpatients.~~
2) Describe anemia management in ~~perioperative~~ patients.
~~3) Describe anemia management in medical patients.~~
3) Describe coagulopathy evaluation and management ~~in surgical patients~~.
4) Discuss the risks and benefits of transfusion of blood components and transfusion avoidance.
5) Review the alternatives to transfusion, including pharmacologic therapies.
6) Evaluate appropriate ordering of blood components based on clinical indicators.

#1 was edited recognizing that the elements in strikethrough fit better in guidance.
#2 was edited to focus on all patients, allowing #3 to be deleted.
#6 was added to ensure that all educational materials given to hospital personnel includes blood ordering requirements based on the clinical situation.

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 change their transfusion directive.

Standard 2.1.2 applies.

The committee added new #4 for completeness recognizing that the patient's ability to change their intent to receive transfusion was included as an element of the consent process.

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.

The committee added the clause in bold to ensure that strategies surrounding coagulopathy are discussed with patients as an element of the consent process.

5.4.1 The program shall have policies for **blood component transfusion volume and frequency** ~~single-unit component transfusion strategies for defined clinical settings~~ **when transfusion is indicated**.

5.4.2 The program shall promote the use of single-unit component transfusion strategies.

The committee added the elements in bold for completeness, while including the clause "when transfusion is required" to reflect the principle of not transfusing blood to patients as the primary course of action.

Standard 5.4.2 is new, however the content previously appeared as a part of standard 5.4.1. The committee recognized that this element should appear as its own standard.

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

The committee replaced the term "measure" with "assess" as it was deemed more accurate.
The committee also inverted the second half of the sentence for clarity.

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 ~~for identification of patients who decline transfusion~~ **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** ~~prescribing and ordering of~~ appropriate blood components or transfusion-related pharmaceuticals (eg, factor concentrates, antifibrinolytics, hemostatic agents).

#1 is new to the proposed edition and was added in in conjunction with the addition to standard 5.3.2.
#2 has been edited to build on the previous wording to expand the standard beyond patients who decline transfusion.
#4 is new to the proposed edition and was added to ensure that programs have the appropriate level of staff and equipment to provide the optimal level of patient care.
#5 previously appeared as #1, the content of the standard has not changed..
#6 has been updated for clarity.

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

#1 previously appeared a #4, the content of the standard has not changed.
#2 has been expanded to include "coagulopathy" to the standard mirroring similar additions to previous standards.
#3 has been edited to mirror subnumber 2.

#4 has been expanded to ensure that a review of the medications the patient has been prescribed prior to surgery.
#5 has been edited to for clarity and mirrors the language in the standard.

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** ~~Identification~~ of unknown **or unidentified** patients.
2) Assessment of bleeding risk**, including review of the patient's current medications, if available.**
3) Assessment of patient for pre-existing anemia and physiologic ability to tolerate blood loss.
4) 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.
5) Timely delivery of blood components.

#1 has been updated for clarity while expanding the content of the standard.
#2 has been expanded mirroring the addition to subnumber 4 in standard 5.6.1.
#4 previously appeared as #5, the content of the standards has not changed.
#5 previously appeared as #4, the content of the standard has not changed.

5.8 Postoperative or Postintervention Patient Care

The program shall ensure **the** monitoring**, evaluation, and treatment of postoperative anemia and coagulopathy** ~~of patients after the procedure to determine the need for postoperative transfusion, or other anemia care, including iron and other micronutrient replenishment~~.

The committee edited standard 5.8 for clarity and to mirror changes made throughout the edition. The elements in strikethrough are covered by the additions in bold and underlined.

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

Standard 5.8.1 previously appeared as the last sentence in standard 5.8. The content of the language has not changed.

5.9 Patients Who Do Not Require Invasive Procedures

The program shall oversee and review:

~~1) Procedures for identifying patients who may benefit from medications or treatments to minimize the need for allogeneic transfusion.~~
1) **Process to discuss with patients the availability of alternative therapies to transfusion.** ~~Procedures for identification of patients who decline transfusion.~~
2) The prescribing and ordering of **blood and** blood components or alternatives to transfusion.

Subnumber 1 previously appeared as subnumber 2 and has been edited to include both concepts that previously appeared as two separate subnumbers. This mirrors changes made throughout the proposed

edition.
Subnumber 3 has been expanded to include "blood and" to mirror the content of other standards.

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.

#2 previously appeared as subnumber 1, and subnumber 1 previously appeared as subnumber 2. Subnumber 2 has also been edited to include the concept in bold that has been added to the edition. #4 is new to the proposed edition and was added for completeness recognizing that ensuring that not optimizing fibrinogen status could lead to clotting.

5.11.1 Postpartum Hemorrhage Preparedness and Management

Postpartum hemorrhage preparedness and management shall identify:

1) Quantitative cumulative assessment of maternal blood loss for all patients.
2) Patients with known high bleeding risk (eg, placental implantation abnormalities).
3) Use of antifibrinolytic agents (eg, tranexamic acid)
4) Consideration of point-of-care testing (eg, viscoelastic testing), auto-transfusion (eg, cell salvage).
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) Patients for whom blood is not an option**, including those who decline blood and blood components**.

#3 has been added recognizing that these agents can help to prevent or treat serious bleeding.
#4 has been added for clarity.
#6 previously appeared as #1, and has been edited to mirror the language included throughout the edition.

~~**5.16 High Blood Use Service Lines**~~

~~The program shall oversee and review policies, procedures, and plans by high blood loss service lines to ensure strategies are in place to manage blood loss and treat anemia.~~

Standard 5.16 has been deleted and added as element #15 in standard 5.16 (previously 5.17).

5.16 Performance Indicators

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

1) Anemia program utilization.
2) Iron and micronutrient deficiency identification and management in the outpatient transfusion setting.

3) Biennial external assessment results (eg, AABB or equivalent accrediting body).
4) Bloodless program enrollment/evaluation of effectiveness.
5) Blood and blood component use.
6) Blood and blood component use appropriateness.
7) Single-unit Red Blood Cell transfusion practice performance metric.
8) Blood and blood component wastage and discard, including reasons for unused components.
9) Transfusion index and transfusion probability.
10) Crossmatch-to-transfusion ratio.
11) Blood administration policy compliance.
12) Deviation from transfusion service procedures or protocols.
13) Transfusion reactions by category.
14) Informed consent for blood transfusion.
15) High usage service lines.
16) Massive transfusion/massive hemorrhage protocol use.
17) Use of intraoperative blood recovery equipment and quality control.
18) Blood infusion equipment and warmer(s) maintenance program (annually).

Standard 8.4 applies.

#1 previously appeared as #12, #2 previously appeared as #13, #3 previously appeared as #15, and #4 previously appeared as #16. These changes were made to move the elements that did not focus on the receipt of blood but rather the patient.
#9 is new to the proposed edition and was added as a data point for programs to track.
#15 is new to the proposed edition and was added with the deletion of standard 5.16 as noted above.

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.

7.4 Investigations of Deviations, Nonconformances, and Adverse Events

The investigation shall, when applicable, include an assessment of the effect of Patient Blood Management 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 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.

Standards 7.4 – 7.4.2 previously appeared as a part of 7.1 in the previous edition. The content of the standards have not changed.

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 needs for next reporting period.
3) Program's financial impact.
4) Compliance with recommendations made by the Patient Blood Management 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 patient blood management activities.

#2 previously appeared as #12, however the content of the standard has not changed.
#3 previously appeared as #11, however the content of the standard has not changed.
#4 previously appeared as #9, however the content of the standard has not changed.
#5 previously appeared as #7, however the content of the standard has not changed.
#6 previously appeared as #5, however the content of the standard has not changed.
#7 previously appeared as #6, however the content of the standard has not changed.
#9 previously appeared as #2, however the content of the standard has not changed.
#10 previously appeared as #3, however the content of the standard has not changed.
#11 previously appeared as #4, however the content of the standard has not changed.
#12 previously appeared as #10, however the content of the standard has not changed.

These changes were made to move the elements that did not focus on the receipt of blood but rather the patient.

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

1) ~~A provider's~~ 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) **Employee knowledge gaps and assigned appropriate training or retraining, as applicable.**

#1 has been updated for clarity, expanding the content.
#5 is new to the proposed edition and was included to recognize that educational elements are a part of corrective action plans.

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 ~~would~~ **does** not include autologous blood donation.

The committee edited the glossary entry for accuracy.

Anemia: ~~A~~ **The** condition **where a reduced healthy hemoglobin impairs the delivery of oxygen to** ~~in which the~~ body **tissues** ~~does not have enough healthy red blood cells. Red cells provide oxygen to body tissues.~~

The committee edited the glossary entry for accuracy.

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.~~

The committee removed the elements in strikethrough as they were deemed too restrictive for the glossary.

Massive Transfusion: The replacement of a patient's entire blood volume in a **within a** 24-hour **period**. ~~This could include at least 6 Red Blood Cell units, along with non-red cell components such as platelets, Fresh Frozen Plasma, and fibrinogen in fixed ratios to reconstitute shed whole blood for the management of hemorrhagic shock.~~

The committee removed the elements in strikethrough as they were deemed too restrictive for the glossary.

Patient Blood Management: 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.

The committee created a new definition based on the concepts covered on the AABB website, the WHO definition and the definition from SABM. The hybridization of the entry mirrors the expectations of the community and provides a definition for the program which was requested by commentors.

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.

The committee added these definitions based on the inclusion of the terms into standard 5.16.

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 of data on 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.

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

1) Leadership and oversight on clinical issues.
2) Consultative and support services on PBM matters that relate to the care and safety of patients.
3) Identification 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 these responsibilities to another qualified individual(s); however, the medical director shall retain ultimate responsibility.

1.1.2 Executive management shall define the activities of the PBM program tied to patient outcomes.

1.1.2.1 A PBM program can be designated as a program activity Level 1, 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:

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
1	Evidence of institutional support for the PBM program at the hospital administration level	X	X	X
2	Budgeting to the level of care required by	X	X	X

	implementing these *PBM Standards*			
3	Metrics regarding transfusion appropriateness consistent with transfusion guidelines	X	X	X
4	Patient evaluation for intervention	X	X	X
5	Patient-or case-specific assessment of potential blood usage	X	X	X
6	Documentation of transfusion including patient consent, observation, adverse events, and outcomes	X	X	X
7	Preprocedure blood ordering including completion of type and antibody testing before procedure start time with a plan for antibody-positive patients	X	X	X
8	Assessment and management of patient coagulation status, as applicable	X	X	X
9	Monitoring of blood component wastage and cause	X	X	X
10	Minimize blood loss due to laboratory testing (iatrogenic blood loss)	X	X	X
11	Process for managing the blood needs or unidentified patients and resolving their identification	X	X	X
12	Process to identify, before or upon admission, patients who may decline transfusion	X	X	X
13	Process to include shared decision-making during documented patient consent for receipt or documented decline of blood and blood components	X	X	X
14	Massive transfusion/massive hemorrhage protocol for all patient populations with documented evaluation of activation and protocol workflow effectiveness and evidence of its use	X	X	X
15	PBM care for preterm, neonate, infant, and pediatric critical care patients, if applicable	X	X	X
16	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	X
17	Single-unit transfusion strategies for defined clinical settings	X	X	X
18	Management of acquired coagulopathy	X	X	X
19	Blood conservation strategies for service lines associated with high blood usage	X	X	N/A
20	Evaluating and managing iron and micronutrient deficiencies in patients with Red Blood Cells ordered in the inpatient and outpatient populations	X	X	N/A
21	Processes and equipment to facilitate rapid decision-making concerning anemia and coagulation	X	N/A	N/A

	management			
22	Evaluation and management of identified anemia in patients	X	N/A	N/A
23	Identification and management of presurgical anemia before elective procedures for patients at risk for Red Blood Cell transfusion and/or adverse consequences of postsurgical anemia	X	N/A	N/A
24	Program to care for patients who decline use of blood or blood derived components	X	N/A	N/A
25	Program to care for patients undergoing cardiac surgical or structural heart procedures	X	N/A	N/A
26	Use of perioperative techniques consistent with current AABB *Standards for Perioperative Autologous Blood Collection and Administration*	X	N/A	N/A

1.1.3 Program Coordinator

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

1.1.4 Program Members

The program shall include representatives 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 components and the management of anemic and bleeding patients.

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, and maintained 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 1.1.2.1 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 define and address 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 all PBM operations and procedures to include all ancillary services and support to this program.

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.

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 year retention time

[1]Applicable 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 clinical 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

[1]Applicable 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.

3.6 Equipment Traceability

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

1) Equipment to be uniquely identified and traceable.
2) Tracing of any given product or service to all equipment associated with the procurement, processing, storage, distribution, and administration of the product or service.

3.7 Information Systems

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

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

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 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.

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	Equipment traceability	5
3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of the system

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

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

[1]Applicable 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.

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 of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated.

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 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) Internal quality metrics are in place and reported.

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.

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

✎5.1.12Monitoring

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.

✎5.1.13Educational Materials

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

1) Describe PBM strategies in the facility including, and as relevant to activity level, general PBM, and any or all PBM in surgical, pediatric, obstetric, and outpatients.
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 pharmacologic therapies.
6) Evaluate appropriate ordering of blood components based on clinical indicators.

5.2 Phlebotomy

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

✎5.3 Consents, Approvals, and Notifications

The program shall participate in developing and revising of 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 change their transfusion directive.

Standard 2.1.2 applies.

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.

5.4 Transfusion Orders

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

5.4.1 The program shall have policies for blood component transfusion volume and frequency when transfusion is indicated.

5.4.2 The program shall promote the use of single-unit 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 pre-transfusion testing policies, processes, and procedures. These policies shall be consistent with the 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. Situations 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 quarterly 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 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.
2) Evaluation and management of preprocedure anemia and coagulopathy.
3) Evaluation of safe and effective discontinuation of anticoagulants and/or platelet inhibitors.
4) Assessment of bleeding risk, including review of the patient's current medications.
5) 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) Management of the blood or blood component needs of unknown or unidentified patients.
2) Assessment of bleeding risk, including review of the patient's current medications, if available.
3) Assessment of patient for pre-existing anemia and physiologic ability to tolerate blood loss.
4) 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.
5) 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.

5.9 Patients Who Do Not Require Invasive Procedures

The program shall oversee and review:

2) 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 suffering from 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:

2) 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.

5.11.1 Postpartum Hemorrhage Preparedness and Management

Postpartum hemorrhage preparedness and management shall identify:

1) Quantitative cumulative assessment of maternal blood loss for all patients.
2) Patients with known high bleeding risk (eg, placental implantation abnormalities).
3) Use of antifibrinolytic agents (eg, tranexamic acid)
4) Consideration of point-of-care testing (eg, viscoelastic testing), auto-transfusion (eg, cell salvage).
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) Patients for whom blood is not an option, including those who decline blood and blood components.

5.12 Massive Blood Loss and Emergent Care

The program shall have policies, processes, and procedures for the timely delivery of blood and blood components to manage patients experiencing massive bleeding and patients in other emergent situations.

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.

5.13 Reversal of Acquired Coagulopathy

The program shall have a plan in place to rapidly reverse acquired coagulopathy. This plan shall include the dispensing of medications and/or blood and blood components as clinically indicated. The program shall monitor the 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 that iron and/or micronutrient deficiency is considered, evaluated, and corrected in patients with Red Blood Cell transfusion orders in the outpatient setting.

5.16 Performance Indicators

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

6) Anemia program utilization.
7) Iron and micronutrient deficiency identification and management in the outpatient transfusion setting.
8) Biennial external assessment results (eg, AABB or equivalent accrediting body).
9) Bloodless program enrollment/evaluation of effectiveness.
10) Blood and blood component use.
6) Blood and blood component use appropriateness.
7) Single-unit Red Blood Cell transfusion practice performance metric.
8) Blood and blood component wastage and discard, including reasons for unused components.
9) Transfusion index and transfusion probability.
10) Crossmatch-to-transfusion ratio.
11) Blood administration policy compliance.
12) Deviation from transfusion service procedures or protocols.
13) Transfusion reactions by category.
14) Informed consent for blood transfusion.
15) High usage service lines.
16) Massive transfusion/massive hemorrhage protocol use.
17) Use of intraoperative blood recovery equipment and quality control.
18) Blood infusion equipment and warmer(s) 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
5.1.12	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

[1]Applicable 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.

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 post-operative/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

[1]Applicable 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 year retention time
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	Equipment traceability	5

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
5.1.12	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
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

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

QSE 7 – Deviations, Nonconformances, and Adverse Events

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

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

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

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

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

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

Nonconformance: Failure to meet requirements.

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

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

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

7.0 Deviations, Nonconformances, and Adverse Events

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

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.

7.4 Investigations of Deviations, Nonconformances, and Adverse Events

The investigation shall, when applicable, include an assessment of the effect of Patient Blood Management 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 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

[1]Applicable 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 needs for next reporting period.
3) Program's financial impact.
4) Compliance with recommendations made by the Patient Blood Management 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 patient blood management 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

[1]Applicable 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) Employee 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

[1]Applicable 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 Time[1]
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	5

[1]Applicable 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.

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).

Damage Control Procedures: Preserving physiology at the expense of normal anatomy including but not limited to packing, shunts, tracheotomy, bowel stapling.

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.

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.

Intraoperative: During a surgical procedure.

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: 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.

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

Preoperative: Before a surgical procedure.

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.

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: Instances when individuals have religious or personal reasons to refuse transfusion, when individuals have unusual blood types or alloimmunization for whom components are not available, and in circumstances of inadequate blood supply.