Significant Changes and Response to Comments Received to the 5th edition of Standards a Patient Blood Management Program

Please note that public comments that were submitted address the proposed 5th edition of *Standards for a Patient Blood Management Program* (*PBM Standards*), and not the final version. The PBM Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 5th edition of *PBM Standards* in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that appears below.

Standard	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome
1.0	SC	NA	NA	The committee revised standard 1.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.0 Organization** The organization shall define the parties responsible for the provision of products or services.
1.1, #1	SC	NA	NA	The committee revised standard 1.1, #1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
1.1, #2	SC	NA	NA	The committee revised standard 1.1, #2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.1 Executive Management** The organization shall have a defined executive management. Executive management shall have: 2) Responsibility for compliance with these PBM Standards and applicable laws and

<table>
<tr><td></td><td></td><td></td><td></td><td>regulations, including all applicable current good manufacturing practice (cGMP) requirements.</td></tr>
<tr><td>1.1.2, Activity Level Chart Item 3 (Item 5)</td><td>SC</td><td>NA</td><td>NA</td><td>Activity Level #3 has been updated reflecting that the term “pretransfusion” implied a “transfusion” would always happen, which is not always the case. The clause, “…for intervention…” were included to ensure that the patient was evaluated to determine what actions would be taken based on the patient evaluation.
The entry reads as follows:
<table><tr><td>3</td><td>Patient evaluation for intervention</td><td>X</td><td>X</td><td>X</td></tr></table></td></tr>
<tr><td>1.1.2, Activity Level Chart Item 4 (DELETED)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee elected to remove former entry #4 from the edition wanting to focus the 5th edition of PBM Standards on patient care and not a financial element.
~~Budgeting to the level of care required by implementing these *PBM Standards*.~~</td></tr>
<tr><td>1.1.2, Activity Level Chart Item 7 (Item 8)</td><td>SC</td><td>NA</td><td>NA</td><td>Activity Level #7 has been edited by removing the term “Preprocedure” from the entry, recognizing that the previous wording implied that a procedure is a guarantee. The addition of “as applicable” complements the edit made as noted above.
The entry reads as follows:
<table><tr><td>7</td><td>Assessment and management of patient</td><td>X</td><td>X</td><td>X</td></tr></table></td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td><table><tr><td></td><td>coagulation status, as applicable</td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>1.1.2, Activity Level Chart Item 11 (Item 12)</td><td>SC</td><td>NA</td><td>NA</td><td>Activity level 11 has been edited by removing the clause, “-with notification to the appropriate individuals (including providers) and noted in the patient’s medical record” 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.
The entry reads as follows:<table><tr><td>11</td><td>Process to identify, before or upon admission, patients who may decline transfusion</td><td>X</td><td>X</td><td>X</td></tr></table></td></tr>
<tr><td>1.1.2, Activity Level Chart Item 12 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>Activity level 12 is new to the 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.
The entry reads as follows:</td></tr>
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<table>
<tr><td></td><td></td><td></td><td></td><td><table>
<tr><td>12</td><td>Process to include shared decision-making during documented patient consent for receipt, or documented decline, of blood and blood components</td><td>X</td><td>X</td><td>X</td></tr>
</table></td></tr>
<tr><td>1.1.2, Activity Level Chart Item 14</td><td>SC</td><td>NA</td><td>NA</td><td>Activity level 14 has been edited by replacing the clause, “Transfusion care and anemia management of” with “PBM care for” recognizing that transfusion and anemia care are a part of PBM care overall.
The entry reads as follows:<table>
<tr><td>14</td><td>PBM care for preterm, neonat</td><td>X</td><td>X</td><td>X</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td><table><tr><td></td><td>al, infant, and pediatric critical care patients, if applicable</td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>1.1.2, Activity Level Chart Item 15</td><td>SC</td><td>NA</td><td>NA</td><td>Activity level 15 has been edited to include the clause, “including those who decline blood and blood components.” for completeness and to maintain parallel construction with other entries in the table.
The entry reads as follows:<table><tr><td>15</td><td>PBM care for obstetric patients, including postpartum hemorrhage protocol with evidence of its use, plan(s) for</td><td>X</td><td>X</td><td>X</td></tr></table></td></tr>
</table>

					patients with known high bleeding risk (eg, placental abnormalities), and plan(s) for patients for whom blood is not an option, including those who decline blood and blood components			
1.1.2, Activity Level Chart Item 20 (Item 19)	SC	NA	NA	Activity level 20 has been moved from level 1 and 2 activity to level 1. This adjustment has been made recognizing that this requirement would not fit for all level 2 programs.				

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<tr>
<td>1.1.2, Activity Level Chart Item 24</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>Activity level 24 has been updated for clarity to focus on patient care by replacing the clause “PBM” with “Program” as it was previously written the entry could be misread.
The entry reads as follows:
<table>
<tr>
<td>24</td>
<td>Program to care for patients undergoing cardiac surgical or structural heart procedures</td>
<td>X</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</table>
</td>
</tr>
<tr>
<td>1.2 (New)</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>The committee revised standard 1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows:
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.</td>
</tr>
<tr>
<td>1.3</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>The committee revised standard 1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows:
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</td>
</tr>
</table>

				procedures shall be in writing or captured electronically and shall be followed.
1.3.1 (New)	SC	NA	NA	The committee added standard 1.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (1.3.1)	SC	NA	NA	The committee revised standard 1.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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, 1.3.3.1 (6.4, 6.4.1)	SC	NA	NA	Standards 1.3.3 and 1.3.3.1 previously appeared in chapter 6 as standards 6.4 and 6.4.1, however the committee felt that they would fit more appropriately in chapter 1. The content and intent of the standards have not changed.
1.4 (New)	SC	NA	NA	The committee added standard 1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.4 Risk Assessment** The facility shall have a process in place to perform risk assessments for activities at defined intervals.
1.4.1 (New)	SC	NA	NA	The committee added standard 1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.4.1** Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.
1.5	SC	NA	NA	The committee revised standard 1.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.5 Operational Continuity**

				The organization shall address continuity in the event that operations are at risk.
1.6 (1.4)	SC	NA	NA	The committee revised standard 1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.6 Emergency Preparedness** The organization shall have an emergency operation plan(s) to respond to the effects of internal and external disasters.
1.6.2 (New)				The committee added new standard 1.6.2 to the edition to focus on PBM program specific requirements as they relate to emergency management plans. The standard reads as follows: **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 (1.6)	SC	NA	NA	The committee revised standard 1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.8 Customer Focus** Executive management shall identify the organization's customers and their needs and expectations for products or services.

2.1.3 (2.1.2)	SC	NA	NA	The committee revised standard 2.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**2.1.3 Training** The organization shall provide training for personnel performing critical tasks.
2.1.4.1 (2.1.3.1)	SC	NA	NA	The committee revised standard 2.1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **2.1.4.1** Action shall be taken when competence has not been demonstrated.
2.1.5 (New)	SC	NA	NA	The committee added standard 2.1.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**2.1.5 Personnel Records** Personnel records for each employee shall be maintained.
2.1.5.1 (New)	SC	NA	NA	The committee added standard 2.1.5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 2.1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**2.1.6 Continuing Education** The organization shall ensure that continuing education requirements applicable to these *PBM Standards* are met when applicable.
3.0	SC	NA	NA	The committee revised standard 3.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.0 Equipment** The organization shall define and control critical equipment.

3.1	SC	NA	NA	The committee revised standard 3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.1 Equipment Specifications** Equipment specifications shall be defined before purchase.
3.2 (New)	SC	NA	NA	The committee added standard 3.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 3.2.1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.2.1 Installation Qualification** Equipment shall be installed per manufacturer specifications.
3.2.2 (New)	SC	NA	NA	The committee added standard 3.2.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.2.2 Operational Qualification** Each piece of equipment and component of an information system shall be verified before actual use.
3.2.3 (New)	SC	NA	NA	The committee added standard 3.2.3 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.2.3 Performance Qualification** Equipment shall perform as expected for its intended use.
3.3 (New)	SC	NA	NA	The committee added standard 3.3 to mirror all other AABB Standards and to match the AABB

				Quality System Essentials. The standard reads as follows: **3.3 Use of Equipment** Equipment shall be used in accordance with the manufacturer's written instructions.
3.4 (New)	SC	NA	NA	The committee added standard 3.4 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.4 Unique Identification of Equipment** Equipment shall have unique identification.
3.5 (New)	SC	NA	NA	The committee added standard 3.5 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.5 Equipment Monitoring and Maintenance** Equipment shall be monitored and maintained in accordance with the manufacturer's written instructions.
3.5.1 (New)	SC	NA	NA	The committee added standard 3.5.1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 3.5.1.1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows:

				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 (New)	SC	NA	NA	The committee added standard 3.5.1.2 based on updates to the AABB Quality System Essentials. The standard appears as follows: **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 (New)	SC	NA	NA	The committee added standard 3.5.1.3 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.1.3** Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.
3.5.2 (New)	SC	NA	NA	The committee added standard 3.5.2 based on updates to the AABB Quality System Essentials. The standard appears as follows: **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 potentially affected products or services (including those that have already been released or delivered) shall be verified.
3.5.3 (New)	SC	NA	NA	The committee added standard 3.5.3 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.3** The organization shall: 1) Define cleaning and sanitation 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 manufacturer's recommendations.
3.6 (New)	SC	NA	NA	The committee added standard 3.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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, #2 (3.8.1, #1)	SC	NA	NA	The committee updated standard 3.7, #2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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:

				2) Validation/verification/qualification of system software, hardware, databases, and user-defined tables before implementation.
3.7, #3 (3.8.1, #2)	SC	NA	NA	The committee updated standard 3.7, #3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 3) Fulfillment of life-cycle requirements for internally developed software.
3.7, #4 (3.1, #2)	SC	NA	NA	The committee updated standard 3.7, #4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 4) Defined processes for system operation and maintenance.
3.7, #5 (New)	SC	NA	NA	The committee added new subnumber 5 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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:

				5) Defined process for authorizing and documenting modifications to the system.
3.7, #6 (New)	SC	NA	NA	The committee added new subnumber 6 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 6) System security to prevent unauthorized access.
3.7, #7 (3.1, #3)	SC	NA	NA	The committee added subnumber 7 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
3.7, #8 (3.1, #4)	SC	NA	NA	The committee revised subnumber 8 to standard 3.7 based on updates to the AABB Quality System Essentials. The committee edited subnubmber 8 focused the display and verification of data before final acceptance of the additions or alterations. The standard reads as follows: **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: 8) Functionality that allows for display and verification of data before final acceptance of the additions or alterations.
3.7, #10 (New)	SC	NA	NA	The committee added subnumber 10 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 10) System design that establishes and maintains unique identity of the donor, the product, or service, and the recipient (as applicable).
3.7, #11 (3.8, #1)	SC	NA	NA	The committee revised subnumber 11 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 11) Training and competency of personnel who use information systems.
3.7, #12 (New)	SC	NA	NA	The committee added subnumber 12 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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: 12) Procedures to ensure confidentiality of protected information.
3.7.2 (New)	SC	NA	NA	The committee added standard 3.7.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 3.7.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7.3** The organization shall support the management of information systems.
3.7.4 (New)	SC	NA	NA	The committee added standard 3.7.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7.4** A system designed to prevent unauthorized access to computers and electronic records shall be in place.
4.0	SC	NA	NA	The committee revised standard 4.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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	SC	NA	NA	The committee revised standard 4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 4.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
4.2	SC	NA	NA	The committee revised standard 4.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**4.2 Agreements** Agreements and any incorporated changes shall be reviewed and communicated.
4.2.1 (New)	SC	NA	NA	The committee added standard 4.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.2.1** Agreements shall be reviewed at defined intervals to ensure that the terms of agreement continue to meet requirements.
4.2.2 (4.2.1)	SC	NA	NA	The committee revised standard 4.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.2.2** Changes to agreements shall be communicated to affected parties.
4.2.3 (New)	SC	NA	NA	The committee added standard 4.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**4.2.3** The responsibilities for activities covered by these *PBM Standards* when more than one organization is involved shall be specified by agreement.
4.3 (New)	SC	NA	NA	The committee added standard 4.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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.
5.0	SC	NA	NA	The committee revised standard 5.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.0 Process Control** The organization shall ensure the quality of products or services.
5.1	SC	NA	NA	The committee revised standard 5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1 General Elements** The organization shall ensure that processes are carried out under controlled conditions**.**
5.1.1 (5.1.2)	SC	NA	NA	The committee revised standard 5.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**5.1.1 Change Control** When the organization develops new processes or procedures or changes existing ones, they shall be validated before implementation.
5.1.2 (5.1.6)	SC	NA	NA	The committee added standard 5.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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 (New)	SC	NA	NA	The committee added standard 5.1.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**5.1.2.1** Quality control results shall be reviewed and evaluated against acceptance criteria.

5.1.2.2 (New)	SC	NA	NA	The committee added standard 5.1.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**5.1.2.2** Quality control failures shall be investigated before release of test results, products, or services.
5.1.2.3 (5.1.6)	SC	NA	NA	The committee added standard 5.1.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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 (New)	SC	NA	NA	The committee added standard 5.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 5.1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.4 Process Validation** Before implementation, the new or changed processes and procedures shall be validated.
5.1.5 (New)	SC	NA	NA	The committee added standard 5.1.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.5 Process Implementation** The implementation of new or changed processes and procedures shall be planned and controlled.
5.1.5.1 (New)	SC	NA	NA	The committee added standard 5.1.5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.5.1** Postimplementation evaluations of new or changed processes and procedures shall be performed.
5.1.6 (New)	SC	NA	NA	The committee added standard 5.1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 5.1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.7 Inspection** The organization shall ensure that products or services are inspected at organization-defined stages.
5.1.8 (New)	SC	NA	NA	The committee added standard 5.1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.8 Identification and Traceability** The organization shall ensure that all products or services are identified and traceable.
5.1.9 (New)	SC	NA	NA	The committee added standard 5.1.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: .**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, #1 (5.1.1, #3)	SC	NA	NA	Subnumber 1 has been edited for clarity, recognizing that the elements deleted "who may or may not need a transfusion are also", "for other means by which anemia may be", and "including by minimizing bleeding and treating anemia with medications" better fit as guidance and the committee felt that providing a straight forward requirement was more appropriate. The subnumber reads as follows: **5.1.10** The program shall ensure that: 1) Patients with anemia are assessed and managed.
5.1.10, #2 (5.1.1, #1)	SC	NA	NA	Subnumber 2 has been edited for clarity through the addition of the clause, "…and blood components are…" The subnumber reads as follows: **5.1.10** The program shall ensure that:

				2) Patients who may need transfusion are evaluated and managed such that blood and blood components are given when clinically indicated.
5.1.11 (5.1.3)	SC	NA	NA	The committee edited the entry sentence to standard 5.1.11 for clarity. The committee removed the clause, "…avoid unnecessary transfusion and ensure early and rapid delivery of blood components to those who need them…" to focus the standard on managing the patient while the language deleted was focused on giving blood as opposed to patient management. The standard reads as follows: **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:
5.1.11, #4 (New)	SC	NA	NA	The committee added subnumber 4 to the standard to recognize that there are instances where blood is needed, with the caveat that blood be administered when appropriate. The subnumber reads as follows: **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: 4) Administration of blood components, when indicated.
5.1.11, #5 (New)	SC	NA	NA	The committee added subnumber 5 to recognize that steps should be taken to avoid, when possible, the administration of blood to a patient.

				The subnumber reads as follows: **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: 5) Avoiding unnecessary transfusions.
5.1.13, #1 (5.1.5, #1)	SC	NA	NA	Subnumber #1 was edited deleting the clause, "… including, and as relevant to activity level, general PBM, and any or all PBM in surgical, pediatric, obstetric, and outpatients" recognizing that the elements deleted fit better in guidance. The subnumber reads as follows: **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.
5.1.13, #2 (5.1.5, #2)	SC	NA	NA	The committee elected to delete the clause, "perioperative" in subnumber 2 focusing the subnumber on all patients allowing for the deletion of subnumber 3. The subnumber reads as follows: **5.1.13 Educational Materials** The program shall develop, review, and distribute educational materials, at defined intervals for hospital personnel and patients, that: 2) Describe anemia management in patients.
5.1.13, #3 (Deleted)	SC	NA	NA	By deleting "perioperative" in subnumber 2, the committee deleted the elements that previously appeared as #3, which read, "3) Describe anemia management in medical patients."
5.1.13, #6 (New)	SC	NA	NA	Subnumber #6 was added to the edition to ensure that all educational materials given to

				hospital personnel includes blood ordering requirements based on the clinical situation. The subnumber reads as follows: ✎**5.1.13 Educational Materials** The program shall develop, review, and distribute educational materials, at defined intervals for hospital personnel and patients, that: 6) Evaluate appropriate ordering of blood components based on clinical indicators.
5.3.1, #4 (New)	SC	NA	NA	The committee added new #4 to the standard for completeness. The purpose of the addition was in recognition that the patient's ability to change their intent to receive transfusion has to be included as an element of the consent process. The subnumber reads as follows: **5.3.1** At a minimum, elements of consent shall include all of the following: 4) The right to change the transfusion directive.
5.3.2	SC	NA	NA	The committee edited standard 5.3.2 by including the clause, "…optimization of any coagulopathy…" to ensure that strategies surrounding coagulopathy are discussed with patients as an element of the consent process. The standard reads as follows: ✎**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.
5.4.1	SC	NA	NA	The committee edited standard 5.4.1 by adding the clause, "blood component transfusion volume and frequency when transfusion is indicated" for completeness. This reflects the principle of not transfusing blood to patients as the primary course of action. The standard reads as follows:

				5.4.1 The program shall have policies for blood component transfusion volume and frequency when transfusion is indicated.
5.4.1	RtC	A clearer statement could be "The program shall establish policies that prioritize alternative treatments before considering blood transfusion. When transfusion is necessary, guidelines for appropriate volume and frequency must be clearly defined to avoid ambiguity and ensure safe and effective patient care." It is unclear if volume refers to the amount per transfusion event, cumulative dose over time, or individualized patient needs. For frequency it would be helpful to indicate whether it refers to set intervals, a maximum number per time duration, or recommendations based on specific clinical indicators. Adding this detail would ensure a standardized approach to interpretation.	No	The committee noted this comment but did not feel that a change was needed at this time. The committee noted this feedback but felt that at the point in the process of patient care, the decision to transfuse has been made and therefore the alternative strategies would not be appropriate. The volume and frequency issue are typically program defined and not always formalized and as such, this should be left to the transfusion guideline
5.4.2 (5.4.1)	SC	NA	NA	The committee added standard 5.4.2, however the content is not new. The elements that form standard 5.4.2 previously appeared as a part of standard 5.4.1. The standard reads as follows: **5.4.2** The program shall promote the use of single-unit component transfusion strategies.
5.5.2	SC	NA	NA	The committee edited standard 5.5.2 by replacing the term “measure” with “assess” as it was deemed more accurate. The committee also inverted the second half of the sentence for clarity. The standard reads as follows: **5.5.2** The program shall create, review, and revise, as necessary, the policies, processes, and procedures to assess transfusion appropriateness and effectiveness.
5.6, #1 (New)	SC	NA	NA	Subnumber 1 is new to the 5th edition and was added in in conjunction with the edits to standard 5.3.2. The subnumber reads as follows: **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.
5.6, #2	SC	NA	NA	Subnumber 2 has been edited to build on the wording that existed in the previous edition. The intent is to expand the standard beyond patients who decline transfusion. The subnumber reads as follows: **5.6 Preoperative or Preintervention Patient Care** The program shall oversee and review: 2) Processes to discuss with patients the availability of alternative therapies to transfusion.
5.6, #3	SC	NA	NA	Subnumber 3 has been edited to recognize the adjustment of the standard reading to focus on the patient having alternatives beyond transfusion. The subnumber reads as follows: **5.6 Preoperative or Preintervention Patient Care** The program shall oversee and review: 3) Processes to document patient preferences for blood transfusion or alternatives, and communicate the decision taken with the patient's multidisciplinary care team.
5.6, #4 (New)	SC	NA	NA	Subnumber 4 is new to the 5th edition and was added to ensure that PBM programs have the appropriate level of staff and equipment to provide the optimal level of patient care. The subnumber reads as follows: **5.6 Preoperative or Preintervention Patient Care** The program shall oversee and review: 4) Processes to ensure the availability of staff, equipment, and hemostatic medications, for blood-sparing techniques.

5.6, #5 (5.6, #1)	SC	NA	NA	Subnumber 5 previously appeared as subnumber 1 but was adjusted in the order to focus the standard on the avoidance of blood appearing at the top of the list in order. The content of the standard has not changed. The subnumber reads as follows: **5.6 Preoperative or Preintervention Patient Care** The program shall oversee and review: 5) Maximum surgical blood ordering schedule (MSBOS) or equivalent, including its review (at least biennially) and updating as needed.
5.6, #6 (5.6, #4)	SC	NA	NA	Subnumber 6 has been edited for clarity. The committee replaced the clause, "…prescribing and ordering of…" with "utilization of." The subnumber reads as follows: **5.6 Preoperative or Preintervention Patient Care** The program shall oversee and review: 6) The utilization of appropriate blood components or transfusion-related pharmaceuticals (eg, factor concentrates, antifibrinolytics, hemostatic agents).
5.6.1, #1(5.6.1, #4)	SC	NA	NA	Subnumber 1 previously appeared as subnumber 4 but was adjusted in the order to mirror proper workflow. The content of the standard has not changed. The subnumber reads as follows: **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.
5.6.1, #2 (5.6.1, #1)	SC	NA	NA	Subnumber 2 has been expanded in the 5th edition to include "coagulopathy" to the

				standard mirroring similar additions to previous standards. The subnumber reads as follows: **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: 2) Evaluation and management of preprocedure anemia and coagulopathy.
5.6.1, #3 (5.6.1, #2)	SC	NA	NA	Subnumber 3 has been edited to ensure that the language styling mirrors the content of subnumber 2. The intent of the subnumber has not changed. The subnumber reads as follows: **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: 3) Evaluation of safe and effective discontinuation of anticoagulants and/or platelet inhibitors.
5.6.1, #4 (5.6.1, #3)	SC	NA	NA	Subnumber 4 has been edited to expand the focus of the content to ensure that a review of the medications the patient has been prescribed prior to surgery occurs. The subnumber reads as follows: **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: 4) Assessment of bleeding risk, including review of the patient's current medications.
5.6.1, #5	SC	NA	NA	Subnumber 5 has been edited to mirror the content of the language included in the entire list. The term "assessment" has replaced "consideration." The subnumber reads as follows:

				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: 5) Assessment and plan for blood or blood component needs and alternatives.
5.6.2, #1	SC	NA	NA	Subnmber 1 has been edited for clarity and to expand the content of the standard to focus on management of the patient needs, as opposed to focus on identification. The subnumber reads as follows: **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.
5.6.2, #2	SC	NA	NA	Subnmber 2 has been edited for parallel construction to mirror the edits to subnumber 4 of standard 5.6.1. The subnumber reads as follows: **5.6.2** For patients undergoing urgent or emergent procedures, there shall be processes and/or procedures for the following: 2) Assessment of bleeding risk, including review of the patient's current medications, if available.
5.6.2, #4, (5.6.2, #5)	SC	NA	NA	Subnumber 4 previously appeared as subnumber 5 but was adjusted in the order to mirror proper workflow. The content of the standard has not changed. The subnumber reads as follows: **5.6.2** For patients undergoing urgent or emergent procedures, there shall be processes and/or procedures for the following: 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.
5.6.2, #5, (5.6.2, #4)	SC	NA	NA	Subnumber 5 previously appeared as subnumber 4 but was adjusted in the order to mirror proper workflow. The content of the standard has not changed. The subnumber reads as follows: **5.6.2** For patients undergoing urgent or emergent procedures, there shall be processes and/or procedures for the following: 5) Timely delivery of blood components.
5.8	SC	NA	NA	The committee edited standard 5.8 for clarity and to mirror changes made throughout the 5th edition. The standard reads as follows: **5.8 Postoperative or Postintervention Patient Care** The program shall ensure the monitoring, evaluation, and treatment of postoperative anemia and coagulopathy.
5.9, #1 (5.9, #1, 2)	SC	NA	NA	The committee edited subnumber 1, which previously appeared as a combination of sunumbers 1 and 2 in the previous edition, mirroring other changes throughout the rest of the 5th edition. The standard reads as follows: **5.9 Patients Who Do Not Require Invasive Procedures** The program shall oversee and review: 1) Processes to discuss with patients the availability of alternative therapies to transfusion.
5.11, #2 (5.11, #1)	SC	NA	NA	Subnumber 2 has been edited to include the clause, "…including those who decline blood and blood components." for completeness and to mirror other changes throughout the edition.

				The subnumber reads as follows: **5.11 PBM for Obstetric Patients** The program shall oversee and review policies, processes, and procedures for obstetric patients, including: 2) Patients for whom blood is not an option, including those who decline blood and blood components.
5.11, #4 (New)	SC	NA	NA	Subnumber 4 is new to the 5th edition and was added for completeness. The subnumber was added recognizing that not optimizing fibrinogen status could lead to clotting. The subnumber reads as follows: **5.11 PBM for Obstetric Patients** The program shall oversee and review policies, processes, and procedures for obstetric patients, including: 4) Optimization of patient coagulation and fibrinogen status.
5.11.1, #2 (5.11.1, #3)	SC	NA	NA	Subnumber 2 has been edited to mirror the entries for clarity. The intent of the standard has not changed. The subnumber reads as follows: **5.11.1 Postpartum Hemorrhage Preparedness and Management** Postpartum hemorrhage preparedness and management shall include: 2) Identification of patients with known high bleeding risk (eg, placental implantation abnormalities).
5.11.1, #3 (New)	SC	NA	NA	Subnumber 3 has been added to the edition for completeness. This addition recognizes that antifibrinolytic agents can help to prevent or treat serious bleeding. The subnumber reads as follows: **5.11.1 Postpartum Hemorrhage Preparedness and Management**

				Postpartum hemorrhage preparedness and management shall include: 3) Proper use of antifibrinolytic agents (eg, tranexamic acid).
5.11.1, #4 (New)	SC	NA	NA	Subnumber 4 has been added to the edition for completeness. The addition ensures that programs consider the use of point-of-care testing as appropriate. The subnumber reads as follows: **5.11.1 Postpartum Hemorrhage Preparedness and Management** Postpartum hemorrhage preparedness and management shall include: 4) Consideration of point-of-care testing (eg, viscoelastic testing), autotransfusion (eg, cell salvage).
5.11.1, #6 (5.11.1, #1)	SC	NA	NA	Subnummber 6 previously appeared as #1, and has been edited to mirror the language throughout the edition. The subnumber reads as follows: **5.11.1 Postpartum Hemorrhage Preparedness and Management** Postpartum hemorrhage preparedness and management shall include: 6) Identification of patients for whom blood is not an option, including those who decline blood and blood components.
5.16 (Deleted)	SC	NA	NA	Former standard 5.16 has been deleted with the content being added as element #15 in new standard 5.16 (previously 5.17).
5.16, #9 (5.17, New)	SC	NA	NA	Subnumber #9 is new to the edition and was added for completeness. This concept was added as a data point for programs to track. The subnumber reads as follows: **5.16 Performance Indicators** The program shall obtain and review the following data at least quarterly (unless noted): 9) Transfusion index and transfusion probability.

5.16, #9 (5.17, New)	RtC	I have a concern for EMR limitations to abstract a count of patients crossmatched data to create a transfusion index.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that if a program retains this data, the EMR should be able to compute said data. This should be the responsibility of the program and their associated IT team to determine what is necessary to meet the intent of the standard.
5.16, #15 (5.16)	SC	NA	NA	Subnumber #15 is new to standard 5.16, however the content previously appeared as standard 5.16 from the 4th edition. The subnumber reads as follows: **5.16 Performance Indicators** The program shall obtain and review the following data at least quarterly (unless noted): 15) High-usage service lines.
6.0	SC	NA	NA	The committee revised standard 6.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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	SC	NA	NA	The committee revised standard 6.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1 Document Control** The organization shall control all documents that relate to the requirements of these BB/TS Standards. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.
6.1.2 (New)	SC	NA	NA	The committee added standard 6.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 BBTS Standards are performed. 5) Are not used when deemed invalid or obsolete. 6) Are identified as archived or obsolete when appropriate.
6.1.3 (New)	SC	NA	NA	The committee added standard 6.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3 Document Changes** Changes to documents shall be reviewed and approved by an authorized individual.
6.1.3.1 (New)	SC	NA	NA	The committee added standard 6.1.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3.1** The organization shall track changes to documents.
6.1.4 (6.1.1)	SC	NA	NA	The committee revised standard 6.1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 Prehospital and Out-of-Hospital Standards.
6.1.6	SC	NA	NA	The committee revised standard 6.1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.6 Document Retention**

				The organization shall determine which documents shall be archived, destroyed, or made obsolete.
6.1.8 (New)	SC	NA	NA	The committee revised standard 6.1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.8 Document Retrieval** The organization shall ensure that documents are retrievable in a timely manner.
6.1.9 (6.1.5)	SC	NA	NA	The committee revised standard 6.1.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
6.2	SC	NA	NA	The committee revised standard 6.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2 Record Control** The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.
6.2.2 (New)	SC	NA	NA	The committee added standard 6.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 6.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 6.2.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.4 Legibility** All records shall be legible and indelible.
6.2.5 (New)	SC	NA	NA	The committee added standard 6.2.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 6.2.5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.5.1** Changes to records (including electronic records) shall be verified for accuracy and completeness.
6.2.6 (New)	SC	NA	NA	The committee added standard 6.2.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.6** Records shall be created concurrently with the performance of each critical activity.

6.2.7 (New)	SC	NA	NA	The committee added standard 6.2.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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 (New)	SC	NA	NA	The committee added standard 6.2.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.8 Confidentiality** The organization shall ensure the confidentiality of records.
6.2.9 (New)	SC	NA	NA	The committee added standard 6.2.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.9 Retention** Records required by these BBTS Standards shall be retained for a period indicated in the record retention table at the end of each chapter.
6.2.10 (New)	SC	NA	NA	The committee added standard 6.2.10 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**6.2.10 Record Review** Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.
6.2.11 (New)	SC	NA	NA	The committee added standard 6.2.11 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to: 1) Preserve record legibility and integrity for the entire retention period. 2) Protect from accidental or unauthorized access, loss, deterioration, damage, destruction, mix-up, or modification.

				3) Permit ready identification. 4) Allow retrieval in a defined time frame.
6.2.12 (New)	SC	NA	NA	The committee added standard 6.2.12 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (6.2.3)	SC	NA	NA	The committee revised standard 6.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**6.3 Electronic Records** The organization shall support the management of information systems.
6.3.1 (New)	SC	NA	NA	The committee added standard 6.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1 Access to Data and Information** Access to data and information shall be controlled.
6.3.1.1 (New)	SC	NA	NA	The committee added standard 6.3.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 6.3.1.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**6.3.1.1.1** Electronic records shall include the date and identity of the person making a change.
6.3.2 (New)	SC	NA	NA	The committee added standard 6.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2 Data Integrity**

				Data integrity shall ensure that data are retrievable and usable.
6.3.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.1** Data shall be accurately, reliably, and securely sent from the point of entry to final destination.
6.3.2.2 (New)	SC	NA	NA	The committee added standard 6.3.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.2** Data shall be retrievable for the entire retention period.
6.3.2.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.2.1** The organization shall archive records or data from media and platforms no longer in use.
6.3.2.3 (New)	SC	NA	NA	The committee added standard 6.3.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.3** There shall be a process in place for routine backup of all critical data.
6.3.3 (New)	SC	NA	NA	The committee added standard 6.3.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.3 Storage Media** Data storage media shall be protected from damage or unintended access and destruction.
6.3.4 (New)	SC	NA	NA	The committee added standard 6.3.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4 Backup Data** The organization shall back up all critical data.
6.3.4.1 (New)	SC	NA	NA	The committee added standard 6.3.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows:

				6.3.4.1 Backup data shall be stored in a secure off-site location.
6.3.4.2 (New)	SC	NA	NA	The committee added standard 6.3.4.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4.2** Backup data shall be protected from unauthorized access, loss, or modification.
6.3.4.3 (New)	SC	NA	NA	The committee added standard 6.3.4.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4.3** The ability to retrieve data from the backup system shall be tested at defined intervals.
7.0	SC	NA	NA	The committee revised standard 7.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 7.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (7.1)	SC	NA	NA	The committee revised standard 7.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**7.2 Nonconformances** Upon discovery, nonconforming products or services shall be evaluated and their disposition determined.
7.2.1 (7.1.1)	SC	NA	NA	The committee revised standard 7.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.1** Nonconforming products shall be quarantined and/or destroyed.
7.2.2 (New)	SC	NA	NA	The committee revised standard 7.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee revised standard 7.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.3** The organization shall: 1) Identify, quarantine, retrieve, recall, and determine the disposition of nonconforming products. 2) Identify and manage nonconforming products or services.
7.2.4 (New)	SC	NA	NA	The committee revised standard 7.2.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee revised standard 7.2.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 7.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3 Adverse Events** The organization shall detect, monitor, evaluate, manage, and report adverse events related to safety and quality.
7.3.1 (New)	SC	NA	NA	The committee added standard 7.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3.1** Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.
7.3.2 (New)	SC	NA	NA	The committee added standard 7.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3.2** Investigation results and analysis shall be communicated among all facilities involved, if applicable.
8.0	SC	NA	NA	The committee revised standard 8.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.0 Internal and External Assessments** The organization shall conduct assessments of operations and quality systems.
8.1 (8.2)	SC	NA	NA	The committee revised standard 8.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (8.0)	SC	NA	NA	The committee revised standard 8.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**8.2 External Assessments** The organization shall participate in an external assessment program applicable to the activities performed in the organization.
8.3 (8.2, 8.2.1, 8.2.2)	SC	NA	NA	The committee revised standard 8.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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	SC	NA	NA	The committee revised standard 8.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.4 Quality Monitoring** The organization shall collect and evaluate quality indicator data on a scheduled basis, including adverse events.
8.4.1 (New)	SC	NA	NA	The committee added standard 8.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.4.1** The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.

8.6, #7 (8.3, #6)	SC	NA	NA	Subnumber 7 previously appeared as subnumer #6, however the intent of the standard has not changed. The subnumber reads as follows: **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: 7) Use of perioperative blood conservation techniques.
8.6, #9 (8.3, #2)	SC	NA	NA	Subnumber 9 previously appeared as subnumber 2, however the intent of the standard has not changed. The subnumber reads as follows: **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: 9) Allogeneic transfusion rates overall and by program-defined high-blood-use service lines.
9.1, #2 (9.2, #2)	SC	NA	NA	The committee revised subnumber 2 to standard 9.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.1 Corrective Action** The organization shall have a process for corrective action that includes: 2) Investigation of the root cause(s) of nonconformances relating to the product or service, the process, and the quality system.
9.1, #3 (9.2, #3, 4)	SC	NA	NA	The committee revised subnumber 3 to standard 9.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.1 Corrective Action**

				The organization shall have a process for corrective action that includes: 3) Determination of the corrective action needed to eliminate the cause of nonconformances, as applicable.
9.1.1 (New)	SC	NA	NA	The committee added standard 9.1.1 based on updates to the AABB Quality System Essentials, which includes some verbiage from standard 9.1 in the previous edition. The standard reads as follows: **9.1.1** Investigation and corrective action shall include consideration of deviations, nonconformances, and complaints.
9.1.2, #5 (New)	SC	NA	NA	Subnumber #5 is new to the edition and was added for completeness. The subnumber was included to recognize that educational elements are a part of corrective action plans. The subnumber reads as follows: **9.1.2** As an element of corrective action, the program shall monitor: 5) Employee knowledge gaps and assigned appropriate training or retraining, as applicable.
9.2, #1 (9.3.1)	SC	NA	NA	The committee revised subnumber 1 of standard 9.2 based on updates to the AABB Quality System Essentials. The subnumber reads as follows: **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.
9.3 (New)	SC	NA	NA	The committee added standard 9.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.
10.0	SC	NA	NA	The committee revised standard 10.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (New)	SC	NA	NA	The committee added standard 10.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: .**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 (New)	SC	NA	NA	The committee added standard 10.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.2 Biological, Chemical, and Radiation Safety** The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.
10.3 (10.1)	SC	NA	NA	The committee revised standard 10.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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.

Glossary – Acute Normovolemic Hemodilution	SC	NA	NA	The committee edited the glossary entry focused on acute normovolemic hemodilution for accuracy. The glossary entry reads as follows: **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.
Glossary – Anemia	SC	NA	NA	The committee edited the glossary entry focused on anemia for accuracy. The glossary entry reads as follows: **Anemia:** The condition where a reduced healthy hemoglobin impairs the delivery of oxygen to body tissues.
Glossary – Massive Hemorrhage	SC	NA	NA	The committee edited the glossary entry focused on massive hemorrhage for accuracy. Many of the elements removed from the previous version was deemed too restrictive. The glossary entry reads as follows: **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.
Glossary – Massive Transfusion	SC	NA	NA	The committee edited the glossary entry focused on massive transfusion for accuracy. Many of the elements removed from the previous version was deemed too restrictive. The glossary entry reads as follows: **Massive Transfusion:** The replacement of a patient's entire blood volume within a 24-hour period.
Glossary – Patient Blood Management	SC	NA	NA	The committee created a new definition for patient blood management based on the concepts covered on the AABB website. The definition mirrors the expectations of the community and provides a definition for the program which was requested by the community. The glossary entry reads as follows: **Patient Blood Management (PBM):** An evidence-based, patient-centered, systematic, multidisciplinary approach to caring for patients who might require a blood transfusion. PBM is meant to improve patient outcomes by preserving a patient's own blood through diagnosis and etiology-specific treatment of anemia and bleeding. PBM encompasses all aspects of the transfusion decision-making process, from the initial patient evaluation through all phases of clinical management. This approach is designed to promote optimal

				patient outcomes while maintaining the blood supply to help ensure that blood components are available when needed.
Glossary – Transfusion Index	SC	NA	NA	The committee created a new definition for transfusion index based the addition of subnumber 9 in standard 5.16. **Transfusion Index:** A blood utilization metric that measures the number of units transfused compared to the number of patients crossmatched.
Glossary – Transfusion Probability	SC	NA	NA	The committee created a new definition for transfusion probability based the addition of subnumber 9 in standard 5.16. **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.