Significant Changes and Response to Comments Received to the 11th edition of Standards for Perioperative Autologous Blood Collection and Administration

Please note that public comments that were submitted address the proposed 11th edition of Perioperative Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 11th edition of Perioperative Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that what appears below.

Standard	SC/RC	Comment	Change Made?	Outcome
General	SC	NA	NA	The 11th edition of Standards for Perioperative Autologous Blood Collection and Administration has incorporated AABB's updated quality system essentials. The updated quality system essentials include the following updates: • All standards are 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 key terms that relate to the content of the chapter, with their definitions. • Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site 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 that a comprehensive record retention table still exists at the end of Chapter 6.
1.1.1.1	RC	This standard relates to the medical director's ability to delegate responsibility	YES	When standard 1.1.1.1 was presented for public comment, the committee edited the standard to

		of autotransfusion to others including nurses and lab scientists. These standards were created in order to reign in conduct of autotransfusion devices by individuals who had no or little training. Autotransfusion is a leading cause of blood related errors and I think that the delegation should be done with some description of the training necessary for the delegates. There needs to be a description of the training necessary to lead these programs and it needs to go beyond the simple button pushing training that is provided by the manufacturers of this equipment.		include a specific list of individuals that could have the responsibilities of the medical director designated to. Based on this comment, the committee re-edited the standard to the previous language from the 10th edition.
1.2	SC	NA	NA	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.
1.2.2	SC	NA	NA	The committee revised standard 1.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: 1.2.2 Management Reviews Management shall assess the effectiveness of the quality system at defined intervals.
1.2.2.1 (DELETED)	RC	Is this standard redundant to 1.2.2? **1.2.2.1** Management shall participate in the review of the quality system.	YES	Standard 1.2.2.1 was originally presented as a part of the Proposed edition, however based on the feedback, the standard was deleted but could be considered for future editions.
1.3	SC	NA	NA	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 *Perioperative Standards*. All such policies, processes, and 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.
1.3.1.1 (NEW)	SC	NA	NA	The committee created new standard 1.3.1.1 to ensure that it was clear that all medical and technical policies, processes, and procedures could not be delegated. The standard reads as follows: **1.3.1.1** Approval of all medical and technical policies, processes, and procedures shall not be delegated.
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.
1.3.2.1 (NEW)	SC	NA	NA	The committee created new standard 1.3.2.1 to ensure that it was clear that the medical director and their designee are the only individuals who can approve exceptions to medical and technical policies, processes, and procedures. The standard reads as follows: **1.3.2.1** The medical director designee shall have the authority to approve any exceptions to medical and technical policies, processes, and procedures, as applicable. Standard 1.1.1.1 applies.

1.3.2.1 (NEW)	RtC	Is this standard redundant to 1.3.2?	YES	The committee noted this comment and as a result edited the original language that was presented for comment.
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.
2.1.1 (2.1)	SC	NA	NA	The committee revised the elements of standard 2.1.1 (which previously appeared as a part of standard 2.1) based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 *Perioperative Standards*.
2.1.4 (2.1.3)				The committee revised the elements of standard 2.1.4 (which previously appeared as a part of standard 2.1.3) based on updates to the AABB Quality System Essentials. The standard reads as follows: **2.1.4 Competence** Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.
2.1.4.2 (NEW)	SC	NA	NA	The committee created new standard 2.1.4.2 to ensure that operators of critical equipment have their competence evaluated to determine their continued ability to operate collection equipment are trained and able to do so. The standard reads as follows: **2.1.4.2** The medical director or medical director designee shall verify at defined intervals that operators of perioperative collection equipment are trained and capable of delivering a safe product.
2.1.6 (2.1.4)	SC	NA	NA	The committee edited standard 2.1.6 (which previously appeared as

				standard 2.1.4) 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 BB/TS 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	SC	NA	NA	The committee revised standard 3.2 based on updates to 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.
3.2.2	SC	NA	NA	The committee revised standard 3.2.2 based on updates to 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	SC	NA	NA	The committee revised standard 3.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.2.3 Performance Qualification** Equipment shall perform as expected for its intended use.
3.5	SC	NA	NA	The committee revised standard 3.5 based on updates to 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.
3.5.1.1 (NEW)	SC	NA	NA	The committee added standard 3.5.1.1 based on updates to the AABB Quality System Essentials. The standard appears 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 (3.5.1.1)	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. 7) Ensure that all critical equipment is stored in accordance with the manufacturer's written instructions.
3.5.3 (New), #7	RtC	Is this entry redundant to standard 3.3?	NO	The committee noted this comment, but did not feel that entry #7 was redundant and worth retaining in the standard.
3.5.4, #2 (3.5.2, #2)	SC	NA	NA	The committee revised subnumber 2 of standard 3.5.4 based on updates to the AABB Quality System Essentials. The subnumber previously read, "Assessment of the effect on donor eligibility and donor and patient safety." The standard now reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 2) Assessment of the effect on the safety of individuals affected. The wording related to Perioperative specific activities has been changed to more general language in the new QSE. The

				intent of the Standard has not changed.
3.5.4, #4 (3.5.2, #4)	SC	NA	NA	The committee revised standard 3.5.4, #4 based on updates to the AABB Quality System Essentials. The previous wording read, "Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected." The standard now reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable.
3.5.4, #6 (3.5.2, #6)	SC	NA	NA	The committee revised standard 3.5.4, #6 based on updates to the AABB Quality System Essentials. The previous wording read, "Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected." The standard now reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.
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 committee expanded the clause to include "verification" and "qualification" beyond "validation" which appeared in the 10th edition. 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, #5 (3.8, #5)	SC	NA	NA	The committee updated 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. This expands the content of the standard.
3.7, #7 (New)	SC	NA	NA	The committee added subnumber 7 to standard 3.7, #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, #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 (New)	SC	NA	NA	The committee added 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.
3.8.4.1 (NEW)	SC	NA	NA	The committee created new standard 3.8.4.1 to ensure that storage temperatures are recorded every 4 hours, mirroring minimum requirements in manufacturer's written instructions. The standard reads as follows: **3.8.4.1** Storage container temperature shall be recorded at least every 4 hours
3.8.4.1 (NEW)	RtC	Does this standard apply to refrigeration and not to coolers that are validated to maintain the temperature for extended periods or time and don't require 4 hour temperature recording? We want consistency with AABB BBTS standards.	NO	The committee noted this comment, but did not feel that a change was needed at this time. This standard and the language mirrors language in the Standards for Blood Banks and Transfusion Services, and requirements set forth by the Food and Drug Administration.
3.9	SC	NA	NA	The committee edited this standard for clarity. The committee added elements in parentheses in the standard as opposed to in the text (as it appeared previously) ensures that users understand these are examples and not the only possible malfunctions that can lead to damage. The standard reads as follows:

				3.9 Warming Devices Warming devices for components prepared for transfusion shall be cleared or approved by the FDA or Competent Authority and shall be equipped with a temperature-sensing device and a warning system to detect malfunctions (eg, overheating) and prevent damage to components (eg, hemolysis). Standards 3.5 and 3.6 apply.
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 (4.1)	SC	NA	NA	The committee revised standard 4.1.1 (which previously appeared as a part of standard 4.1) 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.
4.1.3 – 4.1.3.2	SC	NA	NA	The committee edited standards 4.1.3, 4.1.3.1, and 4.1.3.2 by adding the clause "laboratory" for clarity to the standards, recognizing the testing described in this case would be laboratory focused. The standards read as follow: **4.1.3** Laboratory testing required by these *Perioperative Standards*

				shall be performed in a facility accredited by AABB or an equivalent accrediting body. **4.1.3.1** Laboratory testing shall be performed in a facility certified by the Centers for Medicare and Medicaid Services (CMS) or other regulatory agencies. **4.1.3.2** Laboratory testing by facilities outside of the United States shall be performed by a laboratory authorized as a testing center by the Competent Authority.
4.1.4 (4.1.3)	SC	NA	NA	The committee added a new title to standard 4.1.4 and added a clause in at the end of the standard for completeness. The intent of the standard has not changed. The standard reads as follows: **4.1.4 Third-Party Provider Qualification** The organization shall qualify third-party providers to ensure that contracted activities meet the requirements of these *Perioperative Standards*.
4.2 (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	SC	NA	NA	The committee revised 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 (NEW)	SC	NA	NA	The committee added new 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.
4.2.4 (NEW)	SC	NA	NA	The committee created new standard 4.2.4 to mirror the style and tone of existing standard 4.1.4 with the focus being on the

				agreements defined between third party providers and the receivers of product. The standard reads as follows: **4.2.4 Third-Party Provider Agreements** The organization shall define the agreements required for third-party provider(s) for the contracted activities. Standard 2.1 applies.
4.3.1.1	SC	NA	NA	The committee added the term, "equipment" to standard 4.3.1.1 for completeness. The standard reads as follows: **4.3.1.1** All equipment, containers, and solutions used for collection, preparation, preservation, and storage of perioperative blood, components, and all reagents used for required tests on blood samples shall meet or exceed applicable FDA or Competent Authority criteria.* *21 CFR 606.65.
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.
5.1.1	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.
5.1.1.1, #1 (5.1.1, #1)	SC	NA	NA	The committee expanded subnumber 1 to include the requirement that the scope of change control be defined as a part of process control. The standard reads as follows: 5.1.1.1 This process shall include: 1) Identification and definition of the scope of the change.
5.1.1.1, #2 (5.1.1, #3)	SC	NA	NA	The committee expanded subnumber 2 to include the concept of verification of new or changed

				processes and/or procedures as a part of change control. The standard reads as follows: **5.1.1.1** This process shall include: 2) Verification and validation of new or changed processes and/or procedures before implementation.
5.1.1.1, #2 (5.1.1, #3)	RtC	Should this include a where applicable? Minor changes may not warrant full verification or even validation.	NO	The committee reviewed this comment but did not think that a change was needed at this time. The committee notes that it would be the responsibility of the facility to determine what is and is not applicable.
5.1.1.1, #3 (NEW)	SC	NA	NA	The committee added new subnumber 3 to standard 5.1.1.1. The addition was included for completeness. The standard now reads as follows: **5.1.1.1** This process shall include: 3) Implementation of the new or changed process and/or procedure.
5.1.1.1, #3 (NEW)	RtC	What if it is determined that the change should not be or is not implemented?	NO	The committee noted this comment but did not think that a change was needed at this time. The committee notes that this would be the responsibility of the facility to determine what action to take if a change was not implemented.
5.1.1.1, #4 (5.1.1, #4)	RtC	I recommend this standard should state "where applicable". Some minor changes may not warrant post implementation. Also, is this different than 5.1.5.1?	NO	The committee noted this comment but did not think a change was needed at this time. The committee notes this this would be up to the facility to determine where this would not be required. The committee notes that this addition of the crossreference is purposeful and the concept being included in both standards would assist users in their implementation.
5.1.2	SC	NA	NA	The committee revised 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	SC	NA	NA	The committee updated 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 (5.1.2.1)	SC	NA	NA	The committee updated 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 (5.1.2.2)	SC	NA	NA	The committee updated 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. The committee noted that program have processes to meet these requirements already.
5.1.4 (5.1.1, #3)	SC	NA	NA	The committee updated 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.
5.1.4.1 (New)	SC	NA	NA	The committee added standard 5.1.4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: 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. The committee noted that programs have processes to meet these requirements already.
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. The committee noted that programs have processes to meet these requirements already.
5.1.6 (5.1.3)	SC	NA	NA	The committee revised 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.
5.1.7.1	SC	NA	NA	The committee removed the term "finished" from the standard as it was implied by the title of the standard. The standard reads as follows: ✎**5.1.7.1 Final Inspection** The organization shall ensure that components are acceptable before issue or delivery. Standards 5.4.2.1 and 7.2.2 apply.
5.1.8.2.2 (5.1.6.2.1.1)	SC	NA	NA	The committee removed the clause "may potentially be" and replaced it with "are" as the previous wording was written in a way that could be difficult to assess against. The standard now reads as follows: **5.1.8.2.2** Intermediate components that are separated from the patient shall be labeled with two patient identifiers.
5.1.8.2.3, (5.1.6.2.2)	SC	NA	NA	The committee edited standard 5.1.8.2.3 (previously 5.1.6.2.2) which previously appeared as a paragraph into a list for legibility.
5.1.8.2.3, #3 (5.1.6.2.2) NEW	SC	NA	NA	The committee added subnumber 3 for completeness, by adding the requirement that all final labels include the "component name."

5.1.8.2.3, #4 (5.1.6.2.2) DELETED	SC	NA	NA	The committee removed subnumber 4 from the standard "date and time of initiation of collection" as this information is not typically found on final component labels.
5.1.8.2.3, #5 (5.1.6.2.2) NEW	SC	NA	NA	Subnumber 5 is new to the edition and was included for completeness by adding the requirement that all final labels include the identification of the individual collecting the component, as this is required to be on the label currently.
5.1.8.2.3.1 (5.1.6.2.2.1)	SC	NA	NA	The committee edited the standard to include the clause, "immediately after collection", which was the intent of the original wording but the committee felt it important to include the clause in the standard for completeness. The standard now reads as follows: **5.1.8.2.3.1** When the final component enters the surgical field immediately after collection, labeling requirements shall be defined by the organization.
5.1.8.3 (NEW)	SC	NA	NA	The committee added this standard to the edition in an effort to ensure that all labeling systems can ensure that components can be traced from source to final disposition. The standard reads as follows: **5.1.8.3** The labeling system shall ensure that any component can be traced from its source to final disposition.
5.1.9 (5.1.8)	SC	NA	NA	The committee revised 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. Reference Standard 5.1.9A, Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components, and

				Reference Standard 5.1.9B, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion, apply.
5.2	SC			The committee elected to edit standard 5.2 for clarity. The committee replaced the term "recipient" with "informed" as the term was deemed more inclusive and less narrow in scope. The standard reads as follow: **5.2 Consents, Approvals, and Notifications** The organization medical director shall participate in the development of policies, processes, and procedures regarding informed consent for collection and use of components.
5.2.1, #3 (5.2.1, #2)	SC	NA	NA	The committee elected to edit subnumber 3 of standard 5.2.1 to mirror the language in other sets of AABB Standards that cover the elements of consent. This ensures that standards appear in parallel across the informed consent space. The standard reads as follows: ✎ **5.2.1** At a minimum, elements of consent shall include all of the following: 3) The opportunity for patients to ask questions and receive answers from a knowledgeable health-care professional.
5.2.2	SC	NA	NA	The committee removed the clause "or medical director designee" from this standard as this level of responsibility was not deemed appropriate for a designee, as it relates to the development of policies, processes, and procedures regarding the collection and administration of components.
5.2.3	SC	NA	NA	The committee replaced the term "an order" with "documentation" as it relates to the collection, preparation, and administration/reinfusion of the component.
5.2.3.1 (5.2.3)	SC	NA	NA	The content of standard 5.2.3.1 previously appeared as the second sentence of standard 5.2.3. The

				standard was also expanded for clarity, including the information to be maintained as a part of a collection order, to include collection, preparation, and administration/reinfusion.
5.3	SC	NA	NA	The original content of standard 5.3 now appears as standard 5.3.1, with the creation of new standard 5.3.1 necessitating the new content of standard 5.3. The content of standard 5.3 was added to provide an introduction to the collection section. The standard reads as follows: **5.3 Perioperative Collection** The organization shall have technical policies, processes, and procedures to ensure safe and effective delivery of these services, as well as the safety and quality of the collected perioperative product.
5.3.1 (5.3)	SC	NA	NA	The committee elected to expand the content of standard 5.3.1 (previously appearing as standard 5.3) to focus on intraoperative blood recovery to mirror work flow and to complete the list to ensure that all elements were accurately included. Subnumbers 1, 2, 4, 10, 11, and 12 are all new to this edition and were added for completeness. The standard now reads as follows: **5.3.1 Intraoperative Blood Recovery** The organization shall define the criteria for utilizing intraoperative blood recovery that include the following: 1) Patient inclusion and exclusion criteria. 2) Collection system used. 3) Anticoagulant used. 4) Volume collected/recovered and processed. 5) Circuit configuration. 6) Wash volumes. 7) Pump and centrifugation speeds. 8) Filtration. 9) Minimum blood volume collected for processing. 10) Labeling requirements.

				11) Storage requirements. 12) Final inspection.
5.3.1.1 (NEW)	SC	NA	NA	The committee created new standard 5.3.1.1 for completeness. This standard ensures that cell washing devices are used in accordance with manufacturer's written instructions. The standard now reads as follows: **5.3.1.1** Cell washing devices for intraoperative blood collection shall be used in accordance with the manufacturer's written instructions.
5.3.1.2 (NEW)	SC	NA	NA	The committee created new standard 5.3.1.2 for completeness. The standard requires that programs have policies, processes, and procedures for ultrafiltration if it is used for recovery of an autologous product through extracorporeal cardiopulmonary circuitry. The standard reads as follows: **5.3.1.2** The organization shall have policies, processes, and procedures for ultrafiltration if used for recovery of an autologous product processed through an extracorporeal circuit or concentrating reservoir. The organization shall monitor flow rates and system pressures within the circuitry.
5.3.2 (NEW)	SC	NA	NA	The committee elected to create new standard 5.3.2 focused on acute normovolemic hemodilution for completeness. The elements included in the list mirror some of the content of standard 5.3.1 to ensure parallel construction, where appropriate. The standard reads as follows: **5.3.2 Acute Normovolemic Hemodilution (ANH)** The organization shall have policies, processes, and procedures that define the criteria for performing ANH and shall include the following: 1) Patient inclusion and exclusion criteria. 2) Volume collected based on patient characteristics. 3) Collection procedure.

				4) Anticoagulant used. 5) Product and quality determination. 6) Storage requirements. 7) Labeling requirements. 8) Final inspection.
5.3.2.3 (NEW)	SC	NA	NA	The committee created new standard 5.3.2.3 for completeness. The standard requires that blood containers used for whole blood collection are used in accordance with manufacturer's instructions. The standard reads as follows: **5.3.2.3** Blood containers used for whole blood collection shall be used per the manufacturer's written instructions.
5.3.2.4 (NEW)	SC	NA	NA	The committee created new standard 5.2.3.4 for completeness. This standard ensures that perioperative programs use qualified scales to ensure ratios are achieved for whole-blood-to-anticoagulant ratio. The standard reads as follows: **5.3.2.4** The organization shall use qualified scales to measure the amount of whole blood collected to provide proper whole-blood-to-anticoagulant ratio. Standard 3.5.1 applies.
5.3.4 (NEW)	SC	NA	NA	The committee created new standard 5.3.4 for completeness. Feedback from the membership had been received to create a standard focused on the collection and administration of platelet rich plasma. The standard reads as follows: **5.3.4 Platelet-Rich Plasma (PRP)** The organization shall have policies, processes, and procedures for the collection and administration of PRP, which shall include: 1) Patient inclusion and exclusion criteria. 2) Volume collected. 3) Collection and processing procedures. 4) Infusion, injection, or topical administration, as applicable. 5) Labeling requirements.

				6) Storage requirements. 7) Final inspection. Reference Standard 5.1.9B, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion, and Reference Standard 5.1.9C, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application, apply.
5.3.5 (NEW)	SC	NA	NA	The committee created new standard 5.3.5 for completeness. The committee wanted to include a new standard that would recognize and create a requirement for other products that an accredited program could be using. The standard reads as follows: **5.3.5 Other Topical or Injectable Products** The organization shall have processes and procedures for the collection and safe administration of components for topical or injectable application. Reference Standard 5.1.9C, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application, applies.
5.4	SC	NA	NA	Standard 5.4 previously appeared as only a title without content beyond that. The committee created the standard to provide clarity. The standard reads as follows: **5.4 Component Administration** The organization shall define criteria for component administration.
5.4.1	SC	NA	NA	The committee edited standard 5.4.1 for clarity, the intent of the standard has not changed. The standard reads as follows: ✎ **5.4.1 Patient Identification** Components shall be administered only to the patient from whom they were collected. There shall be

				positive identification of the patient and the component.
5.4.4 (5.4.5)	SC	NA	NA	The committee edited the standard for clarity. The committee replaced the term "infusion devices" with "reinfusion devices." The standard reads as follows: **5.4.4 Administration Protocol** The organization shall have a protocol for the administration of components, including the use of reinfusion devices and ancillary equipment. Standard 6.2.2 applies.
5.4.4.2	RtC	Would the committee consider require a standard for vital signs to be recorded for an organ outside of the body. Would this be particularly appropriate for the use of RBCs?	NO	The committee noted this comment but did not feel that that change would be appropriate at this time. The committee feels that this currently would be considered practice of medicine. The committee will consider such a standard for a future edition.
5.4.4.3 #3 (5.4.5.3) DELETED	SC	NA	NA	The committee elected to remove former subnumber 3, "a record of administration" as it was deemed redundant per the record retention requirement included with the standard.
5.4.6 (NEW)	SC	NA	NA	The committee created new standard 5.4.6 based on similar language included in the 34th edition of Standards for Blood Banks and Transfusion Services. The standard reads as follows: **5.4.6** Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion filter designed to retain particles potentially harmful to the recipient.
Reference Standard 5.1.9B (Reference Standard 5.1.8B #2) DELETED	SC	NA	NA	The committee deleted former entry #2 focused on "Platelet rich plasma intended for reinfusion" as it was noted that this product is no longer in use, and to maintain the requirement would not mirror current practice.
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.
6.1.1 (6.1.2)	SC	NA	NA	The committee revised standard 6.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (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	SC	NA	NA	The committee elected to revise 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 *Perioperative 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.
6.1.7	SC	NA	NA	The committee revised standard 6.1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **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 (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.

6.2	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, #3 (6.2.4, #7)	SC	NA	NA	The committee revised standard 6.2.2, #3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.2** The records system shall ensure traceability of: 3) Date the activity was performed.
6.2.2, #4 (NEW)	SC	NA	NA	The committee added subnumber 4 to standard 6.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.2** The records system shall ensure traceability of: 4) Time the activity was performed, if applicable.
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.
6.2.5 (6.2.6, 6.2.6.1, 6.2.6.2)	SC	NA	NA	The committee revised 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.
6.2.7 (6.2.1.2)	SC	NA	NA	The committee revised 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.
6.2.9 (6.2)	SC	NA	NA	The committee revised 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 *Perioperative 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, #2 (6.2.9, #2)	SC	NA	NA	The committee revised subnumber 2 of 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: 2) Protect from accidental or unauthorized access, loss, deterioration, damage, destruction, mix-up, or modification.
6.2.11, #3 (NEW)	SC	NA	NA	The committee added subnumber 3 to 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: 3) Permit ready identification.
6.2.11, #4 (6.2.9, #3)	SC	NA	NA	The committee revised subnumber 4 of 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: 4) Allow retrieval in a defined time frame.

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 (6.2.81.1)	SC	NA	NA	The committee revised 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.

6.3.3 (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.
6.3.4.2 (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.
7.1 (7.1)	SC	NA	NA	The committee revised 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.
7.1.3	SC	NA	NA	The committee edited standard 7.1.3 for clarity, ensuring that the standard focuses primarily on perioperative components. As previously written the standard could have been understood more broadly. The standard reads as follows: **7.1.3** For deviations having the potential to adversely affect the safety, purity, or potency of a

				component, approval from the medical director and/or the patient's physician/licensed provider shall be obtained before final release of the component.
7.2.1 (7.2.2)	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 or services shall be quarantined and/or destroyed.
7.2.2 (7.2.1)	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 added 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 or services. 2) Identify and manage nonconforming products or services.
7.2.4 (7.2.3)	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.
7.2.4.2 (NEW)	SC	NA	NA	The committee created new standard 7.2.4.2 for completeness. The standard ensures that nonconforming products that had been released are reported to the patient's physician or licensed

				provider. The standard reads as follows: ✎**7.2.4.2** Released nonconforming products shall be reported to the patient's physician/licensed provider and, if applicable, the supplier and regulatory agencies.
7.3	SC	NA	NA	The committee revised 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.
7.3.3.1 (NEW)	SC	NA	NA	The committee edited section 7.3.3 for completeness. As previously written the committee felt that there were gaps included in the section. This led to the creation of new standard 7.3.3.1 focused on the need to pause a collection procedure. The standard reads as follows: **7.3.3.1** Pause the collection procedure or administration of components.
7.3.3.2 (NEW)	SC	NA	NA	The committee edited section 7.3.3 for completeness. As previously written the committee felt that there were gaps included in the section. This led to the creation of new standard 7.3.3.2 focused on the need to evaluate the adverse event while managing the patients clinical needs.

				The standard reads as follows: **7.3.3.2** Evaluate the adverse event while concurrently managing the patient's clinical needs.
7.3.3.4 (7.3.3.1, 7.3.1.3)	SC	NA	NA	The committee elected to edit standard 7.3.3.4 for clarity. The committee removed the clause, "…use of processing devices and materials involved in immediate complication and examine for…"and replaced it with "collection." The committee felt that the terms removed were more appropriate for the guidance. The standard now reads as follows: **7.3.3.4** Discontinue the collection or administration of components if evidence of nonconformance(s) (eg, malfunction or bacterial contamination) is observed. Standard 3.5.4 applies.
7.3.4 (NEW)	SC	NA	NA	The committee created new standard 7.3.4 in conjunction with edits made to standards in section 7.3.3 in consideration of under what circumstances a collection can be restarted once the investigation of a potential adverse event has taken place. The standard reads as follows: **7.3.4** The organization shall have a policy for the resumption of collection or administration of components following the investigation of an adverse event that shall include approval by the medical director or patient's physician/licensed provider.
8.0	SC	NA	NA	The committee added 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 (8.0, 8.1)	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, 8.1)	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, #2, (NEW)	SC	NA	NA	The committee added new subnumber 2 to 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: 2) Evaluated to determine the need for corrective and preventive action.
8.3, #3 (NEW)	SC	NA	NA	The committee added new subnumber 3 to 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: 3) Communicated to the appropriate staff.
8.4 (8.3)	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.
8.4.2, #4 (NEW)	SC	NA	NA	The committee elected to move the monitoring standard that previously appeared as standard 8.5 to appear as standard 8.4.2 under the quality monitoring standard. Subnumber 4 is new to the standard and previously appeared as a part of

				subnumber 3, but the committee felt that "Labeling" should appear as its own entry.
9.0	SC	NA	NA	The committee revised standard 8.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**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, #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	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, #4 (9.1, #5)	SC	NA	NA	The committee revised subnumber 4 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: 4) Ensuring that corrective action is reviewed and found to be effective.
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.
9.2, #1 (9.2.1)	SC	NA	NA	The committee revised subnumber 1 to standard 9.2 based on updates to the AABB Quality System Essentials. The standard 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.
9.2, #2 (9.2.2)	SC	NA	NA	The committee revised subnumber 2 to standard 9.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.2 Preventive Action** The organization shall have a process for preventive action that includes: 2) Determination of steps needed to address any problems requiring preventive action.
9.2, #3 (9.2.3)	SC	NA	NA	The committee revised subnumber 3 to standard 9.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.2 Preventive Action** The organization shall have a process for preventive action that includes: 3) Initiation of preventive action and application of controls to ensure that it is effective.
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.
10.1	SC	NA	NA	The committee revised 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.
Glossary – Acute Normovolemic Hemodilution	SC	NA	NA	The committee elected to edit the definition of acute normovolemic hemodilution with the creation of new standard 5.3.2.
Glossary – New Perioperative Methods	SC	NA	NA	The committee elected to edit the definition of new perioperative methods for clarity.
Glossary – Novel Perioperative Methods	SC	NA	NA	The committee elected to edit the definition of novel perioperative methods for clarity.
Glossary - Processing	SC	NA	NA	The committee added the term "Processing" to the glossary for completeness. The definition reads as follows: **Processing:** As it relates to perioperative blood components, the modification of collected blood for reinfusion, administration, or topical application.
Glossary - Purchase	SC	NA	NA	The committee added the term "Purchase" to the glossary for completeness. The definition reads as follows: **Purchase:** The lease, reagent rental, or any other acquisition of equipment, reagents, disposables, etc made by the organization to support these *Perioperative Standards*.
Glossary - Separated	SC	NA	NA	The committee elected to edit the definition of separated for clarity.
Glossary – Storage Container	SC	NA	NA	The committee elected to edit the definition of storage container for clarity.