Significant Changes and Response to Comments Received to the 34th edition of Standards for Blood Banks and Transfusion Services

Please note that public comments that were submitted address the proposed 34th edition of Standards for Blood Banks and Transfusion Services (*BB/TS Standards*), and not the final version. The BB/TS Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 34th edition of *BB/TS 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 (33rd edition)	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome
General	SC	NA	NA	The 34th edition of Standards for Blood Banks and Transfusion Services (QSEs). 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, #2 (1.1, #3)	SC	NA	NA	The committee revised standard 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: 2) Responsibility for compliance with these BB/TS Standards and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
1.1.1	SC	NA	NA	The committee edited standard 1.1.1 for completeness and clarity. The committee added the terms, "operations and quality" along with additional references to CLIA requirements to the standard, directing users to the responsibilities for laboratory directors in the US. The standard reads as follows: **1.1.1 Medical Director Qualifications and Responsibilities** The blood bank or transfusion service (hereinafter referred to as the BB/TS) shall have a medical director who is a licensed physician, qualified by training, experience, and facility-defined relevant continuing education in activities required by these BB/TS Standards for which the facility is accredited. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedures—including those that pertain to laboratory personnel, operations, quality, and test performance—and for the consultative and support services that relate to the care and safety of donors and/or transfusion recipients. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.*

				*21 CFR 630.3(i), 42 CFR 493.1251, 42 CFR 493.1407, and 42 CFR 493.1445.
1.1.1	RtC	This is a very vital standard as I can see an increasing number of nonqualified people appointed medical directors of blood banks, so we should define the qualification clearly: either transfusion medicine fellowship, or experience with clear evidence of minimum certain number of continuous medical education relevant to the BB/TS.	NO	The committee reviewed this comment but did not feel that a change would be appropriate at this point.
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.
1.3	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 BB/TS 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. Standard 1.1.1 applies.* *42 CFR 493.1251(d), 42 CFR 493.1407, and 42 CFR 493.1445.

				The committee has also added a cross-reference to standard 1.1.1 for clarity. Standard 1.1.1 points to the standard focused on medical director responsibilities.
1.3.2	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. Standard 1.1.1 applies.* *42 CFR 493.1251(d), 42 CFR 493.1407, and 42 CFR 493.1445. The committee has also added a cross-reference to standard 1.1.1 for clarity. Standard 1.1.1 points to the standard focused on medical director responsibilities.
1.3.2	RtC	I suggest editing the standard to read, "CLIA Laboratory Director and/or BB/TS Medical Director".	NO	The committee noted this comment but did not feel that a change was appropriate at this time. The committee did however add the relevant CLIA CFR references to this standard. Requiring that the term "CLIA" be included in the standard would have the focus be on US regulations.
1.4 (New)				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. The committee has developed new guidance to assist facilities in understanding this new standard.
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 (1.4)	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.
2.1	SC	NA	NA	The committee has edited this standard for completeness. The committee edited a reference to the CFR cited which concerns personnel requirements in the US. **2.1 Human Resources** The organization shall employ an adequate number of individuals qualified by education, training, and/or experience.* *21 CFR 606.20(b).
2.1.1 (2.1)	SC	NA	NA	The committee revised standard 2.1.1 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 BB/TS Standards.
2.1.2 (2.1.1)	SC	NA	NA	The committee elected to add cross-references to the CFRs for completeness. These requirements focus on qualification requirements for personnel in the United States, where the CFRs are applicable, however, it should be noted that the CFRs would not apply to facilities outside the US which should follow the applicable laws and regulations to their country. The standard reads as follows: **2.1.2 Qualification** Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training, and/ or experience.†

				†42 CFR 493.1403, 42 CFR 493.1405, 42 CFR 493.1407(a), 42 CFR 493.1421, 42 CFR 493.1441, and 42 CFR 493.1487.
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 BB/TS Standards are met when applicable.
2.1.6 (New)	RtC	Continuous education should be proven to be relevant to the BB/TS.	NO	The committee noted this comment and points to the clause "when applicable" allows facilities to define what continuing education requirement applies to which individuals.
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.
3.5.1.2 (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.
3.5.2 (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.
3.5.4, #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 BB/TS specific activities has been changed to more general language in the new QSE. The intent of the Standard has not changed.
3.5.4, #3 (3.5.2, #3)	SC	NA	NA	The committee revised standard 3.5.4, #3 based on updates to the AABB Quality System Essentials. The previous wording read, "Steps to ensure that the equipment is removed from service." 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: 3) Removal of equipment from service, if indicated. 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, #5 (3.5.2, #5)	SC	NA	NA	The committee revised standard 3.5.4, #5 based on updates to the AABB Quality System Essentials. The previous wording read, "Steps for requalification of the equipment." 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:

				5) Requalification of the equipment. The intention of the Standard has not changed.
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 (3.9.1, #1)	SC	NA	NA	The committee added 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 33rd 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, #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 committee has expanded the scope of the subnumber to focus specifically on policies, processes and procedures and other instructional documents and not just a general requirement concerning the way documents are written. 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 (3.9, #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, #9 (3.9.1, #4)	SC	NA	NA	The committee revised subnumber 9 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: 9) Defined process for monitoring of data integrity for critical data elements.
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.
3.7.1 (3.9.2)	SC	NA	NA	The committee revised standard 3.7.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7.1 Alternative Systems** An alternative system shall be maintained to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. The alternate system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.
3.9 (3.7)	RtC	Nowhere in the actual AABB assessment tool does it state the necessity to ensure the alarm limit testing must show on the recorder wheel. Standards should be written in such a way that ALL information required for compliance is found in the standard. As such, we were very surprised to discover we were not compliant with this checklist item. One should not need to check multiple sources of information in an effort of self-discovery to attain compliance. Upon reviewing the "AABB Methods" the "fire and ice" test can be found as the method for verifying temperature checks. This test seems very antiquated and outdated for today's appliances, especially when a secondary remote testing system is in place in a laboratory staffed 24/7. Newer appliances with the thermoelectric test simulating the heating and cooling of the thermocouple should be acceptable when paired with remote testing. It is the alarm that notifies staff to temperature deviations ... not the recorder. In our laboratory we recently performed the Fire and Ice test in order to be compliant with AABB Standards. In performing this test, it created a patient safety issue because our appliances became so "upset" we ended up removing all of the product from one of our blood fridges because the digital readout became so confused despite the internal temperature of the refrigerator being appropriate. It took 2 hours for	YES	The committee reviewed this comment and as a result made an adjustment. The committee has added a record retention requirement to standard 3.9 for completeness. The record is now required for alarm system check and that those records be retained for 10 years. In addition, the committee has provided guidance to clarify the intent of the standard with regard to the expected alarm tests.

		the temperature to gradually return to acceptable range. The same happened with our freezer. We were very concerned that we had actually damaged the units. After completing the tests, one could not even barely see the blips on the recorder wheel without a magnifying glass. A recorder wheel with larger degradations is not available. Two staff and one engineer spent 3 hours performing this test on 4 appliances. Very respectfully, I do not feel the information gleaned was a wise use of time. I am honestly very afraid of the next time we have to perform this test for fear of damaging the thermocouples on our appliances. Thank you for taking the time to consider my perspective. I am hoping there must be another way to attain compliance.		
3.9.1 (3.7.1)	RtC	Standard 3.9.1 States "*The alarm shell be set to activate under conditions that will allow proper action to be taken before blood, blood components, tissue, derivatives, or reagents reach unacceptable conditions.*" This is open to interpretations, what is considered "time to allow proper action to be taken"? Routinely 0.5C difference prior to the unit storage conditions have been used in many organizations for refrigerated storage. However, it may not be the same for a freezer or a room temperature storage condition. If the facility defines 0.3C to be enough time to take proper action for refrigerated and 3C for freezer that should fit this standard. Also, the standard states the blood, blood components, tissue, derivatives, or reagents reach unacceptable conditions not the storage equipment. That means, the equipment storage conditions might be outside the range but does not mean the contents of the storage unit are unacceptable. It takes longer time for a bag of red cells or a bottle of reagents to reach unacceptable conditions after the equipment reaches unacceptable temperature. Am I interpreting this correctly?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The intention is that the settings be such that the facility could move products before they each unacceptable temperatures; time to respond might vary between facilities.
4.0	SC			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.
4.2 (4.2.1)	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 (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.
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.
5.1.1.1 (5.1.1)	SC	NA	NA	The committee revised standard 5.1.1.1 based on updates to the AABB Quality System Essentials. The elements of this standard previously appeared as the second and third sentences of former standard 5.1.1, which has now been edited to mirror the updated Quality System Essentials. The standard reads as follows: **5.1.1.1** This shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated. Standard 2.1.3 applies.
5.1.2 (5.1.3)	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 (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.
5.1.2.4 (New)	SC	NA	NA	The committee has added new standard 5.1.2.4 for completeness. This standard reflects a CMS and CLIA requirement and its inclusion in this edition will ensure continued conformance with CMS and CLIA requirements. This standard has been incorporated in the Standards for Immunohematology Reference Laboratories and is applicable in the 34th as well. The standard reads as follows: **5.1.2.4** The laboratory shall evaluate the comparability of test results obtained using different methods, instruments, and if applicable, testing sites. This shall be performed twice annually.* *42 CFR 493.1281.
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 facilities have processes to meet these requirements already.
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 facilities 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 facilities have processes to meet these requirements already.
5.1.6 (5.1.4)	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	SC	NA	NA	The committee revised 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 (5.1.6)	SC	NA	NA	The committee revised 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.
5.1.8.2 (5.1.6.2)	RtC	Some transfusion devices don't trace these pharmaceutical products (anti-D immunoglobulin, SD PLASMA) although they are under the blood bank purview and have ISBT 128 codes.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that, if the blood bank dispenses these products, they would need to ensure traceability of the product.

5.1.8.3, #1 (5.1.6.3, #1)	RtC	The labeling should relate the original unit and components back to the donor (21 CFR 606.121(c)(3)), not just identify them.	NO	The committee reviewed this comment but did not think that a change was needed at this time. The committee notes that the requirement to use ISBT 128 labels ensures that units can be traced from source to final disposition.
5.1.8.3.1, #3 (5.1.6.3.1, #3)	RtC	We recommend documenting what can modified by a hand correction – usually only the expiration date/time and eliminating the U.S. License Number when appropriate. The limit on hand-corrections should be based on what is allowed in the Consensus Standards and does not include information that has to be machine readable.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that including the term "usually" would be inappropriate as it is in an undefined time period.
5.1.8.3.1, #4 (5.1.6.3.1, #4)	RtC	We recommend revising this standard item to the following: "Standard Operating Procedures shall specify the procedures to follow to modify blood component labels, including who is authorized to make modifications and when modifications may be made."	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the content of the subnumber as well as Standard 2.1and its subnumbers covering control of personnel performing critical tasks, serve the purpose of the comment.
5.1.8.3.1, #5 (5.1.6.3.1, #5)	RtC	21 CFR 606.121(b) should be addressed which speaks to the requirement to maintain the original label, with some exceptions.	YES	The committee reviewed this comment and felt that a change would be appropriate. The committee based on this comment added a reference to 21 CFR 606.121(b) to subnumber 5. The CFR in question establishes limitations regarding label removal or alteration.
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. Standard 3.8 applies. The committee noted that facilities have processes to meet these requirements already.
5.1.10 (5.1.2)	SC	NA	NA	The committee deleted the second sentence of standard 5.1.10 (formerly 5.1.2) and placed as a new standard 5.1.10.4. The committee felt that the concept did not fit appropriately into standard 5.1.10. The sentence read as follows, "When a CMS-approved program is not

				available, there shall be a system for determining the accuracy and reliability of test results.”
5.1.10.1 (New)	SC	NA	NA	The committee created new standard 5.1.10.1 for completeness. The standard ensures that the BB/TS Standards mirror the requirements set forth by CMS in July 2022 with an effective date of 2024. The requirements address proficiency testing referrals and what communication is and is not allowed until the results of proficiency testing are complete and submitted. The standard reads as follows: **5.1.10.1** Laboratories shall ensure that no interlaboratory communications pertaining to proficiency test events occur until after the submission deadline.* *42 CFR 493.801(b)(3).
5.1.10.2 (New)	SC			The committee created new standard 5.1.10.2 for completeness. This addition was made in conjunction with the addition of the CFR cited, which requires that laboratories that perform proficiency testing to show that they can successfully perform the act. Laboratories that attempt to have their samples outsourced would not meet the requirements in the CFR. The standard reads as follows: **5.1.10.2** The laboratory shall ensure that no portion of a proficiency testing sample is sent to another laboratory for analysis.† †42 CFR 493.801(b)(4).
5.1.10.3 (New)	SC	NA	NA	The committee added new standard 5.1.10.3 to the edition for completeness. This addition was made in conjunction with the addition of the CFR cited, which requires that if a laboratory receives samples for proficiency testing from an outside source that they immediately contact CMS who will instruct them on how to move forward. The standard reads as follows:

				5.1.10.3 Any laboratory that receives a proficiency testing sample from another laboratory for testing shall notify CMS of the receipt of the sample.‡ ‡42 CFR 493.801(b)(4).
5.1.10.4 (5.1.2)	SC	NA	NA	The committee created new standard 5.1.10.4 which was previously the second sentence of standard 5.1.10 (previously standard 5.1.2). The rationale being that this concept did not really fit within the content of the standard. The content or intent of this standard has not changed. The standard reads as follows: **5.1.10.4** When a CMS-approved program is not available, there shall be a system for determining the accuracy and reliability of test results.
5.1.11 (5.1.5)	RtC	We recommended the following revision: Aseptic ~~methods~~ techniques shall be employed to minimize the risk of microbial contamination of blood and blood components. Equipment and solutions that come into direct contact with blood or blood components shall be sterile and pyrogen-free. Single-use equipment and a closed system of product processing shall be used whenever possible.	YES	The committee reviewed this comment and felt that the change was appropriate. The committee did elect to retain the term "methods" as this is the term that appears in the 21 CFR 610.40. The standard appears as follows: **5.1.11 Sterility** Aseptic methods shall be employed to minimize the risk of microbial contamination of blood and blood components. Equipment and solutions that come into direct contact with blood or blood components shall be sterile and pyrogen-free. Single-use equipment and a closed system of product processing shall be used whenever possible.
5.2.4	RtC	Please include a requirement for "timely notification" to the standard.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the term, "timely" is not definitive and as a result difficult to assess. For US facilities, the time period for notification is specified in the CFR cited.
5.3.4.1	RtC	Please address monitoring trends and treating adverse events in this standard.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the monitoring of

				trends are covered already in chapters 7, 8, and 9.
5.4.1.3	SC	NA	NA	The committee, in an effort to ensure that the Standards remain gender neutral and to remain consistent with the Donor History Questionnaire 4.0, the committee removed the terms “males, females” from the standard, and replaced the terms with “donor.” The standard now reads as follows: **5.4.1.3** Plasma, Apheresis Platelets, and Whole Blood for allogeneic transfusion shall be from donors who have not been pregnant, or who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.
5.4.1.3	RtC	The change proposed would affect TRALI mitigation policies. As such, blood centers may require additional time to implement new polices and changes to testing algorithms. Has this been considered by the BB/TS Standards Committee?	NO	The committee noted this comment but did not feel that a change was appropriate. The committee feels that the standard has not inherently changed, and that the updated version of the standard is meeting the reality of facilities using the Donor History Questionnaire v4 which asks all potential donors if they’ve been pregnant.
5.4.3.2	SC	NA	NA	The committee, in conjunction with the updates to the quality systems essentials updated the standard to replace the phrase “shall have a process to reduce” with “mitigate” for legibility. The standard reads as follows: **5.4.3.2** The collection facility shall mitigate the risk of adverse reactions in young donors.
5.4.3.2	RtC	Please note that the word “mitigate” should be replaced with “mitigates” based on the update to the standard.	NO	The committee noted this comment to the standard but did not agree with the suggestion. The standard reads appropriately from a grammatical perspective.
5.5.1, 5.5.3.1	RtC	Both standards (5.5.1 and 5.5.3.1) refer to the Medical Director. Recommend revising this to appear as “Responsible Physician” to be consistent with CFR.	NO	The committee noted this comment but did not feel that a change would be appropriate. The committee feels that the term “medical director” is the correct term in relation to the Standards themselves.

5.5.3.1	RtC	The FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) only states, "December 2007." Does not include complete date, only month and year. Note: Section 5.7.3.1 (page 48) does state, "FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007)." Please update accordingly.	YES	The committee reviewed this comment and updated the standard accordingly.
5.5.3.3	RtC	Reference for guidance states "FDA Guidance for Industry: Technical Correction: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods (February 13, 2001)." Recommend revising guidance reference to state: "FDA Guidance for Industry: Technical Correction: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods (January 2001, Technical Correction February 2001)."	YES	The committee reviewed this comment and updated the standard accordingly.
5.5.3.4.3	RtC	The FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 17, 2007) only states, "December 2007." Does not include complete date, only month and year. Note: Section 5.7.3.1 (page 48) does state, "FDA Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007)." Please update accordingly.	YES	The committee reviewed this comment and updated the standard accordingly.
5.5.3.5	RtC	Reference for guidance states "FDA Guidance for Industry: Technical Correction: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods (February 13, 2001)." Recommend revising guidance reference to state: "FDA Guidance for Industry: Technical Correction: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods (January 2001, Technical Correction February 2001)."	YES	The committee reviewed this comment and updated the standard accordingly.
5.6.5.1	SC	NA	NA	Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical" issued June 23, 2023, the committee edited standard 5.6.5.1. The committee revised the standard as such: **5.6.5.1** Whole Blood and Apheresis Platelets intended for room temperature processing and Apheresis Platelets, shall be transported and

				stored in a manner intended to cool the blood and Apheresis Platelets toward a temperature range of 20 to 24 C. The committee has created guidance that clarifies that "Apheresis Platelets intended for room temperature processing" includes apheresis platelets intended for pathogen reduction using the Intercept method, which is performed at room temperature.
5.6.5.2	SC	NA	NA	Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical" issued June 23, 2023, the committee created new standard 5.6.5.2. The standard was issued as an interim standard in AABB Association Bulletin 23-05. The standard reads as follows: **5.6.5.2** Apheresis platelets intended for cold storage without pathogen reduction shall be placed at 1 to 6 C within 4 hours from the end of collection.* *FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding When Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).
5.6.5.2.1	SC	NA	NA	Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical" issued June 23, 2023, the committee created new standard 5.6.5.2.1. The standard was issued as

				an interim standard in AABB Association Bulletin 23-05. The standard reads as follows: **5.6.5.2.1** If the apheresis product intended for cold storage without pathogen reduction will arrive at the processing facility within 4 hours of collection, the product may be transported in a manner intended to cool the blood and Apheresis Platelets toward a temperature range of 20 to 24 C.
5.6.5.2.2	SC	NA	NA	Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical" issued June 23, 2023, the committee created new standard 5.6.5.2.2. The standard was issued as an interim standard in AABB Association Bulletin 23-05. The standard reads as follows: **5.6.5.2.2** If the apheresis product intended for cold storage without pathogen reduction will not arrive at the processing facility within 4 hours of collection, the product shall be placed at 1 to 6 C within 4 hours from the end of collection.
5.6.5.2.2.1	SC	NA	NA	Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical" issued June 23, 2023, the committee created new standard 5.6.5.2.2.1. The standard was issued as an interim standard in AABB Association Bulletin 23-05. The standard reads as follows: **5.6.5.2.2.1** If the apheresis product intended for cold storage without pathogen reduction has been placed at 1 to 6 C, it shall be transported in

				a qualified container having sufficient refrigeration capacity to maintain a temperature range of 1 to 10 C.
5.6.6.1	SC	NA	NA	The committee elected to edit the wording of the standard for clarity. The edits to the standard do not significantly alter the intent of the standard. The standard now reads as follows: **5.6.6.1** The process used in performing a phlebotomy and processing the blood shall be designed to ensure the safety of any reinfusion to the donor.
5.7.4.10.1, 5.7.4.11.1, 5.7.4.12.1 (DELETED)	SC	NA	NA	The committee elected to delete standards 5.7.4.10.1, 5.7.4.11.1, and 5.7.4.12.1. These standards related to liquid freezing baths that followed requirements for FFP, Plasma Frozen Within 24 hours after Phlebotomy, and Plasma Frozen within 24 Hours After Phlebotomy Held at Room Temperature up to 24 Hours After Phlebotomy as the committee has not seen any evidence that this method is currently utilized. The committee has elected to move the content of these standards to the guidance to the 34th edition for historical purposes. The standards previously reads as follows: ~~5.7.4.10.1 If a liquid freezing bath is used, the container shall be protected from chemical exposure.~~ ~~5.7.4.11.1 If a liquid freezing bath is used, the container shall be protected from chemical exposure.~~ ~~5.7.4.12.1 If a liquid freezing bath is used, the container shall be protected from chemical exposure.~~
5.7.4.16	RtC	We suggest the following revision to the standard: "Pathogen-reduced plasma shall be ~~collected and processed~~ prepared as per the manufacturer's written instructions." It should be noted that PRT plasma is not collected, rather, plasma is further processed to make PRT plasma.	YES	The committee agreed with the comment and the edit suggested. The committee updated the standard accordingly. The standard now reads as follows: **5.7.4.16 PATHOGEN-REDUCED PLASMA** Pathogen-reduced plasma shall be prepared as per the manufacturer's written instructions.

5.7.4.17	SC	NA	NA	The committee updated standard 5.7.4.17 to align with the language in 21 CFR 640.50 which does not require the starting material to be fresh frozen plasma. The fibrinogen and Factor VIII requirements for cryoprecipitated AHF are unchanged from the 33rd edition. The committee also added the phrase, "Validation and quality control…" to ensure parallel construction with the other standards included in the component preparation section (5.7.4). The committee also added a reference to 21 CFR 640.50 which contains the requirements set forth by FDA for Cryoprecipitated AHF. The standard now reads as follows: **5.7.4.17 CRYOPRECIPITATED AHF** Cryoprecipitated AHF shall be prepared from frozen plasma derived from whole blood or apheresis by a method known to separate the cold insoluble precipitate. Validation and quality control shall demonstrate an average content of at least 150 mg of fibrinogen and 80 IU of coagulation Factor VIII per container or unit. In tests performed on prestorage pooled components, the pool shall contain at least 150 mg of fibrinogen and 80 IU of coagulation Factor VIII per component in the pool.* *21 CFR 606.122, 21 CFR 640.50, 21 CFR 640.54, and 21 CFR 640.56.
5.7.4.17	RtC	We suggest the following revision: "Cryoprecipitated AHF shall be prepared by a method known to separate the cold insoluble portion from ~~Fresh Frozen~~ Plasma…" Also please add a reference to 21 CFR 640.50 to the standard. The FDA has allowed for the manufacture of Cryoprecipitated AHF from PF24.	YES	The committee noted this comment and agreed with the content.
5.7.4.20	RtC	International centers may have their own regulations when it comes to the platelet dose which would require an update, this could provide alignment with the CAP standard as well.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes there are instances where a country's Competent Authority may have different regulations than what is contained in

				the Standards and in these cases, the facility may apply for a variance.
5.7.4.26	RtC	We suggest the following revision: "Pathogen-reduced platelets shall be ~~collected and processed~~ prepared as per the manufacturer's written instructions." Please note that PRT platelets are not collected. Rather, platelets are further processed with a PRT device to make this product.	YES	The committee reviewed this comment and felt that this change would be appropriate. The committee noted that pathogen reduced platelets are not collected, rather PR platelets are further processed to make pathogen reduced platelets in this case, the term prepared better encapsulated the committee's intent.
5.7.4.26.1	RtC	Consider citing the following FDA Guidance to the standard, "Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers (November 2021)"	NO	The committee noted this comment but did not feel that a change was needed at this time.
5.7.4.27	SC	NA	NA	Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical" issued June 23, 2023, the committee created new standard 5.7.4.27. The standard was issued as an interim standard in AABB Association Bulletin 23-05. The standard reads as follows: **5.7.4.27 APHERESIS PLATELETS COLD STORED** Apheresis Platelets Cold Stored shall be placed at 1 to 6 C within 4 hours from either the end of collection or completion of the pathogen reduction process. Validation shall demonstrate with 95% confidence that greater than 75% of the platelets stored at 1 to 6 C maintain a pH >6.2 at the end of the allowable storage period, up to 14 days.† Platelet and leukocyte content before storage shall meet the requirements for Apheresis Platelets maintained at room temperature. Quality control shall demonstrate with 95% confidence that greater than 95% of units have a pH >6.2 at the time of issue or within 12 hours after expiration.

				†FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).
5.7.4.27.1	SC	NA	NA	Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical" issued June 23, 2023, the committee created new standard 5.7.4.27.1. The standard was issued as an interim standard in AABB Association Bulletin 23-05. The standard reads as follows: **5.7.4.27.1** The number of Apheresis Platelets Cold Stored components included in the overall monthly quality control testing plan shall represent the proportion of Apheresis Platelets Cold Stored in the total platelet inventory.† †FDA Guidance for Industry: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical (June 2023).
5.8.5	RtC	Should there be a travel deferral added to the DHQ based on the number of variances submitted monthly by accredited facilities outside the United States?	NO	The committee reviewed this comment but did not feel that a change was appropriate. Facilities may implement more stringent criteria or apply for variances to Standards as appropriate to their local epidemiology or local regulations..
5.10.1 (New)	SC	NA	NA	The committee elected to add new standard 5.10.1 to the 34th edition to ensure that the Circular of Information for the Use of Human Blood and Blood Components would be available to the receiving facility or transfusionist with all shipped product. The COI is considered to be the extended labeling (e.g,

				package insert) for blood components. The standard reads as follows: **5.10.1** The current Circular of Information for the Use of Human Blood and Blood Components shall be available.
5.15.5	SC	NA	NA	The committee elected to edit this standard in conjunction with the creation of new standard 5.15.6. The content that was focused on platelets were removed from the standard and made to appear as new standard 5.15.6. The standard now reads as follows: **5.15.5** The red cells in Apheresis Granulocytes ~~and Platelets~~ shall be ABO-compatible with the recipient's plasma and be crossmatched as in Standard 5.16 ~~unless the component is prepared by a method know to result in a component containing < 2mL of red cells.~~. The donor blood cells for the crossmatch may be obtained from a sample collected at the time of donation.
5.15.5	RtC	Some facilities sediment granulocytes to remove incompatible red cells to allow out of ABO blood group transfusions. Is there a reason the statement for components prepared by a method known to result in a component containing <2 ml of red cells was removed?	NO	The committee reviewed the comment but did not feel that a change was appropriate at this time. In this case, the standards were separated purposefully. It is the committee's understanding that the red cell content of Apheresis Granulocytes typically exceeds 2 ml
5.15.6 (New)	SC	NA	NA	The committee created new standard 5.15.6 by removing the content that focused on platelets from standard 5.15.5 and mirroring the tone and style of standard 5.15.5 with new standard 5.15.6. The committee felt that the standards for granulocytes and platelets should be separated because the red cell content of Apheresis Granulocytes is expected to exceed 2 mL of red cells. The standard reads as follows: **5.15.6** The red cells in Platelets shall be ABO-compatible with the recipient's plasma and be crossmatched as in Standard 5.16 unless the component is prepared by a method known to result in a component containing <2 mL of red

				cells. The donor blood cells for the crossmatch may be obtained from a sample collected at the time of donation.
5.20	SC	NA	NA	The committee edited standard 5.20 for clarity. The standard has been edited to include the clause, "In the facility" to ensure that the BB/TS's responsibility related to preparatory steps applies to the processes that it performs. The standard reads as follows: ✎**5.20 Preparation of Tissue** The facility shall ensure that any preparation steps performed in the facility before dispensing tissue are in accordance with the manufacturer's written instructions. The following information shall be maintained: 1) Type of tissue. 2) Numeric or alphanumeric identifier. 3) Quantity. 4) Expiration date and, if applicable, time. 5) Identity of personnel who prepared the tissue and the date of preparation.
5.21	SC	NA	NA	The committee edited standard 5.21 for clarity. The standard has been edited to include the clause, "In the facility" to ensure that the BB/TS's responsibility related to preparatory steps applies to the processes that it performs. The standard reads as follows: ✎**5.21 Preparation of Derivatives** The facility shall ensure that any preparation steps performed in the facility before dispensing derivatives are in accordance with the manufacturer's written instructions. The following information shall be maintained: 1) Type of derivative. 2) Lot number. 3) Quantity. 4) Expiration date and, if applicable, time. 5) Identity of personnel who prepared the derivative and the date of preparation.

5.28.3	SC	NA	NA	The committee elected to edit standard 5.28.3 for accuracy, completeness and to mirror the introduction to standard 5.28.4. The standard reads as follows: **5.28.3** In the presence of the recipient, and before initiating transfusion, the following information shall be verified: 1) The intended recipient's two independent identifiers, ABO group, and Rh type. 2) The donation identification number, the donor ABO group, and, if required, the Rh type. 3) The interpretation of crossmatch tests, if performed. 4) Special transfusion requirements are met, if applicable. 5) The unit has not expired.
5.28.3	RtC	Should standard 5.28.3 and 5.28.4 be written to mirror each standards language? 5.28.3 In the presence of the recipient, and before initiating transfusion… 5.28.4 In the presence of the recipient, and before initiating the transfusion…	YES	The committee agreed with this comment and removed the term "the" in standard 5.28.4. to ensure parallel construction of the language between the standards.
5.28.4	SC	NA	NA	The committee edited the introduction to standard 5.28.4 to mirror the introduction of standard 5.28.3 to ensure parallel construction. The standard reads as follows: **5.28.4** In the presence of the recipient, and before initiating transfusion, the transfusionist and one other individual (or an electronic identification system) shall positively identify the recipient and match the blood component to the recipient through the use of two independent identifiers.
5.30.2	SC	NA	NA	The committee elected to edit standard 5.30.2 by removing gender related terms from standard 5.30.2. The standard reads as follows: **5.30.2** Individuals who are pregnant or who have been pregnant recently shall be considered for Rh Immune Globulin administration when all of the following apply:

				1) The individual's test for D antigen is negative. A test for weak D is optional. 2) The individual is not known to be actively immunized to the D antigen. 3) The RhD type of the fetus/neonate is unknown, or the type of the fetus/neonate is positive when tested for D or weak D. Weak D testing is required when the test for D is negative.
5.30.3	SC	NA	NA	The committee elected to edit standard 5.30.3 for clarity and for the standard to mirror the current practice found in accredited transfusion services. The committee did edit the standard to include a clause that provided an out for facilities that do not issue Rh Immune Globulin would not need to adhere to the standard as written. The standard reads as follows: **5.30.3** If the transfusion service is responsible for issue of Rh Immune Globulin, the transfusion service shall recommend the appropriate dose.
5.30.3	RtC	Standard 5.30.3, is problematic for transfusion services that do not perform KB testing nor stock and issue RhIg. A recently passed law in Pennsylvania requires that only licensed pharmacies can distribute/issue RhIg. Thus, RhIg is now stocked and issued by the pharmacy. The package inserts for Rhogam, Rhophylac and WinRho all differ in the recommended dosing of their product. WinRho for instance recommends 120 mcg after 34 weeks for uncomplicated delivery. None of the package inserts follows the dosing guidelines in the Technical Manual. Thus, the blood bank should be responsible for providing the results of testing but the dose calculation is now in the realm of the pharmacy. Only they know the current RhIg product they stock and the vials size. I suggest the following rewording: 5.30.3 For transfusion services that stock and issue Rh Immune Globulin, the transfusion service shall recommend the appropriate dose of Rh Immune Globulin.	YES	The committee agreed with this comment and adjusted the wording of the standard as proposed to ensure that the standard began with the clause, "If the transfusion service…" This ensures that facilities that do not issue Rh Immune Globulin are not held responsible for adherence to this standard.
5.30.3	RtC	Perhaps it is time to fundamentally rethink whether this standard is needed/helps clinically ALL patients: 1) Due to changes in pharmacy laws, most Rho(D) Immune Globulin is issued out of pharmacy and not the blood bank; therefore pharmacies drive the	YES	The committee agreed with this comment and adjusted the wording of the standard as proposed to ensure that the standard began with the clause, "If the transfusion service…"

<table>
<tr><td></td><td></td><td>formulation(s) offered at a given hospital or clinic, not the blood bank. A given blood bank may be providing dosing support to more than one hospital/clinic with different formulations, which sets the blood bank up for failure. Let the pharmacy do their job of recommending dosing.
2) CAP lab surveys show that there are significant errors in dosing calculations (Ransey G. Archive. 2009;133:465-9), that includes errors with the Tech manual's method of calculation itself (Sandler G. Letter to Editor Archives 2010; 134: 967-8.)
3) The Tech Manual's calculations estimate female TBV as 5000ml and a fetal HCT of 50%. If a patient weights >363.5 lbs, then the calculation will underestimate the # of vials required.
4) There are many formulations of Rho(D) Immune Globulin. In the US, most are either mini- (250iu/50mcg) or full dose (1500iu/300mcg); however, WinRho has more dosing options, up to 15000iu or 3000mcg. Outside of the US, there are many other formulations with different dosing (Rhesonativ, D-Gam, etc).</td><td></td><td>This ensures that facilities that do not issue Rh Immune Globulin are not held responsible for adherence to this standard.</td></tr>
<tr><td>5.30.3</td><td>RtC</td><td>I recommend adding “further dosing based on clear algorithm of testing.”</td><td>NO</td><td>The committee reviewed this comment but did not feel that this change would be appropriate at this time.
The committee feels the change made as noted in the rows above would adequately meet the intent of the comment.</td></tr>
<tr><td>5.1.8A, #16</td><td>SC</td><td>NA</td><td>NA</td><td>The committee elected to edit entry #16 concerning “Autologous Donor” labeling requirements for clarity.
The committee replaced the “Not Required” for the “Collection or Preparation” step, with “Required” phase acknowledging that this information could appear on a tie tag, but not the bag itself.
The committee also replaced the “Not Required” for “Pooled Components” to “Required” to address a possible scenario in which autologous components are pooled.
The standard now reads as follows:
<table>
<tr><th>Item No.</th><th>Labeling Item</th><th>Collection or Preparation</th><th>Final Component</th><th>Pooled</th></tr>
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<table>
<tr><td>16</td><td>Phrase: “Autologous Donor,” if applicable</td><td>R</td><td>R</td><td>R</td></tr>
</table>
[7]The facility has the option of placing information on a tie tag or label.
</td>
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<tr>
<td>5.1.8A, #16 (5.1.6A, #16)</td>
<td>RtC</td>
<td>
<table>
<tr><td>Item No.</td><td>Labeling Item</td><td>Collection or Preparation</td><td>Final Component</td><td>Pooled</td></tr>
<tr><td>16</td><td>Phrase: “Autologous Donor,” if applicable</td><td>~~NR~~ R</td><td>R</td><td>R</td></tr>
</table>
Please replace the “NR” to “R”.
</td>
<td>YES</td>
<td>The committee agreed with the comment and made the change as suggested.</td>
</tr>
<tr>
<td>5.1.8A, #s 26, 31, 33 (5.1.6A, #s 26, 31, 33)</td>
<td>RtC</td>
<td>
<table>
<tr><td>Item No.</td><td>Labeling Item</td><td>Collection or Preparation</td><td>Final Component</td><td>Pooled</td></tr>
<tr><td>26</td><td>Biohazard label, if applicable[14]</td><td>~~NR~~ R</td><td>R</td><td>R</td></tr>
<tr><td>31</td><td>Biohazard label, if applicable</td><td>~~NR~~ R* If status is known.</td><td>R</td><td>R</td></tr>
<tr><td>33</td><td>Biohazard label, if applicable</td><td>~~NR~~ R</td><td>R</td><td>R</td></tr>
</table>
Please replace the “NR” to “R”.
</td>
<td>NO</td>
<td>The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that the collection staff is not always aware of a donor’s status or what needs a biohazard label.
To make these changes this could prove quite difficult to enact. These changes could potentially also visibly distinguish donors in a public setting, causing donor embarrassment</td>
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<tr>
<td>5.1.8A, #s 27, 28, 29, 30 (5.1.6A, #s 27, 28, 29, 30)</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>The committee elected to edit entries 27 – 30 for accuracy. The has revised the labeling requirements of the Pooled components from “Not Applicable” to “Required” to address a possible scenario in which autologous components are pooled.
The updated entries read as follows:</td>
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<table>
<tr><th>Item No.</th><th>Labeling Item</th><th>Collection or Preparation</th><th>Final Component</th><th>Pooled</th></tr>
<tr><td>27</td><td>Phrase: “Donor untested,” if applicable[11,15]</td><td>NR</td><td>R</td><td>R</td></tr>
<tr><td>28</td><td>Phrase: “Donor tested within the last 30 days,” if applicable[11,16]</td><td>NR</td><td>R</td><td>R</td></tr>
<tr><td>29</td><td>Intended recipient information label[7]</td><td>R</td><td>R</td><td>R</td></tr>
<tr><td>30</td><td>Phrase: “Donor tested within the last 30 days,” if applicable[16]</td><td>NR</td><td>R</td><td>R</td></tr>
</table>
</td>
</tr>
<tr>
<td>5.1.9A, #23 (5.1.8A, #14)</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, “Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical” issued June 23, 2023, the committee edited entry #23 (formerly #14) in the reference standard. The standard was issued as an interim standard in AABB Association Bulletin 23-05.
The component nomenclature has been updated to mirror the language in the interim standards cited above. The expiration time and additional criteria for apheresis platelets mirror the language in the recently released FDA Guidance.
The standard reads as follows:</td>
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<table>
<tr><th>Item No.</th><th>Component</th><th>Storage</th><th>Transport[2]</th><th>Expiration[3]</th><th>Additional Criteria</th></tr>
<tr><td>23</td><td>Apheresis Platelets Cold Stored[9]</td><td>1-6 C (agitation optional)</td><td>1-10 C</td><td>14 days</td><td>Suspended in 100% Plasma or platelet additive solution</td></tr>
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<tr>
<td>5.1.9A, #24, 25 (5.1.8A, #24, 25)</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>Based on the issue of Food and Drug Administration (FDA) Guidance for Industry, “Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical” issued June 23, 2023, the committee created new entries #24 and 25 in the reference standard. The standard was issued as an interim standard in AABB Association Bulletin 23-05.
The standard reads as follows:</td>
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<tr><th>Item No.</th><th>Component</th><th>Storage</th><th>Transport[2]</th><th>Expiration[3]</th><th>Additional Criteria</th></tr>
<tr><td>24</td><td>Apheresis Platelets Pathogen Reduced Cold Stored[9]</td><td>1-6 C (agitation optional)</td><td>1-10 C</td><td>14 days</td><td>Suspended in 100% Plasma or platelet additive solution</td></tr>
<tr><td>25</td><td>Whole-Blood-Derived Platelets Cold Stored</td><td>1-6 C (agitation optional)</td><td>1-10 C</td><td>As specified in the instructions for use by the blood collection, processing, and storage system approved or cleared for such use by FDA or Competent Authority.</td><td></td></tr>
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<tr>
<td>5.1.9A, #s 29, 31 (5.1.8A, #27, 29)</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>The committee edited entries 29 and 31 (formerly 27 and 29) for clarity. The committee added clarifications to these allowing for the use</td>
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<td>of FDA cleared cryoprecipitate thawing devices. The intent of the entries have not changed.
The edited standards appear below:
<table>
<tr><th>Item No.</th><th>Component</th><th>Storage</th><th>Transport[2]</th><th>Expiration[3]</th><th>Additional Criteria</th></tr>
<tr><td>29</td><td>Cryoprecipitated AHF (after thawing)</td><td>20-24 C</td><td>As close as possible to 20-24 C</td><td>Single unit: 6 hours</td><td>Thaw at 30-37 C or in an FDA-cleared Cryoprecipitate thawing device.</td></tr>
<tr><td>31</td><td>Pooled Cryoprecipitated AHF (after thawing)</td><td>20-24 C</td><td>As close as possible to 20-24 C</td><td>Pooled in an open system: 4 hours
If pooled using a sterile connection device: 6 hours</td><td>Thaw at 30-37 C or in an FDA-cleared Cryoprecipitate thawing device.</td></tr>
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<tr>
<td>5.1.9A, #s 35, 37, 39, 42
(5.1.8A, #s 33, 35, 37, 40)</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>The committee edited entries 35, 37, 39 and 42 for consistency. The committee added clarifications to these entries allowing for the use of FDA cleared plasma thawing device. The intent of the entries have not changed.
The edited standards appear below:</td>
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<table>
<tr><th>Item No.</th><th>Component</th><th>Storage</th><th>Transport[2]</th><th>Expiration[3]</th><th>Additional Criteria</th></tr>
<tr><td>35</td><td>FFP (after thawing) [10]</td><td>1-6 C</td><td>1-10 C</td><td>If issued as FFP: 24 hours</td><td>Thaw at 30-37 C or by using an FDA-cleared plasma thawing device</td></tr>
<tr><td>37</td><td>Plasma Frozen Within 24 Hours After Phlebotomy (after thawing) [10]</td><td>1-6 C</td><td>1-10 C</td><td>If issued as PF24: 24 hours</td><td>Thaw at 30-37 C or by using an FDA-cleared plasma thawing device</td></tr>
<tr><td>39</td><td>Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up to 24 Hours After Phlebotomy (after thawing)</td><td>1-6 C</td><td>1-10 C</td><td>If issued as PF24RT24: 24 hours</td><td>Thaw at 30-37 C or by using an FDA-cleared plasma thawing device</td></tr>
<tr><td>42</td><td>Plasma Cryoprecipitate Reduced (after thawing)</td><td>1-6 C</td><td>1-10 C</td><td>If issued as Plasma Cryoprecipitate Reduced: 24 hours</td><td>Thaw at 30-37 C or in an FDA-cleared plasma thawing device.</td></tr>
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<tr>
<td>5.4.1A, #9</td>
<td>SC</td>
<td>NA</td>
<td>NA</td>
<td>Based on the FDA guidance issued in May 2023 entitled, “Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products” and verbiage changes to the FDA-accepted donor history questionnaire, the committee included new entries in row 9. These changes were issued as emergent</td>
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<td>standards to the 33rd edition of BB/TS Standards via Association Bulletin 23-03.
<table>
<tr><th>Category</th><th>Criteria/Description/Examples</th><th>Deferral Period</th></tr>
<tr><td rowspan="3">9) Drug Therapy</td><td>Taken any medication by mouth (oral) to prevent HIV infection (i.e., PrEP or PEP)</td><td>3 months[4]</td></tr>
<tr><td>Received any medication by injection to prevent HIV infection (i.e., long-acting antiviral PrEP or PEP)</td><td>2 years[4]</td></tr>
<tr><td>Taken any medication to treat HIV infection</td><td>Permanent [4]</td></tr>
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<tr>
<td>5.4.1A, #9</td>
<td>RtC</td>
<td>Could you please clarify the reason behind the 2-day deferral period for enoxaparin (Lovenox), while heparin and other low-molecular-weight heparins require a 7-day deferral?
Additionally, should enoxaparin be categorized as a low-molecular-weight heparin?</td>
<td>NO</td>
<td>The committee reviewed this comment but did not think that the Standards would be the appropriate place to include this information. This is addressed in the Donor History Questionnaire.</td>
</tr>
<tr>
<td>5.4.1A, #12</td>
<td>RtC/SC</td>
<td>We recommend that the standard be updated to specify donor deferral for allogeneic transfusions IAW FDA Guidance to Industry: Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products (2023).</td>
<td>YES</td>
<td>The committee agreed with the intent of this comment and determined that an update to the entry would be appropriate. This addition will ensure that the Standards remain consistent with FDA Guidelines.
The standard reads as follows:</td>
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<td>III.B.12: Defer for 3 months from the most recent allogeneic transfusion, any individual who has a history of receiving an allogeneic transfusion of Whole Blood or blood components.
The current standard does not distinguish between allogeneic or autologous receipt of blood, components, or human tissue. DoD training protocol has made autologous whole blood transfusion training a semi-annual requirement. The lack of specification for allogeneic transfusion deferral results in a large population of the military being deferred for up to 6 months out of the year. Akeroyd Blood Donor Center (8034) has been granted a variance to reduce the deferral period from 3 months to 7 days for individuals participating in this training. Specifying the deferral requirement is for allogeneic transfusions would eliminate the need for every DoD donor center to seek the same variance approval.</td>
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<table>
<tr><th>Category</th><th>Criteria/Description/Examples</th><th>Deferral Period</th></tr>
<tr><td>12) Receipt of Blood, Blood Component, or Human Tissue</td><td>• Receipt of human cadaveric (allogeneic) dura mater transplant
• Donors previously deferred for human growth hormone
• Receipt of allogeneic blood, components, or human tissue</td><td>Permanent

Permanent in accordance with FDA Guidance

3 months</td></tr>
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<tr>
<td>5.4.1A, #14</td>
<td>RtC/SC</td>
<td>A recombinant RSV vaccine was recently approved, and I wanted to ask the BB/TS Standards Committee to consider adding to the list of vaccines that do not require a deferral- Reference Standard 5.4.1A (14) Immunizations and vaccinations.
Please see for press release: https://www.pfizer.com/news/press-release/press-release-detail/us-fda-approves-abrysvotm-pfizers-vaccine-prevention
Please see for package insert: https://labeling.pfizer.com/ShowLabeling.aspx?id=19589</td>
<td>YES</td>
<td>The committee reviewed this comment and agreed with its intent. As a result, the committee has added the “RSV” vaccine to the list of examples in the second bullet point.
The standard reads as follows:
<table>
<tr><th>Category</th><th>Criteria/Description/Examples</th><th>Deferral Period</th></tr>
<tr><td>14) Immunizations and Vaccinations</td><td>• Receipt of recombinant vaccine [eg, RSV, HPV and Zoster Recombin</td><td>None</td></tr>
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<tr><td></td><td></td><td></td><td></td><td><table><tr><td></td><td>ant, Adjuvanted (Shingrix) Vaccine]</td><td></td></tr></table></td></tr>
<tr><td>5.4.1A, #15</td><td>SC</td><td>NA</td><td>NA</td><td>Based on the FDA guidance issued in May 2023 entitled, “Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products” and verbiage changes to the FDA-accepted donor history questionnaire v4.0, the committee edited entries in row 15. These changes were issued as emergent standards to the 33rd edition of BB/TS Standards via Association Bulletin 23-03.
<table>
<tr><th>Category</th><th>Criteria/Description/Examples</th><th>Deferral Period</th></tr>
<tr><td>15) Relevant Transfusion-Transmitted Infections [7]</td><td>• Present or past clinical or laboratory evidence of infection with HIV, HCV,[12] HTLV, or T. cruzi [13]</td><td>Indefinite</td></tr>
<tr><td></td><td>• Ever had a confirmed positive test</td><td>Permanent</td></tr>
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					result for HIV infection[4]	
					• Use of a needle to inject drugs, steroids or anything not prescribed by their doctor	3 months
					• Contact with blood of another individual through percutaneous inoculation such as a needle stick or through contact with a donor's open	3 months

					wound or mucous membranes	
					Tattoo, ear or body piercing - For tattoos, no deferral if the tattoo was applied by a state regulated entity with sterile needles and non-reused ink. - For ear or body piercings, no deferral if the piercing was done using single-use equipment.	3 months

					Sexual contact with an individual with who ever had a positive test result for HIV infection	3 months [4]
					Sexual contact with an individual who in the past 3 months: -has received money, drugs, or other payment for sex. -has used needles to inject drugs, steroids or anything not prescribed by their doctor.	3 months[4]
					Received money, drugs, or other payment for sex.	3 months[4]

					Have had a new sexual partner in the past 3 months and have had anal sex in the past 3 months.	3 months[4]
					Have had more than one sexual partner in the past 3 months and have had anal sex in the past 3 months.	3 months[4]
5.4.1A, #15	RtC	Please delete "confirmed" in this entry to be consistent with wording in FDA Guidance document with regard to testing for HBsAg.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee wishes to maintain this term to provide clarity to the requirements. The committee has, additionally, provided guidance to distinguish the category requiring permanent deferral from that requiring indefinite deferral in the preceding row.		
5.4.1A, #15	RtC	Please consider reformatting the paragraph concerning contact with a blood of another individual to read: Contact with blood of another individual through: · Percutaneous inoculation such as a needlestick · Contact with a donor's open wound · Contact with a donor's mucous membranes	NO	The committee noted this comment but did not feel that a change was needed at this time.		
5.4.1A, #15	RtC	For acceptance of donors with past history of syphilis infection after a declaration from their treating physician of complete cure, I think it is not acceptable to accept these donations and neglect the serological results of donor screening as the Treponema pallidum antibodies persists for life.	NO	The committee noted this comment but did not feel that this change would be appropriate at this time.		
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 (6.1.1, 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 (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.
6.1.6	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.
6.1.9 (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 BBTS 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, #3 (6.2.4, #3)	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.
6.2.9 (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 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, #2 (6.2.8, #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 (6.2.8, #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.
6.2.12 (6.2.9)	SC	NA	NA	The committee revised 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.
6.3.1 (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 (6.2.7.2)	SC	NA	NA	The committee revised 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 (6.2.7.1.1)	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 (6.2.7.1.1)	SC	NA	NA	The committee revised 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.
6.3.4.2 (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 (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.
7.2.4.1.1 (New)	SC	NA	NA	The committee elected to add new standard 7.2.4.1.1 for completeness. This requirement previously existed as a part of standard 7.1.4. The standard reads as such: **7.2.4.1.1** The records shall include a description of nonconformances and any subsequent actions taken.
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.
7.3.5.3 (7.5.2.3)	SC	NA	NA	The committee elected to remove the clause "including TRALI and TACO" as it was deemed redundant to the verbiage in 7.3.5.2. The standard now reads as follows: ✎**7.3.5.3** Interpretation of the evaluation shall be recorded in the patient's medical record and, if suggestive of hemolysis, bacterial contamination, pulmonary reactions, or other serious adverse event related to transfusion, the interpretation shall be reported to the patient's physician immediately. Standard 7.3.5.4 applies.
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 (8.1)	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 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 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.
8.4.1 (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.
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.
9.1.1 (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.
9.3 (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.
Glossary – Authorized Health Professional (New)	SC	NA	NA	The committee elected to add a glossary entry for "authorized health professional" for clarity and completeness. The entry reads as follows: **Authorized Health Professional:** A person permitted to perform certain tasks in accordance with regulations and based on their credentials, qualification, education, training, and experience.