Significant Changes and Response to Comments Received to the 1st edition of Standards for Emergency Prehospital and Scheduled Out-of-Hospital Transfusions

Please note that public comments that were submitted address the proposed 1st edition of *Standards for Emergency Prehospital and Scheduled Out-of-Hospital Transfusions* (*Prehospital and Out-of-hospital Standards*), and not the final version. The Prehospital and Out-of-hospital Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 1st edition of *Prehospital and Out-of-hospital 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.

Note, where changes have been made to the quality focused standards (AABB's quality system essentials), these edits are related back to the 1st edition of Standards for Out-of-hospital Transfusion Administration Services.

Standard	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome
1.0	RtC	Who specifically is being assessed by AABB as the "organization"? Are the Standards intended to apply to rehabilitation facilities, hospice, etc. for out of hospital activities and emergency medical services (EMS) for prehospital activities? Is it correct to assume that the transfusion administration services (TAS) may be internal or external to the out-of-hospital or prehospital entity? Please confirm if the intent is that out-of-hospital or prehospital entities and applicable transfusion service (TS) would be held accountable together to the *Standards for Emergency Prehospital and Scheduled Out-of-Hospital Transfusions*. Or would the TS, if accredited, be held only to the *Standards for Blood Banks and Transfusion Services (BB/TS)*. If the former, is this an additional accreditation for the TS?	No	The committee noted this comment but did not feel that a change was appropriate at this time. The committee and the standards would require that supplier of product to a prehospital service, requirements and expectations would be governed by all agreements between the entities and that this is further defined in chapter 4, Suppliers and Customers.
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 *Prehospital and Out-of-Hospital Standards* and

				applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
1.1.1	SC	NA	No	The committee edited standard 1.1.1 through the addition of the clause, "…in activities required by these Prehospital and Out-of-Hospital Standards" to ensure that it is clear that the medical director's qualifications are based around the scope of the Standards, and the activity for which they have oversight of.
1.1.2 (NEW)	SC	NA	NA	The committee added new standard 1.1.2 to the edition to provide description of the structure of the transfusion administration services. This standard is parallel to requirements included in other sets of AABB Standards for which AABB provides voluntary accreditation. The standard reads as follows: **1.1.2** The TAS shall have a structure that clearly defines and documents the parties responsible for the activities described in these *Prehospital and Out-of-Hospital Standards*, and the relationship of individuals responsible for key quality functions.
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	RtC	If the organization applying for accreditation is an out-of-hospital or prehospital entity, is the intent that the entity would have their own independent quality system, separate and apart from other contracted entities?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that any program applying for accreditation would require their own quality system, however if they were interested in working with an entity to create their own, that would be appropriate.

1.2.2	RtC	Should a minimal interval be defined for when this should take place?	No	The committee noted this comment, but did not feel that a change was appropriate at this time. The committee would like to see those intervals defined by the program based on their activity levels.
1.3.1	SC	NA	NA	The committee revised standard 1.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.3.1** The medical director and/or laboratory director (as applicable) shall approve all medical and technical policies, processes, and procedures.
1.3.2	SC	NA	NA	The committee revised standard 1.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.3.2** Any exceptions to medical and technical policies, processes, and procedures shall require justification and preapproval by the medical director and/or laboratory director, as applicable.
1.4 (New)	SC	NA	NA	The committee added standard 1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **1.4 Risk Assessment** The facility shall have a process in place to perform risk assessments for activities at defined intervals.
1.4 (New)	RtC	If the organization applying for accreditation is an out-of-hospital or prehospital entity, is the intent that the entity would have their own independent process for risk assessment, separate and apart from other contracted entities? Currently, their focus may be on liability and financial loss, rather than risk as it relates to blood products and transfusion activities.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that it is important to ensure that all programs perform risk assessments of their activities at defined time frames based on the activity for which they have accreditation.
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 (New)	SC	NA	NA	The committee added 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.
2.1.1 (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 *Prehospital and Out-of-Hospital Standards*.
2.1.2 (2.1.1)	RtC	Should this standard include referencing and verifying of licensing requirements to perform certain tasks, e.g., blood administration. For example, in some states first responders cannot administer blood products.	No	The committee reviewed this comment but did not feel a change would be appropriate at this time. The committee noted that as this would differ from jurisdiction to jurisdiction that programs should adhere to what their appropriate Competent Authority requires.
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 *Prehospital and Out-of-Hospital* Standards are met when applicable.
3.0	SC	NA	NA	The committee revised standard 3.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.0 Equipment** The organization shall define and control critical equipment.
3.1	SC	NA	NA	The committee revised standard 3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.1 Equipment Specifications**

				Equipment specifications shall be defined before purchase.
3.2.1 (New)	SC	NA	NA	The committee added standard 3.2.1 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.2.1 Installation Qualification** Equipment shall be installed per manufacturer specifications.
3.2.2 (New)	SC	NA	NA	The committee added standard 3.2.2 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.2.2 Operational Qualification** Each piece of equipment and component of an information system shall be verified before actual use.
3.2.2 (New)	RtC	The phrase "and component of an information system" is random in this standard, and is duplicitous of 3.7 #2, perhaps remove from this standard.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that this inclusion was purposeful and points to the fact that standard 3.7 is focused strictly on information systems, while standard 3.2.2 is focused on all equipment.
3.2.3 (New)	SC	NA	NA	The committee added standard 3.2.3 to mirror all other AABB Standards and to match the AABB Quality System Essentials. The standard reads as follows: **3.2.3 Performance Qualification** Equipment shall perform as expected for its intended use.
3.5.1.2 (New)	SC	NA	NA	The committee added standard 3.5.1.2 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.1.2** Equipment used for calibration, inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards

				exist, the basis for calibration shall be described and recorded.
3.5.1.3 (New)	SC	NA	NA	The committee added standard 3.5.1.3 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.1.3** Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.
3.5.2 (New)	SC	NA	NA	The committee added standard 3.5.2 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.2** When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of potentially affected products or services (including those that have already been released or delivered) shall be verified.
3.5.3 (New)	SC	NA	NA	The committee added standard 3.5.3 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.3** The organization shall: 1) Define cleaning and sanitation methods and intervals for equipment. 2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out. 3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel. 4) Monitor equipment to ensure that defined parameters are maintained. 5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use. 6) Ensure that all equipment maintenance and repairs are performed by qualified individuals and in accordance with manufacturer's recommendations.

3.5.4 (New)	SC	NA	NA	The committee added standard 3.5.4 based on updates to the AABB Quality System Essentials. The standard appears as follows: **3.5.4 Investigation and Follow-Up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 1) Assessment of products or services provided since the equipment was last known to be functioning per the manufacturer's written instructions or organization-defined specifications. 2) Assessment of the effect on the safety of individuals affected. 3) Removal of equipment from service, if indicated. 4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable. 5) Requalification of the equipment. 6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.
3.6 (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, #1 (3.8.1, #3)	SC	NA	NA	The committee updated standard 3.7, #1 based on updates to the AABB Quality System Essentials. **3.7 Information Systems**

				The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 1) Numeric designation of system versions with inclusive dates of use.
3.7, #2 (3.8.1, #1)	SC	NA	NA	The committee updated standard 3.7, #2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 2) Validation/verification/qualification of system software, hardware, databases, and user-defined tables before implementation.
3.7, #3 (3.8.1, #2)	SC	NA	NA	The committee updated standard 3.7, #3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 3) Fulfillment of life-cycle requirements for internally developed software.
3.7, #6 (New)	SC	NA	NA	The committee added new subnumber 6 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and

				modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 6) System security to prevent unauthorized access.
3.7, #7 (3.8, #3)	SC	NA	NA	The committee added subnumber 7 to standard 3.7, #7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
3.7, #8 (3.8, #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 (3.8.1, #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 (3.8, #1)	SC	NA	NA	The committee revised subnumber 11 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 11) Training and competency of personnel who use information systems.
3.7, #12 (New)	SC	NA	NA	The committee added subnumber 12 to standard 3.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and

				modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 12) Procedures to ensure confidentiality of protected information.
3.7.3 (3.8.4)	SC	NA	NA	The committee revised standard 3.7.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7.3** The organization shall support the management of information systems.
3.7.5 (New)	SC	NA	NA	The committee revised added standard 3.7.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.7.5** The organization shall have measures in place to minimize the risk of internal and external data breaches.
3.8 (3.6)	SC	NA	NA	The committee revised added standard 3.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **3.8 Storage and Transport Devices for Blood and Blood Components** Storage and transport devices shall have the capacity and design to ensure that the proper temperature is maintained. Standard 5.1.9 applies.
3.8 (3.6)	RtC	Should have a reference that "Standard 5.1.9 applies". There is no mention of needing alarm systems or alarm checks for blood product storage devices in these standards. Was this purposely left out? Storage devices for blood are required to be verified quarterly at a minimum for alarm activations, and if devices are truly used for storage and not transport, even in pre-hospital or out-of-hospital, they are no exception to this rule.	Yes	The committee agreed with this comment and added a crossreference to standard 5.1.9 for complenteness.
3.8.1 (New)	SC	NA	NA	The committee added standard 3.8.1 to the edition for completeness. This addition recognizes that there are programs to do use devices that have alarm systems and as such, should have requirements surrounding their use.

				These standards appear in other sets of AABB Standards where applicable as well. The standard reads as follows; **3.8.1 Alarm Systems** Storage devices shall have alarms and shall conform to the following standards:
3.8.1.1 (New)	SC	NA	NA	The committee added standard 3.8.1.1 to the edition for completeness. This addition recognizes that there are programs to do use devices that have alarm systems and as such, should have requirements surrounding their use. These standards appear in other sets of AABB Standards where applicable as well. The standard reads as follows; **3.8.1.1** The alarm shall be set to activate under conditions that will allow enough time for proper action to be taken before products reach unacceptable conditions.
3.8.1.2 (New)	SC	NA	NA	The committee added standard 3.8.1.2 to the edition for completeness. This addition recognizes that there are programs to do use devices that have alarm systems and as such, should have requirements surrounding their use. These standards appear in other sets of AABB Standards where applicable as well. The standard reads as follows; **3.8.1.2** Activation of an alarm shall initiate a process for immediate action, investigation, and appropriate corrective action.
3.9 (3.7)	SC	NA	NA	The committee added standard 3.9 to the edition for completeness. The addition recognizes that that programs have warming devices and as such should have warning systems to detect any potential malfunctions. The standard reads as follows: **3.9 Warming Devices for Blood and Blood Components** Warming devices shall be equipped with a temperature sensing device and a warning

				system to detect malfunctions and prevent hemolysis or other damage to blood or blood components. Standard 3.5 applies.
3.9 (3.7)	RtC	The standard should have a reference that "Standard 3.5 applies."	Yes	The committee agreed with this comment and added the crossreference to standard 3.5 which is focused on equipment monitoring and maintenance.
Chapter 4	RtC	As a blood provider and transfusion service for helicopter ambulances and rehabilitation hospitals which themselves are not AABB accredited, do we have to hold the receiving facilities to these standards because we are accredited, or does it not matter since they are not accredited?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that a hospital working with a blood provider would not have to ensure that the provider would not be required to be accredited however through agreement there may be elements of the Standards that would have to be adhered to and those would be defined in the agreements.
Chapter 4	RtC	By this definition, if a blood center or transfusion service is only providing blood products to an out-of-hospital or prehospital entity and this is contractually defined, does the blood center or transfusion service have any additional responsibilities to ensure that the out-of-hospital or prehospital entity complies with blood administration and component selection protocols? Alternatively, if a transfusion service is contracted to provide additional transfusion administration services for the out-of-hospital or prehospital entity, will they be assessed to these *Standards for Out-of-Hospital and Prehospital Transfusion Administration Services*? Or would the TS, if accredited, be held only to the *Standards for BB/TS?*	No	The committee noted this comment but did not feel that a change was needed at this time. When entities enter into contractual agreements with other entities, responsibilities are defined and both parties are expected to adhere to. If a hospital enters into an agreement with a blood supplier and there are elements of the Standards that the receiver would need to adhere to to ensure conformance this should be defined in the supplier and customer agreements and followed accordingly.
4.0	SC	NA	NA	The committee revised standard 4.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.0 Suppliers and Customers** The organization shall ensure that agreements to provide or receive products or services are reviewed, approved, and meet supplier and customer expectations.
4.1	SC	NA	NA	The committee revised standard 4.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.1 Supplier Qualification**

				The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.
4.1.1 (4.1)	SC	NA	NA	The committee revised standard 4.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.1.1** The organization shall evaluate and participate in the selection of suppliers. If executive management is not included in the selection process, there shall be a mechanism to provide feedback to management with contracting authority.
4.2.1 (4.2.2)	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 (4.2.3)	SC	NA	NA	The committee revised standard 4.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.2.2** Changes to agreements shall be communicated to affected parties.
4.3	SC	NA	NA	The committee revised standard 4.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **4.3 Incoming Receipt, Inspection, and Testing** Incoming products or services, equipment, and materials shall be received, inspected, and tested, as necessary, before approval for use.
4.3.1 (New)	SC	NA	NA	The committee added standard 4.3.1 to the edition to ensure that two ABO tests are performed on Whole Blood and Red Blood Cells. This addition mirrors the requirements set forth in 21 CFR 640.5(b). The standard reads as follows: **4.3.1** The TAS shall verify that two ABO blood group tests have been performed on

				Whole Blood or Red Blood Cells by the blood supplier as defined by agreement.
4.3.1 (New)	RtC	Standard 4.3.1 says that the TAS shall verify the two ABO blood group tests have been performed on the whole blood or red blood cells by the blood provider before issue. Does this mean forward and reverse types? Historical blood type? How is the TAS supposed to verify?	No	The committee reviewed the comment submitted but did not feel that a change was needed at this time. The committee notes that this standard would require forward and reverse typing and that relying on historical information would not be appropriate. The assurance that the testing has occurred would be defined by agreement in the case of a blood supplier and receiver relationship.
4.3.1 (New)	RtC	The term "blood provider" either needs to be defined in the glossary or changed to "blood supplier" here	Yes	The committee reviewed the comment and adjusted the standard for clarity. As initially proposed the standard in question used the term "blood provider." Based on this comment the committee elected to replace the term with "blood supplier."
4.3.1 (New)	RtC	I do not know whether it is always feasible for the TAS to verify this from the documentation that typically accompanies a unit? Would the standard documentation include whether two ABOs have been performed? If not, a requirement for performing two ABOs before issuing blood to the TAS should be a required element in the agreement with the supplier.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that this would be defined by agreement by both parties.
4.3.2 (New)	SC	NA	NA	The committee added new standard 4.3.2 to ensure that when blood can be returned to a supplier that it be done so. This return would need to be based on parameters defined by each party in their agreement. The standard reads as follows: **4.3.2** The TAS shall return blood and blood components as defined in agreements.
5.0	SC	NA	NA	The committee revised standard 5.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.0 Process Control** The organization shall ensure the quality of products or services.

5.1	SC	NA	NA	The committee revised standard 5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1 General Elements** The organization shall ensure that processes are carried out under controlled conditions**.**
5.1.1	SC	NA	NA	The committee revised standard 5.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎ **5.1.1 Change Control** When the organization develops new processes or procedures or changes existing ones, they shall be validated before implementation.
5.1.2 (New)	SC	NA	NA	The committee added standard 5.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**5.1.2 Quality Control** A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment, materials, and analytical functions perform as intended.
5.1.2.1 (New)	SC	NA	NA	The committee added standard 5.1.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**5.1.2.1** Quality control results shall be reviewed and evaluated against acceptance criteria.
5.1.2.2 (New)	SC	NA	NA	The committee added standard 5.1.2.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**5.1.2.2** Quality control failures shall be investigated before release of test results, products, or services.
5.1.2.3 (New)	SC	NA	NA	The committee added standard 5.1.2.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**5.1.2.3** The validity of test results and methods and the acceptability of products or

				services provided shall be evaluated when quality control failures occur.
5.1.3 (New)	SC	NA	NA	The committee added standard 5.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.3 Process Planning** Quality requirements shall be incorporated into new or changed processes, products, services, and novel methods. Planning and implementation activities shall include the following: 1) Evaluation of accreditation, regulatory, and legal requirements related to the new or changed process, product, or service. 2) Review of current available knowledge (eg, review of medical practice and/or literature). 3) Evaluation of risk. 4) Identification of affected internal and external parties and mechanism to communicate relevant information. 5) Identification of performance measures applicable to the new or changed process, product, or service. 6) Evaluation of resource requirements. 7) Evaluation of the impact of the new or changed process, product, or service on other organization (or program) processes. 8) Evaluation of the need to create or revise documents for the new or changed process, product, or service. 9) Review and approval of the output of process development and design activities (eg, pilot or scale-up study results, process flow charts, procedures, data forms). 10) Evaluation of the extent and scope of process validation or revalidation depending on the level of risk and impact of the new or changed products or services.

5.1.4.1 (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.
5.1.5 (New)	SC	NA	NA	The committee added standard 5.1.5 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.5 Process Implementation** The implementation of new or changed processes and procedures shall be planned and controlled.
5.1.5.1 (New)	SC	NA	NA	The committee added standard 5.1.5.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: ✎**5.1.5.1** Postimplementation evaluations of new or changed processes and procedures shall be performed.
5.1.5.1 (New)	RtC	I suggest adding the pen symbol so there are records that this has been performed.	Yes	The committee reviewed this comment and agreed with the feedback and added a record retention requirement to the standard.
5.1.7 (New)	SC	NA	NA	The committee added standard 5.1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.7 Inspection** The organization shall ensure that products or services are inspected at organization-defined stages.
5.1.8 (5.1.4)	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 (5.1.4.2)	SC	NA	NA	The committee elected to edit standard 5.1.8.2 for completeness and to mirror similar requirements in other sets of Standards. The committee added the clause, "…from source to final disposition." The standard reads as follows: **5.1.8.2 Traceability** The TAS shall ensure that all blood, blood components, and critical materials used are identified and traceable from source to final disposition.
5.1.8.2 (5.1.4.2)	RtC	Consider the wording of BB/TS standard 6.2.1.1 which includes traceability sufficient to investigate adverse events. Also it is not clear whether the Prehospital standards include sufficient processes for the reporting and investigation of adverse events and for performing lookback. See specific comments/ questions later.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee did however add standard 6.2.1.1 from the BB/TS Standards to chapter 6 to the edition.
5.1.8.3 (5.1.4.3)	RtC	Does the Prehospital TAS notify the supplier of the final disposition and the identity of the recipient? What if the Prehospital TAS transports the component with a patient to another facility, who is responsible for recording the final disposition of the product as transfused or discarded? Is this communicated to the entity that issued the product? If the issuer needs to do a look-back or product withdrawal, how does the issuer determine where the product went and whether the product was transfused?	No	The committee reviewed the comment but did not feel that a change was needed at this time. As the standards relate to notification, if a blood supplier provides blood to a prehospital service they would need to indicate as such. Concerning look-back, the edition includes standard 7.3.5 which is entirely focused on look-back.
5.1.9 (5.1.5)	SC	NA	NA	The committee revised standard 5.1.9 based on updates to the AABB Quality System Essentials. The standard reads as follows: **5.1.9 Handling, Storage, and Transportation** The organization shall ensure that products or services are handled, stored, and transported in a manner that prevents damage, limits deterioration, and provides traceability. Reference Standard 5.1.9A applies.
5.1.9 (5.1.5)	RtC	Alternate location to mention alarm checks as described for standard 3.8 should be noted.	Yes	The committee noted this comment and updated standard 3.8 for clarity.

5.1.9.1 (New)	SC	NA	NA	The committee created this standard to ensure that blood and blood components maintain the appropriate temperature during storage and transport. The standard reads as follows: **5.1.9.1** The TAS shall ensure all containers are validated for the handling, storage, and transport of blood and blood components to ensure that temperatures are maintained within the acceptable range for the expected duration of transport, storage, or shipping. Standard 3.5.1 applies.
5.1.9.1 (New)	RtC	Should have a reference that "Standard 3.5.1 applies".	Yes	The committee reviewed the comment and agreed with the intent and added the crossreference to standard 3.5.1.
5.1.9.1 (New)	RtC	Will EMS be inspected by AABB to ensure that cooler validation is done? What is required for cooler validation in the prehospital setting? Are NIST-certified temperature monitoring devices required? Are the intervals for validation the same as hospital/lab intervals? Will EMS who carry blood products be able to become accredited by AABB?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that an EMS can be accredited and subsequently assessed. Should an EMS not be accredited, they would need to validate their coolers and this would be covered by the supplier and customer agreements.
5.1.9.2 (New)	SC	NA	NA	The committee created new standard 5.1.9.2 to ensure that programs that transport blood and blood components maintain the temperatures defined in reference standard 5.1.9A. This standard applies to both prehospital and out-of-hospital disciplines. The standard reads as follows: **5.1.9.2** The TAS shall ensure blood and blood components remain within the acceptable temperature range during storage and transport. Reference Standard 5.1.9A applies.
5.1.9.2 (New)	RtC	One of the EMS partners we work with thought that because the products were always stored in a cooler that was ready to go on an ambulance, they were always "in transport" and thus thought that only the 1-10C transport temperature applied to them. They store their whole blood in coolers the whole time and thought their acceptable range was 1-10C all the time. They do not	No	The committee noted this comment but did not feel that a change was needed at this time. Per the comment the committee notes that the standards related to storage and transport would apply. In the case where the EMS defines the container as a storage container, the requirement

		have a monitored storage refrigerator at their station. Please make sure that the distinction between storage and transport temperature is clear in the standard.		would be to follow the 1-6 C and if defined as a transport container, the requirement would be to follow the 1-10C.
5.1.9.3 (New)	SC	NA	NA	The committee included standard 5.1.9.3 in this edition for completeness. The standard in question also exists in the Standards for Blood Banks and Transfusion Services. This standard applies to both prehospital and out-of-hospital disciplines. The standard reads as follows: **5.1.9.3** For storage of blood and blood components, the temperature shall be monitored continuously and recorded at least every 4 hours.
5.1.9.3 (New)	RtC	Many out-of-hospital services have been providing component therapy for years safely using commercial "Nonreversible Temperature Sensitive Indicators". The requirement to monitor and record data every 4 hours is excessively burdensome and does not increase patient safety.	No	The committee noted this comment but did not feel a change was needed at this time. It should be noted this for storage purposes this standard would not apply, but for transport purposes the 4 hour recording time would be applicable.
5.2 (New)	SC	NA	NA	The committee created this new standard to ensure that the program receiving blood and blood components are inspected for appropriateness of use. The new standard reads as follows: **5.2 Receipt of Blood and Blood Components** The blood and blood components shall be inspected at the time of removal from the transport container and/or storage device, and it shall be verified that the following conditions are met: 1) The unit has remained in a validated transport container or storage device within the specified period. 2) The unit appearance meets visual inspection criteria. 3) The unit has an attached label or tie tag indicating the donation identification number, and compatibility testing has not been performed. Standards 5.1.9 and 5.3.10 apply.

5.2 (New)	RtC	I suggest adding a record retention symbol to this standard.	Yes	At the time the Standards were issued for comment, a record retention symbol was not included with the standard. Based on this comment, one was included.
5.2, #2 (New)	RtC	"Visual inspection criteria" is not defined in these standards and needs to be. It might be best to mirror the wording in BBTS 5.9.2, 5.10 or 5.22 to help define "visual inspection criteria" and maintain consistency between the standards.	No	The committee noted this comment but did not feel that a change was needed at this time. The committee has addressed visual inspection in the associated guidance.
5.2, #2 (New)	RtC	Are visual inspections expected to be recorded? This could be hard, but I think possible.	No	The committee noted this comment but did not feel that a change was appropriate at this time. The committee shared that some facilities use a checkbox system to ensure that units have been reviewed by visual inspection.
5.3 (New)	SC	NA	NA	The committee added new standard 5.3 to this edition focused on the administration of blood. This standard was modeled off of standard 5.28 from the 34th edition of BB/TS Standards and the language is written in a parallel manner. The standard reads as follows: **5.3 Administration of Blood** There shall be a protocol for the administration of blood and blood components, including the use of infusion devices and ancillary equipment, and the identification, evaluation, and reporting of adverse events related to transfusion. The TAS medical director shall participate in the development of the protocols. The protocol shall be consistent with the Circular of Information for the Use of Human Blood and Blood Components. Standard 7.3.3 applies.
5.3 (New)	RtC	Third line, "The medical director shall participate…." I imagine there will be an administration medical director and a blood bank medical director. I should think it advantageous that they work together on this. So, clarifying which medical director might be advantageous.	YES	The committee noted this comment and agreed with the intent. The committee added the clause "TAS" to the second sentence as per the request.
5.3 (New)	RtC	The protocol shall direct that all available measures to stop life-threatening hemorrhage should be taken prior to resuscitation to include the use of extremity tourniquets, abdominal & junctional tourniquets, and hemostatic	No	The committee noted this comment but did not feel that a change was needed at this time. The committee felt that this would fall under the

		dressings before administration of blood and blood products." These steps MUST come before any administration of blood products unless absolutely impossible (internal thoracic bleed that is life-threatening). In the prehospital environment especially if there are prolonged transport times blood and blood products are too scarce a resource to potentially waste if the hemorrhage is not controlled first.		"practice of medicine" and would be defined by the EMS medical director.
5.3.1 (New)	SC	NA	NA	The committee created new standard 5.3.1 to ensure that the 5 sub-numbers included in the standard are covered before a unit is transfused in a prehospital setting. The standard reads as follows: **5.3.1** Immediately before transfusion, the following information shall be verified: 1) The intended unit for transfusion meets the TAS protocol and has not expired. 2) Unit ABO group. 3) Unit appearance meets visual inspection criteria. 4) The unit has remained in compliance with temperature requirements during storage/transport. 5) The informed and/or implied consent has been obtained.
5.3.1, #1	RtC	What is meant by "ordering criterion"? Is this referring to patient orders, or blood product orders from a blood supplier? In pre-hospital administration, there isn't likely to be an order, but a protocol to guide administration.	Yes	The committee reviewed this comment and agreed with its intent. The committee replaced the term "ordering criterion" as presented in the proposed version with "TAS" protocol" for clarity.
5.3.2 (New)	SC	NA	NA	The committee created new standard 5.3.2 to ensure that most pertinent information attached to the container, remains so to ensure identification of the product to the patient. The standard reads as follows: **5.3.2** All information attached to the container shall remain attached.
5.3.3 (New)	SC	NA	NA	The committee created new standard 5.3.3 to ensure that patients are observed during the transfusion of blood products until the patient is

				transferred to the receiving hospital for treatment. The standard reads as follows: **5.3.3** The patient shall be monitored for potential transfusion-related adverse events by the TAS until the time of transfer of care. Standard 7.3.3 applies.
5.3.4 (New)	SC	NA	NA	The committee created new standard 5.3.4 to ensure that the prehospital providers are in communication with the receiving hospital to ensure that they are aware of the patient's status during transport. The standard reads as follows: **5.3.4** The TAS shall have a process to notify the receiving hospital and/or other prehospital care providers of a patient's transfusion status, with a unique patient identifier, including any transfusion-related adverse reactions through the continuum of care.
5.3.4 (New)	RtC	Who notifies the issuer of the blood component regarding any adverse events? Who notifies the issuer of the blood component regarding the final disposition of the product(s)? Also suggest you define "receiving hospital"—is this the hospital that the patient gets transported to? This entity may not have any record of a transfusion that was administered during transport. What is your intention as to their role in documenting the transfusion or investigating adverse events for these units that were not administered in their facility?	No	The committee reviewed this comment but did not feel that the change was needed at this time. The committee noted that in this case this would be the responsibility of the transfusion administration service.
5.3.4.1 (New)	SC	NA	NA	The committee created new standard 5.3.4.1 to ensure that (when possible) prehospital transfusion providers shall provide materials related to the transfusion to the receiving hospital for testing and follow-up as required. The standard reads as follows: **5.3.4.1**The TAS shall provide materials related to prehospital transfusion (eg, patient samples, empty bags, and segments) for follow-up testing and for identification of blood and blood components transfused (eg, the name of the component, the

				donor ABO/Rh type, the donation identification number). Standard 4.1.3.1 applies.
5.3.4.1 (New)	RtC	The term 'as applicable" is used. I asked myself when this would not be applicable. If it is not applicable then why is it necessary at all? In 5.3.4.1, follow up testing would not be applicable if the patient died on the way to the hospital? Well that in not entirely true.in case one needed to work up a reaction. Why not send the bags to the hospital unless they are not available? At the very least the segments would be needed for crosshatch. 5.13.6 when would it not be applicable to take vital signs. Again, I suppose if the patient were dead VS would not be useful. However at other times vital signs would be taken I should think. This is just a personal "thing" of mine. Thanks for being tolerant	No	When proposed, the term "as applicable" was included in the standard. However, after review of this feedback, the committee edited the standard to read as follows: **5.3.4.1**The TAS shall provide materials related to prehospital transfusion (eg, patient samples, empty bags, and segments) for follow-up testing and for identification of blood and blood components transfused (eg, the name of the component, the donor ABO/Rh type, the donation identification number). Standard 4.1.3.1 applies.
5.3.4.1 (New)	RtC	Specifically, 5.3.4.1, appears NOT to require patient samples per se, just that they should be provided as applicable. We assume this is because hospitals in general want to collect their own samples and EMS do not want to collect them or must deal with all the potential variants of sample tubes that each hospital they serve may want used?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that this would be covered by the agreement and determined between the two parties.
5.3.4.1 (New)	RtC	Suggest making this standard more precise. The receiving hospital should receive the unit DIN, unit blood type, unit attributes/characteristics, dose given, any patient reactions, patient blood type if known, name and contact of transfusion service (be it an ambulance service or whatever). This is because they often get blood from somewhere else. This should be on a document. It's nice to give the old bag and segments too, as you have noted. It is very nice to get the patient sample with label too.	Yes	The committee reviewed this comment, and the standard was updated to include the information requested. Based on the feedback, the committee removed the requirement to have specimens, as they would not be taken in critical situations, and in some cases, not all ambulances carry this testing equipment.
5.3.5 (New)	SC	NA	NA	The committee added new standard 5.3.5 to this edition. This standard was modeled off of standard 5.28.8 from the 34th edition of BB/TS Standards and the language is parallel. The standard reads as follows: **5.3.5** Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.

5.3.6 (New)	SC	NA	NA	The committee added standard 5.3.6 to this edition. This standard was modeled off of standard 5.28.9 from the 34th edition of BB/TS Standards and the language is parallel. The standard reads as follows: **5.3.6 Addition of Drugs and Solutions** With the exception of 0.9% sodium chloride (USP), drugs or medications shall not be added to blood or blood components unless one of the following conditions is met: 1) The additions have been approved for this use by the FDA or Competent Authority. 2) There is documentation available to show that the addition is safe and does not adversely affect the blood or blood component.
5.3.7 (New)	SC	NA	NA	The committee created new standard 5.3.7 to ensure that patients are monitored during transfusion. The standard reads as follows: **5.3.7** Patient vital signs shall be monitored before, during, and after transfusion.
5.3.7 (New)	RtC	I suggest adding a record retention requirement to this standard for clarity.	Yes	The committee noted this comment and agreed with the feedback and added a record retention symbol to the standard.
5.3.8 (New)	SC	NA	NA	The committee created new standard 5.3.8 to ensure that prehospital programs define how adult and pediatric patients are treated during transfusion. The standard reads as follows: **5.3.8** The TAS shall have defined criteria for adult and pediatric transfusion. Standard 5.4.3 applies.
5.3.8 (New)	RtC	Agree about the criteria for transfusion. When these are developed, the medical director of the service that is a physician should be involved in developing the trigger that leads to transfusion, since it's the physician that has to sign the order (link to 5.4.3).	Yes	The committee agreed with the intent of this comment and added a crossference to standard 5.4.3, which did not appear in the proposed edition.
5.3.9 (New)	SC	NA	NA	The committee created new standard 5.3.9 to ensure that all prehospital programs have all their policies, processes, and procedures for the administration of blood.

				The standard reads as follows: **5.3.9** The TAS shall have policies, processes, and procedures for the administration of blood and blood components.
5.3.10 (New)	SC	NA	NA	The committee created new standard 5.3.10 to ensure that the Circular of Information is available in all accredited prehospital programs. The standard reads as follows: **5.3.10** The current Circular of Information for the Use of Human Blood and Blood Components shall be available.
5.3.10 (New)	RtC	Is the intent of this standard to have the COI on every ambulance, helicopter and aircraft? I don't believe that is practical. If the intent was to have the COI available at EMS bases, then this standard should be reworded to state as such.	No	The committee reviewed this comment, but did not feel a change was needed at this time. The committee noted that this would be defined by the EMS in question as to where the COI would be. Of note, many EMS programs are uploading the COI as an app.
5.4 (New)	SC	NA	NA	The committee created new standard 5.4, to ensure that in urgent cases the medical director determines the appropriate conditions for transfusion to each transfusion in emergent situations. The standard reads as follows: **5.4 Requirements for Uncrossmatched Blood and Blood Components** The TAS medical director shall determine the appropriate ABO/RhD component selection for uncrossmatched units of blood and blood components issued as well as the maximum quantity of blood products that can be transfused to each patient in an emergency setting.
5.4.1 (New)	SC	NA	NA	The committee created new standard 5.4.1 to ensure that prehospital programs have policies in place to determine what RhD products are given to patients of childbearing potential. The standard reads as follows: **5.4.1** The TAS shall have a policy concerning the selection of the RhD type of blood products

				for transfusion of blood to patients of childbearing potential.
5.4.1 (New)	RtC	Isn't 5.4.1 redundant compared to 5.3.8 or vise versa?	No	The committee reviewed this comment, but did not feel that a change was needed at this time. The committee felt that the standards were not redundant, as standard 5.3.8 defines which patients can be transfused and standard 5.4.1 is focused on who gets which product when.
5.4.2 (New)	SC	NA	NA	The committee created new standard 5.4.2 to ensure that prehospital programs have policies in place for the transfusion of pediatric patients in emergent situations. The standard reads as follows: **5.4.2** The TAS shall have a policy for the transfusion of pediatric patients in emergent situations.
5.4.2 (New)	RtC	The wording is fine. It's important that it aligns exactly with the CFR wording "(v) Emergency release of blood, including signature of requesting physician obtained before or after release." And assessors should know that it cannot be a mid-level provider, only a physician (maybe that is appropriate for a note)	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the language does align with the federal regulations, while also recognizing that different states may have different requirements.
5.7.4 (New)	SC	NA	NA	The committee created new standard 5.7.4 to the out-of-hospital standards section which also exists in the 34th edition of BB/TS Standards. This addition reflects current practice. The standard reads as follows: **5.7.4** There shall be two determinations of the recipient's ABO group. The first determination shall be performed on a current sample, and the second determination by one of the following methods: 1) Comparison with previous records. 2) Testing a second sample collected at a time different from the first sample, including a new verification of patient identification. 3) Retesting the same sample if patient identification was verified at the time of sample

				collection using an electronic identification system.
5.8 (5.5)	RtC	Replace "the" with "a properly labeled."	No	The committee reviewed the comment but did not feel that a change was needed at this time. The committee felt that the suggested replacement would not strengthen the standard.
5.8 (5.5)	RtC	In the second line "…the patient sample, *accompanied* records …. " Is that really the intent or would "accompanying records" be better?	Yes	The committee agreed with the comment and substituted the clause as suggested.
5.9 (5.6, 5.6.1)	SC	NA	NA	The committee elected to merge former standards 5.6 and 5.6.1 from the 1st edition of Standards for Out-of-hospital Transfusion Administration Services into one standard to appear as new standard 5.9. The committee felt that the concepts enumerated were deemed redundant to one another. As such the opening sentence was adjusted and expanded to include the concepts of "transport" and the use of "storage devices." This expansion reflects the current scope of the work conducted by out-of-hospital programs. The standard reads as follows: **5.9 Receipt of Blood and Blood Components** The blood and blood components shall be inspected each time they are removed from the transport container and/or storage device and verified that the following conditions are met: 1) The unit has arrived to the destination within the validated time period for the transport container. 2) The unit appearance meets visual inspection criteria. 3) The unit has remained in a validated container or storage device. Standard 5.1.9.1 applies.
5.9 (5.6, 5.6.1)	RtC	Please add new #4: 4) A record is kept for receipt of the transport container (on the invoice?) that includes a) a temperature check of products and b) date/time of arrival/removal of products from transport container. As a note: often the units are taken from the containers, stored in a monitored unit for many hours before the units are	No	The committee reviewed this comment but did not feel that a change was needed at this time. The feeling that this would be too prescriptive and better served as an element with the associated guidance.

		entered into the Laboratory Information System (LIS) thereby requiring separate history.		
5.11.1 (5.8.1)	RtC	I suggest adding if possible or if the recipient's medical condition allows it or except for emergency transfusion. For out-of-hospital transfusion, the recipient's condition may not allow to have an informed consent before transfusing.	No	The committee noted this comment but did not feel that a change was needed at this time. In out-of-hospital settings, it is expected that consent, can be acquired as programs have time to acquire it.
5.11.2.1 (New)	SC	NA	NA	The committee has added new standard 5.11.2.1to reflect that there are instances where a patient can lose their identification band, and in those instances the transfusion should not proceed, which does reflect current practice. The standard reads as follows: **5.11.2.1** The patient identifier shall remain attached to the patient for the duration of the transfusion process. In the case where the patient identifier is not attached, the transfusion shall not be initiated.
5.11.3 (5.8.4)	RtC	I suggest changing the term "observed" to "monitored" and adding the record retention requirement. This would be consistent with BB/TS standard 5.28.6.	Yes	The committee reviewed this comment and agreed with the intent. The standard now reads as follows: **5.11.3** The patient shall be monitored for potential adverse events during the transfusion and for an appropriate time thereafter. Standard 7.3 applies.
5.11.4 (5.8.5)	SC	NA	NA	The committee added the clause to open the standard, "when direct medical observation or monitoring of the patient will not be available following the immediate posttransfusion observation period," for completeness recognizing that that there are instances where this could occur. The standard now reads as follows: **5.11.4** When direct medical observation or monitoring of the patient will not be available following the immediate posttransfusion observation period, specific written instructions concerning

				possible adverse events, including emergency medical care contacts, shall be provided to the patient or a responsible caregiver.
5.11.7 (New)	SC	NA	NA	The committee added new standard 5.11.7 to the edition reflecting the need for the COI to be available for use by the out-of-hospital programs. The standard reads as follows: **5.11.7** The current Circular of Information for the Use of Human Blood and Blood Components shall be available.
5.12 (5.9)	SC	NA	NA	The committee elected to update standard 5.12 based on a similar standard that appears in the Standards for Blood Banks and Transfusion Services. The standard reads as follows: **5.12 Medical Record Documentation** The patient's medical record shall include the transfusion order, documentation of patient consent, the name of the component, the donor ABO/Rh type, the donation identification number, the date and time of transfusion, vital signs taken at defined intervals, including before, during, and after transfusion, the amount transfused, the identification of the transfusionist, and, if applicable, any transfusion-related adverse event(s).
5.12 (5.9)	RtC	This standard applies to out of hospital entities and requires the patient's medical record to be updated to include varies elements related to transfusion, to include the donation identification number. There is no similar requirement for a prehospital entity to provide the same transfusion related information to the receiving hospital and/or other prehospital care provider, but rather only the patient's transfusion status (5.3.4).	Yes	The committee reviewed this comment and elected to update standard 5.3.4 to include "the name of the component, the donor ABO/Rh type, the donation identification number" per the request.
5.13 (5.10)	RtC	I suggest adding record retention requirement to the standard so that there are records that this is occurring.	Yes	The committee agreed with this comment and added the record retention symbol per the request.

Reference Standard 5.1.9A	SC	NA	NA	The committee added new Reference standard 5.1.9A to the edition and applies to both out-of-hospital and prehospital disciplines. The table is similar to reference standard 5.1.9A of the of 34th edition of BB/TS Standards.
6.0	SC	NA	NA	The committee revised standard 6.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.0 Documents and Records** The organization shall ensure that documents and records are created, stored, and archived in accordance with record retention policies.
6.1	SC	NA	NA	The committee revised standard 6.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1 Document Control** The organization shall control all documents that relate to the requirements of these BB/TS Standards. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.
6.1.1 (6.1.2)	SC	NA	NA	The committee revised standard 6.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.1 Format** Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual or published in the AABB Technical Manual) may be incorporated by reference.
6.1.2 (New)	SC	NA	NA	The committee added standard 6.1.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.2 Document Review, Approval, and Distribution** The document control process shall ensure that documents:

				1) Are reviewed by personnel trained and/or qualified in the subject area. 2) Are approved by an authorized individual. 3) Are identified with the current version and effective date. 4) Are available at all locations where operations covered by these BBTS Standards are performed. 5) Are not used when deemed invalid or obsolete. 6) Are identified as archived or obsolete when appropriate.
6.1.3 (New)	SC	NA	NA	The committee added standard 6.1.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3 Document Changes** Changes to documents shall be reviewed and approved by an authorized individual.
6.1.3.1 (New)	SC	NA	NA	The committee added standard 6.1.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.3.1** The organization shall track changes to documents.
6.1.4 (6.1.1)	SC	NA	NA	The committee revised standard 6.1.4 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.4 Master List of Documents** The organization shall maintain complete lists of all active policies, processes, procedures, labels, forms, and other documents that relate to the requirements of these Prehospital and Out-of-Hospital Standards.
6.1.6	SC	NA	NA	The committee revised standard 6.1.6 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.6 Document Retention** The organization shall determine which documents shall be archived, destroyed, or made obsolete.

6.1.7	SC	NA	NA	The committee revised standard 6.1.7 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.7 Document Storage** Documents shall be stored in a manner that preserves integrity and legibility; protects from accidental or unauthorized access, loss, destruction, or modification; and ensures accessibility and retrievability.
6.1.8 (New)	SC	NA	NA	The committee revised standard 6.1.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.1.8 Document Retrieval** The organization shall ensure that documents are retrievable in a timely manner.
6.2	SC	NA	NA	The committee revised standard 6.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2 Record Control** The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.
6.2.1.1 (New)	RtC	I suggest considering the addition of BB/TS standard 6.2.1.1, traceability, which includes adverse events to the edition.	Yes	The committee agreed with this comment and included the standard into the edition. The standard reads as follows: **6.2.1.1** The record system shall make it possible to trace any unit of blood, or blood component, from its source to final disposition; to review the records applying to the specific component; and to investigate adverse events manifested by the recipient.
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.
6.2.2, #6 (New)	SC	NA	NA	The committee added subnumber 6 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: 6) Method(s) used.
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.
6.2.8 (6.2.2)	SC	NA	NA	The committee revised standard 6.2.8 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.2.8 Confidentiality** The organization shall ensure the confidentiality of records.
6.2.9 (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.
6.2.11, #4 (6.2.8, #3)	RtC	What is a “defined time frame”? Should this be changed to “appropriate time frame”?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The term “appropriate” is difficult to assess, whereas “defined” is.
6.3.1 (New)	SC	NA	NA	The committee added standard 6.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1 Access to Data and Information** Access to data and information shall be controlled.

6.3.1.1 (New)	SC	NA	NA	The committee added standard 6.3.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1.1** The authorization to access and release data and information shall be defined, and individuals authorized to enter, change, and release results shall be identified.
6.3.1.1.1 (New)	SC	NA	NA	The committee added standard 6.3.1.1.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.1.1.1** Electronic records shall include the date and identity of the person making a change.
6.3.2 (New)	SC	NA	NA	The committee added standard 6.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2 Data Integrity** Data integrity shall ensure that data are retrievable and usable.
6.3.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.1** Data shall be accurately, reliably, and securely sent from the point of entry to final destination.
6.3.2.2 (6.2.7.1.1)	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 (New)	SC	NA	NA	The committee added standard 6.3.2.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.2.2.1** The organization shall archive records or data from media and platforms no longer in use.
6.3.3 (New)	SC	NA	NA	The committee added standard 6.3.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.3 Storage Media**

				Data storage media shall be protected from damage or unintended access and destruction.
6.3.4 (New)	SC	NA	NA	The committee added standard 6.3.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **6.3.4 Backup Data** The organization shall back up all critical data.
6.3.4.3 (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.
6.3.4.3 (New)	RtC	This should have a pen icon as tests of the backup system should be documented as acceptable or flawed and corrected if indicated. Also added to the retention table if agreed.	No	The committee reviewed this comment but did not feel that a change was need at this time. The committee felt that this test should occur when the assessor is on site and that documentation would not be sufficient.
7.0	SC	NA	NA	The committee revised standard 7.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.0 Deviations, Nonconformances, and Adverse Events** The organization shall capture, assess, investigate, and monitor failures to meet specified requirements. The responsibility for review and authority for the disposition of nonconformances shall be defined. These events shall be reported in accordance with specified requirements and to outside agencies as required.*
7.1 (New)	SC	NA	NA	The committee added standard 7.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.1 Deviations** The organization shall capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures.

				The assessment shall ensure timely and appropriate clinical management of the recipient, if applicable.
7.2.1 (New)	SC	NA	NA	The committee added standard 7.2.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.2.1** Nonconforming products shall be quarantined and/or destroyed.
7.2.3 (New)	SC	NA	NA	The committee added standard 7.2.3 to the edition mirroring a standard in the 34th edition of Standards for Blood Banks and Transfusion Services. The standard reads as follows: **7.2.3** The organization shall: 1) Identify, quarantine, retrieve, recall, and determine the disposition of nonconforming products. 2) Identify and manage nonconforming products or services.
7.2.4 (New)	SC	NA	NA	The committee added standard 7.2.4 to the edition mirroring a standard in the 34th edition of Standards for Blood Banks and Transfusion Services. The standard reads as follows: **7.2.4 Released Nonconforming Products or Services** Products or services that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality and/or safety of the product or service.
7.2.4.1 (New)	SC	NA	NA	The committee added standard 7.2.4.1 to the edition mirroring a standard in the 34th edition of Standards for Blood Banks and Transfusion Services. The standard reads as follows: **7.2.4.1** Records shall include the disposition of the nonconforming product or service, the rationale, and the name(s) of the individual(s) responsible for the decision.

7.3 (New)	SC	NA	NA	The committee added standard 7.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3 Adverse Events** The organization shall detect, monitor, evaluate, manage, and report adverse events related to safety and quality.
7.3.1 (New)	SC	NA	NA	The committee added standard 7.3.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3.1** Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.
7.3.2 (New)	SC	NA	NA	The committee added standard 7.3.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **7.3.2** Investigation results and analysis shall be communicated among all facilities involved, if applicable.
7.3.3 (7.3)	SC	NA	NA	The committee edited standard 7.3.3 based on a similar standard in the 34th edition of Standards for Blood Banks and Transfusion Services. The standard reads as follows: **7.3.3 Adverse Events Related to Transfusion** There shall be a process for the recognition, evaluation, and reporting of suspected transfusion-related adverse events.
7.3.3, #3, 4 (7.3)	RtC	If it is the receiving hospital that is notified, how does the supplier/issuer of the blood get notified? How would the receiving facility investigate a reaction to a product transfused during transport and never recorded in their facility?	No	The committee reviewed this comment but did not feel that a change was needed at this time. This information will be defined by the supplier of the blood product and what they define as what needs to be reported back.
7.3.3.1 (7.3.1)	SC	NA	NA	The committee edited this standard by removing the term “immediate” as it was deemed difficult to assess. This allows for the standard to mirror the language included in the 34th edition of BB/TS Standards. This standard applies to both disciplines. The standard reads as follows:

				7.3.3.1 Recognition of and Response to Transfusion Reactions There shall be processes and procedures for the transfusing staff to recognize and respond to transfusion reactions and for the recording of relevant information in the patient's medical record.
7.3.3.3 (7.3.1.2)	SC	NA	NA	The committee edited standard 7.3.3.3 to reflect the expanded content of the Standards, both prehospital and out-of-hospital disciplines. As a result the standards had to be adjusted to accommodate both disciplines. The standard reads as follows: **7.3.3.3** When the transfusion is discontinued, the following shall be performed: 1. The label on the blood product and records shall be examined to detect errors in identifying the patient, blood, or blood component. 2. The ordering provider or TAS medical director shall be notified. 3. The unit (whether or not it contains any blood) shall be sent to the transfusion service or receiving hospital with, whenever possible, the attached transfusion set and intravenous solutions. 4. A posttransfusion sample shall be obtained as soon as possible from the patient and sent to the transfusion service or receiving hospital.
7.3.3.3 (7.3.1.2)	RtC	A pre-transfusion sample is not required, but a posttransfusion sample is after an adverse event related to transfusion. Will the EMS be required to collect this or can the hospital collect it? Is that expected to be outlined in the terms of service? If the EMS is responsible, then they would fall into the same problem of needing to know (and stock) specific tubes on their ambulance. We believe this is an issue for several EMS.	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that would be the hospital in question performing the testing of the sample and not the responsibility of the EMS. This responsibility could also fall under the responsibility of the medical examiner.
7.3.4 (7.3.2)	SC	NA	NA	The committee edited standard 7.3.4 to reflect the expanded content of the Standards recognizing the prehospital requirements and

				how the standards have to be adjusted to accommodate both disciplines. The standard reads as follows: **7.3.4 Transfusion Reactions** The TAS shall provide clear instructions to the patient's responsible caregivers and/or health-care personnel regarding posttransfusion instructions, including recognition of and steps for managing a suspected transfusion reaction. Standard 5.11.4 applies.
7.3.4 (7.3.2)	RtC	Will there be guidance surrounding the safety of switching a non-Group O patient back to type specific RBCs for transfusion after receiving multiple units of Low Titer Group O Whole Blood? Is there a testing protocol? Or is it not an issue?	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee did not feel it appropriate to provide this guidance as this would be facility defined.
7.3.4, 7.3.4.1 (7.3.2, 7.3.2.1)	RtC	Wouldn't the TAS be the one to detect the transfusion reaction? Reword "If a transfusion reaction is suspected or detected, the patient's physician or the TAS medical director shall be notified.	Yes	The committee reviewed the comment and agreed with the intent of the request. The change ensures that the treating physician and the TAS medical director are informed of any transfusion reactions as is the current practice.
7.3.4.2 (7.3.2.2)	RtC	How is the supplier of the product notified of adverse reactions?	No	The committee reviewed the comment and noted that the hospital would be the entity to contact the supplier of the product.
7.3.5 (New)	SC	NA	NA	This standard is new to this edition and was created based on a similar standard in the 34th edition of Standards for Blood Banks and Transfusion Services. This standard applies to both disciplines. The standard reads as follows: **7.3.5 Look-Back** The TAS shall have a process for providing relevant unit and/or patient information as requested when notified by the blood collection facility and/or transfusion service.*
7.3.5 (New)	RtC	Who do you envision the TAS is providing information to? Who is responsible for identifying and notifying the recipient	No	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that this would depend on where the incident occurred and thus who is responsible.

7.4 (7.2)	SC	NA	NA	The committee created standard 7.4 recognizing the need to notify the transfusion service or collection facility in the case of a patient fatality as a result of transfusion. This standard applies to both disciplines. The standard reads as follows: **7.4 Fatality Investigation and Notification** The transfusion service and/or collection facility shall be notified of fatalities suspected to have resulted from transfusion.
7.4 (7.2)	RtC	We assume that if a fatality occurred posttransfusion at the hospital, then the hospital would be obligated to contact the TAS, or would the notification go to the blood suppler and/or the transfusion service that then would contact the TAS? There was not a standard addressing notification to the TAS from the transfusion service/hospital. Under these circumstances, would the BB/TS standards apply? Does the BB/TS standard need to be adjusted to include TAS notification?	No	The committee noted this comment but did not feel that a change was needed at this time. The committee intends for the entity to notify the transfusion service or collection facility in the case of a patient fatality as a result of transfusion.
7.4.1 (New)	SC	NA	NA	In conjunction with the creation of standard 7.4, new standard 7.4.1 has been developed to ensure that an investigation takes place accordingly. This standard applies to both disciplines. The standard reads as follows: **7.4.1** If a fatality is suspected to have occurred as a result of a blood transfusion, the TAS shall report this event to the transfusion service and/or collection facility for investigation.
7.4.2 (New)	SC	NA	NA	The committee created new standard 7.4.2 to ensure that out of hospital and prehospital services notify the FDA in the case where a fatality is confirmed to have occurred as a result of transfusion. The CFR and Guidance for Industry are included for completeness. This standard applies to both disciplines. The standard reads as follows: **7.4.2** If a fatality is confirmed to have occurred as a result of a transfusion, the transfusion service and/or collection facility shall notify the FDA.†

8.0	SC	NA	NA	The committee revised standard 8.0 based on updates to the AABB Quality System Essentials. The standard reads as follows: **8.0 Internal and External Assessments** The organization shall conduct assessments of operations and quality systems.
8.1	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.
8.2 (8.1)	RtC	Define who/what entity would perform the external assessment?	No	The committee reviewed the comment and did not feel that a change was needed at this time. The committee noted that AABB would be an appropriate entity to provide an external assessment.
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.
8.3, #4 (8.1.2)	SC	NA	NA	The committee revised standard 8.3, #4based 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: 4) Reported to executive management.
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, #4	SC	NA	NA	The committee revised subnumber 4 to standard 9.1 based on updates to the AABB Quality

				System Essentials. The standard reads as follows: ✎**9.1 Corrective Action** The organization shall have a process for corrective action that includes: 4) Ensuring that corrective action is reviewed and found to be effective.
9.1.1 (New)	SC	NA	NA	The committee added standard 9.1.1 based on updates to the AABB Quality System Essentials, which includes some verbiage from standard 9.1 in the previous edition. The standard reads as follows: **9.1.1** Investigation and corrective action shall include consideration of deviations, nonconformances, and complaints.
9.3 (New)	SC	NA	NA	The committee added standard 9.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **9.3 Performance Improvement** The organization shall track and identify trends in information related to its operational and quality system performance to identify opportunities for improvement.
10.1 (New)	SC	NA	NA	The committee added standard 10.1 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.1 Safe Environment** The organization shall minimize and respond to environmentally related risks to the health and safety of all individuals and products or services. Suitable quarters, environment, and equipment shall be available to maintain safe operations.
10.2 (New)	SC	NA	NA	The committee added standard 10.2 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.2 Biological, Chemical, and Radiation Safety**

				The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.
10.3 (10.1)	SC	NA	NA	The committee revised standard 10.3 based on updates to the AABB Quality System Essentials. The standard reads as follows: **10.3 Handling and Discarding of Biological Materials** Biological materials shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.