Standards for Blood Banks and Transfusion Services, 29th edition
Summary of Significant Changes

The following table summarizes many of the significant changes made to the 29th edition of *Standards for Blood Banks and Transfusion Services*; it is not, however, exhaustive. Not all changes contained in the *Standards* have been incorporated in detail. Many of the changes that result in the reorganization of a section cannot be fully appreciated without consulting the 29th edition of *Standards* in conjunction with this table; therefore, the numbering follows that of the 29th edition and, where appropriate, the corresponding standard number in the 28th edition is included in parentheses. In cases where a standard has been re-numbered, but the substance of the standard has not changed, there is often no entry listed in the table. Like the crosswalk published with the *Standards*, this table is offered to assist individuals in updating their facility's policies, processes, and procedures to conform to the 29th edition. Use of this table should not take the place of a thorough, line-by-line analysis of each standard. Please note that this summary includes examples of comments submitted by users of the document, along with the program unit's rationale in making or not making a revision to the document.

29th edition standard number (28th edition number in parentheses if changed)	**Source of Change (Changes are made either in response to public comments or as the result of a program unit decision made prior to the public comment period.)**	**Outcome Following Program Unit Discussion** **(Please note that public comments address the proposed Standards. The changes are best understood when the proposed Standards is compared to the final published version. The program unit has elected to make the substance of public comments a part of this document.)**
1.2.1	Public comment submitted, no change made	**Comment:** If I (technical specialist) am the person who deals with all the quality issues (generating reports, writing variances, daily/weekly/monthly quality reviews, validations, etc.) and I report personnel issues to a supervisor (general lab supervisor), blood bank issues to the lab manager, and the blood bank medical director and the lab manager and blood bank med. Director report to executive management, does this follow the standard? Should this quality representative be from the hospital's Quality Management Department or am I sufficient? **Outcome:** The committee noted this comment, but did not feel that a change was needed at this time. The committee feels that the process as described would meet the intent of the standard as written. Regarding the individual that performs the duty of the quality representative, as long as said individual is qualified by training and experience they would be able to serve in that role.
1.3.2	Public comment submitted, change made	**Comment:** Original wording is not clear whether the exceptions are case-by-case or the medical director approval is case-by-case, which means that medical director approval would not be needed in some cases. Shouldn't the medical director approve all exceptions? Recommend the following edit: Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and preapproval by the medical director ~~on a case-by-case basis~~.

29th edition (28th edition)	Source of change	Outcome
		Outcome: The committee reviewed this comment and agreed with the suggestion and the change was made. The standard now reads as suggested by the comment.
1.4, 1.4.1	Public comment submitted, no change made	**Comment:** PI would like to suggest the possible revision to each standard **1.4** The blood bank or transfusion service shall **develop, test and evaluate** emergency operations plans, policies, processes, and procedures to **prevent, mitigate, prepare for**, respond **during and recover from emergencies and disasters, including those resulting from natural, man-made and technological hazards** ~~the effects of internal and external disasters~~. **1.4.1** The emergency plan **should** ~~shall including emergency communication systems, shall be tested at defined intervals.~~ **address such topics as communications, assignments and training for staff, supplies, equipment, facilities and collaboration with external partners. The emergency plan shall be tested, evaluated and revised as needed at least once per year**. Rationale: The current standard is non-specific and overly broad. Even though the AABB's emergency preparedness materials are fairly good, the current standard fails to mention many key activities that should be part of emergency preparedness and response. The standard as written could be interpreted to require little more than an occasional test of a blood bank's emergency phone tree. The standard should be revised to be consistent with FEMA, NFPA and others who identify four or five phases of emergency management: prevention, mitigation, preparedness, response and recovery. Blood establishments should be broadly prepared for a variety of hazards in accordance with federal recommendations (http://www.ready.gov/; http://www.flu. gov/planning-preparedness/; http://emergency.cdc.gov/planning/; http://training.fema.gov/EMIWeb/edu/termdef.asp). The AABB standard should include a specific recommended interval for testing, evaluating and revising the emergency plan and mention staff training and evaluation and encourage collaboration with local emergency management offices, health departments and other stakeholders (http://www.aabb.org/programs/disasterresponse/Pages/default.aspx) **Outcome:** The committee reviewed these comments but did not feel the changes suggested were appropriate at this time. Regarding standard 1.4, the committee intentionally wrote this standard in a manner that allows more flexibility for the user to develop their disaster plans. They did not think that the addition of specific requirements would serve the greater community as disasters can be diverse in nature. The committee notes that a facility is free to include these as part of their plan if they so choose. Concerning standard 1.4.1, the committee again felt that leaving the standard less specific and broader would be more appropriate. In the future, the committee plans to create guidance concerning these standards to assist in their implementation and will provide common examples to the membership.
1.4.1, 6.2C, #3	Public comment submitted, change made	**Comment:** Please add a record retention requirement to this standard. As an assessor, it is difficult to determine whether the Standard is being met and that the required testing actually occurs at defined intervals if the facility is not being required to create records of this testing. **Outcome:** The committee agreed with this comment and added a record retention symbol to align with the standard. The committee incorporated this into 6.2C and assigned a two year record retention period to this standard. The two year period was based on the lifecycle of this edition of *Standards*.
3.2	Public comment submitted, change made	**Comment:** Suggested edit: All equipment shall be ~~initially~~ qualified for its intended use. **Outcome:** The committee agreed with this comment and the change was made. The word "initially" was felt to be limiting.

29th edition (28th edition)	Source of change	Outcome
3.5.1, #3	Public comment submitted, change made	**Comment:** Both 3.3 and 3.5 allow following manufacturer's written instructions as a minimum. Standard 3.5.1 #3 does not state this which seems to indicate that 'forever' thermometers need to be calibrated at prescribed intervals even though the manufacturer's written instruction allow this to be omitted. **Outcome:** The committee agreed with the intent of this comment and has added the clause, "…as described below unless otherwise indicated by the manufacturer:" to appear at the end of the second sentence of the header. The standard now reads as follows: **3.5.1 Calibration of Equipment** Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be performed as described below **unless otherwise indicated by the manufacturer**:
3.6.2	Public comment submitted, change made	**Comment:** Suggested edit: Internal ~~storage~~ temperatures of refrigerators, freezers, and platelet incubators shall be monitored. **Outcome:** The committee agreed with the suggested change as indicated. The committee felt that the term "storage" could be a bit limiting and could cause a misunderstanding that the standard was only focusing on the temperatures of a piece of equipment's motor and not the actual temperature inside the devices listed in the standard.
4.3.2.1	Public comment submitted, change made	**Comment:** 660 does not apply to containers and solutions. Recommend adding the following additional CFR cites to cover containers and solutions: 606.65, 640.2(b), and 640.4(d). **Outcome:** The committee noted this comment and agreed to add references 606.65, 640.2(b), and 640.4(d) but also kept 21 CFR 660 as it relates to reagents which are described in the standard.
5.1.5.1.1	Public comment submitted, change made	**Comment:** Detection methods shall either be cleared or approved by the FDA or be validated to provide sensitivity equivalent to FDA-approved methods. FDA does not 'approve' these tests. **Outcome:** The committee noted this comment, and to ensure there was no confusion, the end of the standard was re-written to include the phrase, "…equivalent to FDA-**cleared** or –approved methods."
5.1.5.2	Committee decision	The committee elected to edit standard 5.1.5.2 to remove the term "appropriate" as it concerned the "sample" in the first sentence. The committee felt this was inherent to the requirement, the change does not change the standard's intent or how it should be interpreted.
5.1.6.1	Public comment submitted, change made	**Comment:** Please be advised that 606.160(a)(1) requires more information be captured in the records in addition to the identifying the person and date when task was done. Should 6.2.4 be referenced? **Outcome:** The committee agreed with this comment and added a cross reference to standard 6.2.4.
5.1.6.3.1, #1	Public comment submitted, no change made	**Comment:** Please clarify - wouldn't units collected before ISBT already be labeled with Codabar? Why would they need to be relabeled? **Outcome:** The committee noted this comment but did not feel that a change was needed at this time. The purpose behind this standard is to recognize that you cannot overlay a Codabar label with an ISBT 128 label, as doing so would result in the loss of important information.
5.1.6.3.1, #2	Public comment submitted, change made	**Comment:** Should the phrase "affixed or" be included in subnumber 2? **Outcome:** The committee agreed with this comment and added the new clause "affixed or…" to subnumber 2. The committee noted that this act is common and including it here would ensure completeness.
5.1.6.5.1	Committee decision	The committee elected to remove the term "specimen" in standard 5.1.6.5.1 for clarity. The committee did not feel that it was necessary to include the term as "tissue" on its own was clear what the intent was.
5.1.8.1.3	Public comment	**Comment:** Re-write as such:

29th edition (28th edition)	Source of change	Outcome
	submitted, change made	✎**5.1.8.1.3** For storage of blood or blood components, the temperature **<u>of the storage area</u>** shall be continuously monitored or ~~the temperature~~ recorded at least every 4 hours. **Outcome:** The committee noted this comment and adjusted the language of the standard, not exactly as suggested, but in an attempt to avoid redundancy while not compromising the intent of the standard. The standard now reads as follows: ✎**5.1.8.1.3** For storage of blood or blood components, the temperature shall be ~~continuously~~ monitored **continuously** ~~or~~ ~~the temperature~~ and recorded at least every 4 hours.
5.2.1, #4 (5.2.3.1)	Committee decision	The committee elected to edit standard 5.2.1, #4 and moved it from a standalone standard (5.2.3.1) to appear as a subnumber of standard 5.2.1, Donor Education, to ensure that it was understood that this step in the process was a part of donor education. The standard now reads as follows: **5.2.1 Donor Education** 4) Donors are informed that they should not donate blood in order to obtain infectious disease testing services and that there are circumstances in which testing is not performed.
5.2.1, #4 (5.2.3.1)	Public comment submitted, no change made	**Comment:** It makes more sense to address this in donor history questionnaire materials prepared as part of the current version of the DHQ by the DHQTF. Requirements or information not included in the current version of the DHQ generates questions as to the adequacy of those materials. • The DHQ materials are then not adequate to meet standards industries without alteration. • The BBTS Standards should not require information not already present in the DHQ; rather coordination with the FHQTF should update current version of DHQ materials, then Standards can up be updated to reflect the new standard which has been established. • Acceptance of this standard will require DHQ modification (not a desired outcome for standardization of donor materials) or addition of more donor educational information in another location (not a desired outcome for standardization of donor materials). • If the DHQTF does not agree that the additional requirements are necessary, it is questionable if this should be required as a standard at this time. Requiring statements or information already included in current version of the DHQ is acceptable. It would be helpful for a note to be added in standards that use of the current DHQ meets the requirements of this standard. Proposal: Establish this informational content in the DHQ prior to establishing this standard. Incorporating this into the DHQ will better allow for consistent and understandable language to fulfill this requirement. **Outcome:** The committee noted this comment but did not feel that a change was needed at this time. The committee and the Donor History Questionnaire Task Force feel that the Standards should be the driving force with what is included in the DHQ and not the other way around. It should also be noted that the DHQ is not used by everyone and is more of a template for how a facility can create their own in-house donor history questionnaire should they not wish to implement the AABB's DHQ.
5.3.4	Public comment submitted, no change made	**Comment:** This is post phlebotomy instructions. Move under 5.3.3. **Outcome:** The committee noted this comment but did not feel that that post-donation instructions and post-phlebotomy instructions are the same thing, nor should one be the subset of the other. The standard will stay in its current location.
5.4.1.1	Public comment submitted, no change made	**Comment:** This is for protection of the recipient, please move it to appear under 5.4.2. **Outcome:** The committee did not make the suggested change. The committee feels that donors implicated with TRALI would fall under donor qualification and fits more appropriately as a measure for allogeneic donor qualification.

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5.4.1.2 (New)	Committee decision	In the proposed 29th edition, the committee had put forth the following standards related to TRALI risk reduction measures with regard to whole blood, plasma, and platelets. The standard concerning platelets when initially proposed did not have a separate effective date, which would be included with the next version. **5.7.4.4 Special Considerations to Reduce the Risk of TRALI** **5.7.4.4.1** Blood collecting facilities shall prevent the preparation of plasma for transfusion from donors known to have leukocyte alloimmunization or known to be at increased risk of leukocyte antibodies. **5.7.4.4.2** Blood collecting facilities shall prevent the preparation of plasma-rich platelet components from donors known to have leukocyte antibodies or to be at increased risk of leukocyte alloimmunization. **5.7.4.4.3** Blood collecting facilities shall prevent the release of allogeneic Whole Blood for transfusion from donors known to have leukocyte antibodies or to be at increased risk of leukocyte alloimunization. Following the review of the multitude of comments received, the feedback generated as a result AABB's Public Workshop: Current Perspectives on TRALI Risk Reduction (held July 8th in North Bethesda, MD), and input from AABB senior management, the committee elected to combine the three standards (see above) into one standard with a separate effective date as it pertained to platelets. Those revised standards appear below: **5.4.1.1.1** High plasma volume components for allogeneic transfusion (i.e. plasma, high plasma volume platelet components, and whole blood) shall be from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies. **5.4.1.1.1.1** For high plasma volume platelet components, standard 5.4.1.1.1 shall be implemented by October 1, 2014. These standards were presented to the membership in August of 2013 via the August 16th issue of AABB's Weekly Report. However, after receiving further feedback from the membership, the standards committee agreed that publication of the Standards as drafted was premature without further study and data becoming available relative to high volume platelet components and the approved risk reduction measures. As a result, the committee has issued the final version of standard 5.4.1.2,focusing only upon TRALI risk reduction measures for whole blood and plasma components: **5.4.1.2** Plasma and whole blood for allogeneic transfusion shall be from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies. To assist the membership with the implementation of this standard, the AABB issued Association Bulletin #14-02 which details how members and accredited facilities can meet the intent of standard 5.4.1.2 successfully. As it relates to platelets, AABB's TRALI Work Group continues to review the data currently available. If necessary, they will submit a draft standard to the BBTS SPU and the AABB Board of Directors for their consideration and review before it would be released to the membership for their input. Any additional standard regarding platelets will either appear as an interim standard to the 29th edition or in the 30th edition.
5.4.2, 5.4.3 5.4.2.1 (New)	Public comment submitted, change made	**Comment:** Is an AABB variance needed when a center obtains information within 24 hours after donation – which will occur next day and after collection? FDA has approved SOPs for this. **Outcome:** The committee noted this comment, but did not make a change to either standard. However, they have created a new standard, 5.4.2.1 to address the issue of new information becoming available concerning a donor within 24 hours. The standard reads as such: **5.4.2.1** If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, FDA recommendations* shall apply.

29th edition (28th edition)	Source of change	Outcome
		*FDA Guidance for Industry: Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application, November 2010. This standard will allow facilities that want to use the unit in question so long as they qualify the donor within 24 hours to ensure the unit is safe for transfusion. It should be noted that for the purpose of these *Standards*, this can be done by conducting a phone call or an in-person meeting. Should the facility choose not to perform these extra steps, it is expected that the unit would be discarded.
5.4.3.2	Public comment submitted, no change made	**Comment:** The plateletpheresis guidance includes monitoring plasma loss as part of donor safety. Should monitoring plasma loss be included here? **Outcome:** The committee reviewed this comment and felt that this could be a good addition in the next edition of *Standards*. The committee felt that this change would require further member input before being finalized , and will include it as a discussion point for the 30th edition.
5.5.1	Public comment submitted, no change made	**Comment:** Should the medical evaluation include assessing the impact on the donor's health vs. the need for the product? Would the need for the product outweigh the safety of the donor? **Outcome:** The committee reviewed this comment but did not feel a change was needed at this time. The committee noted that this is currently under the purview of the facility's medical director. The standards also allow for the length of time between donations to be at the discretion of the medical director in the case where it is necessary. This concept is also covered in the Donor History Questionnaire, which ensures that the health of the donor at the time of donation be evaluated.
5.5.2.2.1	Public comment submitted, no change made	**Comment:** This reference is appropriate if the standard deals with collection volume. If the standard deals with collection frequency, then the reference should be 21 CFR 640.65(b)(8). **Outcome:** The committee did not feel that a change was needed as this reference is already included as a part of standard 5.5.2.2.
5.5.3.1	Public comment submitted, change made	**Comment:** Take out "blood bank" before medical director **Outcome:** The committee agreed with this comment and removed the term "blood bank" to ensure parallel construction with the rest of the document.
5.5.3.2	Public comment submitted, change made	**Comment:** Suggested revision: If a platelet, granulocyte, or leukocyte donor donates a unit of Whole Blood, at least 8 weeks shall elapse before a subsequent automated cytapheresis procedure, unless the extracorporeal red blood cell volume of the apheresis machine <u>is less than</u> ~~does not exceed~~100 mL. (to be consistent with cited FDA guidance) **Outcome:** The committee agreed with this comment and made the suggested change.
5.5.3.5.1	Public comment submitted, change made	**Comment:** Is it clear here that FDA recommends a donor be deferred from <u>all</u> donations for 16 weeks following a 2 RBC collection? **Outcome:** The committee noted this comment and added the clause, "from all donations" in the standard for completeness.
5.5.3.5.2	Public comment submitted, no change made	**Comment:** Can AABB consider including a reference for this value? **Outcome:** The committee did not feel that a reference would add to this standard, and no change was made.
5.5.3.5.2	Public comment	**Comment:** Please capitalize, "Cell" in the title of this standard. **Outcome:** The committee agreed with the comment and the change was made.

29th edition (28th edition)	Source of change	Outcome
	submitted, change made	
5.6.1	Public comment submitted, no change made	**Comment:** Is AABB precluding the use of the Haemonetics PCS2 and the Fenwal Autopheresis-C which are open plasmapheresis systems? **Outcome:** The committee reviewed this comment but did not change the wording of the standard. The committee notes that the system would be considered an open system. Should a facility be using these systems, the committee suggests that you apply for a variance to ensure compliance with the standard.
5.6.3.2	Public comment submitted, no change made	**Comment:** Please replace the term "Containers" with "Samples." **Outcome:** The committee noted this comment but did not feel that the change suggested was needed at this time. The committee feels that the term "containers" is accurate in this case.
5.6.3.2	Public comment submitted, no change made	**Comment:** In the phrase "shall be re-identified with the blood container immediately after filing", it has been my experience performing assessment that the word 'immediate' is not assessable. It ends up being assessed as to whether the re-identification occurred or did not occur, regardless of timeframe. Suggest removing the word 'immediate', or stating what is actually intended. **Outcome:** The committee noted this comment, however, in this case the term "immediate" needs to remain in the document as this is the intent of the committee. This step needs to occur immediately following filling. The committee considered other potential terms and determined that this wording is the most appropriate.
5.7.2.1.1	Public comment submitted, no change made	**Comment:** We recommend that the following FDA guidance document be included as a reference: FDA Guidance for Industry, November 22, 2000, "Use of Sterile Connecting Devices in Blood Bank Practices." **Outcome:** The committee noted this comment but did not feel that the reference was appropriate as it was a guidance document. AABB Standards do not typically cite FDA Guidance documents unless it will strengthen the content of the standard, in this case that was not needed.
5.7.3 in the proposed, no longer a standard	Public comment submitted, change made	**Comment:** How is this different from 5.6.3.1? Outcome: In the proposed 29th edition, standard 5.7.3 stated the following: "At the time of preparation of a final red-cell-containing component intended for transfusion, the integrally connected tubing shall be filled with aliquots of the component and sealed in such a manner that it will be available for subsequent compatibility testing." which was almost identical to what appears in standard 5.6.3.1. As such, the standard was removed and standard 5.6.3.1 was retained.
5.7.3.1 (5.7.4.1)	Public comment submitted, change made	**Comment:** It is not clear if this refers to only apheresis RBCs or includes whole-blood derived RBCs. Also 2012 guidance applies to all RBCs and WB-derived platelets while the 2007 guidance applies to apheresis platelets. Can both references be added for clarity? Suggested revision: Leukocyte-reduced blood and blood components shall be prepared by a method known to reduce the leukocyte number to <5 x 106 for Red Blood Cells* and Apheresis Platelets[£] ~~and Red Blood Cells~~ and to <8.3 x 105 for whole-blood-derived Platelets*. (additional guidance reference) [£]Final Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods, December 2007 **Outcome:** The committee noted this comment and agreed with the suggestion and the changes were made.
5.7.3.2.1 (5.7.4.2.1)	Public comment submitted, change made	**Comment:** As worded it seems like records are maintained annually, semiannually, periodically, etc., when 1) – 4) describes verification testing timeframe. Since there is a pen for this standard, the reference to records in the text may not be needed. Suggested edit. Verification of dose delivery shall be performed using a fully loaded canister ~~Records shall be maintained~~ as follows: **Outcome:** The committee agreed with the suggested change and edited the standard accordingly.

29th edition (28th edition)	Source of change	Outcome
5.7.4.6 (5.7.5.6)	Public comment submitted, change made	**Comment:** Recommend including the guidance document for LR of RBC products Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012) **Outcome:** The committee agreed with this comment and the guidance was included as a reference to ensure clarity.
5.7.4.9 (5.7.5.9)	Public comment submitted, change made	**Comment:** Anticoagulant does not affect when FFP is placed in freezer. Suggested edit Fresh Frozen Plasma shall be prepared from a whole blood or apheresis collection and placed at <–18 C within the time frame required for the ~~anticoagulant or~~ collection, processing and storage system ~~process.~~ **Outcome:** The committee agreed with this suggestion and made the change accordingly.
5.7.4.10 (5.7.5.10)	Public comment submitted, no change made	**Comment:** Suggested revision: Plasma Frozen Within 24 Hours After Phlebotomy shall be prepared from whole blood or apheresis collection, held at room temperature up to 8 hours before being placed at 1 – 6 C and then placed at <–18 C within 24 hours of collection. Please be advised that the operator's manuals for the Amicus and ALYX require PF24 to be frozen within 24 hours. Another option – Plasma Frozen Within 24 Hours After Phlebotomy shall be prepared from whole blood or apheresis collection, stored at 1-6 C within 8 hours and placed at <–18 C within 24 hours of collection. **Outcome:** The committee reviewed this comment but did not feel that this specific change was appropriate. The committee did make adjustments to the standard as noted below.
5.7.4.10 (5.7.5.10)	Committee decision	**The committee elected to edit standard 5.7.4.10 (formerly 5.7.5.10) to remain consistent with the language in the Circular of Information for Blood Components. The standard was edited thusly:** **5.7.4.10 PLASMA FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY** Plasma Frozen Within 24 Hours After Phlebotomy shall be prepared from whole blood or apheresis collection and ~~placed~~ **stored at 1-6 C within 8 hours of collection and frozen** at ≤–18 C within 24 hours of collection.
5.7.4.11 (New)	Committee decision	The committee elected to add new standard 5.7.4.11 to recognize the existence of this new component. A corresponding entry has been included in reference standard 5.1.8A, Requirements for Storage, Transportation and Expiration. The standard reads as such: **5.7.4.11 PLASMA FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY HELD AT ROOM TEMPERATURE UP TO 24 HOURS AFTER PHLEBOTOMY** Plasma Frozen Within 24 hours After Phlebotomy Held At Room Temperature Up to 24 Hours After Phlebotomy shall be prepared from an apheresis plasma collection. The product can be held at room temperature for up to 24 hours after collection and then frozen at ≤–18 C.
5.7.4.11 (New)	Public comment submitted, no change made	**Comment:** Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up to 24 Hours After Phlebotomy shall be prepared from whole blood or apheresis collection, stored at room temperature and frozen at <–18 C within 24 hours of collection. Please be advised that the operator's manuals for the Amicus and ALYX require PF24 to be frozen within 24 hours. **Outcome:** The committee noted this comment but after discussions with the Circular of Information Task Force, felt that the standard as written was and is appropriate.
5.7.4.13 (5.7.5.12)	Committee decision	The committee edited standard 5.7.4.13 to include "Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up to 24 Hours After Phlebotomy" as included in new standard 5.7.4.11. The standard now reads as such: **5.7.4.13 THAWED PLASMA**

29th edition (28th edition)	Source of change	Outcome
		Thawed Plasma shall be prepared from Fresh Frozen Plasma, Plasma Frozen Within 24 Hours After Phlebotomy **or Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy** that has been collected in a closed system.
5.7.4.15 (5.7.5.14)	Public comment submitted, no change made	**Comment:** Suggested revision: Cryoprecipitated AHF shall be prepared by a method known to separate the cold insoluble portion from thawed Fresh Frozen Plasma and result in a minimum of 150 mg of fibrinogen and a minimum of 80 IU of coagulation Factor VIII per container or unit. The product is then placed at < –18°C. For prestorage pooled components, the pool shall contain a minimum of 150 mg of fibrinogen and 80 IU of coagulation Factor VIII times the number of components in the pool. The standards should clarify that cryo can only be prepared in a closed system from Whole Blood-derived FFP (640.50(a)). **Outcome:** The committee noted this comment but did not think that the suggested change was needed. The committee requested that the liaison to the Circular of Information work group review this comment, and it was their feeling that what is currently in the standard is appropriate.
5.7.4.16 (5.7.5.15)	Public comment submitted, no change made	**Comment:** The requirement to prepare the cryo in a closed system is not listed above. **Outcome:** The committee reviewed this comment but did not feel that the inclusion of a clause on the preparation in a closed system would strengthen the standard. The committee also felt that including this would lead readers to believe that they were making a statement on 5 day thawed plasma, which is not their intent.
5.7.4.19 (5.7.5.20)	Public comment submitted, change made	**Comment:** Recommend including the guidance document for LR of WB-derived platelets Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012) **Outcome:** The committee noted this comment and agreed that the guidance should be referenced.
5.7.4.22 (5.7.5.21)	Public comment submitted, no change made	**Comment:** 2 plateletpheresis products with platelet additive solutions have been approved. Does AABB intend to include them here? **Outcome:** The committee noted this comment, and has included new standard 5.7.4.23 below.
5.7.4.23 (New)	Committee decision	The committee elected to add new product "Apheresis Platelets Platelet Additive Solution Added Leukoyctes Reduced" for completeness. The standard reads as such: **5.7.4.23 APHERESIS PLATELETS PLATELET ADDITIVE SOLUTION ADDED LEUKOCYTES REDUCED** Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced shall be collected by apheresis and suspended in variable amounts of plasma and an approved platelet additive solution. Validation and quality control shall demonstrate that at least 90% of units sampled contain ≥3.0 × 10^{11} platelets. At a minimum, 95% of units sampled shall contain a residual leukocyte count <5 × 10^{6}.
5.7.4.24 (5.7.5.22)	Committee decision	The committee elected to edit the last sentence of standard 5.7.4.24 as such for clarity: "**Product** ~~Neonatal~~ requirements for neonates shall be defined by the medical director."
5.8.4 (proposed edition, since deleted)	Public comments submitted, change made	During the comment period, the committee received multiple comments to proposed standard 5.8.4, which read as follows: "Antigen typing of Red Blood Cell products shall be performed using FDA licensed reagents. If FDA-licensed reagents are not available, validated test methods may be used." Below are a sampling of the comments received: • This proposed standard is greatly appreciated to decrease unnecessary repeated serologic testing. This may require changes in blood center computer systems if such data has not been captured in the past. A mechanism for allowing labeling of historic antigen typing performed on one previous donation would be helpful. Future consideration of molecular diagnostic results should be considered in future editions of Standards.

29th edition (28th edition)	Source of change	Outcome
		• It is not clear what is intended by "validated test methods". With regard to molecular typing, individual blood centers will not be able to validate the assay primers; would the manufacturer's validation suffice? With regard to rare antisera, would antibody specificity determination by the commercial supplier or on accredited reference lob suffice? With regard to expired serologic reagents, would running defined controls suffice? Recommendation: Delete these two sentences, since the facility's laboratory director has the responsibility of defining the methods used in a particular laboratory and the degree of process validation required. Alternatively, change wording from "validated test methods" to "test methods approved by the facility's laboratory director." • Please provide clarification in light of CFR prohibition on labeling products on the basis of historical antigen typings. **Outcome:** The committee reviewed these comments and after internal deliberation elected to delete former standard 5.8.4 as its content was similar to proposed standard 5.8.4.1 already. Standard 5.8.4.1 has become new standard 5.8.4 (see below) and based on the comments above removed the sentence that read "Antigen typing of Red Blood Cell products shall be performed using FDA licensed reagents. If FDA-licensed reagents are not available, validated test methods may be used."
5.8.4 (New)	Committee decision	The committee elected to add new standard 5.8.4 to the 29th edition (appearing as standard 5.8.4.1 in the proposed edition) to allow accredited facilities to be able to use historical antigen results for labeling purposes. The standard appears as such: **5.8.4 Red Cell Antigens Other than ABO and RhD** Units may be labeled as antigen negative, without testing the current donation, if units from two previous separate donations were tested by the collection facility and found to be concordant.
5.8.4	Public comment submitted, no change made	**Comment:** Please provide clarification in light of CFR prohibition on labeling products on the basis of historical antigen typings. **Outcome:** The committee reviewed this comment but did not feel it would be appropriate for AABB to comment on a Federal Regulation. The committee did note, however, that there is expected to be guidance from the FDA issued sometime this spring.
5.8.4	Public comment submitted, no change made	**Comment:** We would like to be sure that this standard would not prohibit the labeling of units with "unconfirmed antigen" labels that would require confirmation typing by the hospital. Many hospitals request unconfirmed phenotype information from their supplier. The provision of unconfirmed phenotype labeling dramatically expedites the location of potentially compatible units that are in the transfusion service inventory; potentially compatible units can be identified on the shelves and their type verified by quick confirmatory typing performed at the same time as crossmatching. Recommendation: If the intention is to cut off the option of making unconfirmed antigen labeling available to hospitals, we would strongly object. This would have a dramatic negative impact on the support of alloimmunized patients. 2. **Comment:** For typing performed by molecular methods, this Standard would require genotyping to be performed on two separate DNA extractions. Is this reasonable logistically and financially? Recommendation: lf the concern is mainly transcription errors (as was indicated in the recent workshop), perhaps this concern could/should be addressed in a less expensive way than requiring repeat molecular testing. **Outcome:** The committee reviewed these two comments but did not think that a change was needed at this time. Regarding the first comment, the committee felt that the way the standard was written would prohibit the use of the "unconfirmed antigen" label as stated.

29th edition (28th edition)	Source of change	Outcome
		With regard to the second comment, the committee noted that the 2nd edition of Standards for Molecular Testing for Red Cell, Platelet and Neutrophil Antigens requires two separate extractions already.
5.8.5 (5.8.4), 5.8.6 (5.8.5), 5.8.7 (5.8.6)	Committee decision	The committee elected to add a requirement to standards 5.8.5 and 5.8.6 requiring that all samples to be tested for HBV DNA. This requirement has also been added to 5.8.7 requiring that all repeat reactive donors for HBV DNA have their samples appropriately quarantined. In conjunction with this addition, the committee has added a reference to the FDA guidance requiring that HBV DNA testing be performed.
5.10	Public comment submitted, no change made	**Comment:** Should this be documented (include pen)? **Outcome:** The committee reviewed standard 5.10 but did not feel that a record retention requirement was concerning the process described as it is already required by standard 1.3 that all policies, processes and procedures be documented.
5.11.2 – 5.11.2.2	Committee decision	The committee elected to remove the term "blood sample" and replace it with "sample", anticipating that there could be testing done in the future may not be strictly focused on blood samples. The committee will reconsider this for the 30th edition as the evolution goes forward with potential DNA samples being used as an identification measure.
5.11.2.1	Committee decision	The committee has elected to replace the term "tube" with "sample container" for clarity. The committee felt that the term "tube" was not inclusive enough of what a sample would be contained in and subsequently labeled as.
5.11.2.2	Committee decision	The committee elected to edit the wording of this sample for clarity. The standard now reads as follows: **5.11.2.2** There shall be a mechanism to identify the date of sample collection and the individual**(s) who collected the sample** ~~drew the blood~~ from the patient. The change was made in conjunction with the changes to standard 5.11.2 – 5.11.2.2.
5.12	Committee decision	The committee elected to add "Granulocytes" to standard 5.12 for completeness. The standard now reads as follows; **5.12 Serologic Confirmation of Donor Blood ABO/Rh (including autologous units)** Before transfusion, the ABO group of each unit of Whole Blood, ~~and~~ Red Blood Cell, **and Granulocyte** component and the Rh type of such units labeled as Rh negative shall be confirmed by a serologic test from an integrally attached segment. Confirmatory testing for weak D is not required.
5.12	Public comment submitted, no change made	**Comment:** Granulocytes has been added to the list of products that require ABO group to be confirmed by a "serologic test from an integrally attached segment." We do not currently make segments on Granulocyte products; instead we provide a separate, labeled sample tube for testing. Would this be an alternative for compliance with the standard? We are not aware of any CFR specifically requiring segments for Granulocyte products. The CFR only discusses segments in relation to Whole Blood (21 CFR 640.4(g)(1) and Red Blood Cells (21 CFR 640.15.) **Outcome:** The committee noted this comment and, while there is not a Federal regulation requiring this, the committee felt that this should be a standard. Should a facility not be able to meet the requirement, the committee suggests that they submit a variance, as well as the facilities that subsequently receive this product.
5.13 (New)	Committee decision	The committee elected to add new standard 5.13 to the 29th edition after receiving a high number of requests from the membership and assessors on how to interpret this situation. The standard reads as follows: **5.13** Red blood cell products labeled as negative for red blood cell antigens other than ABO and RhD do not require repeat testing for the labeled antigens.
5.16.1.1 (5.15.1.1)	Public comment submitted, no change made	**Comment:** Please add the word 'serological': "If no clinically significant antibodies were detected in tests performed in Standard 5.14.3 and there is no record of previous detection of such antibodies, at a minimum, detection of <u>serological</u> ABO incompatibility shall be performed." **Outcome:** The committee noted this comment but did not feel the inclusion of "serological" was accurate in this case. The committee purposefully left it out of the Standards to ensure that facilities would be able to use an electronic medium to detect any incompatibility.

29th edition (28th edition)	Source of change	Outcome
5.16.2 (5.15.2)	Committee decision	The committee elected to edit standard 5.16.2 to ensure that there is no confusion with the term "computer crossmatch" which had been misunderstood based on its use by the FDA. The standard's intent has not changed, merely clarified. The standard now appears as such: **5.16.2 ~~Computer Crossmatch~~Use of Computer to Detect ABO Incompatibility** If a computer system is used **as a method** to detect ABO incompatibility, the following requirements shall be met:
5.16.2 (5.15.2)	Public comment submitted, no change made	**Comment:** Should it be added that the antibody screen has to be negative? **Outcome:** The committee reviewed this comment but did not think that this should be added to the standard. The committee noted that facilities can use a computer to potentially detect if an individual has a positive antibody screen.
5.16.2 (5.15.2)	Public comment submitted, no change made	**Comment:** This modification is requested to address the potential problem associated with gel technology when it is used to perform an AHG crossmatch. A properly validated computer system is as reliable as an immediate spin crossmatch in detecting ABO incompatibilities. Standards 5.16.2.1 through 5.16.2.5 add additional safety to this electronic determination and should continue to apply. If a computer system has been deemed an acceptable method for determining ABO incompatibility as a standalone test, logically, it should be deemed acceptable as an adjunct to an AHG crossmatch to accomplish the same end. **Outcome:** The committee noted this comment but did not feel that a change was needed. The committee feels that the standards as written do convey their intent and do allow for the use of a computer assisted crossmatch. To assist with the understanding of this standard, the definition of "Crossmatch" has been edited to include both serological and computer-based methods.
5.16.2.2 (5.15.2.2)	Public comment submitted, change made	**Comment:** FDA recommends that testing the same sample be the last option to avoid WBIT errors and only done with another tube is not possible. Reference: Guidance for Industry: "Computer Crossmatch" (Computer Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type) (April 2011) **Outcome:** The committee reviewed this comment and agreed with the suggestion to move the retesting of the sample to appear as the third option. To allow for this comment, the standard was re-formatted to now appear as a list as opposed to a narrative. The standard reads as follows: **5.16.2.2** Two determinations of the recipient's ABO group as specified in Standard 5.14.1 are made – one on a current sample, and the second by one of the following methods: ~~by retesting the same sample,~~ 1) Testing a second current sample, **or** 2) Comparison with previous records, **or** 3) Retesting the same sample.
5.18 (New)	Committee decision	The committee elected to add new standard 5.18, Special Considerations for Intrauterine Transfusion to address the treatment of hemolytic disease of the fetus and the newborn. The standard reads as such: **5.18 Special Considerations for Intrauterine Transfusion** The blood bank or transfusion service shall have a policy regarding intrauterine transfusion including a mechanism to ensure that fetal transfusion and fetal blood type, when performed, is differentiated from that of the mother.
5.18 (New)	Public comment submitted, no change made	**Comment:** I don't understand what the intent is here. Does this refer to alternate tests to confirm the origin of the sample or separation of record keeping between the fetus and mother? **Outcome:** The committee reviewed this comment and would like to confirm that the intent is to ensure a separation of the records between the mother and the fetus.
5.18 (New)	Public comment	**Comment:** The intent of this standard is unclear to us. For intrauterine transfusion, our policy is to issue blood to the Mother's medical record number (MRN), with a comment stating "Intrauterine transfusion" appended to the computer record and recorded on the transfusion tag. The fetus is not assigned a MRN until birth. We do not perform fetal blood type.

29th edition (28th edition)	Source of change	Outcome
	submitted, no change made	Does this practice meet the intent of the standard? This new standard should not be implemented without further clarification of the intent. **Outcome:** The committee reviewed this comment and felt that the process as described would meet the intent of the standard so long as the mother and the fetus' records were kept distinct from one another. The committee will be providing further guidance on the implementation of this standard in the coming months.
5.18 (New)	Public comment submitted, no change made	**Comment:** We are fully supportive of this new standard. We would recommend that additional background is provided for why this standard is being implemented. **Outcome:** The committee thanks the commenter for the support of standard 5.18. With regard to why this standard was created, the committee noted that there are standards in the 29th edition that related to the requirement to have policies for other special transfusion considerations and that this was lacking from the current edition as it pertains to histocompatible platelets.
5.19.6 (New)	Committee decision	The committee elected to add a new standard concerning Specially Selected Platelets. The committee included this standard initially in conjunction with proposed standard 5.7.4.4.2 concerning TRALI risk reduction for platelets. Once this standard was removed and TRALI focused on plasma and whole blood components, the committee felt that the standard should remain in the 29th edition. The standard reads as follows: **5.19.6 Specially Selected Platelets** The blood bank or transfusion service shall have a policy regarding indications for specially selected platelet requirements—for example, HLA-matched, crossmatch-compatible, HLA antigen-negative, and HPA antigen-negative platelets.
5.24, #1	Committee decision	The committee added the elements in subnumber 1 of standard 5.24 to address where the tissue or derivative in question may be issued in a sealed box; in these cases, the manufacturer's package inserts cannot be accessed easily or without affecting the integrity of the product of the storage container. The standard reads as follows: ✎**5.24 Issue of Tissue and Derivatives** The following information shall be verified: 1) The manufacturer's package insert documents are issued with the product **or listed on the product contents list**.
5.27 (5.25)	Public comment submitted, no change made	**Comment:** Please clarify why 7.2 is referenced in this section. **Outcome:** Standard 7.2 is referenced in this standard as a reminder that when you do have a fatality, it must be reported to the FDA. The committee acknowledges this redundancy but feels it is appropriate in this circumstance.
5.27 (5.25)	Public comment submitted, no change made	**Comment:** Add reference to standard 5.12 to allow for situations where retyping units is not possible. This would require 5.27.5 to be changed as well. **Outcome:** The committee notes that there is a reference to standard 5.27 in standard 5.12 already, and thus no need to add another reference. The committee also notes that when a reference to a standard is included in a "parent" standard (5.12 in this case) that the reference would cascade down.
5.28.4 (5.26.4)	Public comment submitted, no change made	**Comment:** We took this initiative to ensure that the healthcare community and the vendors serving same understand the fundamental differences between electronic matching and electronic recording of the two independent identifiers. If the latter process occurs, the scanning of the patient's wristband and the unit(s) of blood at the bedside only provides a record of the identifiers used and not a match. As such, from a Patient Safety standpoint, we believe that two caregivers should be present under this scenario. Unfortunately, we have recently come across several instances where only one nurse was present at the patient's bedside when the patient/blood unit identification took place because they thought that since they were scanning the patient's wristband and the unit of blood it met the requirements of 5.28.4 when in fact it only recorded the transactions. **5.28.4** The transfusionist and one other individual (or an electronic identification system) shall, in the presence of the recipient positively identify the recipient and match the blood component to the recipient through the use of two independent identifiers. **<u>If an electronic</u>**

<table>
<tr><th>29th edition
(28th edition)</th><th>Source of change</th><th>Outcome</th></tr>
<tr><td></td><td></td><td><u>identification system is used, it must verify that the two independent identifiers match rather than only provide an electronic record (documentation) of the identifiers.</u>
Outcome: The committee reviewed this comment and appreciates the suggested language; however, they did not feel that a change was needed at this time. The committee will consider such a change for the 30th edition going forward.</td></tr>
<tr><td>5.1.6A, #16</td><td>Public comment submitted, change made</td><td>Comment: There is no requirement in the Standard for platelet yield of pooled platelets (no change brought to Std 5.7.5.20)
For Apheresis platelets, Std 5.7.5.21states that 90% of units shall meet the requirement of ≥ 3.0 x 10^{11}. This is therefore a QC test and is not done on all units but on a specific number of units on a monthly schedule. A low yield unit, when collected, could therefore not be detected.
We must not forget that a donor needs a platelet count of ≥ 150,000/µL to be able to donate.
In both cases, the test is performed in our QC lab up to 8 days post collection and therefore the results are usually not available at time of labelling especially when we consider the shelf life of the product. There is currently a statement on the Apheresis platelets label that says that the unit contains approximately 300 x 109 platelets and this statement is based on QC results obtained over the years. For pooled platelets there is no such statement but the fact that we are talking of a pool, a low yield platelet unit in the pool would have no great impact because the other units in the pool would compensate. The probability of having 5 platelets with a low yield in the same pool is very remote. We suggest reverting to the language from the 28th edition.
Outcome: In the proposed edition of the 29th edition the committee had included the following to entry #16 of reference standard 5.1.6A:
Indication that the unit is low volume or, for platelets, low yield, and the actual volume or platelet yield, if applicable.
After reviewing this comment, the committee agreed to remove the new elements in bold.
To simplify the entry further to ensure clarity, the committee edited entry #16 to read now as follows:
“Indication that the unit is low volume, if applicable”</td></tr>
<tr><td>5.1.6A, #19 (New)</td><td>Committee decision</td><td>In conjunction with the creation of new standard 5.13 (see above) to committee has added a new entry in reference standard 5.1.6A. The entry reads as follows:
<table>
<tr><td>19</td><td>Red blood cell antigens other than ABO or RhD, if applicable[6]</td><td>NA</td><td>R</td><td>NA</td></tr>
</table></td></tr>
<tr><td>5.1.6A, #19 (New)</td><td>Public comment submitted, no change made</td><td>Comment: At the last AABB/FDA liaison meeting, FDA asked AABB to explain how they would differentiate historical information on the container label. Will this be done in the standards?
Outcome: The committee noted this comment and will provide this information in an audioconference and in a standards source post in the AABB Communities.</td></tr>
<tr><td>5.1.6A, #19 (New)</td><td>Public comment submitted, no change made</td><td>Comment: Antigen labeling is not “required,” therefore “R” is not appropriate. Please delete the “R” in this case.
Outcome: In response to this comment, the committee notes that the clause “if applicable” is attached with the “R”; therefore, there is no need to edit the entry.</td></tr>
<tr><td>5.1.8A, #4</td><td>Public comment submitted,</td><td>Comment: FDA has only approved 24 hours for an open system.
Suggested revision: Open system: 24 hours ~~or as FDA approved~~
Outcome: The committee agreed with this comment and the change was made.</td></tr>
<tr><td>5.1.8A, #14 – 24, 26, and 28</td><td>Committee decision</td><td>The committee elected to re-insert the clause, “As close as possible to” in the transport temperature requirements column. To further supplement this addition, the committee added a reference to 21 CFR 600.15(a) as well, which is where the language appears in the code of federal regulations. The phrase had originally been removed in the 27th edition of BBTS Standards, but members had subsequently raised concerns about its removal.</td></tr>
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<tr><th>29th edition
(28th edition)</th><th>Source of change</th><th>Outcome</th></tr>
<tr><td>5.1.8A, 14</td><td>Public comment submitted, no change made</td><td>Comment: In the expiration column indicate that day 0 is the day of draw.
Outcome: The committee noted this comment but points out that this appears in standard 5.14.3.2 already, and there is no need to re-include it here.</td></tr>
<tr><td>5.1.8A, #22 (New)</td><td>Committee decision</td><td>With the creation of new standard 5.7.4.23 the committee has added new entry #22 for consistency, the entry reads as such:
<table>
<tr><td>22</td><td>Apheresis Platelets Platelet Additive Solution Added Leukocytes Reduced</td><td>20-24 C with continuous gentle agitation</td><td>As close as possible to 20-24 C[2]</td><td>5 days</td><td>Maximum time without agitation: 24 hours</td></tr>
</table></td></tr>
<tr><td>5.1.8A, #22, 23</td><td>Public comment submitted, change made</td><td>Comment: The regulation cited in the footnote only applies to platelets and not granulocytes. Please remove footnote.
Outcome: The committee agreed with the comment and the citation was removed.</td></tr>
<tr><td>5.1.8A, #25 (#24)</td><td>Committee decision</td><td>The committee elected to edit the column concerning “Additional Criteria” as it relates to Cryoprecipiated AHF to read as such for clarity:
Thaw the FFP at 1-6 C
Place cryoprecipitate in the freezer within 1 hour after <s>separation</s> removal from refrigerated centrifuge</td></tr>
<tr><td>5.1.8A, #25 (#24)</td><td>Public comment submitted, no change made</td><td>Comment:
1. The AABB Technical Manual recommends that cryo be refrozen within 1 hour after thawing.
This proposed Standard appears more lenient. Hos the proposed process been validated?
2. We would like to be sure that the proposed time limit is not intended to apply to pooled cryo.
It would be difficult or impossible to make multiple individual cryos, pool them, label them, and freeze them within 1 hr after removal from the centrifuge.
Outcome: The committee noted this comment but did not feel that a change was needed at this time. The language mirrors that in the Circular of Information, and this message has been passed onto the committee that puts the Technical Manual together for their review.</td></tr>
<tr><td>5.1.8A, #27 (#26)</td><td>Public comment submitted, change made</td><td>Comment: Please add the following:
Thaw the FFP at 1-6 C
Place cryoprecipitate in the freezer within 1 hour after removal from refrigerated centrifuge
Outcome: The committee agreed with this suggestion and the change was made.</td></tr>
<tr><td>5.1.8A, #29 (#28)</td><td>Committee decision</td><td>The committee elected to edit the “Additional Criteria” column as it relates to Fresh Frozen Plasma for clarity. The elements removed already appear in the manufacturer’s package inserts and including them in the reference standard was deemed redundant.
The change appears as such:
Placed in freezer within 8 hours of collection <s>in CPD, CP2D, or CPDA-1 or within 6 hours of collection ACD</s> or as stated in FDA-cleared operator’s manuals/package inserts
Storage at ≤–65 requires FDA approval if product is stored for longer than 12 months</td></tr>
<tr><td>5.1.8A, #30 (#29)</td><td>Public comment submitted, no change made</td><td>Comment: I suggest adding “If issued as Thawed Plasma: 5-days or original expiration date, whichever is sooner”
Outcome: The committee noted this comment but felt that the addition was redundant to the requirement in line #35.</td></tr>
</table>

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<tr><th>29th edition
(28th edition)</th><th>Source of change</th><th>Outcome</th></tr>
<tr><td>5.1.8A, #31
(#30)</td><td>Public comment submitted, no change made</td><td>Comment: Recommend that wording be added to indicate that there can be 8 hour room temp hold after which the whole blood or plasma must be placed at 1-6 C while waiting to be placed in freezer.
Outcome: The committee noted this comment but did not feel that a change was needed at this time.</td></tr>
<tr><td>5.1.8A, #31
(#30)</td><td>Public comment submitted, no change made</td><td>Comment: In the column “expiration” – it should read “placed at 1-6C within 8 hour of collection and placed in freezer within 24 hours”.
Comment – the placing it at 1-6C within 8 hours of collection is how it is different from PF24RT24 which can be left at room temp up to 24 hours prior to freezing)
Outcome: The committee did not feel that a change was needed at this time.</td></tr>
<tr><td>5.1.8, #32
(#31)</td><td>Public comment submitted, no change made</td><td>Comment: Expiration should read ““If issued as Thawed PF24: 24 hours. If issued as Thawed Plasma: 5 days or original expiration date, whichever is sooner”
Outcome: The committee noted this comment, but did not feel a change was needed as the additional clause is already included in the Thawed Plasma entry, #35.</td></tr>
<tr><td>5.1.8, #33
(New)</td><td>Committee decision</td><td>The committee elected to include new entry #33 in conjunction with the addition of standard 5.7.4.11 in Process Control. The entry reads as follows:
<table>
<tr><td>33</td><td>Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24)</td><td>≤-18 or Colder</td><td>Maintain frozen state</td><td>12 months from collection</td><td></td></tr>
</table></td></tr>
<tr><td>5.1.8, #33
(New)</td><td>Public comment submitted, change made</td><td>Comment: Suggested revision:
<u>Can be held at room temperature for up to 24 hours. Frozen</u> within 24 hours of collection
Capitalize all words in product name
Outcome: The committee agreed with the suggestion to capitalize the product name for consistency, however, did not include the elements concerning the product being able to be held at room temperature as it is already stated in the standard.</td></tr>
<tr><td>5.1.8, #34
(New)</td><td>Committee decision</td><td>In conjunction with the addition of entry #33 (as described above) the committee added new entry #34 for consistency. The entry appears below:
<table>
<tr><td>34</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 using an FDA cleared device</td></tr>
</table>
When originally submitted as a part of the proposed edition the entry appeared as such, and received the comments noted below:
<table>
<tr><td>33</td><td>Plasma Frozen within 24 hours after phlebotomy held at Room Temperature up to 24 hours after phlebotomy (after thawing)</td><td>≤-18 C or colder</td><td>Maintain frozen state</td><td>12 months from collection</td><td>Placed in freezer within 24 hours of collection</td></tr>
</table>
Comments:
• Revise to
<u>1-6 C 1-10 24 hours Thaw at 30-37 C or using an FDA-cleared device</u>
Capitalize all words in product name
• Please review this table. The (after thawing) does not make sense for this product transport. Please clarify.</td></tr>
</table>

29th edition (28th edition)	Source of change	Outcome
		• We believe the correct information for these two columns is "1-10C" and "If issued as PF24RT24: 24 hours" respectively. • Expiration is not correct – it should read – "If issued as Thawed PF24RT24: 24 hours. If issued as Thawed Plasma: 5 days or original expiration date, whichever is sooner" **Outcome:** The committee noted the comments received and updated the entry as per the first comment. No other changes were made.
5.1.8A, #35 (#34)	Public comment submitted, change made	**Comment:** Please clarify what is meant by "original expiration." It is not included in line 35. **Outcome:** When the *Standards* were proposed, the "Expiration" column had been updated to read as follows: "5 days from date original product was thawed or original expiration, whichever is sooner." Based on this comment, the committee elected to re-write the entry as follows: "5 days from date product was thawed or original expiration, whichever is sooner."
5.1.8A, #37 (#34)	Committee decision	The committee elected to edit the "Expiration" column entry for Plasma Cryoprecipiated Reduced (after thawing) to remain consistent with standard 5.7.4.16. The edited entry reads as follows: **"If issued as Plasma Cryoprecipitate Reduced:** 24 hours"
5.1.8A, #38 (#35)	Committee decision	The committee elected to edit the "Expiration" column entry for Thawed Plasma Cryoprecipiated Reduced for clarity and to remain consistent with entry #37. The entry now reads as follows: **If issued as Thawed Plasma Cryoprecipitate Reduced:** 5 days from date **product was** thawed **or original expiration, whichever is sooner**.
5.1.8A, #39 (#36)	Public comment submitted, no change made	**Comment:** Citing CFR in the last column is not consistent with the rest of the entries. **Outcome:** The committee noted this comment but feels that as this appears in the "Additional Criteria" column, the way the CFR is referenced is appropriate.
5.1.8A, #41 (#38)	Committee decision	The committee elected to add in multiple CFR references to the "Additional Criteria" column to ensure that the users of the Standards are aware of how the Food and Drug Administration defines "tissue establishment" and "tissue distribution." The entry now appears as such: "21 CFR 1271.3(b), 1271.3(bb), and 21 CFR 1271.15(d) apply"
5.1.8A, footnote #1	Committee decision	The committee edited footnote #1 to ensure that the 4 hours expiration timeframe did not inadvertently imply an extension of the original expiration time. The footnote now read as follows: [1]If the seal is broken during processing, components stored at 1 to 6 C shall have an expiration time of 24 hours, and components stored at 20 to 24 C shall have an expiration time of 4 hours, unless otherwise indicated. **This expiration shall not exceed the original expiration date or time**.
5.1.8A, footnote #2	Public comment submitted, no change made	**Comment:** We would like to thank the SPU for modifying the transport temperature of platelets, granulocytes and thawed cryoprecipitate to mirror the FDA requirements. However, we would like to recommend that clear language is added to footnote 2 to reflect that, "As close as possible to 20-24^{O}C" only applies to components transported from collection to manufacturing. The CFR reference alone does not clarify the intent of the reference standard which could lead to a misinterpretation of the requirement. By adding additional wording to clearly state that "As close as possible to 20-24^{O}C applies only to transportation from collection to manufacturing, will help in the consistent application of the requirement. **Outcome:** The committee noted this comment but did not think that a change would be appropriate at this time. The committee will consider this for the 30th edition to ensure the entire membership is able to provide input for such a change. Regarding the CFR reference, the committee edited it accordingly to ensure that the appropriate regulation was referenced.
5.4.1A, #3	Public comment submitted, no change made	**Comment:** Should this be identified as a frequent plasma collection to distinguish it from an infrequent collection listed above? **Outcome:** The committee reviewed this comment but did not feel that this change would provide any additional clarity.

<table>
<tr><th>29th edition (28th edition)</th><th>Source of change</th><th>Outcome</th></tr>
<tr><td>5.4.1A, #6</td><td>Committee decision</td><td>The committee inserted the following additions to the “Drug Therapy” entry of the reference standard based on suggestions from AABB’s Donor History Questionnaire Task Force:
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<tr><td>6) Drug Therapy†</td><td>Generic medication name [example of trade name(s)]</td><td></td></tr>
<tr><td></td><td>Isoretinoin (eg Absorica, Accutane, Amnesteem, Claravis, Sotret)</td><td></td></tr>
<tr><td></td><td>• Medications that irreversibly inhibit platelet function preclude use of the donor as sole source of platelets
-Aspirin, aspirin-containing medications and piroxicam (eg, Feldene)

- Prasugrel (Effient) and ticagrelor (Brilinta)</td><td>2 full days (>48 hours) after last dose
7 days</td></tr>
<tr><td></td><td>Warfarin (eg, Coumadin, Warfilone, Jantoven)</td><td>For plasma products for transfusion: 1 week (7 days) after last dose</td></tr>
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<tr><td>5.4.1A, #6</td><td>Public comment submitted, no change made</td><td>Comment: Add “Apixaban” as an example of Direct Xa inhibitors and enoxaparin (Lovenox), fondaparinux (atrixtra) as an example of, “Heparin and derivatives.”
Outcome: The committee did not feel that this change was needed at this time and that the examples currently included were sufficient.</td></tr>
<tr><td>5.4.1A, #6</td><td>Public comment submitted, change made</td><td>Comment: Clearly, the medication list process is broken. There are already additional Isotretinoin drugs that are not listed in this proposed Standard. Neither Standards nor the FDA-approved DHQ is revised often enough to keep up with new Isotretinoin drugs, anti-platelet drugs, or anticoagulonts.
Recommendation:
We urge the Donor History Task Force, BB/TS Standards Program Unit, and FDA to work together to create a more nimble process by which the medication list con be kept up to date and blood collection facilities con still claim that they are using the FDA-approved Donor History Questionnaire. For example, perhaps the FDA-approved DHQ can reference a medication list maintained on the AABB website, and AABB can notify its members when this list is updated.
Outcome: The committee noted this comment but did not feel that a change was needed to the standard or the process of updating the medication deferral list on the whole at this time. For AABB, the Standards for Blood Banks and Transfusion Services drive the change process and the DHQ will follow. This decision is based on the timing of updates and frequency of publication. The committee also noted the following footnote which should provide assistance to the users of both the Standards and the DHQ:
†Medication Deferral List current version at http://www.aabb.org/resources/donation/questionnaires/Pages/dhqaabb.aspx.</td></tr>
<tr><td>5.4.1A, #6</td><td>Public comment submitted, no change made</td><td>Comment: As the time required to eliminate 99% of the product is considered to correspond to 5 times the half-life of the product, we have defined the deferral period as 5 days. As this calculation may vary from one blood establishment to another, it would be appropriate to allow variation in the deferral period based on the facility’s medical director decision.
For the expiration column, please edit the entry as such, “7 days or <u>as defined by the facility’s medical director</u>.”</td></tr>
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29th edition (28th edition)	Source of change	Outcome
		Outcome: The committee noted this comment but did not feel that a change would be appropriate at this time. The opportunity for multiple medical directors having multiple different expiration times would not be beneficial to the users of the *Standards*. The committee will continue to look at a deferral period of 5 days as they begin work on the 30th edition.
5.4.1A, #9	Public comment submitted, no change made	**Comment:** Please clarify what types of plasma-derived clotting factor concentrates this is referring to, e.g. only clotting factors made prior to heat or SD treatment for viral inactivation or all clotting factors (including PCCs) regardless how it is manufactured? **Outcome:** The committee reviewed this comment but did not think a change was needed at this time, since such a change could cause confusion as to when products were expiring.
5.4.1A, #10	Committee decision	The committee elected to add "Shingles" with the "Receipt of live attenuated viral and bacterial vaccines" along with "chicken pox" for clarity.
5.4.1A, #10	Public comment submitted, no change made	**Comment:** Will AABB consider including the term "Experimental" to be consistent with DHQ meds list? **Outcome:** The committee noted this comment but felt that the term "unlicensed" was more accurate in this case. The DHQ liaison did indicate that they would consider the removal of "experimental" in their next update.
5.4.1A, #11	Committee decision	The committee elected to add "Positive HBV NAT result[5]" to line 11 to remain consistent with the changes to standards 5.8.5 – 5.8.7.
5.4.1A, #11	Public comment submitted, no change made	**Comment:** Recommend including this memo as a reference: Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes and Source Plasma (6/8/95) **Outcome:** The committee reviewed the comment but did not think that this addition was needed at this time.
5.4.1A, #11	Public comment submitted, no change made	**Comment:** This standard has generated much discussion and requires clarification. The term "state regulated entity" has created confusion. Is there an inspection requirement of state-regulated entities? What states have passed and enforced laws so that regulated entities in those states can be accepted? Enforcement of state laws may vary by county or region. Must blood centers evaluate the performance of county enforcement of state laws? What does state regulation mean? Is the state regulated entity required to obtain a business permit? Does ownership of a permit mean that it is a state-regulated entity? What are acceptable mechanisms to ensure blood centers maintain a current list of states that have regulated activity so that they entities from that state are considered state-regulated entities? Are piercings/brandings/other body art included in this standard as an excluded behavior if applied by a state regulated entity with sterile tools. Proposal: AABB standards committee should develop and maintain an explicit list of states regulating tattoo so that a donor obtaining a tattoo from a listed state can be considered acceptable if the term "state regulated entity" continues to be used in this standard. Expand the list of acceptable exceptions to explicitly include piercings/brandings/other body art as well as tattoos or permanent make-up. Consider a mandatory 4 month deferral for all piercings/brandings/tattoos applied by a permitted business. This window period will allow for detection of the major infectious disease concerns – HIV, Hepatitis B virus, Hepatitis C virus related to this common, now fairly low risk behavior. **Outcome:** The committee reviewed this comment and feels that it is understood that one state's regulations may be acceptable to one blood center and unacceptable to another. The committee determined that this would be appropriate, provided that each blood center had gone through the exercise of determining which states they believe to have appropriate regulations for the application of tattoos. The committee will continue to review this entry with each edition of Standards and propose any changes as needed.

29th edition (28th edition)	Source of change	Outcome
5.4.1A, medical deferral list footnote	Public comment submitted, no change made	**Comment:** My comment concerns reference standard 5.4.1A with regard to FDA approved DHQ 1.3 Flowchart and Medication Deferral List. Absorica was added to the flowchart and also to the Medication Deferral List. Effient and Brilinta were also added to reference standard 5.4.1A but not added to the DHQ 1.3 Flowchart or the Medication Deferral List. What is the plan going forward to resolve this discrepancy? **Outcome:** The committee noted this comment but did not feel that a change was needed to the standard or the process of updating the medication deferral list on the whole was needed at this time. For AABB, the Standards for Blood Banks and Transfusion Services drive the change process and the DHQ will follow. This decision is based on the timing of updates and frequency of publication.
5.4.1A, footnote #3	Public comment submitted, change made	**Comment:** Recommend adding this memo to this item: FDA Memorandum, December 2 1987, "Recommendations for the Management of Donors and Units that are Initially Reactive for Hepatitis B Surface Antigen." **Outcome:** The committee agreed with this comment and made the requested change.
5.4.1A, footnote #4	Public comment submitted, change made	**Comment:** Recommend adding this memo to this item: FDA Memorandum, September 10, 1991, "FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc)." **Outcome:** The committee agreed with this comment and made the requested change.
6.1.1	Committee decision	The committee elected to edit standard 6.1.1 to address situations where facilities have more than one master list of documents. In conjunction with this change, the SPU created a definition of the term "master list" at the request of AABB's Accreditation Department. The standard now reads as such: **6.1.1** ~~A~~ Master list**(s)** of documents, including policies, processes, procedures, labels, and forms that relate to the requirements of these *BB/TS Standards*.
6.2.4 (6.2.3.1)	Public comment submitted, no change made	**Comment:** Was this meant to be an all-inclusive list? It does not include capturing critical timeframes of certain activities, e.g., time out of refer during irradiation procedure. Suggested revision: Records shall be created and maintained to include <u>the following and be as detailed as necessary to provide a complete history of the work performed</u>: **Outcome:** The committee noted this comment but did not feel that a change was needed at this time. The committee felt that the term "include," which is currently in the standard, was sufficient and addressed this adequately.
6.2.4, #5 (6.2.3.1, #5)	Committee decision	The committee elected to edit subnumber 5 of standard 6.2.4 to include the clause "when more than one method is in use." The committee elected to add this clause to clarify that facilities that only use one method for a given test or activity can indicate this by means other than the record system.
6.2A, #29	Public comment submitted, change made	**Comment:** ABO appearing twice seems redundant. Suggested revision: Reporting and resolution of ~~ABO donor~~ ABO/Rh labeling discrepancies to collecting facility. **Outcome:** The committee reviewed this comment and made the change. They agreed that the second ABO was unnecessary and redundant.
6.2B, #2	Public comment submitted, no change made	**Comment:** How are therapeutic bleeds that become donations addressed? **Outcome:** The committee reviewed this comment but did not feel that a change was needed at this time. Therapeutic bleeds that become donations are just treated as if they are donated from a potential donor and screened appropriately.

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6.2B, #2	Committee decision	The committee added the requirements a facility would need to retain when performing a therapeutic phlebotomy into the record retention table for clarity. The committee added the following: "Therapeutic phlebotomy: physician, request, patient identification, diagnosis, vital signs before the procedure, volume removed, and any occurrence of adverse events" The purpose of this addition being to ensure that at a minimum these topics are included in the patient's records.
6.2B, #10, 11	Committee decision	The committee elected to split former entry #10 into two entries for clarity. Entry #10 focuses solely on "Difficulty in blood typing, clinically significant antibodies, significant adverse events to transfusion, and special transfusion requirements" and edited the retention time to an indefinite time period. The rationale being that records concerning ABO/Rh need not be maintained for longer than 10 years, while the difficulty in blood typing, etc. would need to be retained for as long as possible. Concerning entry #11, the committee moved "ABO group and Rh type" to its own line with a 10 year retention time based on feedback from the Immunohematology Reference Laboratories Standards Program Unit who reasoned that these records need not be maintained indefinitely.
6.2B, #10	Public comment submitted, no change made	**Comment:** You have changed standard 5.14.5 from 10 years in the 28th edition to Indefinite in the 29th edition. What do we do about all the files we have stored away that say destroy in 10 Years? Go back and redo them? **Outcome:** The committee reviewed this comment and its response would be that yes, for all records that have to now be retained indefinitely that your facility go back and choose a method, whether it be re-labeling or changing the label, to ensure that the records are retained for the appropriate amount of time, which in this case is indefinitely.
6.2B, #s 28 - 32	Committee decision	The committee elected to edit the retention times in accordance with current FDA requirements which stipulate that the associated records be retained for 10 years and not the 5 that had been previously indicated.
6.2C, #3	Committee decision	As noted in standard 1.4.1 above, the committee added a record retention requirement to standard 1.4.1 and as such added an entry into reference standard 6.2C with an associated retention period of 2 years.
7.0	Public comment submitted, change made	**Comment:** Suggested revision: The blood bank or transfusion service shall have policies, processes, and procedures to ensure the capture, assessment, investigation, and monitoring of -deviations from ~~meeting,~~ or of failure to meet, specified requirements. **Outcome:** The committee reviewed this comment and agreed with the request to delete the term "meeting." The deletion does not change the intent of the standard, it merely removes a word that was not necessary.
7.4.1.2, #2	Public comment submitted, no change made	**Comment:** This appears to conflict with 606.170(a) which requires records maintained of all adverse events related to transfusion. **Outcome:** The committee noted this comment but did not think that the reference was in fact in conflict. The way the standard is worded does allow for an adverse event to be captured but not necessarily reported as it would not be necessary in this case.
8.2	Public comment submitted, no change made	**Comment:** Can this be done post transfusion or is it supposed to be done pre transfusion? We currently review labs after transfusion but we don't require the physicians to state why they are ordering products for transfusion. Should we be doing both and monitoring both? Would this be a good time to implement Blood Management software? **Outcome:** The committee reviewed this comment and notes that there are blood management software providers that can be effective; however, it is not in their purview to recommend one over another. Regardless, the transfusion committee would still need to conduct the review as required by standard 8.2.
8.2, #11	Committee decision	The committee edited this standard after receiving a very large number of comments and questions about what was supposed to be retained and monitored by accredited facilities. The committee expects that the edited version of subnumber 11 would ensure that it is read in a more straight-forward manner, thus allowing for an easier understanding and implementation. The subnumber reads as follows:

29th edition (28th edition)	Source of change	Outcome
		11) ~~Monitor critical~~ **Clinically relevant** laboratory results ~~before and after transfusion~~.
9.1	Public comment submitted, no change made	**Comment:** Does "determination of the cause(s)" mean: • The act of coming to a decision or • Ascertainment, as after observation or investigation In other words, is the intent of the standard to have documentation of the root cause analysis method used (for example, a completed fishbone diagram) or documentation of the root cause (for example, inadequate staffing)? **Outcome:** The committee reviewed this comment but did not feel that editing the language of the standard would be beneficial. The point of the standard is to ensure that your facility uses your defined process to determine the cause of the nonconformance or adverse event and the steps you need to take for corrective and preventative action.
9.1, #4 (New)	Committee decision	The committee elected to add new subnumber 4, "Implementation of the Correct Actions" for clarity and completeness. Previously, the committee assumed most knew to include this as part of the process, but it was felt that it would be better if it was explicitly included.
Glossary – ABO Incompatibility	Committee decision	The committee elected to add a new term to the Glossary, ABO Incompatibility, for the sake of completeness. The term is defined as such: **ABO Incompatibility** Detection: Use of a method (eg, serological or computer-based) to determine incompatibility of ABO group between donor and recipient.
Glossary – Antibody Screen	Committee decision	The committee elected to add a new term to the Glossary, Antibody Screen, for the sake of completeness. The term is defined as such: **Antibody Screen:** A serologic method to detect the presence of clinically significant antibodies in recipients and/or donors.
Glossary – By a Method Know To	Public comment submitted, no change made	**Comment:** Do data need to be published? Some understand this definition to include their internal validation is sufficient to establish a reliable and valid process. **Outcome:** The committee noted this comment but did not feel that a change to the term was needed at this time. The committee will review the term and its usage in the 30th edition in order to allow the membership to provide feedback. However, to the query, we would consider that the data need to be published, rather than be internal data.
Glossary - Crossmatch	Committee decision	The committee elected to add a new term to the Glossary, Crossmatch, for the sake of completeness. The term is defined as such: **Crossmatch:** A method (eg, serologic or computer-based) to detect incompatibility between donor and recipient.
Glossary – ISBT 128	Public comments submitted, no change made	**Comment:** Alternate wording by removing the "the" and "for": "A standard for identification, terminology, coding, and labeling blood, cellular therapy, and tissue products." **Outcome:** The committee noted this comment but did not feel that the suggestion strengthens the definition and no change was made as a result.
Glossary – Leukocyte Alloimmunization	Public comments submitted, change made	**During the comment period, in conjunction with the suggested edits to standard 5.4.1.2 (5.7.3.4) the committee received many comments on how the definition of "Leukocyte Alloimmunization" should be crafted. However with the edits to standard 5.4.1.2 the term was removed from the Glossary completely. What follows are the comments received:** **Comment:** Please consider adding a statement that female donors with no history of pregnancy (answering "no" to a donor history question such as 'have you ever been pregnant?') are not at increased risk for leukocyte alloimmunization Please consider carrying-forward a negative HLA antibody test result. Require repeat screening when a new alloimmunizing event occurs. **Comment:** Revise to:

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		Leukocyte Alloimmunization: The development of white cell antibodies following exposure to allogeneic leukocytes. Individuals at the greatest risk for leukocyte alloimmunization can include female donors with unknown pregnancy history or female donors with a history of pregnancy unless they have been tested and found negative for HLA antibodies. Also clarify – does the statement about testing apply to both types of female donors? **Comment:** Leukocyte Alloimmunization: The development of white cell antibodies following exposure to allogeneic leukocytes. Individuals at the greatest risk for leukocyte alloimmunization can include female donors with known pregnancy history or female donors with a history of pregnancy unless they have been tested and found negative for HLA antibodies, and individuals with a history of transfusion and/or transplant. **Outcome:** As stated above, the term was removed from the Standards and consequently from the Glossary.
Glossary - Master List of Documents	Committee decision	The committee elected to add a new term to the Glossary, Master List of Documents, for the sake of completeness. The term is defined as such: **Master List of Documents**: A reference list, record, or repository of a facility's policies, processes, procedures, forms, and labels related to the Standards which includes information for document control.
Glossary - May	Public comment submitted, no change made	**Comment:** The term for a requirement is defined; however, the term for an option ("may") is not defined. **Outcome:** The committee noted this but did not feel that the term should be defined. The committee notes that the explanation of this term already exists in the Introduction to the *Standards*.
Glossary – Transfusion Service	Public comment submitted, no change made	**Comment:** Using this definition, a facility that only stored blood, like a warehouse or distribution center, would be considered a transfusion service. Recommend removing the storage activity or clarifying that storage is only for in-house transfusion. **Outcome:** The committee noted this comment but did not feel that a change was needed. The committee notes that the term "storage" in this case fits because the product is being stored for its eventual intended use, however in a storage facility, the product is merely being stored, essentially being held.