

Standards for Blood Banks and Transfusion Services, 25th edition

Summary of Significant Changes

The following table summarizes many of the significant changes made to the 25th 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 25th edition of *Standards* in conjunction with this table; therefore, the numbering follows that of the 25th edition and, where appropriate, the corresponding standard number in the 24th 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 25th 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.

25 th edition standard number (24 th 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 <u>(Please note that public comments address the proposed <i>Standards</i>. The changes are best understood when the proposed <i>Standards</i> is compared to the final published version. The program unit has elected to make the substance of public comments a part of this document.)</u>
1.3	Public comment submitted, change made	<p>Comment: Should this standard reference 5.1.1, which talks about change control?</p> <p>Outcome: The program unit agreed with the submitted comment and added a reference to standard 5.1.1 at the end of standard 1.3. In addition, feedback from the Accreditation Department indicated that the lack of planning for revised policies, processes and procedures during change control is a frequent nonconformance.</p>

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2.1.2	Public comment submitted, no change made	Comment: Please re-write the standard as such: “ The blood bank or transfusion service shall have a process for identifying training needs and shall provide training for personnel performing critical tasks they are responsible for. ” Outcome: The program unit chose not to make this change because the new language would expand the requirement to encompass all tasks. The standard focuses on tasks deemed critical.
3.2, 3.3	Committee decision	Standards 3.2 and 3.3 were edited to reflect the fact that per AABB <i>Standards</i> equipment is qualified rather than validated. A process or procedure involving the use of a piece of equipment is validated. Prior to validation, the equipment is qualified for the specific process or procedure. The sentence regarding FDA clearance of equipment previously appeared in standard 3.3. It now appears in standard 3.2. Standard 3.3 was edited to address the use of equipment exclusively rather than qualification, since FDA-clearance is ultimately an aspect of equipment qualification rather than use
3.3	Public comment submitted, change made	Comment: Please re-write the standard as such: The blood bank or transfusion service shall validate devices and equipment, including Food and Drug Administration (FDA)-cleared or approved devices, for their intended use. <i>Should there be a reference here to follow the package inserts/operator’s manuals?</i> Outcome: The clause “or approved” was added to standard 3.2 per this comment. See comment above.
3.5	Public comment submitted, change made	Comment: Please re-write the standard as such: “ The blood bank or transfusion service shall have a process for scheduled monitoring and maintenance of equipment, in accordance with manufacturer’s instructions. The process shall include: frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.” Outcome: The program unit agreed with this suggested change and added the sentence in bold. It was added to set a baseline for the frequency of equipment monitoring and maintenance.
3.5.2 #2	Committee decision	Item 2 is new to this edition of <i>Standards</i> . It was noted that standard 3.5.2 did not specifically require an assessment of the impact of equipment malfunction on donor eligibility or donor and patient safety, as a result the committee added new item #2.

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3.6	Public comment submitted, change made	Comment: Please change the title of this standard to read: “Storage Temperature of Devices for Blood, Components, Reagents, Tissue, and Derivatives” Chapter 3 is about equipment, but the title of this standard implies that the requirements below address blood component storage temperatures. Outcome: The title in standard 3.6 has been changed to reflect the substance of the standards that appear below it.
3.6.2	Public comment submitted, change made	Comment: Please re-write the standard as such: There shall be a process to monitor the temperature of refrigerators, freezers, and platelet incubators <u>shall be monitored</u> . Outcome: The program unit agreed with the suggested comment and made the change. The change to standard 3.6.2 is intended to eliminate redundant verbiage, as the top level standard in each chapter requires that facilities have policies, processes, and procedures to accomplish the objectives of the chapter.
3.6.3 (new)	Committee decision	Previous editions of <i>BB/TS Standards</i> did not address liquid nitrogen temperature or levels as part of monitoring. Liquid nitrogen levels were previously addressed under “Alarm Systems.” New standard 3.6.3 makes storage and monitoring requirements parallel to alarm system requirements. During the comment period, it was noted that the clause, “and documented” was redundant as a result of the pen symbol, so the phrase was removed.
(3.6.4 in 24 th); 5.1.8.1.2.1 (3.6.3 in 24 th)	Committee decision	Standards 3.6.4 in the 24th edition, which required daily monitoring of temperatures when tissues are stored in an open area, was moved in the proposed standards to appear under the “Handling, Storage, and Transportation” header in “Process Control.” However, the requirement for daily monitoring of tissues stored in open areas was deleted based on feedback from the representative from the American Association of Tissue Banks (AATB) indicating that tissue can maintain its viability at temperatures up to 115 C. The program unit also questioned the value of recording ambient temperatures once a day. However, the requirement for daily monitoring of tissue storage temperatures is still a requirement of The Joint Commission. In conjunction with this change, the record retention requirement for daily monitoring of tissue storage in open areas in reference standard 6.2D has been removed. Change: 3.6.3 (Now standard 5.1.8.1.2.1) If blood or components are stored in an open storage area, the ambient temperature shall be recorded at least every 4 hours. 3.6.4 If tissue or derivatives are stored in an open storage area, the ambient temperature shall be recorded daily.

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3.7	Public comment submitted, no change made	Comment: The standards for alarm systems do not seem to include testing the alarm to make sure it works? Outcome: The program unit believes that this requirement is already covered in standard 3.2, which requires that all equipment be qualified and that the process be validated. It was also noted that standard 5.1.3 requires verification that equipment functions as expected.
3.9, #5	Public comment submitted, change made	Comment: Please re-write the std. as such: 5) Description of how modifications to the system are <i>evaluated and</i> authorized and documented. <i>The evaluation should include determine the impact on the interfaces with other systems.</i> Outcome: The program unit agreed with the suggestion of adding “evaluated” to the standard. However, the program unit did not add the suggested statement regarding the evaluation of the system’s interface with other systems, because the program unit believes this is an inherent part of change control.
3.9.1	Public comment submitted, change made	Comment: Do you want to consider including the following guidance document? Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 1/11/02 (www.fda.gov/cber/blood/bldguid.htm) Outcome: The program unit agreed with this comment and added the reference.
3.9.2	Public comment submitted, no change made	Comment: Does this standard need a pen if the alternate system is the use of manual (hard copy) documentation? Outcome: The program unit believes the comment is based on a misunderstanding of the difference between documents and records. The work instructions for an alternate system – whether they are manual or electronic – are documents, not records. The pen symbol indicates the need for a record. The program unit further reasoned that the alternate system would be defined and described in each facility’s policies, processes and procedures. Records of activities performed are tied to the specific action standards for those activities. Records associated with specific actions need to be retained whether they are performed by manual or electronic methods.
4.2.1	Public comment submitted, no change made	Comment: Should the standard identify who should perform this review? Outcome: No change. Each facility should determine who will perform this review and then ensure that the individual or the job position responsible for the review is detailed in the facility’s policies, processes and procedures.
4.3.2.1	Public comment submitted, no change made	Comment: Should there be a reference to standard 5.1.4 here? Outcome: The program unit did not feel that a reference to standard 5.1.4 would add to the standard.
5.1.2	Public comment submitted, no change made	Comment: I do not feel that proficiency testing is part of process control. Proficiency testing is used to assess the performance capabilities of your testing lab, not to control a process in action. Please move this requirement to chapter 8. Outcome: The program unit reviewed this comment and felt that proficiency testing does in fact cover a process action. Therefore, the program unit decided not to move the standard to chapter 8.

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5.1.2	Committee decision	The program unit elected to edit the first sentence of standard 5.1.2 to read, “The blood bank or transfusion service shall participate in a proficiency testing program, if available, for <u>CLIA-regulated testing each analyte tested by the facility</u> performed by the facility.” The change to standard 5.1.2 was made for clarity, because some of the areas for which AABB has deemed status do not involve the testing of analytes (such as microbiology.)
5.1.3	Public comment submitted, change made	Comment: Does AABB want to identify who will do this review (e.g., someone different from the person who performed the testing)? Outcome: The program unit did not choose to specify that the individual reviewing results of quality control should be a different person than the one performing the testing. In response to this comment, the program unit elected to delete the phrase “results shall be reviewed.”
5.1.4	Public comment submitted, no change made	Comment: Should there be a reference to 4.3.2 in this standard? Outcome: The program unit did not feel that a reference was necessary.
5.1.4.1	Public comment submitted, no change made	Comment: Please add a reference to: www.fda.gov/cber/gdlns/bldreagent.pdf Outcome: The program unit did not feel that adding a reference to this FDA guideline was necessary. Typically, FDA regulations are included only when the requirement in the regulation exceeds or in some way differs from a standard. In the case where an FDA regulation mirrors a standard, a citation of said requirement is not deemed necessary.
5.1.5	Committee decision	The program unit elected to remove the phrase “tissues and derivatives” from standard 5.1.5. This standard concerns sterility and the potential for microbial contamination of blood and components. The program unit reasoned that with tissues or derivatives, any manufacturing or processing steps where contamination may occur will be beyond the control of the blood bank or transfusion services.
5.1.5.1	Public comments submitted, no change to proposed edition made	Comment: A number of comments were submitted requesting that the wording of this standard be expanded to include pathogen inactivation, such as the one below. I request that standard 5.1.5.1 be modified in the next edition of Standards to read as follows: 5.1.5.1 The blood bank or transfusion service shall have methods to limit bacterial contamination and to detect or inactivate bacteria in all platelet components. The addition of the words “or inactivate” to this standard would make it more effective and further its intent, to reduce the risk of bacteria in platelets, with possible resultant sepsis, and, potentially, death. Outcome: The program unit did not feel that expanding the requirement to include pathogen inactivation in platelets was appropriate at this time. The program unit is not aware of AABB-accredited facilities using this technology. The program unit anticipates that this standard will be revised when pathogen inactivation technology is cleared for use in the United States.
5.1.5.2 (5.1.5.1.1)	Public comment submitted, no change made	Comment: Would it be helpful here to list the AABB bulletin on this topic as a reference? Outcome: AABB Association Bulletins are not listed as references in the <i>Standards</i> .

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5.1.6.3.1	Public comment submitted, change made	<p>Comment: Please re-write the standard to reflect ISBT terminology: Additionally, the ABO/Rh, unit donation identification number, component name product code, and facility identification shall be in machine readable format.</p> <p>Outcome: The program unit agreed with this suggestion and made the change to this standard as well as to all other standards that contain similar language.</p>
5.1.6.3.1 #1	Public comments submitted, no change to proposed edition made	<p>Comment: During the comment period (June 22 – August 22) the program unit received many comments requesting that the deadline for the implementation of the ISBT 128 labeling standard be delayed. Due to the volume of comments received in response to this standard, a summary of the most common types of feedback received is presented below.</p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> ▪ We would like to request extending this deadline until sometime in 2009. ▪ We are concerned that major blood suppliers will not have fully implemented ISBT 128 by May 2008, and, therefore, will not be in compliance with the proposed standard. Our main blood supplier has repeatedly delayed implementation, most recently by a year. ▪ I realizing this has been an open item for more than a decade; however, I strongly recommend that the implementation date be moved to a later time -perhaps for the next publication of standards. Coming from a hospital that is dependent on the blood supplier, I feel that we are at a great disadvantage in trying to implement this standard in the time frame specified. <p>Outcome: The program unit decided against extending the deadline. A number of factors contributed to this decision; for more information, including guidance and information on how to request a variance, please visit www.aabb.org > Members Area > Labeling > ISBT 128.</p>
5.1.6.3.1 #1	Committee decision	<p>The program unit added a new footnote to standard 5.1.6.3.1 #1 as a result of the requirement to implement ISBT 128 by May 1, 2008. The footnote reads, “†Units collected and labeled before ISBT 128 implementation may be relabeled using Codabar.”</p> <p>The sentence was added for facilities that may receive units still labeled in Codabar. Receiving facilities can maintain legacy systems to control this possible dual inventory. This would also apply to rare frozen units that are currently in storage.</p> <p>Many facilities may need to implement short-term work-arounds during this dual-inventory phase, since Codabar labels do not accommodate all of the information that appears on an ISBT 128 label.</p>
5.1.6.3.1 #2 (deleted)	Committee decision	<p>This standard was obviated by the requirement to implement ISBT 128.</p>

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5.1.6.4	Public comment submitted, change made	Comment: Does the reference to standard 5.9.1 really belong here or in 5.1.6.3? Outcome: The program unit agreed with this comment and moved the reference as suggested.
5.1.7	Public comment submitted, no change made	Comment: Standard 4.3 includes “blood, components, tissue, derivatives and critical materials” so it is not clear why 5.1.6 in the proposed edition limits inspections of tissue and derivatives to the incoming inspection required by standard 4.3. Is the intent that tissues and derivatives are only inspected upon receipt? Suggest the following: “The blood bank...to ensure that blood, components, <u>tissue, derivatives</u> and services are inspected at facility defined stages to verify that specified requirements are met. For tissue and derivatives , Standard 4.3 applies. Outcome: The program unit elected not to make this change, as the “collection to transfusion” cycle for a unit of blood, as described in process control, does not apply to tissue and derivatives, because the accredited facility is not collecting or processing these products.
5.1.8	Committee decision	The clause “and reagents” was added for consistency with CLIA requirements. See also 5.1.8.1.3 below for more information.
5.1.8.1	Public comment submitted, no change made	Comment: The 5.1.8 series should contain a standard that requires that finished products be stored in a manner consistent with 21 CFR 610. Outcome: The program unit felt that the requirement from the FDA is adequately covered throughout the section and the <i>Standards</i> . No change was made.
5.1.8.1.2 (New)	Public comment submitted, change made	Comment: Does this standard need a pen symbol? Outcome: The program unit agreed that this standard should require a record retention requirement and made the addition.
5.1.8.1.3 (5.1.8.1.1)	Public comment submitted, no change made	Comment: The proposed language was changed to read, “For storage of reagents, temperature monitoring shall be consistent with manufacturer’s instructions.” The language should be changed to read, “Reagents storage should follow manufacturer’s instructions.” Instructions from reagent manufacturers may include prescribed storage temperatures, but they would likely not require monitoring of the storage temperature. Is it the intent of AABB to set a new standard that will require many institutions to buy monitoring devices for the reagent refrigerators? Outcome: The program unit agreed with this comment and ultimately concluded that the proposed addition was not necessary. The requirement to follow manufacturer’s instructions for the storage of materials is articulated in standard 5.1.4.
5.2.2.1	Public comment submitted, no change made	Comment: This statement, “donor shall be informed that the blood will be subjected to testing and that there will be notification of any positive infectious disease test results” is confusing since the standard below says that all donors will be notified. Is this discrepancy intended? Outcome: The program unit did not agree that the two standards are in conflict. Standard 5.2.2.1 requires that the donor be alerted to the possibility that performing infectious disease testing may not be possible for a number of reasons; however, if the donor indicates that their blood should not be used for transfusion, the donor’s blood should still be tested unless there is an unexpected event. The program unit believes these two standards work in concert.

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5.2.3	Public comment submitted, no change made	Comment: This regulation “21 CFR 630.6” requires notification for both screening and confirmatory testing. Should this detail be in the standard? Outcome: The program unit did not feel that adding the language of the CFR reference was necessary and that the reference itself was enough.
5.4.1.1 (5.5.3.4), 5.4.1.2 (5.4.3.1)	Public comment submitted, change made	Comment: I have a concern about tracking red cell volume lost for apheresis and whole blood donations. If an individual donates whole blood <i>and</i> by apheresis, the cumulative record of their annual red cell losses should include both types of donation. Additionally, the donor should be deferred if a subsequent whole blood donation would result in a red cell loss greater than the annual maximum permitted by FDA. The placement of this standard suggests that we only need to worry about apheresis donations. Outcome: The program unit agreed with the comment. A donor who is an apheresis donor <i>and</i> a whole blood donor would need to have their red cell losses tracked for a rolling 12 month period. On the other hand, if the donor is exclusively a whole blood donor, the red cell losses do not need to be tracked, as the overall red cell loss that is mathematically possible given the 56-day deferral period following a donation would not exceed annual limits established by FDA.
5.4.1.2 (5.4.3.1)	Public comment submitted, change made	Comment: Please move the standard out from under 5.4.3. Frequently, post-donation information is managed to protect the recipient, not the donor. Maybe pull out from under the parent standard. Outcome: The program unit agreed with this comment and moved standard 5.4.3.1 (as it appeared in the 24 th edition) to fall under standard 5.4.1, Allogeneic Donor Qualification.
5.4.4, 5.4.4.5	Public comment submitted, change made	Comment: Would some of these sub-standards for autologous donor qualification still apply even if you haven’t defined “alternate requirements”? The stem here implies that the only requirements are the ones in this section. Outcome: The program unit agreed and made a minor change to standard 5.4.4 as a result. The standard used to read, “If alternate requirements are defined, they shall include...” The standard now reads, “Autologous donor qualification requirements shall include...” In addition, the statement permitting the cross-over of autologous products for allogeneic use with medical director approval was deleted because an earlier standard allows the medical director to approve exceptions to policies, processes, and procedures on a case-by-case basis.
5.5.1	Public comment submitted, no change made	Comment: This could be a rather liberal standard if misused! Should it be qualified as to what kinds of things could be waived and that the standard is really about urgent patient need when no other suitable donor is available? Outcome: The program unit agreed with the spirit of the comment, but felt that no action needed to be taken with regard to the language in the standard. The program unit believes that the standard provides for the limited application of the medical director’s ability to make exceptions to allogeneic donor criteria.
5.5.3.2	Public comment submitted, change made	Comment: Please rewrite the standard as such: If a platelet, granulocyte, or leukocyte donor donates a unit of Whole Blood, at least 8 weeks shall elapse before a subsequent <i>automated cytapheresis</i> procedure, unless the extracorporeal red cell volume of the apheresis machine does not exceed 100 mL. Standards 5.5.3.1 and 5.5.3.4 apply. Outcome: The program unit agreed with this comment and made the change.

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5.6.2, 5.6.2.1 (New)	Public comments submitted, no change to proposed edition made	<p>During the comment period (June 22 – August 22) the program unit received many comments addressing the requirements in standard 5.6.2 and 5.6.2.1, which require the use of diversion pouches as a means to limit bacterial contamination in platelet components. Due to the volume of comments received in response to this standard, a summary of the most common types of feedback received is presented below. A sampling of the comments received are included below:</p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> ▪ The need to maintain sterility applies to all activities – not just collection. Think about open processing. You are limiting the standard by embedding it in collection. ▪ We are writing to express my concern with the fact that standard 5.6.2.1.1 was not strengthened to require more sensitive testing to detect bacterial contamination in Platelets. ▪ I believe we should encourage improvement in current culturing techniques. I would propose the following as 5.6.2.1.4: Effective September 1, 2008, testing to detect bacteria contamination shall be by a technique that has been approved by the FDA for this purpose or that has been validated to have equivalent sensitivity. ▪ As proposed, this standard does not strengthen the requirement for the detection of bacteria. When originally proposed, the Standards Committee found themselves in a predicament, as bacterial detection could practically be applied to apheresis platelets (with bacterial culture), but did not lend it self to whole blood derived platelets. As a result, more than 90% of apheresis platelets are tested with a culture based method, whereas Whole Blood-derived platelets are screened with a variety of less sensitive methods (mostly non-culture based.) ▪ We strongly recommend that standard 5.6.2.1.2 be modified so that a diversion pouch be used for all transfusable blood components derived from apheresis or whole blood collections and not limited to the collection of platelets only. ▪ There is one older apheresis device that does not have the diversion pouch on the correct dual arm line to capture a skin plug and this will not be modified because the technology is being phased out. If a collection facility has this technology it is not likely that they can quickly change technologies and have licensed products. ▪ Will all FDA approved whole blood bag container manufacturers have the capacity to provide the bags without supply chain issues? ▪ Are you aware if there are CPDA1 blood collection containers manufactured with diversion pouches? <p>Outcome: Standard 5.6.2.1 is new to the 25th edition of <i>Standards</i> and was introduced as proposed standard 5.6.2.1.2 in the proposed 25th edition. When the proposed 25th were sent out for comment current standards 5.1.5, 5.1.5.1 and 5.1.5.1.1, which address bacteria detection, were moved to fall under 5.6.2, which addresses collection. However, the program unit elected to separate general process control requirements for bacteria detection from the requirement for the use of diversion pouches to limit bacterial detection.</p> <p>The program unit elected to keep the language requiring the use of diversion pouches for all platelet collection. However, the program unit did not require the use of culture-based methods for apheresis platelets. The program unit believes there are operational and regulatory issues that need to be addressed before such a requirement can be implemented.</p>

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5.6.3.2	Public comment submitted, change made	Comment: Regulation 640.4(g)(3) requires the samples to be labeled with donor’s identification before collection and regulation 640.5 requires a specimen be taken at time of collection. This standard appears to be combining the two regulations and as a result may not accurately reflect the requirements for this. Outcome: Standard 5.6.3.2 was revised based on this comment. The phrase “at the time of collection” was replaced with language requiring that this labeling be completed before the donation begins.
5.6.4	Public comment submitted, change made	Comment: Please Replace the term “drawn” with the term “collected.” Outcome: The program unit agreed with this suggestion and made the suggested change.
5.6.5	Public comment submitted, change made	Comment: Please re-write the standard as such: If blood is to be transported from the collection site to the component processing laboratory, it shall be placed in a validated container having sufficient refrigeration capacity to cool the blood continuously toward a temperature range of 1 to 10 C until it arrives at the processing laboratory. Outcome: The program unit made a change to the standard in response to the comment. The commenter requested that the term “validated” be used in reference to shipping containers. The program unit used the word “qualified,” because in quality terminology, a process or procedure can be validated, but a piece of equipment can only be qualified for use in the process or procedure. All processes or procedures are required to be validated.
5.6.7.1 #3	Public comment submitted, no change made	Comment: To clarify – the FDA variance is only needed if the center does not want to label the units with the patient’s disease or if the donor will be collected more frequently than every 8 weeks without being examined by a physician. Please consider adding a new item: “4) In order to be approved for this exception, the donors must meet all allogeneic donor eligibility requirements.” Outcome: The program did not feel that it was necessary to add this requirement. This criterion is required by FDA and a reference is provided.
5.7.2.1.2	Public comment submitted, no change made	Comment: Would it be helpful to refer to the FDA guidance: Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices, 11/20/2000 (www.fda.gov/cber/memo.htm) – although there isn’t much detail about checking the weld. Outcome: The program unit did not feel that this addition was necessary.
5.7.4.2.1	Public comment submitted, no change made	Comment: Would it be helpful to refer to the FDA guidance: Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products, 7/22/1993 (www.fda.gov/cber/memo.htm). Outcome: The program unit did not feel that this reference was necessary.
DELETED (5.7.5.2.2 in 24 th edition)	Public comment submitted, change made	Comment: Does the term “closed system” mean there are other procedures for open systems? Is the standard saying that only RBCs prepared in a closed system may be frozen? Outcome: This standard was deleted from the 25 th edition based on comments received. The comment requested clarification as to the intent of the standard. The program unit believes this requirement no longer serves a specific purpose and elected to delete it.

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5.7.5.10	Public comment submitted, no change made	Comment: This product is also being prepared from apheresis collections. Suggest wording similar to 5.7.5.9. Outcome: The program unit elected not to make this change as this is not an FDA-licensed product.
5.7.5.11	Public comment submitted, change made	Comment: 640.34(c) requires Liquid Plasma to be stored at 1-6 C within 4 hours or the timeframe required for the anticoagulant or collection process. Outcome: The program unit agreed with the comment and made the adjustment in reference standard 5.1.8A.
5.7.5.14	Public comment submitted, change made	Comment: Please re-write the standard as such, “Cryoprecipitated AHF shall be prepared by a method known to separate the cold insoluble portion from 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 . In tests performed on 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.” Outcome: The program unit agreed with the suggested change and made the edit.
5.7.5.16	Public comment submitted, no change made	Comment: Please add, “and 640.25(b)(2)” to the reference for this standard. Outcome: The program unit agreed with this addition and made the change.
5.7.5.18	Public comment submitted, no change made	Comment: Although this standard addresses the residual leukocyte content of the product, with licensed systems for pooling and storing platelets would it now be appropriate to include a minimum platelet content similar to Platelets and Apheresis Platelets products? Outcome: The program unit did not make the suggested change at this time.
5.7.5.20	Public comment submitted, change made	Comment: Please add a reference to “640.25(b)(2)” as well. Outcome: The program unit agreed with this suggestion and added the reference.
5.8.1	Public comment submitted, no change made	Comment: Should this standard require that the anti-A and anti-B reagents be FDA-licensed? Outcome: The program unit did not feel that this topic needed to be addressed in this standard as it is already covered in standards 5.1.4 and 5.1.4.1.
5.8.2	Public comment submitted, no change made	Comment: Is AABB requiring that the anti-D reagent be FDA-licensed? Outcome: Please see the response to the comment in the row above.

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5.8.3.2	Public comment submitted, change made	<p>Comment: Please add a reference to: 606.151(d) – screening test must detect agglutinating, coating and hemolytic antibodies.</p> <p>Outcome: The program unit agreed with this suggestion and included this reference to the CFR.</p>
5.8.4.2	Public comment submitted, no change made	<p>Comment: The untested units must be appropriately labeled per 610.40(c)(1)(ii).</p> <p>Outcome: The program unit did not make a change to this standard as the comment’s intent is addressed in footnote #9 to reference standard 5.1.6A.</p>
5.8.4, 5.8.5.1, 5.8.6	Public comment submitted, change made	<p>During the comment period (June 22 – August 22) the program unit received many comments concerning the fact that the BB/TS SPU did not add a requirement for WNV testing to standard 5.8.4 and 5.8.6, but did in 5.8.5.1 (which covers autologous donors). Due to the volume of comments received in response to this standard, a summary of the most common types of feedback received is presented below.</p> <p>A sampling of the comments received are included below:</p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> ▪ Why is a test for West Nile Virus not required in this standard since FDA licensed donor screening test is available? ▪ Please add WNV NAT or WNV RNA to this standard. ▪ There is no mention of WNV testing here, but there is mention of WNV testing in section 5.8.5.1 for autologous donors. Should it be added here too for allogeneic donations? ▪ Please explain the rationale for inclusion of WNV in 5.8.5.1 and not in 5.8.4. ▪ WNV is included as required testing for autologous donations but is not included in 5.8.4. Tests Intended to Prevent Disease Transmission by Allogeneic Donations and 5.8.6 Quarantine and Disposition of Units from Prior Collections. ▪ Should West Nile Virus be included in this standard in accordance with FDA guidance for industry, <i>Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection</i>, dated June 2005? <p>Outcome:</p> <p>The program unit’s original logic in requiring WNV testing for autologous donor was that an autologous donor could have been treated for the disease following the donation, only to be exposed to it again once the unit was transfused. However, after reviewing the comments received and the data supporting these comments, the program unit elected to add the phrase “WNV RNA (seasonal criteria apply)” to standard 5.8.4 (allogeneic donor testing), and to standard 5.8.6 (quarantine of units from prior collections) The program unit used the phrase “seasonal criteria apply” to recognize that some facilities may not perform year-round testing and may instead choose to query donors about travel to areas where the WNV season lasts for the whole calendar year.</p> <p>In addition, FDA recommends that, in the case of a positive test, donations by that individual for the previous 6 months be quarantined and disposed of appropriately.</p>

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5.9.2	Public comment submitted, no change made	Comment: This standard does not specifically state when this inspection should be conducted. 640.5(e) states that whole blood must be visually inspected during storage and immediately before issue. (It is possible that this may be addressed in 5.10) Outcome: As noted in the comment, the program unit believes this requirement is covered in standard 5.10.
5.11	Committee decision	The BB/TS SPU decided to explicitly require the use of two independent identifiers at the time of sample identification. Standard 5.11 is considered a “parent” standard for the entire transfusion section. Accordingly, language requiring the use of two independent identifiers also appears in standards 5.11.1, 5.11.2, 5.18.1, 5.18.2, and 5.19.3 to ensure consistency.
5.11	Public comment submitted, no change made	Comment: The wording here is awkward. How can 2 different identifiers “correspond”? For example, a name can be compared to another name to see if they correspond as a way to confirm the name, but how can a name correspond to and confirm a patient number? These are different types of information. Outcome: The program unit reviewed the comment and agreed that the comment touches on a linguistically relevant problem. However, the program unit believes that the language is clear enough and that the intent will be understandable to the user. The standard was not changed.
5.11.1.1	Public comment submitted, change made	Comment: Per 42 CFR 493.1241(a), the lab must have a written or electronic request for patient testing from an authorized person. Standard 5.11.1 as written does not include “non-transfusion related immunohematology testing.” Recommendation: Please add “tests” to the battery so that standard reads as follows: 5.11.1 Requests: Requests for <u>tests</u> , blood, components... Outcome: The program unit agreed with the suggested change and added “tests” to the standard.
5.11.1.1	Public comment submitted, no change made	Comment: Should tissues be included in this standard? Outcome: The program unit elected not to add tissue to this standard. Orders for tissue are recorded in the patient’s chart, and orders are often mid-surgery. As a result, the committee elected to not make the change.
5.11.2.2	Committee decision	The program unit elected to add a new clause to standard 5.11.2.2 that requires a mechanism to identify the date of sample collection in addition to the individual who drew the blood from the patient. The standard now reads: “There shall be a mechanism to identify <u>date of sample collection</u> and the individual who drew the blood from the patient.”

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5.12	Public comment submitted, no change made	<p>Comment: AABB standards explicitly define which reagents must be used for ABO determination testing, but do not define the reagent(s) to be used for ABO confirmation testing. It is generally interpreted that 1) non-group O units must be tested with both anti-A and anti-B, 2) group O units may be tested with anti-A,B only and 3) ABO testing of plasma is not required. The component ABO label is printed with the A/B antigens that were detected by the ABO determination tests. It is important that ABO confirmation tests (not defined in the Standards) demonstrate that the antigen(s) not printed on the label are not serologically present on the component red cells. The following testing seems appropriate:</p> <ul style="list-style-type: none"> ○ Test Red Blood Cell components labeled group O with anti-A,B to confirm the absence of the A/B antigen(s). A negative test result is confirmatory. A positive test result demonstrates that the A/B antigen(s) are present and that the unit is unacceptable for transfusion. ○ Test Red Blood Cell components labeled group A with anti-B to confirm the absence of the B antigen. A negative test result is confirmatory. A positive test result demonstrates that the B antigen is present and that the unit is unacceptable for transfusion. ○ Test Red Blood Cell components labeled group B with anti-A to confirm the absence of the B antigen. A negative test result is confirmatory. A positive test result demonstrates that the A antigen is present and that the unit is unacceptable for transfusion. ○ Test Red Blood Cells components labeled Rh negative with anti-D to confirm the absence of the D antigen. A negative test result is confirmatory. A positive test result demonstrates that the D antigen is present and that the unit is unacceptable for transfusion. ○ ABO confirmatory testing of Red Blood Cell components labeled AB is not required. ○ Rh confirmatory testing of Red Blood Cell components labeled Rh positive is not required. <p>Red Blood Cell components (labeled A or B) when tested with a single reagent antiserum will be ABO compatible with transfusion recipients (when properly selected by the component ABO label) who are group A or group B even if the components are actually group O. The utility of serologic ABO confirmation of Red Blood Cell components labeled AB is questionable. If the unit is not AB, then it must be A, B or O all of which are ABO compatible when the unit is selected for an AB recipient. My comment is to add new standard “5.12.2 Serological confirmation of the ABO group of a Red Blood Cell component may be limited to demonstration of the absence of A or B antigens that are not printed on the component ABO label. It is not required to test for A/B antigens printed on the ABO label.”</p> <p>Outcome: The program unit did not elect to add this level of specificity to the <i>Standards</i>.</p>
5.12.1	Public comment submitted, no change made	<p>Comment: If the collection facility says that they have confirmed the labeling before shipping, is the transfusion service required to repeat the confirmation?</p> <p>Outcome: The program unit’s intent is that the ABO and Rh of each unit be confirmed by a serologic test from an integrally attached segment. This determination must be performed at least once; if the blood center performs it, the transfusion service does not need to repeat the confirmation.</p>
5.13.1	Public comment submitted, no change made	<p>Comment: Should guidance be provided if there is a historical group and type on the patient and if the component being issued is plasma?</p> <p>Outcome: The program unit noted the comment, but did not make a change at this time. Feedback from Accreditation suggests that assessors are using discretion in applying this standard to the situation described above.</p>

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5.13.3.2	Public comment submitted, no change made	Comment: Should consideration be given to adding medications known to contain red cell antibodies, e.g., IV IgG, RhIG as a reason to use a recent sample for testing for unexpected antibodies? Outcome: The program unit did not feel it was appropriate to make this a standard since the transfusing facility would not necessarily have a way to determine whether the patient received these medications recently.
5.13.3.3	Public comment submitted, no change made	Comment: This appears to be a duplicate of 5.13.3.1. How are these different? Outcome: The program unit reviewed this standard and felt that the requirements are different. Standard 5.13.3.1 focuses primarily on initial testing for clinically significant antibodies, while 5.13.3.3 focuses on repeat patients with previously identified antibodies.
5.13.4	Public comment submitted, no change made	Comment: The standard reads "Pretransfusion testing for autologous transfusion shall include ABO group and Rh type of donor blood and the patient sample." I am objecting to the "Rh type of donor" portion. Performance of ABO and Rh testing for autologous donors is performed by the collection site, as it is with allogeneic and directed units. We confirm all of our units at the time of receipt (which could be considered pretransfusion). We confirm ABO group. We confirm Rh only if the unit is labeled as Rh negative. Why should the requirements for autologous (i.e., Pretransfusion testing for autologous transfusion shall include ABO group and Rh type of donor) be different (more stringent) for autologous blood vs. allogeneic or directed. It seems like an unnecessary step. Outcome: The program unit agrees with this comment and believes that the concern was addressed in the proposed standards. Standard 5.12 addresses this issue by requiring serologic confirmation of Rh in units "labeled as Rh negative." Standard 5.12 applies to both allogeneic and autologous donors. Standard 5.13.4 refers to standard 5.12.
5.14.5	Committee decision	The program unit elected to change the final clause of this standard from "at the time of phlebotomy" to "at the time of donation." This change was made for clarity.
5.15.2.1	Public comment submitted, no change made	Comment: Would it be helpful to include the following guidance document? Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 1/11/02 (www.fda.gov/cber/blood/bldguid.htm) Outcome: The program unit appreciated the comment, however noted that the document is still in draft stage and did not feel it was appropriate to include this reference until the guidance is finalized.
5.15.2.3	Public comment submitted, no change made	Comment: This suggests that when using the computer it is not necessary to confirm the Rh of negative units, or at least that the confirmation is not required to be documented in the computer. Outcome: The program unit did not agree with the comment as stated and noted that standard 5.15.2.4 requires that a check be performed on all units to ensure that the data entry is captured and correct on all units before release.
5.16	Public comment submitted, no change made	Comment: We believe that the committee should consider if RBC units intended for infants, especially premature infants, should be screened for lead concentration. Toxic metals such as lead and mercury in blood have received little attention probably because the levels have been declining in recent years. However, occasional outliers in blood lead concentrations may be found and could result in unacceptably high post transfusion blood lead concentrations in some infants. For more information, see: Bulleova S, et al. Lead levels in Blood Bank Blood. Arch Environ Health. 2001;56:312-13 Bearer CF O'Riordan MA, Powers R. Lead Exposure from blood transfusion to premature infants.J.Pediatr 2000 Oct;137(4) :549-54

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5.18.4.5.1 (New)	Public comment submitted, change made	<p>Outcome: The program unit reviewed this comment and believes that this is a clinical issue that should be addressed individually by each facility.</p> <p>During the comment period (June 22 – August 22) the program unit received many comments requesting that standard 5.18.4.5.1 (5.18.4.6 as it appeared in the proposed edition) to require that the medical director and the recipient’s physician be notified of any abnormal test results for units released under “urgent requirement.” Due to the volume of comments received in response to this standard, a summary of the most common types of feedback received is presented below.</p> <p><u>Comments:</u></p> <ul style="list-style-type: none"> ▪ This is very vague and does not specify what tests are encompassed. It is really not feasible to notify both the transfusion service medical director and patient physician. There is also a big difference between abnormal tests and those that are a “critical” value. The wording for recipient physician should be changed to the attending physician, as in the case in the emergency department, surgeons, or out of town physicians. ▪ "Abnormal tests" is vague, and although it is under Standard 5.18.4, it might not always be interpreted to be related to compatibility or infectious disease testing only for the units issued urgently. Also transfusion service medical director may not always be available. ▪ The language in the proposed standard should be changed. The term “abnormal tests” does not clearly express the positive results of an antibody test. Suggest that the language clearly describe the expression of antibody formation. ▪ This new Standard is extremely vague. Please define the intent of the notification and provide examples of the types of abnormal test results that were intended to be addressed. ▪ The standard is potentially too limited. Some non-test results situations are critical and deserve immediate notification of physicians. These include issues such as blood shortages or other deviations such as when the incorrect unit was dispensed to a patient. ▪ I am concerned that the proposed standard is overly broad in requiring immediate notification for abnormal test results. Would an antibody we can honor (such as anti-D) be an abnormal result? What about a patient in the trauma OR, getting "trauma blood", now found to have a cold antibody that pre-warms away? Would we be required to interrupt the surgery to let him know that there is an antibody of no clinical significance? I would suggest changing the wording to something with a little flexibility <p>Outcome: This standard was added as a means of introducing the concept of critical values in transfusion medicine. The proposed version of this standard has been changed based on these comments. The standard now requires notification of “abnormal results <u>that may affect patient safety.</u>” The issue of additional critical values that might need to be addressed in <i>Standards</i> will be discussed during the cycle for the 26th edition.</p>
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5.19	Committee decision, Internal AABB decision	<p>A comment was submitted to the committee from a facility that was cited during an assessment for having a transfusion protocol that differed slightly from the Circular of Information (COI). This prompted program unit discussion on whether the intent of this language was to elevate the COI to the level of a standard against which AABB assessors would cite facilities.</p> <p>The program unit noted that there are occasionally conflicts between the <i>Standards</i> and the COI. In addition, because the program unit does not specifically review the COI, there was concern about the possibility that this standard might create de facto requirements that were not anticipated or intended by the program unit.</p> <p>Internal AABB technical, legal, and regulatory (TLR) reviewers felt that the statement should remain in the <i>BB/TS Standards</i> because it is product labeling or a package insert. TLR reviewers also noted that the <i>BB/TS Standards</i> require that facilities follow a number of other requirements – such as manufacturer’s instructions – that are not reviewed by the program unit.</p> <p>As a compromise that will allow for further discussion on the topic, staff recommended that the statement remain in the <i>Standards</i> at this time. However, this question will be re-evaluated, and guidance will be provided.</p>
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5.19.1.1	Public comment submitted, no change made	<p>Comment: This is a request for an update regarding standard 5.19.1.1, Recipient Consent, so that it is more complete and in parallel with 5.2.2, Donor Consent.</p> <p>Consent includes a description in understandable terms of the process/procedure. So I propose to you that 5.19.1.1 should be updated as shown below in italics. The requirements for donor and recipient consent should also be parallel in wording and format.</p> <p>5.19.1.1 <i>The consent of all recipients shall be obtained before transfusion. At a minimum consent shall include all of the following:</i></p> <p><i>1) Elements of the transfusion process and procedure shall be explained to the prospective recipient in understandable terms</i></p> <p><i>2) The explanation shall include a description in understandable terms the risks, benefits, and treatment alternatives.</i></p> <p><i>3) The recipient shall have an opportunity to ask questions and have them answered.</i></p> <p><i>4) The recipient shall have the opportunity to give or refuse consent for transfusion. In the case of a minor or a legally incompetent adult, consent shall be addressed in accordance with applicable law.</i></p> <p>5.2.2 Donor Consent</p> <p>The consent of all donors shall be obtained before donation. <i>At a minimum consent shall include all of the following:</i></p> <p><i>1) Elements of the donation process and procedure shall be explained to the prospective donor in understandable terms.</i></p> <p><i>2) The explanation shall include in understandable terms information about risks of the procedure and tests performed to reduce the risks of transmission of infectious diseases to the allogeneic recipient.</i></p> <p><i>3) The donor shall have an opportunity to ask questions and have them answered.</i></p> <p><i>4) The donor shall have the opportunity to give or refuse consent for donation. In the case of a minor or a legally incompetent adult, consent shall be addressed in accordance with applicable law.</i></p> <p>Outcome: The program unit reviewed the request and elected not to make the suggested changes. The program unit did not feel that the requirements for donor and recipient consent should be identical. In addition, the consent process for transfusion recipients is often beyond the direct control of the blood bank or transfusion service.</p>
5.19.8	Committee decision	<p>The program unit decided to add the clause “written” to this standard. Previously it was not stated that instructions had to be in writing. This change was made for clarity. The standard now reads, “Specific <u>written</u> instructions concerning possible adverse events shall be provided to the patient or a responsible caregiver when direct medical observation or monitoring of the patient will not be available after transfusion.”</p>

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Reference Standard 5.1.6A, #14	Public comment submitted, no change made	<p>Comment: The phrase “paid donor” is a required labeling element at the time of collection or preparation. This is more restrictive than FDA and appears different from #13. Reason?</p> <p>Outcome: The program unit chose to leave this field as R (required) as the time of collection is the time when a collection facility would be most likely to know that the donor is a paid donor. Therefore, the program unit believes this information should be on the container at the time of collection rather than being affixed at a later time.</p>
Reference Standard 5.1.6A, footnote #5	Public comment submitted, no change made	<p>Comment: * The processing regs (21 CFR 640.5) do not specifically require that donors (either auto or allogeneic) be screened for antibodies. * However, 21 CFR 606.151(d) states that if an antibody screen was not performed on a unit, the transfusion service must perform a minor side crossmatch. Since minor side crossmatches are no longer performed, by default, an antibody screen is then required on all donations. There is no exemption for autologous donors. * The labeling regs (21 CFR 606.121(e)(1)(iii) and (e)(2)(ii)) require units to be labeled with the identity of the antibody if one was detected during the antibody screen. (21 CFR 606.121(j) states that this information may be included on a tie-tag.) * The autologous unit labeling regs (21 CFR 606.151(i)(5))states that the information about the antibody identity must be on autologous units if they are crossed over into allogeneic inventory. These regs do not specifically exempt auto units from any of the antibody screening requirements. There appears to be an exemption for labeling the auto units with the results of the positive antibody screen (unless the units will be crossed over). It is not clear to me that the regs exempt antibody screens on auto units. 21 CFR 610.40(d) does exempt auto units from some infectious disease testing if the units will only be used for auto transfusions. The bottom line to all the regs above is that if the auto unit will be crossed over into allogeneic inventory, the unit must undergo the full processing procedures and the antibody specificity must be on the label. Outcome: The program unit noted that footnote #5 states that the specificity of antibodies is not required for autologous units that are not crossed over.</p>
Reference Standard 5.1.6A, footnote #7	Public comment submitted, change made	<p>Comment: Concerning autologous units, Biohazard labels or symbol is required for all units with the results listed below. 610.40(h)(2)(ii)(B)</p> <p>HCV NAT Positive or Reactive HIV-1 NAT Positive or Reactive HBV NAT Positive or Reactive</p> <p>Outcome: After reviewing these comments, the phrase “Positive or...” was added to the requirements for HCV NAT, HIV-1 NAT, and HBV NAT. Also, HBV NAT was moved the list of required tests to under the “<i>When Performed</i>” heading. The placement of HBV NAT in the general test area pre-dated the creation of the “<i>When Performed</i>” heading, and the program unit inadvertently overlooked the fact that HBV NAT is not a required test. Also placed under the “<i>When performed</i>” heading was “Antibody screening for Chagas Disease.”</p>
Reference Standard 5.1.8A	Public comment submitted, no change made	<p>Comment The terminology in this standard is too complicated for non-blood banking professionals, please simplify it. Outcome: The program unit noted that the <i>Standards</i> is intended to be used by blood banking professionals and did not change the table.</p>

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Reference Standard 5.1.8A, #1	Public comment submitted, no change made	Comment: Suggest rewording: "If intended for room temperature components, place WB at 1 - 6C (or say 'in the refrigerator') within 8 hours." Outcome: The program unit did not make the suggested change as the change in wording would be primarily stylistic in nature.
Reference Standard 5.1.8A, #24	Public comment submitted, no change made	Comment: Note that FDA has only approved Cryo to be prepared in a closed system (640.50(a)). Also note that cryo can only be made from whole blood collections. Outcome: The program unit elected not to make the suggested change as it was deemed beyond the purview of the reference standard.
Reference Standard 5.1.8A, #26	Public comment submitted, change made	Comment: Please re-word this to indicate that storage for more than 12 months requires FDA approval – storing FFP at -65C does not require FDA approval. Outcome: The program unit changed the language to reflect the comment above.
Reference Standard 5.1.8A, #29	Public comment submitted, change made	Comment: We are looking for consistency in terminology. Should this product be called FP24 or PF24? Outcome: The correct abbreviation is FP24. The entry for this product was adjusted accordingly.
Reference Standard 5.1.8A, #30	Public comment submitted, change made	Comment: Please note that “Thawed Plasma” is not FDA approved and that the 5 day expiration only applies to products collected in closed systems. Products collected and prepared in open systems must be transfused within 6 hours (24 hours with FDA approval). Outcome: The program unit noted the comment and added in an expiration time for Thawed Plasma as, “Closed System: 5 days.”
Reference Standard 5.1.8A, #32	Public comment submitted, change made	Comment: It would be helpful to list the additional criteria for Thawed Plasma in 5.1.8A. This would be helpful for hospitals thinking about switching to 5 day plasma so they can be sure that they don't re-label apheresis plasma collected in an open system as 5 day thawed plasma. Outcome: The program unit believes that the best way to address this issue is through guidance.
Reference Standard 5.1.8A, #27, 30	Public comment submitted, no change made	Comment: Please comment on the fact that some items do not appear to be in compliance with FDA. During the 2006 AABB Annual Meeting <i>Ask the FDA</i> session there were specific directions provided by FDA staff on the use of FFP and thawed plasma. The revised Standards do not support the FDA's position on the use and labeling of these products. Specifically, 1) FDA has a 6 hour expiration requirement for FFP that has been thawed and a 24 hour expiration only if the facility has an approved, alternative procedure, 2) The FDA clearly stated that they have not reviewed a product called Thawed Plasma and there have been no data to support the efficacy for its intended use. Therefore, at this time, it is not a licensable product. See also AABB Regulatory Update from December 2006. Outcome: The program unit noted that these are not licensable products but did not feel that removing them from the Reference Standard would be appropriate.

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Reference Standard 5.1.8A, #33	Public comment submitted, change made	Comment: Would the “5 days after expiration of RBCs” apply to RBCs with additive solutions? Outcome: The program unit reviewed this comment and changed the term “RBCs” in the expiration column to “Whole Blood.”
Reference Standard 5.1.8A, footnote #3	Public comment submitted, change made	Comment: Please re-write footnote 3 as “Storage beyond 5 days requires use of FDA-cleared bags and participation in a monitoring program defined by the FDA.” Outcome: The program unit agreed with the comment and made the suggested change to footnote #3.
Reference Standard 5.4.1A, General	Public comment submitted, change made	Comment: The <i>Standards</i> used the term “indefinite” in relation to deferral. FDA uses the term “indefinite” only when there is a possibility of re-entry. If there is no possibility of re-entry, the deferral would be “permanent.” The DHQ flow chart uses similar language. Outcome: The program unit reviewed the use of these terms throughout this reference standard and has made a number of changes, as suggested by the comment.
Reference Standard 5.4.1A, #8	Committee decision	The BB/TS SPU elected to add Warfarin to reference standard 5.4.1A based on a recommendation from the DHQ Task Force. The deferral is for 7 days following use.
Reference Standard 5.4.1A, #9	Public comment submitted, change made	Comment: Concerning the venipuncture requirement, please add the following, “640.3(b)(6) – venipuncture site must be free from infectious skin disease and any disease that might create a risk of contaminating the blood.” Outcome: The program unit agreed with this suggested change and added the suggested language, but not the reference to the CFR.
Reference Standard 5.4.1A, #12	Committee decision	The program unit added new language to #12 addressing the “receipt of recombinant vaccines.” The program unit previously believed that this deferral could be handled as a deferral for unlicensed vaccines.
Reference Standard 5.4.1A, #13	Public comment submitted, no change made	Comment: I read this entry concerning gonorrhea and syphilis as saying that you are deferred for 12 months from diagnosis, even if you were treated only 3 weeks ago. Is that the intent? Outcome: Due to the many subtleties of a deferral for these diseases, the program unit determined it was best to incorporate FDA criteria by defining the deferral period as “12 months (in accordance with the FDA).”
Reference Standard 5.4.1A, #13	Committee decision	The requirement for a deferral of individuals who “[d]onated the only unit of blood or component that resulted in the apparent transmission of hepatitis, HIV, HTLV,” was removed from the <i>Standards</i> .

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Reference Standard 5.4.1A, footnote #8	Public comment submitted, change made	Comment: The Transfusion Transmitted Disease Committee recommends deleting the footnote addressing a 24-month deferral recommended by the Department of Defense for individuals. Outcome: Footnote #8 was deleted from reference standard #8 based on a recommendation from TTD as well as feedback from the membership. The program unit reasoned that there are a number of other areas that might require a 24-month deferral or longer. Per data from TTD, almost all cases of transfusion-transmitted malaria would not have been prevented by a 24- or 36-month deferral. The program unit was informed of the fact that CDC is currently working on a new tool to bring accurate information about regional malaria risks to the public, which can provide more current information about regional risks.
6.0	Public comment submitted, no change made	Comment: Should this have a pen for the documentation of the review and approval of documents? Outcome: No change. This standard is very general and any record retention that would concern what is written in this standard is covered throughout the rest of the Chapter.
6.2.4 (New), 6.2.4.1 (6.2.4)	Committee decision	Standard 6.2.4 is new to the 25 th edition of <i>Standards</i> and was added from language crafted by the Quality Management Standards Subcommittee. Standard 6.2.4.1 previously appeared as standard 6.2.4. While 6.2.4.1 addresses the recording of test results and is consistent with CLIA, the program unit felt that there should also be a general standard requiring that all records be created concurrently with the performance of the critical activity with which they are associated. Standard 6.2.4 reads, “Records shall be created concurrently with performance of each critical activity.”
Reference standards 6.2A – 6.2D	Public comment submitted, no change made	Comment: Please define the term “indefinite” in the context of record retention. Does “indefinite” not imply that each facility can define a retention time? I think the intended meaning of “indefinite” here is really the life span of the individual, or until something happens to change the rules. Outcome: The program unit reviewed the comment, and did not feel that it was necessary to define “indefinite” in the context of record retention. This term has been used for a number of years.
Reference Standards 6.2A, and 6.2B	Committee Decision	Several retention times in Reference Standards 6.2A and 6.2B have been changed from 5 to 10 years as a result of the FDA finalizing the guidance on HCV lookback.
Reference standard 6.2A, # 8	Public comment submitted, no change made	Comment: What does it mean for a donor to be “on surveillance”? Also, standard 5.2.3 is about donor notification – why would I want to keep copies of my notification records indefinitely. I think what you really mean is that we keep a record of the deferral itself rather than the notification of the donor. Outcome: The program unit retained the term “surveillance” as it is commonly used in situations where infectious disease transmission by a unit of blood has not been ruled out. The intent of the record retention is that the facility have a mean to identify donors who should not be allowed to donate.
Reference standard 6.2A, #28, 6.2B, #15	Public comment submitted, no change made	Comment: I see a conflict between two of the reference standards in the 24th ed.....6.2A (#29) and 6.2B (#14).....they require different retention times for signed statements from the physician in urgent transfusions. Is this being changed in the 25th edition, have I missed some an errata letter, or am I misinterpreting something? Outcome: This difference is intentional. The requirements in 6.2A concerns donor records and 6.2B focuses on patient records.

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Reference standard 6.2C	Public comment submitted, no change made	<p>Comment: I do not believe it is necessary to retain quality assurance records for longer than 3 years. Could this be changed?</p> <p>Outcome: No change made. The program unit believes it is appropriate to retain quality assurance records for 5 years.</p>
Reference Standard 6.2C, #s 15 and 16	Committee decision	<p>After reviewing reference standard 6.2C, the program unit deemed that the previous record retention time of “Lifetime of system or 2 years” for entries 15 and 16 was ambiguous.</p> <p>The language implied that system records could be discarded while the system was still in use. The program unit clarified this requirement with the following wording for the retention period: “2 years after retirement of the system.”</p>
Reference Standard 6.2C, #s 15 and 16	Public comment submitted, no change made	<p>Comment: Let’s say I have a system that’s been in use for 10 years. Why would I want to go back to a 10-year-old validation document? If something goes wrong today, I don’t think a validation performed 10 years ago is the root cause.</p> <p>Outcome: The program unit believes that in some cases, an error can occur as a result of a problem with the original validation of a system.</p>
7.1.4	Public comment submitted, no change made	<p>Comment: What kinds of problems or deviations would render a tissue "nonconforming"? This standard should be rewritten to specifically address problems with distributed tissues. The <i>Standards</i> should also include more clear requirements for communicating tissue problems to the tissue establishment. Specifically, there should be more detailed standards for notifying the tissue establishment about adverse reactions involving communicable diseases related to transplanted tissues. Similarly, there should be more detailed standards for notifying the tissue establishment when tissues are received, stored, handled, or administered that pose a risk (e.g. containers did not maintain integrity, transport solutions leaking, accompanying records missing or incomplete, tissue dropped on the floor, etc.)</p> <p>Outcome: The program unit reviewed this comment and felt that comment was too prescriptive. The program unit also felt that this request is partially covered in standard 7.1.3. However, the substance of this comment is valuable from a guidance perspective.</p>
7.2	Committee decision	<p>The committee chose to remove the clause, “or receipt of tissue” from standard 7.2 in the 25th edition of <i>BB/TS Standards</i>. This change was made in accordance with feedback from the FDA.</p>
7.3	Public comment submitted, change made	<p>Comment: Should the term “captured” be replaced with “documented” or “recorded”? Should a pen symbol be included for recording of adverse events as in standard. 7.4, and should 606.170(a) be referenced?</p> <p>Outcome: The program unit agreed with the bulk of this comment and added a pen symbol to standard 7.3. However, the program unit elected not to reference the CFR. The term “captured” was also removed from standard 7.3 as the addition of the pen symbol made the term redundant.</p>
7.4	Public comment submitted, no change made	<p>Comment: Should 606.170(a) be referenced?</p> <p>Outcome: The program unit did not make this change because the reference does not contain more detail than the standard.</p>
7.4.1.2 #2 (7.4.1.1 #1, 7.4.1.2 #2)	Committee decision	<p>The language that previously appeared as the second sentence in #1 of 7.4.1.1 in the 24th edition has been moved to appear as the second sentence of standard 7.4.1.2 #2. This change was made for clarity and to reflect operational flow.</p>

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7.4.5.1, 7.4.5.1.1 (deleted)	Committee decision	Standard 7.4.5.1.1 was deleted from the 25 th edition as it was deemed redundant per standard 7.4.5.1. The elements of former standard 7.4.5.1.1 were incorporated into standard 7.4.5.1.
List of Blood Component Descriptions	Committee decision	This list has been updated for consistency with ISBT 128 nomenclature.