Significant Changes and Response to Comments Received to the 32nd edition of Standards for Blood Banks and Transfusion Services

The following table summarizes many of the significant changes made to the 32nd 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 32nd edition of *Standards* in conjunction with this table; therefore, the numbering follows that of the 32nd edition and, where appropriate, the corresponding standard number in the 31st 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 32nd 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.

Standard	Significant Change (SC) or Response to Comment (RC)	Comment	Change made?	Outcome
General	RC	It is recommended that AABB not update the standards quite so often. The frequency of the updates is the impetus to the committee to make changes for the sake of changes. It makes it very difficult for organizations to keep up with the changes. Auditors are unclear how to react to the ever-changing requirements when performing an assessment. In the note to readers it says: Requirements, once stated, are not repeated. For example, standard 5.0 requires that all processes and procedures be validated. Therefore, it is not necessary to require in other areas that a specific process or procedure be validated, Yet throughout the standards, more and more cross references are being added. They are a distraction. If you have to crosswalk, maybe the standards are in the wrong place to begin with.	NO	The committee noted this comment but does not feel that this change to the production cycle would be appropriate. The committee points out that for CLIA purposes the standards need to be updated to maintain deemed status every two years. With regard to the cross references, the committee feels that they are helpful to the users, especially in the Standards Portal where they are live linked.
1.1, 1.1.1, 1.3, 1.3.1, 1.3.2	RC	My comment relating to the above listed Standards are focused on the system-wide management structures of today's organizations. The days of single-site entities are gone. Our blood centers and hospitals are merging into larger systems in effort to streamline and operate more efficiently. The Standards for "management oversight" of these systems needs to recognize and accommodate approval authority for a multi-site organization utilizing standardized procedures to a central (or single signatory) entity. I humbly challenge the 32nd edition Standards Committee to modernize the management oversight section to accommodate this approval authority.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the requirement that a laboratory director can only oversee a maximum of 5 laboratories comes from CLIA, of which the BB/TS Standards attempt to remain consistent.
1.1.1	SC	NA	NA	The committee elected to add the clause, "… and relevant continuing education in activities required by these *BB/TS Standards* for which the facility is accredited…" for consistency and

				clarity. This concept appears in other sets of Standards and provides a clear requirement for what qualifies a medical director to serve in this role.
1.1.1	RC	What are the relevant continuing education activities being referenced by this standard change?	NO	The committee reviewed this comment and did not feel that a change was needed. Relevant continuing education is based on the functions of each job as determined by your facility's requirements.
1.1.1	RC/SC	The clause, "activities required by these BB/TS Standards" can be interpreted to mean they need con ed in everything from blood collection technique to facilities management. Also, if you are going to require con ed, you have to say how much.	YES	The committee agreed with the concept contained in the comment and added the clause "…for which the facility is accredited…" to clarify the intent of the standard.
1.1.1	RC	Since many Blood Banks are now involved in the storage and management of Human Tissue I think the Medical Directors of such Blood Banks need to be educated and trained in the field of Tissue Medicine. Storage, handling and adverse effects of Human Tissue might be like that of Blood and Blood Components, but there are differences. It is also a relatively new field and since many physicians and medical technologists are clueless with regards to Tissue Management and Medicine I think that it should be specified that training, experience and possibly continuing education should be required prior to undertaking this responsibility. How many Blood Bank directors (usually a Pathologist) received training/education with regards to identifying the symptoms of an adverse reaction to Tissue Implantation, how to investigate and how to respond? This is usually the area of expertise of a Tissue Implant Surgeon. In short, I think that Medical Directors responsible for tissue management need to have training and education in this area as a requirement prior to accepting responsibility. Anything less would be a disservice to the patient and facility for which they work. The standards should make this point very clear.	YES	The committee agreed with the concept contained in the comment and added the clause "…for which the facility is accredited…" to clarify the intent of the standard.
1.1.1	RC	In the proposed changes to standard 1.1.1, I have some concerns regarding the addition of continuing education. If this would be added, will there be some guidance as to how many hours/timeframe they should obtain? What kind of documentation are you looking for? Although I think it is a great idea, I don't think the standard is specific enough.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The amount of hours of continuing education should be defined by the facility and would be

				maintained in each employee's personnel records.
1.3.1	RC	This requirement is confusing: how do you approve a process? What is within their definition of process? For example: Does MD have to approve executed validation packages, or just the validation protocol before it is used? Also, the reference to CLIA here is confusing. CLIA only allows the individual listed on the CLIA license to approve laboratory testing procedures, (this cannot be delegated); however, Std 1.1.1 above indicates the medical director can delegate their responsibilities to another physician…which responsibilities can they delegate? They cannot delegate approval of laboratory testing procedures, but can they delegate approval donor collection and non-testing related procedures?	YES	The committee agreed with this comment and added additional CFR references to CLIA requirements for clarity.
1.4 (New)	SC	NA	NA	The committee added new standard 1.4 focusing on operational continuity to remain consistent with other sets of AABB Standards. This requirement will exist in all sets of AABB Standards going forward. The committee has crafted guidance on the standard's implementation and expectations.
1.4 (New)	RC	We do not support the addition of Standard 1.4. Standard 1.4.1 of the BB/TS 32nd edition (previously Standard 1.4 of the BB/TS 31st edition) states "The BB/TS shall have emergency operation policies, processes, and procedures to respond to the effects of internal and external disasters." Emergency operation policies, processes, and procedures ensures operational continuity. The requirement is redundant.	NO	The committee reviewed this comment but did not feel that removing the standard would be appropriate. The committee notes that operational continuity does not imply only emergencies, but things that are more routine that would not rise to that level. The committee has crafted guidance to assist users in the standard's implementation and expectations.
1.4.1 (New)	SC	NA	NA	The committee created new standard 1.4.1 in conjunction with the creation of standard 1.4. The committee feels that having a policy in place to address product inventory shortages from the overuse of components (such as group O red cells) is key to operational continuity.
1.4.1 (New)	RC	This is about blood management practice, not emergency response and recovery, which is what the section 1 is supposed to address. This is the wrong placement and does not convey the intent that is described in	YES	The committee agreed with the intent of this comment and moved this standard where it appeared in the proposed edition (as a stand-

		AABB's rationale. No one will know that's what you meant after this is published.		alone standard) to appear under standard 1.4, operational continuity, for clarity.
1.4.1 (New)	RC	We request that the AABB Standards Committee evaluate the efficacy of implementing standard 1.4.2. The proposed standard lacks an underlying regulatory or accrediting requirement. While we recognize the role of inventory management in maintaining and adequate blood supply; ultimately decisions regarding product inventory are proprietary in nature and should not be subject to accreditation standards.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the standard does not require facilities to share their product list with anyone, but merely to have a policy to address what each facility does when its product levels do get low.
1.4.1 (New)	RC	A new standard is needed to require advanced preparation to address possible blood shortages. It would require transfusion services to determine in advance the management of a sudden shortage in inventory and how to address urgent patient needs. Perhaps Standard 1.4 on Emergency Preparedness would be the appropriate location for this new requirement and perhaps it should also include donor centers to ensure that they have also prepared for such events.	YES	The committee agreed with this comment and used it as the basis for the creation of this new standard. Guidance will also expand on its implementation.
1.5.1	RC/SC	The phrase about communication plan was added either because it wasn't always being tested and systems become obsolete quickly without exercising them. If no longer a concern, I am OK with deleting.	YES	The committee reviewed this comment and agreed with it. In the proposed edition the phrase, "…including emergency communication systems…" was removed as the committee felt it was redundant to the rest of the standard. However, based on this feedback and comments from assessors, the committee elected to reinsert the clause for clarity.
2.1.3	RC	CLIA laboratory testing requirements are referenced here and the requirements are specific to laboratory testing, including technical supervisor oversight and 6 competencies which are not all directly applicable to collections or manufacturing. AABB should be more clear of the intent of the CLIA reference and indicate if there are different allowances for competency assessment of non-laboratory testing staff training.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the standard as written is clear.
Chapter 3 – Equipment	RC	Blood bags used for blood and blood component transfusion must be stored in accordance with regulation. Integrity of Identification tags must be kept. If a blood or blood component bag is not consumed, integrity of blood bags and identification tags must be maintained properly. The product bags must be stored in proper temperature. If the products are red-cell blood	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that blood bags are not considered equipment, but actually materials. The committee suggest users follow the

		components, blood sample tube must be kept sealed. The products can be returned to the dispatched department following relevant regulation. Perform return operation in suitable blood management systems.		manufacturer's instructions for their use and maintenance.
3.5.2, #4	SC	NA	NA	The committee elected to add the clause, "… a determination if other equipment is similarly impacted…" to expand the scope of investigations performed by facilities in response to equipment failure.
3.5.2, #4	RC	We do not support the Proposed Standard 3.5.2 4) without the addition of "as appropriate." The investigation may determine the equipment malfunction, failure, or adverse event to be isolated to the equipment being investigated and would not require additional investigation of similar equipment.	YES	The committee agreed with the intent of the comment, that the standard could be made clearer. The committee added the clause, "…a determination.." to clarify that if the issue is an isolated incident as not all similar pieces of equipment need to be shut down as a result of the investigation.
3.5.2, #4	RC	Please clarify the scope of this proposed change. As an organization with over 100 of the same devices in use we would like to clarify the scope of the investigation and associated documentation required to comply with this proposed standard. For example: When there is an equipment malfunction is it expected that all similar models be taken out of service until the investigation concludes that the malfunction is isolated to a single device? Or, is it acceptable, that similar devices remain in-service while the investigation is in-progress?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that an investigation can take place while similar devices are in service, however a check is needed to determine the nature of the malfunction.
3.6.2	SC	NA	NA	The committee added a cross reference to standard 5.1.8.1.3 which requires that temperature recording of stored blood occur every four hours.
3.6.2	RC	Storage temperature shall be monitored in real time with an automatic device or system. Temperature data shall be stored to meet the relevant retention requirement. Additionally, the stored temperature can be accessed anytime.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The standard as written is clear on its intent and requirements.
3.9.6 (New)	SC	NA	NA	The committee created new standard 3.9.6 to ensure that facilities have processes in place that specifically address cybersecurity.

3.9.6 (New)	RC	Please provide examples of what might be expected to satisfy this Standard. Cybersecurity is well outside the scope of the blood bank, especially in a large organization. All we can really provide is a written statement saying we will follow our facility's (DoD / DHA) process.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee understands that smaller departments in small organizations will not have a dedicated cybersecurity unit and that they will adopt those of a larger parent organization, which does meet the intent of the standard.
4.3.2.1	RC/SC	In reference to 5.7.4.16 and 5.7.4.26, which require following manufacturers' instructions for producing PR products- I noticed that standard 5.1.4 "use of materials" references 4.3.2.1, which requires using FDA cleared materials. I would suggest that you add "processing" before "preservation" to 4.3.2.1, so that processes like PR are required to use FDA cleared materials.	YES	The committee agreed with the comment and elected to add the term "processing" to standard 4.3.2.1 for consistency with standard 5.7.4.16 and 5.7.4.26.
5.1.2	SC	NA	NA	The committee elected to edit standard for clarity. The committee moved the final clause in the standard, "…when expected results are not achieved." To the beginning of the sentence to ensure that the standard followed proper workflow.
5.1.5.1	SC	NA	NA	The committee added the terms "processing and sampling" to standard 5.1.5.1 and removed the clause "and point of release if applicable." These changes were made for clarity.
5.1.5.1	RC	Would general cleaning of surfaces suffice?	NO	The committee reviewed this comment but did not feel that a change was needed. The standard itself is focused on all steps from the collection of the unit until transfusion. The purpose is to ensure that bacteria are not transmitted to the recipient.
5.1.6	RC	What I wanted to mention has to do with the storage vs. transport issue. I haven't looked at it recently, but I have always felt that this dichotomy is meaningless without either a time limit or a requirement for continuous monitoring (eg-temperature decals). However, I imagine that would be very difficult to implement.	NO	The committee noted this comment but did not feel that a change was appropriate at this time. The committee will continue to provide guidance on this matter.

5.1.6	RC	Please finally define "storage" and "transport" in terms of blood product coolers. Within the transfusion service community, there is much debate around standard 5.1.8.2.1, where is seems like coolers are considered a "transport" device and should be verified to hold a 1-10C temperature. This directly conflicts with the statement on page 470 of the 19th AABB Technical Manual under the heading "Special Considerations" that states that holding blood in a location outside the blood bank is considered "storage", which would require a 1-6C temperature range. Facilities validate their cooler for different time frames based on this. If a cooler is "storage", then a temperature must also be taken and documented at 4 hours, unless it is continually monitored.		The committee noted this comment but did not feel that a change was appropriate at this time. The committee will continue to provide guidance on this matter.
5.1.6.3	RC/SC	It is recommended to state that all of Standard 5.9 applies, not just 5.9.1 (as other items also apply).	YES	The committee agreed with this comment and made the change to ensure that all of standard 5.9 (and its substandards) applied in this case.
5.1.6.3.1, #4	RC/SC	Please clarify the phrase "…specified and controlled". Does this mean in accordance with SOPs? Documented in the record? Unless these two terms are defined somewhere, it is recommended to use other words to clarify this.	YES	The committee agreed with this comment and removed the clause, "…specified and controlled…" and replaced them with "….follow policies, processes and procedures…" This change should provide clarity.
5.1.8.1.3.1	SC	NA	NA	The committee added a cross reference to standard 3.7 as a parallel to a cross reference concerning standard 5.1.8.3.1 in standard 3.7.
5.1.8.1.3.1	RC	Does the word "continuously" in this standard imply that facilities MUST have an electronic monitoring system in use 24/7? If I am a small facility that still relies on the alarm on the unit and manual temps every 4 hours, am I out of compliance, or is the fact that the alarm is on count as continuous monitoring?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that an alarm system would be sufficient to provide continuous monitoring of stored blood.
5.1.8.2	RC	Temperature monitoring of transport containers of blood and components is required through an onboard real-time automatic device such as RFID tags. The retention time of stored data shall meet specified requirement and shall be accessed at any time. A real-time positioning system should be installed on transport containers of blood and components for tracking their positions when required. The tracking data of the containers shall be stored and accessed at any time.	NO	The committee noted this comment but did not feel that a change was needed at this time. Facilities currently using RFID tags would not have any concerns in meeting this standard, as the standard is written in a way to allow for the use of this technology.

5.2.1, #2	SC	NA	NA	The committee replaced the term "transmitted by blood" with "relevant transfusion transmitted- infections" to remain consistent with language used by the FDA.
5.2.1, #2	RC	Since the use of pre-donation educational materials contents are not limited to Ebola Virus, reference to the Ebola guidance alone may not be appropriate here.	YES	The committee agreed with the comment and the change was made.
5.2.1, #5	SC	NA	NA	The committee added the clause, "…and mitigation strategies." To substandard 5, expanding the requirements for what needs to be included in the educational materials given to donors concerning postdonation iron deficiency.
5.2.1, #5	RC	For clarity, it is recommended Standard 5.2.1 5) state "Donors are given education materials regarding postdonation iron deficiency including risks, populations at risk, and mitigation strategies."	NO	The committee noted this comment but based on other feedback, elected to remove the clause concerning, "…populations at risk…" feeling that the information should be shared with all donors.
5.2.1, #5	RC	Our blood center believes in educating our donors on the importance of iron; we however, do not believe that taking action on a precautionary principle is something we agree with. Giving iron to donors is not without risk health wise, and this also establishes a patient-physician relationship that we would not like to be a part of. Prolonging inter-donation intervals has not been proven to help, and the real value of ferritin testing would be if it could be performed prior to testing, which is logistically impossible. Hence, we feel that the choice of iron mitigation should not be limited to those things listed on the AABB Bulletin; but instead, each center should be allowed to manage this issue the way that they see suitable for their establishment. We already provide iron educational material to donors, and do not actively recruit donors if they are deferred for low hematocrit (a deferral period of one (1) day). Our average annual donations per each donor at our center is two (2). The average hematocrit per donor at our center is forty-four (44). We see no additional benefit(s) from adding any other measures.	YES	The committee noted this comment and agreed with its intent. The committee removed the clause "populations at increased risk" from standard 5.2.1, #5. The committee feels that the absence of data and scientific evidence at this time would not allow for the standard to be adequately supported. Based on feedback, the committee did not feel it would be appropriate to put forth this requirement that in itself was viewed as precautionary. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency.
5.2.1, #5	RC	Giving iron to donors establishes a patient-physician relationship that I would not like to be a part of. I personally am not convinced that we need to "treat" donors. We are not their health care providers. Also, iron	YES	The committee agreed with the intent of this comment and removed the clause

		administration is not without risks. Prolonging inter-donation intervals has not been proven to help. If ferritin testing could be performed prior to donation I can see the value, performing ferritin after we have already drawn a unit seems like we are being self-serving and trying to pretend that we are taking a high road. If we cared that much about storage iron status we should be doing it before we put a needle in their arm. I also want to point out that we – as a manufacturer – do not (in the Circular or anywhere) make any promises that our product will contain so much of storage iron. I feel that that for AABB to restrict choice of iron mitigation to only the strategies listed in the bulletin is limiting and somewhat high handed. I believe that each center should be allowed to manage this issue the way that they see suitable for their establishment. Our donors are provided iron educational material, are warned about the dangers of iron deficiency if they donate frequently and are not actively recruited if deferred for low hemoglobin/hematocrit. On an average each donor at our center donates less than 2 donations per year. I see no additional benefit(s) from adding any other measures to meet this standard the way it is written.		"…populations at increased risk…" from subnumber 5 of standard 5.2.1. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency. The committee feels that the absence of data and scientific evidence at this time would not allow for the standard to be adequately supported. Based on feedback, the committee did not feel it would be appropriate to put forth this requirement that in itself was viewed as precautionary.
5.2.1, #5	RC	Our blood center believes in educating our donors on the importance of iron; we however, do not believe that taking action on a precautionary principle is something we agree with. Giving iron to donors is not without risk health wise, and this also establishes a patient-physician relationship that we would not like to be a part of. Prolonging inter-donation intervals has not been proven to help, and the real value of ferritin testing would be if it could be performed prior to testing, which is logistically impossible. Hence, we feel that the choice of iron mitigation should not be limited to those things listed on the AABB Bulletin; but instead, each center should be allowed to manage this issue the way that they see suitable for their establishment. We already provide iron educational material to donors, and do not actively recruit donors if they are deferred for low hematocrit (a deferral period of one (1) day). Our average annual donations per each donor at our center is 1.9 times per year. The average hematocrit per donor at our center is 42%. We see no additional benefit(s) from adding any other measures.	YES	The committee agreed with the intent of this comment and removed the clause "…populations at increased risk…" from subnumber 5 of standard 5.2.1. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency. The committee feels that the absence of data and scientific evidence at this time would not allow for the standard to be adequately supported. Based on feedback, the committee did not feel it would be appropriate to put forth this requirement that in itself was viewed as precautionary.

5.2.1, #5	RC	These standards reference "populations at increased risk". Please clarify if you will define 'populations at increased risk', and if so, how it is being defined. Explanatory point #4 in the document references "facility defined at-risk populations"; in addition the document references AABB Bulletin #17-02, which defines donor populations at risk as a) young donors b) premenopausal females c) frequent donors (males ≥3x/12 mo; females ≥1x/12 mo), and d) donors with hgb values near the minimum for eligibility (i.e. males 13-13.5 g/dL, females 12.5-13 g/dL). If AABB is permitting facilities to define at-risk populations or expects facilities to adhere to the populations described in the Bulletin, we suggest including a footnote.	YES	The committee agreed with this comment and removed the term "populations at increased risk" from the standard . The committee wishes for the standard to be applied to all donors, that they all be given educational materials concerning the risks of postdonation iron deficiency.
5.2.2	SC	NA	NA	The committee elected to add the clause, "…and potential adverse effects related to the donation…" to standard 5.2.2. as well as a cross reference to standard 5.2.1, #5, which focuses on educational materials given to donors. The committee feels that when parental permission is required, the information about the donation process that is presented to parent(s) should be consistent with the information presented to the donor.
5.4.3	SC	NA	NA	The committee added the requirement under standard 5.4.3 that the facility have processes to minimize the adverse effects of donation for completeness. The content that previously appeared in standard 5.4.3 now appears as new standard 5.4.3.1.
5.4.1.3	RC	Change references to "women" or "females" to a genderless term ("Women who are pregnant or who have been pregnant recently shall be considered for Rh Immune Globulin"). The donor standards may need different treatment if they use a specific definition for who is considered a woman.	NO	The committee agreed with the intent of this comment, but specifically for standard 5.4.1.3 could not make this change. The committee has updated the language in the standards in other areas. The committee plans to expand the guidance on this issue to ensure that there is clarity. Also, the DHQ task force will continue to review the topic and make a recommendation that the committee can follow during the life of

				the 32nd edition of BB/TS Standards and going forward.
5.4.3.2 (deleted)	RC	Proposed Standard 5.4.3.2 is based on Bulletin #17-02 which warns of the "potential for adverse health consequences before anemia occurs". There are two references here. The first (no. 4, Pratt and Khan) actually reported no association with non-anemic iron deficiency and exercise tolerance, educational attainment and infant development, while the second (no. 5, Sohrabi) is a student essay submitted at the 5th Annual Royal Medical Society of Edinburgh Student Conference in 2015. My comment is not intended to be dismissive of earnest effort on the part of students, but it is reasonable to expect more authoritative literature justifications when discussing standards revision. Subsequently in #17-02, none of the references (6-23) to adverse effects included any study on a scale that would have relevance to the donor setting. The one study which is of appropriate scale (no. 13, Rigas et al) found no quality of life sequelae, It would be worth updating this reference section with reference to the suitably scaled (45,000 donors) NHS Blood and Transplant INTERVAL study which also looked at quality of life issues (Di Angelantonio E et al. Lancet 2017;390:2360-2371) 2). With regard iron supplementation, when treatment recommendations are made, donors become indistinguishable from patients. That being the case, they deserve follow-up to confirm efficacy of treatment, and investigation should treatment fail. This responsibility is ignored in the proposed standards. 3). Implementing donor ferritin testing is addressed in the proposed standards to qualify subsequent donation. However, given, for example, that some 30% of first time female Canadian donors (Goldman M et al. Transfusion 2017;57:564-570) already have low iron stores, those believing that these individuals are at risk should invoke ferritin screening as a qualifying test to ensure deferral of volunteers whose donation will aggravate pre-existing storage iron deficiency. The proposed standard does not address this concern. 4). Since the ferritin assay is non-specific, the proposed standard should alert those choosing this approach that management of some donors will be incomplete without the additional testing that will become available with the development of hepcidin assays.	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward.
5.4.3.2 (deleted)	RC	This standard requires interventions to address iron deficiency in at populations increased risk for developing iron deficiency. I believe this requirement is made on the misguided, as yet un-demonstrated theory that	YES	The committee reviewed this comment and agreed with the intent. The committee elected to

		iron deficiency related to blood donation causes harm. Invoking a Standard such as this is like requiring a transfusion at a particular Hb/HCT cutoff. This is treating a number, not a pathology. Your references do not make the case that iron depletion in this setting causes pathology. I have done a literature review and find that there are studies showing a variety of deficits related to iron deficient diet. However, the deficiency started at birth. This, to me, is very different from the transient iron deficiency one might have with blood donation and not comparable. I think that adults should have the freedom to decide whether or not iron supplementation is necessary in order for them to be a blood donor. Naturally, it is important for donors have unbiased access to the risks of blood donation, a document the AABB should produce, including those risks related to iron deficiency in the literature they receive. However, iron supplementation is a treatment to be undertaken between a physician and his/her patient or personal choice. Making the decision for an adult as to how many times they can give within established parameters removes the choice/responsibility from the donor. I my opinion this is wrong, as long as the donor is informed regarding POTENTIAL consequences associated with blood donation. If the concern here is so great, the FDA could invoke a change in the interdonation interval. Ferritin testing may be adequate in a clinical setting to indicate an iron deficient state. However, to my knowledge we have nothing that is approved for screening volunteer blood donors by the FDA. In addition, the case still has not been made that an iron deficient state in the background of blood donation leads to disease. Finally, the recommended changes will result in and increased cost to the blood products and potentially affect product availability. Even though transfusion rates are falling, national seasonal blood shortages seem to be rising and the group O negative RBC shortage is relentless. In my opinion, the changes you recommend should be made with cooperation and consent of the FDA, or this Standard should be rewritten.		remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency.
5.4.3.2 (deleted)	RC	This statement should be reworded to remove the word <u>policies</u>. Policies should be replaced with strategies. The *AABB Donor Iron Deficiency Risk-Based Decision-Making Assessment Report of 2018* stated the "detection of risk is difficult." The "clinical consequences of IDA were not extensively reviewed by the working group as it is unclear to what extent the consequences would apply to donors who are iron deficient before donation and then made anemic after blood donation." Further, no national guidelines currently exist for mitigating iron deficiency in adolescents.	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that

		Regarding the risk of cognitive performance, ongoing brain development in adolescents and fetal development the RBDM stated the risks are "theoretical." Regarding the proposed strategies, there is no uniform agreement on treatment (iron supplementation or standard length of deferral) of a low ferritin. Adherence to iron supplementation is not well characterized in the high school and teenage population. Additionally, research has found that some iron supplements may increase the formation of cancer biomarkers. https://www.sciencedaily.com/releases/2018/04/180412140623.htm Furthermore, no guidance has been provided on how to manage/address donors who refuse to take iron supplements following a low ferritin result. Ferritin testing also has the potential to change the donor/blood center relationship. Donor education on potential risks should be the starting point for the discussion until there is more definitive information regarding risks.		there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency.
5.4.3.2 (deleted)	RC	The inclusion of 5.4.3.2 within the 32nd edition of the BB/TS Standards is premature, at best, and its wording lacks requisite specificity. Much more research is needed to inform our membership about the clinical necessity, regulatory validity, and operational practicality of the proposed interventions for populations deemed to be at risk for iron deficiency due to blood donation. Fundamentally, at this juncture the medical consequences of iron balance, either high or low, are too unclear to warrant any AABB policy making on the subject. Although both the AABB Ad Hoc Iron-Deficiency Working Group[1] and the authors of the CHILL study[2] invoke the precautionary principle to advocate for iron boosting interventions, this is an overreach because they do not address the potential risks of excess iron, which are presumed to be mitigated through blood donation. High concentrations of iron are neurotoxic and there is literature that supports its role in Alzheimer's, Parkinson, and Huntington disease. Iron is also associated with the risk of colonic tumorigenesis[3], Type 2 diabetes[4], and other maladies. The quality of this "anti-iron" research is on par with that referenced by iron interventionists. In such an ambiguous situation as this, it bears noting that Koen Kramer and colleagues at the Sanquin Blood Supply Foundation maintain that there are constraints that should apply to the precautionary principle. They assert that certain risks can be tolerated if applying safety measures will lead to "more harm than they prevent."[5] If the committee should decide to include the proposed 5.4.3.2 into the 32nd edition of the Standards, a sunset clause or provision seems warranted. This mechanism would help promote high quality research to		The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency. The committee also notes, as a point of clarity, that all standards are reviewed every two years and are considered for deletion or maintenance, and that all standards can be "sunseted."

		understand benefits accruing to donors by the regulation. Likewise, an intentional time frame for revisiting this controversial subject would encourage a better understanding of potential drawbacks. This seems all the more reasonable, given that the Risk Based Decision Making process, as deployed in the original AABB evaluation of the topic, was flawed per admissions of many of its participants. Additionally, the proposed standard does not adequately specify the "increased risk" being mitigated, leaving interpretation far too subjective for consistent compliance. The clinical consequences of low iron levels need to be clear stated. This may well be problematic, given 1) the paucity of relevant donor research and 2) that the oft cited cognitive detriments are either extrapolated from animal and embryonic studies or are extracted selectively from conflicting psychometric data sets. The recently published donor studies, such as CHILL, are notable for the absence of clinical correlates for the lab findings, which by themselves cannot reasonably represent a "risk." It is worth noting in this regard that the medical community outside of blood banking does not pronounce concern about iron intervention that approaches that which Standard 5.4.3.2 seeks to legitimize. Public health organizations and medical specialty societies have issued no calls to action regarding the management of iron balance for blood donors, young or old. For example, iron deficiency is not listed in the 26 Leading Health Indicators for Healthy People 2020, a decade long effort led by the Office of Disease Prevention and Health Promotion to improve the health of all Americans.[6] Likewise, the American Board of Internal Medicine (ABIM) Foundation's Choosing Wisely program has no mention of donor-related iron among its 540 specialty society recommendations and 150 patient-friendly resources.[7] Prevention of iron deficiency and its public health consequences do not register on the websites of many healthcare organizations, including the American Medical Association, American College of Physicians, American Society of Hematology, American Academy of Neurology, American College of Preventative Medicine, etc. The US Preventive Services Task Force (USPSTF) summarized the evidentiary challenges in setting iron guidelines when it noted relative to young children, "Few well-designed long-term studies on the effects of iron deficiency anemia…are available. Based primarily on observational data, studies have found an association between iron deficiency (with or without anemia) in infancy and childhood and impaired neurodevelopment in older children. Cognitive and behavioral delays in children have also been found to be associated with iron deficiency anemia. However, these observational		

		studies have limitations due to the types of measures reported and confounding with nutritional and socioeconomic factors, making causation difficult to determine."[8] Lastly, to eliminate confusion the proposed standard should, itself, enumerate the acceptable interventions referenced in the contents of "AABB Proposed Standards on Donor Iron Management".[9] AABB communications aver that the Blood Banks/Transfusion Services Standards Committee holds these measures valid in meeting the intent of the new rule. It should be relatively easy, then, to memorialize this understanding that at least one of the following interventions is acceptable: comprehensive education, iron supplementation, lengthening the interdonation deferrals, or implementing donor ferritin testing. Without this diligence, compliance with the standard may be needlessly complicated by subjective interpretations of inspectors and/or blood operators. More concerning, vague and informal concepts of "standards of practice" or "standards of care" may arise in the future and encroach upon the range of options understood presently to be sufficient for requirements. The possibility of such an undisciplined and unmanaged policy drift should be obviated by inserting the specific language already promulgated. References 1. AABB Donor Iron Deficiency Risk Based Decision-Making Assessment Report [cited 2019 June 24]. Available from: http://www.aabb.org/tm/Documents/AABB-Donor-Iron-Deficiency-RBDM-Assessment-Report.pdf). Supplemental Material [cited 2019 June 24]. Available from: http://www.aabb.org/tm/Documents/AABB-Donor-Iron-Deficiency-RBDM-Assessment-Report-Supplemental-Material.pdf. 2. Spencer B, Bialkowski W, Creel D, et al. Elevated risk for iron depletion in high-school age blood donors. Transfusion 2019;59:1706-1716. 3. Sayers M. Iron supplementation? Ferritin Screening? Why questions persist. Transfusion 2019;59:1616-1619. 4. Simcox J and McClain D. Iron and diabetes risk. Cell Metab 2013;17:329-341. 5. Kramer K, Zaaijer H, and Verweij M. The precautionary principle and the tolerability of blood transfusion risks. Am J Bioeth 2017;17:32-43. 6. Leading Health Indicators for Healthy People 2020—Midcourse Review [cited 2019 June 24]. Available from: https://www.healthypeople.gov/2020/data-search/midcourse-review/lhi. 7. Clinician Lists at Choosing Wisely, an initiative of the ABIM Foundation. [cited 2019 June 24]. Available from:http://www.choosingwisely.org/wp-		

		content/uploads/2015/01/Choosing-Wisely-Recommendations.pdf. 8. Final Recommendation Statement—Iron Deficiency Anemia in Young Children: Screening, US Preventive Services Task Force [cited 2019 June 24]. Available from: https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/iron-deficiency-anemia-in-young-children-screening. 9. AABB Proposed Standards on Donor Iron Management [cited 2019 June 24]. Available from: http://www.aabb.org/sa/standards/Documents/proposed-standards-on-donor-iron-management.pdf		
5.4.3.2 (deleted)	RC	The majority of physicians believe in some form of the Hippocratic Oath or believe "First do no harm." The Hippocratic Oath is sometimes used as a moral compass to assist physicians in making difficult decisions. That is why I believe blood bank physicians will not put our donors or patients in harm's way. As physicians we are taught not to treat a value or number, signs and symptoms that are read in a chart but to do a complete history and physical. WHOA! I am not asking to practice medicine on our donors but I am simply asking to allow us to manage our donation process as an individual blood center(s). The editorials in the May issue of Transfusion succinctly cover the salient points in the iron management for blood donors. Both authors point out that there is inconclusive data. There are risks with supplemental iron consumption (right dose, compliance), and other detrimental effects by taking iron not listed here. I agree that the methods for donor iron management are not perfect but we should not draw conclusions and rush to implement solutions based on the current literature. Until there is a reliable point of care ferritin assay, we should delay ferritin testing, for logistical and economical purposes. Treating a ferritin number in a asymptomatic donor seems contrary to good clinical practice. As a physician scientist, I need more conclusive evidence that providing access to iron, measuring ferritin and increasing donor intervals will be the best way to manage our donors.	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward.
5.4.3.2 (deleted)	RC	I am writing to express my opposition to proposed standard 5.4.3.2. In particular, I am opposed to AABB forcing BB's to implement at least one of the four interventions from AABB Bulletin #17-02. I serve as CLIA director for a small blood center, and I feel none of the interventions are necessary when there is no industry consensus that donating whole blood is causing an epidemic of iron deficient donors. The recent studies published on the alleged causation between blood donation and iron deficiency are anecdotal in my opinion, and the conclusions reached in these studies are	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that

		not settled science. I have a great deal of respect for AABB as one of the leading organizations for transfusion and cellular therapy, and I would expect a standard that will have such a large impact on donor eligibility as well as the blood supply will be based on years of research and sound facts. Blood banking has been around for an extremely long time, if there was a direct link between blood donations causing a pathologic iron deficiency in blood donors it would have manifested itself decades ago. I feel it is premature of AABB to adopt this standard and feel the current standard 5.2.1 should remain the status quo until iron deficiency in blood donors can be researched in a more powerful and exhaustive manner. The industry is aware that pathologic iron deficiency MAY be a problem for some blood donors, but until it is proven, blood centers should be allowed to manage this concern the way that best suits their operations and not have to conform to only four interventions that will have a negative impact on their ability to provide for patients. For the reasons stated above, I want to strongly encourage all members of this committee to vote against proposed standard 5.4.3.2.		there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency.
5.2.1, #5, 5.4.3.2 (deleted)	RC	Regarding Donor Iron Management: as many of us in the blood collection field have commented on in the previous months, iron deficiency is not a sure thing for most donors. Granted, donors who are already low on iron, or who donated especially frequently can become iron deficient, but most donors replace iron on their own through normal mechanisms and do not become iron deficient and certainly do not display signs or symptoms of iron deficiency or anemia. The vast majority of our donors do not donate more than once a year. And more importantly, the risks of iron deficiency in blood donors is largely if not completely theoretical at this point. Whereas the risk of a diminished blood supply is very real. I am very concerned about mandating things that will scare donors away from donating, or worse, will scare our blood drive sponsors away from hosting blood drives. We are already in a position that we have a tenuous blood supply for Rh negative units of red cells, and sometimes other types. Last week my blood center had ZERO units of B negative blood on the shelf. We routinely have to short change hospitals on the number of O negative units they would like to stock. And of course the Rh negative donors are the ones we call upon most frequently to donate. These iron mitigation strategies will impact them the most. AABB, by putting in place these	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency.

		standards to address theoretical risks, is jeopardizing the safety of our patients. Those among us who say "just collect blood from more donors" obviously haven't been on the front lines, working in a blood center in recent times. It is not that easy nor simple.		
5.4.3.2 (deleted)	RC	I believe there is substantial evidence among health blood donors that they are at risk (especially young women) for iron deficiency anemia. Below are just a few of the references. -Newman B. Iron depletion by whole-blood donation harms menstruating females: the current whole-blood-collection paradigm needs to be changed. Transfusion 2006;46:1667-81. -Finch CA, Cook JD, Labbe RF, et al. Effect of blood donation on iron stores as evaluated by serum ferritin. Blood 1977;50: 441-7. -Simon TL, Garry PJ, Hooper EM. Iron stores in blood donors. JAMA 1981;245:2038-43. -Cable RG, Glynn SA, Kiss JE, et al. Iron deficiency in blood donors: analysis of enrollment data from the REDS-II Donor Iron Status Evaluation (RISE) study. Transfusion 2011;51:511-22. -Cable RG, Glynn SA, Kiss JE, et al. Iron deficiency in blood donors: the REDSII donor iron status evaluation (RISE) study. Transfusion 2012;52:702-11. -Spencer BR, Bialkowski W, Cable RG, et al. Elevated risk for iron depletion in high school blood donors. [Transfusion. https://doi.org/10.1111/trf.15133 -Schotten N, Pasker-de Jong PC, Moretti D, et al. The donation interval of 56 days requires extension to 180 days for whole blood donors to recover from changes in iron metabolism. Blood 2016;128:2185-8. -Rigas AS, Sorensen CJ, Pedersen OB, et al. Predictors of iron levels in 14,737 Danish blood donors: results from the Danish Blood Donor Study. Transfusion 2014;54:789-96. -Goldman M, Uzicanin S, Scalia V, et al. Iron deficiency in Canadian blood donors. Transfusion 2014;54:775-9. -Badami KG, Taylor K. Iron status and risk-profiling for deficiency in New Zealand blood donors. N Z Med J 2008;121:50-60. -Patel E, White J, Bloch E, et al. Association of blood donation with iron deficiency among adolescent and adult females in the United States: a nationally representative study. Transfusion 2019;59:1723-33.	NO	The committee reviewed this comment but did not feel that the data presented would support keeping standard 5.4.3.2 in the 32nd edition would be appropriate. The committee will continue to monitor the data put forward and all new scientific evidence and will decide at what point a standard may be needed.

		I believe other standards have been created with less support from the medical literature. I also believe the previous standard had substantial leeway for many different interventions. During the call, it was mentioned that there should be more large epidemiologic research in this area. As an NIH funded research scientist, I would not be enthusiastic to pursue this area. There is already so much data, very few prominent publications would be produced.		
5.4.3.2 (deleted)	RC	I understand and acknowledge the concerns we face ("Harm to the Donors" vs. "Harm to the Blood Supply'), however, the failure to include "populations at risks" in 5.2.1 #5 and the elimination of 5.4.3.2 is contrary to the finding of the RBDM and 50 years of research addressing iron depletion/deficiency in blood donors. What constitutes enough information to put Standards such as these into place? These Standards are not prescriptive; they do not require ferritin testing or distribution of iron replacement tablets. These Standards would allow the Blood Centers to choose their approach to meeting the requirements, maintaining the blood supply, and keeping donors safe.	NO	The committee reviewed this comment but did not feel that the information provided was sufficient in that it does not provide hard scientific evidence of research performed on blood donors that shows that a standard should be put forth beyond what is included in standard 5.2.1, #5 and 5.2.2.
5.4.3.2 (deleted)	RC	Although I completely agree with the need for continued research on postdonation iron deficiency, I strongly feel that the available data, along with our current understanding of the relationship between progressive iron depletion and iron deficiency anemia, warrant measures to educate the donor at present.	NO	The committee noted this comment and feels that the content of standard 5.2.1, #5 would be sufficient to meet the request set forth in the comment.
5.4.3.2 (deleted)	RC	There has been consensus over my tenure that enough data exist to show that there is an issue and that a standard would be the best way to address this. 5.2.2 is not sufficient and would likely emphasize acute adv effects; e.g, vasovagal.	NO	The committee noted this comment but did not feel that the information presented was sufficient to retain the standard as written. The committee will continue to follow all new data and scientific evidence that becomes available as it relates to postdonation related iron deficiency.
5.4.3.2 (deleted)	RC	This is an appropriate requirement as an AABB Standard for blood collectors to protect blood donors.	NO	The committee noted this comment but does not feel that at this time a standard based on a precautionary measure would be appropriate and that more data and scientific evidence is needed.
5.4.3.2 (deleted)	RC	We can argue about whether or not there is sufficient data to determine whether iron deficiency per se (i.e., without anemia) is a problem. Indeed, our own research program is addressing this issue and we will be able to report out on our results in a year or so.	NO	The committee noted this comment but did not feel it would be appropriate to maintain a standard based on the precautionary principle. The committee will continue to review the data and scientific evidence as it relates to

		However, we do know that we make a significant number of altruistic, iron deficient blood donors anemic by allowing them to donate, even if their hemoglobin determination at the time of donation is satisfactory. This has been well documented over and over again. Thus, we produce the disease of "iron deficiency anemia" in otherwise healthy blood donors. This is a disease according to every textbook of medicine and if that individual went to see his/her physician with anemia, that physician would be obligated to work up that person, who is now a patient, determine that they, indeed, have iron deficiency anemia, and make a medical decision of how to care for them. These blood donors are then patients in the same fashion that we identify analogous patients with hemochromatosis (e.g., high ferritin levels on an annual checkup, followed by a genetic test) and polycythemia vera (e.g., high hemoglobin on an annual checkup, followed by a genetic test). These latter two types of patients have no symptoms and are unlikely to have any long-term consequences, if they are cared for properly. Indeed, we treat them by therapeutic phlebotomy, even in blood collection centers! Stating that our donors with induced anemia "do not have symptoms" does not absolve us of the fact that we induced the disease in them. They have not provided appropriate informed consent in what I believe should be considered a medical experiment. Indeed, if blood donor phlebotomy were a new procedure today, the FDA would not allow it to occur in the setting of inducing anemia unless we proved it was safe, which we have not.		postdonation related iron deficiency going forward and will take steps needed as the evidence becomes available.
5.4.3.2 (deleted)	RC	We have grave concerns of the findings of the authors of the CHILL Study. The authors claim that 16, 17 and 18 yr olds have a low iron issue. That may very well be correct. But how is it that this "supposed" issue with these young people is all of a sudden the problem of the blood industry?! If these young people do indeed have a low iron problem, why didn't the authors study what is causing this problem. My uneducated guess is that it is diet related. Our opinion is that we need to treat these young people like we do all donors. We need to check and see if their iron is high enough for them to donate. If it isn't, then we will counsel them as we do all other donors and let them know what they need to do before they	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data at this time to adequately support this standard.

		come back in. We adamantly disagree with dispensing iron supplements to donors. This is fraught with red flags. (i.e. "will these donors have a reaction to these iron supplements?", "will the parents of these minors become upset with the blood center for dispensing iron supplements to these minors?", "Will these donors take the iron supplements and return to donate?", etc.) And not only would blood centers bear the cost of these supplements, but the authors say that ferritin testing should be done on these donors, adding yet more cost to blood centers. And it is questionable about the motivation of the authors. About half of the authors are with organizations who have previously endorsed doing ferritin testing. And these orgs provide blood testing to other blood centers. Is there a bias here? Is this decision motivated by how much money these orgs can generate by doing ferritin testing? There are studies out that say high iron levels can cause cardiac issues. Alzheimer's researchers have found that autopsies of deceased Alzheimer's patients have high levels of iron in their brain. For years blood centers have been advocating to donors the benefit of regular blood donation as a way to reduce the irons stores, especially in male donors. Now all of a sudden we are saying that individuals' iron must be higher. If this becomes a "Standard" and 16, 17, and 18 year old's donations are restricted or denied, there will be a significant reduction in the supply of blood.		The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency.
5.4.3.2 (deleted)	RC	My center does not wish to cause harm to anyone. However we do want to be using logic in our decision making process. We have not witnessed any harm to any donors that are not currently being deferred due to hemoglobin. This study did an excellent job in reporting ferritin test results in repeat donors. 1) It did not however show that harm was taking place to these donors but only a possibility. Actually to the contrary by quoting the INTERVAL study. AABB should sponsor a study to review the effects of blood donation on this population so we have conclusive data we are doing harm. 2) The study quoted "Iron status at enrollment was a strong predictor of the onset of low hemoglobin with subsequent donations. Donors with ferritin less than 12ng/ml at enrollment had 5.9 times the odds of being deferred for a low hemoglobin (95% CI, 3.9-8.8) compared to donors with ferritin 26 ng/mL or higher at enrollment''. It is important to note that our current Hemoglobin requirements are working to stop these subsequent donations. Further regulation is not needed if the current model is working sufficiently. At some point that becomes over reach and too cumbersome to be able to function.	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how

		3) Ferritin/ Iron stores job in the body is to replenish the hemoglobin in the blood stream. If the Ferritin is low but the hemoglobin is high enough to allow them to donate it stands to reason the iron stores are doing their job. 4) If the committee does feel it is reasonable to add additional constraints on allowing donations of this population, I would recommend they review its requirements for Patient blood management transfusion requirements at 7 hemoglobin. This same population is in the hospital from time to time. If a hemoglobin that low is acceptable at the hospital why are we to believe our deferral at 12.5 hemoglobin is not ok for donation? Its not logical and should be evaluated. Lastly I want to thank the members of this committee for reviewing this study and the AABB guidance on the subject matter. As I stated earlier my center does not wish to do harm. So your decision does matter greatly to me. I am just asking that we research harm and hemoglobin deferrals and not just grasping for a regulation.		donor centers manage potential postdonation iron deficiency.
5.4.3.2 (deleted)	RC	Please understand that I am not arguing that there is not a reduction in ferritin in individuals no matter what the age; studies have clearly proven this. What studies have failed to do is determine what lab value is indicative of a problem and does that value have a real link to clinical symptoms that affect an individual's quality of life? It is my view that the only conclusion you can draw from this study is a certain percent of 16–18 year olds have a ferritin level below 12 ng/mL and below 26 ng/mL. The data also states that the percentages increased with prior donations. They are comparing three age groups to a population of 19-49 year olds consisting of thirty age groups. The research also states that we defer twice as many 16-18 year olds compared to 19-49 year olds for hemoglobin deferral. This indicates that our industry is ensuring that we are diligent in checking that individuals meet a requirement that is indicative of documented safety levels. There are so many uncontrolled variables that can impact the reduction of ferritin in individuals, such as diet, genetics, menstruation, etc. Using this data to show that blood donation is the common link and that we need to make changes because of a precautionary principle is irresponsible. In the discussion on page 7, "Any clinical impact from donation-associated iron depletion may be subtle and challenging to detect, and this issue would benefit from further scientific inquiry". Yes, I agree with this statement and no changes to our current process should proceed until we have the answer! The discussion pointing to brain development in 12–16 year olds and iron depletion is on shaky ground, and to make the link to blood	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data of research performed on blood donors at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward. The committee notes that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency.

		donation, I feel, is also irresponsible. The discussion also points out that the "impact on blood availability of new restrictions remains unknown and should be measured with predicative models or simulations". Yes, I also agree, so again as a profession, we should not make changes until we have data to make an informed decision along with the risks associated with that decision.		
5..4.3.2 (deleted)	RC	The issue of the clinical impact of iron depletion in blood donors and/or caused by blood donation remains controversial and among our members there is little consensus about how aggressive we need to be, from a medical standpoint, at mitigating its effects. The available data do not support serious morbidity from iron depletion in otherwise health donors. That said, subtle effects in vulnerable cohorts, teen donors and women with childbearing potential especially, may not be apparent from published studies and some have accepted the need for a precautionary approach in those specific donor groups. Given this level of controversy, it is unclear that a Standard will be received positively by a large proportion of the blood community. If a Standard is, nevertheless, proposed it clearly must not be prescriptive in nature. The example of the original platelet bacterial Standard 5.1.5.1 is germane. That required methods to limit and detect bacterial contamination with no detailed specifications. It seems an excellent starting approach. Such a Standard for donor iron status might read "methods to detect and/or limit iron depletion in donor cohorts identified as at risk" or words to that effect. Aggressive education and recommendations during donor recruitment and consent procedures at the time of donation would fulfill such a Standard. Additional alternatives could be suggested as well, if desired, consistent with those listed in the AABB Donor Iron Deficiency Risk-Based Decision-Making Assessment Report. Implied in such an initial Standard is an imperative that some or all collection facilities undertake validation and evaluation of their chosen strategies to demonstrate their effect.	YES	The committee reviewed this comment and while they elected to delete proposed standard 5.4.3.2, they do feel that the addition of "mitigation strategies" to standard 5.2.1, #5 is a positive interim step while the community at large continues to provide data and scientific evidence on the effects of postdonation iron deficiency. The committee will continue to follow the work put forth by the community and adjust course as needed.
5.4.3.2 (deleted)	RC	At our community blood center it is difficult to recruit and retain donors. We know that this situation is not unique, rather commonplace across the country. Our center has implemented specific educational materials for all donors to read concerning iron depletion in blood donors. We have developed our intervention strategy to limit or prevent iron deficiency in select groups of blood donors. We hope that the intervention strategies proposed in the AABB Association Bulletin 17-02 are not going to be mandated by the organization and hinder our ability to collect blood from	YES	The committee reviewed this comment and notes that the four options included in Association Bulletin #17-02 are starting points and not requirements or standards for how donor centers manage potential postdonation iron deficiency. The committee is counting on the membership to share what mitigation strategies they are taking with regard to postdonation iron

		select donors and thus decrease our ability to be our community's blood resource in the future.		deficiency and what preventive measures they are taking.
5.4.3.2 (deleted)	RC	In recent years there has been discussion about a potential AABB standard that would address iron depletion in high school donors. In healthcare we emphasize evidence based medicine. Give the results of the INTERVAL study which found no difference in cognitive function by donation frequency in 45,000 donors, we cannot support an AABB standard requiring ferritin testing or iron supplementation or vouchers at this time as there is no scientific evidence of a problem that we are trying to fix. We are aware that donors ages 16 to 18 are at higher risk for iron deficiency and that frequent donation can reduce iron stores, however, we are not aware of substantial scientific evidence describing resulting clinical effects. In absence of evidence of clinical impact of iron deficiency, it is difficult for us to understand the risk:benefit ratio of providing iron supplemention or vouchers. In addition, ferritin testing is of limited utility since it is completed following the donation and we are unsure of the clinical impact. We are taught in transfusion medicine to not treat a number and we believe that this applies in this situation as well. We propose consideration of an AABB standard only if the following 2 criteria are met: 1) Scientific study shows clinically significant impact of blood donation on donor cognitive or physical function 2) Availability of a waived, point-of-care ferritin test. Thank you again for considering our comments.	YES	The committee reviewed this comment and agreed with the intent. The committee elected to remove proposed standard 5.4.3.2 that would have required that facilities have policies to limit the risk of iron deficiency in populations of increased risk. The committee removed the proposed standard because they did not feel that there was enough evidence and scientific data at this time to adequately support this standard. The committee will continue to monitor all new data and studies that are made available during the life of the 32nd edition of BB/TS Standards and going forward.
5.4.3.2 (deleted)	RC	Please give blood center's flexibility to adopt approaches that work best for their donor populations (similar to the AABB bulletin 17-02). While I respect the efforts made by AABB, blood centers should have options and the standard should not be prescriptive in recommending one option over others.	YES	The committee reviewed this comment and they note that the four options included in Association Bulletin #17-02 are starting points and not requirements for how donor centers manage potential postdonation iron deficiency. The committee is counting on the membership to share what mitigation strategies they are taking with regard to postdonation iron deficiency and what preventive measures they are taking.
5.4.3.2 (deleted)	RC	The issue of the clinical impact of iron depletion in blood donors and/or caused by blood donation remains controversial among our members, and there is little consensus on the appropriate approach, if any, in mitigating its effects. Additional studies to characterize the clinical impacts of non-	YES	The committee reviewed this comment and while they elected to delete proposed standard 5.4.3.2, they do feel that the addition of

		anemic iron depletion in blood donors are a critical priority as available data do not support serious morbidity from iron depletion in otherwise healthy donors. That said, subtle effects in vulnerable cohorts, teen donors, and women with childbearing potential especially, may not be apparent from published studies and some have accepted the need for a precautionary approach in those specific donor groups. Given the diversity of thought within the blood community, and the need for additional data, we do not believe a *Standard* is appropriate at this time. If a *Standard* is nevertheless proposed, it clearly must not be prescriptive in nature and addressed with consideration of its impact to supply. The example of the original platelet bacterial *Standard* 5.1.5.1 is germane and could be an acceptable approach. That required methods to limit and detect bacterial contamination with no detailed specifications. Such a *Standard* for donor iron status might read, "methods to detect and/or limit iron depletion in donor cohorts identified as at risk" or words to that effect. Aggressive education and recommendations during donor recruitment and consent procedures at the time of donation would fulfill such a *Standard.* Additional alternatives could be enumerated as well, consistent with those listed in the AABB *Donor Iron Deficiency Risk-Based Decision-Making Assessment Report.* We believe it is imperative that collection facilities undertake validation and evaluation of their chosen strategies to demonstrate their effect. As such, we urge *Standards* to recognize the importance of first analyzing the impacts of any proposed mitigation interventions to understand the approaches that reduce iron depletion with a tolerable impact on supply.		"mitigation strategies" to standard 5.2.1, #5 is a positive interim step while the community at large continues to provide data and scientific evidence on the effects of postdonation iron deficiency. The committee will continue to follow the work put forth by the community and adjust course as needed.
5.4.3.2	RC	Given recent interest in the TM community related to iron depletion, we anticipate that standards related to iron may be proposed in the next update. While we recognize the need to be cognizant of the possible risk of iron deficiency in donors and that some donors may be at higher risk for iron deficiency, we strongly believe that blood collection centers need to be allowed to maintain the flexibility to choose the intervention to be implemented to mitigate iron deficiency in high risk donors, as there are not clear data on what intervention is most effective for this purpose. We also strongly support the flexibility for facilities to define populations at risk for iron deficiency from blood donation and provide appropriate education of donors related to the risk of post donation iron deficiency.	YES	The committee reviewed this comment and while they elected to delete proposed standard 5.4.3.2, they do feel that the addition of "mitigation strategies" to standard 5.2.1, #5 is a positive interim step while the community at large continues to provide data and scientific evidence on the effects of postdonation iron deficiency. The committee will continue to follow the work put forth by the community and adjust course as needed.
5.5.2.4	RC/SC	The collection of PAS platelets is not a concurrent collection of plasma or a plasmapheresis procedure; The plasma unit is a "prepared" unit from a	YES	The committee noted this comment and removed the clause "under applicable FDA variance"

		plateletpheresis procedure. Therefore, a request for an alternative procedure (variance) under 21 CFR 640.120 is not needed.		based on the comment received. The committee notes that plasma units are prepared from a plateletpheresis procedure and therefore a variance would not be needed.
5.6.3.2	RC/SC	Suggest adding "during or" to the standard as illustrated below in bold: Tubes for laboratory tests shall be properly labeled before the donations begins, shall accompany container and shall be re-identified with the blood container during or after filling.	YES	The committee agreed with this comment and elected to add the clause "during or.." to the standard.
5.6.5	RC	A real-time temperature monitoring device and a real-time positioning system, such as RFID tags, shall be installed on transfer containers.	NO	The committee noted this comment but felt that the request was too prescriptive and would benefit only one piece or type of equipment which is contrary to the intent of the *Standards*.
5.7.4.1 (New)	SC	NA	NA	The committee created new standard 5.7.4.1 focused on Whole Blood Leukocyte Reduced products for completeness.
5.7.4.1 (New)	RC	Although some standards for "low titer group O Whole Blood" in emergency use are outlined in standard 5.27.1, does AABB expect to implement standards with respect to preparation of these components? If so, these could also be outlined under 5.7.4?	NO	The committee reviewed this comment and noted that they have not stated what would be considered low titer. As such the standard could not be expanded upon to include. The guidance for this standard will however have more information.
5.7.4.16 (New)	SC	NA	NA	The committee created new standard 5.7.4.16 focused on Pathogen Reduced Plasma for completeness.
5.7.4.20 (5.7.4.18)	RC	"Platelets – Cold Stored" are listed as a distinct component in the table for Reference Standard 5.1.8A but not described under 5.7.4. If AABB expects standards will apply to their preparation, it may be appropriate to include in this section.	NO	The committee reviewed this comment but did not feel a change was needed at this time. The committee feels that the inclusion in the table is sufficient and to add something in this section would not strengthen the *Standards*.
5.7.4.23, 5.7.24, 5.7.4.25 (5.7.4.21, 5.7.4.22, 5.7.4.23)	RC	FDA criteria for platelet content based on the cited Guidance is: 95% confidence that greater than 75% of the components meet $>3.0 \times 10^{11}$. If AABB standards differ from what is in FDA Guidance it may not be correct to cite FDA Guidance. For pH: FDA criteria in the Guidance are 95% confidence that greater than 95% of the components meet >6.2. However, the reg 640.25 (b) only cites	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee will continue to provide guidance on this issue.

		pH >6.2. The references should correspond to what is included in the standard. – Reference should include both the CFR and Guidance for pH.		
5.7.4.26 (New)	SC	NA	NA	The committee created new standard 5.7.4.26 focused on Pathogen reduced platelets for completeness.
5.8.5, 5.8.6, 5.8.7	SC	NA	NA	The committee has added the requirement to standards 5.8.5, 5.8.6 and 5.8.7 that facilities perform testing for Zika Virus as required by the FDA.
5.8.5, 5.8.5.1 (New), 5.8.5.2 (New), 5.8.6, 5.8.6.1 (New), 5.8.6.2 (New), 5.8.7	SC	NA	NA	The committee issued updates to standards 5.8.5, 5.8.6, and 5.8.7 and created new standards 5.8.5.1, 5.8.5.2, 5.8.6.1, and 5.8.6.2 as interim standards to the 31st edition of Standards for Blood Banks and Transfusion Services requiring that donations collected in states specified by FDA guidance undergo nucleic acid testing for *Babesia*. The requirements take effect on May 10, 2020, a month after the rest of the 32nd edition of BB/TS Standards become effective in conjunction with the FDA Guidance for Industry. Standards 5.8.5.2 and 5.8.6.2 note that testing for Zika and *Babesia* is not required if all transfusable components from the donation are prepared using FDA approved pathogen reduction technology.
5.8.5, 5.8.6, 5.8.7, 5.1.6A	RC	Will Babesia be added to these Standards and Reference Standard 5.1.6A?	YES	The committee noted this comment and had already set in motion the interim standard process for the 31st edition covering this very topic.
5.14.2	SC	NA	NA	The committee elected to edit standard 5.14.2 to mirror the style of content that is standard 5.14.1 which is focused on the ABO group.
5.14.2	RC	I think the term “females of child bearing potential” needs to be more clearly defined. For example, the standards can mention females of child bearing potential which at a minimum should include all females between	NO	The committee noted this comment but did not make the suggested edit. The committee felt that

		the ages of 10 and 60 of unknown pregnancy status. Facilities should feel free to extend this range as needed.		the appropriate age range should be stated within facility defined policies and procedures.
5.14.3.1	SC	NA	NA	The committee edited standard 5.14.3.1 for clarity, removing "clinically significant" from the beginning of the standard and placing the clause "…to identify antibodies of clinical significance." At the end of the standard.
5.14.3.3	SC	NA	NA	The committee edited standard 5.14.3.3 in line with the changes made to standard 5.14.3.1. The standard has been updated to reflect the intent of both standards.
5.14.3.3	RC	Please confirm if the following method complies with the proposed standard: Crossmatching will be performed, and if crossmatching shows incompatibility an additional test will be performed to identify the antibody. The additional test will only be performed if crossmatching shows incompatibility. Or, is the expectation to always perform the other test to identify antibodies if present, regardless of crossmatching results?	NO	The committee noted this comment but did not feel a change was needed. The committee feels that this standard (as well as standard 5.15.3) are necessary and not redundant and should not exist separately.
5.14.5	SC	NA	NA	The committee elected to edit the order of the subnumbers in standard 5.14.5 to reflect the order of which they take place in practice, matching workflow.
5.14.5, #3	RC/SC	The requirement for a second sample collected at a different time will have a negative impact on care of TRAUMA patients. Emergency release will be our only option until a second sample can reach us. This will negatively affect our type O blood supply and delay patient care. We agree that testing a second sample, collected at a time different from the first sample, is the safest practice. However, our current practice (allowing both samples to be collected simultaneously) has not affected patient care. There needs to be an exception to this policy for Trauma patients and other patient populations such as neonates.	YES	The committee agreed with this comment and added a clause to substandard #2 (which previously appeared as #1). The additional clause reads, "…including a new verification of patient identification." This should provide clarity on the intent of the requirement.

5.14.5, #3	RC/SC	We identified that the statement "or another process validated to reduce the risk of misidentification" has been deleted from item 3, however it is not marked as a change. Please confirm the acceptability of using another validated process to verify patient identification. We recommend that the current allowance to use "another process validated to reduce the risk of misidentification" remain in the standard for the following reasons: • Hospitals served by Bloodworks transfusion service have policies that dictate the performance of a validated, 2-person verification prior to the sample draw for pre-transfusion testing. Both people must be licensed health care professionals (phlebotomist, RN, LPN, NA, PA, MD). The witness to the blood draw is required to stay in the room and observe the identification of the patient, the blood draw, and sample labeling. Both people sign the requisition for pre-transfusion testing. • If the use of this validated process is no longer acceptable Bloodworks has concerns that the transfusion service will deplete its supply of group O red cells waiting for a second sample in an emergent situation as the majority of hospital customers do not use an electronic identification system. Also, we recommend that AABB provide and/or maintain a list of all FDA approved electronic identification systems to assist in members verifying compliance with the standard.	YES	The committee noted this comment and based on the feedback elected to reinsert the language to subnumber 2 (previously subnumber 1.) Based on other comments received, the committee removed the requirement that the approval of the electronic identification system by approved by the FDA or Competent Authority but it does need to be validated.
5.14.5, #3	RC	It is recommended to add "as appropriate to the nation-state in which it is used." Specifically, the system used in the United States may have been approved by the European Union, but not yet approved by the FDA.	NO	The committee elected to remove the clause "…that is approved by the FDA or Competent Authority." That was added into the standard when the Standards were released for public comment.
5.14.5, #3	RC	Most hospitals that use an electronic identification system do so within their HIS, not their 510K cleared blood bank module. Most HIS are NOT FDA approved. Requiring HIS companies such as Epic and Cerner to be FDA approved for "electronic scanning" will likely not occur, forcing a second sample for many hospital inpatients. This standard should indicate that the electronic identification system is validated, but not that it must be FDA approved. "Facilities outside the US that require clarity on item 3" should not include creating a new requirement that was not in place before.	YES	The committee agreed with this comment and removed the clause that the electronic identification system be approved by the FDA or Competent Authority.

5.14.5, #3	RC	What is the outcome based evidence for removing the option of "another process validated to reduce the risk of misidentification" from method 3? What is the meaning of "approved by the FDA"? The electronic health record systems are approved by the FDA but not specifically for use as electronic identification systems. The FDA does not require BECs for sample collection.	YES	The committee noted this comment and based on the feedback elected to reinsert the language to subnumber 2 (previously subnumber 1.) Based on other comments received, the committee removed the requirement that the approval of the electronic identification system by approved by the FDA or Competent Authority.
5.14.5, #3	RC	Instead of just saying "testing a second sample collected at a time different from the first sample" I think the statement can be made more accurate by saying "testing a second independently collected (drawn) sample." As we know 2 samples can be collected at different times from the same draw/venipuncture e.g. 7.01AM and 7.02AM with just a few seconds between them. Another option is to say the samples must be collected at least 10 minutes apart. This would ensure that the samples are independent.	NO	The committee noted this comment but did not feel the suggested edit was appropriate. The committee feels that the updated language based on other comments received would cover this request.
5.14.5, #3	RC	I have an issue with this standard item #3. If we are using a system to reduce the risk of misidentification (red band), and we are not utilizing the computer crossmatch, but we are doing an "immediate spin" crossmatch, why do we have to retest the sample for ABO. The immediate spin crossmatch is detecting ABO incompatibility, therefore wouldn't this be as good as retesting the same sample if we are using the red band system?	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee will expand in guidance on how to implement the requirement.
5.15	RC	The total number of patient red blood cell (RBC) transfusions has steadily declined in the USA since 2008, but, antithetically, the demand for O Rh(D) negative (Oneg) red cells remains high and continues to grow. Between 2013 and 2015 the National Blood Collection and Utilization Survey (NBCUS) reported that although the total number of RBCs transfused dropped by 13.9% (Ellingson KD, *et al*., *Transfusion* 2017 S2:1588), the percentage transfused as Oneg increased from 9.7% to 10.8% (Sapiano MRP, *et al., Transfusion.* 2017 2:1599). Our own experience at the Red Cross seems to be even more stark and worsening, with our average distribution of Onegs for 2018 above 12.5 % while RBC utilization has been falling steadily yearly (see graph below). In fact, during the latter part of 2018, only 6 of our 78 regions across the country did not exceed their Oneg allotment, and 9 regions demonstrated a utilization rate of greater than 17%!	NO	The committee reviewed this comment and feels that the updates made to the standards in the 5.15 section, changes in chapter 1 (see standards 1.4 and 1.4.1) as well as the addition to subnumber 7 of standard 8.2 should be a positive step in the direction outlined in the request.

		The struggle to maintain an acceptable level of inventory and mitigate impact on patient care is getting increasingly difficult, despite proactive as well as real-time notification to hospitals regarding their utilization rate and other efforts by our Red Cross physicians and other team members to continually educate and provide information on evidence-based clinical guidelines on appropriate utilization of O negative RBCs. Moreover, the industry experience of excessive and sometimes inappropriate Oneg utilization is supported by a recently published article by the Collaborative on Biomedical Excellence for Safer Transfusion (BEST), which indicated that Oneg RBCs (or Group O in general) may still be over-utilized unnecessarily (Dunbar NM, et al., *Transfusion* 2018 Jun;58: 1348–1355). We are grateful to have had the opportunity recently to comment on the well-crafted draft of an AABB bulletin developed which addresses this significant problem of group O overutilization. We hope the helpful recommendations to both hospitals and blood centers will be well received by our professional community. We strongly support this endeavor although it is not clear how these may be translated into changes in practice. Without the addition of these recommended practices to Transfusion Services Standards, we suspect that they may not easily be adopted. We are writing to solicit AABB's leadership in this area, which is so vital to a sustainable blood supply, with collaboration and support from us and other key stakeholders. Some ideas we would like to propose for consideration is the creation of an *ad hoc* working group to focus on this topic. Top priorities for consideration may be to partner with The Joint Commission to augment hospital awareness and oversight on O RBC utilization. Since many hospitals still do not follow O utilization guidelines provided by the Choosing Wisely campaign, it may be helpful to engage the American College of Surgeons and Trauma Surgeons to advocate for more uniform O RBC utilization in trauma and emergent transfusions. ASBMT may be another group with whom to partner to standardize Oneg use in stem cell transplant patients. Finally, we would strongly support changes to the Transfusion Service Standards which hospitals are expected to follow utilization of rare blood products, such as Oneg RBCs and AB plasma, as part of their quality metrics. Currently, most blood centers track adverse events and product wastage but not specific types of product utilization. In conclusion, we appreciate AABB taking an important initiative this year to address a potential future medical crisis regarding the alarmingly		

		increasing use of Oneg RBCs. We look forward to AABB expanded their efforts to address this important issue.		
5.15.2.1	SC	NA	NA	The committee elected to add the clause, "…including during times of critical inventory levels." To the standard in conjunction with the creation of new standards 1.4 and 1.4.1 concerning operational continuity and the requirement to have a policy in place to address product inventory shortages.
5.15.3	SC	NA	NA	The committee elected to add a cross reference to standard 5.27.5 to this standard for clarity. Standard 5.27.5 requires that records indicate that the physician made a request for units whose compatibility testing was not complete due to the urgency of the situation.
5.15.3	RC	We have extremely rare low prevalence antibodies (i.e., anti-Jsa) that we will only use when the antibody is no longer demonstrating. AABB accredited transfusion services will point to this standard requiring us to use this rare antibody because the standard states that the units shall be antigen negative. Can an exception be made for these antibodies?	NO	The committee noted this comment but did not feel that a change was appropriate at this time. The committee will expand in guidance to ensure that what is requested by an assessor matches the intent of the standard.
5.15.3	RC	We have hospitals that are requesting typing of units with rare low prevalence antibodies (i.e., anti-Jsa) when the antibody is still demonstrating in their plasma. The IRLs do not want to waste this precious reagent and suggests to the hospital that crossmatching is appropriate; however, the hospital will refer to this standard requiring that the unit must be typed using the rare antisera.	NO	The committee reviewed this comment but felt it would be best served by discussing with the IRL Standards Committee. They will provide further guidance as will the BB/TS SC in their respective guidance documents.
5.16.2.1	RC	Should this specify the Laboratory Computer system has been validated?	NO	The committee noted this comment but did not feel that the addition would be appropriate. The committee points to standard 5.16.2 that already covers this, as do elements in chapter 3, Equipment.
5.16.2.1.1 (New)	SC	NA	NA	The committee created new standard 5.16.2.1.1 to ensure that facilities use FDA 510 (k) cleared blood bank laboratory information systems, and not "homegrown" software.

5.16.2.1.1 (New)	RC	We discussed this at length in our facility (which happens to be developing our own internal BECS system currently – ours will be 510(k) cleared, but it makes us very familiar with this whole process) My understanding is that FDA does not require blood banks to use FDA cleared blood bank systems unless they are going to market them or share them with another site out of state. So why should AABB be stricter than FDA on this issue? If we wanted to develop our own internal software and validate it for donor manufacturing purposes, FDA would be all right with that as long as we did not try to sell it or do other interstate commerce. Same should apply for transfusion service computer. See comment below from my colleague Shankar Goudar. 1) FDA does not 'approve' anything they simply issue 510(k) clearance. So, I think 'approve' need be replaced by 'clearance' 2) FDA does not prevent blood establishment using 'homegrown' software. They simply require that the 'homegrown' software development and maintenance must have followed verifiable 'design control' and 'quality system guidelines' 3) Lastly, 510(k) clearance is required only if a blood center wants to market the software or use it across state lines.	NO	The committee reviewed this comment and agreed with the rationale, however did not feel that a change was needed as the standard does not prohibit facilities from innovating, so long as they receive FDA clearance.
5.17.2.1	RC	Does this standard also apply to adult patients? What's the logic behind it? Most likely the benefit is to reduce the risk of misidentification and to identify the effects of transfusion elsewhere upon new admission. The same logic should also apply to adult patients. I think that a similar standard should be written regarding adult patients if this has not already been included elsewhere. This would answer questions such as: if a patient is discharged today and is readmitted tomorrow is the specimen from the previous day still valid for crossmatch? Exceptions are made for presurgical patients who were/are not pregnant or were not transfused in the 3 months prior to surgery. Their specimens are given 21 days from the date of collection to expire. They have a specimen drawn, leave the facility and can return on the day of surgery. But what about regular inpatients?	NO	The committee reviewed this comment but did not feel that a change was needed at this time.
5.19.3 (New)	SC	NA	NA	The committee created new standard 5.19.3 focused on the use of washed cellular products in the "selection of blood and blood components" section of the *Standards*.
5.19.3 (New)	RC	Why is this standard necessary?	NO	The committee feels that this standard is important because as cellular product is lost in

				washing that could affect potency and efficacy they want to ensure that individuals ordering these products have a specific policy for doing so.
5.19.7, #2 (New)	SC	NA	NA	The committee created new subnumber 2, requiring that the BB/TS have a policy regarding indications the use of cold stored platelets.
5.19.8 (5.19.7)	SC	NA	NA	The committee added to the title of the standard to read, "Patients at Increased Risk for…" for consistency and clarity. The intent of the standard has not changed.
5.19.8 (5.197)	RC	Transfusion Services that do not perform component modifications should not be required to have a SOP with instructions for Transfusion Service testing personnel to advise primary care providers how blood should be administered. Hospital/Nursing policies/procedures with clear instructions that explain how providers can manage these patients should suffice.	NO	The committee noted this comment but did not feel that a change was necessary. The committee feels that the language is proactive in what it is requiring of facilities.
5.19.8 (5.19.7)	RC	The terminology "patients identified by the ordering physician or other authorized health professional as being at increased risk of TACO" should be modified. These patients may be identified by the physician/authorized health care professional as being at increased risk of TACO but if this is not reported to the Blood Bank then the Blood Bank cannot respond accordingly. The term "patients identified and reported to the Blood Bank as being at increased risk of TACO" should be used instead. In addition, I think the standards should mention some minimum requirements instead of just recommending having a policy in place e.g. Transfusion of such patients should involve prior consultation with the Blood Bank medical director or designee (who must also be a physician).	NO	The committee noted this but did not feel that a change was needed at this time. The committee feels that the way the standard is written is clear in its intent.
5.22	SC	NA	NA	The committee updated the standard to require that a visual inspection of blood, blood components, tissue and derivatives occurs before issue.
5.22	RC	Why are you asking for a policy now instead of directly requiring that the task be done? Every time we back off on a requirement and ask for a policy or procedure instead, it weakens the requirement. What if my policy says I don't have to inspect?	NO	The committee noted this comment but did not think that a change was needed at this time. The committee notes that there has to be a record of the activity being performed and a protocol has

				to exist to show that the individual is aware of what they are looking for.
5.23, #7 (New)	SC	NA	NA	The committee added new subnumber 7 to be consistent with the requirements contained in standard 5.22.
5.23, #7 (New)	RC	It seems that in Standard 5.22 you are emphasizing the visual inspection of the product. Should part 7 under 5.23, also specify final VISUAL inspection of the product? I ask because the note says that item 7 was added to 5.23 for consistency with 5.22.	YES	The committee agreed with this comment and edited new subnumber 7 to require a final visual inspection of the product before issue.
5.23, #7 (New)	RC	This does not cover what is involved in the final inspection of the product. Is this the visual inspection described in 5.22? Recommend they reference the standard that describes what is included in the inspection of the product.	NO	The committee noted this comment but did not think that a change was needed at this time. The committee does not feel that a cross reference would be necessary in this case.
5.23, #7 (New)	RC	Suggest deleting this entry. This standard is focused on matching RECORDS against product labeling to make sure everything matches. The visual inspection happens in the previous standard. You aren't going to visually inspect, create a record of it, and then look to see if you just created a record.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the clause "final visual inspection" would cover this request.
5.25	RC/SC	Suggestion: The BB/TS shall ~~have a process to~~ confirm agreement of the identifying information, the records, the blood or blood component, and the blood product order ~~provider's product order~~. Discrepancies shall be resolved before issue. Rationale: "Provider's product order" sounds kind of weird. Who calls it that? Was there really a problem understanding what was meant in this standard all these years?	YES	The committee reviewed the comment and agreed with one of the suggestions. The committee removed the clause "provider's product order" and replace it with "product order." The committee feels that this provides greater clarity.
5.25	RC	It is unclear if the agreement should be confirmed using the product order from the treating healthcare personnel or the product order received by the blood provider.	YES	The committee noted this comment and agreed with its intent. The committee feels that the change as described in the row above would satisfy the request.
5.26, #4	SC	NA	NA	The committee added the term "visually" to subnumber 4 to remain consistent with changes to 5.22 and 5.23.
5.26	RC	Does the 30-minute rule still apply? Wasn't there a time when Blood/Blood Components had to be returned within 30 minutes and meet	NO	The committee reviewed the comment but did not think an edit to the standard would be

		the temperature requirement before being accepted back into inventory? The current standard mentions "'The appropriate temperature has been maintained." This makes sense if the Blood was sent in a cooler that has been validated for 4 hours and returns within the 4 hours. But what if a unit of Blood (which was not sent in a cooler) is returned one hour later and the temperature is within range? It might be possible that the Blood/Blood Component was cooled in an environment that was not approved for cooling Blood/Blood Components. It is also possible that the unit was left unrefrigerated (was out of range for some time) and then cooled just prior to being returned. I think some time limit should be mentioned in this standard. A time limit would reduce the risk of such problems.		appropriate. The committee notes that the "30 minute" rule is not something that is discussed in standards and suggests that individuals follow the requirements for storage, transport and expiration as detailed in reference standard 5.1.8A.
5.27.1.1, #3 (Deleted)	SC	NA	NA	The committee elected to remove subnumber 3 which required that patients be monitored for adverse effects as it related to the use of low titer group O Whole Blood. The committee felt that the removal was appropriate based on many published studies and hospital experience that have shown that additional testing for hemolysis was not necessary.
5.27.3	SC	NA	NA	The committee added a cross reference to standard 5.22.1 to standard 5.27.3 for clarity. Standard 5.22.1 indicates what is required to be included on a blood container.
5.28	RC	Under Standard 5.28 Administration of Blood and Blood Components, should there be added a standard for the first 15 minute post start, administration rate? And 15 minute post start vital signs? Which at this time are not required documentation by the AABB, should they not be?	NO	The committee noted this comment but did not feel that this change would be appropriate. The committee feels that the timeframe for monitoring should be defined and validated by the facility as to when vitals should be taken. Standard 5.29.1 was updated to require vital signed be performing during the transfusion (see below).
5.28.6	SC	NA	NA	The committee elected to edit standard 5.28.6 for clarity. The committee replaced the terms "observed" with "monitored" and "thereafter"

				with “post transfusion.” The intent of the standard has not changed.
5.28.7	SC	NA	NA	The committee added the clause, “…including emergency medical contacts…” as an element given to patients as a part of the specific written instructions post transfusion.
5.29	RC	After a blood transfusion is completed, two independent identification codes must be used to confirm the blood components and the recipient. Save the transfusion time and date if the data can be stored in the blood information management system.	NO	The committee reviewed this comment but did not feel that a change was needed at this time.
5.29.1	SC	NA	NA	The committee elected to edit standard 5.29.1 to expand when a patient is monitored for adverse events detected by vital sign changes during transfusion. This includes adding the clause, “…vital signs taken at facility defined intervals including…” and the inclusion of “during” transfusion being an element to monitor.
5.29.2	SC	NA	NA	The committee edited the verbiage of the standard for accuracy. In the place of the term “using” as it related to tissue, the committee added “responsible for the clinical application.”
5.29.2	RC	What about the order and consent for the tissue related procedure, pre and post procedure vitals and dimensions of the tissue if applicable (e.g. 10x15cm, 10x20cm etc.)? I think this information should be a part of the medical record as well.	NO	The committee noted this comment but did not feel that the change was appropriate. The committee feels that the requested change was too prescriptive.
5.30.2, #3	SC	NA	NA	The committee elected to replace the term “infant” with “neonate” for accuracy.
5.1.6A, #16 (New)	RC/SC	21 CFR 606.121(i)(3) states that the label for an autologous product must also state “Autologous Donor” and show the date of donation 606.121(i)(2). These should be added as required on the final container label (middle column).	YES	The committee agreed with this comment and have added a new entry to cover, “Phrase: Autologous Donor, if applicable” as number 16 in the reference standard.
5.1.6A, #22	RC	The statement “For autologous use only” is required only if the donor/recipient fails to meet eligibility requirements under 630.10 or if the donor/recipient has a reactive test result for one or more RTTIs (606.121(i)(5))	NO	The committee noted this comment but did not think that a change was appropriate at this time. The standards do not allow for the crossover of units, and it should be noted that autologous

				donors are usually handled in a manner different from allogeneic donors.
5.1.6A, #23 (New)	SC	NA	NA	The committee added new entry #23 which requires that the "Date of Donation" be included in the "Additional Autologous Labeling Requirements" section for clarity.
5.1.6A, footnote 6	RC	Footnote 6 is cited for labeling requirements other than historical antigen typing (ex. Number of units in pool, and autologous labeling requirements such as recipient name and identification number). It is recommended that AABB keep the current footnote which states, "The facility has the option of putting information on a tie tag or label" and creating a new footnote specific to the FDA Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen typing results.	YES	The committee noted this comment and agreed with the change requested. In the proposed edition, the committee had removed this footnote and replaced it with a new one (new footnote #7) and inadvertently deleted this requirement. The footnote has been reinserted into the table.
5.1.6A, footnote 7 (New)	SC	NA	NA	The committee added new footnote #7 which applies to the labeling of red blood cell antigens other than ABO and RhD to encompass facilities within and outside the United States. The footnote reads as such: "For facilities subject to US laws and regulations, FDA Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen typing results (December 2018) applies. For facilities not subject to US laws and regulations, follow Competent Authority, where applicable."
5.1.6A, footnote 13 (New)	SC	NA	NA	In conjunction with edits to standards 5.8.5. 5.8.6 and 5.8.7, the committee has added a requirement that "Zika NAT" be added to the Biohazard labeling requirements footnote.
5.1.6A, footnote 13 (New)	SC	NA	NA	In conjunction with edits to standards 5.8.5. 5.8.6 and 5.8.7, the committee has added a requirement that has added "Babesia NAT" to the "When performed" section of footnote 13 as it relates to biohazard labeling.

5.1.6, footnote 14	SC	NA	NA	The committee elected to replace the term “infectious diseases” with “relevant transfusion-transmitted infections” to the footnote to remain consistent with FDA language.
5.1.8A, title	RC	If you are removing language that applies to transportation from collection site to processing site, then please make it absolutely clear that this table only apples to transportation of finished products	YES	The committee noted this comment and have adjusted the entries where appropriate to ensure that this is understood.
5.1.8A, #1	RC/SC	Why is “cooling towards” being removed from the reference table if it is still allowed in Standards 5.6.5 and 5.6.5.1?	YES	The committee agreed with this comment and have removed the elements “cooling towards” and the clauses that read, “if intended for room temperature components then store at 1-6 C within 8 hours after collection.” These elements are already covered in standards 5.65 and 5.6.5.1 as noted in the comment.
5.1.8A, #3 (New)	SC	NA	NA	The committee created new entry number 3 focused on “Whole Blood Leukocyte Reduced” in conjunction with the creation of new standard 5.7.4.1.
5.1.8A, title between entry 3 and 4	SC	NA	NA	The committee added to the Red Blood Cell Components title, “Whole Blood or Apheresis Derived” to reflect the ways in which red blood cells may be collected.
5.1.8A, #11	RC	Column for Pooled Component, recommend using a footnote for referring to Pooled Platelets as pooled component that may contain RBC antibodies (as this does not apply to cryo).	NO	The committee noted this comment but did not feel that this change would be appropriate at this time.
5.1.8A, #12 and 13 (deleted)	SC	NA	NA	With the expansion of the title to this section the committee removed the entries for apheresis red blood cells and apheresis red blood cells leukocytes reduced as they were deemed redundant to entries #4 and #8.
5.1.8A, title between entry 12 and 13	SC	NA	NA	The committee elected to add the phrase, “The temperature range decided upon at the time of manufacturing shall be maintained,” which were removed from the “Additional Criteria” column

				and placed in the heading for clarity. A footnote with a reference to 21 CFR 640.24 which details the maximum storage times allowed by the FDA based on the original temperature decided upon storage has been added to the title as well.
5.1.8A, #14 (New)	SC	NA	NA	The committee added a new entry #14 which focuses on Platelets that are cold stored. The addition of this entry is based on standard 5.19.7, subnumber 2.
5.1.8A, #14 (New)	RC/SC	We recommend transport of Cold Stored Platelets be changed to 1-10 C to mirror red cells unless there are published/peer reviewed papers/research/data out there dictating the need for this more stringent temperature range for transport.	YES	The committee agreed with this comment adjusted the proposed transport temperature range of "As close as possible to 1-6 C" to the suggested 1-10 C.
5.1.8A, #14 (New)	RC/SC	The transport temp is "as close as possible to 1-6 C." Per 600.15(a), platelets labeled indicating storage between 1-6 C are shipped at 1-10 C.	YES	The committee agreed with this comment adjusted the proposed transport temperature range of "As close as possible to 1-6 C" to the suggested 1-10 C.
5.1.8A, #14 (New)	RC	Are there any manufactures requirements for cold platelets? Why not follow the FDA regulations?	YES	The committee reviewed this comment and noted that the footnote included with this entry references the bag manufacturer and CFR requirements.
5.1.8A, #14	RC	I believe agitation should be mandatory, not optional as is stated. The in-press article in Transfusion ("Platelets stored in whole blood at 4C: in vivo posttransfusion platelet recoveries and survivals and in vitro hemostatic function") by Slichter SJ et al clearly shows that end-over-end agitation is necessary to obtain platelet yields mandated by the FDA for platelet concentrates prepared from whole blood. When not subjected to end over end rotation during storage, these cold stored platelets suffered decrements in functional tests compared to their baseline or prestorage values.	NO	The committee noted this comment but did not feel that there is adequate evidence to make the change suggested at this time.
5.1.8A, #23 (New)	SC	NA	NA	The committee added new entry #23 focused on Apheresis Platelets Pathogen Reduced in conjunction with the creation of new standard 5.7.4.26.
5.1.8A, #23 (New)	RC	For entry 23, the maximum time without agitation should state 24 hours not 30 hours for Apheresis Platelets, Pathogen Reduced. The study, indicated below, documented in the journal Transfusion, support Apheresis Platelets	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee will continue to review the literature

		in plasma is the better medium to support a 30-hour maximum storage time without agitation and Apheresis Platelets Platelet Additive Solution (PAS) should have a maximum storage time without agitation of 24 hours. *Moroff et al. (2012). Comparative in vitro evaluation of apheresis platelets stored with 100% plasma or 65% platelet additive solution III/35% plasma and including periods without agitation under simulated shipping conditions, Transfusion, 52:834-843.* Please provide further clarification to support a maximum storage time without agitation of 30 hours for Apheresis, Platelets Pathogen Reduced.		to determine if changes are needed to other entries that have platelets in platelet additive solution.
5.1.8A, #27	RC	Cryoprecipitate (if collected in a closed system) should be allowed to be extended beyond 6hrs if used for fibrinogen replacement. (Std 5.1.8.A). This is now more critical with blood shortages and requirement for cryoprecipitate with massive transfusion protocols. And more importantly, there are several studies recently published showing potency (of fibrinogen) and safety when extending the expiration time – Sounder EP, et al. Blood Transfusion 2018;16(5)443-446. Green L, et al. Transfusion 2016;56(6):1356-61. Lokhandwala PM, et al. Transfusion 2018;58(5):1126-1131. Fenderson JL, et al. Transfusion 2019;59(S2):1560-1567.	NO	The committee reviewed the comment but did not feel that a change was needed at this time.
5.1.8A, #41	RC	21 CFR 606.121I(4)(iii) requires that the type of anticoagulant with which product was prepared must be on the label of Recovered Plasma. This is covered in line (3). It is recommended to repeat this requirement in this section.	NO	The committee reviewed this comment but did not feel that the change would be appropriate as suggested. The duplication of the requirement would be a massive change to the entire reference standard for little gain.
5.1.8A, #42 (New)	SC	NA	NA	The committee included new entry #42 focused on Plasma Pathogen Reduced in conjunction with the creation of new standard 5.7.4.26.
5.4.1A, #9	SC	NA	NA	The committee elected to edit entry number by removing all of the medications and associated deferral periods. The committee feels that the medication deferral list maintained by the DHQ Task Force should be the list of record. For each new version of the medication deferral list released by the DHQ Task Force, facilities will have six months to achieve compliance with the list.

5.4.1A, #9	RC	Please keep the list in the standards and use an association bulletin to update as needed. By using this approach, there is no chance for public input. Should there be? Also, the URL already doesn't work and you haven't even published yet. How will AABB actively notify each member facility that the list has changed. Publishing in a newsletter may not be good enough.	NO	The committee noted this comment but did not feel that reverting to the former language was appropriate. The ability for the *Standards* to maintain pace with the updates to that DHQ Task Force resulted in this section of the reference standard frequently being out of date.
5.4.1A, #14	SC	NA	NA	The committee added "Zoster Recombinant, Adjuvated (Shingrix) to the list of "Receipt of recombinant vaccine" list with no associated deferral period. This addition reflects the new vaccine's availability since the last edition of Standards was released.
5.4.1A, #14	RC/SC	I understand that AABB is an international organization, but since the only cholera vaccine available in the US is Vaxchora (a live vaccine), it should not be listed among those with no donor deferral.	YES	The committee agreed with this comment and added a new entry in the immunization and vaccinations section that reads: Vaxchora (live attenuated, non systemically absorbed, oral Cholera vaccine) There is no associated deferral period.
5.4.1A, #15	RC/SC	Term Relevant Transfusion-Transmitted Infections should include hyphen between Transfusion and Transmitted as stated throughout the CFR. This should be revised accordingly, e.g., "A history of a positive test result for Babesia, obtained from either a medical diagnosis or reactive donor screening test result – indefinite deferral, if testing for Babesia or PRT is not performed or 2 year deferral from the date of the positive test, if evaluated for requalification according to the recommendations in the guidance." **Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis – Guidance for Industry (May 2019)*	YES	The committee agreed with this comment and have since replaced the term "transfusion transmitted infections" with the more appropriate, "relevant transfusion-transmitted infections." The committee also agreed with the comment concerning *Babesia.* The committee replaced the former entry which required "A history of babesiosis" with "Reactive test for *Babesia.*"
5.4.1A, #15	SC	NA	NA	In conjunction with the additions made to standards 5.8.5, 5.8.6 and 5.8.7, the committee has added an entry concerning "Zika Virus" to the Relevant Transfusion-Transmitted Infections line in the edition. The deferral period sends users to the July 2018 FDA Guidance for Industry.

6.2.2	SC	NA	NA	The committee added cross references to standards 3.9.5 and 3.9.6 for completeness. The referenced standards address electronic records and data breach, both internal and external.
7.3	RC	This is very vague. Is there a standard setting organization (or two) that AABB considers competent to classify adverse events? What are their event classifications? Why not just specify a certain set of donor and patient event classifications – or else list the classification options that AABB deems acceptable?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the requested change to provide specifics would prove too restrictive. The committee will expand the guidance to assist users in the interpretation of the standard.
7.5.1.1, #2	RC	Who makes the decision to interrupt or discontinue the transfusion? A nurse?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. This requirement, to discontinue transfusion, is facility defined. The facility defines who is responsible for this, in some facilities it can be a nurse, in others another individual. The review is typically done and approved by the medical director.
7.5.1.2	SC	NA	NA	The committee revised the content and the way standard 7.5.1.2 is presented. The committee moved the beginning of clause #3, "The BB/TS shall be notified" to appear as subletter "a" under #3, subnumber 4 will now appear as subletter "b" and subnumber 5 will now appear as subletter "c." The intent of the standard has not changed and has only been updated for clarity.
7.5.1.2	RC	Who is making decision whether it is mild allergic or not? Mild allergic symptoms can be early sign of other type of transfusion reaction. Does this indicate that transfusion should not be interrupted in mild transfusion reaction? Who makes decision? Nurse? Who is making decision to report or not report to the blood bank	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The facility would determine who makes the call of the type of transfusion reaction and actions needed. . The committee will expand on this issue in the guidance as well.
7.5.1.2, #2	RC	This requirement is confusing and ambiguous. I discussed with the staff about it. It is not consistent with other description in the 7.5.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee will expand the guidance and assist users in the implementation of this requirement.

7.5.1.2 #4 (7.5.1.2, #3b)	RC/SC	I disagree with the standard relating to 7.5.1.2 because of item 4. Drawing a tube of blood from every patient is excessive and often unnecessary. These patients are (in the case of RBC transfusions) already anemic, and every drop of blood is important for them. It is also important to note that the treatment for EVERY transfusion reaction is supportive. Indeed, by the time the lab completes their workup and the pathologist has issued her interpretation, most patients have either been treated or have died. Thus, the tube is blood is drawn primarily for the purpose of determining the cause of a reaction – not, in most situations, for guiding patient care. Drawing blood from EVERY patient with a reaction (minus the allergic reactions) in the absence of a clinical need to do so in THAT patient is inappropriate, unfair, and harmful. I would much rather have the standard read that a tube of blood should be drawn in cases of suspected hemolytic transfusion reactions, or, better yet, after consultation with pathologists, blood bank, and clinical team. If we permit folks to use their clinical decision making skills to decide if a reaction is an allergic one or not, should we not allow them to use their clinical decision making skills to decide, for example, when a TACO reaction has occurred? Indeed, these types of reactions are often obvious. What good does a tube of blood do in a patient with TACO? I've heard it argued that a BNP could be obtained to help distinguish between TACO and TRALI, but the sensitivity and specificity of that test are insufficient to rely on it for diagnostic purposes. Is a BNP really the leg we want to stand on when demanding that blood be drawn from a patient? I think a much better test is rapid improvement with diuresis, *which will be started long before the BNP comes back and regardless of what the BNP value is.* Never mind the fact that the Standard does not specify what type of tube should be drawn for what precise purposes, leaving open the possibility of drawing a rainbow to cover all of them? We should make every effort to determine the cause of a patient's transfusion reaction. But in only one type of reaction (the acute hemolytic transfusion reaction) is the immediate drawing of blood necessary if we want to make a laboratory diagnosis. However, I would argue that even in those cases, we don't need a positive DAT to determine we transfused B blood into an A patient. We should certainly retest the patient in those situations, but does it have to be done *immediately*? Again, we are striving to learn what has happened, but let's not do it at the expense of patient safety. And I'm tired of hearing that a tube of blood is an insignificant amount of blood – that kind of attitude has led to lakes of blood being sent	YES	The committee reviewed and feels that the updated language in 3b which says, "The blood container (whether or not it contains any blood) shall be sent to the BB/TS with the attached transfusion set and intravenous solutions, when possible, is sufficient.

		down the drains over the years. We, the AABB of all people, should be aspiring to be better than that. So let's reword that standard to include language that incorporates shared clinical decision making. Almost all transfusion reactions can be accurately diagnosed based on such consultations. In the rare case when blood is actually needed from the patient, it almost always can be drawn after consultation has been completed. Requiring a tube of blood from every patient harms people and provides those individual patients almost no benefit. I will bring up a final point of harm – harm to caregivers in the form of wasting their time. One of the reasons that so few transfusion reactions are reported is that reporting them is so onerous. Rather than patting ourselves on the back by building really stringent standards (that don't really help patients), and then issuing citations when people ignore the said standards (for the good of their patients), why don't we acknowledge the obvious – perhaps people will report (for example) more TACOs if they don't' have to take time to make an already uncomfortable patient more uncomfortable by sticking another needle in them? As it is today, it's easier to give the patient Lasix and forget the reaction ever occurred. Finally, please don't try to tell me that the harm of drawing blood from every patient is outweighed by the benefit of (extremely rarely) saving someone based on the result of (whatever) lab test. I am unaware of any randomized controlled trials looking at this, so such a statement would be, at best, a guess. However, I can, with exacting precision, tell you how much a patient's hemoglobin will drop every time one draws a tube of blood. If we want to practice evidence-based medicine, we have no evidence to support the harm we are doing. I certainly acknowledge that sometimes good guesses are all we have, but, as I write about at length above, I'm not particularly fond of the logic behind the guesses.		
8.2, #7 (New)	SC	NA	NA	The committee elected to expand subnumber 7 to ensure that facilities are focused on the overuse of group O/O Rh (D-) red blood cells and AB plasma consistent with Association Bulletin 19-02.
8.2 # 7 (New)	RC	I think "including the use of group O/O Rh(D)-RBCs and AB plasma" is redundant. Appropriateness of use of Blood and Blood Components covers that. Blood Banks generally use O RBCs and AB plasma on patients of other types only if these products are about to expire and need to be used soon to prevent wastage. Otherwise they are used on patients of the same	NO	The committee reviewed this comment but did not think that a change was appropriate. The committee feels that highlight the overuse of these products is important, especially in light of the release of Association Bulletin #19-02.

		type and those of unknown types in emergency situations. Any Blood Bank doing otherwise would be incurring unnecessary costs.		
10.1.1, 10.1.1.1, and 10.1.1.1.1 (New)	SC	NA	NA	The committee added these standards concerning the hazards needing to be addressed around liquid nitrogen tanks based on a similar addition to the 9th edition of *Standards for Cellular Therapy Services*. These standards regarding liquid nitrogen concerns will be included in all sets of AABB Standards where appropriate.
10.1.1.1 (New)	RC/SC	Change the term "laboratories" to "locations" as LN2 tanks are not just in laboratories.	YES	The committee agreed with the intent of this comment and replaced the term "Laboratories" with "Blood banks and transfusion services…"