Significant Changes and Response to Comments Received to the 12th edition of Standards for Immunohematology Reference Laboratories
Please note that public comments that were submitted address the proposed 12th edition of IRL Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The program unit has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 12th edition of IRL Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that what appears below.

Standard	RC/SC	Comment	Change made?	Outcomes
1.1	SC	NA	NA	The committee elected to add a cross reference to standard 4.2 which covers agreements for completeness.
1.4	RC	I do not see where it is that a change in the quality representative requires notification, but in the records section, that documentation is required to be retained for 5 years	YES	The committee noted this comment and removed the term "quality representative" from entry #4 in reference standard 6.2A for parallel construction.
2.2B – In (New)	SC	NA	NA	The committee elected to add a new source of India in reference standard 2.2B for completeness. The new entry gives accredited laboratories one more opportunity to achieve the 65% threshold as required by standard 2.2.2.
2.2B – In (New)	RC	Adding the requirement for 1 source of anti-Inb and 1 source of In(b-) red cells to Reference Standard 2.2B Additional Resources can be problematic. Since this antibody and antigen negative red cells are only found in certain ethnic backgrounds, it is a difficult resource to maintain in areas that do not have a high population of that ethnic background and would rarely be needed in certain parts of the world without that ethnic population. There can be patient's that there is difficulty in finding blood such as Rh-46 etc. that are also found in certain ethnic populations but those antisera and antigen negative red cells do not appear as a requirement in standard 2.2B. Please clarify	NO	The committee reviewed this comment but did not feel that a change was needed at this time. It should be noted that this antisera being in reference standard 2.2B which only requires meeting the 65% threshold, and as a result, laboratories are not required to have this component. To the question of how the committee determines which elements are introduced into the two reference standards it is because it is available in the community, and during the last round of Standards creation, the committee conducted a survey of accredited laboratories to determine what they did and did not have as such the committee felt that this inclusion is at least representative of laboratories that are AABB accredited. If a laboratory has a resource that is not included in the chart, but would assist them in meeting the 65% threshold, the committee encourages those laboratories to share this with an AABB assessor or with the Standards committee so that they can evaluate if said

		why a particular antigen/antisera was added over another.		antisera should be included in a forthcoming version of the Standards.
2.2B – In (New)		I object to adding the requirement for 1 source of anti-Inb and 1 source of In(b-) red cells to Reference Standard 2.2B Additional Resources. While standard 2.2B requires you to only have at least 65% of the resources listed it appears that this was added because of the notoriety of the case of the child needing In(b-) blood and the world wide search for that blood. Since the antibody and antigen negative red cells are only found in certain ethnic backgrounds, it is a difficult resource to maintain in areas that do not have a high population of that ethnic background and would rarely be needed in certain parts of the world without that ethnic population . There are patient's that we have difficulty in finding blood for that are also found in certain ethnic populations but those antisera and antigen negative red cells do not appear as a requirement in standard 2.2B. What is the criteria for the addition of antisera and antigen negative red cells to Reference Standard 2.2B Additional Resources?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. It should be noted that this antisera being in reference standard 2.2B which only requires meeting the 65% threshold, and as a result, laboratories are not required to have this component. To the question of how the committee determines which elements are introduced into the two reference standards it is because it is available in the community, and during the last round of Standards creation, the committee conducted a survey of accredited laboratories to determine what they did and did not have as such the committee felt that this inclusion is at least representative of laboratories that are AABB accredited. If a laboratory has a resource that is not included in the chart, but would assist them in meeting the 65% threshold, the committee encourages those laboratories to share this with an AABB assessor or with the Standards committee so that they can evaluate if said antisera should be included in a forthcoming version of the Standards.
3.5.2, #4	SC	NA	NA	The committee added a new clause to subnumber 4 for completeness. The clause reads as such, "…and a determination if other equipment is similarly affected." This clause exists in the BBTS Standards which the IRL Standards wish to mirror in terms of quality language.
3.5.2, #4	RC	Please clarify if this standard pertains to a generic weakness/fault or, for example if a freezer malfunctions and the compressor needs to be replaced as a result of normal	NO	The committee reviewed this comment and felt that no change was needed at this time. The expectation for the committee is that if there is an issue with a piece of equipment, individuals will determine the cause and if the issue is something that could affect other similar pieces of equipment. This would exclude your normal

		wear and tear, do all freezers need to be checked?		wear and tear that occurs for equipment. The expectation is that laboratories must take action based on their finding, otherwise, the fix is made to the piece of equipment.
3.5.2	RC	My concern is the determination if other equipment is similarly affected part. This needs to be more specific. For example, if I have a centrifuge where the lid lock needs to be replaced due to every day heavy usage than do I also have to check other centrifuges of the same make and model or do I have to check all centrifuges in the site? And what kind of documentation and records need to be maintained for this. Or is this standard designed for other events besides repair/replacement of parts due to normal wear and tear. This could potentially require removing all centrifuges from service until inspected which would effectively shut down any testing or processing in laboratories.	NO	The committee reviewed this comment and felt that no change was needed at this time. The expectation for the committee is that if there is an issue with a piece of equipment, individuals will determine the cause and if the issue is something that could affect other similar pieces of equipment. This would exclude your normal wear and tear that occurs for equipment. The expectation is that laboratories must take action based on their finding, otherwise, the fix is made to the piece of equipment.
3.7	SC	NA	NA	The committee added a crossreference to standard 10.2.1.1 to standard 3.7. Standard 10.2.1.1 requires that liquid nitrogen safety standards be in place for accredited laboratories. Standard 10.2.1.1 was a new standard introduced in the 11th edition.
3.9.6 (New)	SC	NA	NA	Standard 3.9.6 is new to this edition and was added to remain consistent with the 32nd edition of BB/TS Standards. This requirement ensures that laboratories have processes in place to minimize the risk of internal and external data breaches.
3.9.6 (New)	RC	Recommend replacing “laboratory” in this standard to “laboratory or IRL”.	NO	The committee elected to use the term “laboratory” when describing what is being accredited for against this edition of Standards. The term “laboratory” is used throughout.
4.0	SC	NA	NA	The committee elected to replace the title of the standard (and chapter) with “Suppliers and Customers” from “Supplier and Customer Issues.” The term “issues” no longer felt appropriate or necessary in terms of the content of the standard and chapter.
4.3 (4.4)	SC	NA	NA	In line with the change to the title of the chapter and standard 4.0, the title of standard 4.3 (formerly 4.4) has changed from “Customer

				Issues" to "Customers." This ensures parallel construction with the rest of the chapter.
Former 4.3	SC	NA	NA	The committee moved former standards 4.3 and 4.3.1 to chapter 5, Process Control, where their placement makes more sense.
5.1.3 (4.3)	SC	NA	NA	The committee moved former standard 4.3 to appear as new standard 5.1.3 as it was felt that the content was a better fit in chapter 5.
5.1.3.1 (4.3.1)	SC	NA	NA	The committee, after deciding to move standard 4.3.1 to chapter 5 have expanded the requirement to include the following clause, "…as defined by the laboratory or IRL and/or manufacturer. Standard 6.1.3 applies." The addition expands the standard for clarity.
5.1.3.1.1 (New)	SC	NA	NA	Standard 5.1.3.1.1 is new to the 11th edition and was included to ensure that laboratories review package inserts when they receive new materials. This standard ensures that laboratories remain in compliance with the new or adjusted requirements. The crossreference to standard 5.1.1 in the standard refers to the standard focused on change control.
5.1.3.2 (New)	SC	NA	NA	The committee added new standard 5.1.3.2 for clarity and to ensure that the IRL Standards remain in conformance with current CLIA requirements. The new standard reads as such, "Where manufacturer's instructions are used as a standard operating procedure, any new or revised instructions that impact test results shall be reviewed and approved for use by the laboratory director."
5.1.3.2 (New)	RC	Please clarify whether the medical director is required to sign off on a revised package insert or if this a broader standard.	YES	When proposed, standard 5.1.3.2 did not have a focus of requiring the laboratory director to review manufacturer's instructions, merely requiring the medical director to do so. Based on this comment the change was made to ensure that the laboratory director was involved with this review.
5.1.3.2 (New)	RC	What constitutes "the basis for a procedure"? Many procedures are loosely based on the manufacturer's instructions for use of the product, kit or reagent; such as the number of drops to use, the length of spin times, centrifuge rpm speeds etc. Does this	YES	The committee reviewed this comment and based on it, they edited the standard from what appeared in the proposed version. The committee replaced the medical director review with the review being performed by the laboratory director. Also, the clause, "…that impacts test results…" ensures that the laboratory director

		constitute being used as the basis for the procedure? Is the intent of the standard to have the medical director sign off on revised package inserts? If my procedure states to follow the manufacturer's instructions for anti-D in the most current package insert, does that mean the medical director must approve any new or revised instructions in the package insert including minor verbiage changes and format changes without any substantiative changes to content or testing. This standard definitely requires clarification. The medical director in our facility approves all SOPs including the ones needed because of changes to a manufacturer's package insert that affect the testing, controls, interpretation or other substantive changes in the SOP. An IRL technologist accesses changed/revised manufacturer's package insert for changes that would affect any sops and documents that review and alerts management of the need for an SOP change. Would this practice meet the intent of the new standard?		does not have to be involved with slight wording changes as highlighted in the comment.
5.1.3.2 (New)	RC	Can you clarify, you are talking about changes the manufacturer makes to their instructions for use, and not changes the IRL makes to the instructions? (this is not clear, and we recommend clarification) If you are talking about changes the manufacturer makes to their instructions for use, we don't see the value of having the Medical Director review and approve the changes if we are obligated to use the material per manufacturer instructions. We're assuming you don't expect the	YES	When proposed, standard 5.1.3.2 did not have a focus of requiring the laboratory director to review manufacturer's instructions, merely requiring the medical director to do so. Based on this comment the change was made to ensure that the laboratory director was involved with this review. As noted above, the standard was updated to ensure that the change had to potentially affect test results to trigger a laboratory director review.

		Medical Director to review and approve all changes to package inserts, i.e. including minor changes to the instructions for use that don't affect the way the testing is performed?		
5.1.3.2 (New)	RC	Requesting a definition be added to the glossary and clarification on the term Medical Director cited in the standard. 42 CFR 493.1251(d) is cited as the reference for this standard – "Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use." In some larger institutions, the CLIA Laboratory Director and the Immunohematology Medical Director are not the same person. Manufacturer's instructions are followed per the package insert but the instructions may not be detailed out in an approved SOP, only the package insert referenced to follow. In this scenario, does AABB expect that both the CLIA Laboratory Director per the CLIA requirement and the Immunohematology Medical Director per the standard (if not the same person) would review and approve revised changes in FDA cleared reagents prior to being used in the Laboratory?	YES	The committee reviewed this comment but did not feel that a change was needed at this time. It should be noted that the CLIA medical director is different from the medical director included in the IRL Standards medical director. For questions concerning the medical director, please note the content of standards 1.1.1 and 1.1.1.1 which detail the requirements associated with an IRL medical director, and as it pertains to what is covered by the CLIA regulations, please reach out to the Centers for Medicare and Medicaid Services.
5.1.5.1 (5.1.4)	SC	NA	NA	The committee edited this standard (and other standards throughout this section) to divide the requirements included herein based on licensed and approved materials, reagents and antisera prepared by the laboratory, and finally tests developed by the laboratory. Standard 5.1.5.1 has been expanded to focus on FDA licensed or approved materials, by including the clause, "FDA licensed or approved" in the title and in the body of the standard.

5.1.5.1.1 (New)	SC	NA	NA	Standard 5.1.5.1.1 is new to the 11th edition and was included in the Standards to cover the instances where reagents used in the laboratory that do not strictly adhere to the manufacturer's instructions are covered. It should be noted that this is a common practice in reference laboratories.
5.1.5.1.1 (New)	RC	For "tested per laboratory or IRL defined procedures" is it sufficient to test controls or is a written procedure/SOP required to cover this standard?	NO	In this instance the committee notes that having a defined procedure in a laboratory for what should and does occur when you have a situation where it is necessary to perform an exception to the written procedure.
5.1.5.1.1 (New)	RC	Would this standard require a specific procedure with instructions on what to test in each instance of not following the manufacturers written instructions or is it sufficient to state that proper controls should be tested and medical or supervisory approval is needed if reagents are not used in accordance with manufacturer's written instructions? It would be hard to have specific procedures for every instance when a reagent might not be used in accordance with manufacturer's written instructions. Often times the way a reagent might need to be tested outside the manufacturer's written instructions occurs spontaneously because of a certain situation or patient case and there is not time to make an SOP change and get medical director approval before test results are needed.	NO	The committee reviewed this comment and noted in the cases where exceptions to existing policies occur, and in those cases, it is important to refer to standard 1.3.1. This is important to ensure that the exceptions noted take place with approval. This is especially in the case if this is a truly emergent situation and time is of the essence.
5.1.5.2, 5.1.5.2.1 (New)	SC	NA	NA	Standards 5.1.5.2 and 5.1.5.2.1 are new to this edition and were added for completeness. When reagents are prepared by a laboratory, the need to follow instructions or the literature is necessary to ensure the safest possible product. Examples of relevant publications would include the Technical Manual, Judd's Methods, Applied Blood Group Serology, and other published studies.

5.1.5.2.2 (5.1.4.2)	RC	The comma after "noncommercial" is unnecessary and the period preceding ")" should follow it. Recommend that the standard should read: Criteria shall be defined for the use and/or preparation of unlicensed reagents (e.g., noncommerical or expired).	YES	The committee agreed with this comment and removed the comma.
5.1.5.2.2.1 (5.1.4.2.1)	SC	NA	NA	The committee elected to replace the clause "…policy for managing…" with "…policy for the use of…" This change was made for clarity.
5.1.5.2.4 (5.1.4.5)	SC	NA	NA	In an effort to ensure the standard is not United States centric, the committee added the clause, "…or Competent Authority criteria established for licensed reagents." following "FDA."
5.1.6 (New)	SC	NA	NA	The committee created new standard 5.1.6, "Tests or Methods Developed by the Laboratory" for completeness. It should be noted that this standard does not reflect what the FDA refers to laboratory developed tests.
5.1.7 (New)	SC	NA	NA	The committee created new standard 5.1.7 for completeness. The standard ensures that laboratories document in the report presented the content covered in the sections above, including: 1) Testing is not performed in accordance with the manufacturer's written instructions. 2) Controls are not available. 3) A test created by the laboratory is used.
5.1.7 (New)	RC	Clarification requested if AABB considers in house prepared anti-sera used in testing to fall under 5.1.7, 3rd point scenario – a test created by the laboratory or IRL is used?	NO	The committee noted this comment but did not feel that a change was needed at this time. The content of this comment is best addressed in the standards above 5.1.7 that discuss the use in house prepared antisera and reagents, and not specifically test kits created and used by an IRL.
5.1.9.1.1 (5.1.5.1.1)	RC	We request clarification regarding whether a facility that is not yet labeling units based on historical information needs a written policy indicating the FDA guidance is not applicable.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. As the standard requires the existence of a policy, while you may not perform this labeling currently, your policy would state you do not have a policy for something you do not do and not a requirement to add one. This standard also serves to inform a laboratory's staff that they do not do something just that they are aware.

5.1.10 (5.1.6)	SC	NA	NA	The committee edited the content of this standard as a result of moving former standard 5.1.6.1 to appear as new standard 5.5 that appears at the end of chapter 5.
5.1.10 (5.1.6)	RC	Standard 5.1.10, in the Summary of Significant Changes, refers to “laboratory-defined stages”, but the complete proposed standards refer to “laboratory or IRL-defined stages.” Both should refer to “laboratory- or IRL-defined stages.”	NO	The committee noted this comment, and after consideration reverted to the language of “laboratory” as the catch all term for the facility where accredited activities are performed.
5.1.10 (5.1.6)	RC	Please clarify what aspects for blood and components would need to be monitored in the IRL.	NO	The committee reviewed this comment but did not feel a change was needed at this time. If a laboratory has blood and components present, then there would be a need to monitor them for all the expected reasons one would, including temperature, viability, appearance, etc. However in the case where a laboratory does not store or maintain blood or components in the laboratory then the requirement would not apply in this case and that would be indicated ahead of any assessment to AABB.
5.2	SC	NA	NA	The committee added new subnumber 3 which reads, “A combination of shipping at least 7 units to other par-ticipating laboratories through the ARDP and screening at least 500 donors for high-prevalence antigens.” This was added at the request of the American Rare Donor Program representative to the committee. This provides members to participate in a way that is a combination of subnumbers 1 and 2.
5.2	RC	In standard 5.2 and the glossary, it is recommended that “American Rare Donor Program” should be followed by “(ARDP)” to clarify the meaning of the abbreviation in the rest of the standards.	YES	The committee noted this comment and made the change accordingly.
5.2	RC	Maintaining compliance to this standard imposes a high cost on blood centers. We respectfully requests that the committee evaluate or consider a form of reimbursement as part of the national rare blood program.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. While the committee understands there could be a cost associated with compliance, however the committee feels that being an accredited IRL must require this participation.
5.2.1 (New)	SC	NA	NA	The committee added new standard 5.2.1 to this edition and is being included to ensure that the ARDP is receiving information on high

				prevalence antigen negative donors. This information has become vital for the program to continue to operate successfully. It should be noted that this standard would only apply for the 12th edition forward and would not require a retrospective look at donors potentially not included previously. The standard reads as such, "All laboratories shall register donors with a current or subsequent donation identified as lacking a high-prevalence antigen(s)."
5.2.1 (New)	RC	This standard is extremely onerous and would require a huge effort for tracking the paperwork. Donor center based IRL's are already required to submit at least 10 donors to ARDP on an annual basis. Standard 5.2.1 is vague and broad in scope and it does fit into the ARDP requirements for submission of rare donors which requires confirmation of common antigen types with 2 different sources and sometimes additional genomic testing to confirm the rare type. This will be a burden on the facility to ensure they are submitting all registered donors and to maintain evidence of such submission. This also creates a problem to verify that all donors are being submitted. How will this be tracked and how will it be found/documented/cited that the facility is not submitting all donors? This is also problematic submitting donors without their consent to be registered with the ARDP and some donors do not wish to participate. Please provide clarification for the standard and, if implemented, how this will be evaluated by an accessor.	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 need to applied retrospectively and that only going forward from the effective date of the edition. Tracking of this requirement will be through documentation between the laboratory and the ARDP. It should be noted that this standard only applies to donors with high prevalence antigens.
5.2.1 (New)	RC	Standard 5.2.1 poses operation challenges as both serology and molecular testing results are required in the same timeframe. Consider	NO	The committee reviewed this comment but did not feel that a change was needed at this time. At this time, there currently is not a time frame required outside of the 10 donors that are required to be registered annually with the ARDP.

		revising standard 5.2.1 and/or relaxing the requirements in standard 5.2.2.		As it relates to the requirement, the ask is for laboratories to submit information on high prevalence antigens as of the effective date of the 11th edition, April 1, 2022.
5.2.1 (New)	RC	This standard is extremely onerous and would require a huge amount of tracking and paperwork and donor center based IRL's are already required to submit at least 10 donors to ARDP on an annual basis. Standard 5.2.1 is very vague and broad in scope and it does not fit into the ARDP requirements for submission of rare donors which requires confirmation of common antigen types with 2 different sources of antisera and sometimes additional genomic testing to confirm the rare type. The ARDP sops require specific testing to confirm some donors lacking high prevalence negative antigens which can be costly for donor centers to perform and unless the donors meet these specific guidelines then the ARDP doesn't want the donors registered. Often times the donor unit or donor samples are no longer available for further testing to confirm the lack of high incident antigens by the time initial screening testing is complete. This would require tracking that donor and waiting for the next donation to complete testing and then keeping records of which donors have not been submitted. It would be a huge burden on a facility to ensure they are submitting all registered donors with a current donation and to maintain evidence of such submission. As an accessor, it also creates a burden to verify that all donors are being submitted, how will	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The goal of this standard is to ensure that high prevalence antigens are identified as those are the most difficult to fulfill and find. This requirement is about heightening awareness of the need to find more donors and to help identify these individuals. Note there isn't a number, nor is there a requirement to submit all donors. The committee in their interpretation would want to see that you are submitting some high prevalence antigens that come through and that you can either show that you have participated on a basis that meets the laboratory's abilities or that the laboratory while you have not, that there is documentation that efforts were made to search for high prevalence antigens.

		this be tracked and how will it be found/documented/cited that the facility is not submitting all of their donors? I would be opposed to having to submit donors without there consent to be registered with the ARDP and some donors do not wish to participate. How would this be evaluated by an accessor. In addition, this standard appears to favor some facilities over others. Often ARDP faxes are sent to facilities and only units from facilities that are within the Red Cross system will be accepted. My facility has offered many units for ARDP requests to rarely have them taken. It is more of a futile activity for us to be submitting our donors to ARDP when it appears as if only donors/ units from the Red Cross facilities are the ones that are actually being used/ scheduled for donation. It used to be that the charges for units acquired from the ARDP were higher for facilities that are not part of the Red Cross system. If this is still the practice, then that is unfair given IRL's have to be a member of ARDP to be able to access the donors and are required to participate through these standards but yet are charged more money. If the ARDP is having trouble operating, I don't know that the solution is for more restrictive AABB standards to be implemented.		
5.2.1 (New)	RC	Standard 5.2.1 needs re-wording. "All laboratories shall prospectively register donors with a current donation identified as lacking a high prevalence negative	YES	The committee reviewed this comment and based on the content, adjusted the language of the standard to match the comment submitted.

		antigens." Please remove "negative" at the end so it reads "lacking a high prevalence antigen(s)" instead of "lacking a high prevalence negative antigens"		
5.2.1 (New)	RC	We were previously exempted from registering donors as a hospital based IRL (5.2.2) due to HIPAA concerns from our legal department. We assume that the exception for hospital based IRLs will apply to the new standard 5.2.1 as well, correct?	NO	The committee reviewed this comment and noted that standard 5.2.1 does apply to all laboratories as written, not a specific subset. It should be noted that standard 5.2.2 is focused on specific donors and the requirements contained therein would allow for an exemption to be provided.
5.2.1 (New)	RC	Requesting a definition be added to the glossary in reference to "current donation" with clarification on the timeframe that is considered for a current donation. Also, is current donation considered to be their last donation in an institution's BEC system? The standard only references registering donors lacking high prevalence negative antigens. What about registering multiple common antigen negative donors? Also requesting additionally clarification on AABB's intent of the standard beyond ARDP receiving information.	NO	The committee reviewed this comment but did not feel that a change was necessary at this time. It should be noted that standards only apply prospectively from the date the edition becomes effective, in this case April 1, 2022.
5.2.1 (New)	RC	We see contradictions of purposed new standard 5.2.1 and the old standard that will still be present in the 12th edition as standard 5.2.2. Standard 5.2.1 requires we register all donors lacking a high prevalence negative antigens and 5.2.2 requires we register at least 10 donors. Requiring a laboratory/donor center to register all the donors as they find them creates more of a burden on the facility to ensure they are submitting all registered donors and to maintain evidence of such	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that standard 5.2.1does not apply to all donors. Standard 5.2.1 applies to donors with high prevalence antigens, and all laboratories must search for these donors. However if no such donors are to be found, then a laboratory would indicate as such to the assessor on site.

		submission. As an accessor, it also creates a burden to verify that all donors are being submitted, how will this be tracked and how will it be found/documented/cited that the facility is not submitting all of their donors? Final comment, this seems to favor some facilities over others. Often ARDP faxes are sent to facilities and only facilities that are within the Red Cross system will be accepted. My facility has offered many units for ARDP requests to rarely have them taken. It is more of a futile activity for us to be submitting our donors to ARDP when it appears as if only donors/ units from the Red Cross facilities are the ones that are actually being used/ scheduled for donation. The requirement of 10 donors is more of a feasible effort on the facilities part and easier on the accessor's part to ensure the centers are meeting the required standard.		
5.3.3	SC	NA	NA	The committee edited the title from "Procedures" to "Investigational Techniques" of the standard in an effort to ensure that the standard better reflects the content of the standard. The committee has also reshaped this standard to focus on investigational techniques moving away from procedures as many of the elements in the standard did not meet the regulatory definition of a "procedure."
5.3.3, #2 (5.3.3, #4)	SC	NA	NA	The committee edited entry #2 placing "Adsorption" as the content with "allogeneic and autologous" in parentheses. This change was made for clarity.
5.3.3, #3 (5.3.3, #5)	SC	NA	NA	The committee edited entry #3 by removing the clause "for antibody identification and adsorptions" which previously appeared as a part of subnumber 5 (in the previous edition). This change was made for clarity.
5.3.3, #5 (5.3.3, #7)	SC	NA	NA	The committee edited entry #5 by adjusting the standard to add the clause "…through molecular methods…" to the body of the entry,

				and removing the clause, “Molecular typing to…” The intent of the change is for clarity, but does not alter the intent of the standard.
5.3.3, #7 (5.3.3, #9)	SC	NA	NA	The committee edited the standard by removing the clause, “testing” from the standard for clarity.
5.3.3, #8 (New)	SC	NA	NA	Subnumber 8 is new to this standard and requires that the laboratory have processes for “Dilution.” This requirement is currently in place in most laboratories.
5.3.4 (New)	SC	NA	NA	In an effort to ensure clarity, the committee created new standard 5.3.4 focusing solely on procedures that would fall under the regulatory definition of what is and is not a “procedure.” These are the most common procedures found in laboratories accredited by AABB. Subnunmbers 1-4 and 7 are new to the edition and are being added for completeness. While submbers 4 – 6 have been removed from standard 5.3.3 and moved to be incorporated into standard 5.3.4. The standard reads as follows: **5.3.4 Procedures** The laboratory shall have the following procedures: 1) ABO group. 2) RhD typing. 3) Unexpected antibody detection. 4) Donor and patient red cell antigen typing. 5) Antibody identification. 6) Determination of antibody titer. 7) Direct antiglobulin testing. Standard 5.1.2 applies.
5.3.5, #4 (New)	SC	NA	NA	The committee added new subnumber 4 to standard 5.3.5 in conjunction with the creation of new standard 5.3.4. The standard reads as follows: **5.3.5 Antibody Investigation** The laboratory shall: 4) Evaluate the testing performed and determine the impact test results have on the final workup interpretation and recommendations, if provided.
5.3.5, #4 (New)	RC	Please clarify if the intent of the standard is to require IRL to assess all results and draw a conclusion.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The intent of the standard, is to assess the results from tests performed. In this case the laboratory provides the report based on the request from the individual

				requesting the test performed. Following that the test is performed, the report written and provided.
5.3.6 (New)	SC	NA	NA	Standard 5.3.6 is new to the 12th edition and was included per member and staff comments to allow accredited reference laboratories to exist outside of an accredited transfusion service. Because of a CMS rules interpretation compatibility testing is required as a part of proficiency testing, and as such without the inclusion of this standard, accredited IRLs would need to carry Transfusion Service accreditation as well, which many deem onerous and unnecessary.
5.5 (5.1.6.1)	SC	NA	NA	The committee elected to move this standard from where it previously appeared as standard 5.1.6.2 for clarity. The title of the standard has been changed from "Investigation" to "Results and Reports." The inclusion of the CFR (42 CFR 493.1291) was included for completeness.
6.0	SC	NA	NA	The committee added a reference to *42 CFR 493.1105 for completeness.
6.2.5.1	SC	NA	NA	The committee replaced the term "observed" to "performed" for clarity. This matches the terminology in the Standards for Blood Banks and Transfusion Services.
6.2.6	SC	NA	NA	The committee rewrote this standard for clarity. The standard now reads as a sentence as opposed to as a phrase; the intent of the standard has not changed.
6.2A	SC	NA	NA	The committee edited entries 14, 16, 33, 56, and 57 retention times from 5 years to 10 to remain in alignment with the BB/TS Standards. Every edition the committee receives queries from members as to the difference in retention times between the two sets of Standards and this adjustment should assist members.
7.1.1.1.1 (New)	SC	NA	NA	The committee added this new standard for completeness. The standard ensures that steps are taken to ensure that any components related to nonconforming products are evaluated to ensure that they pose no risk to a patient. The standard reads as such: **7.1.1.1.1** When a nonconforming blood component is identified, previously collected components, and other components associated

				with the nonconformance shall be evaluated, and their disposition determined.
9.1, #4 (New)	SC	NA	NA	The committee added new subnumber 4 for completeness. The requirement fills a blank spot that was performed in practice but not included in the standards. The requirement reads as such: **9.1 Corrective Action** The laboratory shall have a process for corrective action of deviations, nonconformances, and complaints relating to test reports and test services, which includes the following elements: 4) Implementation of corrective action(s).
10.2 (New)	SC	NA	NA	The committee included new standard 10.2 based on a similar standard in the Standards for Cellular Therapy Services. The requirement ensures that the environmental conditions in the laboratory are monitored, controlled and recorded. The standard reads as follows: **10.2 Environmental Monitoring** The laboratory shall monitor, control, and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. Standard 3.5 applies.
10.2.1	SC	NA	NA	The committee expanded standard 10.2.1 to provide additional information for clarity. Subnumbers 1 and 2 are new to the edition and read as follows: **10.2.1** Where liquid nitrogen is stored, specific hazards shall be addressed, including but not limited to: 1) Visible signage posted both inside and outside the storage space. 2) Ventilation and airflow adequate to the space where the liquid nitrogen is stored.
10.2.3.1 (New)	SC	NA	NA	The committee created new standard 10.2.3.1 for completeness. The standard ensures that oxygen sensors are installed per the manufacturer's instructions only. The standard reads as follows: **10.2.3.1**Oxygen sensors shall be installed per manufacturer's written instructions.