Response to Comments Received to the 9th edition of Standards for Immunohematology Reference Laboratories

Please note that public comments that were submitted address the proposed 9th 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. This document does not represent a full summary of significant changes to the 9th edition of IRL Standards. Guidance that appears with the 9th 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	Comment	Change made?	Outcomes
General, CFR references	AABB is increasingly an international organization, as such it seems inappropriate to reference American regulations or at least if one references American regulations, one should also put in language so that non American facilities are also considered. If AABB agrees with these standards with or without the CLIA requirements, and the references to CLIA requirements could just be listed as demonstrating that the AABB standards are consistent with such requirements for American facilities that would be more appropriate.	No	The committee noted this comment, and understands the concern. However, the committee feels that the inclusion of these references will assist the greater percentage of accredited laboratories in fully understanding what is required of them. It should be noted that standard 4.1.2.1 requires laboratory testing be done in a CMS certified laboratory in the US, thus allowing facilities outside the US some flexibility.
2.2	We suggest making the following edits to proposed standard 2.2: 2.2 Inventory Resources – The laboratory shall maintain an appropriate inventory of antisera, reagent red cells, and reagents for testing. Confirmation of reagent red cell phenotype, shall be performed by molecular testing for the following specificities: hrB-, hrS-, V-, VS-, U-, Do(a-), and/or Do(b-) ~~when available~~ **when possible**. If serologic testing is unavailable, molecular testing is acceptable as the sole method of determination of the following phenotypes: Hy-, Jo(a-), Js(a-), and/or Lu(a-) **or for other specificities if antisera becomes scarce/unavailable.** Using "**when possible**" would allow flexibility and also open the possibility for accepting molecular phenotyping as sole method for any other antiserum that becomes unavailable.	Yes	The committee noted this comment and agreed with the idea behind the addition of the second clause. To ensure that the standards remains flexible as more resources become available for molecular testing as approved by the American Rare Donor Program, the clause was adjusted to read, "**or for other specificities as defined by the current standard operating procedures of the American Rare Donor Program**." With regard to the first suggested edit, the committee elected to remove the clause "when available" entirely as it implied that these resources could be tested by another method, which is not the case.
2.2	As you know, we now have an approved molecular test that will determine the	No	The committee noted this comment but did

	phenotypes. It wasn't clear in the proposed Standards if a reference lab could use a laboratory developed test or unlicensed test in lieu of an approved test. Does this clarification need to be made?		not feel that adding a potential link to the forthcoming FDA regulations would be appropriate as they are not final at this time. Should a regulation become effective during the life cycle of the 9th edition, the committee will update the guidance in the Standards Portal.
2.2	Standard 2.2 could use some clarification in that it states that molecular testing can be the sole method for Hy-, Jo(a-), Js(a-) and/or Lu(a-). The prior sentence indicates that molecular testing is required or other antigens and it is unclear whether molecular testing is required for Hy-, Jo(a-), Js(a-) and/or Lu(a-). I think it should be made explicit.	No	The committee noted this comment, but did not feel that a change was needed at this time. If antisera is available, we suggest that you perform serologic testing.
2.2	The statement, "Confirmation of reagent red cell phenotype, shall be performed by molecular testing for the following specificities: hrB-, hrS-, V-, VS-, U- Do(a-), and/or Do(b-) when available" should be clarified to state newly frozen red cells and would not apply to previously frozen rare red cells currently in inventory.	No	The committee noted this comment, and as stated in the row above, if you have antisera is available to use, we suggest that your facility perform the appropriate serologic testing. It should be noted that the committee has crafted and published guidance to this standard (and most others) which are available in the 9th edition of Standards for Immunohematology Reference Laboratories now in the Standards Portal.
2.2A – P1PK/P1PK	Should subscript "1" be uppercase to match the Systems or Collection Name/ISBT Symbol column?	Yes	The committee agreed with this suggestion and the change was made.
2.2A – Cartwright	Should one of the "Yt" be removed to make consistent with the rest of the table?	Yes	The committee noted this comment and made the appropriate change, removing "Cartwright" and replace the identifier with "Yt/YT"
5.1.3.3	It is unclear whether this biennial assessment must be made of all the methods in use: group ABO, Rh, Rh phenotype, DAT, screening, identification and compatibility testing for red blood cells. Our immunohematology methods are validated and in use in laboratory for many years, therefore we would like to know how many samples will be necessary for these comparisons.	No	The committee noted this comment, and so long as you are meeting the requirements of the competent authority for your country, they feel that you will meet the intent of the standard. Concerning the number of samples to use to perform this comparison;

			that would be defined in each facility's standard operating procedures and then validated to ensure successful implementation.
5.1.5.4	We have understood that every time you use a non-commercial reagent it is required to report an identification code of the sample. Is this right?	No	The committee noted this comment and notes that as the commenter points out, traceability is what is being requested with this new standard. As long as a laboratory can link from the source of the reagent to its final disposition, they will remain in conformance with the standard.
5.6	Is a more appropriate reference for this standard, 42 CRF 493.1291(c)(7), in place of 42 CFR 493.1242(a)(7)?	No	The committee reviewed both citations and found that A7 discusses specimen acceptability and rejection, while C7 is focuses specifically on test report, disposition and acceptability of the criteria for the sample. The purpose in this case is to reference back to the sample and not the report. To reference the report would force laboratories to print out a full report at a time when that is unnecessary.
6.1.3	We suggest the addition of the words: "with significant changes" and the deletion of "when used" to allow some leeway in the standard so that the medical directors would not have to sign documents with minor non critical changes.	No	The committee noted that the cited code of federal regulations require that all lab policies, processes and procedures must reflect the director's modification or change, regardless of how minute or tiny. In common practice, a laboratory would not receive a nonconformance if they did not document or review the change of a phone number, addresses, etc. for a source or a misspelling of a simple word, however, a nonconformance could be given if you the spelling error in question could lead to an adverse event.
6.1.3	Since CLIA specifies that the Laboratory Director must perform this function (review	No	The committee reviewed this comment but

	and approval of new and revised documents before use), consideration should be given to add the CLIA medical director to this standard.		did not feel that a change was needed at this time. The committee feels that the added CLIA reference provides an important cross reference for users of the Standards, and as noted if a facility does not do business in the US they are not held to the standard set forth by CLIA or the FDA, merely their competent authority.
Chapter 7	While I don't disagree with removing "Adverse Events" from Chapter 7 and that an adverse event can result from a deviation, I would challenge that an adverse event can occur outside of a deviation. How do IRL labs handle the workup and investigation when they test a sample and prepare a blood product for distribution to a hospital that is then involved in a transfusion reaction? Who is ultimately responsible for the workup and investigation of that transfusion reaction? Shouldn't there be a policy to address these issues and it be defined in a section under Chapter 7. From a customer standpoint, as a medical director of a Transfusion Service I've been involved in this situation several times and it is not always clear who should handle the reaction workup. Also from a "standardization approach" shouldn't the Chapter title be similar across the different SPU? I would agree that deleting “adverse events” could potentially limit IRLs involvement. I’d certainly advocate to reintroduce the term if I could think of an example where an adverse event is <u>not</u> a deviation. As an example, an anaphylatic reaction and the patient has a peanut allergy. Did the donor consume peanuts? (not something IRL can solve) Donor consumes a bucket of fava beans – patient has hemolysis (still tough for IRL to solve) But any unexplained hemolysis may be something that is an adverse event and not a deviation. Unit is T-activated, expresses a significant rbc PNH clone, … a couple of things come to mind, Would DTL always detect T-activation(?), could a person be ‘healthy’ and have a PNH clone	Yes	The committee noted this comment, and agreed with its intent. The term adverse events has been re-introduced into the title of standard 7.0. and the clause has been placed in the standard as well, in the final sentence concerning notifications to outside agencies as required.