Response to Comments Received to the 11th edition of Standards for Immunohematology Reference Laboratories

Please note that public comments that were submitted address the proposed 11th 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 committee 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 11th edition of IRL Standards. Guidance that appears with the 11th 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
1.1.2.1, #1	Please provide examples of equivalent credentials. Also, please clarify if an international equivalent credential is acceptable in the US.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the guidance provides examples of international equivalence and the means to determine if an international degree would meet the standard. With regard to the second query the committee notes that if the international equivalent met US standards and was approved by a laboratory's human resources requirements then an individual with an international equivalent could serve in the supervisor role.
1.4 (New)	Please clarify the intent of the requirement to communicate to the AABB initial appointments and staffing changes for the laboratory supervisor(s) and quality representative. We recommend that this requirement for communicating laboratory supervisor(s) and quality representative be removed.	YES	The committee agreed with the intent of this comment and added the clause that if the laboratory supervisor is meeting the requirements contained in standard 1.1.2.1 they would not need to provide notice to AABB.

			They committee also removed the requirement that the quality representative be included in this standard.
1.4 (New)	Why is AABB requiring notification of staffing changes in IRLs and Relationship Testing Labs but not in other AABB standards? What gap is this standard attempting to fill? Additionally, how should these changes be made (via APEX, email, etc...)? We question the value that this standard would provide IRLs if implemented as is.	NO	The committee noted this comment but did not feel that a change was needed at this time. The rationale for the inclusion of this requirement in the IRL Standards is because (like the RT Standards) they have specific laboratory supervisor requirements that are different from what one would find in the BB/TS Standards for instance. The committee also requests that these changes be made in APEX as a first option and email as a second email.
1.4 (New)	We request the IRL Standards Committee reevaluate the scope of newly proposed Standard 1.4. While we recognize the efficacy of reporting medical director/designee staffing changes, we question the efficacy of reporting laboratory supervisor staff who already meet the criteria stipulated in Standards 1.1.2.1 & 1.1.2.1.1. We recommend that Standard 1.4 be reworded to only require reporting of laboratory supervisors who do not meet the qualifications outlined by Standard 1.1.2.1.	YES	As noted above, the committee updated the standard to only apply to the laboratory supervisor in the case where they do not meet the requirements covered by standard 1.1.2.1. The committee feels that the inclusion of a cross reference to standard 1.4 should address the concerns in the comment.
2.2	Does molecular confirmation of the listed specificities (would be better to replace “specificities” with the word “antigens”) apply only to reagent red cells identified by the IRL for in-house use?	YES	The committee agreed with this comment and replaced

	If this change is not limited to in-house panels, then this standard would result in major problems with use of commercial panel cells as very few are typed at the DNA level. As there are multiple ways to be hrB– or hrS– what level of testing is expected for this? The standard states that "Molecular testing is acceptable as the sole method of determination for these phenotypes". Thus, when determining the V, VS status of RBCs is it expected that laboratories will analyze the RHCE alleles (rather than rely on targeting a single nucleotide change) so as to be aware of alleles that silence or greatly reduce V/VS expression?		the term specificities with "antigen status." Based on the comment received the committee removed the sentence that the comment was referring to. The standard was reworded to allow for a laboratory to determine their best method for molecular testing
2.2.1	As the standard requires the laboratory maintain 100% of the resources listed in 2.2A we recommend that the word "Minimum" be removed from the reference standard title. We recommend the title be "Inventory Resources".	YES	The committee agreed with this comment and the change was made.
2.2.1	The table lists "Cartwright" as the name of blood group system 011. The name of this system is YT. This may be an opportunity to correct the name.	YES	The committee noted the error in the spreadsheet passed around and updated the sheet accordingly.
2.2.1	Though majority of the resources listed in Reference Standard 2.2A are commercially available, several are only available from a single supplier. Increasing the threshold to 100% does not allow tolerance in case of manufacturer backorder, production delay, or product discontinuation. Though many of these reagents may be formulated in-house in case of issues with procuring the supply commercially, some (such as Anti-IgG lacking an IgG4 specificity) cannot be readily manufactured by most laboratories. Due to the reliance on commercially available products, we suggest reducing the inventory resource threshold proposed in Standard 2.2.1 to 98% of the resources listed in Reference Standard 2.2A.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that the resources noted are rarely if ever not available and as such did not make the change.
2.2.1	How does increasing the threshold of minimum inventory resources increase the number of laboratories able to receive AABB accreditation?	NO	The committee reviewed this comment and feels that the adjustment of the reference standards based directly on feedback from the membership and laboratories seeking accreditation will allow the Standards to facilitate a broader audience,

			especially in other parts of the world.
2.2.1	The addition of P1 and Lewis substance to the 2.2A required resources list reagents seems inappropriate especially with a 100% availability requirement (standard 2.2.1). Although neutralization is a tool that can be used for antibody identification it currently is not a tool that is essential to resolve antibody cases. If this change was implemented our laboratory would have to purchase, validate and maintain a reagent that will never be used. P1 and Lewis antibodies can be accurately identified whether alone or in combination with other antibodies, without the use of P1 or Lewis substances. By adding these reagents to the required resources with the 100% availability requirement, it could be interpreted that the AABB IRL Standards committee is mandating how these common antibodies must be identified. If the committee feels strongly that substances should be listed as a resource either the percentage required for 2.2A should be modified to less than 100% or substances should be moved to 2.2B.	YES	The committee noted this comment and agreed with the note that both P1 and Lewis should be in reference standard 2.2B. The committee did not feel that moving away from 100% compliance for reference standard 2.2A was appropriate for this edition however.
2.2.2	Due to the addition of molecularly characterized red cells (and in some cases the removal of antigen negative red cells identified by serology alone, such as U-) to Reference Standard 2.2B, we expect many laboratories may initially fall below the proposed 65% threshold. We propose a continuation of the 50% threshold through the 11th Edition of the IRL Standards to allow laboratories time to update their inventories with red cells characterized by molecular methods.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee did a thorough review of what resources facilities had on had and what was commercially available at the time of the publication of this draft.
2.5 (Deleted)	If resource sharing is not a requirement, why is a policy needed?	YES	The committee agreed with this comment and elected to delete the proposed standard which would have required that laboratories have a policy for responding to requests for resource sharing. The committee will enhance guidance to include this concept as an element contained therein.

2.5 (Deleted)	Why do we need a policy to respond yes or know to someone? In our experience, most of these types of requests come in as friendly emails or SCARF requests. I'm not sure what purpose having a policy is going to serve. our manuals and vaults and cabinets are getting too full as it is. this doesn't seem like a worthwhile item to spend time drafting and having to review/revise every 2 years.	YES	The committee agreed with this comment and elected to delete the proposed standard which would have required that laboratories have a policy for responding to requests for resource sharing. The committee will enhance guidance to include this concept as an element contained therein.
2.5 (Deleted)	If there is no requirement to share resources then why is a policy needed? The term resource sharing is too broad and needs to be defined. Is this referring to policies, reagents, antisera, products or everything??	YES	The committee agreed with this comment and elected to delete the proposed standard which would have required that laboratories have a policy for responding to requests for resource sharing. The committee will enhance guidance to include this concept as an element contained therein.
2.5 (Deleted)	We appreciate that the committee is promoting sharing of rare recourse among IRLs. However, as a smaller IRL that is not associated with a large blood center we wonder who will facilitate sharing of reagent red blood cells with known genotypes example: RHCE*ce733G733G? Will sharing be facilities by AABB or will IRLs be encouraged to use SCARF?	YES	The committee agreed with this comment and elected to delete the proposed standard which would have required that laboratories have a policy for responding to requests for resource sharing. The committee will enhance guidance to include this concept as an element contained therein.
2.5 (Deleted)	Please clarify which type of resources are intended by this standard. The comment from the committee “The committee created new standard 2.5 to encourage laboratories to share	YES	The committee agreed with this comment and elected to

	resources, however it is not a requirement to do so." implies this standard may be strengthened in a future edition of Standards in order to require the sharing of resources. Please be aware that due to legal constraints, some facilities may be unable to share biological resources.		delete the proposed standard which would have required that laboratories have a policy for responding to requests for resource sharing. The committee will enhance guidance to include this concept as an element contained therein.
2.2A	We recommend the AABB Standards Committee separate EDTA glycine acid (EGA) apart from Chloroquine diphosphate to clarify their distinct testing applications.	YES	The committee agreed with this comment and separated the two concepts into two separate lines in the table.
3.92.2 (3.8.2)	During the merger of two hospital systems, I was shocked to hear that there is more than 1 IRL who does not utilize a patient database for IRL testing and work. Standard 3.9.2 allows for this: An alternative system that ensures continuous operation shall be available in the event that computerized data and computer-assisted functions are unavailable. The alternative system shall be tested at -defined intervals. Processes and procedures shall address mitigation of the effects of disasters and recovery plans. I think it is time for IRLs to move forward and be required to use a computer system to house antibody ID info. Most of them have a computer system for Transfusion Services anyway. Would you please bring this back to the group for discussion?	NO	The committee noted this comment but do not feel that it is in their purview to mandate that all hospitals have a patient database.
5.1.2.2.1	Proficiency testing is regulated by the Centers for Medicare and Medicaid Services. The AABB IRL Standards define Proficiency Testing as "The structured evaluation of laboratory test results that encompass the suitability of processes, procedures, equipment, materials, and personnel." Due to the discrepancy of the definition between AABB and CMS and considering AABB is not a CLIA approved provider of proficiency testing programs, we recommend revising this standard to clarify samples sent by AABB for the purposes of continuation of AABB Accreditation are not proficiency samples as defined by CMS. This disambiguation would be beneficial to the membership, as some facilities apply CFR493 Subpart H and CFR493 Subpart I to the testing of AABB proficiency testing samples.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee felt their definition of proficiency testing was appropriate, but will expand the guidance to ensure that it is understood.
5.1.4.1	It would be helpful if the committee could add further guidance to the standard portal for standard 5.1.4.1. There is confusion among IRL assessors and laboratories about this standard specifically if the standard requires the IRL to perform antigen testing on expired manufactured panel cells when the cell is used to rule out. The guidance for standard 5.1.4.2 is very helpful with regards to this situation.	NO	The committee appreciates this comment and will add guidance to this edition as it relates to standard 5.1.4.1.

5.1.5.1.1 (New)	Since the FDA guidance states that in order to be labeled a donor must have 2 historic/licensed typings on file, could the standard be more specific to read, "The laboratory shall have a policy for the labeling of red blood cell units with historical antigen typing results when the laboratory is capable of capturing the appropriate historical typings." I feel this way, the lab needs to show that they are capable of capturing this specific data. In our lab, we are able to capture historical typings, however, we cannot capture "2" historical licensed typings and I feel it creates confusion when the wording only says historical typings.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the reason to highlight the FDA Guidance along with the standard ensures that laboratories reference it when determining their courses of action.
5.2	The laboratory shall participate in the ARDP system. Perhaps a better choice would be to leave it open for the IRL to use another means of networking for RARE donor inventory. The reference lab should be able to participate in a network but not be restricted and required to be a part of ARDP.	NO	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee continues to feel that the ARDP provides the best opportunity for laboratories to acquire and share rare units.
5.3.1.1	Please clarify what the expectation is if weak or mixed-field red cell typing cannot be resolved? For Example – The sample is from an outside institution and the laboratory is unable to confirm transfusion.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that example provided would be included as part of the history. The guidance to this standard will be supplemented to address these and other situations.
5.3.1.2	Requiring resolution of ABO discrepancies when there is a "potential to affect the ABO interpretation" is vague. Does this only apply to Anti-M as this change was initiated after IRL Proficiency sample 2018-2 where 71% (47 of 66 labs) IRLs did not perform ABO testing using M antigen negative cells yet obtained the intended ABO type? If this change is not specific to anti-M will IRLs be required to perform cold panels on every sample regardless of clinical indications? Is it appropriate to perform and bill for testing that does not improve patient care?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee has shared this information with the IRL accreditation

	As all new allogenic antibodies start as IgM will the standards committee define when there is a potential to affect? If "potential to affect" is not defined by the standards committee will volunteer IRL assessors be able to accurately and appropriately assess against this standard?		committee and will also include further guidance to assist users in the standard's implementation.
5.3.1.2	Routine ABO/Rh typing does not typically include a screen for antibodies reactive at the immediate spin phase of testing. This standard may be interpreted to require this testing in order to result blood typing, otherwise reactivity in the plasma that has the potential to affect the ABO interpretation is unknown. Please clarify if this standard is intended to require an investigation of potential reactivity that may affect the ABO interpretation prior to reporting a blood type, or if investigation is warranted only if such reactivity is observed in other routine testing. Further, please clarify if this standard is intended to require laboratories to perform adsorption studies for patients with cold autoantibodies reactive at immediate spin phase and/or repeat reverse typing with antigen negative A and B cells for patients with identified alloantibodies. Current standards require unexpected or missing typing be resolved unless justified by history or previous testing. Reactivity in the plasma that has the potential to affect the ABO interpretation is currently required to be resolved by this standard, unless the patient's blood type is O and the patient is known to have an antibody that could impact the reverse type. As proposed, revision of this standard creates a requirement for additional cost with little increased value to the patient. We propose to maintain the current 5.3.1.2. However, if there is strong desire to specifically require laboratories to address immediate spin reactivity, we propose rewording this standard to "The laboratory shall recognize and have a process to investigate reactivity in the plasma that has the potential to affect the ABO interpretation."	YES	The committee agreed with the intent of the comment and brought back some language from the 10th edition while editing the updated language based on the comment.
5.3.2, #9	I would like to suggest to the committee to please re-evaluate the relevance of the requirement for all AABB IRLs to have serologic capabilities to perform Polyagglutination studies when there is no longer any lectin panels available commercially for purchase and making a lectin panel is not always feasible or possible for all participating AABB IRLs. As an AABB IRL Assessor I know this has been a struggle to be met by most AABB IRLs.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee will update the guidance to assist users in their implementation of the standard.
5.3.3, #9, 10 (New)	The addition of inhibition/neutralization to the required procedures seems unnecessary at this time, as neutralization is not a tool that is essential to resolve antibody cases. The addition of neutralization to the list of required procedures would require our laboratory to develop and maintain a process that would not be utilized for serologic cases. If in the future there is an interfering substance that can best be overcome by neutralization then adding neutralization as a required serologic capability at that time would be reasonable.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that these two procedures should be in evidence as a possibility to fall back on if necessary.

5.4.2 (2.3)	Please clarify what the “policy for the management of allele determinations for RHCE variants” means? What is the intent of this standard? Can you provide an example of how a laboratory could manage allele determinations?	YES	The committee reviewed this comment and agreed with the query. This standard applies to RH and other variants. The committee will update the guidance to assist users in their implementation of the standard
5.4.2 (2.3)	We recommend the AABB Standards Committee clarify that Standard 2.3 applies to reagent red cells. As drafted, it is not clear that Standard 2.2 Inventory Resources is applicable to the requirement for a policy. We recommend the standard be reworded to include reagent red cells and or a note be included that standard 2.2 applies.	YES	The committee noted this comment and felt that the change to standard 2.2.2 would satisfy this request.
10.2.1, 10.2.1.1	We recommend the systems proposed include a requirement for an audible oxygen alarm in the immediate area of liquid nitrogen storage to alert employees (including non-laboratory personnel) and emergency responders of the immediate danger of low oxygen levels. As written, the standard does not require this alert to those who may respond in the event of an alarm, representing a significant hazard to untrained personnel and emergency responders. We recommend strengthening the standard to include other areas (not just areas of liquid nitrogen storage) where individuals are at a reasonable risk of exposure to low-oxygen environments, such as unventilated areas where dry ice may be stored. Please clarify if this standard applies to facilities where liquid nitrogen is stored on-site, but not used by or contained in the area of the accredited laboratory.	NO	The committee reviewed this comment but did not think a change would be appropriate at this time. It should be noted that assessors would not review an area of a facility that was not being assessed.
10.2.1.1	We've looked into the need to monitor O2 in the past, but our QM and safety committee decided that the lab doesn't qualify as a "confined spaced" per OSHA, and because of that O2 monitoring is not required. According to OSHA, O2 (or environmental monitoring for hazardous atmosphere) is only required if the gas is stored in a confined space. According to OSHA a "confined space" means a space that: (1) Is large enough and so configured that an employee can bodily enter and perform assigned work; and (2) Has limited or restricted means for entry or exit (for example, tanks, vessels, silos, storage bins, hoppers, vaults, and pits are spaces that may have limited means of entry.); and (3) Is not designed for continuous employee occupancy. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9797 I don't see "confined space" in the standard. I'm curious if this standard is intended to be in line with the OSHA regulations, and if so, is O2 monitoring only for labs storing N2 in confined spaces such as a small storage room?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that the safety of individuals working in the laboratory is of paramount concern. The committee also points out that these requirements appear in the CAP checklist.

10.2.1.1	We recommend the AABB Standards Committee consider adding clarifying language that actions taken should mitigate the risk to personnel and facility. As currently written the language indicating “action to be taken” is ambiguous and does not address risk mitigation.	NO	The committee reviewed this comment but did not feel that a change would be appropriate at this time. The committee will provide guidance to assist users in their implantation of this standard.