Response to Comments Received to the 10th edition of Standards for Immunohematology Reference Laboratories

Please note that public comments that were submitted address the proposed 10th 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 10th edition of IRL Standards. Guidance that appears with the 10th 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
1.3.1 (New)	RC	We propose adding "or designee" to the standard, similar to CAP wording.	No	The committee reviewed this comment and elected not to change the language of the standard. The standard is in line with CLIA regulations which require that the exceptions be signed by the Medical Director who is on the CLIA license.
2.1.1	RC	The CT Standards contain this standard: CT 2.1.1 Job Qualifications - The facility shall identify qualifications for each job position on the basis of education, training, and experience. Should it be included in the IRL Standards?	No	The committee reviewed this comment, but felt that the language that exists in this standard which is in line with the *Standards for Blood Banks and Transfusion Services* was more appropriate.
2.3 (New)	RC	Please clarify, what does "plan for implementation" exactly mean for determination of RHCE variants? Is it the intent that each IRL will implement testing for these variants?	No	The committee reviewed this comment and noted that this will be further articulated in guidance. However, in response to the comment, all that is needed is a plan to get ready for implementation of performing these determinations potentially in the next two years. Like ISBT 128 implementation this is the first step towards implementation.
2.2A, 2.2B	RC	The inventory levels required should be revised to allow smaller reference laboratories that wish to be accredited be able to meet the standard. The Accreditation department has been in touch	No	The committee has reviewed this comment and will not be

		with several smaller reference laboratories that wish to become accredited but are unable to meet the inventory levels required by this standard I would like the committee to revise this standard to allow the IRL Standards to be more readily adopted by the IRL community to raise the level of quality and patient safety for all reference laboratories.		adjusting the percentages at this time. However AABB is exploring the possibility of activity levels being incorporated into future editions of the Standards for Immunohematology Reference Laboratories, much like what exists in AABB's *Standards for a Patient Blood Management Program.*
2.2A, 2.2B	RC	Is the intent that vials be labeled following ISBT terminology? Would the current inventory need to be relabeled if that is the intent?	No	The intent of the standard is to use ISBT terminology on all labels from the date of implementation of the 10th edition. Standards are not retroactive and are not applied for reagent vials already in inventory.
2.2A, 2.2B	RC	Does this change only apply to the labeling and naming of newly acquired resources in 2.2A and 2.2B or is this a requirement to label and name prior acquired resources using ISBT terminology? We request that consideration be given to only requiring new resources be identified in this way with previously labeled and stored resources not requiring relabeling which would be an exhaustive task and potentially put these resources at risk.	No	The intent of the standard is to use ISBT terminology on all labels from the date of implementation of the 10th edition. Standards are not retroactive and are not applied for reagent vials already in inventory.
2.2B	RC	My proposal is to consider recombinant blood group proteins as complementary reagents for detection and identification of RBC antibodies. Using these recombinant proteins it would be much easier for laboratories to maintain the resources listed in Reference Standard 2.2A and 2.2.B. The proteins are widely used in reference laboratories in central Europe and are CE-marked. For more information, please, refer to: 1) imusyn.com 2) Seltsam A et al. Recombinant blood group proteins facilitate the detection of alloantibodies to high-prevalence antigens and reveal underlying antibodies: results of an international study. Transfusion. 2014 Jul;54 (7):1823-30	No	The committee did not feel it was appropriate at this time to make such a large change without member input. The committee will continue to evaluate this information and will consider this change for the 11th edition.
3.6	RC	Chp 3 IRL IRL	No	The committee noted this comment but did not feel that

		3.6 If storage devices utilize liquid nitrogen, either liquid nitrogen levels or temperature shall be monitored. There shall be a process in place to ensure that action is taken if liquid nitrogen reaches an unacceptable level. 3.7.2 The alarm system in liquid nitrogen freezers shall be activated before the contained liquid nitrogen reaches an unacceptable level. Versus <u>Chp 5 CT</u> 5.11.2 Storage devices shall have the capacity and design to ensure that proper temperature and/or liquid nitrogen level is maintained. 5.11.3 Storage devices containing cellular therapy products and critical materials shall have a system to continuously monitor and also record at defined intervals the temperature and/or liquid nitrogen levels. In CT the standard for liquid nitrogen level and temperature is much stricter. Why do we not require such monitoring and recording for IRL?		a change was needed at this time. Such a change would require that some accredited immunohematology reference laboratories would have to purchase brand new equipment to meet this standard which would not be appropriate at this time without the ability to comment from the membership. The committee will consider this for the 11th edition
3.7.2 (New)	RC	Are non-electronic liquid nitrogen tanks included or does this standard only apply to liquid nitrogen freezers with alarm systems? Is it required to add alarms to existing manual liquid nitrogen monitoring systems that do not currently have such alarm systems? This may be overly burdensome for facilities with only non-electric liquid nitrogen tanks.	No	The committee noted this comment but did not see a change needed. This standard will be further explained in the Standards Portal. It should be noted that this standard does not require laboratories to purchase electronic liquid nitrogen tanks, merely that if a facility has one that they must follow this standard
5.1.3.3	RC	Please add a CFR reference to the standard, specifically 42 CFR 493.1281.	No	The committee reviewed this comment but did not think this addition was needed at this time. The standard as written meets the requirement cited in the regulation and therefore would be redundant.

5.1.5.3	RC/SC	Please move the words "for noncommercial antisera" to the beginning of the standard. **5.1.5.3** <u>For noncomerical antisera</u> ~~T~~the laboratory shall ensure that the source, ABO group, antibody specificity(ies), and reactivity phase can be identified ~~for noncommercial antisera~~.	Yes	The committee agreed with the suggested change.
5.1.5.4	RC/SC	Please move the words "for noncommercial red cells" to the beginning of the standard. **5.1.5.4** <u>For noncommercial red cells</u> ~~T~~the laboratory shall ensure that the source, ABO group, phenotype, and/or genotype can be identified ~~for noncommercial red cells~~.	Yes	The committee agreed with the suggested change.
5.2.1 (5.2, #2)	RC	Will the ARDP requirements be revised regarding the demographics information they currently require? Our facility does not allow the release of even the partial demographics information required by ARDP.	No	The committee notes that the ARDP does not require demographic information be retained, only the identifying number and phenotype.
5.2.1 (5.2, #2)	RC	The IRL at ARUP is considered a donor center based laboratory by ARDP however neither the donor center or the products they collect are licensed by the FDA. The donor center is a registered center because we only supply the local university hospital system and do not have collection capacity sell products to local or out of state facilities. The ARUP IRL does not do any compatibility testing, donor unit testing, processing or distribution. Almost all the centers requesting products through ARDP will not accept our products because they are not licensed. We have had two cases recently where we had liquid products available but the requesting facility would not accept them because they are not licensed. Requiring us to register donors with the ARDP when the transfusion facility that use ARDP will likely not accept the products form these donors seems unproductive.	No	The committee noted this comment but did not feel a change was needed at this time. The committee notes that if the facility is not performing donor antigen testing, then it should be assumed that no antigen negative products would be issued.
10.1	RC	Why is there no mention of environmental controls in IRL?	No	The committee noted this comment and feels that this is covered broadly in standard 10.1
10.2	RC	Why is there no requirement for Liquid nitrogen safety? We already mention that IRL facilities may have LN2 storage capacity in chapter 3 – but no mention of LN2 or oxygen safety requirements.	No	The committee noted this comment but did not feel a change or addition was needed at this time. The committee feels that this is already covered by standard 10.2.