Significant Changes and Response to Comments Received to the 13th edition of Standards for Immunohematology Reference Laboratories

Please note that public comments that were submitted address the proposed 13th edition of Standards for Immunohematology Reference Laboratories (*IRL Standards*), and not the final version. The IRL Standards Committee has elected to make the substance of public comments that were submitted a part of this document. Guidance that appears with the 13th 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 (12th edition)	Significant Change (SC)/Response to Comment (RtC)	Comment	Change made?	Outcome
General	SC	NA	NA	The 13th edition of Standards for Immunohematology Reference Laboratories incorporates AABB's updated Quality system essentials. (QSEs). The updated quality system essentials. include the following updates: • All standards are written in the active voice. • Once a requirement has been stated, it is not repeated. • Each chapter begins with a description of what the standards therein cover. • Each chapter contains a list of key terms that relate to the content of the chapter, with their definitions. • Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site assessment; however, this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only. • Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table still exists at the end of Chapter 6.

1.1.2	SC	NA	NA	The committee elected to update standard 1.1.2 for completeness and to respond to member requests. Understanding that most laboratories have multiple supervisors, the committee wanted to ensure that the reading of the standard applied to the one individual who has this responsibility, and not all individuals who have this title. The committee noted that there is typically one supervisor who serves as the leading individual in this role. The updated standard reads as follows: **1.1.2 Supervisor Qualifications and Responsibilities** The laboratory shall have an individual (hereinafter referred to as a supervisor) who is responsible for all aspects of immunohematology testing and services and who is qualified by education, training, and/or experience.
1.1.2.1.1	SC	NA	NA	The committee added a CLIA reference to standard 1.2.1.1 for clarity. This CFR provides specifications of what a technical supervisor must have to meet the requirements of this standard. The standard reads as follows: **1.1.2.1.1** When the individual does not possess one of these qualifications, * exceptions shall be considered on a case-by-case basis by the Immunohematology Reference Laboratory Accreditation Committee. *42 CFR 493.1449(q).
1.1.2.1.1	RtC	1.1.2.1 lists 3 acceptable qualifications for supervisor. CLIA Technical Supervisor qualification is not required by this standard. Standard 1.1.2.1.1 places the asterisk after "...possess one of these qualifications*," which adds the Technical Supervisor requirement to 1.1.2.1. Was the intent that qualification as a Technical Supervisor per 42 CFR 493.1449(q) would be considered in lieu of one of the 3 acceptable qualifications identified in 1.1.2.1? If so, please clarify the wording.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that at this time, SBBs cannot serve in the role of supervisor, regardless of what occurs when the rule is published. Of note, the standard does not include the term technical supervisor and does not have a place in the standard.

				The committee also points out however, that the qualifications of the technical supervisor as defined would not be appropriate in this case.
1.2	SC	NA	NA	The committee revised standard 1.2 based on updates to the AABB Quality system essentials. **1.2 Quality System** The organization shall have a quality system. The organization's executive management shall ensure that this quality system is implemented and followed at all levels of the organization.
1.2.2	SC	NA	NA	The committee revised standard 1.2.2 based on updates to the AABB Quality system essentials. ✎**1.2.2 Management Reviews** Management shall assess the effectiveness of the quality system at defined intervals.
1.3	SC	NA	NA	The committee revised standard 1.3 based on updates to the AABB Quality system essentials. ✎**1.3 Policies, Processes, and Procedures** Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these IRL Standards. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.
1.3.1 (New)	SC	NA	NA	The committee added standard 1.3.1 based on updates to the AABB Quality system essentials. **1.3.1** The medical director and/or laboratory director (as applicable) shall approve all medical and technical policies, processes, and procedures.
1.3.2 (1.3.1)	SC	NA	NA	The committee revised standard 1.3.2 based on updates to the AABB Quality system essentials. **1.3.2** Any exceptions to medical and technical policies, processes, and procedures shall require justification and preapproval by the medical director and/or laboratory director, as applicable.
1.4 (New)				The committee added standard 1.4 based on updates to the AABB Quality system essentials. ✎**1.4 Risk Assessment** The facility shall have a process in place to

				perform risk assessments for activities at defined intervals.
1.4.1 (New)	SC	NA	NA	The committee added standard 1.4.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **1.4.1** Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.
1.8	SC	NA	NA	The committee revised standard 1.8 based on updates to the AABB Quality system essentials. **1.8 Customer Focus** Executive management shall identify the organization's customers and their needs and expectations for products or services. Standard 4.2 applies.
2.1.1 (2.1)	SC	NA	NA	The committee revised standard 2.1.1 based on updates to the AABB Quality system essentials. **2.1.1 Job Descriptions** The organization shall establish and maintain job descriptions defining the roles and responsibilities for each job position related to the requirements of these IRL Standards.
2.1.1.1 (2.1.1)	SC	NA	NA	The committee elected to edit this standard to reflect the status of staffing that currently accredited laboratories are experiencing. The clause, "continuous (on site or on call)" was removed, however the term "adequate" to ensure that coverage still exists to allow for business operations to continue. **2.1.1.1** The laboratory shall hire staff to ensure adequate coverage by qualified persons for the following activities: 1) Serologic investigation. 2) Serologic consultation. 3) Procurement of antigen-negative donor units, if applicable. 4) Response to requests for rare donor units from the American Rare Donor Program (ARDP), if applicable. Standard 4.4 applies.

<table>
<tr><td>2.1.1.1, #3, 4 (2.1.1)</td><td>RtC</td><td>The clause, “if applicable” is only true for non-collection IRL Accredited IRLs. The “if applicable” should not be used if it is because the IRL is not staffed 24/7.</td><td>NO</td><td>The committee noted this comment but did not feel that a change was needed at this time. There are laboratories currently accredited that do not collect donors and as such would not be able to meet this standard without the clause “if applicable” was not included.</td></tr>
<tr><td>2.1.6 (New)</td><td>SC</td><td>NA</td><td>NA</td><td>The committee added standard 2.1.6 based on updates to the AABB Quality system essentials.
✎2.1.6 Continuing Education
The organization shall ensure that continuing education requirements applicable to these IRL Standards are met when applicable.</td></tr>
<tr><td>2.2.3</td><td>SC</td><td>NA</td><td>NA</td><td>The committee elected to edit standard 2.2.3 for completeness. The committee added the clause “…before an AABB assessment.” to ensure that facilities submit their AABB resource and inventory spreadsheet prior to their assessment, and not at any other time during the effective period of the edition. The standard reads as follows:
2.2.3 The laboratory shall submit its AABB Resources and Inventory spreadsheet biennially before an AABB assessment. Reference Standards 2.2A, Inventory Resources, and 2.2B, Additional Inventory Resources, apply.</td></tr>
<tr><td>Reference Standard 2.2B</td><td>SC</td><td>NA</td><td>NA</td><td>The committee elected to add a second example to the RH system in the additional resources row, based on the inclusion of the new entry for another set of RBCs for the RH system. This provides potential laboratories with two more options when attempting to meet the 65% threshold.
The updated entry reads as follows:
<table>
<tr><th>ISBT Symbol</th><th>System or Collection</th><th>Antisera</th><th>No. of Examples</th><th>RBCs</th><th>No. of Examples</th></tr>
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<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>No./ Antigen No.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>RH</td><td></td><td></td><td></td><td>r′S r′S</td><td>1</td></tr>
</table>
</td></tr>
<tr><td>Reference Standard 2.2B</td><td>RTC</td><td>In the table below from the IRL standards:
RHCE*ce733G/733G is missing the number of samples. It looks like 2 but the actual table is blank.
That one and two others are molecular designations. There should be an antigen for each.
RHCE*ce733G/733G would be V+ VS+
RHCE*ce733G/733G would be partial C+ (or altered)
RHCE*ce(48C,733G,1006T)/ce(48C,733G,1006T) would be V-VS+, hrB-, partial c+, partial e+</td><td>YES</td><td>The committee agreed with the intent of this comment noting that when originally proposed there was a clerical error in the added RH system entry.
Based on this comment the committee updated the entry to read:
<table>
<tr><th>ISBT Symbol</th><th>System or Collection No./ Antigen No.</th><th>Antisera</th><th>No. of Examples</th><th>RBCs</th><th>No. of Examples</th></tr>
<tr><td>RH</td><td></td><td></td><td></td><td>r′S r′S <s>RHD* DIIIa-CE(4-7)-D; RHCE*ce(48C,733G,1006T)/ce(48C,733</s></td><td>1</td></tr>
</table>
</td></tr>
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3.0	SC	NA	NA	The committee revised standard 3.0 based on updates to the AABB Quality system essentials. **3.0 Equipment** The organization shall define and control critical equipment.
3.1 (New)	SC	NA	NA	The committee added standard 3.1 based on updates to the AABB Quality system essentials. **3.1 Equipment Specifications** Equipment specifications shall be defined before purchase.
3.2.2	SC	NA	NA	The committee revised standard 3.2.2 based on updates to the AABB Quality system essentials. **3.2.2 Operational Qualification** Each piece of equipment and component of an information system shall be verified before actual use.
3.5.1	SC	NA	NA	The committee revised standard 3.5.1 based on updates to the AABB Quality system essentials. **3.5.1 Calibration and Accuracy of Equipment** Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be confirmed as described below unless otherwise indicated by the manufacturer: 1) Before use. 2) After activities that may affect the calibration. 3) At prescribed intervals.
3.5.1.1 (3.5, 3.5.1.2)	SC	NA	NA	The committee revised standard 3.5.1.1 based on updates to the AABB Quality system essentials. **3.5.1.1** Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and specified limitations.
3.5.1.2 (New)	SC	NA	NA	The committee added standard 3.5.1.2 based on updates to the AABB Quality system essentials. **3.5.1.2** Equipment used for calibration,

				inspection, measuring, and testing shall be certified to meet nationally recognized measurement standards. Certification shall occur before initial use, after repair, and at prescribed intervals. Where no such measurement standards exist, the basis for calibration shall be described and recorded.
3.5.2 (New)	SC	NA	NA	The committee added standard 3.5.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.5.2** When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of potentially affected products or services (including those that have already been released or delivered) shall be verified.
3.5.3 (New)	SC	NA	NA	The committee added standard 3.5.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.5.3** The organization shall: 1) Define cleaning and sanitation methods and intervals for equipment. 2) Ensure that environmental conditions are suitable for the operations, calibrations, inspections, measurements, and tests carried out. 3) Remove equipment from service that is malfunctioning/out of service and communicate to appropriate personnel. 4) Monitor equipment to ensure that defined parameters are maintained. 5) Ensure that the handling, maintenance, and storage of equipment are such that the equipment remains fit for use. 6) Ensure that all equipment maintenance and repairs are performed by qualified individuals and in accordance with manufacturer's recommendations.
3.5.4, #1 (3.5.2, #1)	SC	NA	NA	The committee revised subnumber 1 of standard 3.5.4 based on updates to the AABB Quality system essentials. the tone of the language that

				appears as subnumber 1 has been updated from the previous edition. The subnumber previously read, “Assessment of blood components and/or services provided.” The standard now reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 1) Assessment of products or services provided since the equipment was last known to be functioning per the manufacturer’s written instructions or organization-defined specifications.
3.5.4, #3 (3.5.2, #3)	SC	NA	NA	The committee revised subnumber 3 of standard 3.5.4 based on updates to the AABB Quality system essentials. The previous wording read, “Steps to ensure that the equipment is removed from service”, in the 13th edition, the subnumber reads, “Removal of equipment from service, if indicated.” The intent of the standard has not changed. The standard reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 3) Removal of equipment from service, if indicated.
3.5.4, #4 (3.5.2, #4)	SC	NA	NA	The committee revised subnumber 4 of standard 3.5.4 based on updates to the AABB Quality system essentials. The subnumber reads as follows: **3.5.4 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable.

3.6 (New)	SC	NA	NA	The committee added standard 3.6 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.6 Equipment Traceability** The organization shall maintain records of equipment use in a manner that permits: 1) Equipment to be uniquely identified and traceable. 2) Tracing of any given product or service to all equipment associated with the procurement, processing, storage, distribution, and administration of the product or service.
3.7, #2 (3.9.1, #1)	SC	NA	NA	The committee revised subnumber 2 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 2) Validation/verification/qualification of system software, hardware, databases, and user-defined tables before implementation.
3.7, #3 (3.9,.1, #2)	SC	NA	NA	The committee revised subnumber 3 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 3) Fulfillment of life-cycle requirements for internally developed software.†
3.7, #4 (3.9, #2)	SC	NA	NA	The committee revised subnumber 4 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: The standard reads as follows: **3.7 Information Systems**

				The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 4) Defined processes for system operation and maintenance.
3.7, #6 (New)	SC	NA	NA	The committee added subnumber 6 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 6) System security to prevent unauthorized access.
3.7, #7 (New)	SC	NA	NA	The committee added subnumber 7 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
3.7, #8 (3.9, #4)	SC	NA	NA	The committee revised subnumber 8 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and

				modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 9) Defined process for monitoring of data integrity for critical data elements.
3.7, #10 (New)	SC	NA	NA	The committee added subnumber 10 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 10) System design that establishes and maintains unique identity of the donor, the product, or service, and the recipient (as applicable).
3.7, #11 (New)	SC	NA	NA	The committee added subnumber 11 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include: 11) Training and competency of personnel who use information systems.
3.7, #12 (New)	SC	NA	NA	The committee added subnumber 12 of standard 3.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **3.7 Information Systems** The organization shall have controls in place for the implementation, use, ongoing support, and modifications of information system software, hardware, and databases. Elements of planning and ongoing control shall include:

				12) Procedures to ensure confidentiality of protected information.
3.9	RtC	There is a reference in Standard 3.9 to Standard 10.4.3 and in your clarification statement it states, "requires that that laboratory personnel move when an oxygen alarm is activated." Upon review of standard 10.4.3, there is no indication of this requirement. Was this an oversight by the committee?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee feels that the crossreference is appropriate and that when an alarm activates, that personnel should act as appropriate.
4.0	SC			The committee revised standard 4.0 based on updates to the AABB Quality system essentials. The standard reads as follows: **4.0 Suppliers and Customers** The organization shall ensure that agreements to provide or receive products or services are reviewed, approved, and meet supplier and customer expectations.
4.1	SC	NA	NA	The committee revised standard 4.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **4.1 Supplier Qualification** The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.
4.1.1 (4.1)	SC	NA	NA	The committee revised standard 4.1.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **4.1.1** The organization shall evaluate and participate in the selection of suppliers. If executive management is not included in the selection process, there shall be a mechanism to provide feedback to management with contracting authority.
4.2	SC	NA	NA	The committee revised standard 4.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **4.2 Agreements** Agreements and any incorporated changes shall be reviewed and communicated.
4.2.1 (New)	SC	NA	NA	The committee added standard 4.2.1 based on updates to the AABB Quality system essentials. The standard reads as follows:

				4.2.1 Agreements shall be reviewed at defined intervals to ensure that the terms of agreement continue to meet requirements.
4.2.3 (New)	SC	NA	NA	The committee added standard 4.2.3 based on updates to the AABB Quality system essentials. The standard reads as follows: ✎ **4.2.3** The responsibilities for activities covered by these IRL Standards when more than one organization is involved shall be specified by agreement.
4.3 (New)	SC	NA	NA	The committee added standard 4.3 based on updates to the AABB Quality system essentials. The standard reads as follows: ✎**4.3 Incoming Receipt, Inspection, and Testing** Incoming products or services, equipment, and materials shall be received, inspected, and tested, as necessary, before approval for use.
5.1.1.1 (5.1.1)	SC	NA	NA	The committee elected to edit standard 5.1.1.1 for clarity. The committee edited this standard to focus specifically on testing processes, and not testing procedures. The intent of this standard focuses on what can impact the testing performed while also mirroring the requirements of the CFR. The standard reads as follows: **5.1.1.1** This shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed testing procedures shall be validated.* Standard 2.1.2 applies. *42 CFR 493.1253.
5.1.1.1 (5.1.1)	RtC	The change to delete “processes and” does not clarify the intent of the standard.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee notes that the change made better reflects what is required by the current Code of Federal Regulations.
5.1.2 (5.1.4)	SC	NA	NA	The committee revised standard 5.1.2 based on updates to the AABB Quality system essentials. The standard reads as follows:

				5.1.2 Quality Control A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment, materials, and analytical functions per-form as intended.
5.1.2.1 (New)	SC	NA	NA	The committee added standard 5.1.2.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **5.1.2.1** Quality control results shall be reviewed and evaluated against acceptance criteria.
5.1.2.4 (5.1.4.3)	RtC	Suggest the "s" in "evaluates" be removed. Additionally, the "or testing sites" should be "and testing sites". The use of "or" implies only one of the items in the list must be compared to meet the standard, when it is all that must be compared.	YES	The committee agreed with the intent of the comment and a change was made. The committee has added a reference to 21 CFR 493.1281 to make clear what has been evaluated in terms of the testing site.
5.1.3 (New)	SC	NA	NA	The committee added standard 5.1.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **5.1.3 Process Planning** Quality requirements shall be incorporated into new or changed processes, products, services, and novel methods. Planning and implementation activities shall include the following: 1) Evaluation of accreditation, regulatory, and legal requirements related to the new or changed process, product, or service. 2) Review of current available knowledge (eg, review of medical practice and/or literature). 3) Evaluation of risk. 4) Identification of affected internal and external parties and mechanism to communicate relevant information. 5) Identification of performance measures applicable to the new or changed process, product, or service. 6) Evaluation of resource requirements.

				7) Evaluation of the impact of the new or changed process, product, or service on other organization (or program) processes. 8) Evaluation of the need to create or revise documents for the new or changed process, product, or service. 9) Review and approval of the output of process development and design activities (eg, pilot or scale-up study results, process flow charts, procedures, data forms). 10) Evaluation of the extent and scope of process validation or revalidation depending on the level of risk and impact of the new or changed products or services.
5.1.4.1 (New)	SC	NA	NA	The committee added standard 5.1.4.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **5.1.4.1** Validation activities shall include the following: 1) Identification of objectives, individual(s) responsible, expected outcomes, and/or performance measures. 2) Criteria for review of outcomes. 3) Approval of validation plan. 4) Review and approval of actual results. 5) Actions to be taken if objectives are not met. The committee noted that laboratories have processes to meet these requirements already.
5.1.5 (New)	SC	NA	NA	The committee added standard 5.1.5 based on updates to the AABB Quality system essentials. The standard reads as follows: **5.1.5 Process Implementation** The implementation of new or changed processes and procedures shall be planned and controlled.
5.1.5.1 (New)	SC	NA	NA	The committee added standard 5.1.5.1 based on updates to the AABB Quality system essentials. The standard reads as follows:

				✎**5.1.5.1** Postimplementation evaluations of new or changed processes and procedures shall be performed.
5.1.5.1 (New)	RtC	The addition of the record retention requirement could be very burdensome if it applies to all or new changed processes.	NO	The committee noted this comment but did not believe that a change was needed at this time.
5.1.5.1 (New)	RtC	We recommend adding a qualifier, post implementation evaluations are not indicated for all changes to processes/ procedures when applicable or when indicated, not all changes require evaluation, which would not include minor /clerical updates.	NO	The committee reviewed this comment but did not feel that a change was needed at this time.
5.1.6 (5.1.5)	SC	NA	NA	The committee revised standard 5.1.6 based on updates to the AABB Quality system essentials. The standard reads as follows: **5.1.6 Use of Materials** All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.
5.1.8.2 (5.1.9.1)	SC	NA	NA	The committee elected to edit standard 5.1.8.2 for clarity. The committee added the clause, "if performed" to the standard recognizing that there are laboratories that do not modify components. The standard reads as follows: **5.1.8.2** The laboratory shall have a procedure for modifications to the labeling of a blood component, including antigen-negative products, if per-formed.
5.1.9 (5.1.11)	SC	NA	NA	The committee revised standard 5.1.9 based on updates to the AABB Quality system essentials. The standard reads as follows: **5.1.9 Handling, Storage, and Transportation** The organization shall ensure that products or services are handled, stored, and transported in a manner that prevents damage, limits deterioration, and provides traceability. Standard 3.8 applies.
5.1.9 (5.1.11)	RtC	Is services supposed to mean samples? As such, please remove the reference to 3.10. 3.10 only applies to storage of products and does not apply to samples as written is appears we would need to alarm our transport containers. Sample storage and critical materials have not required alarm systems, only critical	YES	The committee reviewed this comment but did not feel that the change proposed would be appropriate. The committee for clarity, did

		reagents and blood components. If the reference to 3.10 is included please specify it only applies to products and critical reagents		remove the crossreference to standard 3.10 but has included a crossreference to standard 3.8.
5.1.9.1 (5.1.11.1)	RtC	Why aren't critical materials, blood components, and samples, just listed in 5.1.9?	NO	The committee reviewed this comment but noted that standard 5.1.9 is a part of the revised AABB Quality system essentials., and does apply to all sets of AABB Standards and therefore appears in a general fashion. Standard 5.1.9.1 exists to focus on IRL requirements.
5.1.10.1 (5.1.2.1)	SC	NA	NA	The committee elected to edit standard 5.1.10.1 for clarity. This change was made in conformance with current requirements set forth by CLIA. By removing the specificity of analytes tested allows the standard to mirror the CLIA requirements cited and the new CLIA requirement. The standard reads as follows: **5.1.10.1** US laboratories shall participate in a CMS-approved proficiency testing program for each analyte requiring proficiency testing under CLIA. For other tests and procedures, there shall be a system for determining the accuracy of results twice annually.* *42 CFR 493.801(b)(3), 42 493.857, 42 CFR 493.959(c), and 42 CFR 493.1236.
5.1.10.1 (5.1.2.1)	RtC	Please include the number of samples in the standard for consistency and ease of use.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that the number of samples would be decided on each laboratory, specifically based on the testing performed. This standard does not allow for a "one size fits all" approach.
5.1.10.1.1 (New)	SC	NA	NA	The committee created new standard 5.1.10.1.1 for completeness. The standard ensures that the IRL Standards mirror the requirements set forth by CMS in July 2022 with an effective date of 2024. This mostly focuses on wave testing, which is not performed by our laboratories, however the requirement does focus on proficiency testing referrals and what is and is

				not allowed until the results of proficiency testing is complete and submitted. The standard reads as follows: **5.1.10.1.1** Laboratories shall ensure that no interlaboratory communications pertaining to proficiency test events occur until after the submission deadline.* *42 CFR 493.801(b)(3).
5.1.10.1.2 (New)	SC			The committee created new standard 5.1.10.1.2 for completeness. This addition was made in conjunction with the addition of the CFR cited, which requires that laboratories that perform proficiency testing to show that they can successfully perform the act. Laboratories that attempt to have their samples outsourced would not meet the requirements in the CFR. The standard reads as follows: **5.1.10.1.2** The laboratory shall ensure that no portion of a proficiency testing sample is sent to another laboratory for analysis.† †42 CFR 493.801(b)(4).
5.1.10.1.2 (New)	RtC	Please add "until after the submission deadline."	NO	The committee noted this comment but did not feel that a change was needed at this time. The content is not included as a part of the CFR cited, so we will not include.
5.1.10.1.3 (New)	SC	NA	NA	The committee added new standard 5.1.10.1.3 to the edition for completeness. This addition was made in conjunction with the addition of the CFR cited, which requires that if a laboratory receives samples for proficiency testing from an outside source that they immediately contact CMS who will instruct them on how to move forward. The standard reads as follows: **5.1.10.1.3** Any laboratory that receives a proficiency testing sample from another laboratory for testing shall notify CMS of the receipt of the sample.‡ ‡42 CFR 493.801(b)(4).

5.1.10.2 (5.1.2.2)	SC	NA	NA	The committee edited standard 5.1.10.2 for clarity. The title of the standard was removed as it was deemed redundant per standard 5.1.10. The committee also edited the content of the standard to ensure that it was clear that this test is provided by AABB and not merely approved. The standard reads as follows: **5.1.10.2** The laboratory shall participate in the proficiency testing program that is provided by the AABB Immunohematology Reference Laboratory Accreditation Committee.
5.1.11.1 (5.1.3.1)	RtC	The text is confusing, at least to me. Is the intent to refer to "previous" or "current" manufacturer's instructions. The tricky part is that the manufacturer's instruction as received for a specific reagent could apply to that reagent and be required to be followed for that reagent. Or, the new manufacturer's instructions might apply to all previous lot numbers. This could also be true for equipment. It seems to this reviewer that the important thing is to identify changes in a newly received updated version of the manufacturer's instructions versus the current version in use in the IRL and the determination of appropriate actions to take.	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that they would identify these issues in guidance to provide clarity.
5.1.11.1.1 (5.1.3.1.1)	RtC	Should this specify upon receipt?	NO	The committee reviewed this comment but did not feel that a change was needed at this time. The committee noted that comparisons do not only occur upon receipt. The committee notes that this occurs at any point before use, and not the minute a sample arrives in the laboratory.
5.1.12 (5.1.6)	RtC	Both standards 5.1.14 and 5.1.13. appear like they should be subheadings under 5.1.12?	NO	The committee noted this comment but did not agree with the assertion. The committee feels that these standards are distinct in their requirements and would not fit under standard 5.1.12. The committee does note that they do apply to one another.
5.2, #3 (New)	SC	NA	NA	The committee has added new subnumber 3 to standard 5.2 for completeness. This addition was initially based upon input from AABB's representative from the American Rare Donor Program. ARDP has noted that they are receiving an increase in requests for IgA deficient plasma

				from member laboratories thus resulting in a supply that is lessening for the IgA deficient plasma donors. By including new subnumber 3 this should help raise the opportunity to find more IgA deficient plasma donors. The standard reads as follows: **5.2 American Rare Donor Program** All laboratories shall participate in the ARDP system by per-forming at least one of the following functions on an annual basis: 3) Screen at least 1000 donors for immunoglobulin A deficiency.
5.2	RtC	In our opinion, this standard does not seem to take into account the limitations of a true Blood Bank (FDA registered facility that collects, manufactures, labels and distributes blood and blood products for in-house use). These smaller programs may not have the volumes or resources to meet the listed requirements in this standard but are able to meet the other standards for safely providing compatible and efficacious products for transfusion needs. We suggest a modification to the standards as either; a) Modification to STD 5.2 to "All laboratories, except FDA registered Blood Banks*, shall… b) Add STD 5.2.3 as, FDA registered hospital Blood Banks* may be exempted from standard 5.2 *= the Blood Bank must meet the FDA registration requirements that they collect, manufacture, label and distribute their products for patient use within their facility.	NO	The committee noted this comment but did not feel that a change was needed at this time. The committee notes the main reason to have 6 options in 5.2 is to give laboratories a number of options to meet this requirement and to support the ARDP. The committee feels that a laboratory, regardless of size should be able to meet at lease one of these options to participate in the ARDP.
5.2.1	SC	NA	NA	The committee elected to edit this standard for clarity. Standard 5.2.1 was new to the previous edition and created at the request from ARDP. In the time since the 12th edition became effective there have been requests for clarification on which laboratories have to register their donors with ARDP. As such, the committee added the clause, "…within organizations that perform collections…" to ensure that it was clear that this requirement only applies to facilities that collect and register donors. The standard reads as follows: **5.2.1** All laboratories within organizations that perform collections shall register donors with a

				current or subsequent donation identified as lacking a high-prevalence antigen(s).
5.3.2.1 (5.3.2, #9)	SC	NA	NA	The committee created new standard 5.3.2.1 from what previously appeared as subnumber 9 of standard 5.3.2. Subnumber 9 has been removed from standard 5.3.2 and its content moved to new standard 5.3.2.1. The committee received a number of comments indicating that polyagglutination is a very rare occurrence and to have to investigate and recognize it as a regular process would be unnecessary. New standard 5.3.2.1 was created to recognize that while rare, the need to identify polyagglutination is required, though only when it occurs, hence the writing of the standard. The standard reads as follows: **5.3.2.1** The laboratory shall identify or distinguish polyagglutinable red cells, when applicable.
5.3.4	SC	NA	NA	The committee elected to edit standard 5.3.4 by adding an updated title to the standard. The title now reads, "Testing Procedures." This title reflects that the standard is in the testing section. The standard reads as follows: **5.3.4 Testing Procedures** The laboratory shall have the following procedures: 1) ABO grouping. 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 5.1.10 applies.
6.1	SC	NA	NA	The committee revised standard 6.1 based on updates to the AABB Quality system essentials. The standard reads as follows:

				6.1 Document Control The organization shall control all documents that relate to the requirements of these IRL Standards. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.
6.1.2 (New)	SC	NA	NA	The committee added standard 6.1.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.1.2 Document Review, Approval, and Distribution** The document control process shall ensure that documents: 1) Are reviewed by personnel trained and/or qualified in the subject area. 2) Are approved by an authorized individual. 3) Are identified with the current version and effective date. 4) Are available at all locations where operations covered by these IRL Standards are performed. 5) Are not used when deemed invalid or obsolete. 6) Are identified as archived or obsolete when appropriate.
6.1.3 (New)	SC	NA	NA	The committee added standard 6.1.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.1.3 Document Changes** Changes to documents shall be reviewed and approved by an authorized individual.
6.1.3.1 (New)	SC	NA	NA	The committee added standard 6.1.3.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.1.3.1** The organization shall track changes to documents.
6.1.6	SC	NA	NA	The committee revised standard 6.1.6 based on updates to the AABB Quality system essentials. The standard reads as follows:

				✎**6.1.6 Document Retention** The organization shall determine which documents shall be archived, destroyed, or made obsolete.
6.1.7	SC	NA	NA	The committee revised standard 6.1.7 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.1.7 Document Storage** Documents shall be stored in a manner that preserves integrity and legibility; protects from accidental or unauthorized access, loss, destruction, or modification; and ensures accessibility and retrievability.
6.1.8 (New)	SC	NA	NA	The committee added standard 6.1.8 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.1.8 Document Retrieval** The organization shall ensure that documents are retrievable in a timely manner.
6.1.9 (6.1.5)	SC	NA	NA	The committee revised standard 6.1.9 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.1.9** The organization shall use only current and valid documents. Applicable documents shall be available at all locations where activities essential to meeting the requirements of these IRL Standards are performed.
6.2	SC	NA	NA	The committee revised standard 6.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.2 Record Control** The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.
6.2.2, #1 (6.2.4, #8)	SC	NA	NA	The committee revised subnumber 1 of standard 6.2.2 based on updates to the AABB Quality system essentials. The standard reads as follows:

				6.2.2 The records system shall ensure traceability of: 1) Critical activities performed.
6.2.2, #4 (New)	SC	NA	NA	The committee added subnumber 4 to standard 6.2.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.2.2** The records system shall ensure traceability of: 4) Time the activity was performed, if applicable.
6.2.3 (New)	SC	NA	NA	The committee added standard 6.2.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.2.3 Information to Be Retained** Records shall demonstrate that a material, product, or service conforms to specified requirements and that the quality system is operating effectively.
6.2.9 (6.2)	SC	NA	NA	The committee revised standard 6.2.9 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.2.9 Retention** Records required by these IRL Standards shall be retained for a period indicated in the record retention table at the end of each chapter.
6.2.10 (New)	SC	NA	NA	The committee added standard 6.2.10 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.2.10 Record Review** Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.
6.2.11, #2 (6.2.8, #2)	SC	NA	NA	The committee revised subnumber 2 of standard 6.2.11 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to:

				2) Protect from accidental or unauthorized access, loss, deterioration, damage, destruction, mix-up, or modification.
6.2.11, #3 (New)	SC	NA	NA	The committee added subnumber 3 of standard 6.2.11 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to: 3) Permit ready identification.
6.2.11, #4 (6.2.8, #3)	SC	NA	NA	The committee revised subnumber 4 of standard 6.2.11 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.2.11 Storage of Records** Records shall be stored to: 4) Allow retrieval in a defined time frame.
6.3 (6.2.7)	SC	NA	NA	The committee revised standard 6.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3 Electronic Records** The organization shall support the management of information systems.
6.3.1 (New)	SC	NA	NA	The committee added standard 6.3.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.1 Access to Data and Information** Access to data and information shall be controlled.
6.3.1.1 (New)	SC	NA	NA	The committee added standard 6.3.1.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.1.1** The authorization to access and release data and information shall be defined, and individuals authorized to enter, change, and release results shall be identified.
6.3.1.1.1 (New)	SC	NA	NA	The committee added standard 6.3.1.1.1 based on updates to the AABB Quality system essentials. The standard reads as follows:

				6.3.1.1.1 Electronic records shall include the date and identity of the person making a change.
6.3.2 (6.2.7.2)	SC	NA	NA	The committee revised standard 6.3.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.2 Data Integrity** Data integrity shall ensure that data are retrievable and usable.
6.3.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.2.1** Data shall be accurately, reliably, and securely sent from the point of entry to final destination.
6.3.2.2 (6.2.7.2)	SC	NA	NA	The committee revised standard 6.3.2.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.2.2** Data shall be retrievable for the entire retention period.
6.3.2.2.1 (New)	SC	NA	NA	The committee added standard 6.3.2.2.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.2.2.1** The organization shall archive records or data from media and platforms no longer in use.
6.3.3 (New)	SC	NA	NA	The committee added standard 6.3.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.3 Storage Media** Data storage media shall be protected from damage or unintended access and destruction.
6.3.4 (New)	SC	NA	NA	The committee added standard 6.3.4 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.4 Backup Data** The organization shall back up all critical data.
6.3.4.1 (6.2.7.3)	SC	NA	NA	The committee revised standard 6.3.4.1 based on updates to the AABB Quality system essentials. The standard reads as follows:

				6.3.4.1 Backup data shall be stored in a secure off-site location.
6.3.4.2 (New)	SC	NA	NA	The committee added standard 6.3.4.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.4.2** Backup data shall be protected from unauthorized access, loss, or modification.
6.3.4.3 (New)	SC	NA	NA	The committee added standard 6.3.4.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **6.3.4.3** The ability to retrieve data from the backup system shall be tested at defined intervals.
7.1 (New)	SC	NA	NA	The committee added standard 7.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **7.1 Deviations** The organization shall capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. The assessment shall ensure timely and appropriate clinical management of the recipient, if applicable.
7.2.1 (7.1.1.1)	SC	NA	NA	The committee revised standard 7.2.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **7.2.1** Nonconforming products shall be quarantined and/or destroyed.
7.2.2 (7.1.1.2)	SC	NA	NA	The committee revised standard 7.2.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **7.2.2** The unintended distribution or use of products or services that do not conform to specified requirements shall be prevented.
7.2.3, #1 (7.1.1, #1)	SC	NA	NA	The committee revised subnumber 1 of standard 7.2.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **7.2.3** The organization shall: 1) Identify, quarantine, retrieve, recall, and

				determine the disposition of nonconforming products or services.
7.2.4 (7.1.1.3)	SC	NA	NA	The committee revised standard 7.2.4 based on updates to the AABB Quality system essentials. The standard reads as follows: ✎**7.2.4 Released Nonconforming Products or Services** Products or services that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality and/or safety of the product or service.* *42 CFR 493.1291(k).
7.2.4.1 (New)	SC	NA	NA	The committee added standard 7.2.4.1 based on updates to the AABB Quality system essentials. The standard reads as follows: ✎**7.2.4.1** Records shall include the disposition of the nonconforming product or service, the rationale, and the name(s) of the individual(s) responsible for the decision.
7.3	SC	NA	NA	The committee revised standard 7.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **7.3 Adverse Events** The organization shall detect, monitor, evaluate, manage, and report adverse events related to safety and quality.
7.3.1 (New)	SC	NA	NA	The committee added standard 7.3.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **7.3.1** Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.
7.3.2 (New)	SC	NA	NA	The committee added standard 7.3.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **7.3.2** Investigation results and analysis shall be communicated among all facilities involved, if applicable.

8.0	SC	NA	NA	The committee revised standard 8.0 based on updates to the AABB Quality system essentials. The standard reads as follows: **8.0 Internal and External Assessments** The organization shall conduct assessments of operations and quality systems.
8.1	SC	NA	NA	The committee revised standard 8.1 based on updates to the AABB Quality system essentials. The standard reads as follows: ✎**8.1 Internal Assessments** The organization shall conduct internal assessments. Internal assessments shall be performed by personnel independent of those having direct responsibility for the activity being assessed.
8.2 (8.1)	SC	NA	NA	The committee revised standard 8.2 based on updates to the AABB Quality system essentials. The standard reads as follows: ✎**8.2 External Assessments** The organization shall participate in an external assessment program applicable to the activities performed in the organization.
8.3, #2 (New)	SC	NA	NA	The committee added subnumber 2 to standard 8.3 based on updates to the AABB Quality system essentials. The standard reads as follows: ✎**8.3 Management of Assessment Results** The results of assessments shall be: 2) Evaluated to determine the need for corrective and preventive action.
8.3, #3 (New)	SC	NA	NA	The committee added subnumber 3 to standard 8.3 based on updates to the AABB Quality system essentials. The standard reads as follows: ✎**8.3 Management of Assessment Results** The results of assessments shall be: 3) Communicated to the appropriate staff.
8.4.1 (New)	SC	NA	NA	The committee added standard 8.4.1 based on updates to the AABB Quality system essentials. The standard reads as follows:

				8.4.1 The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.
9.0	SC	NA	NA	The committee revised standard 9.0 based on updates to the AABB Quality system essentials. The standard reads as follows: **9.0 Process Improvement** The organization shall collect data, perform analysis, and follow up on issues requiring corrective and preventive action, including near-miss events.
9.1, #2	SC	NA	NA	The committee revised subnumber 2 of standard 9.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **9.1 Corrective Action** The organization shall have a process for corrective action that includes: 2) Investigation of the root cause(s) of nonconformances relating to the product or service, the process, and the quality system.
9.1, #3	SC	NA	NA	The committee revised subnumber 3 of standard 9.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **9.1 Corrective Action** The organization shall have a process for corrective action that includes: 3) Determination of the corrective action needed to eliminate the cause of nonconformances, as applicable.
9.1.1 (New)	SC	NA	NA	The committee added standard 9.1.1 based on updates to the AABB Quality system essentials. The standard reads as follows: **9.1.1** Investigation and corrective action shall include con-sideration of deviations, nonconformances, and complaints.

9.2, #1 (9.2.1)	SC	NA	NA	The committee revised subnumber 1 of standard 9.2 based on updates to the AABB Quality system essentials. The standard reads as follows: **9.2 Preventive Action** The organization shall have a process for preventive action that includes: 1) Analysis of appropriate sources of information to detect, analyze, and eliminate potential causes of nonconformances.
9.3 (New)	SC	NA	NA	The committee added standard 9.3 based on updates to the AABB Quality system essentials. The standard reads as follows: **9.3 Performance Improvement** The organization shall track and identify trends in information related to its operational and quality system performance to identify opportunities for improvement.
Glossary – Contracting Authority (New)	SC	NA	NA	The committee created a new definition for completeness. The definition reads as follows: **Contracting Authority:** An individual who has the authority to enter into, administer, or terminate contracts, and who is responsible for the management of the contracts.
Glossary – Novel Methods (New)	SC	NA	NA	The committee created a new definition for completeness. The definition reads as follows: **Novel Methods:** A procedure that has not been peer-reviewed for the purposes of immunohematology. It may include a procedure that has been peer-reviewed for other purposes or a method that has not been peer-reviewed for other purposes.
Glossary – Polyagglutination				The committee edited the definition of polyagglutination for completeness and clarity. The addition of "but not by cord sera" ensures that the definition reflects the will of the membership. The definition now reads as follows: **Polyagglutination:** Condition in which an individual's red cells are agglutinated by

				virtually all normal adult human sera, but not by cord sera.