PROPOSED 14th edition of Standards for Immunohematology Reference Laboratories

A Note to Readers

Individuals not familiar with the standards-setting practices of AABB should be aware of the following:

- Requirements, once stated, are not repeated. For example, standard 5.0 requires that all processes and procedures be validated. Therefore, it is not necessary to require in other areas that a specific process or procedure be validated.
- Words or phrases used in a way different from their usual meaning are defined in the glossary.
- The term "specified requirements" is defined broadly to include accreditation requirements, national, state, or local laws, and any other applicable requirement.
- Please note, that the Summary of Significant Changes to the proposed 14th edition begins on page 2 and runs through page 7. The proposed 14th edition begins on page 8 and runs through page 108.

General
Where appropriate, the following phrase was added to all applicable standards that are CMS related:
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

1.1.2.1 The supervisor shall have one of the following qualifications:

1) Certification as a Specialist in Blood Banking (SBB) or ~~international~~ equivalent **international** credential.

The committee flipped the placement of the term "international" for accuracy purposes. The committee will be creating guidance based on what has been included in other sets of Standards.

1.1.3 Staffing Changes
The laboratory shall communicate initial appointments and staffing changes, **or interim leadership** for the medical director, medical director designee, and immunohematology reference laboratory supervisor within 30 days to AABB's Accreditation and
Quality Department. **Standards 1.1.1, 1.1.2, and 1.2.1 apply.**

The committee added the clause "or interim leadership" to the standard to ensure that AABB be made aware of changes in the time period where a leadership change is occurring but not complete. The committee added the crossreferences to the standard for completeness.

1.9 Facility Status Changes
The facility shall communicate to AABB within 30 days a change that directly or indirectly impacts a facility's accreditation status.

1.9.1 If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, they shall

notify AABB within 7 days.

The committee added new standards 1.9 and 1.9.1 to the proposed edition to mirror the addition of the same standards to all other AABB Standards, which include to date, the 12th edition of CT Standards and 17th edition of RT Standards.

Reference Standard 2.2B, Additional Inventory Resources

ISBT Symbol	System or Collection No./Antigen No.	Antisera	No. of Examples	Red Cells	No. of Examples
GE	020 / 002 020 / 003 **020 / 004**	Ge2 Ge3	1 1	Ge:–2,3 Ge:–2,–3 **Ge:-2, -3, -4**	1 1 **1**

The committee added the new Gerbich system to the Standards reflecting the availability thereof.

3.8 Technology Infrastructure
The organization shall have an active program to ensure that critical technology and communication infrastructures function as intended, including risk based monitoring or testing at facility defined intervals. Standards 1.4, 1.5, and 1.6 apply.

The committee added new standard 3.8 to the proposed edition to mirror the addition of the same standard to all other AABB Standards, which include to date, the 12th edition of CT Standards and 17th edition of RT Standards.

3.9.3 The organization shall ensure that storage devices undergo quality control testing at facility defined intervals. Standards 3.11.1, 3.11.2, and 5.1.2 apply.

The committee added new standard 3.9.3 reflecting a gap in the standards. On assessments, assessors are using standard 3.9 to provide a space to review laboratories for this purpose. Providing a specific standard closes this loophole.

✎ **3.11.3 The organization shall ensure that alarms undergo quality control testing to verify alarms are activated when the temperature sensing device detects an unacceptable temperature.**

The committee added new standard 3.11.3 to mirror a change being made to the proposed 35th edition of BB/TS Standards recognizing the need to ensure that quality control testing of the activations of alarms at facility defined intervals.

✎ **5.1.2.5 The laboratory shall have a facility defined process to detect titration testing errors by performing controls each day testing is performed. Standard 5.3.3 applies.***

***42 CFR 493.1256(d)(3)(iii).**

The committee created new standard 5.1.2.5 to cover and address the CFR included and requisitions for clarity on AABB's behalf to CMS as it relates to if tittered results applied in the IRL standards. The response from CMS was affirmative, but the direction of the standard's level of specificity led to a more general approach for each laboratory.

5.1.11.2 Where manufacturers' instructions are used as a standard operating procedure, any new or revised instructions that impact test results shall be reviewed and approved **by the laboratory director** before use ~~by the laboratory director~~.* **Standard 1.3.1** applies.

*42 CFR 493.1251(d).
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

The committee edited the order of the language of the standard and added a crosseference to standard 1.3.1, focused the required approval of all policies, processes, and procedures by the laboratory director before implementation. This was added for completeness.

5.1.14 Appropriate controls shall be used to ensure reliability of the test results when deviating from manufacturers' **written** instructions for immunohematology investigations.

The clause "written" was included for completeness and parallel structure with other sets of Standards.

5.2.1 **Donor-center-based laboratories** ~~All laboratories within organizations that perform collections~~ shall register donors ~~with a current or subsequent donation~~ identified as lacking a high-prevalence antigen(s).

In an effort to match the structure of standard 5.2.2, standard 5.2.1 was edited to mirror the language of standard 5.2.2.

5.3.1.2.1 **This shall include the review of any serological finding(s) that could potentially interfere with the forward and reverse grouping interpretations regardless of ABO type.**

This proposed standard was crafted based on existing guidance that was built for standard 5.3.1.2. The standard was added for completeness and ensures that laboratories should be able recognize potential discrepancies in ABO/D type determination arising from missing or unexpected reactivity.

~~**5.3.2.1** The laboratory shall identify or distinguish polyagglutinable red cells, when applicable.~~

The committee elected to remove standard as it is not something that is not

done by laboratories, and to include it was deemed superfluous. The committee will address the issue in guidance to standard 5.3.2.

5.3.3 Investigational Techniques

The laboratory shall have the following processes:

1) Elution.
2) Adsorption (autologous and allogeneic).
3) Enzyme treatment of red cells.
4) Use of reducing agent(s).
5) Prediction of antigen status through molecular methods and/or cell separation for determination of red cell phenotype.
6) Immunoglobulin removal from red cells.
7) Inhibition/neutralization.
8) Dilution.
9) **Titration.**

The committee added new #9 to standard 5.3.3 to mirror the inclusion of standard 5.1.2.5 to mirror the CMS requirements and clarification given by the agency to AABB.

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.

***42 CFR 493.1256(d)(3)(iii).**

Standard 5.1.10 applies.

The committee added the CFR to the standard for completeness with the inclusion of new standard 5.1.2.5, and the addition of titration to standard 5.3.3.

7.2.1.1 When a nonconforming blood component is identified, **the laboratory shall perform an investigation to determine the need for further action by the laboratory or the blood provider** ~~previously collected components and other components associated with the nonconformance shall be evaluated, and their disposition determined~~.

The committee edited standard 7.2.1.1 to mirror the current practice in accredited laboratories. As previously written, the standard could only be understood that laboratories have the ultimate responsibility, however in reality, the determination of action to take can be in the hand of the laboratory or their appropriate blood supplier.

Glossary

Antibody Screen: A serologic method to detect the presence of clinically significant antibodies in recipients and/or donors.

The committee added the definition to the proposed edition, and was pulled from the Standards for Blood Banks and Transfusion Services.

Regulatory Enforcement Action: Measures taken by a Competent Authority that include but are not limited to progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues, deficiencies in risk management systems.)

The committee added this term to the Glossary in conjunction with new standard 1.9.1.

QSE 1 – Organization

Key Concepts

This quality system essential (QSE) describes the responsibilities of executive management, the nature of the quality system, and the need for ongoing attention to operational and quality issues through demonstrated management commitment.

Key Terms

Customer: The recipient of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

Emergency Management: Strategies and specific activities designed to manage situations in which there is a significant disruption to organization operations or a significantly increased demand for the organization's products or services.

Executive Management: The highest-level personnel within an organization, including employees, clinical leaders, and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

Organization: An institution, or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

Policy: A set of basic principles or guidelines that direct or restrict the organization's plans, actions, and decisions.

Procedure: A defined series of tasks and instructions that specify how an activity is to be performed.

Process: A set of related activities that transform inputs into outputs.

Quality Management System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Organizational charts or documents describing roles, responsibilities, and decision-making authority.
- Evidence of executive management review of a quality system.
- Applicable federal, national, state, and local laws and regulations, as well as copies of any required certificates.
- Defined quality system.
- Process for approving exceptions to policies, processes, procedures, as well as documented examples, if applicable.
- Risk assessments and mitigation strategies.
- Emergency operation and disaster continuity plan(s).
- Executive management review of customer feedback.

1. Organization

1.0 Organization

The organization shall define the parties responsible for the provision of products or services.

1.1 Executive Management

The organization shall have a defined executive management. Executive management shall have:

1) Responsibility and authority for the quality system and operations.
2) Responsibility for compliance with these ***IRL Standards*** and applicable laws and regulations, including all applicable current good manufacturing practice (cGMP) requirements.
3) Authority to establish or make changes to the quality system.

1.1.1 Medical Director Qualifications and Responsibilities

The laboratory shall have a medical director who is a licensed physician and qualified by education, training, and/or experience. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedures,* including those that pertain to laboratory personnel, test performance, and services. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.

*42 CFR 493.1251(d).

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

1.1.1.1 The medical director shall:

1) Be available to the supervisor, designee, and/or technical staff.

2) Approve services that are not routinely performed by the facility. Standard 7.1 applies.

3) Serve as a consultant for the community on transfusion medicine issues.

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 The supervisor shall have one of the following qualifications:

1) Certification as a Specialist in Blood Banking (SBB) or equivalent international credential.

2) Doctorate in an immunohematology-related field.

3) Medical license and certification in blood banking/transfusion medicine by the American Board of Pathology or equivalent agency outside the United States.

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(d).
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA),

refer to the Verification of CLIA Compliance Form before on-site assessment.

✎ **1.1.3 Staffing Changes**
The laboratory shall communicate initial appointments and staffing changes, or interim leadership for the medical director, medical director
designee, and immunohematology reference laboratory supervisor within 30 days to AABB's Accreditation and Quality Department. Standards 1.1.1, 1.1.2, and 1.2.1 apply.

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.

1.2.1 Quality Representative
The quality system shall be under the supervision of a designated person who reports to executive management.

✎ **1.2.2 Management Reviews**
Management shall assess the effectiveness of the quality system at defined intervals.

✎ **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 The medical director and/or laboratory director (as applicable) shall approve all medical and technical policies, processes, and procedures.

✎ **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.

Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

✎ **1.4 Risk Assessment**

The facility shall have a process in place to perform risk assessments for activities at defined intervals.

1.4.1 Mitigation strategies shall identify, assess, and address the level of risk associated with quality and safety.

1.5 Operational Continuity

The organization shall address continuity in the event that operations are at risk.

1.6 Emergency Preparedness

The organization shall have an emergency operation plan(s) to respond to the effects of internal and external disasters.

✎ **1.6.1** The emergency management plan, including emergency communication systems, shall be tested at defined intervals.

1.7 Communication of Concerns

The organization shall have a process for personnel to anonymously communicate concerns about quality or safety. Personnel shall be given the option to communicate such concerns either to their organization's executive management, AABB, or both. AABB's contact information shall be readily available to all personnel.

Standards 6.1.9 and 9.1 apply.

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.

1.9 Facility Status Changes

The facility shall communicate to AABB within 30 days a change that directly or indirectly impacts a facility's accreditation status.

1.9.1 If the organization is the subject of regulatory enforcement action by a relevant Competent Authority, they shall notify AABB within 7 days.

Excerpt of Record Retention Standard 6.2.9A Relevant to Organization

Standards	Record to Be Maintained	Minimum Retention Time (Years)[1]
1.1.1.1, #2	Medical director approval of services that are not routinely performed by the facility	5
1.1.3	Medical director, medical director designee, laboratory supervisor(s) change notification within 30 days	5
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	10
1.3.2	Exceptions to policies, processes, and procedures	10
1.4	Risk assessment	5
1.6.1	Emergency operation plan tested at defined intervals	2 years, or two organizational testing intervals (whichever is longer)

[1]Applicable state or local law may exceed this period.

QSE 2 – Resources

Key Concepts

This QSE describes the need for resources—human, financial, and otherwise—to support the work performed. It also describes personnel issues such as the qualification of staff assessments of competence [including those performed under Clinical Laboratory Improvement Amendment (CLIA) regulations], and continuing education requirements.

Key Terms

Competence: An individual's demonstrated ability to apply knowledge and skills needed to perform the job tasks and responsibilities.

Qualification (individuals): The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Current job descriptions.
- Evaluation of staffing levels and workload, if performed.
- Process for recruiting and hiring.
- Personnel records (eg, certifications, qualifications, competence assessments, diplomas, transcripts).
- Training records.
- Evaluations of competence records.
- Evidence that job qualifications are met.
- Continuing education records.

2. Resources

2.0 Resources

The organization shall have adequate resources to perform, verify, and manage all the activities described in these ***IRL Standards***.

2.1 Human Resources

The organization shall employ an adequate number of individuals qualified by education, training, and/or experience.

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 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.

2.1.2 Qualification

Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training, and/or experience.

2.1.3 Training

The organization shall provide training for personnel performing critical tasks.

2.1.4 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.*

*42 CFR 493.1235 and 42 CFR 493.1451(b)(8)(9).

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

2.1.4.1 Action shall be taken when competence has not been demonstrated.

2.1.5 Personnel Records

Personnel records for each employee shall be maintained.

2.1.5.1 For those authorized to perform or review critical tasks, records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

2.1.6 Continuing Education

The organization shall ensure that continuing education requirements applicable to these ***IRL Standards*** are met when applicable.

2.2 Inventory Resources

The laboratory shall maintain an appropriate inventory of antisera, reagent red cells, and reagents for testing. Confirmation of newly identified reagent red cell phenotypes shall be performed by molecular testing for the prediction of antigen status for the following: hr^B, hr^S, V, VS, U, Do^a, Do^b, Hy, Jo^a, Js^a, and Lu^a. RHCE allele information for the most common variant alleles should be used in the confirmation of the hr^B, hr^S, V, and VS antigen status. Standard 1.5 applies.

2.2.1 The laboratory shall maintain 100% of the resources listed in Reference Standard 2.2A, Inventory Resources.

2.2.2 The laboratory shall maintain at least 65% of the resources listed in Reference Standard 2.2B, Additional Inventory Resources.

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.

2.3 Educational Resources

The laboratory shall provide access to current immunohematology publications, textbooks, and appropriate journals.

Reference Standard 2.2A—Inventory Resources

ISBT Symbol	System or Collection No./ Antigen No.	Antisera	No. of Examples	Red Cells	No. of Examples
ABO	001 / 001 001 / 002 001 / 003	A B A,B	2 2 1	A_2	2
MNS	002 / 001 002 / 002 002 / 003 002 / 004	M N S s	2 2 2 2	S–s–U–	2
P1PK	003 / 001	P1	1		
RH	004 / 001 004 / 002 004 / 003 004 / 004 004 / 005 004 / 008	D C E c e C^W	2 2 2 2 2 1		
LU	005 / 001 005 / 002	 Lu^b	 1	Lu(a+b–)	2
KEL	006 / 001 006 / 002 006 / 003 006 / 004 006 / 006	K k Kp^a Kp^b	2 2 1 2	 K+k– Kp(a+b–) Js(a+b–)	 2 2 2
LE	007 / 001 007 / 002	Le^a Le^b	2 2		

FY	008 / 001 008 / 002 008 / 003	Fy^{a} Fy^{b}	2 2	Fy(a–b–)	2
JK	009 / 001 009 / 002	Jk^{a} Jk^{b}	2 2		
DI	010 / 001 010 / 003	Wr^{a}	1	Di(a+)	2
YT	011 / 002			Yt(a–b+)	2
DO	014 / 003			Do(a+b–) Do(a–b+)	2 2
CO	015 / 002			Co(a–b+)	2

Other Resources	Name
Lectin	• *Dolichos biflorus* • *Ulex europaeus*
Enzyme	• Ficin or papain
Chemical	• Chloroquine diphosphate (CDP) • EDTA glycine acid (EGA) • Dithiothreitol (DTT) or 2-mercaptoethanol (2-ME) or 2-aminoethylisothiouronium bromide (AET)
Enhancement media	• Low-ionic-strength saline (additive or wash) • Polyethylene glycol
Antihuman globulin (AHG)	• Rabbit Anti-IgG or polyspecific AHG • Anti-IgG lacking an IgG4 specificity
Other	• Cord red cells

Reference Standard 2.2B—Additional Inventory Resources[†]

ISBT Symbol	System or Collection No./ Antigen No.	Antisera	No. of Examples	Red Cells	No. of Examples
MNS	002 / 005	U	1	U+^{var} (*GYPB*230T*	1
				or *270+5t*)	1
				U–	
	002 / 006	He	1	(*GYPB*Del*	1
	002 / 011	M^g	1	*exons 2-5*)	1
				He+	
				M^g+	
P1PK	003	$PP1P^k$	1	PP_1P^k–	2
RH	004 / 006	f	1		
	004 / 007	Ce	1		
	004 / 010	V	1	V+	1
	004 / 012	G	1	r^G	1
	004 / 020	VS	1	VS+	1
	004 / 030	Go^a	1	Go(a+)	1
	004 / 032	Rh32	2	Rh:32	2
				D– –	1
				D••	1
				Rh_{null}	1
				r¢r¢	2
				r^2r^2	2
				*RHCE*ce733G/733G*	2
				$r¢^Sr¢^S$ ‡	1

LU	005 / 001 005 / 006 005 / 008	Lu[a] Lu[b]	1 1	 Lu(a–b–) Lu:-6 Lu:-8	 1 1 1
KEL	006 / 006 006 / 007	Js[a] Js[b]	1 2		
JK	009 / 003	Jk3	1	Jk(a–b–)	2
DI	010 / 001 010 / 002 010 / 003	Di[a] Di[b]	1 1	Di(a+b–) Wr(a+)	2 1
YT	011 / 001 011 / 002	Yt[a] Yt[b]	2 1		
XG	012 / 001	Xg[a]	1		
SC	013 / 001 013 / 002	Sc1 Sc2	1 1	Sc:–1 Sc:2	2 1
DO	014 / 001 014 / 002 014 / 003 014 / 004 014 / 005	 Gy[a] Hy	 1 1	*DO*A/DO*A* *DO*B/DO*B* Gy(a–) Hy– Jo(a–)	1 1 1 1 1
CO	015 / 001 015 / 002 015 / 003	Co[a] Co[b]	1 1	 Co(a–b–)	 1
LW	016 / 005 016 / 006 016 / 007	LW[a] LW[ab]	1 1	 LW(a–b–) LW(a–b+)	 1 1

RG	017 017 / 011	Ch Rg	1 1	Ch– Rg–	1 1
H	018 / 001	H (human)	1	O_h	1
GE	020 / 002 020 / 003 020 / 004	Ge2 Ge3	1 1	Ge:–2,3 Ge:–2,–3 Ge:-2, -3, -4	1 1 1
CROM	021 / 001	Cr[a]	1	Cr(a–)	1
KN	022 022 / 001 022 / 003 022 / 004 022 / 005	 Kn[a] McC[a] Sl1 Yk[a]	 1 1 1 1	Helgeson phenotype Kn(a–) McC(a–) Sl:–1 Yk(a–)	1 1 1 1 1
IN	023 / 002	In[b]	1	In(b–)	1
JMH	026 / 001	JMH	1	JMH–	2
I	027 / 001	I	1	i_{adult}	2
GLOB	028 / 001	P	1	P–	1
JR	032 / 001	Jr[a]	1	Jr(a–)	2
LAN	033 / 001	Lan	1	Lan–	2
VEL	034 / 001	Vel	2	Vel–	2
AUG	036 / 002	AUG2	1	AUG:–1,–2	1
SID	038 / 001	Sd[a]	1	Sd(a–)	2

COST	205 / 001	Cs[a]	1	Cs(a–)	2
Ii	207 / 002	i	1		
AnWj	901 / 009	AnWj	1	AnWj–	2

[†]Refer to the most recent ISBT blood group allele tables (http://www.isbtweb.org/working-parties/red-cell-immunogenetics-and-blood-group-terminology).
[‡]Molecularly characterized.

Other Resources	Name
Enzyme	• Trypsin • a-chymotrypsin • Pronase
Enhancement media	• Polybrene
Substances	• Lewis substance • P1 substance
Other	• Drug antibodies • Drug-treated red cells • Recombinant blood group protein

Excerpt of Record Retention Standard 6.2.9A Relevant to Resources

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
2.1.1	Job descriptions	5
2.1.2	Qualification of personnel performing critical tasks	5
2.1.3	Training records of personnel	5
2.1.4	Evaluations of competence	5
2.1.5	Personnel records of each employee	5 years following conclusion of employment period
2.1.5.1	Records of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
2.1.6	Continuing education (definition of requirements and verification of fulfillment) of all employees	5
2.2	Resources in inventory	5

[1]Applicable state or local law may exceed this period.

QSE 3 – Equipment

Key Concepts

This QSE describes the selection, use, maintenance, and monitoring of equipment, including information systems. It also describes the use and testing of alternative systems when primary systems fail.

Key Terms

Backup: Digital data and/or physical storage containing copies of relevant data.

Calibrate: To set or align measurement equipment against a known standard.

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the quality of the organization's products or services.

Data Integrity: The accuracy, completeness, and consistency of information.

Equipment: A durable item, instrument, or device used in a process or procedure.

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and the manufacturer's recommendations in an environment suitable for its operation and use.

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Processes for equipment selection, qualification, and maintenance.
- List or tool used for critical equipment identification.
- Equipment calibration and maintenance records, if applicable.
- Equipment qualification records.
- Manufacturer's written instructions.
- Records of investigation of equipment malfunction, failure, repair, and requalification, if applicable.
- Alarm system testing and records of alarm management, if appropriate.
- Evidence of information system backup and records of testing.

3. Equipment

3.0 Equipment
The organization shall define and control critical equipment.

3.1 Equipment Specifications
Equipment specifications shall be defined before purchase.

✎3.2 Qualification of Equipment
All critical equipment shall be qualified for its intended use.
Equipment shall be requalified, as needed, after repairs and upgrades.

3.2.1 Installation Qualification
Equipment shall be installed per manufacturer's specifications.

3.2.2 Operational Qualification
Each piece of equipment and component of an information system shall be verified before actual use.

3.2.3 Performance Qualification
Equipment shall perform as expected for its intended use.

3.3 Use of Equipment
Equipment shall be used in accordance with the manufacturer's written instructions.

✎3.4 Unique Identification of Equipment
Equipment shall have unique identification.

3.5 Equipment Monitoring and Maintenance
Equipment shall be monitored and maintained in accordance with the manufacturer's written instructions.

✎ 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 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 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.

3.5.1.3 Equipment shall be safeguarded from adjustments that would invalidate the calibration setting.

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 The organization shall:

1) Define cleaning and sanitization 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 the manufacturer's recommendations.

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.
2) Assessment of the effect on the safety of individuals affected.
3) Removal of equipment from service, if indicated.
4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected, as applicable.
5) Requalification of the equipment.
6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.*

*21 CFR 830.30.
FDA Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Device Software Functions (June, 2023).
FDA Final Guidance for Industry and FDA Staff:

General Principles of Software Validation (January 11, 2002).

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 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:

1) Numeric designation of system versions with inclusive dates of use.
2) Validation/verification/qualification of system software, hardware, databases, and user-defined tables before implementation.
3) Fulfillment of life-cycle requirements for internally developed software.†
4) Defined processes for system operation and maintenance.
5) Defined process for authorizing and documenting modifications to the system.
6) System security to prevent unauthorized access.
7) Policies, processes, and procedures and other instructional documents developed using terminology that is understandable to the user.
8) Functionality that allows for display and verification of data before final acceptance of the additions or alterations.
9) Defined process for monitoring of data integrity for critical data elements.

10) System design that establishes and maintains unique identity of the donor, the product, or service, and the recipient (as applicable).
11) Training and competency of personnel who use information systems.
12) Procedures to ensure confidentiality of protected information.
13) Risk analysis, training, validation, implementation, and evaluation of postimplementation performance.

†21 CFR 820.30, if applicable.
FDA Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Device Software Functions (June, 2023).
FDA Final Guidance for Industry and FDA Staff: General Principles of Software Validation (January 11, 2002).

3.7.1 Alternative Systems
An alternative system shall be maintained to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. The alternate system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.

3.7.2 Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect the use of the system.

3.7.3 The organization shall support the management of information systems.

3.7.4 A system designed to prevent unauthorized access to computers and electronic records shall be in place.

3.7.5 The organization shall have measures in place to minimize the risk of internal and external data breaches.

✎**3.8 Technology Infrastructure**

The organization shall have an active program to ensure that critical technology and communication infrastructures function as intended, including risk based monitoring or testing at facility defined intervals. Standards 1.4, 1.5, and 1.6 apply.

3.9 Storage Devices for Blood, Blood Components, and Reagents

3.9.1 Storage devices shall have the capacity and design to ensure that the proper temperature is maintained.

✎ **3.9.2** Internal storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored.

✎ **3.9.3** The organization shall ensure that storage devices undergo quality control testing at facility defined intervals. Standards 3.11.1, 3.11.2, and 5.1.2 apply.

✎**3.10 Liquid Nitrogen Storage and Alarms**

If storage devices for reagents utilize liquid nitrogen, either liquid nitrogen levels or temperature shall be monitored. Standards 10.4.1 and 10.4.3 apply.

3.10.1 The laboratory shall ensure that action is taken if liquid nitrogen reaches an unacceptable level or temperature.

3.10.2 If liquid nitrogen freezers are equipped with an alarm, the alarm shall be activated before the contained liquid nitrogen reaches an unacceptable level or temperature.

3.11 Alarm Systems

Storage devices for blood, blood components, and reagents (other than liquid nitrogen freezers) shall have alarms and shall conform to the following standards:

3.11.1 The alarm shall be set to activate under conditions that will allow enough time for proper action to be taken before blood, blood components, and/or reagents reach unacceptable conditions.

3.11.2 Activation of an alarm shall initiate a process for immediate action, investigation, and appropriate corrective action.

3.11.3 The organization shall ensue that alarms undergo quality control testing at least annually to verify that alarms are activated when the temperature sensing device detects an unacceptable temperature.

Excerpt of Record Retention Standard 6.2.9A Relevant to Equipment

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
3.2	Equipment qualification	10 years after retirement of the equipment
3.4	Unique identification of equipment	10
3.5.1	Equipment calibration activities	10 years after retirement of the equipment
3.5.2	Equipment found to be out of calibration	10
3.5.3	Equipment monitoring, maintenance, calibration, and repair	10 years after retirement of the equipment
3.6	Equipment traceability	10
3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of system
3.8	Monitoring or technology infrastructure	10
3.9.2	Temperature monitoring of refrigerators, freezers, and platelet incubators	10
3.9.3	Quality control of storage devices	10
3.10, 3.10.1	Monitoring of liquid nitrogen levels or temperature	10

3.11	Alarm system check	10
3.11.3	Quality control of alarm activation	10

[1]Applicable state or local law may exceed this period.

QSE 4 – Suppliers and Customers

Key Concepts

This QSE describes the need for agreements between the organization and its suppliers and customers. The agreements define expectations between both parties and measures taken when one entity fails to meet the expectations of an agreement.

Key Terms

Agreement: A contract, order, or understanding between two or more parties, such as between an organization and one of its customers.

Agreement Review: Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.

Customer: The receiver of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

Qualification (materials): For materials that come into contact with the product, verification that the materials are sterile, the appropriate grade and suitability for the intended use and, whenever possible, approved for human use by the United States Food and Drug Administration (FDA) or relevant Competent Authority.

Quality: Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.

Quality Control: Testing routinely performed on materials and equipment to ensure their proper function.

Supplier: An entity that provides a material, product, or service.

Supplier Qualification: Evaluation of a potential supplier to assess its ability to consistently deliver products or services that meet specified requirements.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Processes for defining and updating or changing agreements.
- Process for recording verbal agreements, if practiced.
- Agreement records.
- Agreement review records.
- Supplier qualification records.
- Supplier evaluation records.
- Supplier selection process.
- Evidence of action taken when a supplier fails to meet expectations, if applicable.
- Evidence of receipt of product(s) as stipulated in agreements.
- Records of inspection and testing.

4. Suppliers and Customers

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 Supplier Qualification

The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.

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.

4.1.2 When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.

4.1.3 Tests or services required by these ***IRL Standards*** shall be performed in a laboratory accredited by either the AABB or other, equivalent, accrediting body.

4.1.3.1 For US laboratories, testing shall be performed in a laboratory certified by the Centers for Medicare and Medicaid Services (CMS) and registered with the FDA, if indicated by 21 CFR 610.40(f).

4.1.3.2 For laboratories outside of the United States, testing shall be performed by a laboratory authorized as a testing center by the Competent Authority where testing is performed.

4.2 Agreements

Agreements and any incorporated changes shall be reviewed and communicated.

✎ **4.2.1** Agreements shall be reviewed at defined intervals to ensure that the terms of agreement continue to meet requirements.

4.2.2 Changes to agreements shall be communicated to affected parties.

✎ **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 Incoming Receipt, Inspection, and Testing**

Incoming products or services, equipment, and materials shall be received, inspected, and tested, as necessary, before approval for use.

4.4 Customers

The immunohematology reference laboratory shall make the following available:

1) Information for sample collection, labeling, storage, and transport.
2) Criteria for sample acceptability and rejection.
3) Information regarding test methods, specifications, and data that may affect the interpretation of test results, as applicable or upon request.

✎ **4.4.1** When a sample has been rejected and is unsuitable for testing, documentation of customer notification shall be maintained.*

*42 CFR 493.1291(c)(7).

Excerpt of Record Retention Standard 6.2.9A Relevant to Suppliers and Customers

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.3	Agreements concerning activities involving more than one organization	5
4.3	Inspection of incoming critical materials	10
4.4.1	Customer notification of sample rejection	5

[1]Applicable state or local law may exceed this period.

QSE 5 – Process Control

Key Concepts

This QSE covers the organization's operations and production functions. It describes the need to ensure that this work is controlled, that processes function as expected, and that expected outcomes are met. This QSE encapsulates what occurs in each organization and forms the basis of its accreditation.

Key Terms

Change Control: A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the quality of the organization's products or services.

Executive Management: The highest-level personnel within an organization, including employees, clinical leaders, and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

Process Control: Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.

Product: A tangible output from a process.

Reference Standard: Specified requirements defined by the AABB. Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.

Service (noun): An intangible output of a process.

Service (verb): An action that leads to the creation of a product or a result that can affect donors, patients, and/or recipients.

Standard: A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Implementation records.
- Records enabling traceability.
- Storage records.
- Quality control records.
- Process planning, process validation, and change control records.
- Records of material storage, handling, and use.
- Records of inspection of materials.
- Product inspection records.
- Testing records.

5. Process Control

5.0 Process Control

The organization shall ensure the quality of products or services.

5.1 General Elements

The organization shall ensure that processes are carried out under controlled conditions.

✎ **5.1.1 Change Control**

When the organization develops new processes or procedures or changes existing ones, they shall be validated before implementation.

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.
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

✎ **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 perform as intended.

✎ **5.1.2.1** Quality control results shall be reviewed and evaluated against acceptance criteria.

5.1.2.2 Quality control failures shall be investigated before release of test results, products, or services.

5.1.2.3 The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.

5.1.2.4 The laboratory shall evaluate the comparability of test results obtained using different methods, instruments, or testing sites. This shall be performed twice annually.* Standard 1.1, #2 applies.

*42 CFR 493.1281.
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.2.5 The laboratory shall have a facility defined process to detect titration testing errors by performing controls each day
testing is performed. Standard 5.3.3 applies.*

*42 CFR 493.1256(d)(3)(iii).

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 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 Process Validation

Before implementation, the new or changed processes and procedures shall be validated.

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.

5.1.5 Process Implementation

The implementation of new or changed processes and procedures shall be planned and controlled.

5.1.5.1 Postimplementation evaluations of new or changed processes and procedures shall be performed.

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.

5.1.6.1 FDA Licensed or Approved Materials

All laboratory materials that are FDA licensed or approved or cleared shall be used in accordance with the manufacturers' written instructions and shall meet specified requirements.

5.1.6.1.1 When reagents are not used in accordance with the manufacturer's written instructions, they shall be tested per laboratory-defined procedures.

5.1.6.2 Reagents Prepared by the Laboratory

5.1.6.2.1 Reagents prepared in the laboratory shall be used in accordance with laboratory instructions or as described in relevant publications.

5.1.6.2.2 Criteria shall be defined for the use and/or preparation of unlicensed reagents (eg, noncommercial or expired).

5.1.6.2.2.1 The laboratory shall have a policy for the use of rare reagents when appropriate control materials are not available.

5.1.6.2.3 Labeling of laboratory-prepared reagents shall meet or exceed CLIA requirements.*

*42 CFR 493.1252
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.6.2.4 Reagents (antisera, red cells) prepared by the laboratory and used instead of available commercial reagents shall meet or exceed applicable FDA or Competent Authority criteria established for licensed reagents.†

†21 CFR 660.25(a) and 21 CFR 660.33.

5.1.6.2.5 For noncommercial antisera the laboratory shall ensure that the source, ABO group, antibody specificity(ies), and reactivity phase can be identified.

5.1.6.2.6 For noncommercial red cells, the laboratory shall ensure that the source, ABO group, phenotype, and/or genotype can be identified.

5.1.7 Inspection

The organization shall ensure that products or services are inspected at organization-defined stages.

5.1.7.1 The laboratory shall verify that specified requirements are met for critical materials, samples, blood, and components.

✎ **5.1.8 Identification and Traceability**
The organization shall ensure that all products or services are identified and traceable.

✎ **5.1.8.1** This shall include blood components, samples, critical materials, and requests.

5.1.8.2 The laboratory shall have a procedure for modifications to the labeling of a blood component, including antigen-negative products, if performed.

5.1.8.2.1 The laboratory shall have a policy for the labeling of Red Blood Cell units with historical antigen typing results.*

*FDA Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen Typing Results (December 2018).

5.1.8.3 The laboratory shall ensure that test requests are received for all samples submitted.

✎ **5.1.8.3.1** For laboratories that accept verbal requests, a written or electronic authorization shall be requested within 30 days. If the requested written or electronic authorization is not provided, the laboratory shall maintain evidence of efforts to obtain the authorization.

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.

5.1.9.1 This shall include critical materials, blood components, and samples.

5.1.10 Proficiency Testing Program

The laboratory shall participate in a proficiency testing program for each analyte tested by the laboratory. Results shall be reviewed and corrective action taken, where appropriate, when expected results are not achieved.

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)(4), 42 CFR 493.857, 42 CFR 493.959(c), and 42 CFR 493.1236.
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

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)(4).
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA

Compliance Form before on-site assessment.

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)(5).
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

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)(5).
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.10.2 The laboratory shall participate in the proficiency testing program that is provided by the AABB Immunohematology Reference Laboratory Accreditation Committee.

5.1.10.2.1 The laboratory shall have no more than one failed AABB immunohematology reference laboratory proficiency test within a 2-year period.

5.1.11 Receipt of Materials

Incoming materials shall be received, inspected, and tested, as necessary, before acceptance or use.

5.1.11.1 Critical materials shall meet specified requirements as defined by the laboratory and/or manufacturer.

5.1.11.1.1 A comparison with the manufacturer's previous instructions shall be performed and procedures updated as needed.

5.1.11.2 Where manufacturers' instructions are used as a standard operating procedure, any new or revised instructions that impact test results shall be reviewed and approved by the laboratory director before use.* Standard 1.3.1 applies.

*42 CFR 493.1251(d).

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.1.12 Tests or Methods Developed by the Laboratory

Tests or methods developed by the laboratory shall be validated.

5.1.13 The report shall contain a disclaimer if any of the following conditions occur:

1) Testing is not performed in accordance with the manufacturer's written instructions.
2) Controls are not available.
3) A test created by the laboratory is used. Standard 5.5 applies.

5.1.14 Appropriate controls shall be used to ensure reliability of the test results when deviating from manufacturers' written instructions for immunohematology investigations.

5.2 American Rare Donor Program

All laboratories shall participate in the ARDP system by performing at least one of the following functions on an annual basis:

1) Ship 15 units to other participating laboratories through the ARDP.
2) Screen at least 1000 donors for high-prevalence antigens.
3) Screen at least 1000 donors for immunoglobulin A deficiency.
4) A combination of shipping at least 7 units to other participating laboratories through the ARDP and screening at least 500 donors for high-prevalence antigens.
5) Provide antisera (or for noncollecting facilities, provide resources) to another ARDP member laboratory for use in screening donors for high- or low-prevalence antigens for the purpose of identifying rare donors.
6) Perform at least one family study to identify rare donors.

5.2.1 Donor-center-based laboratories shall register donors identified as lacking a high-prevalence antigen(s).

5.2.2 Donor-center-based laboratories shall also register at least 10 donors with the ARDP on an annual basis. Standards 5.2 and 5.2.1 apply.

5.3 Serologic Investigation

The laboratory shall demonstrate the capability of performing complex immunohematology testing.

5.3.1 ABO/D Problem Resolution

Before the blood type is reported, ABO group and D type discrepancies shall be investigated and resolved unless justified by history or previous testing.

5.3.1.1 Weak or mixed-field red cell typing shall be investigated and resolved.

5.3.1.2 Unexpected or missing reactivity in the plasma that has the potential to affect ABO interpretation shall be investigated and resolved.

5.3.1.2.1 This shall include the review of any serological finding(s) that could potentially interfere with the forward and reverse grouping interpretations regardless of ABO type.

5.3.2 Serologic Capabilities

The laboratory shall recognize and investigate each of the following:

1) Single and multiple antibodies.
2) Autoantibodies.
3) Drug-dependent antibodies.
4) Hemolytic disease of the fetus and newborn.
5) Hemolytic transfusion reaction.
6) Antibodies to high- and low-prevalence antigens.
7) Aberrant and/or discrepant red cell antigen typing results, including ABO subgroups and other weak antigen expressions.
8) Reagent-dependent reactivity.
9) Interfering therapeutic agents.
10) Cold-reactive antibodies.

Standard 1.3 applies.

5.3.3 Investigational Techniques

The laboratory shall have the following processes:

1) Elution.
2) Adsorption (autologous and allogeneic).
3) Enzyme treatment of red cells.
4) Use of reducing agent(s).
5) Prediction of antigen status through molecular methods and/or cell separation for determination of red cell phenotype.
6) Immunoglobulin removal from red cells.
7) Inhibition/neutralization.
8) Dilution.
9) Titration.

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.

*42 CFR 493.1256(d)(3)(iii).

Standard 5.1.10 applies.

5.3.5 Antibody Investigation

The laboratory shall:

1) Evaluate available historical patient information and antibody history.

2) Exclude commonly encountered clinically significant red cell alloantibodies. When commonly encountered clinically significant red cell alloantibodies are not excluded due to special circumstances, blood released for transfusion shall lack the corresponding antigen(s).

3) Assign new antibody specificity after demonstrating reactivity with at least two antigen-positive red cell samples and nonreactivity with at least two antigen-negative red cell samples.

4) Evaluate the testing performed and determine the impact test results have on the final workup interpretation and recommendations, if provided.

Reference Standard 5.5.1A, Requirements for Investigation Reports, applies.

5.3.6 Compatibility

If testing is performed, the laboratory shall have a procedure to demonstrate red cell compatibility between patient serum/plasma and donor red cells. Standard 5.1.10 applies.

5.3.7 Testing Records

Records of testing, including records of previously identified antibodies, shall be maintained.

5.4 Molecular Tests

The laboratory shall have a policy for the use of red cell genotype information obtained by molecular test methods.

5.4.1 Results and interpretations shall be compared with available serologic results and discrepancies investigated.

5.4.2 The policy shall address the identification, procurement, and management of rare donors with allele determinations for RH

and other variants that can aid in antibody identification and molecular matching. Standard 2.2 applies.

5.5 Results and Reports

The laboratory shall ensure that test results and immunohematology reports are reviewed and deemed acceptable before release.*

*42 CFR 493.1291.
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

5.5.1 Interpretations of immunohematology investigations shall be reported in a timely manner.

5.5.2 Investigation reports shall contain the information required by Reference Standard 5.5.1A, Requirements for Investigation Reports.

5.5.3 The laboratory shall control the release of test results.†

†45 CFR 164.506(c)(4), 45 CFR 164.524(c)(3)(ii).
For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

Reference Standard 5.5.1A—Requirements for Investigation Reports

Item	Requirement
Internal Investigation Reports	
1	Patient name or unique identifier*
2	Identification or accession number*
3	Date sample was drawn
4	Final interpretation of results
External Investigation Reports*†	
1	Patient name or unique identifier
2	Identification or accession number
3	Date(s) sample was drawn and received
4	Date of final written report
5	The test performed‡
6	Clinically significant antibodies detected
7	Other reactivity that would affect compatibility
8	Previously identified clinically significant alloantibodies
9	Blood selection criteria, where appropriate
10	ISBT-accepted terminology for blood group antigens/antibodies§

11	Information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability
12	Laboratory identification a. Laboratory name, address, and telephone number b. Name of person responsible for report
13	Name of referring facility or physician

*42 CFR 493.1291(c).
For accredited facilities that are assessed for CLIA conformance by AABB, refer to the Verification of CLIA Compliance Form before on site assessment.
†Standard 7.1.1.3 applies.
‡42 CFR 493.1291(c)(4) refers to interpretive guidelines.
§ISBT = International Society of Blood Transfusion; www.isbtweb.org.

Excerpt of Record Retention Standard 6.2.9A Relevant to Process Control		
Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	10
5.1.2.1	Comparison of test results using different test methods	10
5.1.2.4	Review of quality control results for reagents, equipment, and methods	10
5.1.2.5	A process to detect immediate testing errors and monitor test system performance on a daily basis or when testing is performed	10
5.1.5.1	Evaluations of new or changed processes and procedures	5
5.1.6.2.4	Documentation that reagents prepared by the laboratory meet or exceed applicable FDA criteria	5
5.1.6.2.5	Source, ABO group, antibody specificity, and reactivity phase for noncommercial antisera	5
5.1.6.2.6	Identification of noncommercial red cells	5

5.1.7	Inspection of critical materials, samples, blood, and components	5
5.1.8	Identification and traceability of products	5
5.1.8.1	Identification and traceability of samples, critical materials, and requests	5
	Identification and traceability of blood components	10
5.1.8.3.1	Written or electronic authorization of oral requests within 30 days	5
5.1.10	Participation in proficiency testing program	5
5.1.11	Inspection of incoming materials and samples	10
5.1.11.1	Manufacturer's instructions	5
5.1.11.1.1	Comparison of previous manufacturer's instructions to current version	5
5.2	Participation in the ARDP	5
5.3.4	Testing procedures	2 years after a procedure has been discontinued
5.3.6	Red cell compatibility	5
5.3.7	Testing records	10

5.3.7	Patient antibody history	Indefinite
5.4.2	Management of rare donors with allele determination for RH and other variants	5
5.5	Review of completed test results and reports	10
5.5.2	Investigation reports (or a duplicate of the original report)	10

[1]Applicable state or local law may exceed this period.

QSE 6 – Documents and Records

Key Concepts

This QSE focuses on the need to maintain all documents and records in a manner that ensures their confidentiality, traceability, completeness, uniformity, and ability to be retrieved and located in a time deemed adequate. This QSE also includes the need to ensure data integrity and that all data can be backed up and retrieved.

Key Terms

Backup: Digital data and/or physical storage containing copies of relevant data.

Confidentiality: The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure.

Data Integrity: The accuracy, completeness, and consistency of information.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

Document (verb): To capture information through writing or electronic media.

Label: An inscription affixed or attached to a product for identification.

Labeling: Information that is required or selected to accompany a product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

Master List of Documents: A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the ***IRL Standards,*** including information for document control.

Record (noun): Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Record (verb): To capture information for use in records through writing or electronic media.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Records of activities performed.
- Record system.
- Master list of documents.
- An electronic record system, if applicable.
- Uniform storage media and ability to track newer technologies to older ones as needed.
- Evidence of document and record review.
- Evidence of standardized formats for all documents and records.
- Record retention periods.
- Record traceability.
- Data backup plans.
- Record change process.
- Obsolescence of records and disposition.
- Record destruction.

6. Documents and Records

6.0 Documents and Records

The organization shall ensure that documents and records are created, stored, and archived in accordance with record retention policies.*

*42 CFR 493.1105.

For accredited facilities that are assessed by AABB for conformance with the Clinical Laboratory Improvement Amendments (CLIA), refer to the Verification of CLIA Compliance Form before on-site assessment.

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.

6.1.1 Format

Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual or published in the AABB **Technical Manual**) may be incorporated by reference.

6.1.1.1 If a referenced document serves as the source of a process or procedure, it shall be identified and available. Standard 6.1.1 applies.

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 Document Changes**
Changes to documents shall be reviewed and approved by an authorized individual.

6.1.3.1 The organization shall track changes to documents.

✎ **6.1.4 Master List of Documents**
The organization shall maintain complete lists of all active policies, processes, procedures, labels, forms, and other documents that relate to the requirements of these ***IRL Standards***.

✎ **6.1.5 Review of Policies, Processes, and Procedures**
Review of each policy, process, and procedure shall be performed by an authorized individual at a minimum of every 2 years.

6.1.5.1 The organization shall review and approve all new and revised documents before use, including manufacturers' instructions and operator's manuals when used as a standard operating procedure. Standard 1.1.1 applies.*

*42 CFR 493.1251(d).

✎ **6.1.6 Document Retention**
The organization shall determine which documents shall be archived, destroyed, or made obsolete.

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 Document Retrieval

The organization shall ensure that documents are retrievable in a timely manner.

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 Record Control

The organization shall maintain a system for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.

6.2.1 Records

Records shall be complete, retrievable in a period appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.

6.2.2 Record Traceability

The records system shall ensure traceability of:

1) Critical activities performed.
2) The individual who performed the activity.
3) Date the activity was performed.
4) Time the activity was performed, if applicable.
5) Results obtained.
6) Method(s) used.
7) Equipment used.
8) Critical materials used.
9) The organization where the activity was performed.

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.

6.2.4 Legibility
All records shall be legible and indelible.

6.2.5 Record Change
The organization shall establish processes for changing records. The date and identity of the person making the change shall be recorded. Record changes shall not obscure previously recorded information.

6.2.5.1 Changes to records (including electronic records) shall be verified for accuracy and completeness.

6.2.6 Records shall be created concurrently with performance of each critical activity.

6.2.6.1 The actual result of each test performed shall be recorded immediately, and the final interpretation shall be recorded upon completion of testing.

6.2.7 Copies
Before destruction of original records, copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.

6.2.8 Confidentiality
The organization shall ensure the confidentiality of records.

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 Record Review**

Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.

6.2.11 Storage of Records

Records shall be stored to:

1) Preserve record legibility and integrity for the entire retention period.
2) Protect from accidental or unauthorized access, loss, deterioration, damage, destruction, mix-up, or modification.
3) Permit ready identification.
4) Allow retrieval in a defined time frame.

6.2.12 Destruction of Records

Destruction of records shall be conducted in a manner that protects the confidential content of the records.

✎ **6.3 Electronic Records**

The organization shall support the management of information systems.

6.3.1 Access to Data and Information

Access to data and information shall be controlled.

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** Electronic records shall include the date and identity of the person making a change.

6.3.2 Data Integrity

Data integrity shall ensure that data are retrievable and usable.

6.3.2.1 Data shall be accurately, reliably, and securely sent from the point of entry to final destination.

6.3.2.2 Data shall be retrievable for the entire retention period.

6.3.2.2.1 The organization shall archive records or data from media and platforms no longer in use.

6.3.2.3 There shall be a process in place for routine backup of all critical data.

6.3.3 Storage Media

Data storage media shall be protected from damage or unintended access and destruction.

6.3.4 Backup Data

The organization shall back up all critical data.

6.3.4.1 Backup data shall be stored in a secure off-site location.

6.3.4.2 Backup data shall be protected from unauthorized access, loss, or modification.

6.3.4.3 The ability to retrieve data from the backup system shall be tested at defined intervals.

Excerpt of Record Retention Standard 6.2.9A Relevant to Documents and Records

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
6.1.2	Document control, including review and approval of all documents before use	5
6.1.3	Review and approval of changes to documents	5
6.1.4	List of all active policies, processes, procedures, labels, and forms	5
6.1.5	Biennial review of each policy, process, or procedure	5
6.1.6	Documents that are archived, destroyed, or made obsolete	5
6.2.5	Record change	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	5
6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	5
6.3	Electronic records	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	5

[1]Applicable state or local law may exceed this period.

Reference Standard 6.2.9A—Retention of Records

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
1.1.1.1, #2	Medical director approval of services that are not routinely performed by the facility	5
1.1.3	Medical director, medical director designee, laboratory supervisor(s) change notification within 30 days	5
1.2.2	Management review of effectiveness of the quality system	5
1.3	Policies, processes, and procedures	10
1.3.2	Exceptions to policies, processes, and procedures	10
1.4	Risk assessment	5
1.6.1	Emergency operation plan tested at defined intervals	2 years, or two organizational testing intervals (whichever is longer)
2.1.1	Job descriptions	5
2.1.2	Qualification of personnel performing critical tasks	5
2.1.3	Training records of personnel	5
2.1.4	Evaluations of competence	5

2.1.5	Personnel records of each employee	5 years following conclusion of employment period
2.1.5.1	Records of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
2.1.6	Continuing education (definition of requirements and verification of fulfillment) of all employees	5
2.2	Resources in inventory	5
3.2	Equipment qualification	10 years after retirement of the equipment
3.4	Unique identification of equipment	10
3.5.1	Equipment calibration activities	10 years after retirement of the equipment
3.5.2	Equipment found to be out of calibration	10
3.5.3	Equipment monitoring, maintenance, calibration, and repair	10 years after retirement of the equipment
3.6	Equipment traceability	10
3.7	Implementation and modification of software, hardware, or databases	2 years after retirement of system

3.8	Monitoring or technology infrastructure	10
3.9.2	Temperature monitoring of refrigerators, freezers, and platelet incubators	10
3.9.3	Quality control of storage devices	10
3.10, 3.10.1	Monitoring of liquid nitrogen levels or temperature	10
3.11	Alarm system check	10
3.11.3	Quality control of alarm activation	10
4.1	Evaluation and participation in selection of suppliers	5
4.2	Agreements	5
4.2.1	Agreement review	5
4.2.3	Agreements concerning activities involving more than one organization	5
4.3	Inspection of incoming critical materials	10
4.4.1	Customer notification of sample rejection	5
5.1.1	Validation of new or changed processes and procedures	5
5.1.2	Quality control records and review of quality control results	10

5.1.2.1	Comparison of test results using different test methods	10
5.1.2.4	Review of quality control results for reagents, equipment, and methods	10
5.1.2.5	A process to detect immediate testing errors and monitor test system performance on a daily basis or when testing is performed	10
5.1.5.1	Evaluations of new or changed processes and procedures	5
5.1.6.2.4	Documentation that reagents prepared by the laboratory meet or exceed applicable FDA criteria	5
5.1.6.2.5	Source, ABO group, antibody specificity, and reactivity phase for noncommercial antisera	5
5.1.6.2.6	Identification of noncommercial red cells	5
5.1.7	Inspection of critical materials, samples, blood, and components	5
5.1.8	Identification and traceability of products	5
5.1.8.1	Identification and traceability of samples, critical materials, and requests	5
	Identification and traceability of blood components	10
5.1.8.3.1	Written or electronic authorization of oral requests within 30 days	5

5.1.10	Participation in proficiency testing program	5
5.1.11	Inspection of incoming materials and samples	10
5.1.11.1	Manufacturer's instructions	5
5.1.11.1.1	Comparison of previous manufacturer's instructions to current version	5
5.2	Participation in the ARDP	5
5.3.4	Testing procedures	2 years after a procedure has been discontinued
5.3.6	Red cell compatibility	5
5.3.7	Testing records	10
5.3.7	Patient antibody history	Indefinite
5.4.2	Management of rare donors with allele determination for RH and other variants	5
5.5	Review of completed test results and reports	10
5.5.2	Investigation reports (or a duplicate of the original report)	10
6.1.2	Document control, including review and approval of all documents before use	5
6.1.3	Review and approval of changes to documents	5

6.1.4	List of all active policies, processes, procedures, labels, and forms	5
6.1.5	Biennial review of each policy, process, or procedure	5
6.1.6	Documents that are archived, destroyed, or made obsolete	5
6.2.5	Record change	5
6.2.7	Verification that copies of records contain the original content and are legible, complete, and accessible before the original records are destroyed	5
6.2.10	Review of records for accuracy, completeness, and compliance with applicable standards, laws, and regulations	5
6.3	Electronic records	5
6.3.1.1.1	Date and identity of person making change(s) to electronic records	5
7.1	Deviations	10 years after any impacted product is used or discarded
7.2	Nonconforming products or services	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10

7.2.4.1	Disposition of the nonconforming product or service	10
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10
10.4.3	Alarm investigation	5

[1]Applicable state or local law may exceed this period.

QSE 7 – Deviations, Nonconformances, and Adverse Events

Key Concepts

This QSE focuses on the need to ensure capture of, management of, and response to deviations, nonconformances, or adverse events. This also includes the need to maintain records of resolution.

Key Terms

Adverse Event: A complication. Adverse events may occur in relation to organization-defined activities.

Conformance: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Disaster: An event (internal, local, or national) that can affect the safety and availability of the organization's products or the safety of individuals.

Near-Miss Event: An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.

Nonconformance: Failure to meet requirements.

Root Cause(s): The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Traceability: The ability to follow the history of a product or service from source to final distribution or disposition using records.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Records and evaluation of deviations, nonconformances, and adverse events.
- Notification to customer(s) following investigation, if appropriate.

- Records of evidence that measures were taken to ensure deviations, nonconformances, and adverse events do not recur.
- Planned deviation records, if any.
- Records of deviation reporting to appropriate parties (eg, FDA).

7. Deviations, Nonconformances, and Adverse Events

7.0 Deviations, Nonconformances, and Adverse Events

The organization shall capture, assess, investigate, and monitor failures to meet specified requirements. The responsibility for review and authority for the disposition of nonconformances shall be defined. These events shall be reported in accordance with specified requirements and to outside agencies as required.*

*21 CFR 606.171, 21 CFR 1271.350, and 42 CFR 493.1103(d).

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 Nonconformances

Upon discovery, nonconforming products or services shall be evaluated and their disposition determined.

7.2.1 Nonconforming products shall be quarantined and/or destroyed.

7.2.1.1 When a nonconforming blood component is identified, the laboratory shall perform an investigation to determine the need for further action by the laboratory or the blood provider.

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 The organization shall:

1) Identify, quarantine, retrieve, recall, and determine the disposition of nonconforming products or services.

2) Identify and manage nonconforming products or services.
3) Notify customers and outside agencies as required.

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 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 Adverse Events

The organization shall detect, monitor, evaluate, manage, and report adverse events related to safety and quality.

7.3.1 Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.

7.3.2 Investigation results and analysis shall be communicated among all facilities involved, if applicable.

Excerpt of Record Retention Standard 6.2.9A Relevant to Deviations, Nonconformances, and Adverse Events

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
7.1	Deviations	10 years after any impacted product is used or discarded
7.2	Nonconforming products or services	10 years after any impacted product is used or discarded
7.2.4	Nature of nonconformances discovered after release and subsequent actions taken, including acceptance for use	10
7.2.4.1	Disposition of the nonconforming product or service	10

[1]Applicable state or local law may exceed this period.

QSE 8 – Internal and External Assessments

Key Concepts

This QSE addresses the organization's internal quality assessment functions as well as processes to support external assessments by accreditors, health authorities, and regulators. This chapter also describes the need for the organization to engage in ongoing quality monitoring and utilization review.

Key Terms

Adverse Event: A complication. Adverse events may occur in relation to organization-defined activities.

Assessment: A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.

Competent Authority: The agency responsible under its national law for regulations applicable to the organization.

Conformance: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Nonconformance: Failure to meet requirements.

Preventive Action: An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances, or other undesirable situations.

Quality Indicator Data: Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by executive management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data

used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

Root Cause(s): The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Records of internal assessments scheduled and conducted.
- Records of evidence that deficiencies discovered during assessments and inspections have been addressed, including changes to quality or operational functions.
- Records of external assessments being conducted.
- Quality indicator data collection and review.

8. Internal and External Assessments

8.0 Internal and External Assessments

The organization shall conduct assessments of operations and quality systems.

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 External Assessments

The organization shall participate in an external assessment program applicable to the activities performed in the organization.

8.3 Management of Assessment Results

The results of assessments shall be:

1) Reviewed by the personnel having responsibility for the area assessed.
2) Evaluated to determine the need for corrective and preventive action.
3) Communicated to the appropriate staff.
4) Reported to executive management.

8.3.1 When corrective action is taken, it shall be developed, implemented, and evaluated in accordance with Chapter 9, Process Improvement.

8.4 Quality Monitoring

The organization shall collect and evaluate quality indicator data on a scheduled basis, including adverse events.

8.4.1 The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.

Excerpt of Record Retention Standard 6.2.9A Relevant to Internal and External Assessments

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
8.1	Internal assessments	5
8.2	External assessments	5
8.3	Management of assessment results	5

[1]Applicable state or local law may exceed this period.

QSE 9 – Process Improvement

Key Concepts
This QSE focuses on the use of corrective and preventive actions to drive process improvement. It describes measures to ensure that the root causes of nonconformances are effectively addressed.

Key Terms
Adverse Event: A complication. Adverse events may occur in relation to organization-defined activities.

Assessment: A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Near-Miss Event: An unexpected occurrence that did not adversely affect the outcome but could have resulted in a serious adverse event.

Nonconformance: Failure to meet requirements.

Preventive Action: An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances, or other undesirable situations.

Root Cause(s): The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Records of collected data analysis and corrective action taken when near-misses, deviations, or adverse events are discovered.
- Tracking of relevant data that affect the organization's current and future operations.

- Records indicating that corrective and preventive action was taken.
- Records indicating that corrective and preventive action taken was effective and is being monitored.
- Documentation that process improvement data are included in executive management review.

9. Process Improvement

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 Corrective Action

The organization shall have a process for corrective action that includes:

1) Description of the event.
2) Investigation of the root cause(s) of nonconformances relating to the product or service, the process, and the quality system.
3) Determination of the corrective action needed to eliminate the cause of nonconformances, as applicable.
4) Ensuring that corrective action is reviewed and found to be effective.

9.1.1 Investigation and corrective action shall include consideration of deviations, nonconformances, and complaints.

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.
2) Determination of steps needed to address any problems requiring preventive action.
3) Initiation of preventive action and application of controls to ensure that it is effective.

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.

Excerpt of Record Retention Standard 6.2.9A Relevant to Process Improvement

Standard	Record to Be Maintained	Minimum Retention Time (Years)[1]
9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
9.1	Corrective action	5
9.2	Preventive action	5

[1]Applicable state or local law may exceed this period.

QSE 10 – Facilities and Safety

Key Concepts
This QSE addresses the safety and adequacy of areas where the work required by these ***IRL Standards*** is performed. This includes occupational safety, biohazardous material disposal, environmental monitoring, and compliance with applicable local and national regulations.

Key Terms

Environmental Monitoring: Policies, processes, and procedures used for monitoring any or all of the following: temperature, humidity, particulates, and microbial contamination in a specific area. Where appropriate, the program shall include sampling sites, frequency of sampling, and investigative and corrective actions that should be followed when specified limits are exceeded.

Executive Management: The highest-level personnel within an organization, including employees, clinical leaders, and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

Organization: An institution, or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

Examples of Objective Evidence

- Policies, processes, and procedures related to this chapter.
- Safe environmental conditions for all individuals in the organization.
- Local, state, and national regulations being followed.
- Proper discard of hazardous and potentially hazardous materials.
- Personal protective equipment (PPE) is available and in use.

10. Facilities and Safety

10.0 Facilities and Safety

The organization shall ensure safe environmental conditions. The work area shall be suitable for the activities performed. Safety programs shall meet local, state, and national regulations.

10.1 Safe Environment

The organization shall minimize and respond to environmentally related risks to the health and safety of all individuals and products or services. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

✎10.2 Biological, Chemical, and Radiation Safety

The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.

✎10.3 Handling and Discarding of Products

Products shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

10.4 Environmental Monitoring

The laboratory shall monitor, control, and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. Standard 3.5 applies.

10.4.1 Where liquid nitrogen is stored, specific hazards shall be addressed, including but not limited to:

1) Visible signage posted both inside and outside the storage space.
2) Ventilation and airflow adequate to the space where the liquid nitrogen is stored.

10.4.2 Laboratories with liquid nitrogen tanks shall have a system in place to monitor oxygen levels and an alarm system set to activate under conditions that will allow action to be taken.

10.4.3 Oxygen alarm activation shall require personnel to investigate and document the condition activating the alarm and to take immediate corrective action as necessary.

10.4.3.1 Oxygen sensors shall be installed per manufacturers' written instructions.

Excerpt of Record Retention Standard 6.2.9A Relevant to Facilities and Safety

Standard	Record to Be Maintained	Minimum Retention Time[1]
10.2	Monitoring of biological, chemical, and radiation safety	5
10.3	Appropriate discard of products	10
10.4.3	Alarm investigation	5

[1]Applicable state or local law may exceed this period.

Glossary

Adsorption: A process that removes antibody from a sample using a substance or cell that contains the target antigen to which the antibody is directed.

Adverse Event: A complication. Adverse events may occur in relation to organization-defined activities.

Agreement: A contract, order, or understanding between two or more parties, such as between an organization and one of its customers.

Agreement Review: Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.

American Rare Donor Program: A program that functions primarily in the United States to coordinate the registry of rare donors and the location of rare blood components for patients in need of transfusion.

Analyte: Substance or constituent for which the laboratory conducts testing.

Antibody: A protein resulting from an immune response to an antigen.

Antibody History: The historical record of previously identified blood group antibodies from internal and/or external sources.

Antibody Screen: A serologic method to detect the presence of clinically significant antibodies in recipients and/or donors.

Antigen: A substance that can stimulate an immune response in the form of an antibody.

Antisera: Reagents (commercial or noncommercial) containing documented, characterized, antibody specificity(ies).

Assessment: A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.

Backup: Digital data and/or physical storage containing copies of relevant data.

Blood Groups: Antigenic determinants present on blood cells, which include red cells, platelets, and neutrophils for the purpose of these ***IRL Standards***.

Calibrate: To set or align measurement equipment against a known standard.

Certified by the Centers for Medicare & Medicaid Services (CMS): Having met the requirements of the Clinical Laboratory Improvement Amendments of 1988 for nonwaived testing through inspection by the CMS, a deemed organization, or an exempt state agency.

Change Control: A structured method of revising a policy, process, or procedure, including hardware or software design, transition planning, and revisions to all related documents.

Clinically Significant Antibody: An antibody that is frequently associated with hemolytic disease of the fetus and newborn, hemolytic transfusion reactions, or a notable decrease in survival of transfused red cells.

Competence: An individual's demonstrated ability to apply knowledge and skills needed to perform their job tasks and responsibilities.

Competent Authority: The agency responsible under its national law for regulations applicable to the organization.

Compliance: See Conformance.

Confidentiality: The protection of private, sensitive, or trusted information resources from unauthorized access or disclosure.

Conformance: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.

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.

Corrective Action: Actions taken to address the root cause(s) of an existing nonconformance or other undesirable situation in order to reduce or eliminate recurrence.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the quality of the organization's products or services.

Customer: The recipient of a product or service. A customer may be internal (eg, another organizational unit within the same organization) or external (eg, a patient, client, donor, or another organization).

Data Integrity: The accuracy, completeness, and consistency of information.

Deviation: A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Disaster: An event (internal, local, or national) that can affect the safety and availability of the organization's products or the safety of individuals.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

Document (verb): To capture information through writing or electronic media.

Drug-Dependent Antibody: An antibody, the action of which requires the presence or product of a drug or chemical. The product of a drug or chemical may include a metabolite of the drug or an alteration of antigen or antibody caused by the drug or chemical.

Elution: Recovery/release of bound antibody from its antigen.

Equipment: A durable item, instrument, or device used in a process or procedure.

Emergency Management: Strategies and specific activities designed to manage situations in which there is a significant disruption to organization operations or a significantly increased demand for the organization's products or services.

Environmental Monitoring: Policies, processes, and procedures used for monitoring any or all of the following: temperature, humidity, particulates, and microbial contamination in a specific area. Where appropriate, the

program shall include sampling sites, frequency of sampling, and investigative and corrective actions that should be followed when specified limits are exceeded.

Establish: To perform all of the activities required to plan, validate, and implement a system or process.

Executive Management: The highest-level personnel within an organization, including employees, clinical leaders, and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

Facility: A location or operational area within an organization. The part of the organization that is assessed by the AABB and receives AABB accreditation for its specific activities.

Family Study: The testing of various members of a pedigree to determine the inheritance of traits.

Genotype: The genetic makeup of an organism, or group of organisms, with reference to a single trait, set of traits, or an entire complex of traits; the specific allelic composition of a gene, or set of genes, established at the DNA level.

Hemolytic: Capable of causing the release of free hemoglobin from a red cell, usually by rupture of the cell; capable of causing intravascular or extravascular immune destruction of red cells.

High-Prevalence Antigen: An antigen present on the surface of red cells in more than 99.9% of most human populations.

Immunohematology: The study of blood group antibodies, antigens, and associated problems.

Immunohematology Reference Laboratory: A facility equipped for performing investigational procedures pertaining to immunohematologic studies.

Inspect: To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements.

Installation Qualification: Verification that the correct equipment is received and that it is installed according to specifications and the manufacturer's recommendations in an environment suitable for its operation and use.

Interfering Therapeutic Agent: A biological or chemical entity, including antibody preparations or substance administered to the patient, that may affect the interpretation of serologic results (eg, antibodies).

Key Quality Functions: Essential job functions that affect the quality of products or services provided by the organization.

Label: An inscription affixed or attached to a product for identification.

Labeling: Information that is required or selected to accompany the product, which may include content, identification, description of processes, storage requirements, expiration date, cautionary statements, or indications for use.

Lectin: Proteins, generally of plant origin, that bind specifically with carbohydrates and cause agglutination of red cells.

Low-Prevalence Antigen: An antigen present on the surface of red cells in fewer than 1% of most human populations.

Maintain: To keep in the current state; to preserve or retain; to keep in a state of validity.

Master List of Documents: A reference list, record, or repository of an organization's policies, processes, procedures, forms, and labels related to the ***IRL Standards***, including information for document control.

Material: A supply item used in a process or procedure.

Molecular Typing: For the purpose of these ***IRL Standards***, molecular testing is defined as the analysis of nucleic acid to determine blood group alleles and predict the phenotype.

Near-Miss Event: An unexpected occurrence that did not adversely affect the outcome but could have resulted in an adverse event.

Nonconformance: Failure to meet requirements.

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.

Operational Qualification: Verification that equipment will function according to the operational specifications provided by the manufacturer.

Operational Systems: Processes, resources, and activities that work together to result in a product or service.

Organization: An institution or a location or operational area within that organization; the entity assessed by the AABB and receiving AABB accreditation for specific activities.

Performance Qualification: Verification that equipment performs consistently as expected for its intended use in the organization's environment, using the organization's procedures and supplies.

Phenotype: The expression of blood group antigens on a cell membrane detected by an antibody. The observed biochemical, physiological, and/or morphological characteristics of an individual, as determined by the interaction of the genotype and the environment in which it is expressed.

Policy: A set of basic principles or guidelines that direct or restrict the organization's plans, actions, and decisions.

Polyagglutination: Condition in which an individual's red cells are agglutinated by virtually all normal adult human sera, but not by cord sera.

Preventive Action: An action taken to reduce or eliminate the potential for unexpected deviations, nonconformances, or other undesirable situations.

Procedure: A defined series of tasks and instructions that specify how an activity is to be performed.

Process: A set of related activities that transform inputs into outputs.

Process Control: Activities designed to ensure that processes are stable and consistently operate within acceptable limits of variation in order to produce predictable output that meets specifications.

Product: A tangible output from a process.

Proficiency Testing: The structured evaluation of laboratory test results that encompasses the suitability of processes, procedures, equipment, materials, and personnel.

Qualification (individuals): The aspects of an individual's education, training, and experience that are necessary for the individual to successfully meet the requirements of a position.

Qualification (materials): For materials that come into contact with the product, verification that the materials are sterile, the appropriate grade and suitability for the intended use, and, whenever possible, approved for human use by the US Food and Drug Administration (FDA) or relevant Competent Authority.

Quality: Characteristics of a product or service that bear on its ability to fulfill customer expectations. The measurable or verifiable aspects of a product or service that can be used to determine if requirements have been met.

Quality Control: Testing routinely performed on materials and equipment to ensure their proper function.

Quality Indicator Data: Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by executive management in its quality policy. Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

Quality Management System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

Quarantine: To isolate suspect nonconforming materials or products in a clearly marked area to ensure they are not accidentally used.

Reagent: A substance used to produce a reaction that detects and/or quantitates, enhances the detection of, or modifies other substances.

Record (noun): Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Record (verb): To capture information for use in records through writing or electronic media.

Reducing Agent: Chemical that disrupts the disulfide bonds in a protein (this term also applies more generally to oxidation reduction reactions, which add or remove hydrogen ions).

Reference Standard: Specified requirements defined by the AABB. Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.

Regulation: Rules promulgated by federal, national, state, or local authorities to implement laws enacted by legislative bodies.

Regulatory Enforcement Action: Measures taken by a Competent Authority that include but are not limited to progressive measures (eg, suspension or termination of operations, information notices requiring specific documentation or data, fines incurred) or critical triggers (eg, pattern of recurrent, unresolved issues, deficiencies in risk management systems.)

Release: Removal of a product from quarantine or in-process status for the purpose of distribution.

Review for Acceptability: A designated point of inspection for testing a service, blood product, or report. This task ensures the quality of documentation, validity of testing interpretation, and proper quality control of the serologic investigation. The review may be a self-check or second-person check and shall be recorded.

Risk: The threat of damage or any other negative occurrence that is caused by external or internal vulnerabilities.

Risk Assessment: An analysis of risk includes predictable kinds of negative occurrences, their severity, and the probability of their happening.

Root Cause(s): The underlying cause(s) of an event or nonconformance that, if eliminated, would prevent recurrence.

Service (noun): An intangible output of a process.

Service (verb): An action that leads to the creation of a product or a result that can affect donors, patients, and/or recipients.

Shall: A term used to indicate a requirement.

Specified Requirements: Any requirements in these ***IRL Standards***, including, but not limited to: FDA requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as the AABB.

Standard: A set of specified requirements upon which an organization may base its criteria for the products, components, and/or services provided.

Supplier: An entity that provides a material, product, or service.

Supplier Qualification: Evaluation of a potential supplier to assess its ability to consistently deliver products or services that meet specified requirements.

Test Service: Any testing or contributing factor performed related to the provision of a test result.

Traceability: The ability to follow the history of a product or service from source to final distribution or disposition using records.

Validation: Establishing evidence that a process, executed by users in their environment, will consistently meet predetermined specifications.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.