“CROSSWALK” BETWEEN THE PROPOSED AABB QUALITY SYSTEMS FRAMEWORK AND THE CURRENT QSE TEMPLATE

The following “crosswalk” traces each standard in the proposed 2021 Quality Systems Framework (QSF) and the Quality System Essentials (QSE). Each standard in the proposed QSF corresponds to the equivalent standard in the QSEs. The “crosswalk” is offered as assistance for users to determine what is new or has been edited in the proposed QSF and the QSEs. This resource can be used when preparing comments to the proposed QSF.

Note: *The standards included in the QSE template column are pulled from the most recent sets of AABB Standards that AABB offers accreditation for.*

Standard Name	**Acronym**
Standards for Blood Banks and Transfusion Services	BBTS
Standards for Cellular Therapy Services	CT
Standards for Immunohematology Reference Laboratories	IRL
Standards for Molecular Testing for Red Cell, Platelet and Neutrophil Antigens	MT
Standards for Out of Hospital Transfusion Administrative Services	OoTAS
Standards for a Patient Blood Management Program	PBM
Standards for Perioperative Autologous Blood Collection and Administration	Periop
Standards for Relationship Testing Laboratories	RT

Chapter 1 - Organization

Quality Systems Framework 2021	QSE Template	Appears in Standards
1.0 Organization The organization shall define the parties responsible for the provision of products or services.	**1.0 Organization** The blood bank or transfusion service (hereinafter referred to as the BB/TS) shall have a structure that clearly defines and documents the parties responsible for the provision of blood, blood components, tissue, derivatives, and services and the relationship of individuals responsible for key quality functions.	**ALL**
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) The responsibility for compliance with these *Standards* and applicable laws and regulations.	**1.1 Executive Management** The BB/TS shall have a defined executive management. Executive management shall have: 1) Responsibility and authority for the blood bank's or transfusion service's operations. 2) The authority to establish or make changes to the blood bank's or transfusion service's quality system. 3) The responsibility for compliance with these BB/TS Standards and applicable laws and regulations. 4) Participation in management review of the quality system.	**ALL**
1.2 Quality System The organization shall have a quality system. The organization's executive management shall ensure that this quality policy is implemented, and followed at all levels of the organization.	**1.2 Quality System** A quality system shall be defined, documented, implemented, and maintained. All personnel shall be trained in its application.	**ALL**
1.2.1 Quality Representative The quality system shall be under the supervision of a designated person who reports to executive management.	**1.2.1 Quality Representative** The quality system shall be under the supervision of a designated person who reports to executive management.	**ALL**
1.2.2 Management Reviews	**1.2.2 Management Reviews** Management shall assess the effectiveness of the quality	**ALL**

Management shall assess the effectiveness of the quality system at defined intervals.	system through assessments and scheduled management reviews.	
1.3 Policies, Processes, and Procedures Policies, processes, and procedures shall be implemented and maintained to satisfy the applicable requirements of these *Standards*.	**1.3 Policies, Processes, and Procedures** Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these BB/TS Standards are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.	**ALL**
1.3.1 The medical director shall approve all medical and technical policies, processes, and procedures.	**1.3.1** The medical director shall approve all medical and technical policies, processes, and procedures.	**ALL**
1.3.2 Any exceptions to policies, processes, and procedures shall require justification and preapproval by the medical director.	✎**1.3.2** Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and preapproval by the medical director.	**ALL**
✎**1.4 Assessment of Risk** The facility shall have a process in place to perform risk assessments for activities at defined intervals.	✎**1.6 Assessment of Risk** The facility shall have a process in place to perform risk assessments for activities at defined intervals. Standards 5.1.1 and 6.1.4 apply.	**CT, RT**
1.4.1 Mitigation strategies shall identify, assess, and address the level of risk associated with product quality and safety.	**1.6.1** Mitigation strategies shall identify, assess, and address the level of risk associated with the activities performed in the facility.	**CT, RT**
1.5 Operational Continuity The organization shall address continuity in the event that operations are at risk.	**1.4 Operational Continuity** Executive management shall ensure that the facility has policies, processes, and procedures that address continuity for potential events that put operations at risk.	**ALL**
1.6 Emergency Preparedness The organization shall have emergency operation plan(s) to respond to the effects of internal and external disasters.	**1.5 Emergency Preparedness** The BB/TS shall have emergency operation policies, processes, and procedures to	**ALL**

	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.	✎ **1.5.1** The emergency management plan, including emergency communication systems, shall be tested at defined intervals.	**ALL**
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.	**1.6 Communication of Concerns** The BB/TS 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 facility's executive management, AABB, or both. AABB's contact information shall be readily available to all personnel.	**ALL**
1.8 Customer Focus Executive management shall identify the organization's customers and their needs and expectations for products or services.	**1.7 Customer Focus** Executive management shall identify the blood bank's or transfusion service's customers and their needs and expectations for products and services.	**ALL**

Chapter 2 - Resources

Quality Systems Framework 2021	QSE Template	Appears in Standards
2.0 Resources The organization shall have adequate resources to perform, verify, and manage all the activities described in these *Standards*.	**2.0 Resources** The BB/TS shall have policies, processes, and procedures to ensure the provision of adequate resources to perform, verify, and manage all activities in the BB/TS.	**ALL**
2.1 Human Resources The organization shall employ an adequate number of individuals qualified by education, training, and/or experience.	✎**2.1 Human Resources** The BB/TS shall have a process to ensure the employment of an adequate number of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.	**ALL**
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 *Standards*.	✎**2.1 Human Resources** The BB/TS shall have a process to ensure the employment of an adequate number of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.	**ALL**
2.1.2 Training The organization shall provide training for personnel performing critical tasks.	✎**2.1.2 Training** The BB/TS shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.	**ALL**
2.1.3 Competence Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.	**2.1.3 Competence** Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.	**ALL**
2.1.3.1 Action shall be taken when competence has not been demonstrated.	**2.1.3.1** Action shall be taken when competence has not been demonstrated.	**ALL**
2.1.4 Personnel Records Personnel records for each employee shall be maintained.	✎**2.1.4 Personnel Records** Personnel records for each employee shall be maintained.	**ALL**
2.1.4.1 For those authorized to perform or review critical tasks,	✎ **2.1.4.1** 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.	records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.	
2.1.5 Continuing Education Requirements for relevant continuing education in activities performed by the organization as required by these *Standards* shall be met by all employees who perform critical tasks.	**✎C 2.1.7 Continuing Education** Requirements for relevant continuing education in activities performed by the facility as required by these CT Standards shall be defined for and met by all employees who perform critical tasks.	**CT, MT, PBM, Periop**

Chapter 3 - Equipment

Quality Systems Framework 2021	QSE Template	Appears in Standards
3.0 Equipment The organization shall define and control critical equipment.	**3.0 Equipment** The BB/TS shall identify the equipment that is critical to the provision of blood, blood components, tissue, derivatives, and/or services. The BB/TS shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conforms to these BB/TS Standards and other specified requirements.	**ALL**
3.1 Equipment Specifications Equipment specifications shall be defined before purchase.	**3.1 Equipment Specifications** Equipment specifications shall be defined before purchase.	**CT**
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 Qualification of Equipment** All equipment shall be qualified for its intended use. Equipment repairs and upgrades shall be evaluated and equipment requalified, as appropriate, based on the facility's policies and manufacturer recommendations.	**ALL**
3.2.1 Installation Qualification Equipment shall be installed per manufacturer's specifications.	**3.2.1 Installation Qualification** Equipment shall be installed per the manufacturer's specifications.	**ALL**
3.2.2 Operational Qualification Each piece of equipment and component of an information system shall be verified before actual use.	**3.2.2 Operational Qualification** The functionality of each piece of equipment and each component of a computer system shall be verified before actual use and shall meet the manufacturer's operational specifications.	**ALL**
3.2.3 Performance Qualification Equipment shall perform as expected for its intended use.	**3.2.3 Performance Qualification** The BB/TS shall demonstrate that equipment performs as expected for its intended use. Performance specifications established by the manufacturer shall be met.	**ALL**
3.3 Use of Equipment Equipment shall be used in accordance with the manufacturer's written instructions.	**3.3 Use of Equipment** Equipment shall be used in accordance with the manufacturer's written instructions.	**ALL**

3.4 Unique Identification of Equipment Equipment shall have unique identification.	✎**3.4 Unique Identification of Equipment** Equipment shall have unique identification.	**ALL**
3.5 Equipment Monitoring and Maintenance Equipment shall be monitored and maintained in accordance with manufacturer's written instructions.	✎ 3.5 **Equipment Monitoring and Maintenance** The BB/TS shall have a process for scheduled monitoring and maintenance of equipment that at a minimum is in accordance with manufacturer's written instructions. The process shall include frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.	**ALL**
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 Calibration 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 performed as described below unless otherwise indicated by the manufacturer: 1) Before use. 2) After activities that may affect the calibration. 3) At prescribed intervals.	**ALL**
3.5.1.1 Calibration of equipment shall include details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and limitations.	✎**3.4.1 Calibration and Accuracy of Equipment** The facility shall: 3) Define the process for the calibration of equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and limitations.	**CT**
3.5.1.2 Equipment used for calibration, inspection, measuring, and testing before initial use, after repair, and at prescribed intervals, shall be certified to meet nationally recognized measurement standards. Where no such measurement standards exist, the	✎**3.4.1 Calibration and Accuracy of Equipment** The facility shall: 4) Calibrate equipment used for inspection, measuring, and testing before initial use, after repair, and at prescribed intervals, using equipment certified to meet	**CT**

basis for calibration shall be described and recorded.	nationally recognized measurement standards. Where no such measurement standards exist, the basis for calibration shall be described and recorded.	
3.5.1.3 Equipment shall be safeguarded rom adjustments that would invalidate the calibration setting.	✎**3.4.1 Calibration and Accuracy of Equipment** The facility shall: 5) Safeguard equipment from adjustments that would invalidate the calibration setting.	**CT**
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 potential affected products or services, including those that have already been released or delivered shall be assessed.	✎**3.4.2** There shall be a defined process when equipment is found to be out of calibration or specification. When equipment is found to be out of calibration or specification, the validity of previous inspection and test results and the conformance of provided cellular therapy products and services to the required specifications shall be assessed.	**CT**
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 including communication 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	✎**3.4.3 Monitoring, Maintenance, and Repair** The facility shall: 1. Define cleaning and sanitization methods and intervals for each piece of equipment. 2. Ensure that environmental conditions are suitable for the calibrations, inspections, measurements, and tests carried out. 3. Define a process to inform personnel when equipment is malfunctioning/out of service. 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 critical equipment maintenance and repairs are performed by qualified	**CT**

and in accordance with manufacturer's recommendations.	individuals and in accordance with 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 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. 4) investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly impacted. 5) requalification of the equipment. 6) reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.	**3.5.2 Investigation and Follow-up** Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include: 1) Assessment of blood, blood components, tissue, derivatives, and services provided since the equipment was last known to be functioning per manufacturer's written instructions, or facility-defined specifications. 2) Assessment of the effect on donor eligibility and donor and patient safety. 3) Steps to ensure that the equipment is removed from service. 4) Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected. 5) Steps for requalification of the equipment. 6) Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.	**BBTS, CT, IRL, MT, Periop, RT**
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.	**3.5 Equipment Traceability** The facility shall maintain records of equipment use in a manner that permits: 1) Equipment to be uniquely identified and traceable. 2) Tracing of any given cellular therapy product to all equipment associated with the procurement, processing, storage, distribution, and administration of the cellular therapy product. 3) Identification and recall of all cellular therapy products associated with a specific piece of equipment.	**CT**
3.7 Information Systems	**3.6 Information Systems** Implementation and modification of information system software,	**CT (specific), ALL (in some version)**

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) numerical designation of system versions with inclusive dates of use. 2) validation/verification/ qualification of system software, hardware, databases, and user-defined tables prior to 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 donor, product or service, and recipient (as applicable). 11) training and competency of personnel who use information systems.	hardware, and databases shall be planned and controlled. Elements of planning and ongoing control shall include: 1) Designation of system versions with inclusive dates of use. 2) Validation/verification of system software, hardware, databases, and user-defined tables prior to 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, 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, product, and recipient (as applicable). 11) Training and competency of personnel who use information systems. 12) Procedures to ensure confidentiality of protected health information.	

12) procedures to ensure confidentiality of protected health information.		
3.7.1 Alternative Systems An alternate 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.	**3.9.2** An alternate 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.	**ALL**
3.7.2 Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect their use.	**3.9.3** Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect their use.	**ALL**
3.7.3 The organization shall support the management of information systems.	**3.9.4** There shall be processes and procedures to support the management of information systems.	**ALL**
3.7.4 A system designed to prevent unauthorized access to computers and electronic records shall be in place.	**3.9.5** A system designed to prevent unauthorized access to computers and electronic records shall be established and followed.	**ALL**
3.7.5 The organization shall have measures in place to minimize the risk of an internal or external data breach.	**3.9.6** A process shall be in place to ensure that the facility has measures in place to minimize the risk of an internal or external data breach.	**ALL**

Chapter 4 – Suppler and Customer Agreements

Quality Systems Framework 2021	QSE Template	Appears in Standards
4.0 Supplier and Customer Agreements The organization shall ensure that agreements to provide or receive products or services are reviewed and approved.	**4.0 Supplier and Customer Issues** The BB/TS shall have policies, processes, and procedures to evaluate the ability of suppliers of critical materials, equipment, and services to consistently meet specified requirements.	**ALL**
4.1 Supplier Qualification The organization shall evaluate the ability of suppliers of critical materials, equipment, and services to meet specified requirements.	✎**4.1 Supplier Qualification** The BB/TS shall evaluate and participate in the selection of suppliers, when possible, before acceptance of an agreement.	**A**LL
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.	**NEW**	**NONE**
4.1.2 When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.	**4.1.1** When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.	**ALL**
4.2 Agreements Agreements and any incorporated changes shall be reviewed and communicated.	**4.2 Agreements** Agreements, or changes to agreements, shall define supplier and customer expectations and shall reflect agreement.	**ALL**
4.2.1 Agreements shall be reviewed at defined intervals.	4.1.2 Agreements shall be reviewed at defined intervals to ensure that the terms of the agreement continue to meet requirements.	**CT, Periop**
4.2.2 Changes to agreements shall be communicated to affected parties.	**4.2 Changes to Agreements** The facility shall define how changes to agreements are made and communicated to affected parties.	**CT**
4.2.3 The responsibilities for activities covered by these *Standards* when more than one	✎**4.2.2** The responsibilities for activities covered by these BB/TS Standards when more than one	**BBTS, CT, Periop,**

organization is involved shall be specified by agreement.	facility 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 acceptance or use.	**✎4.3 Incoming Receipt, Inspection, and Testing** Incoming blood, blood components, tissue, derivatives, and critical materials shall be received, inspected, and tested, as necessary, before acceptance or use.	**BBTS, CT, IRL, RT**

Chapter 5 – Suppler and Customer Agreements

Quality Systems Framework 2021	QSE Template	Appears in Standards
5.0 Process Control The organization shall ensure the quality of products or services.	**5.0 Process Control** The BB/TS shall have policies and validated processes and procedures that ensure the quality of the blood, blood components, tissue, derivatives, and services. The BB/TS shall ensure that these policies, processes, and procedures are carried out under controlled conditions.	**ALL**
5.1 General Elements The organization shall ensure that processes are carried out under controlled conditions.	5.0 **Process Control** The BB/TS shall have policies and validated processes and procedures that ensure the quality of the blood, blood components, tissue, derivatives, and services. The BB/TS shall ensure that these policies, processes, and procedures are carried out under controlled conditions. **5.1 General Elements**	**ALL**
5.1.1 Change Control The organization shall develop new processes or procedures or change existing ones. Before implementation, the new or changed processes or procedures shall be validated.	✎ **5.1.1 Change Control** The BB/TS shall have a process to develop new processes or procedures or to change existing ones. This process shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated.	**ALL**
5.1.2 Quality Control A program of quality control shall be established that is sufficiently comprehensive to ensure that products, equipment and materials perform as expected.	**5.1.3 Quality Control** A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods perform as expected.	**ALL**
5.1.2.1 Quality control failures shall be investigated before release of test results, products or services.	**5.1.3.2** Quality control failures shall be investigated before release of test results, products, or services.	**ALL**
5.1.2.2 The validity of test results and methods and the acceptability	**5.1.3.1** The validity of test results and methods and the acceptability	**BBTS, CT, IRL, MT, Periop, RT**

of products or services provided shall be evaluated when quality control failures occur.	of products or services provided shall be evaluated when quality control failures occur.	
5.1.3 Process Planning Quality requirements shall be incorporated into new or changed processes, products or 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 literature). 3) evaluation of risk. 4) identification of affected internal and external parties and mechanism to communicate relevant information. 5) identification of performance measures applicable to the new or changed process, product or service. 6) evaluation of resource requirements. 7) evaluation of the impact of the new or changed process, product or service on other organization (or program) processes. 8) evaluation of the need to create or revise documents for the new or changed process, product or service. 9) review and approval of the output of process development and design activities (eg, pilot or scale-up study results, process flow charts, procedures, data forms). 10) evaluation of the extent and scope of process validation or re-validation depending on the level of risk and impact of the new or changed products or services.	**5.2.2 Process Planning** Quality requirements shall be incorporated into the development of new or changed processes, products, services, and novel methods. Standard 4.0 applies. Planning and implementation activities at a minimum 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 literature). 3) Evaluation of risk vs benefit. 4) Identification of affected internal and external parties and mechanism to communicate relevant information. 5) Identification of performance measures as 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 facility (or program) processes. Standard 2.1.4 applies. 8) Evaluation of the need to create or revise documents for the new or changed process, product, or service. 9) Review and approval of the output of process development and design activities (eg, pilot or scale-up study results, process flow charts, procedures, data forms). 10) Evaluation of the extent and scope of process validation or revalidation depending on the level of risk and impact of the new or changed products or services.	**CT**

5.1.4 Process Validation Before implementation, the new or changed processes and procedures shall be validated.	**5.1.1 Change Control** The BB/TS shall have a process to develop new processes or procedures or to change existing ones. This process shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated.	**ALL**
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.	**5.2.3.1** Validation activities at a minimum shall include the following: 1) Identification of goals, 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 goals are not met.	**CT**
5.1.5 Process Implementation The implementation of new or changed processes and procedures shall be planned and controlled.	**5.2.4 Process Implementation** The implementation of new or changed processes and procedures shall be planned and controlled.	**CT**
5.1.5.1 Postimplementation evaluations of new or changed processes and procedures shall be performed.	**5.2.4.1** Postimplementation evaluations of new or changed processes and procedures shall be performed.	**CT**
5.1.6 Use of Materials All materials shall be stored and used in accordance with the manufacturer's written instructions.	**5.1.4 Use of Materials** All materials (including containers and solutions used for collection, processing, preservation, and storage of blood and blood components, and all reagents used for tests) shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.	**BBTS, IRL, MT, Periop**
5.1.7 Inspection	**5.1.7 Inspection** The BB/TS shall have a process to ensure that blood, blood compo-	**BBTS, IRL, MT, Periop**

The organization shall ensure that products or services are inspected at organization-defined stages.	nents, tissue, derivatives, and services are inspected at facility-defined stages to verify that specified requirements are met.	
5.1.8 Identification and Traceability The organization shall ensure that all products or services are identified and traceable.	**5.1.5 Identification and Traceability** The laboratory shall ensure that blood components, samples, critical materials, and requests are identified and traceable.	**BBTS, CT, IRL, MT, Periop**
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.	**5.1.8 Handling, Storage, and Transportation** The BB/TS shall have a process to ensure that blood, blood components, tissue, derivatives, samples, and critical materials (including reagents) are handled, stored, and transported in a manner that prevents damage, limits deterioration, and meets requirements contained in Reference Standard 5.1.8A, Requirements for Storage, Transportation, and Expiration.	**BBTS, CT, IRL, MT, Periop**

Chapter 6 – Documents and Records

Quality Systems Framework 2021	QSE Template	Appears in Standards
6.0 Documents and Records The organization shall ensure that documents and records are created, stored, and archived in accordance with record retention policies.	**6.0 Documents and Records** The BB/TS shall have policies, processes, and procedures to ensure that documents are identified, reviewed, approved, and retained and that records are created, stored, and archived in accordance with record retention policies.	**ALL**
6.1 Document Control The organization shall control all documents that relate to the requirements of these *Standards*. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.	**6.1 Document Control** The facility shall establish, implement, and maintain policies, processes, and procedures to control all documents that relate to the requirements of these *CT Standards*. Documents shall be protected from unauthorized access and accidental or unauthorized modification, deletion, or destruction.	**ALL**
6.1.1 Format Documents shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual) may be incorporated by reference.	**6.1.1 Format** Policies, processes, and procedures established by the facility shall be in standardized formats. Additional policies, processes, and procedures (such as those in an operator's manual) may be incorporated by reference.	**ALL**
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 *Standards* are performed.	**6.1.2 Document Review, Approval, and Distribution** The facility shall review and approve all controlled documents before use. The document control process shall ensure that policies, processes, and procedures: 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.	**ALL**

5) invalid or obsolete documents are not used. 6) any archived or obsolete documents are identified as such.	4) Are available at all locations where operations covered by these *CT Standards* are performed. 5) Prevent the use of invalid or obsolete documents. 6) Suitably identify any archived or obsolete documents as such.	
6.1.3 Document Changes Changes to documents shall be reviewed and approved by an authorized individual.	**6.1.3.1** Changes to documents shall be reviewed and approved by an authorized individual before new and/or revised procedures become effective.	**CT**
6.1.3.1 The organization shall track changes to documents.	**6.1.3.2** The facility shall have processes to track changes to documents.	**CT**
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 *Standards*.	**6.1.1** Master list(s) of documents, including policies, processes, procedures, labels, and forms that relate to the requirements of these BB/TS Standards.	**ALL**
6.1.5 Review of Policies, Processes, and Procedures Review of each policy, process, and procedure shall be performed at a minimum every 2 years.	**6.1.4** Review of each policy, process, and procedure shall be performed by an authorized individual at a minimum every 2 years.	**ALL**
6.1.6 Document Retention The organization shall determine which documents shall be archived, destroyed, or made obsolete.	**6.1.6 Document Retention** The facility shall determine which documents shall be archived, destroyed, or made obsolete.	**ALL**
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 is accessible and retrievable.	**6.1.7** Storage in a manner that preserves legibility and protects from accidental or unauthorized access, destruction, or modification.	**ALL**
6.1.8 Document Retrieval The organization shall ensure that documents are retrievable in a timely manner.	**6.1.7 Document Retrieval** The facility shall ensure that documents are retrievable in a timely manner, as defined by the facility.	**CT**

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 Original Records** The facility shall establish and maintain policies, processes, and procedures for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of original records.	**CT**
6.2.1 Records Records shall be complete, retrievable in a period of time appropriate to the circumstances and protected from accidental or unauthorized destruction or modification.	**6.2.1 Facility Records** Records shall be complete, retrievable in a period of time appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.	**ALL**
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.	**6.2.1.1 Record Traceability** The records system shall ensure the traceability of all of the following: 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 facility where the activity was performed.	**BBTS, CT, IRL, MT, Periop, RT**
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.	**6.2.2 Information to Be Retained** Records shall be maintained that demonstrate that a material, product, or service conforms to specified requirements and that the quality system is operating effectively. Records from suppliers shall be an element of this information.	**CT**
6.2.4 Legibility All records shall be legible and indelible.	**6.2.3 Legibility** All records shall be legible and indelible.	**ALL**
6.2.5 Record Change The organization shall establish processes for changing records. The date and identity of the person	**6.2.4 Record Change** Facilities shall establish and maintain processes for	**BBTS, CT, IRL, MT, Periop, RT**

making the change shall be recorded. Record changes shall not obscure previously recorded information.	changing records. The date and identity of the person making the change shall be recorded. Record changes shall not obscure previously recorded information.	
6.2.6 Records shall be created concurrently with performance of each critical activity.	**6.2.5** Records shall be created concurrently with performance of each critical activity.	**BBTS, CT, IRL, MT, Periop**
6.2.7 Copies Copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.	✎**6.2.7 Copies** Before the destruction of the original records, copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.	**ALL**
6.2.8 Confidentiality The organization shall ensure the confidentiality of records.	**6.2.8 Confidentiality** The facility shall have policies that ensure the confidentiality of donor, employee, and patient records.	**ALL**
6.2.9 Retention Records required by these *Standards* shall be retained for a period of time indicated in the record retention table at the end of each QSE.	**6.2.9 Retention** Records required by these CT Standards shall be retained for at least 10 years following either their creation (C) or the final disposition (F) of the cellular therapy product with which they are associated. Applicable national, state, or local law may exceed this period.	**ALL**
6.2.10 Record Review Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.	✎**6.2.10 Record Review** Records shall be reviewed for accuracy, completeness, and compliance with applicable standards, laws, and regulations.	**ALL**
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.	**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.	**BBTS, CT, IRL, MT, Periop, RT**

3) permit ready identification 4) allow retrieval in a defined timeframe.	3) Permit ready identification. 4) Allow retrieval in a defined timeframe.	
6.2.12 Destruction of Records Destruction of records shall be conducted in a manner that protects the confidential content of the records.	**6.2.12 Destruction of Records** Destruction of records shall be conducted in a manner that protects the confidential content of the records.	**BBTS, CT, IRL, MT, Periop, RT**
6.3 Electronic Records The organization shall support the management of information systems.	6.2.7 **Electronic Records** There shall be processes and procedures to support the management of computer systems.	**ALL**
6.3.1 Access to Data and Information Access to data and information shall be controlled.	**6.3.1 Access to Data and Information** Access to data shall be controlled. Unauthorized access to and release of data and information shall be prevented.	**CT**
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** The authorization to access and release data and information shall be defined, and individuals authorized to enter, change, and release results shall be identified.	**CT**
6.3.1.1.1 Electronic records shall include the date and identity of the person making a change.	**6.3.1.1.1** Electronic records shall include the date and identity of the person making a change.	**ALL**
6.3.2 Data Integrity Data integrity shall ensure that data are retrievable and usable.	**6.2.7.1.1** Procedures shall be in place to ensure that data are retrievable and usable.	**ALL**
6.3.2.1 Data shall be accurately, reliably, and securely sent from the point of entry to final destination.	**6.3.2.1** Data shall be accurately and reliably sent from the point of entry to final destination in a timely manner.	**CT**
6.3.2.2 Data shall be retrievable for the entire retention period.	**6.3.2.2** Data shall be retrievable for the entire retention period.	**CT**
6.3.2.2.1 The organization shall archive records or data from media and platforms no longer in use.	**6.3.2.2.1** The facility shall have a process to access archived records on media and platforms no longer in use.	**CT**
6.3.3 Storage Media Data storage media shall be protected from damage or unintended access and destruction.	**6.3.3 Storage Media** Data storage media shall be protected from damage or unintended destruction.	**CT**

6.3.4 Back-Up Data The organization shall back up all critical data.	**6.2.7.1** There shall be a process in place for routine backup of all critical data.	**ALL**
6.3.4.1 Back-up data shall be stored in a secure off-site location.	**6.2.7.1.2** Backup data shall be stored in an off-site location and be secured to prevent unauthorized access.	**ALL**
6.3.4.2 Back-up data shall be protected from unauthorized access, loss, or modification.	**6.3.4.2** Backup data shall be protected from unauthorized access, loss, or modification.	**CT**
6.3.4.3 The ability to retrieve data from the back-up system shall be tested at defined intervals.	**6.3.4.3** The ability to retrieve data from the backup system shall be tested periodically.	**CT**

Chapter 7 – Deviations, Nonconformances and Adverse Events

Quality Systems Framework 2021	QSE Template	Appears in Standards
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.	✎**7.0 Deviations, Nonconformances, and Adverse Events** The BB/TS shall have policies, processes, and procedures to ensure the capture, assessment, investigation, and monitoring of deviations from or of failure to meet, specified requirements. The investigation shall, when applicable, include an assessment of the effect of the deviation on donor eligibility and donor and patient safety. The responsibility for review and authority for the disposition of nonconforming blood, blood components, tissue, derivatives, critical materials, and services shall be defined. Deviations, nonconformances, and adverse events shall be reported in accordance with specified requirements and to outside agencies as required.	**ALL**
7.1 Deviations The organization shall capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. The evaluation shall include an assessment of the patient and shall not delay proper clinical management of the patient.	**7.1 Deviations** The perioperative program shall have a process to capture, assess, investigate, and report events that deviate from accepted policies, processes, or procedures. The evaluation shall include an assessment of the patient and shall not delay proper clinical management of the patient.	**ALL**
7.2 Nonconformances Upon discovery, nonconforming products or services shall be evaluated and their disposition determined.	✎**7.1 Nonconformances** Upon discovery, nonconforming blood, blood components, tissue, derivatives, critical materials, and services shall be evaluated and their disposition determined.	**ALL**
7.2.1 Nonconforming products or services shall be quarantined and/or destroyed.	**7.1.1** Nonconforming blood, blood components, tissue, and derivatives shall be quarantined and/or destroyed.	**BBTS, CT, IRL, MT**

7.2.2 The unintended distribution or use of products or services that do not conform to specified requirements shall be prevented.	**7.1.2** The unintended distribution or use of blood, blood components, tissue, derivatives, critical materials, or services that do not conform to specified requirements shall be prevented.	**BBTS, CT, IRL, MT, RT**
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.	**7.1.3** The BB/TS shall have a process for: 1) The identification, quarantine, retrieval, recall and disposition of nonconforming blood, blood components, tissue, and derivatives. 2) The identification and management of nonconforming services.	**BBTS, IRL, MT, Periop, RT**
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.	✎**7.1.4 Released Nonconforming Blood, Blood Components, Tissue, or Derivatives** Blood, blood components, tissue, or derivatives that are determined after release not to conform to specified requirements shall be evaluated to determine the effect of the nonconformance on the quality of	**BBTS, CT, IRL, MT, Periop**
7.2.4.1 Records shall include the disposition of the product or service the rationale, and the name(s) of the individual(s) responsible for the decision.	✎**7.1.4.1** Records shall include the disposition of the product or service, the rationale, and the name(s) of the individual(s) responsible for the decision.	**BBTS, CT, Periop**
7.3 Adverse Events The organization shall detect, monitor, evaluate, manage and report adverse events related to safety and quality.	**7.3 Adverse Events** ✎**7.3.1** The procurement facility shall have a process to detect, monitor, evaluate, manage, and report donor adverse events.	**BBTS, CT, IRL, PBM, Periop**
7.3.1 Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.	**7.3.4** Records of adverse events and the related investigations, evaluations, and notifications shall be maintained.	**BBTS, CT, IRL, PBM, Periop**
7.3.2 Investigation results and analysis shall be communicated among all facilities involved as appropriate.	**7.3.5** Investigation results and analysis shall be communicated among all facilities involved in the procurement, processing, and administration, as appropriate.	**ALL**

Chapter 8 – Assessments: Internal and External

Quality Systems Framework 2021	QSE Template	Appears in Standards
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.	✎**8.1 Internal Assessments** The facility shall establish, implement, and maintain policies, processes, and procedures for scheduling, conducting, documenting, and reviewing internal assessments. Internal assessments shall be performed by personnel independent of those having direct responsibility for the activity being assessed.	**ALL**
8.2 External Assessments The organization shall participate in an external assessment program applicable to the activities performed in the organization.	✎**8.2 External Assessments** The facility shall participate in an external assessment program applicable to the activities performed in the facility.	**ALL**
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 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 (Chapter 9, Process Improvement, applies). 3) Communicated to the appropriate staff. 4) Reported to executive management.	**ALL**
8.4 Quality Monitoring The organization shall collect and evaluate quality indicator data on a scheduled basis, including adverse events.	**8.3 Quality Monitoring** The BB/TS shall have a process to collect and evaluate quality indicator data on a scheduled basis, including adverse events.	**ALL**
8.4.1 The organization shall provide data generated to the personnel who have responsibility for the quality indicator data collected.	**8.3.1** The perioperative program shall provide quality indicator data to the personnel with responsibility for oversight including third-party providers.	**Periop**

Chapter 9 – Process Improvement

Quality Systems Framework 2021	QSE Template	Appears in Standards
9.0 Process Improvement The organization shall collect data, perform analysis, and follow-up of issues requiring corrective and preventive action, including near-miss events.	**9.0 Process Improvement Through Corrective and Preventive Action** The BB/TS shall have policies, processes, and procedures for data collection, analysis, and follow-up of issues requiring corrective and preventive action, including near-miss events.	**ALL**
9.1 Corrective Action Corrective action shall include: 1) investigation of the root cause of nonconformances relating to the product or service the process, and the quality system. 2) investigation of complaints. 3) determination of the corrective action needed to eliminate the cause of nonconformances. 4) ensuring that corrective action is reviewed and found to be effective.	**9.1 Corrective Action** The process for corrective action shall include: 1) Investigation of the root cause of nonconformances relating to the product, the process, and the quality system. 2) Investigation of complaints. 3) Determination of the corrective action needed to eliminate the cause of nonconformances. 4) Ensuring that corrective action is reviewed and found to be effective.	**ALL**
9.2 Preventive Action Preventive action shall include: 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.	**9.2 Preventive Action** The process for preventive action shall include: 1) The analysis of appropriate sources of information (such as policies, processes, and procedures that affect product or service quality, assessment results, proficiency testing results, quality control records, customer complaints, and other aggregate data) to detect, analyze, and eliminate potential causes of nonconformances.	**ALL**

	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.	**9.3 Performance Improvement** The facility shall track and identify trends in information related to its operational and quality system performance to identify opportunities for improvement.	**CT, PBM**

Chapter 10 – Facilities and Safety

Quality Systems Framework 2021	QSE Template	Appears in Standards
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 federal regulations.	**10.0 Facilities and Safety** The BB/TS shall have policies, processes, and procedures to ensure the provision of safe environmental conditions. The facility shall be suitable for the activities performed. Safety programs shall meet local, state, and federal regulations, where applicable.	**ALL**
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.	**10.1 Safe Environment** The BB/TS shall have processes to minimize and respond to environmentally related risks to the health and safety of employees, donors, volunteers, patients, and visitors. Suitable quarters, environment, and equipment shall be available to maintain safe operations.	**BBTS, CT, IRL, MT, Periop, RT**
10.2 Biological, Chemical, and Radiation Safety The organization shall monitor adherence to biological, chemical, and radiation safety standards and regulations.	**10.2 Biological, Chemical, and Radiation Safety** The BB/TS shall have a process for monitoring adherence to biological, chemical, and radiation safety standards and regulations, where applicable.	**BBTS, CT, IRL, MT, Periop, RT**
10.3 Discard of Products Products shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.	✎**10.3 Discard of Blood, Components, Tissue, and Derivatives** Blood, blood components, tissue, and derivatives shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.	**BBTS, CT, IRL, Periop**