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**Topic of Policy:** Quality Plan

**I. Purpose:** The Blood Connection’s Quality Plan describes the systems for serving our community by supplying quality products and services that meet or exceed the expectations of our customers.

**II. Application:** Center-wide

**III. Policy:**

- A.** Quality of processes, products, and people are the cornerstones for building the quality system of The Blood Connection. The quality system supports the quality ideals set forth in the mission statement of The Blood Connection. The organization of the quality system monitors processes and operations in The Blood Connection through the performance of self-assessment audits, error management, and customer feedback. By conforming to regulatory standards, we abide by the law. By conforming to requirements for accreditation/certification, we adhere to high standards for quality established by the FDA, AABB, FACT, and other accrediting and regulatory organizations. By conforming to our customer’s standards, we practice the philosophy of continuous quality improvement.

The following quality system essentials applied to our facility operations.

**IV. Elements:**

- A. Organization and Leadership:** A defined leadership structure with defined roles and responsibilities to ensure the effective implementation and maintenance of quality management and operational systems.
1. The Blood Connection is a not-for-profit volunteer program, locally governed by a volunteer Board of Trustees, composed of area business and civic leaders and physicians, which recruits donors, collects, processes, stores, and distributes blood, blood components, and hematopoietic progenitor cells.
  2. The quality goals of The Blood Connection for its product and services are to:
    - Detect and prevent errors.
    - Improve effectiveness and efficiency of processes.
    - Respond to customer needs.
    - Develop and maintain a competent staff.
    - Comply with all required regulations and accreditation standards.
  3. Management support for quality system initiatives:  
Executive Management consists of the President/Chief Executive Officer; Executive Vice President, Operations/Chief Operating Officer; Vice President, Quality Systems/Chief Quality Officer; Vice President, Business Development/Chief Technical Officer; Vice President, Business and Administration, Vice President, Operational Support, Vice President, Clinical Support Services, and the Medical Director.

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- The President/CEO is responsible for the development and implementation of all administrative functions related to The Blood Connection.
  - The Executive Vice President, Operations/COO provides leadership and administrative guidance, and direction to VP/CTO, Operational Support, Production Planning, and stem cell laboratory.
  - The Vice President, Quality Systems/CQO is responsible for developing, coordinating, implementing, and evaluating quality assurance programs for The Blood Connection and ensuring that complaint practices with the requirements of all regulatory and accrediting agencies.
  - The Vice President, Business Development/CTO is responsible for management of the donor recruitment, marketing, operations of automated, fixed site and mobile collections, and the technical functions of the testing laboratory, reference laboratory, blood and cellular therapy component manufacturing and distribution.
  - The Vice President, Business and Administration is responsible for the management of financial and human resources activities.
  - The Vice President, Operational Support is responsible for the management of the operational support of information technology and facilities management.
  - The Vice President, Clinical Support Services provides enterprise-wide leadership, administrative guidance and direction to the Donor Services and clinical staff teams
  - The Medical Director is responsible for the assurance that the medical, technical, and scientific activities of TBC comply with requirements of all regulatory and accrediting agencies.

Executive management shall have the ultimate responsibility for all the quality management and operational systems. Executive management shall:

- Ensure that quality management and operational system policies, processes, and procedures comply with applicable laws and requirements.
- Define the roles, responsibilities, authority, relationships, and required qualifications of personnel who perform or oversee the activities of the blood center.
- Provide the facilities, adequate resources, critical materials, and equipment needed for quality management and operational system activities.
- Implement systems effectively communicating relevant information throughout the organization and to suppliers and customers.
- Oversee the quality management and operational systems to ensure that policies, processes, and procedures clearly documented, consistently followed, and continuously improved.

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- Ensure that process improvements implemented and reviewed for effectiveness.
4. Organizational chart of key personnel and functions maintained.
  5. The Vice President, Quality Systems/CQO initially reviews The Blood Connection's Quality Plan with final approval by the Medical Director.
    - The facility's quality essential process descriptions approved and reviewed according to the document control procedures described below.
  6. Reporting of Quality Issues.
    - The Vice President, Quality Systems/CQO prepares and submits a summary of operational changes annually to the Food and Drug Administration and other regulatory agencies as required. In addition, the CQO guides submissions to the Food and Drug Administration for changes that need prior approval (CBE-30 and PAS).
    - Monitoring of quality initiatives reported periodically to the Board of Trustees.
    - Reports of quality management activities (i.e. occurrence management, internal assessments, etc.) reviewed periodically with Executive Management and TBC operational and regional directors, managers and supervisors.

**B. Human Resources:** Establish and maintain policies, processes, and procedures to provide adequate number of qualified (by education and/or experience), trained, and competent staff to perform and manage the activities required.

1. Job Descriptions
  - Job descriptions maintained that define the roles, responsibilities, and reporting structure for each position involved in blood center activities.
  - Job descriptions accurately maintained for each position.
2. Job Qualifications
  - Job qualifications, including the knowledge, skills, and abilities required to perform the duties of each position identified.
3. Staff Selection
  - Staff selection shall include a process to verify that candidates are qualified for the position.
4. Staffing
  - Adequate human resources to perform, verify, and manage all quality management systems and operational activities shall be available.
5. Orientation
  - New staff shall be oriented to the organization and policies.
6. Staff Identification
  - Individuals authorized to create, sign, initial or review reports or records uniquely identified with an employee code.

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- Records of names, signatures, initials, employee codes, and inclusive dates of employment maintained for individuals authorized to perform or review critical tasks.
7. Training and Training Verification
- Training requirement for job codes at The Blood Connection outlined on specific Job Code Training Requirements Form (FPD.CW.9720A). Orientation training requirements listed on CWTR Form (F.CW.14).
  - Staff development provided to meet individual needs, regulatory and accreditation requirements, and/or the changing needs of the facility.
  - Training topics have a training plan outlining learning objectives, training methods, release-to-task competency assessment criteria, and remedial training guidelines.
  - Training shall include all of the following:
    - Application of the quality management system.
    - Performance of job specific processes and procedures.
    - Application of safety policies, processes, procedures, and practices.
    - Training considered complete when the individual demonstrates sufficient knowledge and skills for the job task.
    - Retraining initiated when indicated.
  - Documentation of training maintained either in our current learning management system or on manual training rosters (FPD.CW.9720B) *Currently going through a transition of documenting training electronically; therefore, there could be the presence of both methods available to support training occurred and trainee is released to perform task.*
8. Competence Assessment:
- Competence assessed after six months and at least annually thereafter for positions determined to perform high or moderate complexity tasks.
  - Competency assessment completed for selected tasks not considered moderate/high complexity annually after completion of training.
  - Tasks/concepts evaluated for competency assessment for job titles within technical operational departments. Selection of the task/concept influenced by noncompliances found during internal quality assessments, occurrence trending reports, quality indicator reporting or issues determined significant by the department director or manager.
  - Competency after initial release from training (six-month, annual) documented within electronic learning /training application or respective manual form (F.QS.5400 or F.CW.00279) completed for each individual within each operational job title.
  - Appropriate actions taken when there is a failure of competency.

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8. Continuing Education

- The Blood Connection encourages (but does not require) personnel to participate in continuing education activities. The organization provides educational opportunities for employee participation. These activities may exist outside of the organization.

9. Trainers

- Selected individuals, considered subject matter experts, function as trainers in this facility.
- The following are expectations of a trainer: strong verbal and writing skills, a willingness and temperament for supervising and training, the ability to identify and select right training methods, the characteristics of a role model/leader, have a positive attitude, and possess effective problem solving skills.

**C. Equipment Management:** Establish and maintain policies, processes, and procedures to ensure that critical equipment, including computer systems, validated, calibrated, maintained, and performs as expected for its intended use.

1. Identification of Equipment

- Equipment uniquely identified.
- A current and accurate inventory of all equipment identified as critical maintained.

2. Equipment Qualification

- Equipment, including computer systems shall be qualified and found acceptable before actual use in work processes.
- Equipment installed per manufacturer's specifications. (Installation Qualification)
- The functionality of each piece of equipment and computer system components verified before actual use, and meeting the manufacturer's operational specifications. (Operational Qualification)
- TBC shall demonstrate that equipment performs as expected for its intended use in the facility's work processes. (Product/Performance Qualification)

3. Calibration Program

- Measuring equipment calibrated and adjusted as necessary before use, after activities that may affect the calibration, and in accordance with a defined calibration schedule.
- Measuring equipment calibrated against reference standards.
- Calibration shall be scheduled and performed at intervals recommended by the manufacturer or regulatory/accreditation agency.

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- Calibration procedures shall follow manufacturer's instructions and shall include:
    - Instructions for performing calibration.
    - Acceptance criteria.
    - Actions taken when unsatisfactory results obtained.
  - Investigation and follow-up of calibration failures shall include:
    - Actions to ensure that the equipment removed from service.
    - Investigation of the failure.
    - Assessment of the conformance of products and services provided when equipment found to be out of calibration.
    - Actions for adjusting or re-calibrating the equipment.
4. Maintenance and Repair of Equipment
- Equipment maintained in good working order and, as appropriate, repaired.
  - Preventative maintenance schedules shall be prepared and followed for equipment and at a minimum, meet the frequency recommended by the manufacturer.
  - Maintenance procedures shall follow manufacturer's instructions and/or regulatory/accrediting recommendation.
  - Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:
    - Actions to ensure that the equipment removed from service.
    - Investigation of the malfunction, failure, or adverse event.
    - Assessment of the conformance of products and services provided when equipment found to be malfunctioning or have failed.
    - Reporting the nature of the malfunction, failure, or adverse event to the manufacturer and other affected parties, when indicated.
    - Equipment without a manufacturer maintenance interval subject to an annual review of respective equipment maintenance log. A reported failure within the review year deems the equipment requiring revalidation to ensure equipment is at its optimum functional state.
5. Computer Systems
- Modifications to computer systems software, hardware, and databases shall be planned and controlled.

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**D. Suppliers and Supply Management:** Providers of critical goods and services obtained from outside sources can consistently meet the specified requirements.

1. Good or Service Requirements
  - A master list of critical goods [services] maintained.
  - Requirements and specifications for critical goods [services] identified and recorded on applicable specification forms.
2. Supplier Qualification and Selection
  - Criteria for qualification and selection of suppliers of critical goods [services] are established.
  - Critical goods [services] purchased through purchasing groups such as ABC or BCA qualified by the purchasing group.
3. Critical goods [services] purchased outside of the purchasing group affiliations are qualified internally.
4. Supplier Agreements/Contracts
  - Agreements/Contracts shall identify TBC's requirements, reflect agreement and incorporate changes as needed.
  - Agreements/Contracts are reviewed according to ensure that customer and supplier agreements are met and changes are appropriately recorded and communicated.
5. Agreements/Contracts filed electronically in a repository maintains expiration dates and provides notifications to appropriate TBC management for review and renewal.
6. Supplier Evaluation
  - Suppliers of critical goods [services] periodically evaluated whether suppliers of goods [services] have met agreed upon requirements and specifications.
7. Receipt, Inspection, and Testing of Incoming Critical Goods [Services]
  - Incoming critical goods segregated until they inspected and tested as necessary for acceptance before use.
  - An assessment on the critical goods received and releases critical goods that have met established specifications.
  - Rejected critical goods returned to manufacturer, used for research, or discarded.
8. Inventory Management
  - TBC shall have an inventory management process that addresses the availability, control, storage, and handling of critical materials and products.
  - Adequate quantities of in-date materials and products shall be available to meet the needs of the organization.
  - TBC shall maintain proper conditions for storage, handling, distribution, and transportation of materials and products.

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**E. Process Management:** Method(s) of ensuring that process steps accomplished as expected and performed in a manner consistent with defined procedures designed to ensure the quality of products and services.

1. Process Development and Change

- Development of new processes and procedures or changes to existing ones controlled.
- A process to document and approve changes maintained.
- Quality requirements incorporated into the development of new or changed products or services. Planning activities at a minimum shall include the following:
  - Evaluation of accreditation, regulatory, and legal requirements related to the new or changed process, product or service
  - Review of current available knowledge
  - Identification of affected parties and mechanism to communicate relevant information
  - Evaluation of resource requirements
  - Evaluation of the need to create or revise documents for the new or changed process, product, or service.

2. Process Validation

- Before implementation, the new or changed processes and procedures validated.
- Revalidation performed when process changes occur that could affect the process outcome.
- Written approved validation protocols used for all validations.
- Results of all validation activities documented.
- Validation results reviewed and approved prior to process implementation.

3. Process Implementation

- The implementation of new or changed processes and procedures controlled.

4. Process Performance

- Current policies, processes, and procedures followed.

5. Planned Deviation

- Planned exceptions to policies, processes, and procedures shall require justification and approval by Executive Management.

6. Process Control

- Controls established to ensure that processes perform as expected. Process controls shall allow staff to intervene in the event of a process failure before finished products and services delivered.

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- In the event there is a question that a product may not be suitable, electronic and paper methods exist to allow staff to request a hold on the products.
  - Holds placed on products initiates an investigation of the event and resolution of the products involved.
  - Investigation and resolution of products documented.
7. Process Quality Control
- Quality control activities established that are sufficiently comprehensive to ensure that reagents, equipment and methods function as expected.
  - Quality control performed at time intervals recommended by the manufacturer or applicable accrediting/governing agencies.
  - Quality control results reviewed and evaluated against acceptance criteria. Quality control failures investigated before release of test results, products, or services.
  - The validity of test results, products, or services provided evaluated when quality control results are unacceptable.
8. Proficiency Testing
- Proficiency testing measures and compares testing systems at TBC with the outcome of testing performed by other laboratory peers.
  - The Blood Connection participates in proficiency testing programs appropriate for its level of testing.
  - The Proficiency Testing Program includes designation of testing personnel, frequency of challenges, forms/documents, routine review, and corrective action.

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**F. Documents and Records:** There shall be a process to generate, modify, control, distribute, and archive documents and records.

1. Document Control

- The creation, use, maintenance, and disposition of documents controlled.
- Documents are created/designed and written in a manner that provides clear and understandable information.
- Policies, processes, and procedures created using an approved format.
- Each document shall be uniquely identified and include:
  - Title
  - An indicator of the current version
  - Facility identification
- New or revised documents reviewed and approved by authorized personnel before use.
- Only current and approved versions of documents shall be in use.
- An inventory of documents, including policies, processes, procedures, labels, and forms maintained.
- Documents reviewed on a periodic basis.
- Appropriate documents shall be available where activities performed.
- Invalid and obsolete documents promptly removed from all points of use, or protected against inadvertent use, and archived or destroyed as appropriate.
- Archived documents shall have appropriate identification to prevent their inadvertent use.
- Documents shall be stored in a manner that preserves legibility and protects from accidental or unauthorized access, destruction, or modification.
- Documents shall be retrievable during the retention period.
- Archived documents retained accordingly.

2. Records

- Records created concurrently with performance of each critical activity.
- Records shall identify:
  - The activity performed, method(s) used, and results obtained.
  - The individual performing the activity.
  - When the activity performed.
  - The facility where the activity performed.
- The actual result of each observation recorded immediately.
- There shall be a means to display and verify electronic data before final acceptance.

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- The record system shall make it possible to trace products and services from source to final disposition, including identification of:
    - Individuals who performed critical activities.
    - Equipment used.
    - Critical materials used.
  - Records reviewed according to defined requirements in respective procedures.
  - Appropriate action taken when acceptance criteria met.
  - Changes to records controlled.
  - An audit trail of the date of changes to the record and identity of the person who changed the record created and maintained at least for the retention period of the original record.
  - Record changes shall not obscure previously recorded information.
  - Archived records shall be stored in an organized manner that:
    - Preserves legibility for the entire retention period.
    - Protects from accidental or unauthorized access, destruction, or modification.
    - Enables access and retrieval within a timeframe appropriate to the circumstances.
  - Records retained accordingly.
  - Records destroyed in a manner that ensures confidentiality of the information contained within.

**G. Non-Conforming Events:** A process to capture, assess, investigate, and monitor events that deviate from accepted policy, or procedure, or fail to meet the expectations of the facility or any applicable regulatory/accrediting requirement.

1. Detection

- A systematic approach used to detect deviations from policies, processes, and procedures and nonconforming products and services. Sources of information shall include at least:
  - Complaint files.
  - Record reviews.
  - Reports of unexpected or adverse events and near-misses.
  - Monitoring and assessment activities.

2. Immediate Action

- Upon discovery of deviations and nonconformances, immediate action taken to protect patients, donors, and clients and to prevent unintended distribution or use of potentially affected products and services.

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- When the quality of a product or service is in doubt, immediate action taken that includes the retrieval, quarantine, or recall of affected products pending further investigation.
  - Nonconforming products or services already in distribution reported to the customer as soon as possible.
  - If still available, nonconforming products retrieved and destroyed, reworked to meet specifications, or accepted by the customer after disclosure.
3. Investigation
- Nonconformances and deviations thoroughly investigated to determine the scope of the effect on processes, products, and services.
4. Event Report
- A record of the event created and reviewed.
  - Records shall include the disposition of the product or service and the rationale for the disposition decision.
  - A Risk Priority Number (RPN) calculated for each event. RPN is a rating of the severity, detectability, and frequency of the event. A rating scale 0 – 5 used. The three rating values multiplied to determine the RPN for the event, which provides a recommendation for action. A RPN of 0 – is an event that is merely documentation of the event to provide information at a later time to fill in details not captured on another form. RPN of 1 – 48 is an event in which monitoring for a trend recommended. A RPN equal or greater than 49 would require the initiation of a Corrective Action Preventative Action Plan (CAPA).
  - Corrective action preventative action plans (CAPA) initiated for events deemed correctable. The initiation of a CAPA starts with performing root cause analysis for the event. A root cause tool used to assist in the searching for why or how the event occurred. Following the completion of root cause analysis, the action plan developed and executed. Upon completion of the action plan, an effectiveness check conducted with final review and approval by the VP, Quality Systems/CQO/or designee and the Medical Director.
  - Nonconforming events deemed FDA reportable reported to CBER within appropriate reporting time limits.

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**H. Monitoring and Assessment:** A process to actively monitor and assess the performance of the quality management system and technical operations and verifying conformance of activities to specified requirements.

- Quality indicator data to monitor the effectiveness of critical processes and conformance to requirements.
- Internal assessments of operations and the quality management system.
- External assessments of operations and quality systems.
- Outcomes data and information to assess the ongoing effectiveness of products and services for their intended use.
- Data and information about nonconforming events.
- Information obtained through customer feedback and complaints.
- Identified nonconformances from internal or external assessments captured and reported to responsible departments for investigation.
- Corrective action preventative action plans (CAPA) initiated for events deemed correctable.
- Significant assessment findings reported to Executive Management and TBC operational and regional directors and managers.

**I. Process Improvement:** Maintain policies, processes, and procedures to use methods of identification, data collection, analysis, and follow-up of preventative action.

1. Opportunities for Improvement

- Data and information about operational processes and quality management system performance identify opportunities for improvement.
- The following activities serve as a source of opportunities for improvement:
  - External assessment report findings.
  - Reports of customer complaints.
  - Analysis and trending of occurrence reports.
  - Internal monitoring and assessments.

2. Implementing Corrective Action Preventative Actions

- Improvements to policies, processes, and procedures through corrective actions and preventive actions implemented.
- Corrective action taken when actual nonconformances, deviations, complaints, and process failures occur. Corrective actions shall address the root cause(s) of such events to reduce or eliminate their recurrence.
- Preventive action taken when data analysis or trends indicate the potential for a nonconforming product or service.

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- Corrective actions and preventive actions shall be appropriate to the level of risk and potential for serious adverse outcomes associated with the issue addressed.
3. Monitoring
- Corrective actions and preventive actions monitored to verify successful implementation.
  - Effectiveness checks completed to determine the completion and effectiveness of the corrective actions and preventive actions.
  - Results of effectiveness checks reviewed by VP, Quality Systems and the Medical Director or designee.
  - Acceptability of the effectiveness check documented.

**J. Facilities, Work Environment and Safety:** Maintain policies, process, and procedures for providing a work environment that minimizes health and safety risks and meets applicable laws and regulations.

1. Facilities and Work Environment
- Space allocation and design shall be adequate to support the activities carried out in the facility.
  - The work environment shall be clean and maintained.
  - Storage for critical materials, products, samples, and records shall be adequate to meet specified requirements and to prevent mix-ups.
2. Health and Safety
- Safety programs shall address fire, biological, chemical, and where applicable, radiation safety.
  - Biological, chemical, and radioactive materials such as reagents, supplies, products, and samples handled and discarded in a manner that minimizes the potential for human exposure to infectious or other harmful agents.
3. Emergency Management
- Emergency management plan shall address preparation for, response to, and recovery from the effects of internal and external disasters and other emergent situations.
  - Emergency management plan including emergency communication systems periodically tested.