COMMUNITY BLOOD BANK

A Member of America's Blood Centers

Community Blood Bank (CBB) of Erie County
dba
CBB of Northwest PA
And
CBB of Western NY

QUALITY PLAN

2646 PEACH ST. ERIE, PA 16508

MISSION STATEMENT

The Community Blood Bank of Northwest PA and Western NY connects donors to patients who are in need of life-sustaining blood products in the communities we serve.

I. ORGANIZATION (Organizational Chart included)

a. Quality goals are included in the Mission Statement.

b. The CBB Board of Directors has ultimate responsibility for the functions of CBB.

c. Executive Management consists of
   i. Medical Director (CLIA Laboratory Supervisor)
   ii. Executive Director
   iii. Quality Assurance (QAD) Director
   iv. Technical Director (TD)
   v. Information Technology Specialist

d. The Quality Committee consists of:
   i. Medical Director
   ii. Executive Director
   iii. QAD
   iv. Representatives from:
      1. Laboratory
      2. Donor Collections

e. The Executive Director is responsible for the daily operation of the organization. These operations are conducted in accordance with regulatory requirements.

f. The Medical Director is responsible for quality activities and has the authority to approve all medical and technical policies, processes and procedures and changes required to support the quality system. Justification and pre-approval of exceptions to policies, processes and procedures warranted by clinical situations is the responsibility of the Medical Director. The Medical Director fulfills the requirements of a CLIA Laboratory Director.

g. The QA Director is responsible for quality assurance, regulatory affairs. The QA Director reports directly to the Executive Director.

h. The QA Department is organizationally separate from operations.

i. Executive Management is responsible for oversight of all quality systems. They meet to discuss continuous quality improvement of overall products and services.

j. Department Heads are responsible to incorporate quality into processes and verify that procedure and policy are followed.

k. All employees are trained and supported to perform quality work.

l. The QA Committee meets regularly to discuss improvement to systems.

II. RESOURCES

a. Position descriptions exist for each position.
b. Available positions are posted internally and/or externally as needed.
c. Qualified personnel are hired or appointed to available positions.
d. Training protocol is established and implemented for each position.
e. A confidentiality statement is signed.
f. The training program is evaluated annually.
g. Annual competency is completed.
h. Continuing education is available.
i. Personnel records are maintained and reviewed.

III. EQUIPMENT

a. A selection criteria process exists for choosing equipment.

b. All critical equipment has unique identification.

c. All critical equipment shall be monitored and include the following elements:
    i. Validation or Re-validation as needed
        1. Installation Qualification (IQ)
        2. Operational Qualification (OQ)
        3. Performance Qualification (PQ)
    ii. Calibration
    iii. Maintenance
    iv. Quality Control

d. A process exists to identify defective equipment, remove it from service and resolve problems prior to return to service.

e. A process exists for training of personnel in use of equipment.

IV. SUPPLIER & CUSTOMER ISSUES

a. A process exists for qualification of suppliers prior to the acceptance of an agreement or purchase.

b. Vendors of critical supplies are identified and reviewed for their ability to consistently meet standards set by regulations, standards and CBB.

c. The Finance department and/or Executive Director reviews contracts and agreements.

d. Receipt and review of critical supplies is documented.

e. Critical supplies are inspected, tested (when required) and approved prior to release into the inventory.

f. Package inserts are reviewed for changes upon receipt.

g. Critical supplies that are found to be unacceptable or have package insert changes are quarantined.

h. Critical supplies are stored in accordance with manufacturer's instructions.

i. Use of critical supplies is traceable throughout the manufacturing process.

V. PROCESS CONTROL

a. Standard Operation Procedures and policies are developed and carried out in accordance with regulations, standards, contracts and good manufacturing practices. There is an annual review of these policies and procedures by Medical Director or Department Head.

b. CBB has a change control process that includes:

   i. Identification of specifications
   ii. Verification that specifications have been met.
   iii. Implementation of change is controlled.

c. CBB participates in a proficiency testing program.

d. There is a quality control process in place to ensure reagents, equipment, and methods function as expected and in accordance with regulations, standards, manufacturer's instructions and good manufacturing practices.

e. There is a process to identify, inspect and trace all blood products from source to final disposition and identify each individual involved in critical manufacturing steps.

f. Labels to be attached to blood products are reviewed and approved prior to use.

g. There is a process to ensure that blood products and critical materials are handled, stored, distributed and transported in manner that prevents damage and meets requirements.

h. Informed consent is obtained from all allogeneic, Autologous, apheresis (platelet, 2RBC, and plasma) and therapeutic donors prior to donation.

i. There is a process to ensure quality care of donors before, during and after the donation process.

j. Donors are educated and qualified prior to the donation process.

k. There is a process for handling of post donation information.

l. Testing of all donor blood is done in accordance with manufacturer's specifications, regulations, standards and good manufacturing practices.

m. There is a process to identify and quarantine non-conforming blood products and to quarantine and dispose of prior collections of blood products, if required.
n. There is a process for final inspection of blood products prior to distribution.

VI. DOCUMENTS & RECORDS

a. There is a document control process that outlines the development, approval, review, and implementation of documents.

b. Document format is defined.

c. Annual review of documents is performed.

d. Documents are retained according to procedure and regulations.

e. There is a process to archive obsolete documents.

f. There is a process to identify and destroy copies of original documents.

g. There is a system to prevent unauthorized access or destruction of documents.

h. There is a process to support the introduction or modifications of new software, hardware, or databases of the computer system.

i. Computer backups are stored in an off-site location.

j. There is a process to evaluate and implement, when necessary, changes to Regulations, AABB Standards, the AABB Technical Manual. When these documents are referenced in SOP's, the format shall be as follows: e.g.: AABB Technical Manual, current edition

VII. DEVIATIONS AND NONCONFORMANCES

a. Deviations and non-conformances are identified and documented.

b. Deviations and non-conformances are investigated, evaluated and analyzed.

c. Products from deviations and non-conformances are segregated.

d. Management is involved in the review and resolution of deviations and non-conformances.

e. Corrective action is implemented and monitored, if required.

f. There is a process to report biological product deviations of distributed products to the FDA.

g. There is a process to notify consignees of unsuitable products.

h. There is a process to capture, assess and monitor adverse donor reactions.

i. There is a process to track and trend deviations & non-conformances for system problems.

VIII. ASSESSMENTS: INTERNAL & EXTERNAL

a. There is a process to perform internal assessment at defined intervals. This is the responsibility of the QA Department.

b. There is a review of assessment results by management, department heads and QA.

c. There is a process to manage external assessments.

d. There is a process to manage assessment results to include, but not limited to:

   i. Root cause analysis
   ii. Corrective action plan
   iii. Follow up

e. Executive management reviews results, and corrective and preventative actions of all assessments.

IX. PROCESS IMPROVEMENT

a. There is a process for corrective action that includes:

   i. Documentation of non-conformances, deviation and complaints
   ii. Investigation into cause of non-conformances, deviation and complaints
   iii. Determination of corrective action
   iv. Monitoring of corrective action

b. There is a process for preventative action that includes:

   i. Review of assessment results
   ii. Review of proficiency results
   iii. Review of QC records
   iv. Review of complaints
   v. Determination of steps necessary to deal with potential problems

c. Data is collected and evaluated on a regular basis to determine possible areas for process improvement.

X. FACILITIES AND SAFETY

a. The safety program at CBB includes training in the following:
   i. Fire protection
   ii. Chemical hygiene
   iii. Blood borne pathogen
   iv. General Safety
   v. Disaster Protocol

b. The safety manual includes policies on the following:

   i. Exposure control
   ii. Hazard communication
   iii. Documentation of occupational accidents/illnesses
   iv. Electrical safety
   v. Emergency preparedness plan

c. Safety training and manual access is provided to all employees

d. The safety program is in accordance with applicable local, state and federal requirements.

e. Personal protective equipment is available to employees.

f. Blood products are handled and discarded in accordance with all regulations.

g. CBB provides a safe, appropriate and adequate environment.

COPY

TITLE: CBB QUALITY PLAN

Original Effective Date	Revised by	Revision	Supersedes Revision #
1996	D. Pirschel	There is a process to evaluate and implement, when necessary, changes to Regulations, AABB Standards and the AABB Technical Manual. When these documents are referenced in SOP's, the format shall be as follows: e.g.: AABB Technical Manual, current edition QA Coordinator to QA Director CBB of NW PA to CBB New SOP Format	1.000
	D. Pirschel	Remove BRD Union Square Address	1.001
	D. Pirschel	Deleted: To assist communities in the region to meet their own needs for a safe, adequate supply of blood and blood products to local hospitals, meeting or exceeding all safety and compliance requirements, at the most cost efficient price. Added: The Community Blood Bank of Northwest PA and Western NY connects donors to patients who are in need of life-sustaining blood products in the communities we serve. Executive Management consists of Medical Director (CLIA Laboratory Supervisor) Executive Director Quality Assurance (QAD) Director Technical Director (TD) Director, Donor Services (DDS) The Quality Committee consists of: Medical Director Executive Director QAD Representatives from: Laboratory Donor Collections quality activities The Medical Director fulfills the requirements of a CLIA Laboratory Director Critical procedures by Medical Director or Department Head standards, manufacturer's instructions Disaster Protocol	1.002
	A Gomez	Deleted: Executive Director Added: President and CEO Informed consent is obtained from all allogeneic, Autologous, apheresis (platelet, 2RBC, and plasma) Information Technical Director Tracy Dorsch	1.003
1996	D. Pirschel	Deleted: President/CEO Director, Donor Services (DDS) Added: Executive Director	1.004
1996	K. Kramer	Deleted: Director (ITD) accounting Added: Specialist Finance	1.005

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TITLE: CBB QUALITY PLAN

REVIEW/APPROVAL/IMPLEMENTATION

REVIEWED BY:			
Department Head	**Name**	**Signature**	**Date**
Information Technology Specialist	Jason Radel		10-22-19
Finance Manager	Sarah Uglow		10/21/19
Collections Management	Jennifer Stephany		10-22-19
Technical Director	Tracy Collier		10/17/19
QA Director	Kristin Kramer		10-17-19
APPROVED BY:			
Position	**Name**	**Signature**	**Date**
Executive Director	Deanna Renaud		10/17/19
Medical Director	Jeffrey A. Richmond, MD		10-21-19
IMPLEMENTATION DATE:	DEC 01 2019		

REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

COPIES: POLICY, CBB Website

RETIRED SOP

SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED

COPIES RECEIVED				
LAB	ITS		BRDM	
HR	ED	CBB	WNYM	WNYV