Status **Active** PolicyStat ID **15343098**

Beaumont

Origination	1/6/2022
Last Approved	4/24/2024
Effective	5/15/2024
Last Revised	4/24/2024
Next Review	4/24/2026

Document Contact	Kelly Sartor: Mgr, Division Laboratory
Area	Laboratory-Blood Bank
Applicability	All Beaumont Hospitals

Blood Bank Quality System

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

A. The Blood Bank Quality System is intended to support and maintain quality processes, products and staff and to ensure the highest possible standard of patient services by complying with all required regulations and accreditation standards. The Blood Bank shall demonstrate compliance with the key Quality System Essentials (QSE) which will be described in detail in separate individual policies and documents.

B. The Quality System is organized to monitor functions and systems in the Blood Bank. These policies provide for a quality system through the performance of self-assessment audits, occurrence management and feedback from hospital administration and Blood Bank customers. The Quality System is expected to change and grow based on the results of self-assessment activities, the increasing maturity of the plan, organizational changes and technical developments.

C. The Quality System is written to conform to the requirements of the AABB's "*Standards for Blood Banks and Transfusion Services", "Accreditation Information Manual",* and the College of American Pathologist's *"Transfusion Medicine Checklist".* The Quality System Essentials (QSE) are described in the sections below.

II. POLICY STATEMENT:

A. **Quality Goals:**
The Beaumont Health Blood Banks are hospital-based blood banks, consisting of transfusion services and at some sites tissue storage and tracking. The quality goals of the Blood Bank are to ensure that all products issued are uniformly safe and the services rendered of highest quality. The quality goals include, but are not limited to:

1. detecting and preventing errors in transfusion medicine processes;
2. reducing process variations that can cause errors;
3. improving effectiveness and efficiency of processes;
4. responding to customer needs in provision of blood components and services;
5. developing and maintaining competent and educated staff;
6. complying with all required regulations and accreditation standards.

B. **QSE 1: Organization:**
The management team of the Blood Bank is responsible for establishing, implementing, and maintaining the Quality System. This team consists of the Laboratory Medical Director/Blood Bank Medical Director, the Operations Director of Laboratory Services, and the Blood Bank Supervisor. The Laboratory Medical Director has final authority over all medical and technical policies, processes, and procedures and for ensuring qualified personnel are employed and receive training appropriate to their tasks. These responsibilities may be delegated to another qualified physician; however, the Laboratory Medical Director shall retain ultimate responsibility for medical director duties. The Blood Bank Medical Director is responsible for medical consultations, reviewing and interpreting transfusion reactions, reviewing procedures and proficiency testing, and other daily medical decisions. The management team of Blood Bank is responsible for the Blood Bank's operations, including:

1. Ensuring compliance with accrediting agencies such as AABB, College of American Pathologists, and Joint Commission.
2. Identification of processes to assure quality of components and services.
3. Ensuring the selection, performance, and review of appropriate internal and external assessments including competency evaluation and proficiency testing.
4. Ensuring that Quality Assurance (QA) is ongoing and processes are improved through review of records, errors, and accident reports (i.e., performing management review).
5. Documenting training and education programs for all employees to include procedures, QA, Quality Control, computer operations, and continuing education.

C. **QSE 2: Resources**
Beaumont Laboratory employs qualified individuals who meet the education, certification, training and experience necessary to perform assigned tasks as defined in job descriptions for each job title in the Blood Bank. An individual being considered for employment must provide evidence of education, training and experience that meet the qualifications stated in the job description. A copy of the job description is provided to each employee by human resources at the time of hire. New employees are provided corporate, hospital, and laboratory orientations. The laboratory strives to recruit and retain quality employees. Employees are selected, trained, updated on new policies and procedures, appraised and observed on a periodic basis using guidelines designed to ensure that quality personnel are at work in the Blood Bank.

1. Responsibilities of the Blood Bank Staff:
    a. The Blood Bank Medical Technologist and/or Medical Laboratory Technician must follow established policies and procedures

b. Use judgment obtained by training and experience to evaluate unusual or unexpected situations; and to communicate any problems or occurrences that may affect patient care to the medical staff and Blood Bank Supervisor in a timely manner.

c. The Blood Bank staff is charged with safeguarding the patient welfare in all actions taken while performing Blood Bank tests and procedures.

d. Only Blood Bank staff are allowed to remove blood products and tissues from their storage areas.

2. Responsibilities of the Blood Bank Supervisor/Manager:

    a. Maintaining operations in conformance to the AABB Standards for Blood Banks and Transfusion Services, the College of American Pathologists (CAP) Transfusion Medicine Checklist, or Joint Commission.

    b. Establish, implement, and maintain the Quality System.

    c. Ensure written procedures exist and are updated for policies and procedures in the Blood Bank.

    d. Ensuring performance of adequate process and equipment validation and adequate preventive maintenance.

    e. The Blood Bank Supervisor/Manager also ensures compliance with technical, administrative and personnel policies and procedures of the Laboratory and Hospital.

3. Training and Competency of Blood Bank Personnel

    a. The supervisor/manager or designee will train all new personnel. New employees must complete their education/competency checklists prior to beginning their assigned duties. All items must be completed to the satisfaction of the trainer. The trainer will use unknowns, direct observation and work review to assess performance. Critical tasks will also be evaluated. These are tasks that are not directly involved in testing and can include but not limited to thawing of frozen components, relabeling of units that have been altered by thawing, irradiating, or issuing of blood components. The supervisor will note any areas for improvement. Unsatisfactory performance will result in additional training and/or termination of employment during the probationary period.

    b. Employee competency will be assessed as indicated in the Laboratory Education - Employee Competency Assessment.

4. Therapeutic Apheresis

    a. The transfusion service medical director is not responsible for therapeutic apheresis. That responsibility lies with the ordering physician and the contracted apheresis service.

5. Intra and Perioperative Reinfusion

    a. The transfusion service medical director reviews and approves of intra and perioperative collection and reinfusion procedures and quality metrics to

help ensure efficacy and patient safety.

6. Personnel Records
   Personnel records are maintained for each employee, which include documentation of education, training, and experience, documentation of orientation, competency testing, and continuing education and performance appraisals. Documentation may be found in the laboratory's locked personnel file or in Human Resources. Performance appraisals are maintained on-line by Human Resources.

D. **QSE 3: Supplies and Equipment**
A vital part of a transfusion service being able to perform quality testing is the supplies and equipment used. Supplies that have been defined as "critical" in the Blood Bank are those that impact the safety and quality of the blood supply. These critical items include: serological antisera, reagent red blood cells, ID-MTS™ reagents (cards and diluent), rare antigen typing sera, elution kits, test tubes, pipettes, normal saline, centrifuges, microscope, refrigerators, freezers, platelet storage systems, Rh Immune Globulin and an adequate supply of blood and blood components. The lot numbers of all blood bank reagents are documented in the Laboratory Information System (LIS) or on the Reagent Inventory Log as the reagent is received into the department.
All critical equipment and reagents are used only as intended by the manufacturer unless alternative use has been validated and approved by the Laboratory Medical Director / Blood Bank Medical Director.

1. **Supplies**
   Approval of Suppliers
   When possible, the Blood Bank will participate in the evaluation and selection of suppliers prior to the acceptance of an agreement. Suppliers must meet specified requirements as indicated below:
   a. Suppliers of reagents and derivatives must:
      i. Provide materials that meet applicable Food and Drug Administration (FDA) requirements.
      ii. Be able to supply products at a level that meets the department's needs.
      iii. Ship products in an appropriate manner as to not compromise the integrity or performance of the product.
      iv. Supply training and/or support as needed.
      v. Provide written instructions for use of their products.
      vi. Provide directions for handling and storage of products.
      vii. Provide Safety Data Sheets (SDS) where applicable.
      viii. Have a corporate-approved contract when feasible.
   b. Blood suppliers and blood bank reference / consultation services must meet the following requirements:
      i. FDA licensed
      ii. AABB accredited

iii. Have a quality system in place
iv. Ship products appropriately
v. Report reference testing results promptly by fax
vi. Supply requested products in a timely manner
vii. Provide notification of recalls in a timely manner
viii. Have a system to address customer complaints

c. Agreements or changes to agreements shall define supplier and customer expectations and shall reflect agreement. Changes to agreements shall be reviewed and communicated to all parties involved.

d. When a supplier fails to meet specified requirements, it shall be reported to the purchasing department. If not corrected, supplies and equipment will no longer be obtained from that supplier until such time when requirements can again be met.

2. **Equipment**

a. Blood Bank equipment is selected by the management team based on the following criteria:

i. Equipment is FDA cleared (if available) or validated and meets applicable AABB standards.
ii. A reasonable warranty covering parts and labor is provided as applicable.
iii. If necessary, the supplier offers a preventive maintenance service contract – OR – parts are available so that service and repair may be performed by Biomedical Services.
iv. When feasible, equipment is obtained from a corporate-approved vendor.
v. Operator's manual or equipment instructions is provided by the manufacturer.

b. Each piece of critical equipment is inspected prior to use. Biomedical Services is notified upon receipt of new equipment. Biomedical will assign a unique asset tag number for the equipment and add it to their preventive maintenance schedule, if needed.

c. Equipment is validated prior to use. Equipment will be set up according to manufacturer's instructions for installation. A copy of the manufacturer's instructions will be initialed by the installer and Blood Bank Supervisor. Additional validation requirements will also be noted.

d. Equipment shall be calibrated, maintained and checked as needed (based on type of equipment and manufacturer and regulatory recommendations). Calibration is performed prior to use, after activities that may affect the calibration, and at prescribed intervals. Re-validation of the equipment will be performed if necessary.

e. Procedures, forms, and checklists will be updated as needed to incorporate the new equipment in testing, quality control, calibration, and function checks. See Blood Bank Equipment list for a listing of all equipment and function checks required.

f. In the event of equipment malfunction, failure, or adverse event, a determination will be made if other equipment has been similarly impacted.

g. Malfunctioning / out-of-service equipment are clearly tagged with a Service Request or Out of Service tag until appropriate service, re-calibration and equipment checks have been performed or equipment has been appropriately disposed of.

h. Equipment failure and corrective / preventive actions taken must be documented on the appropriate quality control or function logs.

i. The nature of the malfunction, failure, or adverse event will be reported to the manufacturer when indicated.

E. **QSE 4: Process Control**

The Blood Bank has processes, policies, and procedures that ensure the quality of blood, components and services. These critical processes are actions that have a direct impact on the safety of patients. Specifications are determined from regulations and accreditation standards and are incorporated into respective procedures. The transfusion service utilizes process control measures that include the following:

1. **Development and use of Procedures** – There are written policies and procedures for all procedures performed.
2. **Change Control** – Processes exist to change established processes and/or procedures. Such changes are documented and approved.
3. **Process validation for new or changed processes or procedures** – validation activities include equipment installation and documentation that the process works as intended before actual use. Revalidation is performed when the process changes occur that could affect the outcome of a process. Validation results are reviewed and approved prior to process implementation. Results of all validation activities are documented.
4. **Computer software** – There are processes established by Blood Bank management and the Information Technology department to validate new or updated software.
5. **Proficiency Testing** – The Blood Bank participates in a proficiency testing program appropriate for its level of testing. Proficiency testing measures and compares testing systems of the transfusion service with the outcome of testing performed by other laboratory peers.
6. **Quality Control** – There is a quality control program established to ensure that reagents, equipment and methods function as expected. The program ensures that the information generated gives optimum patient specimen and result integrity throughout the preanalytical, analytical and post-analytical processes. Opportunities for system improvement are identified and based on such evaluations, corrective actions are developed and implemented. Limits for acceptable performance are

established, monitored, and documented.

7. **Use of Materials** – Materials used in the transfusion service are used in accordance with manufacturer's written instructions or other specified requirements. The means to identify and handle materials not meeting requirements are incorporated into their respective procedures.
8. **Identification and Traceability** – There is a process to identify individuals performing each critical step in collection, processing, compatibility testing, and distribution of blood and blood components. This is achieved either through electronic means or paper trail.
9. **Traceability of Blood and Blood Components** – There are processes (either electronic or paper) in place to ensure that all blood, blood components and critical materials used in their processing as well as laboratory samples and patient records are identified and traceable.
10. **Inspection** – There are established criteria in place to ensure that blood and blood components are inspected and meet specified requirements. There is documentation of these inspections.
11. **Handling, Storage, Distribution, and Transportation** – The Blood Bank has established processes to ensure that blood and blood components, samples and critical materials are handled, stored and distributed according to standards and accrediting agencies. Storage requirements for blood components are maintained and followed. There are methods to trace any blood component distributed, issued, or returned. Criteria have been developed for the release of blood, blood components, and tissues.
12. **Patient Safety** – There are processes in place to identify critical control steps that have a direct impact on the patient's safety. The steps identified are:
    a. Provisions of blood and blood components by an accredited Blood Center
    b. Visual inspection of all donor units prior to and at the time of issue
    c. Confirmation of ABO and the Rh of negative units for all donor units before releasing to inventory
    d. Recipient and sample acceptance by the Blood Bank
    e. Pretransfusion testing of patient sample
    f. Selection of compatible blood and components for transfusion
    g. Issue for transfusion
    h. Administration of blood and blood components
    i. Monitoring of blood utilization
    j. Monitoring of adverse effects of transfusion
    k. Storage, issuing and tracking of tissues

F. **QSE 5: Document Control**

1. Beaumont Laboratory maintains a process to ensure uniformity of procedures based upon the Laboratory Document Management and Record Retention Procedure and

Policy on Policies and Other Related Documents. Procedures that were written, updated, and maintained prior to the implementation of the corporate wide document management system are being standardized when able to, and put in the policy management system. As described in these procedures, new and substantially revised procedures are approved by the Laboratory Medical Director. Minor revisions will be approved by either the Blood Bank Medical Director or the Blood Bank Supervisor. Policies and procedures will be reviewed at least every two years by the Blood Bank Medical Director and/or Laboratory Medical Director.

2. When a procedure is taken out of service, for non-policy management system documents the date it is removed is recorded on the Document Control page of the document. The document is then stored for a minimum of ten years. Policy management system documents are kept for legal length of time required for the given policy or a minimum of seven years as per the policy Inactive Policies.

G. **QSE 6: Blood Bank Records**

1. Records are generated according to instructions described in related procedures. Regulatory requirements and accreditation standards by AABB and CAP are used to determine what records are reviewed and the review schedule. All records are reviewed by the Blood Bank Supervisor and/or Lead Medical Technologist and evidence of this review on the record itself by signature and date. As errors in documentation are discovered during the review process, a notation is made on the record itself, along with any corrective action that may have been taken. Records are retained for the appropriate length of time according to regulatory requirements and Beaumont Health retention policies.

2. Paper records are either stored within the Blood Bank, in a laboratory designated area, or off-site storage. A log is maintained of the records sent to the off-site storage company to facilitate easy retrieval, if necessary.
Electronic records are maintained by the Laboratory Information Systems department according to regulatory guidelines. All laboratory personnel accessing Blood Bank records are assigned passwords linked to security levels based upon their job description.

H. **QSE 7: Deviations, Nonconformances, and Adverse Effects**

1. The Blood Bank has a mechanism to capture, document and evaluate events that have the potential to adversely affect the delivery of quality services. For patient or hospital related incidents, a Quality & Safety Report (QSR), found on the Beaumont intranet under Quality / RL Solutions Quality and Safety Reporting, is generated. QSR reports created under the category Blood Product, no matter where in the hospital they are generated, are reviewed at least weekly by the Blood Bank Supervisor and forwarded to the appropriate manager for review and response. Periodically, a summary of these reports are reviewed by the Laboratory Medical Director or Blood Bank Medical Director. As indicated based on frequency or seriousness of the occurrences, a deviation from policy or safety event will become the focus of an in-depth review. The nature of the in-depth review will be dependent on the type of occurrence and will be determined by the hospital Quality Department and Blood Bank leadership. When sufficient data is gathered and the review is complete, a plan of action will be devised. This plan will include input from any individuals affected by

the problem or the solution. The plan will then be monitored and reviewed for effectiveness.

2. The Quality Department provides feedback to the hospital Quality Care and Safety Committee on a quarterly basis summarizing significant issues and plans for correction.
3. A Blood Bank Internal Variance Report will be completed on-line or on a downtime variance form for deviations from policies and procedures occurring within the blood bank. This includes, but is not limited to, exceptions to policies and procedures approved by the blood bank supervisor or a pathologist. This report is reviewed by the Blood Bank Supervisor and Blood Bank Medical Director. If indicated, issues reported by this method will have a QSR report generated and tracked through that system.
4. Adverse events related to transfusion are investigated according to the Transfusion Reaction Investigation procedure. Results of the investigation are reviewed for interpretation by a pathologist. Notification of outside agencies, when applicable, is done based upon regulatory requirements.
5. As required by the FDA, a report is sent to the FDA Industry Systems (FIS) if the Blood Bank releases a blood product from its control and the error has the potential to effect the safety, potency or purity of the product, even if it is not administered to the patient.

I. **QSE 8: Assessments: Internal and External**

In addition to documenting deviations from policy and procedures, assessments of the Blood Bank are performed by both internal and external means. Internal assessments are done by performing a self-audit, using the checklist from the AABB or CAP, on years in which there is no external inspection. These assessments are performed by qualified personnel such as the Blood Bank Supervisor, Lead Technologist, pathologist, or a blood bank supervisor or qualified technologist from another Beaumont Health facility.

External assessments are performed by outside agencies not associated with the hospital, including inspections/assessments by CAP, AABB, and The Joint Commission. The Blood Bank Supervisor, Operations Director of the Laboratory, and Medical Directors of the Laboratory and Blood Bank will review any findings from the inspections/assessments. The Blood Bank Supervisor will document all required written responses to a citation or recommendation following the inspection/assessment process. These responses will be reviewed by the above directors prior to being submitted to the accrediting agency.

J. **QSE 9: Process Improvement**

Beaumont Laboratory is committed to the continuous improvement in the quality of services to our patients and customers. Opportunities for prevention and improvement are identified from the review of self-assessment activities, proficiency testing surveys, customer complaints, QSR reports and other quality assurance reports. Where non-conformance or opportunities for improvement have been identified, strategies for improvement will be selected. The process of evaluation for needed improvement will either be an informal departmental study or formal hospital key process. Either measure will include documentation and follow-up to determine the effectiveness of the action taken. Reports are prepared and communicated to the appropriate personnel. If possible, statistical tools are utilized to present the information in an effective manner.

K. **QSE 10: Facilities and Safety**

1. Beaumont Health ensures a safe and adequate environment for the provision of our operational activities through defined processes and training programs for employees. The assigned processes and training programs and documentation of such training exists for:
    a. Emergency and disaster preparedness
    b. Chemical hygiene
    c. Blood borne pathogens
    d. General safety
2. Procedures are specifically formulated to be in compliance with AABB, CAP, Occupational Safety and Health Administration, and Clinical Laboratory Improvement Act Standards and/or Regulations. The physical design of the facility supports the provision of a safe and adequate working environment. A process of reporting on the job accidents or injuries exists. These reports are reviewed by the Laboratory and Pathology Administration and serve as a basis for preventive or corrective action or process improvements.

III. REFERENCES:

A. AABB *Standards for Blood Banks and Transfusion Services*, current edition
B. College of American Pathologists, *Transfusion Services Checklist*, current edition
C. AABB Technical Manual, current edition
D. AABB Commendable Practices, AABB.org

Approval Signatures

Step Description	Approver	Date
	Kristina Davis: Staff Physician	4/24/2024
	Ann Marie Blenc: System Med Dir, Hematopath	4/18/2024
	Hassan Kanaan: OUWB Clinical Faculty	3/19/2024
	Muhammad Arshad: Chief, Pathology	3/18/2024
	Masood Siddiqui: Staff Pathologist	3/15/2024

	Jeremy Powers: Chief, Pathology	3/13/2024
	Ryan Johnson: OUWB Clinical Faculty	3/13/2024
	John Pui: Chief, Pathology	3/12/2024
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Mgr, Division Laboratory	3/12/2024
	Kristen DiCicco: Mgr, Laboratory	3/12/2024
	Fatima Bazzi: Medical Technologist Lead	3/12/2024
	Katherine Persinger: Mgr, Laboratory	3/11/2024
	Hilary Morey: Medical Technologist Lead	3/1/2024
	Michele Ferla: Medical Technologist Lead	2/29/2024
	Teresa Lovins: Supv, Laboratory	2/29/2024
	Ashley Beesley: Mgr, Laboratory	2/29/2024
	Karrie Torgerson: Supv, Laboratory	2/29/2024
	Kelly Sartor: Mgr, Division Laboratory	2/29/2024
	Kelly Sartor: Mgr, Division Laboratory	2/29/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne