**Policy**

The Harborview Medical Center Transfusion Service (HMC TSL) is part of the University of Washington Department of Laboratory Medicine. The leadership structure has defined roles and responsibilities in order to ensure the effective implementation and maintenance of the quality management and operational systems and to comply with regulatory requirements.

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| **Executive Management** | Consists of:   * Chief of Service, Department Laboratory Medicine, HMC * Head of Hematology Division Laboratory Medicine, HMC * Head of Transfusion Committee, HMC * Transfusion Service Medical Director(s) * Transfusion Service Manager |
| **Role of Executive Management** | * Define, document, implement, and maintain the Quality Program. * Ensure that Quality Policies and Objectives are communicated, understood, implemented, and maintained. * Plan for the design and delivery of products and services that meet customer needs and quality requirements. * Ensure that quality management and operational system policies, processes, and procedures comply with the regulatory requirements, are documented, consistently followed, and continuously improved. * Ensure that the commitment to Quality is made known to and encouraged in all staff through Quality Systems training. * Annually reviews and assesses the Quality Program for effectiveness and makes changes when required. * Ensure that all documents are reviewed by the Medical Director when there is a change in that position. |
| **Chief of Service, Laboratory Medicine** | * Designated CLIA Director for the Department of Laboratory Services at Harborview Medical Center. * Ultimate authority for Executive Management’s performance. * CLIA Director for all the HMC Laboratories within the Dept. of Laboratory Medicine. |
| **Transfusion Service Medical Director or Designee** | * Has been designated by Dr. Robert Coombs final authority to create, implement, and authorize all medical and technical policies, processes, and procedures, including those that pertain to laboratory personnel over and above those standards established by UW Medicine and the Department of Laboratory Medicine, and test performance in the TSL * Has authority and responsibility for all consultative and support services that relate to the care and safety of transfusion recipients. * CLIA Director Designee for all Transfusion Service Activities * Is a licensed physician and is qualified by training, experience, and relevant continuing education in activities for which the facility is accredited. |
| **Transfusion Service Manager** | * Oversees and maintains the Quality System * Has been designated the duties of oversight of the quality of service provided by the Transfusion Service laboratory and activities carried out in support of the Quality System for the Transfusion Services Laboratory. * Ensures corrective and preventive actions are implemented for any performance issues that could interfere with patient care or safety. * Reports to Executive Management annually on the effectiveness of the Quality Plan. * Oversees Transfusion Service staff and operations. * Reports to Transfusion Service Medical Director * Has been delegated by the Transfusion Services Medical Director to ensure that testing personnel competency assessments meet the defined regulatory requirements. * Has been delegated by the Transfusion Services Medical Director to ensure all equipment and reagents are appropriately maintained and quality control performed * Has been delegated by the Transfusion Services Medical Director to ensure required health and safety training is maintained for all staff in TSL. Overseas annual review of chemical spill kit and maintains safe work practices |
| **Compliance Analyst** | * Responsible for the supervision of the quality system * Reports to Executive Management * Tracks and trends errors, incidents and supplier issues that may interfere with patient care services. * Initiates and documents follow-up actions when performance levels are not being met. * Prepares and oversees annual audit plan to include pre-analytic, analytic and post-analytic phases. * Responsible for Quality Plan training * Tracks autologous tissue storage and disposition * Has been delegated by the Transfusion Service Medical Director to review QC and Maintenance of all blood and tissue storage equipment |
| **Transfusion Safety Officer** | * Responsible for coordination of blood administration education and recognition of transfusion reactions. * Reports to Hospital Administration * Investigates all occurrences involving safety of Blood Administration. * Works with Compliance Analyst, Manager, and Medical Director for corrective and preventive action to ensure safety of blood administration |
| **Transfusion Service Staff** | * Report to the authorities as defined in the facility organizational structure. * Follow all policies, processes, and procedures as written. * Communicate directly with CAP or AABB if quality or safety concerns are not being addressed by laboratory management. |

**Reference**

Standards for Blood Banks and Transfusion Services, Current Edition. American Association of Blood Banks, AABB Press, Bethesda MD

