University of Washington Medical Center 1959 NE Pacific St., Seattle, WA, 98195 Transfusion Services Laboratory	Original Effective Date: 08-08-2017	Number:
	Revision Effective Date: 06-30-2022	OR-0001.05
TITLE: **Quality Plan**		

The Transfusion Service Laboratory (TSL) of University of Washington Medical Center (UWMC) conducts a comprehensive, structured quality program providing the framework for implementing, and monitoring all processes and aspects of blood product handling and transfusion. The TSL Quality System is envisioned as a program of continuous improvement which is enhanced through internal and external assessment, occurrence management, and customer feedback. Our goal is to improve patient safety and product quality by identifying, decreasing, and preventing errors.

The Quality Program supports the quality ideals set forth in the mission statement of University of Washington Medical Center, and conforms to regulatory standards of FDA, CAP, TJC, AABB and CLIA. The quality goals of the UWMC Transfusion Service are to ensure needed blood products are available that all blood products issued are safe and effective, and the services rendered by staff are efficient and accurate. Intermediate goals are:

- Complying with all required regulations and accreditation standards
- Detecting and preventing errors in transfusion medicine processes
- Reducing process variations that can cause errors
- Improving effectiveness and efficiency of processes
- Developing and maintaining competent staff
- Responding to customer needs in provision of blood components and services

The Quality Plan is organized around core quality elements consisting of the following:

- Organization and Leadership
- Personnel
- Equipment Management
- Suppliers and Supply Management
- Process Management
- Documents and Records
- Management of Nonconforming Events
- Monitoring and Assessment
- Process Improvement
- Information Management
- Customer Focus

ORGANIZATION AND LEADERSHIP

The UWMC TSL is part of the University of Washington Department of Laboratory Medicine and Pathology (DLMP). The leadership structure has defined roles and responsibilities to ensure the effective implementation and maintenance of the quality management and operational systems and to comply with regulatory requirements (**See Appendix 1: Organizational Chart)**

ROLES	RESPONSIBILITIES
Executive Management	Consists of: • Chairman, DLMP, UW • Chief of Service, DLMP, UWMC • Division Head, DLMP, UWMC • Transfusion Service Medical Director • Transfusion Service Associate Medical Director(s) • Transfusion Service Laboratory Manager • Transfusion Service Laboratory Quality Manager
Role of Executive Management	• Define and oversee the Quality Program. • Ensure that quality policies and objectives are communicated, understood, implemented, and maintained. • Ensure the design and delivery of products and services that meet customer needs • 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 • Annually reviews and assesses the Quality Program for effectiveness and makes changes when required.
Chief of Service, Laboratory Medicine	• Designated CLIA Director • Ultimate authority for Executive Management's performance. • CLIA Director for all the UWMC Laboratories • Reviews and approves all new and revised policies and procedures
Transfusion Service Medical Director or Designee	• Has final authority and responsibility for all medical and technical policies, processes, and procedures, including those that pertain to laboratory personnel 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 • Participates in the development of institutional transfusion guidelines and policies • Participates in the development of policies and procedures related to intra and perioperative collection and reinfusion • CLIA Director Designee for all transfusion service activities • Reviews and approves all new and revised policies and procedures • Is a member of the UWMC Transfusion Practice and Patient Blood Management Committees

ROLES	RESPONSIBILITIES
Transfusion Service Laboratory Manager or Designee	• Carries out TSL operations following policies, processes and procedures as outlined • Responsible for the service provided by the department and the quality activities carried out in support of the Quality System. • Oversees Transfusion Service staff and operations. • Reports to Transfusion Service Medical Director regarding quality and compliance issues • In conjunction with the TSL Quality Manager, ensures staff training and competencies meet departmental and regulatory requirements • Reviews and approves all new and revised policies and procedures • Ensures all procedures are reviewed every two years and comply with all regulating agency and manufacturer requirements
Transfusion Service Laboratory Quality & Regulatory Manager or Designee	• Maintains the policies, processes and procedures that are the quality plan and directs the activities that are the Quality Program • Reports to Transfusion Service Medical Director regarding quality and compliance issues • Ensures that Biologic Product Deviations are reported to the FDA within the required timeframe and corrective actions are taken and monitored for effectiveness • Maintains SOP, equipment, and reagent change control and archival documents according to current Good Manufacturing Practices (cGMP) • Documents and approves validation protocols and maintains written records of validated processes. When modifications are made, analyzes SOP content to assess impact on other systems or functions • In conjunction with the TSL Manager, ensures staff training and competencies meet departmental and regulatory requirements • Reviews and approves all new and revised policies and procedures • Ensures all procedures are reviewed every two years and comply with all regulating agency and manufacturer requirements
TSL MLS Leads and MLS 2	• Provide floor level leadership for shifts and/or activities such as training and equipment • Participates in writing SOPs • Develop training documents and provide training for transfusion service personnel. • Performs personnel competency evaluations in compliance with the CLIA 88 and ensures training/competence testing is documented and performed at required intervals • Reviews QC records and ensures appropriate documentation and corrective actions. Ensures corrective action is documented and analyzes effectiveness of measures taken to correct QC or equipment problems • Participates in proficiency testing program as defined in the Laboratory Medicine Proficiency Testing Policy and ensures participation is rotated among staff members and follows up with staff members as appropriate when there are PT failures.

ROLES	RESPONSIBILITIES
Transfusion Service Staff	• Perform testing, product modification and provide blood product support to patients. • Perform quality control and preventative maintenance on reagents and equipment. • Complete training and proficiency testing as assigned. • Participate in validations of processes and procedures. • Order and maintain inventory of blood products, reagents and supplies. Follow all policies, processes, and procedures as written.

PERSONNEL

Transfusion Service collaborates with the DLMP Human Resources Department to hire and maintain adequate, qualified, and competent staff.

ROLES	RESPONSIBILITIES
Laboratory Medicine Human Resources	• Recruit and post job openings • Screen applications for specified qualifications • Forward resumes of screened applicants to the Transfusion Service Manager • Negotiate Union Contracts (where applicable) • Interact with Union representatives • Provide guidance for employee disciplinary action
TSL Manager	• Works with TSL Medical Director to set staffing levels appropriate for department workload • Ensures that adequate staffing levels maintained • Requests adequate resources when workloads exceed established staffing levels. • Ensures that job descriptions reflect work performed for the position • Interview applicants together with appropriate team members • Performs annual performance evaluations of the Transfusion Service Quality Manager, Lead Technologists, Medical Technologists/Technicians
Staffing	• The TSL employs an adequate number of qualified individuals: • Staffing levels are set according to workload and service standards • Staffing is reviewed periodically and when processes are modified
Qualifications and Job Descriptions	• Job descriptions define appropriate education, training, and/or experience for each position • DLMP and Human Resources review and approve job descriptions for class and category.
Staff Training	• The TSL maintains a process for identifying training and retraining needs for all personnel performing critical tasks • Quality Improvement reports capture information used in the assessment of training needs. • Each new employee completes task-based training on relevant department procedures and processes

ROLES	RESPONSIBILITIES
Staff Competency	The TSL maintains processes for evaluating staff competence before independent performance of critical tasks, and for evaluating continued competence at required intervals • Initial competency after training (comprehensive) • Semiannually within the first year of hire • Annually after the first year • Competency may be assessed at any time as part of corrective action and process improvement
Personnel Records	The TSL in conjunction with DLMP Administration maintains personnel records for each employee. The following records are maintained and retained for those authorized to perform or review critical tasks: • Names • Signatures • Initials or Identification codes • Inclusive dates of employment • Summary of Training and experience • Competency • Formal certification • Records of Continuing Education • Performance Evaluation

EQUIPMENT MANAGEMENT

UWMC TSL has established and maintains processes and procedures in collaboration with the DLMP Equipment Management Policy for the provision and use of laboratory equipment that is appropriate for the medical needs, scope, and workload of the laboratory, and is in accordance with the organization's critical equipment selection process. TSL defines critical equipment as that which is essential to providing required services to patients and customers.

Equipment and instruments are qualified (validated) for its intended use prior to initial use and after major service or relocated. Initial qualification includes Installation, Operational, and Performance qualification as they apply to the equipment, manufacturer's specification and intended use. Evaluation of service or relocation impact on the operation of the device will determine the extent of requalification needed and may not require repeating the full initial validation.

ROLES	RESPONSIBILITIES
TSL Management	• Determines criteria and methods for acquisition/replacement, installation, validation, maintenance, operation, inspection, troubleshooting, service and repair are in place. • Ensure that a program that regularly monitors and demonstrates proper calibration and function of instruments, reagents, and analytical systems is established. • Ensure that only authorized users operate equipment. • Provide a safe work environment for the operation of equipment.
TSL Medical Director	• Has ultimate responsibility for processes and procedures including instrument use, validations, and maintenance

ROLES	RESPONSIBILITIES
	• Authorizes deviations based on medical need
TSL Manager and Quality Manager	• Maintains a critical equipment list. • Ensure that equipment qualifications are performed before use and after repairs as appropriate and include installation, operational and performance qualification as applicable. • Ensure that processes and procedures are in compliance with appropriate standards and regulations and manufacturer requirements • Ensure that scheduled maintenance and routine calibrations are performed • Monitor equipment performance
Laboratory Staff	• Follow manufacturer's instructions and applicable safety procedures for the safe operation of equipment. • Perform equipment qualification and routine calibration. • Perform scheduled maintenance. • Troubleshoot equipment performance. • Respond to equipment alarms in a timely manner
Scientific Instruments	• Perform validation, scheduled maintenance and calibration per manufacturer and TSL specifications
Facility Engineering	• Perform installation qualification as part of equipment validation process • Perform validation, scheduled maintenance and calibration per manufacturer and TSL specifications • Assess and provide necessary physical requirements for the safe operation of laboratory equipment.
Supplier/Vendor	• Provide proof that the equipment meets the specified needs of the laboratory, and meets the installation qualification requirements for new, or repaired, equipment. • Provide support for the equipment for a defined period of time as defined in the warranty or contract. This may include preventive maintenance, repairs, technical support, and recalibration.
Reference Ranges	• As applicable, reference and therapeutic ranges are established before equipment is placed into use.
Equipment Maintenance	A process and schedule are in place for preventive maintenance, monitoring, and documenting the performance of all equipment.

SUPPLIERS AND SUPPLY MANAGEMENT

UWMC has established policies, processes, and procedures for the selection, acquisition, and replacement of critical services and supplies. The TSL works with other UWMC department resources including contracting, finance and compliance to ensure that contracted services are aligned, consistently managed throughout the organization and lowest pricing is obtained.

ROLES	RESPONSIBILITIES
TSL Medical Director	• Overall responsibility for ensuring appropriateness and quality of the services, instruments, reagents, and consumable supplies. • Participate in the selection of suppliers for critical services and supplies. • Work with manager to identify critical materials and services. • Work with manager to prioritize new programs and critical needs.

ROLES	RESPONSIBILITIES
TSL Manager	• Identify needs for the department, develop and evaluate potential solutions. • Recommend services and product selections • Participate in prioritization of new programs. • Assess daily operational needs and ensure that laboratory inventory is managed effectively and efficiently.
TSL Quality Manager	• Ensures supplies are chosen in conformance with policies and procedures and meet regulatory requirements
Laboratory Staff	• Follow applicable policies, processes, and procedures. • Read manufacturer's inserts for reagents and consumables • Review package inserts for changes before putting lots into use • Use supplies and consumables appropriately • Complete lot acceptance and tracking of critical supplies • Evaluate acceptability of incoming supplies • Notify supervisors of the need for more supplies, problems with existing services or supplies, or other issues around services or supplies
Supply Chain	• Request quotes for the purchase and management of ordered laboratory supplies and services. • Place orders as requested from authorized laboratory personnel • Follow up with vendors in case of difficulties or disputes about the quality of purchased services or supplies.
UWMC Receiving Dept.	• Receive orders into the facility. • Complete preliminary assessment of acceptability of order. • Follow-up and document problems discovered with the order during the receiving process. • Notify and document applicable individuals if problems are identified at facility receipt.
UW Health Warehouse	• Accept and store laboratory inventory. • Deliver such inventory to the laboratory in a timely manner. • Notify (and document) applicable individuals if problems are identified during storage, or delivery of supplies to the laboratory.
CATEGORY	**ACTION**
Supply Management	• Processes and procedures are established for the verification, storage, and use of reagents and consumables. • Reagents and consumables are not used until deemed acceptable for their intended purpose. • Reagents and consumables to be used are verified to ensure they are compatible with the equipment and method selected. • An inventory of reagents and consumables is maintained and documented in accordance with established process. • Records are maintained in accordance with regulatory requirements, as applicable.

ROLES	RESPONSIBILITIES
Medical Alerts or Product Recalls	• Supply Chain subscribes to an alert system for manufacturer recalls or safety alerts. • Laboratory Medicine Designee receives these alerts and distributes to appropriate staff. • Upon notification of manufacturer recall, any recalled inventory is removed from use and disposition recorded.
Service Providers and Purchased Services	• Failure to meet established timelines and quality measures is reported through the occurrence management and Process Improvement processes

UWMC has defined requirements and established criteria that must be met by the vendors who are selected to provide critical services, products, and supplies used by the TSL. Vendor/Supplier issues will be monitored through the QI process for any trends or ongoing failures to supply products that meet the TSL requirements.

VENDOR CATEGORY	VENDOR REQUIREMENTS
Reagent, Instrument, Equipment, and Consumable Suppliers	• Provide materials and equipment that meet applicable FDA requirements. • Complete new vendor qualification as defined by Lab Med and Hospital Purchasing departments • Supply products at a level that meets the needs of the department. • Ship products/equipment appropriately. • Supply training and support as needed. • Provide written instructions for use of the products/equipment supplied. • Provide directions for handling and storage of products/equipment. • Provide Material Safety Data Sheets (MSDS) where applicable.
Blood Suppliers and Reference/Consultation Services	• FDA/CBER-licensed and meets FDA requirements. • AABB accredited and meet AABB requirements. • CLIA compliant. • Able to supply products or services at a level that meets the needs of the department. • Provide delivery services that are cost-effective, reliable, timely, and frequent enough to meet the department needs. • Ship products at in validated shipping containers to ensure product transport temperature requirements are met and product arrives without damage. • Reports reference testing results promptly in a timely manner. • Provides timely billing and credit processing • Maintain competitive pricing that is comparable to other blood suppliers. • Provides timely notification when concerns affecting the safety or efficacy of blood products are discovered, including look-back, recall and market withdrawal.
Courier	• Provide 24/7 availability. • Meet Stat timelines for delivery and pick-up. • Provide courteous service.

VENDOR CATEGORY	VENDOR REQUIREMENTS
	• Provide timely billing and crediting.

PROCESS CONTROL

The TSL operates under written policies, process, procedures, and forms designed to provide safe patient care and meet regulatory, accreditation and customer requirements. Current processes are maintained and when need arises changed in a controlled manner to prevent unexpected consequences that could compromise patient safety and product quality. The following is a list of actions for ensuring policies, processes, and procedures are carried out under controlled conditions.

STEP	ACTION

Request for new or change of a process	• Any member of the TSL may propose a change or new process
	• Change to processes, procedures, or protocols should include the following as applicable:
	  ○ Definition of scope
	  ○ Goal of the change
	  ○ Resources required
	  ○ Verification and/or Validation required
	  ○ Appropriate documentation.
	• Any change may be more or less detailed, dependent on the magnitude of the change.
	• Will be reviewed and approved by the TSL Medical Director and TSL Manager
	• Proposal may be forwarded for approval to the Transfusion Practice Committee if deemed appropriate by the Medical Director.
	• Records of Change Control are maintained

Implementation Plan Development	• A multi-disciplinary team approach is used for changes affecting other stakeholders. • Discuss and evaluate proposed changes with key staff and stakeholders prior to implementation • Evaluate and determine whether processes and procedures meet regulatory requirements. • Evaluate and determine resources required for the change • Evaluate validation, training and implementation needs • Evaluate the need for future competency assessments
Verification	• Verify any supplies, reagents, equipment, or blood products required for the process meet specifications
Validation	• All equipment if validated prior to being placed in use or after major repairs • New processes are validated prior to implementation • LIS software updates are validated prior to implementation. • Validation meets acceptance criteria prior to implementation.
Change Review	• Review of the change should take place post-implementation. • Corrective actions should be monitored for effectiveness using the Process Improvement Process and/or audits • Staff Competency performed if required
Documentation	• All Records of Change Control are maintained in conformance with policy

Quality Control (QC)	• QC is performed each day of use and must be acceptable prior to reporting of patient and donor testing • QC is reviewed monthly by TSL manager and documented on the *Monthly Reagent QC Review Form*

DOCUMENTS AND RECORDS

The TSL follows the UWMC DLMP Document Management Policy that complies with applicable standards and regulatory requirements for the retention of time-sensitive and critical laboratory documents and records. TSL records are retained as per the following table:

TYPE OF RECORD	MINIMUM RETENTION TIME
Information stored in the Laboratory Information System • Laboratory Test results • Patient information (difficulty in blood typing, clinically significant antibodies, significant adverse events to transfusion, special transfusion requirements) • Blood product history and final disposition	Indefinite
• Records of names, signatures, initials, or identification codes, and inclusive dates of employment for staff that performs or review critical tasks.	10 years
Patient specific requests for Blood Products • Manual Blood Product Order Forms • Electronic orders are maintained in the HIS	5 years

• Emergency Release of Uncrossmatched Blood Forms signed by physicians (may be maintained in EMR)
• Notification of abnormal results
• Investigation of Transfusion Related Adverse Events
  ○ Suspected Transfusion Reaction Workups
  ○ Fatalities
• Look-back investigations
• Blood Product Deviation reports
• Preventative Actions
• Corrective Actions
• Quality Improvement Reports
	10 years

• Reagent and blood product inspection and acceptability • Use of control system appropriate to the method of testing—All QC records. • Records of blood storage temperatures • Daily Reagent Quality control results • Daily TANGO Quality control results • Additional reagent Quality Control results • Temperature monitoring of refrigerators, freezers, and platelet incubators	10 years

TYPE OF RECORD	MINIMUM RETENTION TIME
• Validation of Computer Systems	2 years post retirement of the system
• Antibody Identification workups	Indefinitely
• Evaluation and performance of suppliers • Supplier agreements	5 years
• Biennial Review of SOPs • Proficiency testing records • Archival of obsolete policies and procedures	5 years
Assessment Records • CAP Survey results • Internal Audits • Corrective Actions • Blood Utilization Review	5 years
Personnel records • Job descriptions • Training records • Competency records • Qualifications to perform critical tasks	5 years

MANAGEMENT OF NONCONFORMING EVENTS

The UWMC TSL maintains processes and procedures that ensure the capture, assessment, investigation, analyze and take corrective action of deviations or failures to meet specified requirements, nonconforming events, and/or adverse reactions to transfusion. Biologic Product Deviations are reported and tracked according to the Laboratory Medicine Biological Product Deviation Reporting Policy. These may include but not limited events related to blood, components, critical materials, equipment, patients, services and suppliers that fail to meet specified requirements

The TSL tracks these events and deviations internally, and reports deviations to outside agencies or through the facility wide event reporting system as required.

ROLE	RESPONSIBILITY
TSL Medical Director	• Approves planned deviations from policy beforehand when required for patient care • Approve any release of nonconforming products • Evaluates, consult and advises on medical management of Immediate Transfusion-related adverse events. • Review and write pathology consultations on all Adverse Reactions to Transfusion both immediate and delayed. • Advises and notifies recipient's physician and/or recipient as specified by the FDA for Look-Back process.
TSL Manager and Quality Manager	• Maintains processes and procedures for capturing, assessing, investigating and monitoring deviations. • Monitor occurrences, categorizing and reporting as required. • Maintains corrective action processes.

ROLE	RESPONSIBILITY
Laboratory Staff	• Identifies, documents and reports deviations from laboratory policy and procedures • Documents and takes immediate action to gain control of any non-conforming reagents, blood products or test results • Participates in corrective and preventive actions as applicable
NONCONFORMANCE	**ACTION**
Planned Deviation	• Approved by Medical Director prior to event • Documented on QI or other Deviation Approval Form
Unplanned Deviation	• Documented on QI Form • Reported through occurrence management process • Assessed for patient safety by TSL Manager, Quality Manager and/or Medical Director as applicable
Nonconforming Critical Materials & Services	TSL maintains processes and procedure for the review, evaluation, and disposition of nonconforming materials and services
Temperature Variances	• Relocate products to acceptable alternate location(s) within 30 minutes of equipment failure/temperature outage. • Quarantine products that have been stored outside of acceptable temperature range for ≥30 minutes • Document temperature variances and corrective actions on QI form

Nonconforming Blood Products	• TSL maintains processes and procedures for:
	  ○ Identification, quarantine, and disposition of nonconforming blood products.
	  ○ Notification of providers, recipients (lookbacks), and outside agencies as required
	• The TSL Medical Director evaluates products determined to be nonconforming after issue or transfusion, to determine effect of nonconformance on the product and will determine if notification of the recipient or their provider is required.
	• Recipients and/or next of kin are notified in the case of product Lookbacks as per FDA regulations

Biological Product Deviations (BPD)	• Biologic Product Deviation reported to FDA within 45 days of discovery
Safety or Environment of Care deviations	• Reported through the hospital UHC Safety Intelligence system and to any other appropriate agency as required
ADVERSE TRANS. EVENT	**ACTION**
Immediate Suspected Transfusion Reaction	TSL maintains processes and procedures for: • Immediate notification of the transfusion service and the responsible physician. • Prompt evaluation of all suspected transfusion-related adverse events in a manner that does not delay the proper clinical management of the patient. • Indicating under which circumstances additional testing is performed, and what the testing will be. • Notification of the collecting facility when a transfusion-related adverse event is thought to be caused by an adverse condition of the blood component.

ROLE	RESPONSIBILITY
	• In the event of a fatality thought to be transfusion related, the FDA will be notified as soon as possible • Documentation of the investigating and findings in the patient's medical record
Delayed Transfusion Reaction	TSL maintains processes and procedures for: • Performance of testing. • Evaluation of testing. • Reporting to the patient's physician when a delayed reaction is detected or suspected.
Transfusion-Transmitted Disease	The TSL maintains a process for: • Identifying suspected cases of transfusion-transmitted diseases. • Investigating suspected cases of transfusion-transmitted diseases. • Reporting the identity of any implicated donor units to the collecting facility.

MONITORING and ASSESSMENT

The UWMC TSL uses data and information about its operational processes and quality management system performance to identify opportunities for improvement. In addition to the process listed below, the TSL utilizes internal deviation reporting and customer requests to monitor operations for quality and compliance.

The TSL also participates directly in external assessments by the College of American Pathologists (CAP) and inspections by the Food and Drug Administration (FDA) every two years. During a CAP non-inspection year, the TSL performs an internal assessment using the CAP checklist to identify areas of needed improvement.

OPERATIONAL PROCESS	QUALITY INDICATOR	METHOD	FREQUENCY
Sample Collection	• Sample Rejection	• Rejection Report	• Monthly
Pretransfusion Testing	• Reagent QC documentation • QA over-ride report • Antibody Identification Accuracy	• Check by second technologist. • Manager/Quality review • Report reviewed by Supervisory staff	• Each occurrence • Daily • Each occurrence
Inventory Management	• Wastage • Expiration • Unit Age	• SQ Product File List Report • Custom inventory report	• Monthly • Monthly
Blood Product Ordering Practice	• C/T Ratio • Special Product Attributes	• SQ Finalized/Issued Report • Medical Director blood order review	• Monthly • Each order

PROCESS IMPROVEMENT

The TSL collects and analyzes data including near miss events, to determine where preventive and corrective actions are needed, and implementing the necessary preventive or corrective actions. Opportunities may be identified through any avenue including record review, non-conforming events, customer requests and/or Patient Safety Net reports, external and internal assessments, and staff requests.

In addition to internal process improvements, the TSL participates in interdisciplinary process improvements to improve patient care across disciplines.

ROLE	RESPONSIBILITY
TSL Medical Director	• Receives policy from Executive Management • Participate in policy decisions regarding quality indicators and data collection methods. • Follow regulatory requirements for data collection, such as transfusion practice review. • Review and approve processes and procedures. • Participate in decisions about corrective action. • Review and approve corrective action results. • Participate in improvement teams.
TSL Manager/Quality Manager	• Participate in policy decisions regarding quality indicators and data collection methods. • Review and implement new processes and procedures. • Participate in decisions about corrective action. • Review and implement corrective action results. • Participate in data collection • Prepare monthly reports for Transfusion Practice Committee and quality committees • Use data and information about operational processes and performance, as well as occurrence management to identify opportunities for quality improvement. • Participate in improvement teams
Laboratory Staff	• Participate in improvement teams as required • Assist with data collection as assigned • Identify opportunities for quality improvement observed through operational processes
UWMC Center for Clinical Excellence	• Monitors nonconformance reported through the UHC Safety Intelligence system • May assist in multidisciplinary and intradepartmental process improvements • Reviews and monitors patient safety events for appropriate corrective and preventative actions
STEP	**ACTION**
Continual Improvement	UWMC TSL has a defined, systematic approach for continual improvement of operational processes and the quality management system that includes the review of the following:

	• Assessment Results • Audit Results • Proficiency Testing Results • Quality Control Records and Review • SQ Quality Assurance Report • Quality Indicator Data • Quality Improvement Reports
Implementing Corrective Actions and Preventive Actions	• Corrective action is taken when actual nonconformances, deviations, complaints, and process failures occur. • Corrective action will address the root causes of such events to reduce or eliminate their recurrence. • Preventive action is taken when data analysis or trends indicate the potential for a nonconforming product or service. • Preventive actions are intended to eliminate the root causes of potential nonconformances in order to prevent their occurrence. • Corrective actions and preventive actions will be appropriate to the level of risk and potential for serious adverse outcomes associated with the issue being addressed.
Monitoring	• Corrective actions and preventive actions are monitored to verify successful implementation. • The results are reviewed by the Medical Director.

INFORMATION MANAGEMENT

The DLMP and the TSL maintain policies, processes, and procedures for the appropriate use, management, and protection of information. The TSL complies with the Lab Medicine Compliance to Health Insurance Portability and Accountability Act, Results Reporting Policy, Verbal Release of Results/Reports Containing Protected Health Information (PHI) for Purpose of Treatment policies

ROLE	RESPONSIBILITY
TSL Medical Director	• Participates in the selection of Laboratory Information Systems (LIS) • Approves all significant changes to the LIS or clinical decision support applications within the department • Review and approve validations and modifications
TSL Manager	• In conjunction with Laboratory Medicine and UWMC IT, ensures that policies for confidentiality of data, information and verbal and written communications shall be established and followed • In conjunction with Laboratory Medicine and UWMC IT, ensures that access to data is controlled to prevent unauthorized access to and release of information • Ensures that the authorization to access and release data and information is defined and individuals authorized to enter, change, and release results are identified, qualified, and trained • Develops LIS processes, workflow, and procedures • Ensures the computer validation is performed and acceptable prior to implementation
Quality Manager	• Develops LIS processes, workflow, and procedures

	• Ensures the computer validation is performed and acceptable prior to implementation
Laboratory Staff	• Follow policies processes, and procedures to maintain integrity of confidential information • Report any inadvertent release of confidential information to manager immediately • Quality and courtesy of telephone communication is defined by scripts and observed by coworkers
DLMP IT Division	• Develop LIS processes, workflows, and procedures that record the choice, implementation, validation, integration, and security of laboratory information systems or clinical decision support systems • Ensure reports and electronically viewable results are designed to provide clear and understandable information to the user. • Ensure that all report formats meet CLIA requirements. • Establish and maintain a process for ensuring that data integrity is maintained. • Ensures that data are retrievable and usable for the entire retention time. • Ensures that data is reliably sent from the point of entry to final destination in a timely manner. • Ensures that data storage media is protected from damage or unintended destruction. • Provide routine preventative maintenance and troubleshooting support of the laboratory information system or clinical decision support systems • Validate computer performs as intended after repairs or systems upgrade • Ensures computer equipment is given a unique identification and is traceable Back-up Data • Ensures routine back-up of all critical data. Back-up data. • Ensures back-up data is protected from unauthorized access, loss, or modification. • Tests periodically, the ability to retrieve data from the back-up system. Alternative System • Maintains and tests periodically, an alternative system in the event that computerized data or the primary source of information is unavailable.
LIS (Sunquest)	**STORES THE FOLLOWING INFORMATION**
Donor Component Record	• Name of Manufacturer • Donor Identification Number • Product code and description • Expiration Date • Special Attributes • Donor ABO/Rh • ABO/Rh Confirmatory Testing • Results of testing and crossmatch, when applicable • Additional processing such as irradiation, volume reduction, thawing • Recipient name and medical record number • Issue documentation including final inspection at issue • Return documentation if returned after issue • Final disposition of component
Patient Record	• Name and medical record number • Antibody and antigen history • Documentation of history checks • Laboratory workup of suspected transfusion reactions

	• Required attributes and other special requirements required • Difficulties with testing • Date of birth and age • Test and crossmatch results	• Allocated components • Transfused components
Laboratory Staff	• Identification of the person who performs patient or donor component testing and including the date and time of testing • Identification of the person who performs any processing of a donor component from receipt to final disposition and include the date time of action	
CATEGORY	**ACTION**	
Computer System Validation	Computer system programs and processes are validated or revalidated to ensure the integrity and accuracy of data and calculation after initial installation, system upgrades and system modifications	
Computer Identification	Each item of computer equipment is given a unique label or other identification	

CUSTOMER FOCUS

The UWMC TSL provides transfusion services at three campus locations: UWMC Montlake, UWMC Northwest and Seattle Cancer Care Alliance (SCCA) Eastlake (also known as Fred Hutch Cancer Center FHCC). Services include patient and product testing for both inpatients and outpatients including patient testing for UW Neighborhood Clinics. Testing and component processing is performed at UWMC Montlake except for thawing of plasma components at the Northwest Campus

The TSL participates in multiple committees and meetings with customers and other hospital departments to review transfusion practices, identify need for new processes or services and identify opportunities for process improvements. New processes and improvements may be developed in conjunction with customers or internally within the TSL.

MEETING	ATTENDEES	FREQUENCY
Transfusion Practice Committee	UWMC Hospital Staff	Bi-Monthly
SCCA (FHCC) Continuous Quality Improvement Meeting	SCCA (FHCC)Transfusion Safety Office and Support Service	Monthly
NW Continuous Quality Improvement Meeting	UWMC Northwest Laboratory Operations Leadership	Monthly
Montlake Quality Meeting	UWMC TSL Leadership	Monthly
UWMC Daily Safety Brief	Leadership representation from critical hospital departments	Daily
TSL/SCCA (FHCC) Daily Status Brief	UWMC TSL Staff, SCCA (FHCC) Transfusion Safety Office and Support Service	Daily
SCCA (FHCC) Transfusion	SCCA (FHCC) Staff UWMC TSL Staff	Quarterly

Committee		

UWMC SOP Approval:		
UWMC CLIA Medical Director	Andrew Bryan, MD	Date
Transfusion Service Manager	Nina Sen	Date
QA Manager	Tayler Reeves	Date
Transfusion Service Medical Director	Monica Pagano, MD	Date
UWMC Biennial Review:		
		Date
		Date

REVISIONS:
01-23-19: Responsibility for Intraoperative/Perioperative Program involvement by the TSL Medical Director

06-15-21: Updated organization chart and added NW and SCCA campuses as customer locations Update responsibilities for LIS maintenance and specified information stored in the LIS.

06-10-22:Updated organization chart, updated staff competency
07-01-22:Updated organization chart, added monthly supervisory QC review

Appendix1: Organizational Chart