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Quality Program: SCPMG Transfusion Service

Purpose

The Southern California Permanente Medical Group (SCPMG) Quality Program for the Transfusion Service the is based on the AABB Quality SystemEssent ials, the ISO 9002 Standard, and the FDA Quality SystemRegulati on. This Quality Programi s meant to be flexible to meet the changing regulatory climate and industry changes but is also meant to provide structure and stability to the Kaiser Permanente transfusion services. This Quality Program supports the mission of Kaiser Permanente to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

Scope

The Transfusion Service Quality Programi s a collection ofquali tysy stems. Each quality systemi s built around the AABB Quality System Essentials (QSE) and serves as the organizational structure upon which the responsibilities, policies, processes, and procedures evolve. There are 10 Quality System Essentials, and each has at least one overall policy statement that is supported byupper management. These policies reflect the commitment of the Transfusion Medicine Committee and Quality Unit and the SCPMG LaboratoryOperat ions Management Group and complement the goals and vision of the Kaiser Permanente Foundation Medical Care Program. Policy statements may also address the federal, state, and local regulations, rules, laws, and guidelines by which we are governed.

- Each Quality Systemm ayb e subdivided into sections, which identify the various processes within the systems. The processes explain how a function, or process works, or what happens to make the system work. This usually is more than one department or group of employees.
- Each process is usually supported by specified policies, processes, and procedures. The procedures define how to perform, process or do an operation or function.
- Documents or forms may support processes and procedures. Forms are used to collect or hold data or information and are kept as records. All records are retained as required by current standards.

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Organization

Background Information

Kaiser Permanente Southern California (KPSC) is a medical care program comprised of three closelyal igned organizations. These organizations are: Kaiser Foundation Health Plan, Inc. (KFHP), Kaiser Foundation Hospitals (KFH), and the Southern California Permanente Medical Group (SCPMG). These three entities together serve over 4 million Southern California Health Plan members.

SCPMG operates and manages a system of clinical laboratories within KPSC, referred to as the Laboratory Care Delivery System (LCDS). The LCDS provides comprehensive laboratory services including hospital based, clinic based and centralized regional laboratories. The overwhelming majority ofl aboratory services are offered bythe LCDS, however, contracts with outside laboratories for selected specialty laboratoryservices are utilized. The LCDS does not collect tissues, cellular therapy products, blood or blood products.

Executive Management

Definition

- LaboratoryOperati ons Committee consists of the Chiefs of Pathologyand LaboratoryOperati ons Directors for all SCPMG Medical Centers, as well as representatives and administrative personnel from the Regional Laboratories.
- The Medical Director of the each of the Medical Centers Transfusion Services is the licensed physician qualified by training or experience who has responsibility for the policies, processes and procedures as they pertain to:
    - Laboratory personnel and test performance
    - Consultative and support services for the care and safety oftransfusio n recipients

Role of Executive Management

The executive management of the transfusion services with responsibility for quality is the LaboratoryOperati ons Committee, and the Medical Directors of the Transfusion Service. These groups develop and/or aid in the development of quality objectives and policies, and ensure that personnel understand, implement and maintain this quality program.

Executive management ensures that our quality policies and objectives meet the needs of our customers and support the goals of Kaiser Permanente. As changes occur in customer needs, institutional goals and/or SCPMG goals, executive management can review and revise our quality policies and objectives to meet those needs.

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Role of Transfusion Medicine Committee/ Quality Unit
The Transfusion Medicine Committee/Quality Unit is the policym aking committee. The Transfusion Medicine Committee/Quality Unit (TMC/QU)

- Oversees transfusion practices at the regional medical centers
- Works with the Transfusion Services Workgroup (TSWG) in implementation ofpolicies , processes, and procedures.

These committees report to the Quality Sub Committee and Laboratory Operations Director Committees which are sub committees of the Laboratory Operations Committee.

Quality System

The Transfusion Medicine Committee and Quality Unit of SCPMG have established a Quality System that covers all activities that affect the quality of a product or service provided by the Transfusion Services. This systemi s continually under development as processes and or policies change to meet our needs. This system will be continually maintained to ensure that the testing, processing, and transfusion of blood and blood components and the provision of services conform to local, state, and federal requirements and all other regulatory agencies dealing with our facilities.

The Quality Systemi s a part of the Quality Program as outlined by the 10 Quality Systems listed in the program. This part of the Quality Programprovi des evidence of documentation, planning and maintaining processes and procedures as they relate to Southern California Kaiser Permanente transfusion services.

A Quality Representative is appointed who has authorityf or ensuring that the transfusion services establish, implements, and maintains a quality system that meets national, state and regional regulatoryrequi rements.

Quality Representative
The Regional Blood Bank Compliance Officer is the quality representative. The person in this position:

- Attends and participates in the Transfusion Medicine Committee/Quality Unit
- Attends and participates in the Transfusion Service Committee
- Interacts with the medical directors, operations directors and lab managers of the transfusion services in issues of transfusion medicine qualityand regulations.
- Reports to executive management on the status and performance of the quality system.
- Has authority to step in and make changes if a situation is perceived to adversely affect the safety,qualit y, identity,potency or purityof the blood components or the safety of the patient or staff. This action is immediately

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reported to the Transfusion Medicine Committee/Quality Unit committee for further action and/or review.

Management Reviews
Management assesses the effectiveness of the quality system through assessments and scheduled reviews of deviations, nonconformances, and adverse events.

Policies, Processes, and Procedures

Conformance to regulations
The Transfusion Medicine Committee and Quality Unit reviews and directs the implementation of policies dealing with operational and regulatorym atters. These include:

- Food and Drug Administration (FDA)
- California Department of Public Health (CDPH)
- Center for Medicare and Medicaid Services (CMS; formerly HCFA, which administers the Clinical LaboratoryIm provement Act (CLIA)).
- Joint Commission (JC)
- AABB (formerly American Association of Blood Banks)
- College of American Pathologists (CAP)
- The transfusion services adhere to all applicable Standards of the AABB (California-Health and Safety Code - HSC § 1602.5)
- Regulations and standards are reviewed biennially or when issued or revised, and policies, processes, and procedures are brought into compliance, and documented as compliant in a timely manner.

Recommendations made as a result of inspections or assessments from internal groups or outside agencies are used to improve our conformance to regulations.

Medical Directors for each Transfusion Service approves all medical and technical policies, processes, and procedures.

- Variances (exceptions) to policies, processes, and procedures warranted byclinical si tuations require approvalf rom the Medical Director.

Operational Continuity

Each Transfusion Service facility has site specific policies, processes, and procedures to ensure operational continuity.

- There is a regional policy to address blood product inventoryshortages.

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Emergency preparedness

Each Transfusion Service facility has site specific policies, processes, and procedures for internal and external disasters.

- The emergencym anagement plan, including emergency communication systems is tested at defined intervals.

Communication of Concerns

The SCPMG and KFH provide many avenues for staff to anonymously communicate concerns about quality or safety and are communicated to all personnel.

Customer Focus

The Transfusion Services of Kaiser Permanente in Southern California are committed to good customer service. Our customers, both internal (our physicians, nurses, staff) and external (patients and public) are treated with courtesy and all attempts are made to provide the best service possible. Any problems with service are recorded in our Quality Improvement Monitoring process, and corrective action is taken when necessary to resolve problems. Staff is encouraged to attend classes or workshops offered by Kaiser Permanente Education departments to improve our service to our customers.

Resources

Kaiser Permanente maintains a process for qualifications for job functions based on education and experience. This process follows state and federal regulations. Each medical center transfusion service has established policies, processes, and procedures related to orientation, training, and competence for personnel.

Personnel

- Job Descriptions or work skills lists are kept for each employee in the transfusion service.
- The job descriptions or work skills are reviewed and updated as needed.
- All Clinical LaboratoryScient ists working in the laboratory have their current licenses posted in a conspicuous location in the laboratory.
- Staff are trained and deemed competent prior to performing laboratorytests .
- Each transfusion service facility determines that an adequate number of qualified personnel is employed.

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Qualifications

- The qualifications requirements of personnel performing tasks in the transfusion services are in compliance with federal and state regulations and are agreed upon by the unioncontracts.
- Job postings and qualifications are established by the LaboratoryOperati ons Directors and/or the Transfusion Service Managers with the oversight of the Human Relations Departments.

Training

- Processes and procedures exist for orientation and training of new employees to the Kaiser Permanente transfusion services or for transfer of employees from one facility to another.
- All orientation and training processes agree with union contracts.
- All orientation and training processes include a review period, and a determination of competence before the employee can work without supervision.

Competence

- Policies, processes, and procedures exist for the documentation of initial training and competency of new and existing employees on an annual basis.
- Competencyi s assessed annually for all employees working in the transfusion services, twice during the first year for all new employees, and as determined by the site for all new or ongoing critical tasks. All competency processes agree with existing union contracts.
- Competency assessment is performed by documentation of the six elements as defined by CLIA for testing performed.
    - Other critical tasks (e.g. emergencydispense) that are not testing may also have annual competency evaluated.
    - Appropriate action is taken when competence is not demonstrated.

Records

All records of orientation, training and competence are retained as required per current standards and regulations.

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Equipment

The Transfusion Services of Kaiser Permanente in Southern California have policies, processes, and procedures to select, qualify, use, monitor, and maintain equipment and devices used to store, inspect, measure, transfuse (blood warmers/perioperative) or test blood products (incoming, in-process or final) which conforms to the requirements defined by good manufacturing practices. There are also policies, processes, and procedures regarding equipment used in patient testing. These policies, processes, and procedures conform to local, state, and federal requirements and all other regulatory agencies dealing with our facilities.

Software and hardware are validated prior to use. Policies, processes, and procedures exist that define the extent and frequency of these validations and records are maintained per current record retention policies.

The processes listed below are performed under controlled conditions that require procedures for all operations, and records of criticalactivi ties. This control includes continual monitoring of the process, and audits to ensuring patient and/or product testing of the blood supply is not compromised.

Selection

Criteria have been established for equipment selection that includes:

- Intended use and identification of our requirements
- Capability to meeting requirements and appropriateness of our use
- FDA-cleared for use (when applicable)
- Equipment performance record
- Physical requirements
- Cost
- Service/Support issues

The selection process includes transfusion services managers, laboratory operations directors and/or medical director as applicable.

Qualification

Equipment and measuring devices used to store, inspect, measure or test products or used for patient testing undergo qualification processes prior to use that includes:

- Installation qualification
- Operationalqualificat ion
- Performance qualification

Validation plans are developed and approved to test for the desired results under variable conditions. Completed validation plans and results are reviewed and

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appropriate action taken either to approve for use in production or plan further testing.

Use of Equipment

- Equipment is used in accordance with the manufacture's written instructions.
- Equipment and/or testing devices are safeguarded against improper adjustments by allowing only trained and qualified personnel to use them.

Unique Identification

- Each piece of critical equipment has unique identification; this list is maintained byL aboratoryTechnol ogy Services (LTS).
- Each site has access to the critical equipment inventory and related documents.

Equipment Monitoring and Maintenance

- Preventive maintenance (PM) requirements are identified according to manufacturer's specifications and/or recommendations.
- PM procedures are developed and scheduled by Laboratory Technical Services (LTS) or contracted vendor
- Transfusion Services manager or designee review scheduled performance and results of PM procedures. Appropriate action is taken for questionable or unacceptable results

Investigation and Follow-up

Equipment that fails, malfunctions or is associated with an adverse event is taken out of service. Repairs or service are made by vendors or LFS departments and reported to the Transfusion Services manager or designee.
These events are investigated for:

- Assessment of blood and/or blood components affected
- Assessment of patient safety (Potential impact on products or patient testing)
- Steps to ensure equipment is removed from service
- Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected
- Step for requalification of the equipment
- Reporting the event to the manufacturer when indicated.

Storage Devices for Blood, Blood Components, and Reagents

- Storage devices shall have the capacity and design to ensure that the proper temperature is maintained.
- Storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored.

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Alarm Systems

- Storage Devices for Blood, Blood Components, and Reagents shall have alarms and shall conform to the following:
    - The alarm shall be set to activated under conditions that will allow proper action to be taken before blood, blood components, or reagents reach unacceptable conditions.
    - Activation of the alarm shall initiate a process for immediate action, investigation, and appropriate corrective action.

Blood Warmers and Perioperative Equipment

- The Transfusion Service Medical Director provides guidance to the medical center in the area of regulations relating to blood warmers and perioperative collection/transfusion activities.
- The Transfusion Service Medical Director may provide guidance for Quality Controlof equi pment and processes.
- Warming devices used for blood and blood components are equipped with a temperature sensitive device and a warning system to detect malfunctions.
- Records of PM, QC, repairs, and calibration are maintained on site.

Information Systems

- FDA 510K cleared computer systems are used in the transfusion services for input, collection and processing data for patient and donor management.
- Processes exist to support the implementation and modification of the software, hardware, and databases relating the transfusion service computer system(s).
- All new versions and patches to existing versions are validated and that validation is documented.
- The computer systemi s monitored routinely. Anyprobl ems withthe computer system or software are reported to the manufacturer for resolution of the problems. These communications are documented, and actions taken are followed up to ensure effectiveness of the system.
- An alternate (downtime) system shall be maintained to ensure continuous operation. The alternate systemi s tested yearly.

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Supplier and Customer Issues

The Transfusion Services of Kaiser Permanente in Southern California have policies, processes, and procedures that ensure that products and services purchased conform to specified requirements. All blood and blood components must meet state, federal and local regulations. Records are kept of all shipments ofcri tical supplies, inspection of those supplies, and tests performed, when applicable.

Supplier Qualification

- With the Kaiser purchasing group, the transfusion services evaluate potential new and current suppliers through a formalized process.
- The transfusion services have a Quality Improvement Monitoring (QIM) process to document and track anyprobl ems from criticalsuppliers
- A process exist that would immediately alert all transfusion services if a critical supplier's product did not meet expectations, and that failure would compromise the safety potency or purityof a blood product or could adversely affect an employee or patient. This report would also be channeled to the Kaiser purchasing group and other relevant group(s).

Agreements

- Agreements, or changes to agreements, shall define supplier and customer expectations and shall reflect agreement.
- Purchasing documents are kept with the Kaiser purchasing group. When copies or data is requested from these documents, they can be contacted for purchasing information.
- Laboratoryop erations directors and lab managers are encouraged to participate in the selection of critical suppliers for the transfusion services.

Southern California Kaiser Permanente Transfusion Services work with representatives of the contracted purchasing groups to review contracts of suppliers of selected critical supplies, reagents, and solutions. Contracts for blood and blood components are reviewed by the RegionalTransfusi on Medicine Committee/Quality Unit.

Review

- The contract for blood and blood components, and other select supplies critical to the transfusion service are reviewed by representative(s) from the RegionalTransfusi on Medicine Committee/Quality Unit working with the Kaiser Permanente Contracts group. This review is performed prior to acceptance of the contract, when applicable.

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- In some instances, the Kaiser contracted purchasing group or other local purchasing organization may need to be contacted in order to obtain copies to the appropriate contracts. Many of these contracts may be available through the Regional Labs.

Changes to Agreements
The representative(s) from RegionalTransfusi on Medicine Committee/Quality Unit working with the National Purchasing Organization shall review critical changes to contract dealing with blood suppliers or other suppliers considered critical to the safety,potency , or purityof the blood products.

- All transfusion services are provided an opportunity to comment or make suggestions. These suggestions and comments are channeled through the RegionalTransfusi on Medicine Committee/Quality Unit and/or the National Purchasing Organization.

Records
All records of agreements are retained as required per current standards and regulations.

Service Agreement for the Provision of Services and Blood
The regional Agreement for Transfusion Support document is available.
All transfusion services will maintain an enough quantity ofbl ood components to adequatelym eet the needs of their facility.

Incoming receipt, inspection, and testing

The Transfusion Services of Kaiser Permanente in Southern California have processes and procedures for incoming blood, blood components, and critical materials for receipt, inspection, and testing, as necessary, before acceptance or use.

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Process Control

The Transfusion Services of Kaiser Permanente in Southern California has policies, processes, and procedures that ensure the quality of the blood, blood components, and testing services provided. These policies, processes, and procedures are carried out under controlled conditions.

Change Control

The Transfusion Services of Kaiser Permanente in Southern California have processes to develop and implement new processes or procedures or to change existing ones. This process includes identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated.

Proficiency Testing

The Transfusion Services participates in applicable proficiency testing for following regional policies, processes, and procedures established by the Laboratory Care Delivery System.

Transfusion Service Activities

There are policies, processes, and procedures for the following transfusion service activities:

Use of materials:

- All equipment and materials are stored and used in accordance with manufacturer's written instructions
- All blood and blood components are stored at the appropriate temperature for that component and follow AABB Standards and FDA regulations.
- All critical steps in testing, processing, storing and transporting blood and blood components are recorded.

Identification and Traceability:

- All blood components transfused to a patient are traceable back to the unit number, and a process exists to identify the facility supplying the component. Those shipping facilities are expected to be able to identify the donor as required by state, federal and local agencies.

Labeling of Blood and Blood components:

- There are labelling processes regarding labelling of blood and blood components to be in conformance with current standards and regulations.
- Processes are in place to define the labeling process, when blood or blood components are modified in the transfusion service.

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Inspection of critical supplies, blood, and blood components:

- There are processes to ensure that materials are inspected to verify that specified requirements are met.

Handling, storage, and transportation:

- There are processes to ensure that critical supplies, blood, and blood components are handled, stored, and transported in a manner that prevents damage, and conforms to current standards and regulations.

Preparation and Processing of Components:

- There are processes to ensure the quality and safety of blood and blood components are practiced.
- Irradiation-all blood and blood components irradiated by the transfusion service use methods known to ensure that irradiation has occurred
- Sterility-Aseptic methods are employed in component medication processes to minimize contamination.
- Pooling of components- Blood components are not generally pooled, but when they are, each component in the pool is identified, and traceable back to that pool.

Samples for testing and requests:

- There are policies, processes, and procedures regarding patient specimen requirements and receipt of test and/or product orders. Samples and segments from blood or blood components containing red blood cells are retained after transfusion.

Serologic confirmation of donor blood:

- There are policies, processes, and procedures regarding the serologic confirmation of blood or blood components containing red blood cells received from suppliers.

Pretransfusion Testing:

- ABO group, Rh type and detection of clinically significant antibodies are performed prior to issuance of blood or blood components containing red blood cells.
- There are policies, processes, and procedures regarding patient sample identification and collection, and receipt of samples in the transfusion service.
- There are policies, processes, and procedures ensuring two determinations of the patient's ABO/Rh group is performed prior to dispense of red blood cells (including whole blood and granulocytes)
- There are policies, processes, and procedures to address these testing processes including comparison with previous records.
- There are policies, processes, and procedures for the pretransfusion (compatibility) testing of patient with clinically significant alloantibodies, which includes an antiglobulin crossmatch.

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Selection of Blood and Blood Components for Transfusion:

- There are policies, processes, and procedures for transfusion services to select the appropriate units of components of blood according to the blood orders.
- There are policies, processes, and procedures that provide guidance when the selection of blood or blood components is not identical to the blood type of the patient. These policies also define when medical director or physician approval must be obtained.
- There are policies, processes, and procedures for selection of blood and blood components in special circumstances, such as Leukocyte-reduced, irradiation, cytomegalovirus, massive transfusion, specially selected platelets and/or for patients at increased risk for transfusion associated circulatory overload.
- Policies exist to describe the selection of blood components for neonatal exchange transfusion and for neonatal transfusions.

Compatibility Testing:

- There are policies, processes, and procedures Serologic and Electronic Compatibility Testing
- There are policies, processes, and procedures for infants. This includes testing the mother of the infant, or the pregnant mother
- There are policies, processes, and procedures for transfusion reactions

Issuance and Re-issuance of Blood and Blood Components:

- There are policies, processes, and procedures describe issuing of blood components. This includes the issuing of blood components with special attributes.
- There are policies, processes, and procedures to describe how to issue blood components under emergency conditions. This includes the appropriate documentation, and all follow up after the emergency or testing is completed.
- There are policies, processes, and procedures on when to allow blood components to be returned to the transfusion service, and when these units are acceptable to be reissued.

Administration of Blood and Blood Components:

- There is a regional protocol for the administration of blood and blood components, which include the identification, evaluation, and reporting of adverse events related to transfusion.
- The transfusion order, consent, and other details of the transfusion are documented in the medical record of the recipient.

Rh Immune Globulin:

- There are policies, processes, and procedures regarding prophylaxis administration of Rh Immune Globulin to Rh-negative patients who may have been exposed to Rh-positive red cells.
- There are policies, processes, and procedures to describe the testing of the mother and infant to determine the need for and the quantity required of Rh immune globulin.

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Informed consent and approvals:

- Processes exist for the hospital to obtain informed consent and approvals for transfusion. These processes are documented and available to the transfusion service, and there is a mechanism for transfusion service physician input.
- The brochure "A Patient's Guide to Blood Transfusion" (Paul Gann Act) is available from the California Department of Public Health. https://www.mbc.ca.gov/Publications/Brochures/Blood_Transfusions.aspx
- A policy and process exist for Patient Refusal to Receive Blood or Blood Products. https://kppl.policytech.com/dotNet/documents/?docid=24701

Documents and Records

There are established processes policies, and procedures to control documents in the transfusion services. This ensures documents are identified, reviewed, approved, and retained and that records created, stored, and archived in accordance with current record retention policies.

- Master list(s) of documents are available.
- Standardized formats for all policies, processes, procedures, and forms are in use.
- There is a process that requires all processes, procedures to have established review, for accuracy of content and conformity to regulations and standards.
- The process for biennial review of policies, processes, and procedures aids in the identification of a need to revise or update existing policies, processes and/or procedures.
- The appropriate current and valid documents are available to staff needing these documents. They are in areas where the operations are occurring.
- All invalid or obsolete documents are archived and not available for staff use. Records are archived for the applicable period stated in current regulations and standards.

Retention

- Records are retained as required by current regulatory standards and applicable federal, state, and local regulations.
- Records are retained in a safe location, to prevent accidental destruction.
- A record is kept of retained records stored off site.
- Lab manager review is required of the records or record lists before the records are destroyed. Documentation is kept of the destruction, and the reason for this destruction.

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Records

- Records are created concurrently with performance of each critical activity.
- Changes to records are controlled.
- Records are not usually copied.
- If a record must be copied, the copy legible and indelible, is stamped as a copy, and is issued only to authorized personnel.
- The control of the record resides with the department creating the record. This department ensures that only authorized personnel have access to the records, that they are stored properly, and archived (if applicable) in a timely manner.

Deviations, Non-Conformances Adverse Events

The Quality Sub-Committee and Transfusion Medicine Committee and Quality Unit reviews and oversees the reporting and evaluation of non-conforming products and services as well as activities or performances that could result in non-conformances of products or services. Once identified, each occurrence of a non-conformance or potential non-conformance is individually reviewed, analyzed and monitored as needed.

Occurrences are viewed as "Quality Improvement Opportunities" (QIO), and the process of monitoring these QIO is the Quality Improvement Monitoring (QIM) process. Through the cooperative actions of staff, lab managers and management, the QIM process allows for the identification, tracking and trending of QIO to result in the reduction of non-conforming products or services entering or being used in the transfusion services. Once identified, non-conforming products may be quarantined, destroyed, sent back to the supplier or re-processed. Once identified, testing activities may be evaluated for impact on patient/product results and patient/donor safety. These activities are documented and are traceable to the finished product or test result.

Quality Improvement Monitoring Process

Identification:

QIM form is an important tool to improve process improvement in our department

- Staff uses the QIM Report to report non-conforming products or services.
- Staff uses the QIM Report to document any personnel actions that could result in a non-conforming product or service.
- Internal products and services as well as external products and services are reported on the QIM Report.
- Upon discovery nonconforming blood, blood components, critical materials, or shall be evaluated and their disposition determined.
- The lab manager reviews the QIM Report and follows up as needed.
- Monthly summary reports are created by the RBBCO and reviewed by the lab manager or designee, the Laboratory Operations director or designee, and the Transfusion Services Medical Director or designee.

Quality Program: SCPMG Transfusion Services, Continued

- The QIO are trended and tracked and evaluated. Data is reported quarterly to the Quality subcommittee and the Transfusion Service Workgroup.
- There is a process that identifies how to return or dispose of non-conforming reagents, solutions or other critical products used in the laboratory.
- There is a process that includes re-testing or re-processing of the non-conforming product when appropriate. This process also includes re-inspection of the re-tested, re-processed product.
- There is a process to evaluate non-conforming testing results. This process also includes correction of results, invalidating of results, and assessment of patient/donor safety.

Release of Nonconforming Blood and Blood Components

The transfusion service has a process to allow the release of blood or blood components which are determined after release not to conform to specified requirements.

- Evaluation determines the effect of the nonconformance on the quality of the product and recipient safety.
- Records include the disposition of the product or service, the rationale, and the name(s) of the individuals responsible for the decision.

Fatality Reporting

FDA/CBER is notified of fatalities due to transfusion associated events according to processes and procedures.

Adverse Events

- There are processes and procedures for the transfusing staff to recognize and respond to adverse events related to transfusion, these are classified by nationally recognized classifications.
- The transfusion services have policies, processes, and procedures for the evaluation and reporting of suspected transfusion reactions (including delayed transfusion reactions)
- The transfusion service has policies, processes, and procedures to evaluate and report diseases transmissible by blood and blood components.
- The transfusion service has policies, processes, and procedures upon notification from the blood supplier to identify recipients and notify (if appropriate) the recipient as specified in current FDA regulations and recommendations.
- The transfusion service has a process for investigation adverse effects, disease transmission, or other suspected adverse events related to transfusion of blood and blood components.

Quality Program: SCPMG Transfusion Services, Continued

Assessments

The Transfusion Services of Kaiser Permanente in Southern California has processes, policies, and procedures to ensure that internal and external assessments of operations and quality systems are scheduled and conducted.

Management of Assessment Results

- Results of internal and external assessments shall be reviewed by personnel having responsibility for the areas being assessed.
- When corrective action is taken, it is developed, implemented, and evaluated.
- The results of internal and external assessments and associated corrective and preventative actions shall be reviewed by executive management.

Utilization Review

The Transfusion Service has a peer-reviewed program that monitors and addresses transfusion practices for allcategori es of blood and blood components.

Quality Monitoring

The Transfusion Service has processes to collect and evaluate quality indicator data on a scheduled basis, including adverse events.

Process Improvement

The Transfusion Services of Kaiser Permanente in Southern California have policies, processes, and procedures for performing corrective and preventive action. The corrective action and preventative action plans have the following elements (as applicable)

Corrective Action

- Description of event
- Investigation of event
- Determination of the causes(s)
- Implementation of corrective actions(s)
- Evaluation to ensure that corrective action is taken and that it is effective.

Preventive Action

- Review of information, including assessment results, proficiencytesting results, qualitycontrol records, and complaints, to detect and analyze potential causes of nonconformances
- Determination of steps needed to respond to potential problems requiring preventative action.
- Initiation ofprevent ive action and application of controls to monitor effectiveness.

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Facilities and Safety

The Transfusion Services of Kaiser Permanente in Southern California have processes and procedures for training staff and making staff aware of all safety procedures and protocols and environmental safety protocols.

Safety

- Each Medical Center has policies and processes in place to annually review the safety regulations withstaff.
- Biological, chemical and radiologicalsafety i s included in the training when applicable to the staff's responsibilities.
- Blood and blood components are discarded in a manner that minimizes the potentialf or human exposure to infectious agents.
- The Medical Centers assume the responsibility of offering staff the regulated Personal Protective Equipment (PPE).
- The Medical Centers have policies and processes to train staff on bloodborne pathogens, and what to do if the staff member is exposed to potentially hazardous materials.
- All staff training, and refresher courses are documented and maintained on site.

Non-Controlled Documents

The following non-controlled documents support this policy.

- AABB Standards, current ed.
- CAP Requirements, checklist, current ed
- Quality SystemRegulati on, 21CFR 840

Authors

All SCPMG Transfusion Services Managers
RegionalBl ood Bank Compliance Officer

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Reviewed and approved by:

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Gary Gochman, MD, Medical Director – Bellflower, Harbor City,Bal dwin Park MSA	Date
Signature Electronically Collected	March 7, 2000
Michael Kanter, MD. Medical Director – Woodland Hills, Panorama CityMSA	Date
Signature Electronically Collected	January 20, 2000
Joseph Thompson, MD. Medical Director –Los Angeles, West Los Angeles MSA	Date
Signature Electronically Collected	March 6, 2000
Hrag Marganian, MD. Medical Director – Anaheim, MSA	Date
Signature Electronically Collected	January 21, 2000
Dong Quach, MD. Medical Director –Riverside, Fontana MSA	Date
Signature Electronically Collected	November 6, 2001
Ramesch Doshi, MD. Medical Director- Tri-CentralSA	Date

Quality Program: SCPMG Transfusion Service

DOCUMENT HISTORY PAGE
Effective Date: March 8, 2000

Change type: new, major, minor etc.	1) Changes Made to Document – Describe	Signature responsible person/Date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ Date	Date change Imp.
Major	Added sections: 10, 11, 12, 15, 16, 17, 20, 21	Ginny Tyler 03-05-2001	All collected by 03-05-01		
Minor	1) Changed #3 to remove National Purchasing Organization to "contracted purchasing group" and "purchasing group". 2) #18 Training. Changed 18.2 #1 from "reviewed annually" to "reviewed periodically". Difficult to coordinate with the union and HR to always make itwi thin a year.	Ginny Tyler 05-10-01	NA.		
Major	Added sections 4, 5, 6, 7, 8, 9, 14, and 19. Added Dr. Doshi to signature list.	Ginny Tyler 11-28-01	All collected by 11-28-01		
Minor	1) Fix a few typos.	Ginny Tyler Sept. 15, Version 4	N.A.	N.A.	
Minor	2) Fixed some typos 3) Made sure headers were the same throughout the document. 4) Added information for section #4.	Ginny Tyler July 31, 2006	N.A.		
Minor	1. Added Workplace Safety 2. Changed KQE on History page – error 3. Reformatted first section to be Policy and Process	Ginny Tyler 02/11/08	N.A.	N.A.	

Continued on next page

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Minor V.07	Fixed some names, TJC instead of JCAHO, etc. Fixed typos	Ginny Tyler 11/25/09	N.A.	N.A.	
Minor V.08	1. Fixed several typos 2. Changed documentation to be held for 10 years. 3. Removed the number of MC, as this can change.	Ginny Tyler 11/03/10	N.A.	N.A.	

5)
IMP = Implemented

MasterControl History of Change:		
Change type: new, major, minor etc.	**Version #**	**Description of Change**
Major	10	Changed reviews for Policies, Procedures etc., to biennial. Removed KQE and replaced withQualit y System
Major	11	Removed references to SCPMG Blood Donor Centers. Reformatted document from ISO 9000 QSE to AABB QSE. Condensed or removed descriptions of processes, policies or procedures to better give overview of quality program. Added non controlled documents, authors, and distribution.
Minor	12	Removed references to SCPMG Blood Donor Centers, clarified informed consent and right of refusal for blood products. Updated section on Non-conformances to current processes (frequency and submissions of QIM report summaries).
Minor	13	Updated to follow AABB Quality SystemEssent ials, update links in Section 5.