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Quality Program: SCPMG Transfusion Service

Policy

The Quality Program for the Transfusion Medicine Committee and Quality Unit of the Southern California Kaiser Permanente Medical Group (SCPMG) is based on the AABB Quality System Essentials, the ISO 9002 Standard, and the FDA Quality System Regulation. This Quality Program is 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.

Process

The Transfusion Service Quality Program is a collection of quality systems. Each quality system is 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 by upper management. These policies reflect the commitment of the Transfusion Medicine Committee and Quality Unit and the SCPMG Laboratory Operations 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 System may be subdivided into sections, which identify the various processes within the systems. The processes explain how a particular 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 and procedures. The procedures define how to perform, process or do an operation or function. They are written usually for one employee or one set of tasks.
- 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 maintained in a defined manner and reflect the quality of the process and procedures

Quality Program: SCPMG Transfusion Services, Continued

The 10 Quality Systems are:

1. **ORGANIZATION**
   - 1.1 Executive Management
   - 1.2 Quality System
   - 1.3 Policies, Processes, and Procedures
   - 1.4 Emergency Preparedness
   - 1.5 Communication of Concerns
   - 1.6 Customer Focus

2. **RESOURCES**
   - 2.1 Personnel
   - 2.2 Qualifications
   - 2.3 Orientation
   - 2.4 Training and Competency
   - 2.5 Resources

3. **EQUIPMENT**
   - 3.1 Selection and Qualification of Equipment
   - 3.2 Preventive Maintenance, Quality Control and Calibration of Equipment
   - 3.3 Equipment Repair
   - 3.4 Blood Warmers and Perioperative Equipment
   - 3.7 Computer Systems

4. **SUPPLIER AND CUSTOMER ISSUES**
   - 4.1 Evaluation of Suppliers
   - 4.2 Purchasing Information
   - 4.3 Review
   - 4.4 Changes to Agreements
   - 4.5 Service Agreements for the Provision of Blood and Services
   - 4.6 Incoming Receipt, Inspection and Testing

5. **PROCESS CONTROL**
   - 5.1 Change Control of Computer Systems
   - 5.2 Change Control of Testing and Products
   - 5.5 Proficiency Testing
   - 5.4 Transfusion Service Activities

Quality Program: SCPMG Transfusion Services, Continued

6. DOCUMENTS AND RECORDS
- 6.1 Document Approval and Distribution
- 6.2 Document Changes
- 6.3 Original Records
- 6.4 Copies

7. DEVIATIONS, NON-COMFORMANCES, AND ADVERSE EVENTS
- 7.1 Non-Conformances
- 7.2 Fatality Reporting
- 7.3 Adverse Events

8. ASSESSMENTS: INTERNAL AND EXTERNAL
- 8.1 General
- 8.2 External Assessments
- 8.3 Internal Assessments

9. PROCESS IMPROVEMENT
- 9.1 Statistics
- 9.2 Corrective and Preventative Action Plans
- 9.3 Quality Monitors

10. FACILITIES AND SAFETY
- 10.1 Safety

Quality Program: SCPMG Transfusion Services, Continued

1. ORGANIZATION

Background Information

Kaiser Permanente Southern California (KPSC) is a medical care program comprised of three closely aligned 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 "SCPMG Laboratory Systems". SCPMG Laboratory Systems provides comprehensive laboratory services including hospital based, clinic based and centralized regional laboratories as well as non-Kaiser outside laboratory services. The overwhelming majority of laboratory services are offered by the SCPMG Laboratory Systems, however, the SCPMG Laboratory Systems does contract with outside laboratories for selected specialty laboratory services. SCPMG Laboratory Systems does not collect tissues, cellular therapy products, blood or blood products.

1.1 Executive Management

Definition

- Laboratory Operations Committee consists of the Chiefs of Pathology and Laboratory Operations 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 of transfusion recipients

Role of Executive Management

The executive management of the transfusion services with responsibility for quality is the Laboratory Operations 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 policy.
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.

Quality Program: SCPMG Transfusion Services, Continued

Role of Transfusion Medicine Committee/ Quality Unit

The Transfusion Medicine Committee/Quality Unit is the policy making committee.
The Transfusion Medicine Committee/Quality Unit (TMC/QU)

- oversees transfusion practices at the regional medical centers
- works with the Transfusion Services Committee (TSC) in implementation of policies and processes.

These committees report to the Quality Sub Committee of the Laboratory Operations Committee.
Supporting Document: Charters for the TMC/QU and TSC

Charters for TMC/QU and TSC

These charters define the roles of the committee members and their relations to the Quality Subcommittee of the Laboratory Operations Committee.

- The responsibilities defined in the charters ensures
  - The processing and transfusion of blood and blood components and the provision of services conform to specified requirements.
  - That any problems relating to the quality system, the processing and transfusion of blood and blood components or the provision of services are identified and documented.
  - That corrective action is implemented by established processes.
  - That corrective action will be monitored and its success or failure verified.
  - That a process exists to control further processing or transfusion of blood and blood components or the provision of services until the problem has been corrected.

Mission Statement

To provide the safest and highest quality blood and blood components and services to the Kaiser Permanente members in Southern California in a timely and cost effective manner.

Vision Statement

To be the benchmark of quality and services for Transfusion Services

Quality Program: SCPMG Transfusion Services, Continued

Table of Organization

These documents describe the relationship of the:

- Chief of Pathology within the medical center to the Medical Director and or Hospital Administrator
- The relationship of the Medical Director of Transfusion Services to Laboratory Operations Director, and Transfusion Service Manager

The relationship of the transfusion service to the hospital Quality Departments.

1.2 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 system is 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 System is a part of the Quality Program as outlined by the 10 Quality Systems listed in the program. This part of the Quality Program provides 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 authority for ensuring that the transfusion services establish, implements, and maintains a quality system that meets national, state and regional regulatory requirements.

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 quality and 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, quality, identity, potency or purity of the blood components or the safety of the patient or staff. This action is immediately reported to the

Quality Program: SCPMG Transfusion Services, Continued

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

Management Review of the quality policies will take place biennially

The Quality Policies and the Quality Program will be reviewed at least biennially by the members of the respective chartered committees. These reviews and suggestions for changes may be brought to the attention of the Laboratory Quality Sub Committee as appropriate.
Review includes:

- Mission and vision are being met.
- Policies reflect the organizational goals
- Quality is ensured for blood and blood components, personnel, and services.

Reviews are kept in the electronic management system.

1.3 Quality System Policies, Processes, and Procedures

Conformance to regulations

- The Transfusion Medicine Committee and Quality Unit reviews and directs the implementation of policies dealing with regulatory matters. 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 Laboratory Improvement 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
- 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.

Quality System Documentation

- There is a standardized regional process for creating, changing, reviewing and validating documents and records.
- The standardized process is outlined by the SCPMG Quality group in the Regional Labs, and is defined as the Electronic Document Management System (Master Control).

Quality Program: SCPMG Transfusion Services, Continued

- Processes are developed that support our Quality System, internal policies, and all applicable regulations and standards.
- These processes are further supported by detailed procedures.
- Data or documentation of processes is documented on forms, and these records are kept according to a defined process as outlined in the Documents and Records section.

1.4 Emergency preparedness

- Site specific plans are available for internal and external disasters.

1.5 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.

1.6 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.

2. RESOURCES

Kaiser Permanente maintains a process for qualifications for job functions based on education and experience. This process is in compliance with state and federal regulations. Each medical center has established orientations procedures for all staff dealing with transfusion service activities.

2.1 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.
- 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 union contracts.

Quality Program: SCPMG Transfusion Services, Continued

- All Clinical Laboratory Scientists 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 laboratory tests by processes outlined below.

2.2 Qualifications

- Qualified personnel are selected on the basis of education, training, experience and job qualifications defined in the appropriate job description.
- Job qualifications are established for the critical jobs for the transfusion service. These qualifications adhere to federal and state requirements
- Job postings are established by the Laboratory Operations Directors and/or the Transfusion Service Managers with the oversight of the Human Relations Departments.

2.3 Orientation

- Processes and procedures exist for orientation of new employees to Kaiser Permanente transfusion services or for transfer employees new to the transfusion services.
- All orientation processes are in agreement with union contracts.
- All orientation processes include a review period, and a determination of competency before the employee is allowed to work without supervision.
- All records of orientation are retained as required per current standards and regulations.

2.4 Training and Competency

- Processes and procedures exist for the documentation of initial training and competency of new and existing employees on an annual basis.
- Competency is 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 processes. All competency processes are in agreement with existing union contracts.
- Competency assessment is performed by documentation of the six elements as defined by CLIA for testing performed. Other critical processes that are not testing may also have annual competency performed (e.g. emergency dispense),
- A process exists to re-orient individuals if competency is not demonstrated on the initial process.
- All records of training and competency are retained as required per current standards and regulations.

Quality Program: SCPMG Transfusion Services, Continued

2.5 Resources

- Medical assistance is available from the local medical staff, or by using the calling tree that includes the names of the medical directors of transfusion services in the region.
- Quality and compliance assistance is available from the Regional Blood Bank Compliance Officer or from other qualified lab directors or managers throughout the region.
- Administrative assistance is available through the local Laboratory Manager, medical directors or other Laboratory Managers through the region.

Resources must be provided the transfusion services to perform their responsibilities according to this Quality Program. To include:

- Access to management
- Trained personnel
- Verification of performance, including internal quality audits.

3.0 EQUIPMENT

General

The Transfusion Services of Kaiser Permanente in Southern California have processes and procedures to select, control, calibrate and maintain equipment and devices that is used to store, inspect, measure or test product (incoming, in-process or final) conforms to the requirements defined by good manufacturing practices. There are also processes and procedures regarding equipment used in patient testing. These and regulatory processes and procedures conform to local, state, and federal requirements and all other regulatory agencies dealing with our facilities.

All critical equipment is maintained on a scheduled basis and records are kept of all quality control, preventive maintenance, calibrations and preventive actions taken when applicable. All new critical equipment is validated to ensure that it will meet the requirements for that product or process for which it is intended. Installation processes for new critical equipment is planned prior to implementation, and the physical installation is safe and meets manufacturer requirements.

Equipment and/or testing devices are safeguarded against improper adjustments by allowing only trained and qualified personnel to use them.

Test software or comparative references such as test hardware are validated prior to use as a form of inspection, and are revalidated as appropriate. Policies and processes exist that define the extent and frequency of these validations and records are maintained as evidence of control of conformance to these established policies.

Quality Program: SCPMG Transfusion Services, Continued

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

3.1 Selection and Qualification

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

3.2 Equipment Preventive Maintenance, Quality Control and Calibration

Identification
- Each piece of critical equipment has unique identification; this list is maintained by SCPMG Laboratory Technology Services (LTS).
- Each site has access to the critical equipment inventory and related documents.

Preventive Maintenance
- Preventive maintenance (PM) requirements are identified according to manufacturer's specifications and/or recommendations.
- PM procedures are developed and scheduled by LTS
- Transfusion Services manager or designee review scheduled performance and results

Quality Program: SCPMG Transfusion Services, Continued

of PM procedures. Appropriate action is taken for questionable or unacceptable results.

Quality Control

- Quality control (QC) requirements are identified according to manufacturer's recommendations and/or regulatory/accrediting agency requirements.
- QC procedures are developed and scheduled and personnel qualified to perform QC is identified.
- Transfusion Services manager or designee review scheduled performance and results of QC procedures. Appropriate action is taken for questionable or unacceptable results.

Calibration

- Calibration requirements are identified according to manufacturer's recommendations and/or regulatory/accrediting agency requirements.
- Calibration procedures are developed and scheduled and the staff to perform calibration is identified.
- Transfusion Services manager or designee review scheduled performance and results of calibration procedures. Appropriate action is taken for questionable or unacceptable results

Records

- Records of PM, QC and calibration are maintained on site.

3.3 Equipment Repair

Repairs

Equipment that fails, malfunctions or is in need of repair is taken out of service, prominently identified as out of service and arrangements are made for service. Repairs or service are made by vendors or LFS departments and reported to the Transfusion Services manager or designee.

Assessment

The transfusion service manager or designee assesses the extent of repair/service for:

- Indications that the instrument requires QC testing or re-validation prior to placing back into service.
- Indications that products or services previously performed may have been affected.
- Potential impact on products or patient testing

The transfusion service manager or designee ensures that appropriate action is taken when further testing or product/service follow up is indicated.

Records

Records of PM, QC, repairs, and calibration are maintained on site.

Quality Program: SCPMG Transfusion Services, Continued

3.4 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 perioperative collection.
- The Transfusion Service Medical Director may provide guidance for Quality Control of equipment 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

3.5 Computer Systems

- FDA cleared computer systems are used in the transfusion services for input, collection and processing data that as it applies to all critical aspects of process control. This applies to computer systems used within the transfusion service, and not laboratory systems that transfer reports.
- All new versions and patches to existing versions are validated and that validation is documented.
- The computer system is monitored routinely. Any problems with the 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.

4.0 SUPPLIER AND CUSTOMER ISSUES

General
The Transfusion Services of Kaiser Permanente in Southern California have 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 of critical supplies, inspection of those supplies, and tests performed, when applicable.

4.1 Evaluation of Suppliers

- 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 any problems from critical suppliers. This QIM process is linked to reporting to the laboratory management and then to the Kaiser purchasing group, when a supplier does not meet expectations.
- The transfusion services have a list of expectations for critical suppliers. This is the basis for the QIM reports.

Quality Program: SCPMG Transfusion Services, Continued

- 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 purity of 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).

4.2 Purchasing Information

- 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.
- Laboratory operations 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 Regional Transfusion Medicine Committee/Quality Unit.

4.3 Review

- The contract for blood and blood components, and other select supplies critical to the transfusion service are reviewed by the Regional Transfusion Medicine Committee/Quality Unit working with the Kaiser Permanente Contracts group. This review is performed prior to acceptance of the contract, when applicable.
    - Note: In some cases 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.
- The contract is not signed until all differences between the agreement requirements and the products or services offered under the agreement are resolved.
- If the blood and blood component supplier cannot meet the requirements, and there is no other vendor capable of meeting the requirement, the Transfusion Medicine Committee working with the local medical center administrations and the Kaiser Permanente Contracts group reconsider the requirements. This could result in a request that the vendor works toward meeting the requirement, or toward Kaiser Permanente reconsidering the requirement, but should not unduly delay the award of the contract.
- Supplier issues are tracked in the QIM (Quality Improvement Monitoring) process and supplier(s) or other vendor(s) are notified of any issues noted.

Quality Program: SCPMG Transfusion Services, Continued

4.4 Changes to Agreements

- The Regional Transfusion 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 purity of the blood products.
- Once changes have been negotiated with the supplier, Regional Transfusion Medicine Committee/Quality Unit and the National Purchasing Organization, a copy is made available to the transfusion services for their records.

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

Records

- The original agreements are kept at the National Purchasing Organization in Oakland CA, the local purchasing organization, or at a designated Kaiser location.
- All records of agreements are retained as required per current standards and regulations.

4.4 Service Agreement for the Provision of Services and Blood

- The regional Agreement for Transfusion Support document is available in Master Control

4.5 Incoming receipt, inspection, and testing

The Transfusion Services of Kaiser Permanente in Southern California have processes and procedures that allow each facility to determine, either visually or via computer, the test status and completion of inspection of every unit of blood or blood component as well as critical supplies and reagents. The status of testing or inspection is controlled either by tagging the unit or product, placing units in designated areas (quarantined, "crossmatched" shelves, etc.), or any combination of these or other methods.

4.6 Inspection and testing on receipt of product (Incoming products)

- All blood and blood components are inspected upon receipt, and documentation of this inspection is available for review.
- All red cell components received by a transfusion service are tested for ABO, and all Rh-negative red cell units are tested for D.

    - Note: The test for D does not need to include the test for weak D.

Quality Program: SCPMG Transfusion Services, Continued

- All critical reagents, defined as reagents that are used to test the product which could impact the quality, potency or purity of the product, are inspected upon (or shortly after) receipt.
    - Processes exist that describes the receipt process and testing process of the critical reagents.

In-process inspection and testing of product

Processes exist to inspect and test blood products prepared in house.

- Established Quality Control values for blood products are regulated, and all results are measured against those values.
- The quality control process is monitored, and unacceptable trends or changes in quality are investigated.
- Products not meeting the expected quality measures are discarded, or not released until the discrepancy or quality issue is resolved.
- Processes exist to ensure that in-process blood products are not released until appropriate inspection and testing (if required) is performed and acceptable.

Final inspection activities of products

- All blood and blood components are released for distribution only after all required testing is completed and acceptable, and documentation to that effect exists.
- Prior to release of blood or blood components, there is a documented inspection of the components.
- Any blood or blood component not meeting regulations for release is quarantined.
    - Exceptional situations may exist that will justify the release of non-compliant blood or blood components. These situations require complete documentation of the process and traceability of the components.

Inspection and testing of services provided to others

Audits allow for tracking of the quality of the service the Transfusion Service providesto clinical services.

- Any deviations from operating procedures are documented in the Quality Improvement Monitoring (QIM) process, and follow-up is reported back to the reporting service.

Inspection and test records

- All records of inspection and testing of critical products are retained as required per current standards and regulations.
- Records or inspection ad testing of critical products or supplies are kept in a safe place, and are retrievable in a timely manner.
    - Records within the last 12 months are retrievable within one working day.
    - Records older than 2 years, or records stored off-site, are retrievable within 3-5 working days.

Quality Program: SCPMG Transfusion Services, Continued

5.0 PROCESS CONTROL

General
The Kaiser Permanente Transfusion Services have identified and planned those processes as they relate to each specific facility for the testing, processing, and transfusion of blood and blood components and the provisions of services which directly affect quality. All required documents are collected and the records stored for the proscribed length of time according to current regulations.

5.1 Change Control of Computer Systems

Product designs and software designs are strictly regulated in the transfusion services. The Kaiser Permanente facilities in Southern California do not develop any unique products or software that would require design control, or submission to the FDA as a medical device. Change control processes exist for new systems or upgrades to current systems.

5.2 Change Control of Testing and Products

The Transfusion Services of Kaiser Permanente in Southern California have processes to ensure that specified requirements for all new or changed testing processes, product processing and/or changes to critical products or equipment. Validation plans are developed to ensure that the safety, quality, identity, potency and purity of the product is as expected. Validation processes also exist for changes in testing processes or equipment. All changes are validated and controls are developed and in place to ensure that quality is maintained according the manufacturer's specifications and or regulated values.

5.3 Proficiency Testing

The Transfusion Services participates in applicable proficiency testing for following regional processes and procedures established by the SCPMG Laboratory Systems.

5.4 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 are in compliance with AABB Standards and FDA regulations.

Quality Program: SCPMG Transfusion Services, Continued

  - 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.
- 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 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 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.

Quality Program: SCPMG Transfusion Services, Continued

  - There are policies and procedures regarding patient sample identification and collection, and receipt of samples in the transfusion service.
  - There are policies and procedures to address these testing processes including comparison with previous records.
  - A process exists for the pretransfusion (compatibility) testing of patient with clinically significant alloantibodies, which includes an antiglobulin crossmatch.
- Selection of Blood and Blood Components for Transfusion
  - Processes exist for transfusion services to select the appropriate units of components of blood according to the blood orders.
  - There are policies and processes 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.
  - A policy exists in the transfusion services to document which patients require irradiated blood components and to provide those products from that point on, unless specifically notified otherwise.
  - Policies exist to describe the selection of blood components for neonatal exchange transfusion and for neonatal transfusions.
- Compatibility Testing-Policies and procedures exist for:
  - Serologic and Electronic Compatibility Testing
    - Compatibility testing for infants. This includes testing the mother of the infant, or the pregnant mother
  - Transfusion Reactions
- Issuance and Re-issuance of Blood and Blood Components
  - Processes exist to describe issuing of blood components. This includes the issuing of blood components with special attributes.
  - There are processes 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 processes 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 are local protocols 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 regarding prophylaxis administration of Rh Immune Globulin to Rh-negative patients who may have been exposed to Rh-positive red cells.

Quality Program: SCPMG Transfusion Services, Continued

  - Policies exist to describe the testing of the mother and infant to determine the need for and the quantity required of Rh immune globulin.

- 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. http://www.mbc.ca.gov/Publications/Brochures/blood_transfusion_english-web.pdf
  - A policy and process exists for Patient Refusal to Receive Blood or Blood Products. http://npl.kp.org/pl/do/public/record?rgid=1040&subcatid=5721&VIEW=M&rid=124512601
- All transfusion services will maintain a sufficient quantity of blood components to adequately meet the needs of their facility.

6.0 DOCUMENTS AND RECORDS

General
There are established processes and procedures to control all documents and information that relates to quality functions in the transfusion services. These processes include control of new and revised documents (policies, processes, procedures and forms), as well as documented distributions of documents.

6.1 Document Approval and Distribution

- 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 documents are available to staff needing these documents. They are located in areas where the operations are occurring.
- A document master list (Master Control Organizer) exists to make it easier to locate and follow policies, processes, and procedures, and is accessible to the transfusion services staff.
- Data originating on forms relate back to specific processes or procedures. These records are maintained for the length of time required, and are traceable back to the original form.

Quality Program: SCPMG Transfusion Services, Continued

- All invalid or obsolete documents are not available for staff use in the Master Control Organizer, and are listed as Archived in the Documents History. All information such as the date archived is documented in Master Control. Records are archived for the applicable period stated in current regulations and standards.
- A regional list of individuals approved for review and approval of documents is available as well as a list of local site individuals approved for review and approval of transfusion service documents.

6.2 Document Changes

Procedures

- There is a process for regional and local review of changes to existing documents. The process includes:
  - Review for technical merit
  - Review for compliance to regulations
  - A validation if the change is a major change of a critical process
- Individuals responsible for review have access to all supporting documents, regulations or standards during the review process.
- A process exists to revise the changed document as reviewers give input. All revised documents, except for minor or clerical changes, are again reviewed by the approved reviewers.
- A process exists to replace the changed document in the MasterControl Organizer, and to alert personnel when the change has occurred.

Change Control

Change Control Processes

- There is a process to document and track changed processes or procedures.
- The process of changing documents or processes includes a definition of the type of change and the amount of review and signatures required for those changes.
- There is a process to introduce new processes or procedures that include the review process and signatures required.
- There is a process to validate new processes and changes to processes or procedures that are significant to critical aspects of the transfusion service. This validation is documented, and allows for improvement to the process or procedures prior to implementation.

Biennial Review of Procedures

- There is a process for the biennial review of all procedures and forms.
  - This process includes the electronic document management system and defines the authorized individuals or roles to perform this review.
  - The process allows for the tracking of who performs each step of the review process.

Quality Program: SCPMG Transfusion Services, Continued

- The biennial review checks the current processes and procedures to ensure continued compliance with all regulations and standards when applicable.

6.3 Original Records

The Transfusion Services of Kaiser Permanente in Southern California have processes and procedures to control quality records. These processes and procedures ensure that quality records are stored in a manner to protect the records, and that only authorized personnel have access to these records.

- Quality records are identified with a title that describes their intent and content.
- Quality records are identified, and are associated with processes or procedures. These records are traceable back to the process or procedure.
- Responsibility for performing critical processes and procedures, such as performing tests and reviewing quality records, are defined in the facility policies or processes.
- There is a policy and procedure for record corrections.
- Quality records are filed in the area of use, until they are completed. These records are protected from destruction by methods used in each medical center to include but not limited to, storing on clipboards away from the testing areas, or keeping in books or file cabinets when not in use.
- When records are no longer required to be in the general laboratory, they are archived for the proscribed amount of time for that quality record. Record storage requirements are defined for the laboratories.

Confidentiality

- All quality records with patient test results are considered confidential.
- Access to confidential records is protected by security methods when these quality records are in the computer, and by storing paper quality records in secure laboratory rooms or cabinets.
    - An area is considered secure for non-critical test results, if these records are in a laboratory that is staffed 24 hours by trained staff.
    - Critical test results, such as infectious disease test results associated directly to a patient name must be kept in a locked file cabinet or a room with controlled access.

Retention

- Quality records are kept for the amount of time required by federal, state and local regulations.
- Quality records are retained in a safe location, to prevent accidental destruction.
- A record is kept of quality 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.

Quality Program: SCPMG Transfusion Services, Continued

6.4 Copies

- Quality records are not usually copied.
- If a Quality record must be copied, the copy is stamped as a copy, and is issued only to authorized personnel.
- The control of the quality 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.

7.0 DEVIATIONS, NON-CONFORMANCES, AND ADVERSE EVENTS

General

The Southern California 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. All of these activities are documented and are traceable to the finished product.

7.1 Non-Conformances

Quality Improvement Monitoring Process

Identification:

- 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.

Quality Program: SCPMG Transfusion Services, Continued

Evaluation:

- The staff evaluates the immediate requirements of the situation and removes or re-process according to procedures.
- The lab manager reviews the QIM Report and suggests actions as needed.
- Monthly reports are reviewed by the lab manager or designee.
- The QIO are trended and tracked using statistical process control tools. This data is reported quarterly.
- The quarterly regional report is presented to the Laboratory Operations committee or Quality subcommittee.

Segregation:

- Once identified, non-conforming products are removed from inventory and quarantined until they are discarded, re-processed, or returned to the supplier.
- Quarantined areas are clearly marked as such.

Notification:

- Suppliers are notified if products or blood components are found to be non-conforming upon receipt, or upon use.
- Suppliers are also notified if their products or blood components are identified as a cause of an adverse reaction in a patient that directly relates to a malfunction or lack of sterility, potency or purity of a product.
- Transfusion service medical directors are notified within the regulated timeframe when blood or blood components require recipient notification (lookback).
- Physicians and/or patients are notified within the regulated timeframe upon learning of a lookback situation from the blood supplier.
- The manufacturer is notified of critical equipment malfunction.
- The manufacturer is notified of when critical materials do not meet specified requirements.

Non-Conforming Product

- There is a process to dispose of non-conforming blood or blood components, and to document that disposition. This includes but is not limited to:
  - Broken or leaking components
  - Outdated components
  - Upon the request of the blood supplier
- There is a process to return blood or blood components to the blood supplier when indicated, e.g. upon request, and after notification to the blood supplier of non-conforming products.
- 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.

Quality Program: SCPMG Transfusion Services, Continued

Unavailability of Compatibility Test Results
The transfusion service has a process to allow the release of blood or blood components before compatibility testing can be completed. The process requires the following be collected:

- Statement from the ordering physician or designee stating the urgency for the transfusion.
- A patient blood sample to allow for immediate testing.

Non-Conforming Autologous Units
Processes exist to allow non-conforming autologous units to be shipped to the transfusion services which includes:

- Segregating the autologous units from the general inventory.
- Documentation that the transfusion will accept the units.

Non-Conforming Service

- The QIM process allows for the review of non-conforming services.
- The non-conforming service can be repeated, but must be re-inspected or assessed after it has been repeated.
- The non-conforming service may be accepted by the transfusion service if agreed upon by the RCCBO, TS manager or lab operations director. Records of non-conforming service are tracked.
- Contracts are reviewed with staff, management and supply chain management when excessive non-conformances occur.

7.2 Fatality Reporting

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

7.3 Adverse Events

- There are processes and procedures for the transfusing staff to recognize and respond to immediate transfusion reactions.
- The transfusion services have policies processes and procedures for the evaluation and reporting of suspected transfusion reactions.

8.0 ASSESSMENTS: INTERNAL AND EXTERNAL

8.1 General

The Transfusion Services of Kaiser Permanente in Southern California have processes and procedures to define responsibilities of staff during external assessments, as well as their responsibilities during internal assessments or audits.

Quality Program: SCPMG Transfusion Services, Continued

8.2 External Assessments

- Processes and procedures define how to welcome external assessors, inspectors or auditors.
- These processes and procedures define what records or procedures can be given to or copied for these assessments or audits.
- The processes and procedures define the responsible personnel that need to be notified when external inspectors arrive.
- Processes and procedures exist on how to respond to the assessment report.
- Processes are also in place to monitor progress on improvements identified by assessments.

8.3 Internal Assessments

- Internal assessments are scheduled annually for all Transfusion Services.
- The internal assessment processes include a complete assessment of the Transfusion Service, or a focused assessment of specific areas.
- The internal assessor will provide the facility with a written report.
- The assessment is followed up; either in writing or at the next annually scheduled assessment.

Internal Audits

- There are processes for Transfusion Services to conduct internal audits.
- The selection of audits is directed by the Transfusion Service Medical Committee/ Quality Unit or by other involved parties.
- Audit results are reviewed annually by the Transfusion Service Medicine/ Quality Unit Committee.

9.0 PROCESS IMROVEMENT

9.1 Statistical Techniques

The Transfusion Services of Kaiser Permanente in Southern California have processes and procedures that use statistical techniques to evaluate data, and to track and trend results.

Knowledgeable staff is available and can identify and use appropriate statistical techniques as necessary to verify the acceptability of processes, as well as the acceptability of critical products or services.

Quality Program: SCPMG Transfusion Services, Continued

Statistical techniques are available to all lab manager and management staff through training sessions at each medical center. In addition, each lab manager or manager has access to a computer with spreadsheet capabilities. Knowledge of statistical technique can also be acquired by requesting the individual Quality Assurance departments for assistance.

Statistical techniques are used for analysis of the Quality Improvement Processes. Pareto charts and u-charts are used for tracking and trending events. If root cause analysis is required, an array of tools may be used.

Statistical tools are used when an analysis of data is required before making a decision. These tools are also used when problems occur and retrospective or prospective review is needed in order to track or trend data. These data are reviewed by knowledgeable staff, which could include physicians, statisticians, staff in the Quality Assurance departments or staff trained or experienced in these procedures.

A process is also available for root cause analysis, which works with local Quality Assurance departments. An array of statistical tools is available as needed.

9.2 Corrective Action and Preventative Action Plans

The Transfusion Services of Kaiser Permanente in Southern California have processes and procedures for performing corrective and preventive action.

Corrective Action

- The transfusion services use the Quality Improvement Monitoring (QIM) process to identify, and track non-conforming products or activities.
- Within the QIM process, the transfusion services will investigate non-conforming products or activities, and may perform a root cause analysis when indicated.
- Based on information from QIM investigations, audits, or customer complaints, the transfusion services will determine the corrective action needed to eliminate the cause of the non-conformance.
- Based on information from QIM investigations, audits, or customer complaints, the transfusion services will determine the corrective action needed to eliminate the cause of the non-conformance.

Preventive Action

- The transfusion services have identified several areas that are critical to the safety, potency and purity of blood components and the safety of patients and staff.
- The areas identified as critical functions are audited on an ongoing basis. Records are reviewed, and investigations are initiated when non-conformities are detected.

Quality Program: SCPMG Transfusion Services, Continued

- Based on audits, the transfusion service determines corrective actions needed to eliminate potential causes of non-conformities.
- The transfusion services annually train staff on changes in processes, and the importance of good manufacturing practices, as part of the employee competency.

Effectiveness Check

- The transfusion services perform an effectiveness check on corrective action and preventative action plans implemented.

9.3 Quality Monitoring

- The transfusion services have identified several quality monitors. This data is collected and evaluated on a scheduled basis.

10.0 FACILITIES AND SAFETY

General

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.

10.1 Safety

- Each Medical Center has policies and processes in place to annually review the safety regulations with staff.
- Biological, chemical and radiological safety is included in the training when applicable to the staff's responsibilities.
- 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.

Quality Program: SCPMG Transfusion Services, Continued

Uncontrolled Documents

AABB Standards, current ed.
Quality System Regulation, 21CFR 840

Reviewed and approved by:

Virginia Vengelen-Tyler –*Original signed*	March 7, 2000
Virginia Vengelen-Tyler, MBA, MT,ASCP(SBB), CQA(ASQ) Regional Blood Bank Compliance Officer	Date
Signature Electronically Collected	January 21, 2000
Michael Bonin, MD. Medical Director- San Diego -MSA	Date
Signature Electronically Collected	March 8, 2000
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Signature Electronically Collected	March 7, 2000
Michael Kanter, MD. Medical Director – Woodland Hills, Panorama City MSA	Date
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Joseph Thompson, MD. Medical Director –Los Angeles, West Los Angeles MSA	Date
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Signature Electronically Collected	November 6, 2001
Ramesch Doshi, MD. Medical Director- Tri-Central SA	Date

Quality Program: SCPMG Transfusion Services

DOCUMENT HISTORY PAGE
Effective Date: March 8, 2000

Change type: new, major, minor etc.	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 it within 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	1) Fixed some typos 2) Made sure headers were the same through out the document. 3) Added information for section #4.	Ginny Tyler July 31, 2006	N.A.		
Minor	1. Added Work Place 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.	
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.	Ginny Tyler 11/03/10	N.A.	N.A.	

Quality Program: SCPMG Transfusion Services

	3. Removed the number of MC, as this can change.				

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 with Quality 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).

Authors All SCPMG Transfusion Services Managers
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Distribution All SCPMG Transfusion Services