KAISER PERMANENTE

Kaiser Permanente Medical Center, San Francisco
Northern California Region
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Work Instruction

Title:	**TQ-Blood Bank Document and Records**	**WI Number** SFOWI-0152 **Revision:** 20
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Document is in the Final Approval Process. 2 - approvals are required***	
Type of Document: Policy		**Review Period -** 340 **Days**

PURPOSE

To have policies (rules), processes (what we do), and procedures (how we do things) in the Transfusion Service; to ensure that documents are identified, reviewed, approved and retained; and to create, store and archive the records in accordance with record retention policies.

SCOPE

Transfusion Service Staff

PROCEDURE

A. **Master List**

The Transfusion Service has a master list of all the documents, including policies, processes, procedures, labels, and forms that relate to the requirements of the AABB standards.

B. **Document Format**

The Transfusion Service adopts a standard format for all policies, processes, and procedures in addition to the operator's manuals and reagent inserts.

C. **Document Control**

1. Each document is identified by its title name, document number and revision number.
2. New and revised documents are implemented after approval by the Medical Director.
3. The Transfusion Service supervisor audits unchanged documents annually.
4. The Transfusion Service uses only current and valid documents.
5. Documents are available at all locations where activities essential to meeting the requirements of these standards are performed.

D. **Policy and Procedure**

1. Work instructions and SOPs are written in Quality Systems International (QSI) environment which ensures documents are controlled.
2. New and revised policy and procedure are implemented after electronic approval by the Medical Director.
3. Old documents are automatically archived by QSI when the new revision is implemented.
4. QSI automatically tracks review period and send email notifications to the author and manager for document audit annually.
5. The Transfusion Service supervisor reviews and revises policies and procedures to ensure compliance with AABB standards, CAP requirements, state and federal regulations.

E. **Forms**

1. Forms are designed to meet the needs of the institution and used in a manner that satisfied these needs.
2. Each form should have a title that explains its intended use and should include the name of the facility and sufficient information, e.g., address, to distinguish it from other institutions with a similar name.
3. Forms include as much information as possible to minimize manual entries needed.
4. Record formats should also be designed to eliminate the need for repetitious signing by the same individual.
5. New and revised local forms are assigned a form number and revision number, and approved by the Medical Director.
6. Each form is revised concurrently with the revision of its associated SOP when necessary.
7. Old and obsolete forms are archived electronically. Any remaining paper copies are destroyed.
8. Regional forms are standardized forms created by the Regional Laboratory for use by all NCAL Kaiser facilities.

F. **Review by Medical Director**

1. The CLIA Medical Director reviews and approves new and revised technical policies and procedures before implementation.
2. The CLIA Medical Director or designee reviews each policy, process, and procedure annually.
3. The new CLIA Medical Director has up to 6 months to complete the review of all current policies and procedures.

G. **Creation of records**

1. Records are created concurrently with performance of each critical task e.g. result is recorded as the test is read and interpretation is recorded upon completion of testing.
2. Electronic patient tests and transfusion records are created in the LIS whenever results are entered or blood product(s) is dispensed.
3. Paper records are generated when forms are used for documentation e.g. QC, patient testing, PT, competency assessments, validation, and variances.
4. Records shall be complete, legible and indelible. Only pens with indelible ink should be used for writing.
5. The Transfusion Service supervisor or designee reviews the records to ensure completeness.

6. Records generated include documentation of the following information whenever applicable:
    a. Description of the critical activity
    b. Initials of the individual performing the activity
    c. The date (and time) of performance
    d. Results obtained
    e. Method(s) used
    f. Equipment used
    g. Critical materials used
    h. The facility where the activity was performed.

H. **Retention of records**

The Transfusion Service supervisor or designee ensures identification, collection, indexing, access, filing, storage, and disposition of records as required by the AABB Standards for retention of records.

Indefinite Retention

A. **Patient Records:**
1. Difficulty in blood typing
2. Clinically significant antibodies
3. Significant adverse events to transfusion
4. Special transfusion requirements

Minimum 10 Years Retention

A. **Patient Records:**
1. Results and interpretation of ABO/Rh and antibody screen of patient
2. Results and interpretation of compatibility testing
3. Final inspection of blood products and verification of recipient and donor unit information (per dispense protocol) at issue (LIS and transfused Crossmatch/Component Report)
4. Emergency release of unit before completion of compatibility/infectious disease testing including the physician's signed statement.
5. Evaluation and interpretation of transfusion reactions
6. Fatality reports
7. Transfusion administration records (Note: KPHC records are retained indefinitely)
8. Therapeutic phlebotomy/apheresis records (Note: KPHC records are retained indefinitely)
9. Transfusion Service evaluation and reporting of transmissible diseases
10. Look-back to identify recipients who may have been infected with HCV or HIV
11. Notification of critical results.

B. **Blood Product Records:**
1. Inspection of incoming blood and components (Blood Product Receipt Report)
2. Source to final unit disposition (Product History Review and Transfer/Destroy Report)
3. ABORh confirmation of donor units
4. Emergency release of unit before completion of donor testing
5. Recall and Lookback investigation
6. Unique identification of each unit
7. Disposition of non-conforming products
8. Report and resolution of ABORh labeling discrepancies to collecting facility

C. **Employee Records:**
1. Names, signatures, initials, identification codes of employees and employment dates

D. **Testing Records:**
   2. Identification of individuals performing each critical step/task

E. **Quality Control Records:**
   1. Completed Quality Control worksheets and review of QC results
   2. Inspection of incoming critical materials and containers

F. **Equipment Records:**
   1. Monitoring and preventive maintenance of equipment records - 10 years after retirement of the equipment
   2. Equipment qualification records - 10 years after retirement of the equipment
   3. Cooler qualification and validation records
   4. Continuous temperature monitoring or every 4 hours record of blood products storage temperatures

G. **Variance and Corrective Action Records:**
   1. Variance Log and FDA reports
   2. Exception to policies, processes, and procedures
   3. Patient/Unit Correction Report
   4. Nonconformances, preventive action and corrective action

Minimum 5 Years Retention

A. **Transfusion Service Records:**
   1. Transfusion Service Laboratory Requisition forms

B. **Employee Records:**
   1. Job descriptions
   2. Training, competency and personnel records
   3. Qualification of personnel performing critical tasks

C. **Document Records:**
   1. All superseded procedures, manuals, and publications including review and approval (QSI)
   2. Contracts and Agreements
   3. Change control and process control including review, approval and validation of new and revised processes and procedures (QSI and hardcopies)
   4. Annual document audit of policies, processes and procedures (QSI)
   5. Identification and appropriate archival of obsolete documents (QSI)

D. **Assessment Records:**
   1. Proficiency testing records and all corrective actions
   2. Review of assessment results

E. **Equipment Records:**
   1. Unique identification of equipment

F. **Quality Records:**
   1. Management review of Quality System

Minimum 2 Years Retention

A. Emergency operation plan tested at defined intervals

B. Data Integrity Check records

2 Years After Retirement of System

A. **Software, Hardware, and Databases**
   1. Implementation and modification of software, hardware, or databases
   2. Validation of system software, hardware, databases, user-defined tables, electronic data transfer, and/or electronic data receipt
   3. Fulfillment of applicable life-cycle requirements
   4. Numerical designation of system versions, if applicable, with inclusive dates of use
   5. Monitoring of data integrity for critical data elements

NOTE: Regional Integrated Laboratory Information System (RILIS) is responsible for regulatory compliance and maintenance of the software, hardware and databases of the laboratory computer system. Certain validation will be performed on-site when deemed necessary by RILIS or required by regulations.

I. **Storage and Retrieval**

1. The Transfusion Service supervisor identifies and appropriately archives old or obsolete documents.
2. Documents are properly indexed and organized so that they are retrievable. The Transfusion Service supervisor or designee files the records in a systematic way to enable retrieval in a time period appropriate to the circumstances.
3. The Transfusion Service supervisor or designee fills out the Regional Storage Control form when sending records to be stored at the Central Records Depository (CRD) in Livermore. A copy of the form is kept in the Laboratory Administration office for retrieval purposes.
4. Records may be kept on paper, either printed or indelibly handwritten, or they may be retained in entirety as electronic records, provided they can be easily retrieved for reference or review and adequate backup exists in case of system failure.
5. Backup or archived computer records, databases, operating system and applications software are stored off-site under appropriate conditions in accordance with the manufacturer's recommendations and instructions.
6. Records are stored in a manner that protects them from damage and from accidental or unauthorized access, destruction or modification.
7. Transfusion Service supervisor or designee transfers records from short term to long term storage and periodically selects records from long term storage that may be destroyed.
8. The method of destruction used by Kaiser Permanente protects the confidentiality of the records' contents.
9. **Location of records:**

Type of Records	**Storage Location**
Software, Hardware, and Databases	RILIS (except for records of on-site validation)
LIS (RILIS Millennium)	Indefinite in the LIS database
Age of Records (Other than LIS Records)	**Storage Location**
0 months - 2 years	On site in Transfusion Service Lab

2 - 5 years	Central Records Depository in Livermore

NOTE: Refer to SFOWI-0011 Retention and Retrieval of Lab Records GEN.41300 for details on the laboratory's storage and retrieval process.

J. **Security and Access**

1. To ensure confidentiality of records, only authorized personnel is allow in the Transfusion Service.
2. Employee is required to wear KP SFO identification while on the premises.
3. Password is required to run instrument and access the data, to make computer inquiries and entries.
4. New-hire is required to sign a statement not to share password.
5. Computer access is terminated when employee is no longer working in the Transfusion Service.
6. Different security level for computer systems is assigned to staff according to their job requirements .
7. Transfusion Service records, like all medical information, are never released to unauthorized persons and are discarded in the confidential waste container.

K. **Copies**

1. There is only one official paper copy of each policy/procedure located in the Transfusion Service binders. No other paper copy should be used as reference by staff. Staff can refer to the electronic copy of the policy/procedure in QSI.
2. If original records are in a medium (e.g. paper) and converted to another medium (e.g. microfilm or microfiche), copies of records shall be verified as containing the original content and shall be legible, complete and accessible.
3. If a record must be copied and used for legal purposes, a designated responsible person must review and, by means of a signed and dated certification of record, ensure authenticity and completeness of each document copied.

4 Before the destruction of the original records, the Transfusion Service supervisor visually verifies copies as containing contents identical to the original records and that the copies are legible, complete, and accessible.

5. When copies are made for reference e.g. during inspection or for training and meetings, the first page of the document should be identified with the word 'Copy' written or stamped.

L. **Corrections and Changes to Records**

1. The audit trail shall identify the original data, the person(s) entering the data, and the modification if any, the changed data, and the date/time of change.
2. The original records are never obliterated; in written records, it may be circled or crossed out, but it should remain legible. Use of white-out is not permitted.
3. Handwritten or computer records permit tracking of both original and corrected data to include the date/time and the identification of the person making the change.
4. **Manual Error Correction:**
   a. For any erroneous UNIT result that has been issued or made available for clinical decision making,
      i. A follow-up report showing the correct result marked as "CORRECTED" will be issued through the Transfusion Service.
      ii. If the original document is available, the erroneous result will be

crossed out with one line and "SEE CORRECTED", initials and date written adjacent to the wrong results.

iii. Both reports will be maintained as part of the permanent patient record.

b. For any handwritten error,

i. The erroneous entry shall be crossed out with one line, with the correct entry, initials and date written adjacent to it. White-out should not be used.

c. For corrections of critical data, the person making the modification shall write a Variance Log explaining the reason and specifying the changes.

5. **LIS Error Correction:**

a. The Transfusion Service adheres to the ECR protocol in the General Laboratory TQM Manual except that correction in LIS for Blood Bank result is only performed once.

b. Provider (or RN) notification and read back shall be performed and documented in LIS whenever an interpretation (i.e. ABO, Rh, ABSC, ABID) is corrected.

c. The LIS captures all corrections for traceability.

d. Corrected results are automatically transmitted to interfaced patient electronic record and downtime backup database.

6. When there are sequential corrections of a single test, subsequent reports will list all corrections in sequential order, including dates and results of corrections made.

7. The Transfusion Service supervisor or designee reviews the daily Blood Bank LIS Correction and Exception Reports and Variance Logs, and verifies the accuracy and completeness of the corrected record or modified data.

M. **Traceability**

1. The current record system makes it possible to trace any unit of blood or component from its source to final disposition, to review records that apply to specific component, and to investigate adverse reactions manifested by the recipient.
2. The computer system ensures that the donor and patient identifications are unique. The computer system will give a warning and prevent duplicate entry.
3. Results of each test or critical step must be recorded as observations are made or as each step is performed. Interpretation, if separate from results, must be recorded upon completion of testing.
4. Records include information that identify the person immediately responsible for the performance of each critical activity, the dates of performance, the dates of modification, results obtained, method(s) used, equipment(s) and materials used and the facility identity.
5. Recorded data can be traced to the person who created it. This is accomplished by maintaining a record of employees with inclusive dates of employment, signatures or identifying initials and employee ID, and of personnel authorized to sign, initial, or review reports and records.
6. Rubber stamps, brackets, or ditto marks are not acceptable means of identifying responsible personnel.

N. **Electronic records**

NAPAC (off-site) data center backs up all critical data everyday. There are procedures in place to ensure that stored data is retrievable and reusable.

PROCEDURE NOTE(S)

See SFOWI-0076 Plasmapheresis for Apheresis records retention period.

REFERENCE

A. AABB Standards for Blood Banks and Transfusion Services, current edition, Bethesda, MD.

B. Food and Drug Administration, Department of Health and Human Services. Title 21, Code of Federal Regulations, Parts 200-299. Washington, DC: U.S. Government Printing Office (revised annually).

C. Food and Drug Administration, Department of Health and Human Services. Title 21, Code of Federal Regulations, Parts 600-799. Washington, DC: U.S. Government Printing Office. (Revised annually).

D. CAP Checklist, current version, Northfield, IL.

Associated Documents:

External Documents

SFOWI-0001 Controlled Document Writing Guidelines
SFOWI-0011 Retention and Retrieval of Lab Records GEN.41300
SFOSOP-0036 Report Review and Error Detection
Associated Quality System Documents - None

Documents Generated:

Document Revision History:

Revision: 20	**Date Created:** 10/02/2005 **Date of Last Revision:** 01/17/2019	**Last Approval Date:** 10/30/2017

Document Author: Cara H Lim/CA/KAIPERM	**Document Manager:** Richard Chui/CA/KAIPERM

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	
2	Error Correction	Include File maintenance of Lifeline and RILIS error correction.	9/30/06
2	Approver	New Lab Director	11/27/06
3	Approver	New Lab Director	1/14/07
4	Approver	New Lab Director	07/31/07
5	Procedure G-2 & 3	Add and delete record because of change in computer system	11/30/07
	Procedure L-4-5	Document error correction.	11/30/07
6	Procedure	Move donor record and visual inspection from 5 years to 10 years	11/8/08
7	Approver	New Lab Director	6/1/11
8	Procedure	L-5 Follow general lab ECR SOP N Add electronic records.	12/4/11
9	Whole document Procedure C. Procedure D.	Corrected spellings and reformatted sentences and numbering. New. Added identification of documents. New.	9/17/12

	Procedure K.7.d. Procedure E. Procedure L.3. Procedure O.5. Procedure N.5. Procedure N.6. Procedure N.7. & 8. Procedure F.6. Procedure F.7. Procedure M.1. Procedure I. Procedure R. Procedure K.3. Procedure O.4. Procedure J.	Added LIS records. Added section for QSI documents. Added instrument. Added that records can be traced to its creator. Deleted computer instructions. Added HealthConnect and RILIS Millennium. Added instructions for documenting correction and review. Added obsolete forms. Added Regional forms. Clarified locations of official paper copy and electronic copy. Changed to J. Added protection of record confidentiality. Added CRD storage. Changed wordings to align with the 28th ediition of AABB standards. Changed retention from 5 to 10 years for QC records and preventive maintenance records. Added Training and Personnel records, Validation of new/revised processes and Agreements records for 5 years retention. Added equipment qualification for 10 years retention after retirement. Added FDA reports for 10 years retention.	
10	Approver Procedure G. Procedure G.3.	New Lab Director. Section reformatted. New, added 6 months as time frame for new Med. Dir to complete review of current policies and procedures.	3/1/13
11	Approver Whole document Procedure C.2.&3. Procedure D.5. Procedure G. Procedure I.9.a. Procedure K.3. Procedure H.2.c.vi) & H.2.k & l., & 3.g. Procedure E.6. Procedure I. NOTE Associated Documents	New BB Medical Director. Reformatted and renumbered. Added approval by Med Dir before implementation and annual audit by Supervisor. New. Added review and revision by BB Sup to ensure compliance. New section, Creation of Records. Changed from 3 to 2 months old records stored in BB. Added 'for legal purposes'. New. Added more record categories for retention. New. Added concurrent revision of form and SOP. New. Added reference to SFOWI-0011. Added SFOWI-0001 and SFOWI-0011.	9/19/13
12	Procedure F.	Added CLIA to Medical Director and deleted designee for review and approval of new and revised technical policies and procedures.	11/1/13
13	Procedure G.6. Procedure H.2.a.vi) Procedure H.2.b.vii) Procedure H.2.m. Procedure H.3.h. procedure H.4.	New. Added required elements for records. Added Fatality reports for 10 yrs retention. Added Disposition of non-conforming products for 10 yrs retention. Added Cooler qualification and validation for 10 yrs retention. Added Unique identification of equipment for 5 yrs retention. Added Emergency operation plan drills for 2 yrs retention.	9/19/14
14	Procedure H.3.i. Procedure H.2.a.viii) Procedure Notes	Added Quality management reviews for 5 years retention as currently in practice. TRM.32250. Added Transfusion administration records for 10 years retention per TRM.32250. Added reference to SFOWI-0076 Plasmapheresis for Apheresis records retention period.	2/6/15
15	Procedure L.4 & 5	New subsections for manual and LIS error corrections.	7/17/15
16	Procedure L.4.b.i.	Added to include date when doing manual error correction.	9/9/15
17	Procedure H. Procedure I.9.	Changed to Table format for easy reference. Updated retention records for 10 years, 5 years and 2 years to current requirements. Changed to Table format for easy reference. Updated storage locations.	12/3/15
18	Procedure H. Minimum 10 years. A.3. Approver	Revised to match AABB standards. New CLIA Director.	10/28/16
19	Procedure G.4. Procedure F.1. Procedure L. Procedure H.Table Procedure I.9.	Added that only pens with indelible ink should be used for writing. Added equipment monitoring. Added that use of white-out is not permitted. Added retention requirement for software, hardware and databases. Added storage location for Software, Hardware, and Databases.	5/18/17 9/8/17 10/23/17
20	Procedure H.Retention of Records Indefinite Retention 10 Years Retention	 Transfusion Service evaluation and notification to recipients of potential exposure to disease transmissible by blood - Moved from Indefinite to 10 years per 31st edition AABB Std. Removed Transfusion reaction and added Significant adverse events to transfusion. Added Evaluation and interpretation of Transfusion reactions,	10/1/18 10/1/18, 1/8/19

		Therapeutic phlebotomy records, Evaluation and reporting of transmissible disease, HCV & HIV Lookback, Notification of critical results.	

Notification List:

Approvals:

First Approver's Signature

Name: Maria F Serrano/CA/KAIPERM
Title: Transfusion Service Medical Director

Second Approver's Signature

Name: Eric Suba/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section