TRAINING UPDATE

Lab Location:	SGAH	**Date Implemented:**	12.18.2012
Department:	Blood Bank	**Due Date:**	12.31.2012

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Transfusion Service—Records Management Process

Description of change(s):

- AABB added or changed standards. These standards have been updated in our procedure.
  - Records shall be stored to preserve legibility and integrity for the entire retention; protect from accidental or unauthorized access, destruction, or modification
  - Destruction should be conducted in a manner that protects the confidential content of the records
  - Records shall ensure the traceability of all of the following:
    - Critical activities performed
    - The individual who performed the activity
    - When the activity was performed
    - Results obtained
    - Methods used
    - Equipment used
    - Critical materials used
    - Facility where the activity was performed
  - Change in the retention requirements for the following:
    - ABO/Rh results, ABO/Rh discrepancy, significant transfusion reactions, and special transfusion requirements (attributes) changed from 5 to 10 years
    - Equipment qualification, monitoring, and maintenance must be kept for 10 years after the equipment is retired
    - Inspection of critical materials changed from 10 to 5 years
    - Blood product storage temperatures changed from 10 to 5 years
    - Cooler validation and QC changed from 10 to 5 years
    - PI/Variances and FDA reportables from 10 to 5 years
- **Know that we keep records and you can refer to the Records Retention procedure to determine the retention period**

Non-Technical SOP

	Title	**Transfusion Service – Records Management Process**	
	Prepared by	Dhyan Krampetz, Priscilla Sundara	Date: 11/23/09

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to electronic signature page for approval and approval dates.		

Review:			
Print Name		**Signature**	**Date**

Procedure Retired by:			
Print Name and Title		**Signature**	**Date**
Procedure superseded by (title / version):			

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TABLE OF CONTENTS

1. PURPOSE

To define the management of controlled records generated from transfusion service activities.

2. SCOPE

This procedure applies to all controlled records generated in the Transfusion Services.

3. PROCEDURE

Note: Quest Diagnostics Record Management Program must be followed.

Responsible Party	Activity	Document
Transfusion Services Staff	1. Records observations and interpretations on forms (hardcopy or electronic) designated in the SOPs 2. Dates and initials all records generated as specified in SOPs 3. Places all records in designated short term storage areas	Worksheets Computer printouts Log sheets Log books Labels, etc.
Transfusion Services Supervisor Designated personnel	1. Transfers records from short term to long term storage area(s) 2. Selects records from long term storage that may be destroyed	Attachment C

4. RELATED DOCUMENTS

- Quest Diagnostics Record Management Program

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5. RECORDS MAINTENANCE

Step	Action
1	Records are maintained in accordance with the Quest Diagnostics *Records Management Program.*
2	Records will be stored in a manner that preserves legibility and integrity for the entire retention period; protects from accidental or unauthorized access, destruction, or modification; and allows retrieval.
3	The records system shall ensure the traceability of all of the following A. Critical activities performed B. The individual who performed the activity C. When the activity was performed D. Results obtained E. Method(s) used F. Equipment used G. Critical materials used H. The facility where the activity was performed
4	Destruction of records shall be conducted in a manner that protects the confidential content of the records.

6. REFERENCES

- Standards for blood banks and transfusion services, 28th ed. Bethesda, MD: AABB, 2012.
- Transfusion medicine checklist, v 7.31.2012. Chicago, IL: CAP, 2012.
- 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).
- 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).

7. REVISION HISTORY

Version	Date	Section	Revision Purpose	Reviser	Approval
1.0	11/1/10		Minor formatting changes to header and footer Supersedes SOP SGAH.B831.003	L. Barrett	Dr Cacciabeve
A	12/17/12	5	Updated procedure to reflect new standards for record retention (steps 2-3)	SCodina	NCacciabeve
A	12/17/12	Attach B	Updated retention periods to reflect changes in regulatory requirements	SCodina	NCacciabeve

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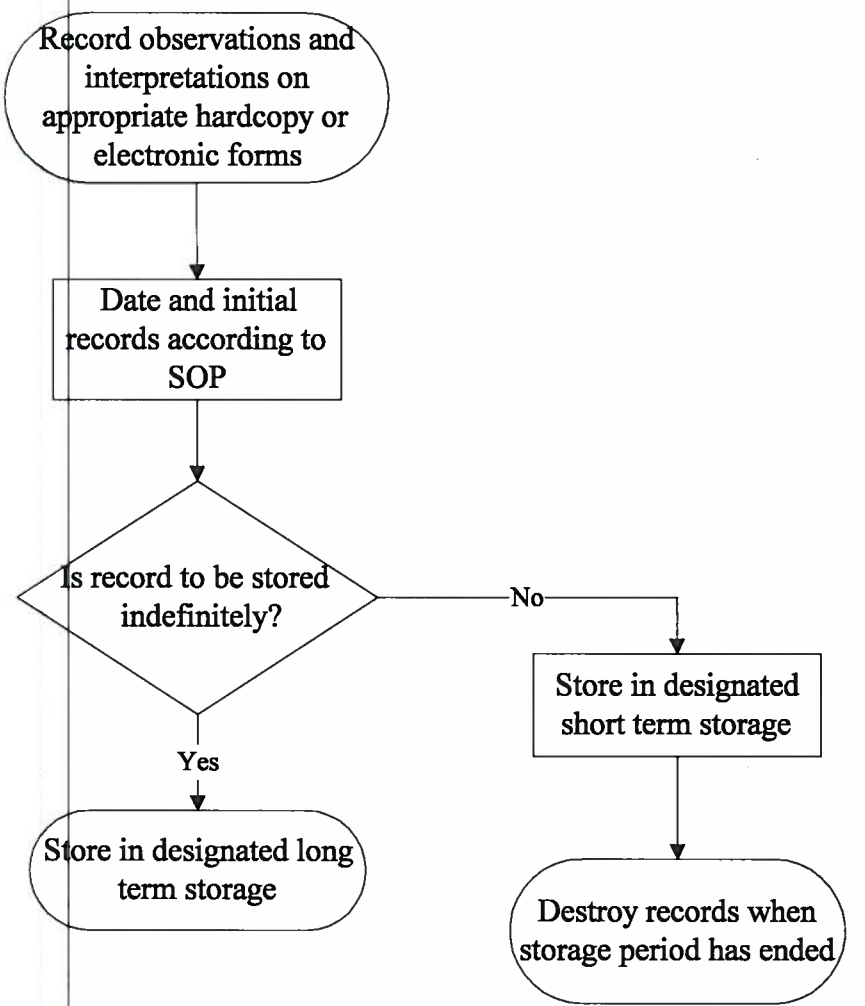
8. ADDENDA AND APPENDICES

A: Flowchart
B: AABB/CAP Record Storage Requirement
C: Local Record Storage Table

Attachment A

RECORDS MANAGEMENT



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Attachment B

Note: This table lists some of the highpoints of the record. For the complete listing; refer to Standards for Blood Banks and Transfusion Services, 28th Edition, Reference Standard 6.2 pages 64-78.

TYPE OF RECORD	RETENTION PERIOD		
Donor Records	**CAP**	**AABB**	**Recommended**
Blood/component donor information, consent and collection Donor blood testing Donor notification of significant findings Component production Look back investigation/disease reporting Final unit disposition	*10 years*	*10 years*	*10 years*
Indefinitely and permanently deferred donors Donors placed under surveillance (for recipient protection	*Indefinitely*	*Indefinitely*	*Indefinitely*
Patient Records			
Transfusion administration records Final unit disposition including verification at issue and emergency release forms	*10 years*	*10 years*	*10 years*
Therapeutic phlebotomy/apheresis records	*10 years*	*5 years*	*10 years*
Patient pre-transfusion testing results/interpretations	*5 years*	*10 years*	*10 years*
Interpretation of computer or serologic crossmatches	*Not specified*	*10 years*	*10 years*
Irradiation of cellular components	*Not specified*	*10 years*	*10 years*
Immediate evaluation/interpretation of transfusion reactions	*5 years*	*5 years*	*5 years*
Transfusion problems such as transfusion reactions, unexpected antibodies, and special transfusion requirements. AABB- Difficult in typing, clinically significant antibodies, significant adverse events to transfusion requirements, and special transfusion requirements	*Indefinitely*	*10 years*	*Indefinitely*
Notification of abnormal test results	*Not specified*	*10 years*	*10 years*
Look-back to identify recipients who may have been infected with HCV or HIV Viruses	*Not specified*	*10 years*	*10 years*

Employee signatures, initials, and identification codes AABB- dates if employment for personnel who perform or review critical tasks	*10 years*	*10 years*	*10 years*
Other Documents and Records			
Temperature of blood products shall be recorded every 4 hours	*Not specified*	*10 years*	*10 years*
Implementation and modification of software, hardware, or databases	*Not specified*	*2 years after retirement of the system*	*2 years after retirement of the system*
Equipment qualification	*5 years*	*10 years after retirement of equipment*	*10 years after retirement of equipment*
Quality Control Records			
Proficiency testing records Irradiation dose delivery Control systems for patient testing Annual procedure review/procedures discontinued	*5 years*	*5 years*	*5 years*
Fatality Reporting	*Not specified*	*5 years*	*5 years*
Inspections of blood/critical materials Description and evaluation of nonconforming blood, blood components, tissue, derivatives, critical materials, and services	*5 years*	*10 years*	*10 years*
Quality management reviews Instrument/equipment quality control and maintenance	*5 years*	*10 years*	*10 years*
Retyping of donor units	*5 years*	*10 years*	*10 years*
Control systems for donor testing	*10 years*	*10 years*	*10 years*
Tissue Records (including bone marrow and/or progenitor cells)			
Collection, transportation, processing, issuing, disposition	*10 yrs beyond tissue's disposition or expiration, whichever is longer*	*10 years beyond the date of distribution, date of transplantation, date of disposition, or date of expiration, whichever is the latest date*	*10 years beyond the date of distribution, date of transplantation, date of disposition, or date of expiration, whichever is the latest date*
Daily temperature monitoring for Tissue	*10 years*	*Not specified*	*10 years*

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Attachment C

RECORD STORAGE TABLE
Washington Adventist Hospital Blood Bank

Record Name and/or Number	Required storage	Short Term Storage		Long Term Storage		Total Length of Storage
		Location	Length	Location	Length	
Donor record cards	10 years			Off-site storage	10 years	10 years
Permanent donor deferrals	Indefinite			Off-site storage	Indef	Indef
Patient record cards (prior to 9/15/98)	10 years			Off-site storage	10 years	10 years
Patient records 9/15/98-1/06/02	5 years			SCC backup file on Blood Bank PC	Indef	Indef
Patient records of ABO/Rh, typing problems, clinically significant antibodies, special transfusion needs	Indef			Online in LIS (SQ) Back up daily to independent PC and manual antibody file	Indef	Indef
Quality control (reagents)	5 years	Blood Bank File	≥2 years	Off-site storage	≤3 years	5 years
Quality control (equipment)	10 years	Blood Bank File	≥2 years	Off-site storage	≤8 years	10 years
Component receipt, prep, and processing	10 years	Post 1/5/02 online in LIS (SQ)		4/91 thru 1/02 - secure network drive	Indef	Indef
Weld inspection records, ID numbers of components and lot numbers of disposables	5 years	Blood Bank File	≥2 years	Off-site storage	≤3 years	5 years
Irradiation records, verification of dose delivery, component log, radiation safety and increased controls documents.	Indef	Blood Bank file	5 years	Off-site storage	Indef	Indef
Component disposition	10 years	Post 1/5/02 online in LIS (SQ)		Pre 4/91 – off site and microfich file in BB 4/91 thru 9/98 – PC database (Concordance) 9/98 –1/02 PC database (BB Unit Conversion)	Indef	Indef

Record Name and/or Number	Required storage	Short Term Storage		Long Term Storage		Total Length of Storage
		Location	Length	Location	Length	
Transfusion reaction reports	5 years	Blood Bank file	5 years	Interpretation of transfusion reactions in LIS	Indef	Indef
Look-back/tx-transmitted disease investigations	10 years	Blood Bank file	≥2 years	Off-site storage	≤8 years	10 years
Component Recalls	5 years	Blood Bank file	≥2 years	Off-site storage	≤8 years	10 years
LIS QA report	10 years	Blood Bank file	≥2 years	Off-site storage	≤8 years	10 years
Superseded procedures/policies	5 years	MasterControl System	5 years	NA MasterControl System	5 years	5 years
Personnel training records	5 years	Laboratory file	While employed	Previous employees – personnel file	5 years	5 years post emp.
Staff signature/ID records	10 years	Procedure manual	10 years	Blood Bank File	10 years	10 years
Competency and proficiency	5 years	Blood Bank file or QA	5 years	Blood Bank file or QA	5 years	5 years
Performance Improvement	10 years	Quality Assurance file	≥2 years	Off-site storage	≤3 years	5 years
Process/computer validations	2 years after retirement of system	Blood Bank file	≥2 years	Off-site storage	≥3 years	Indef
Transfusion Committee minutes	5 years	Hospital QA Dept. file	5 years	Hospital QA Dept. file	5 years	5 years
Emergency Release records	5 years	Blood Bank file	5 years	Blood Bank file	5 years	5 years