PURPOSE

To ensure that documents are identified, reviewed, approved, and retained; that records are created, stored, and archived in accordance with record retention policies.
To describe when and how to review documents as well as the corrective actions taken by a supervisor or designee when incomplete or inadequate documentation is encountered.

POLICY

Documents

The Transfusion Service (TS) shall have a process for document control that includes the following elements:

- A master list of documents, including policies, processes, procedures, labels, and forms that relate to the requirements of these standards.
- Use of a standardized format for all policies, processes, and procedures.
- Review and approval of new and revised documents before use.
- Each policy, process, and procedure is reviewed at least every 2 years by an authorized individual.[1]
- Use of only current and valid documents.
- Appropriate and applicable documents shall be available at all locations where activities essential to meeting the requirements of these standards are performed.
- Identification and appropriate archival of obsolete documents.
- Ability to track documents sent outside department and request their destruction when obsolete.

Records

The TS shall ensure identification, collection, indexing, access, filing, storage, and disposition[2] of records as required by Reference Standards:

[1] Per AABB Standard 6.1.4.
[2] All patient care documents are destroyed (shredded) after their specific storage time. Refer to Addendum 1 for "Record Retention".

- Records shall be complete, retrievable in a period of time appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.
- Prior to the destruction of the original records, TS shall have a process to ensure that copies of records are identified as such. Copies of records shall be verified as containing the original content and shall be legible, complete, and accessible.
- A system designed to prevent unauthorized access and ensure confidentiality of records shall be established and followed.
- The record system shall make it possible to trace any unit of blood or component from its source (donor or the collection facility) to final disposition, to review the records applying to the specific component, and to investigate adverse reactions manifested by the recipient.
- The system shall ensure that the donor and patient identifiers are unique.
- The result of each test observed shall be recorded immediately, and the final interpretation shall be recorded upon completion of testing.

Computer Systems

The TS shall have a process to support the introduction of new software, hardware, or databases, or modifications of existing software, hardware, or databases relating to the requirements of these standards. Refer to:

- Pathology P&P 935 *LIS Validation of Transfusion Service Functions*
- BB2310.A *Quality Plan*

PROCEDURE

I. The Training and Competency Assessment Records

Competency must be evaluated before independent performance of an assigned activity. The Clinical Laboratory Scientist Specialist A (CLSS A) will review training and competency records for accuracy, discrepancies, completeness, and compliance with departmental SOP's. The Quarterly Problems Management Report[3] is completed and submitted to the Supervising Clinical Laboratory Scientist (SCLS) for corrective action as needed. The completed report is submitted to the Medical Director for review.

[3] Refer to Forms and Documents binder for examples of all forms and documents listed in this procedure.

Corrective Action:

The SCLS assesses the needs for corrective actions for staff with unsatisfactory or incomplete performance in training and/or competency assessment. Proceed as per administrative procedures BB2323.A *Training Program* and BB2324.A *Competency Testing & Evaluation*.

Documentation:

Document unsatisfactory or incomplete performance on the *Problem Management Report* (Example 1) and submit to SCLS and medical director for review. Records are kept in the possession of the CLSS[4] in specific folders for each employee and are to be kept a minimum of 5 years.

II. Equipment, Reagent Quality Control (QC), and Log Sheets

The SCLS and/or CLSS A[5] review the following records for completeness, accuracy, and compliance with department SOP's as needed. Refer to procedures BB2331.A *Equipment Management* and BB2333.A *Monitoring Equipment Temperatures*.

A. Equipment: Refrigerators/freezers, incubators, heat blocks, cell washers, serofuges, centrifuge, irradiator, calibrated pipettes, timers, plasma thawers and Provue automated system.

1. Temperature records:

- Daily temperature logs (heating blocks, refrigerators, freezers, platelet incubators, and ambient temperature)
- Refrigerator Temp logs from Cancer Center Adult and Pediatric Infusion and Rocklin PCN Infusion Centers
- Weekly temperature charts
- Any Temperature Record Forms generated when manual monitoring of refrigerator temperature every 4 hours is required

2. Equipment QC:

- Cell washer/Serofuge (speed, timer, and function check record)
- MTS Gel centrifuge calibration record

[4] Classification abbreviations: SCLS (Supervising Clinical Laboratory Scientist), CLSS (Clinical Laboratory Scientist Specialist), CLS (Clinical Laboratory Scientist), HCLA (Hospital Clinical Laboratory Assistant). Abbreviations used: TS (Transfusion Service), LIS (Laboratory Information System), SARC (Specimen & Report Center), SOP (Standard Operating Procedures), BBk (Blood Bank),

[5] See Job Responsibilities BB2303.A for responsibilities of SCLS, CLSS A, CLSS B.

- Irradiator
  - Quarterly sealed source inventory and wipe check reports (Health Physics)
  - Annual Dose Map Dosimetry System test (Nordion)
- Quarterly alarm check record of refrigerators, freezers, and platelet incubator
- Quarterly Cell washer QC and post maintenance/repair QC records
- Biannual pipette calibration records
- Annual determination of optimal centrifugation (serofuge) time

3. Preventive maintenance records:

   - Task/QC/Maintenance Checklists (Examples 2 and 3)
   - Problem Management Report (Example 1)
   - Equipment Problem/Maintenance Form (Example 4)

Documentation:

- Preventative maintenance is documented on Task/QC/Maintenance Checklists (See BB2307.A *Completion of Tasks, QC, and Maintenance Checklist*).

- SCLS will review checklists monthly. Report any unresolved problems to the medical director using the *Problem Management Report*.

Corrective Action:

1. Document equipment problems on the *Equipment Problem/Maintenance Log* and place the form in the Equipment Maintenance folder. Urgent problems are also noted on the *Patient Information Sheet*.

2. The "A Bench" CLS notifies CLSS and SCLS of equipment problem and documents notification on the Patient Information Sheet and Equipment Problem Log.

3. The CLSS reviews the folder at least weekly and notifies Clinical Engineering and SCLS of problems requiring repair. Document follow-up of unresolved problems on the problem log. Once resolved, log is given to SCLS for review.

4. The SCLS reviews (date & sign) completed Equipment Problem/Maintenance Logs. Reviewed logs are filed in Equipment Maintenance binder according to piece of equipment.

5. Clinical Engineering maintains records of work performed by them and ATR refrigeration contractor. Outside vendor repair work order copies are placed in the *Equipment Maintenance* binder according to piece of equipment.

6. The SCLS reports significant equipment problems to the Medical Director through the *Problem Management Report*.

7. The equipment maintenance logs and Problem Management Reports are kept for 5 years.

8. The *Patient Information Sheet* is used as an aid and discarded after 1 month or when no longer useful.

B. Reagent & Critical Supply QC records:

- Daily Reagent QC
- Miscellaneous Reagent QC
- Hemo-Temp Sticker QC
- RadSure Label validation
- New lot number Reagent QC

C. Log sheets or LIS printouts

- Exsanguination Sheet Log
- Daily Task/ Maintenance Lists and Inventory Inspection Log Sheet
- Shipment Temperature Log Sheets
- Portable Refrigerator and Cooler Monitoring Log
- Irradiated component printouts
- Thawed component printouts

Corrective actions:

For documentation which is incomplete or not in compliance with the departmental SOPs:

1. Make a copy of the documentation in question.

2. Request the task performing CLS, or a designee, to complete the documentation or take the proper corrective actions to resolve the problem.

3. Complete an Incident/ Deviation Reporting Worksheet according to BB2318.*A Error Management* and attach copies of documentation before and after the follow up actions. Submit copy of report and documentation to CLSS B.

4. CLSS B investigates all reported accidents, errors, incidences and variances. Significant errors (Level 1, 2 and FDA reportable) are reported to SCLS, Medical

Director, Transfusion Committee and other QA committees according to BB2318.A *Error Management.*

Documentation:

- Use the *Monthly Quality Control Review* to document review of the following:
  - Daily QC
  - Miscellaneous QC
  - Temperature Records
  - Cell Washer QC (IBM & Cobe)
  - Instrument Function Checks
- Document unresolved problems on the *Problems Management Report* and submit to medical director or designee for review.

Storage:

- Department records are kept in file folders and then placed in specifically labeled storage boxes monthly. Most of these documents are kept a minimum of 5 years.
- Clinical Engineering Dept. keeps the list of equipment property numbers for 5 years.
- The washed red cell worksheets and cell washer QC worksheets are kept in specifically labeled storage boxes for 10 years.

III. Reagents and Supplies

A. In-Department Tracking:

Weekly, the SCLS or designee will review reagent and supply records for discrepancies, wastage, shipping problems, costs, and compliance with departmental SOP's:

- Reagent/Supply Discard Log
- Reagent/Supply Problem

Corrective action:

1. Decrease or increase the ordering quantity to eliminate the wastage or prevent shortage as appropriate.

2. Decrease the cost by acquiring the product with similar/same specifications from a new supplier.

3. Communicate with the manufacturer's representative on problems needing further investigation.

Documentation:

Document unresolved problems on the *Problem Management Report*, and submit to medical director or designee for review.

Storage:

Once reviewed, these documents do not need to be kept any longer than their in-department usefulness. They are stored in file drawer for the current year.

B. Reagent & Critical Supply Records[6]:

- Review the reagent inserts for consistency with previous inserts.
- Review packing slips for discrepancies with items received.

Corrective action:

1. Immediately bring to the attention of either the Department of Pathology Purchasing Dept. or directly to the supplying company any damaged supplies or inconsistent packing slips.

2. Assess the need to change the existing department SOPs if there are new or additional directions or reagent concerns.

Documentation:

- Packing slips or shipping documents
- Circular of Information
- Reagent & Critical Supply inserts.

Storage:

- After review, store the current packing slips in the binder for 1 month. Each month's slips are transferred to a specifically labeled binder that holds 1 year. The yearly binders are kept for 5 years.

[6] Refer to BB2338.A *Reagent & Critical Supply Control*

- Keep the current reagent insert in the *Reagent Insert* binder for test procedure reference. Place the older version in the Reagent Insert file folder in the file cabinet for 1 year and then to a specifically labeled storage box for 5 years.

- BloodSource provides the *Circular of Information*. They are kept in the department as an information source and given to clinical staff as requested. When the *Circular of Information* is revised, BloodSource notifies Transfusion Service to return remaining outdated copies and replaces them with latest update.

IV. Review of Patient's Test Result Data (in LIS or on worksheets)

- While requisitioning a test specimen, examine the request slip (if included) for completeness[7]. Be sure the phlebotomy information is written on the specimen tube.

- CLS reviews patient LIS blood type history, special component/transfusion needs, and antibody status prior to specimen testing.

- Upon conclusion of the testing, the CLS reviews all work for completeness and accuracy. If the test results are entered directly into the LIS, on screen review is performed by the testing CLS.

- A second CLS must review the results for blood type and type recheck for patients requiring a type recheck and perform an on screen review. The on screen review is documented by the CLS entering his/her initials at the ABO/Rh verified or ABD Rck/SPCK fields as appropriate.[8]

- Worksheets are reviewed by the testing CLS and initialed. Antibody identification and antibody titer worksheets are reviewed for completeness and accuracy by a second CLS and initialed. They are filed once the results can be entered into the LIS. Worksheets are stored for one month in the designated file and then moved to specifically labeled boxes to be stored for 5 years.

- The EMR order or requisition forms are reviewed for special requirements.[9] Special requirements will be noted and added to patient history in LIS. If there are products available for patient, make sure that they match those requirements. If special requirements do not seem appropriate, consult the medical director or designee and

[7] Refer to BB2390.A *Handling of Blood Samples*
[8] The *ABO/Rh verified* is initialed by the primary CLS and the ABD Rck/SPCK is initialed by either the type recheck CLS or another CLS.
[9] The Order Questions query the physician for special requirements when order for crossmatch is generated in EMR. It states quantity, clinical indications and special blood component needs.

requisition an ADBBP[10]. **The CLS will *circle a positive response and check mark or highlight the order questions and comment section of the EMR order and initial each* to document review.**

- The medical director(s) review test results of any patients with difficult typing, newly identified alloantibody(ies), and unexpected reactivity. Their review is documented in the electronic medical record as a Transfusion Service Physician Evaluation or Transfusion Reaction Investigation, when appropriate. A BBMDS[11] or TRR is generated in LIS.

- The medical director or designee reviews adverse reactions to transfusion and generates a consultation report, Transfusion Reaction Investigation (TRR) [12] for the patient's chart.

- Blood product utilization review is documented by the ADBBP consult report.

- The *Outstanding Specimens* report is generated 2 times daily[13]and reviewed. Pending specimens and tests are accounted for by a CLS or SCLS.

- All Hospital Incident Reports and Incident/ Deviation Reporting Worksheets and supporting documentation are reviewed by the QA CLSS and SCLS.[14]Any incidents which could be life threatening, have a serious potential of causing harm or are FDA reportable must be reviewed within 24 hours and reported to the SCLS and Medical Director.

Corrective Action:

For documentation which is incomplete or not in compliance with the departmental SOP's:

1. Attempt to obtain the phlebotomy information. Document on the EMR order or requisition form that the information was per phone call.

2. Make a copy of the specimen printout or worksheet in question.

3. Request the task performing CLS or a designee to complete the documentation or to take the proper corrective actions to resolve the problem.

[10] ADBBP (authorized deviation of blood bank procedure)
[11] BBMDS (difficult crossmatch consult report)
[12] TRR (transfusion reaction report)
[13] Refer to BB2587.*A Reviewing Outstanding Specimens, Etc in LIS.*
[14] Per CA state regulation effective 7/1/07, all IR s must be reviewed within 4 days and those with serious harm or death must be responded to within 24 hours. Notify the Transfusion Services Medical Director immediately.

4. Complete an Incident/ Deviation Reporting Worksheet and, if indicated, the online Hospital Incident Report and attach copies of documentation before and after taking the follow up actions[15].

5. Correct discrepancies discovered when reviewing the *Outstanding Specimens* report.

The SCLS or CLSS assess the need for corrective actions such as additional training or competency evaluation for staff with unsatisfactory performance. Proceed as per administrative procedures BB2323.A *Training Program* and BB2324.A *Competency Testing & Evaluation*.

Documentation:

The original copy of the requisition slip is saved as a permanent record of the phlebotomy data, the requested test, and the ordering physician.

- Manually generated antigrams for antibody identification, antibody titer worksheets are their own documentation of results.

- Transfusion Services, when notified of an adverse reaction to transfusion, requests that a *Transfusion Reaction Investigation Form* be completed. The patient's physician (or nurse) completes the form as soon as possible after the suspected adverse reaction.

  - The CLS may generate the *Transfusion Reaction Checklist*. The Medical Director generates a *Transfusion Reaction Classification & Interpretation Form*. This information can also be utilized online through the Hospital Incident Report system.

- Document all errors/problems which are not life threatening, or serious but may have the potential of causing harm to patient care on the Problem Monitoring Report Form and submit to medical director or designee for review.

Storage:

- Transfusion Services submits "wet receipts" (original signed requisition forms) to Client Services to scan and save. These must be saved for 5 years.

[15] Manage all accidents, errors, incidence, and variance according to BB2318.A *Error Management.*

- The LIS data is periodically stored on a magnetic tape backup system by the LIS staff. The CLSs can access this patient data[16] for 5 years; the LIS staff can access this information indefinitely.

- Worksheets used in lieu of LIS direct entry are filed and stored for a minimum of 5 years; they reflect the "direct entry results".

- Records of difficulty in blood typing, clinically significant antibodies, significant unexpected adverse reactions to transfusions, and special transfusion requirements are kept indefinitely.

- Routine Hospital Incident Reports and Incident/ Deviation Reporting Worksheets are stored on site for the current and previous year and then sent to the hospital warehouse to be kept for a minimum of 5 years.

- FDA reportable and Level 1, Level 2 incident reports are kept on site for a minimum of 5 years.

V. Donor Unit & Transfusion Record:

- Inspect each donor unit upon arrival and compare the blood supplier's packing slip to each unit. Initial the packing slip that the units meet standards[17].

- Immediately review donor unit ABD test results after testing. After review, enter initials at *Result Review* in LIS worksheet.

- The person performing any significant step in the processing, testing, storage, or distribution of blood and blood components must be the person who documents these steps in the LIS, worksheets, etc. using their assigned user ID or signature.

- Daily the "A bench" CLS assures that the donor unit inspection has been completed by reviewing the Daily Checklist and Inventory Inspection Logsheet.

- The completed lab file copies of the Unit Crossmatch & Transfusion Record Form are returned to TS after transfusion.

[16] Donor unit information can be retrieved via "Donor Inquiry" for ~ 2 years; it can be retrieved from years 2-5 by accessing "BBk History Transfusion Inquiry".
[17] Refer to BB2367.A *Donor Unit Processing and Resulting*

- Any unit returned for re-issue is examined for acceptability and stated so on the blood order form and in the unit comments in LIS. (See *Return to Prior Status… BB2570.A).*
- The requesting physician must sign for any donor unit released prior to all viral testing or compatibility testing.[18]

Corrective Action:

1. Contact the blood supplying facility to correct the donor unit discrepancy.

2. Assess the needs for corrective actions such as additional training or competency evaluation for staff with unsatisfactory performance. Complete online Hospital Incident Report if appropriate.

3. Assess the need to involve Nurse Manager(s) for resolution on a consistent error or omission.

Documentation:

- The person entering received units into inventory initials the *BloodSource Shipping Document.*

- The *Unit Crossmatch & Transfusion Record Form* is its own document. No other document is generated unless it is part of an internal audit.

- The *BloodSource Transfer Sheet* copy (along with an *LIS Transferred Unit printout*) documents stock units that were recalled (component retrieval). An *LIS Unit Inquiry* printout of each unit documents previously transfused units that are recalled (component retrieval).

- The UCDMC Broken Product Discard Form is faxed to the BloodSource to document broken units that are discarded at UCDMC. Broken products are reviewed by the medical director or supervisor and reported to the Transfusion Committee as part of the Unused Blood Component Report.

- The *Exsanguination Sheet* — request for uncrossmatched blood — is its own document. It must be signed by the requesting physician as well as by the person picking up the blood and the CLS or HCLA issuing the blood.

[18] The BloodSource requires the ***Emergency Release of Blood Components (without required testing)*** form to release untested units. Uncrossmatched units are requested using the pink *Special Blood Requisition For Exsanguination* (pink sheet).

- The blood supplying facility sends an *Emergency Release of Blood Components* form signed by their medical director. It must be signed by the requesting physician and the TS medical director.

Storage:

- The donor unit packing slips are kept in the department for the current month and then stored in a specifically labeled storage box for a minimum of 5 years.
- The printed weekly review of quality control specimens is for internal use only and is discarded when no longer needed by SCLS.
- The Lab Copy of the *Unit Crossmatch & Transfusion Record Form* is stored with the *Blood Order Form* and filed in alphabetical order for each day. These are kept in storage boxes for 10 years.[19]
- A copy of the signed request for uncrossmatched units and emergency released units is sent to Medical Records for scanning into the EMR while the original is kept in a specific file folder for the current month and then kept in storage boxes for a minimum of 5 years.
- Blood Order Forms, Issue/Transfusion lab copies, and information regarding nonconforming ("recalled") units are filed and kept for a minimum of 10 years.

VI. Quality:

- The audit or self assessment performed to evaluate a potential system failure is reviewed as soon as possible by either the SCLS or CLSS.
- Audit for routine system evaluation is reviewed as soon as possible.
- Documentation of deviation for standard practice (LIS function "ADBBP" — Authorized Deviation of Blood Bank Protocol) is created by the CLS. The medical director reports the reason for action.
- Validation of SOPs is recorded on the *Validation of SOP* form. The medical director approves SOPs before being put into use and on a biennial basis[20]. This is documented on the *Procedure History* page at the end of each SOP.

[19] Even though the transfusion data (patient/unit) is stored indefinitely in the LIS, a record must be kept for 10 years for the identification of the transfusionist, the 2nd verifier, the date & time transfusion started and ended, if a transfusion reaction occurred, and the transfused volume. We also use the form to document the use of a blood warmer.
[20] After initial approval, a designee can perform biennial review.

- CLSs and HCLAs sign the *New SOP Signature Page* to document they've read the SOP. This sheet for each new or revised SOP is located on the shared "S" drive (S:APS/Clin lab/BBK/SOPs/Signature pages for SOPs read folder) or in front page of each SOP volume if the whole volume is to be reviewed.

Corrective Action:

- Assess the needs for corrective actions or retraining for staff[21].
- Assess the needs for editing department SOP(s).
- Assess the need to involve Nurse Manager(s) for resolution on a consistent error or omission.
- Assess the needs for hospital ward staff in-service.
- Assess the need to involve the Transfusion Committee for resolution of an ongoing problem.

Documentation:

- The audit report is its own document. Sign and date the report before giving it to the SCLS or CLSS.
- The *ADBBP*, the *SOP Validation form*, and the *New SOP* signature page are their own documents.
- The SOP *Procedure History* signature page at the end of each SOP identifies the approving and the annual reviewing medical director or designee. It also tracks the revision and retirement of the procedure.

Storage:

- Audit reports, ADBBPs, & Validation forms are filed in specific file folders for the current year.
- The New SOP Signature pages are kept in a specific binder.
- The History Signature pages are kept with the specific SOP.
- All retired (or archived) SOPs are kept in binders or boxes.
- All the above documents are kept for a minimum of 5 years.

[21] Refer to BB2323.A *Training Program* and BB2324.A *Competency Testing & Evaluation.*

REFERENCES:

1. *American Association of Blood Banks Technical Manual* (AABB) Current Edition. American Association of Blood Banks, 8101 Glenbrook Road, Bethesda, Maryland, 20814-2749.

2. *Standards* Committee (American Association of Blood Bank, Standards for Blood Banks and Transfusion Services, Current Edition. American Association of Blood Banks, 8101 Glenbrook Road, Bethesda, Maryland, 20814-2749.

3. *Code of Federal Regulation.* Food & Drug Administration, April 1, 2004. Title 21, 640.2. http://www.fda.gov.

PROCEDURE HISTORY

Date	Written/ Revised by	Revision	Approved by	Approved date
11/21/05	C.During R. Perry	Merger of 2 SOPs: *Review of Patient's Worksheets & Review Documents;* add retention list; update documents	Hanne M. Jensen, MD	12/2/05
Annual review inadvertently missed in 2006				
8/14/07	R.Perry	On screen review, EMR order questions, delete plasma stamp	Hanne M. Jensen, MD	9/19/07
1/27/15	R.Perry	Biennial review	Hanne M. Jensen, MD	2/10/15
11/9/16	D Richardson	Add Retain revised or retired SOPs 10 yrs	Hanne M. Jensen MD	11-9-16
11/9/16	D Richardson	QA Review		11/9/16

S/BBank/SOP Complete/2352.A Documents & Records; rp; 12/30/14

Record Retention

Donor Unit Records to Keep	# Years to Keep
Irradiator Records	5
Annual Dose Mapping	5
Radiation Safety:	5
Radiation Safety Training	5
Irradiator Wipe Tests	5
Irradiator user names and ID#/ pin codes	10
Irradiation of Cellular Components:	5
Printed Component Logs	5
Irradiator Print-Outs	5
Preparation of Washed units:	10
Washed unit worksheets	
Cell washer QC	
Shipping Documents:	5
Inspection of incoming blood and components	5
Inspection of incoming derivatives	5
Serologic Confirmation of donor unit ABO/Rh:	5
Unit Inquiry in LIS: specimen results	
Unit returned for reissue: Confirmation that blood or component has been inspected and is acceptable:	5
Returned Blood Order Forms	
Unit Inquiry in LIS: (comment)	
Final disposition of each unit	10
Component retrieval form (BloodSource)	
Returned Issue/Transfusion Forms	
Unit Hx in LIS	
Unused blood product forms	
Wasted product Incident Reports	
ADBBP- medical director approval of:	5
Units with ports not intact, abnormal appearance	

DOCUMENTS AND RECORDS — Administrative Procedure BB 2352.A

Donor Unit Records to Keep (cont'd)	**# Years to Keep**
Emergency Release of Units (without required testing)	5
Look-back investigations Hepatitis, HIV, HCV, etc.	10
Transfusion Reaction Workups (immediate & delayed)	10 yrs for lookback
Patient MR#, transfusion order, component name, donor unit# or pool #, date & time of transfusion, pre and post vital signs, amount transfused, ID of transfusionist, reaction, lot #, quantity, administration date.	10 yrs
Blood Order Form w/ Issue Transfusion Form	10
Rh immune Globulin injection forms	10
Exsanguination Sheets	10

Other Records to Keep	**#Years to keep**
Management review of Quality System:	5
Audits	5
Current Job Descriptions	5
Qualification of personnel performing activities affecting quality	5
Training Records	5
Competency Evaluations	5
Personnel Records for Each Employee	5
Record of names, initials, identification codes with inclusive dates of employment: Employee Signatures Irradiation Operator ID Codes LIS User names and Passwords	10
Proficiency Testing records CAP Surveys RISE Direct Observation Checklist	5
SOP validation Annual Review of policies, processes, procedures- SOP History page Review and approval of New or Revised Documents Before Use	5
Exceptions to policies, processes, procedures: ADBBP *(authorized deviation of BB protocol)*	5
Archival of Obsolete Documents Retired Documents Retired or revised SOPs	5 10

Other Records to Keep (cont'd)	#Years to keep
Review of QC results for reagents, equipment, and methods:	5
Quality Control	5
Daily QC	5
QC of panel cells, screen cells, new reagents	5
QC of pooled cryoprecipitates	5
Parallel studies: new reagents, new tests	5
Reagent inspection: noted on shipping documents	5
Equipment Management:	5
Equipment Validation	5
Monitoring and Maintenance of Equipment	5
Temp records of refrigerators, freezers, platelet incubators recorded q 4 hours	10
Room temp recorded q 4 hours when components stored in open storage area.	10
Unique identification of critical equipment - assigned by Clinical Engineering	5
Equipment Qualification - UCDMC Purchasing Department	5
Supplier Qualification and Selection - UCDMC Purchasing Department	5
Agreements - Lab Manager	5
Agreement Review - Lab Manager	5
Peer-review assessment of blood utilization- Transfusion Committee Reports	5
ADBBP reports	5
Error Management	5
Investigation of Deviations, nonconformance, complaints regarding blood, components, services, processes and quality system	5
Result of follow-up to preventative actions	5
Implementation of changes to policies, processes, procedures resulting from corrective and pre-ventative action	5
Maintained by LIS Department:	
Implementation of new or modified software, hardware or databases	
Modification of software, hardware, or databases	
Computer Validation, software, hardware	Lifetime of System or 2 years whichever is greater
Database, user defined tables	
Monitoring data integrity for critical data elements	
Dates of use for each version of software	
Fulfillment of life cycle requirements	

LIS user names and passwords	10

Patient Records to Keep	**# Years to Keep**
Patient ABO/Rh type	5
Antibody Screen, Antibody Identification:	5
Antibody Identification worksheets, antigrams, etc	
Interpretation of Serologic Crossmatch:	5
Manual Crossmatch Worksheets	
Difficulty in ABO/Rh typing Clinically Significant Antibodies Significant Transfusion Reactions Special Transfusion Requirements BBMDS consults Antibody ID workups Backup BBK history card LIS patient history	Indefinite
Type cards with significant antibody or special requirements not in LIS	
Final Check of Transfusion Service Records at Issue: *(Patient Name and Medical Record#* *Patient's ABO group and Rh type* *Donor unit# or pool ID# and donor ABO/Rh* *Interpretation of crossmatch, if performed* *Date and Time of issue):* Blood Order Forms with Issue/Transfusion Form copy Issue units routine in LIS *Patient history in LIS*	10
Verification of patient identification before Transfusion: Returned copy of issue/transfusion form	10