1. **Principle**

Defined record retention guidelines are an integral part of a Quality Management System and a requirement for provincial licensing.

1. **Scope and Related Policies – N/A**
2. **Specimen – N/A**
3. **Material – N/A**
4. **Quality Control** 
   1. An annual audit of a representative number of records should be performed to confirm compliance.
5. **Procedure**
   1. The following Table identified the appropriate retention period for specific types of records:

**RECORD RETENTION - TRANSFUSION MEDICINE**

|  |  |  |  |
| --- | --- | --- | --- |
| **MINIMUM RETENTION** | | **DESCRIPTION** | |
| 50 years | |  | |
|  | | Records of release of blood components and products for transfusion (disposition) including recipients identification, donation codes of components, lot number of products | |
|  | | Record of distribution, including exceptional distribution and any recalls, inter-hospital transfers, returns to supplier | |
|  | | Blood supplier packing slip; Issue voucher/packing slip for product shipped between facilities | |
|  | | Record of final disposition of blood components and products (including donor code), lot number of product | |
|  | | Patient records – issuing, dispensing, transfusion of allogeneic components and blood products | |
|  | | Records of recall/withdrawal (notifications received from supplier, follow up of implicated inventory and reports to Health Canada | |
| 10 years | |  | |
|  | | Records of employee qualifications, training, competency, signature, ID, initials† | |
|  | | Blood component preparation and transformation (date of activity, name of person performing modification, inspection checks, quality control, method and equipment used, facility name). This includes records of washing, pooling or irradiating components | |
|  | | Record of shipment, testing (including ABO/Rh and transmissible disease testing), final disposition of autologous blood components including identification of the recipient and donation code | |
|  | | Master copies of superseded procedures and manuals (includes all controlled documents) | |
|  | | Investigations and reports of adverse transfusion events and errors and accidents (non-serious and serious) including reports to Health Canada | |
|  | | All documents related to traceback or lookback process | |
| 5 years | |  | |
|  | | Temperature monitoring records for blood storage equipment | |
|  | | Quality control testing of blood components (untransformed), reagents and equipment – date, tests performed, observed results, interpretation, ID of person performing QC test, corrective action, ID of person reviewing results and date of review | |
|  | | Autologous donor collection record | |
|  | | Records of inspection of blood components before release | |
|  | | Product complaints | |
|  | | Records of internal audits | |
|  | | Quality assurance reports | |
| 3 years | |  | |
|  | | Critical supplies used in transformation (qualification of critical supplied) | |
|  | | Documentation of maintenance, validation, calibration and performance verification of critical equipment (used in transformation) | |
|  | | Records concerning the operation of computer systems (changes made, maintenance, security and access control, incidents and failures, error corrections made) | |
|  | | Records concerning the validation of computer systems (changes made, training records, validation plan) | |
| 1 year | |  | |
|  | | Date and time a sample was drawn, and phlebotomist’s identification | |
|  | | Shipping documents (courier documentation or weigh bills) for transfer of any blood components/products (from supplier or between hospitals) | |
|  | | Lot number of critical supplies for each transforming process and the name of the supply manufacturer | |
| As per hospital policy | |  | |
|  | | Blood inventory management – notification of inventory levels or problems, records of any response or action taken | |
|  | | Patient requisition for pre-transfusion testing | |
|  | | External quality assurance (EQA) and inspection/assessment records, corrective actions and responses to accreditation/regulatory agencies | |
|  | | Confirmation of ABO grouping of donor units | |
| Life of Equipment plus 5 years | | Capital Equipment records of purchase, validation, date put into service, maintenance, repair, decommissioning and disposal | |

† 10 years after the individual ceases to be an employee.

1. **Reporting – N/A**
2. **Procedural Notes**

8.1Patient transfusion service records (includes transfusion record, test results, antibody identification investigation worksheets) should be retained as per facility requirements for medical records9.3

1. **References**
   1. IQMH Requirements and Guidance Information, Section II – Quality Management System. Apr 2017 v7.1 II.A.2, II.F.13
   2. CAN/CSA Z902-15 Blood and Blood Components, Canadian National Standard, Dec 2015. Tables 4 and 5
   3. Standards for Hospital Transfusion Services v4 April 2017 Canadian Society for Transfusion Medicine, Appendix A
2. **Revision History**

|  |  |
| --- | --- |
| **Revision Date** | **Summary of Revision** |
| August 10, 2015 | * Revised name of manual * Revised section 6.0 * Updated list of references to include most recent editions |
| July 18, 2016 | * Updated to CSA Z902-15 |
| August 14, 2017 | * Updated to CSTM v4 April 2017 and IQMH v7.1 |