# RECORDS RETENTION FOR TRANSFUSION MEDICINE DOCUMENTS

<table>
<thead>
<tr>
<th>Office of Administrative Responsibility</th>
<th>Issuing Authority</th>
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<tbody>
<tr>
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Overview

Records and documents are required to be available upon request, easily located and retained for a specified amount of time. The amount of time retained is dependent on the type of information contained in the documentation.

Policy

1. Transfusion Medicine Laboratories shall retain documents and records according to CSA standards.
2. The following documents shall be retained for 1 year:
   2.1. the record of the date and time a recipient blood sample was drawn and phlebotomist’s identification; and
   2.2. shipping documents.
3. The following documentation shall be retained for 3 years:
   3.1. validation of computer systems; and
   3.2. calibration and performance verification of critical equipment.
4. The following records shall be retained for 5 years:
   4.1. recipients adverse events;
   4.2. temperatures of storage;
   4.3. product complaints;
   4.4. quality assurance reports and records of internal audits; and
   4.5. quality control testing of blood components, reagents, equipment and proficiency testing surveys (including dates, tests performed, observed results, interpretations, identification of personnel carrying out the tests, and any appropriate corrective action).
5. Documentation shall be retained for 10 years regarding:
   5.1. investigations and reports of errors and accidents that could lead to serious adverse reactions and unexpected or serious adverse events;
   5.2. all documents related to a lookback or traceback process;
   5.3. the qualifications, training, and the competency of each individual personnel member engaged in any these activities (10 years after the date the individual ceases to be an employee);
5.4. final disposition of autologous blood components, including identification of recipient; and
5.5. master copies of superseded procedures and manuals.

6. The following must be retained for 50 years:
   6.1. donation codes;
   6.2. the health care facility’s record of release for transfusion and the record of transfusion of blood components and products;
   6.3. records of final disposition of blood components and blood products, including identification of the recipient (for transfused components);
   6.4. records of importations of blood components from international sources; and
   6.5. records relating to the distribution from the blood centre to the hospital, and transfer between hospitals, including exceptional distribution and any recalls.

Key Words
Records, retention, documents

References