6.2.1 Facility Records
Records shall be complete, retrievable in a period of time appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.

6.2.1.1 Records shall be legible and indelible.

6.2.1.2 Copies
Before the destruction of the original records, the BB/TS shall have a process to ensure that copies of records are:
1) Verified as containing the original content.
2) Legible, complete, and accessible.

6.2.2 A system designed to prevent unauthorized access and ensure confidentiality of records shall be established and followed.

6.2.3 The record system shall make it possible to trace any unit of blood, blood component, tissue, or derivative from its source to final disposition; to review the records applying to the specific component; and to investigate adverse events manifested by the recipient.

6.2.4 Records shall be created and maintained to include:
1) Critical activities performed.
2) The individual who performed the activity.
3) When the activity was performed.
4) Results obtained.
5) Method(s) used (when more than one method is in use).
6) Equipment used.
7) Critical materials used.
8) The facility where the activity was performed.

6.2.4.1 The system shall ensure that the donor and patient identifiers are unique.

6.2.5 Records shall be created concurrently with performance of each critical activity.

6.2.5.1 The actual result of each test performed shall be recorded immediately, and the final interpretation shall be recorded upon completion of testing.
6.2.6 Changes to Records
Changes to records shall be controlled.

6.2.6.1 The date of changes and the identity of the individual who changed the record shall be documented, and this information shall be maintained for the retention period of the original record.

6.2.6.2 Record changes shall not obscure previously recorded information.

6.2.6.3 Changes to records (including electronic records) shall be verified for accuracy and completeness.

6.2.7 Electronic Records
There shall be processes and procedures to support the management of computer systems. Standard 6.2.2 applies.

6.2.7.1 There shall be a process in place for routine backup of all critical data.

   6.2.7.1.1 Procedures shall be in place to ensure that data are retrievable and usable.

   6.2.7.1.2 Backup data shall be stored in an off-site location and be secured to prevent unauthorized access.

6.2.8 Storage of Records
Records shall be stored to:
1) Preserve record legibility and integrity for the entire retention period.
2) Protect from accidental or unauthorized access, destruction, or modification.
3) Allow retrieval.

6.2.9 Destruction of Records
Destruction of records and back up data shall be conducted in a manner that protects the confidential content of the records.

*21 CFR Part 11.
## Reference Standard 6.2A—Retention of Donor/Unit Records

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Standard</th>
<th>Record to Be Maintained</th>
<th>Minimum Retention Time (in years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4.3</td>
<td>Inspection of incoming blood and blood components</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>5.1.6.1</td>
<td>Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>5.1.6.2</td>
<td>Traceability of blood, blood components, and critical materials</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>5.1.6.5</td>
<td>Source to final disposition of each unit of blood or blood component and, if issued by the facility for transfusion, identification of the recipient</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>5.1.6.5.1</td>
<td>Unique identification of each unit</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>5.1.6.5.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>5.2.1 #7</td>
<td>Donor acknowledgment that educational materials have been read</td>
<td>10</td>
</tr>
<tr>
<td>7</td>
<td>5.2.2</td>
<td>Parental permission for donation</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>5.2.3</td>
<td>Consent of donors</td>
<td>10</td>
</tr>
<tr>
<td>9</td>
<td>5.2.4</td>
<td>Notification to donor of significant abnormal findings</td>
<td>10</td>
</tr>
<tr>
<td>10</td>
<td>5.2.4</td>
<td>Donors placed on permanent deferral, and indefinite deferral for protection of recipient</td>
<td>Indefinite</td>
</tr>
<tr>
<td>11</td>
<td>5.4.1, 5.4.2</td>
<td>Donor information, including address, medical history, physical examination, health history, or other conditions thought to compromise suitability of blood or blood component</td>
<td>10</td>
</tr>
<tr>
<td>12</td>
<td>5.4.4.1</td>
<td>A medical order from the patient’s physician is required to collect blood for autologous use</td>
<td>10</td>
</tr>
</tbody>
</table>

(Continued)