history, transfusion reaction, and transfusion transmitted diseases investigation records are retained permanently.

LB.29.3 The implemented anatomical pathology records retention system ensures the following:

LB.29.3.1 Surgical pathology reports, outside consultations report and images of studies are retained for ten years.

LB.29.4 Discontinued (retired) blood bank and transfusion controlled documents are retained for five years after the retirement date.

LB.29.5 Discontinued (retired) general laboratory controlled documents are retained for three years after the retirement date.

Standard Intent:

Documentation provides a framework for understanding and communication throughout the organization. Documents describe how processes are intended to work, how they interact, where they must be controlled, what their requirements are, and how to implement them. On the other hand, records provide evidence that the process was performed as intended and provide information needed to assess the quality of products and services. Together, documents and records are used by quality oversight personnel to evaluate the effectiveness of a facility's policies, processes, and procedures.

The laboratory should maintain a log listing all current policies, processes, procedures, forms and labels with the locations of copies. The log contains other information as appropriate, such as dates when documents were placed in service, schedule of review, identity of reviewer(s), and dates when documents were discontinued/superseded.

When forms are used for capturing or recording data, steps, or test results, the forms become records. Data should be recorded in a format that is clear and consistent. Records provide evidence that critical steps in a procedure have been performed appropriately and that products and services conform to specified requirements. Review of records is an important tool to help evaluate the effectiveness of the quality management system. Records should be created concurrently with the performance of each significant step and should clearly indicate the identity of the individuals who performed each step and when it occurred. The process for managing records should address the following items:

1. Creation and identification.
2. Protection from accidental or unauthorized modification or destruction.
3. Verification of completeness, accuracy, and legibility.
4. Storage and retrieval.
5. Retention periods.
6. Confidentiality.

If records are maintained electronically, adequate backups should exist in case of system failure. Electronic records should be readable for the entire length of their retention period.

The length of time that records are retained may vary; however, the records must be retained for that period encompassing a high frequency of requests for retrieval.

LB.30 The laboratory has a system for sample retention.

LB.30.1 There is a sample retention policy to ensure that general laboratory specimens are retained under appropriate conditions for no less than the periods specified below:

LB.30.1.1 Whole blood specimens and urine specimens are retained for twenty-four hours.

LB.30.1.2 Serum, plasma, cerebrospinal fluid and other body fluids specimens are retained for forty-eight hours.

LB.30.1.3 Permanently fixed and stained blood films are retained for seven days.

LB.30.1.4 Permanently fixed and stained microbiology slides are retained for seven days.

LB.30.2 The sample retention policy ensures that donors and patients samples are retained under appropriate conditions for no less than the periods specified below:

LB.30.2.1 Outpatient specimens (not for compatibility testing) are retained for twenty-four hours.

LB.30.2.2 Inpatient specimens are retained for seventy-two hours.

LB.30.2.3 Specimens of patients who receive blood transfusion are retained for seven days after transfusion.

LB.30.2.4 Segment/specimens from transfused RBC are retained for seven days after transfusion.

LB.30.2.5 Specimens for transfusion reaction investigation are retained for seven days.

LB.30.3 The sample retention policy ensures that anatomical pathology specimen is retained under appropriate conditions for no less than the periods specified below:

LB.30.3.1 Gross specimens of wet or fixed tissues are retained for fourteen days after the release of final report.

LB.30.3.2 Paraffin blocks are retained for ten years.

LB.30.3.3 Glass slides are retained for ten years.