Standard Intent:

Retaining both the patient's sample and the donor's sample allows repetition or additional testing if the patient has a transfusion reaction. Appropriate storage conditions (refrigeration, sealed containers) are necessary to prevent specimen degradation and contamination. Testing of stored samples should be based on the sample storage limitations in the reagent manufacturers' package inserts.

LB.31 The laboratory develops a process for internal (self) and external assessment of operations and quality management system.

LB.31.1 The laboratory develops and implements policies and procedures on quality indicators and systems checks.

LB.31.2 The implemented system covers the selection, data collection, reporting, and monitoring of quality indicators.

LB.31.3 The laboratory selects and monitors key quality indicators covering the pre-analytical, analytical, and post-analytical phases of the laboratory operations.

LB.31.4 Selected general laboratory indicators may include, but are not limited to, the following:

LB.31.4.1 Patient identification errors.

LB.31.4.2 Rejected specimens.

LB.31.4.3 Turnaround Time (TAT) of routine, STAT and urgent requests.

LB.31.4.4 Critical value reporting failures.

LB.31.4.5 Customer satisfaction.

LB.31.4.6 Corrected laboratory reports.

LB.31.4.7 Blood culture contamination.

LB.31.5 The selected transfusion services indicators may include, but are not limited to, the following:

LB.31.5.1 Rejected donors.

LB.31.5.2 Rejected units.

LB.31.5.3 Donor satisfaction.

LB.31.5.4 Adverse donor reactions.

LB.31.5.5 Usage and discards.

LB.31.5.6 Ability to meet the patient's needs.

LB.31.5.7 Blood ordering practices (cross matched/transfused ratio).

LB.31.5.8 Blood administration practices.

LB.31.6 The laboratory has a system for process improvement that covers the following activities:

LB.31.6.1 Identification of opportunities for improvement.

LB.31.6.2 Corrective and preventive actions.

LB.31.6.3 Description of the selected quality improvement tool used in the laboratory.

LB.31.7 The laboratory is involved in hospital-wide/multidisciplinary improvement projects. During the current accreditation cycle, the laboratory was engaged in at least four quality improvement projects, including:

LB.31.7.1 Two general laboratory projects.

LB.31.7.2 One blood bank project.

LB.31.7.3 One transfusion services project.

Standard Intent:

Assessments are systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments can be internal or external and can include quality assessments, peer reviews, self-assessments, and proficiency testing.

The laboratory must establish and maintain a process for internal (self) and external assessments. Results of assessments must be reviewed by the medical director and the organization's executive management to determine the appropriateness and effectiveness of corrective/ preventive actions (if taken).

Quality indicators are specific performance measurements designed to monitor one or more processes during a defined time and are useful for evaluating service demands, production, adequacy of personnel, inventory control, and process stability. The blood bank must regularly compare the performance against available benchmarks.

Process improvement includes determination of root causes, implementation of corrective actions and preventive actions, and evaluation of the effectiveness of these actions. Several process improvement methodologies used in the healthcare systems, including, Plan–Do–Check–Act (PDCA) cycle, Failure Modes and Effects Analysis (FMEA), Define-Measure-Analyze, Improve, and Control (DMAIC) and Lean Six Sigma. These are systematic step-wise approaches for identifying all possible failures within a process, product, or service to improve performance, reduce costs and waste, cut time, and eliminate non-value-added actions.