LB.4 The laboratory has a system for personnel audit trail.

LB.4.1 The system allows for the identification of who performed a critical task/step.

LB.4.2 The system allows for the identification of when, where, and why the task/step is performed.

Standard Intent:

An audit trail (also called audit log) is a security-relevant chronological record that provides documentary evidence of the sequence of activities that have affected or contributed to a specific outcome. Laboratory records must be complete and all relevant data available, including results, interpretation, dates, and identity of persons performing the work. A personnel audit trail must be maintained for each significant step in the collection, processing, testing, storage, and distribution of blood and blood components.

LB.5 The laboratory has a comprehensive training and competency assessment program.

LB.5.1 The laboratory implements an orientation, training and competency assessment program that ensures:

LB.5.1.1 Satisfactory completion of training program for all lab personnel in their assigned area.

LB.5.1.2 Training on new equipment or method.

LB.5.1.3 Competency assessment of all laboratory personnel before working independently and annually thereafter.

LB.5.1.4 Corrective action plan and reassessment in the event of unsatisfactory performance.

LB.5.1.5 Utilization of the appropriate competency assessment tools, including technique observation for technical competency, assessment of personnel's knowledge about the contents of the procedures and instruments operation manuals (written/verbal exam), and assessment of personnel's problem solving skills (unknown samples).

LB.5.1.6 Laboratory personnel performing tests or tasks requiring color discrimination undergo a color discrimination test.

Standard Intent:

To ensure that skills are maintained, the laboratory should have regularly scheduled competency evaluations of all staff members whose activities affect the quality of laboratory testing, manufacturing of products, or provision of products or services. Depending on the nature of the job duties and when applicable, the following methods of competency assessment must be employed during the pre-operational period of hiring and annually thereafter:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing,
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results,
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records,
4. Direct observation of performance of instrument maintenance and function checks,
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills.

?Analysis of competency assessment data can be very useful in identifying staff learning needs.

LB.6 The laboratory has a system for the receipt of incoming supplies and services, inventory management, and tracking of critical materials.

LB.6.1 The laboratory implements policies and procedures on documenting the receipt, inspection, and testing (as applicable) of incoming critical material or service.

LB.6.2 The laboratory implements policies and procedures on inventory management and tracking the use of critical materials, supplies, and reagents to ensure the following:

LB.6.2.1 Materials are used within their expiration dates.

LB.6.2.2 New reagents lot numbers are tested against old lots or suitable reference materials before use.

LB.6.2.3 Kit components are used within the kit lot number.

LB.6.2.4 Lot number use is traceable to patient/blood donors or inclusive dates of use.

Standard Intent:

Before acceptance and use of critical materials, reagents, supplies or services, they should be inspected and tested (if necessary) to ensure that they meet specifications for their intended use. It is essential that supplies used in the collection, processing, preservation, testing, storage, distribution, transport, and administration of blood, components meet predefined acceptance criteria. Laboratories must develop procedures to control and prevent inadvertent acceptance and use of materials, reagents and services that do not meet specifications. Corrective action may include returning the material to the vendor or destroying it. Receipt and inspection records provide the