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**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.

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**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.

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**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.

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**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: