must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers.

LB.16 The Laboratory develops a process for the control of deviations and exceptions.

LB.16.1 There is a written policy, process, and forms for the control and documentation of deviations and exceptions to policies and procedures.

LB.16.2 Deviations and exceptions warranted by clinical situations or special circumstances are justified, pre-approved, and documented on a case-by-case basis.

LB.16.3 Deviations and exceptions must be approved for only one implementation event by the authorized person who signs the policy or procedure for implementation.

Standard Intent:

Exceptions to policies, processes, and procedures warranted by clinical situations are justified and pre-approved on a case-by-case basis and for one implementation event. A wide variety of routine procedures may, from time to time, require the medical director or designee to authorize an alternative approach because of specific clinical situations.

LB.17 The laboratory has a comprehensive safety and infection control programs.

LB.17.1 The laboratory implements safety and infection control policies and procedures that are in compliance with the national and international laboratory safety standards as well as the hospital safety and infection control plan. Policies define the following:

LB.17.1.1 Chemical hygiene plan.

LB.17.1.2 Mercury reduction/elimination plan.

LB.17.1.3 Mechanism of fumes and vapors monitoring.

LB.17.1.4 Mechanism of compressed and flammable gases control.

LB.17.1.5 Radiation safety plan.

LB.17.1.6 Biological safety procedures and use of standard precautions.

LB.17.1.7 Tuberculosis and other biological hazards exposure plan.

LB.17.1.8 Electrical safety plan.

LB.17.1.9 Fire prevention and control plan.

LB.17.1.10 Provision and use of Personal Protective Equipment (PPE).

LB.17.1.11 Provision and control of negative pressure in sections dealing with highly infectious materials.

LB.17.1.12 Provision, use, and control of fume hoods.

LB.17.1.13 Provision, use, and control of biological safety cabinets.

LB.17.1.14 Provision of safety equipment (eye wash, emergency shower, fire extinguisher, fire blanket, biological and chemical spill kits).

LB.17.1.15 Waste disposal/control plan (chemical, biological and sharps) using prick proof containers and leak proof bags.

LB.17.1.16 Provision and use of first aid kits.

LB.17.1.17 Reporting of infection and safety incidents.

LB.17.2 The laboratory has safety and infection control training program that includes:

LB.17.2.1 Initial training and competency assessment.

LB.17.2.2 Annual training, recertification and competency assessment.

LB.17.3 The laboratory has a system for monitoring the laboratory safety and infection control program.

LB.17.3.1 Documented safety and infection control audits are conducted at regular predefined-intervals (at least twice yearly).

LB.17.3.2 Findings of the audits are reported to the laboratory director, the facility safety officer, the infection control department, and other concerned parties.

LB.17.3.3 Corrective actions, whenever needed, are taken and documented.

Standard Intent:

The laboratory director is the ultimate responsible person for laboratory safety. He/she will be responsible for providing laboratory personnel with a comprehensive safety manual and assigning a safety officer to provide guidance and monitoring. The safety manual outlined above addresses common laboratory risks and hazards. Specialized laboratories might need to develop additional safety requirements to meet specific risk factors.

LB.18 The laboratory has a services/specimen collection manual.

LB.18.1 The laboratory develops a services/specimen collection manual that includes the following:

LB.18.1.1 Available tests and services on and off-site (reference laboratory) and their Turn Around Times (TAT).

LB.18.1.2 Methods of patient preparation.

LB.18.1.3 Procedures for positive patient identification.

LB.18.1.4 Quality and quantity of sample.

LB.18.1.5 Phlebotomy and sample collection procedures.

LB.18.1.6 Recognizing and handling adverse reactions to phlebotomy.

LB.18.1.7 Specimen labeling.

LB.18.1.8 Requisition and required clinical data.

LB.18.1.9 Specimen handling and transportation.

LB.18.1.10 Specimen rejection criteria.