
1. Organization

1.0 Organization

The blood bank or transfusion service (hereinafter referred to as the BB/TS) shall have a structure that clearly defines and documents the parties responsible for the provision of blood, blood components, and services and the relationship of individuals responsible for key quality functions.

1.1 Executive Management

The BB/TS shall have a defined executive management. Executive management shall have:

- 1) Responsibility and authority for the blood bank's or transfusion service's operations, and the quality management system.
- 2) The authority to establish or make changes to the blood bank's or transfusion service's quality system.
- 3) The responsibility for compliance with these *Fundamental Standards for Blood Collection and Transfusion (Fundamentals)* and applicable Competent Authority requirements, local laws, and regulations.
- 4) Responsibility to support safe transfusion practices and the appropriate use of blood, such as working toward implementation of a patient blood management program.

- 1.1.1** The BB/TS shall have a director who is a licensed physician/scientist who is qualified by appropriate education, training, and/or experience. The director shall have responsibility and authority for all policies, processes, and procedures—including those that pertain to laboratory personnel and test performance. The director may delegate these responsibilities to another qualified individual,

referred to as a designee; however, the director shall retain ultimate responsibility for director duties.

- 1.1.2** The BB/TS shall have a licensed physician who is qualified by appropriate education, training, and/or experience as per relevant Competent Authority requirements. The physician shall have responsibility for all medical issues and the support services that relate to the medical care and safety of transfusion recipients or donors and can serve as the director of the BB/TS.

1.2 Quality Management System

The facility shall have a quality management system in place.

- 1.2.1** The quality management system shall be documented, implemented, and maintained.
- 1.2.2** All personnel shall be educated and trained in its application.



1.2.3 Management Reviews

Management shall assess the effectiveness of the quality management system through scheduled management reviews at planned intervals.

1.3 Policies, Processes, and Procedures

Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these *Fundamentals* are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

- 1.3.1** All policies, processes, and procedures shall be approved by the director (or qualified designee); the BB/TS licensed physician (or qualified designee) shall approve medically related policies, processes, and procedures.



- 1.3.2** Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and preapproval by the BB/TS licensed physician (or qualified designee). Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

1.4 Emergency Preparedness

The BB/TS shall have emergency operation policies, processes, and procedures to respond to the effects of internal and external disasters.

1.5 Sufficiency of the Blood Supply

The facility shall have plans (including policies, processes, and procedures) to ensure the availability of blood donors, blood, blood components, and critical materials for the scope of operations conducted.

- 1.5.1** The facility shall have processes to address shortages of component and critical materials, including the identification of alternative suppliers, when available.

- 1.5.2** The facility shall have a continuity plan to address disruptive events (eg, disasters, pandemics, etc) that may affect supply chain and component inventory that could place operations at risk.