
5. PROCESS CONTROL

5.0 Process Control

The BB/TS shall have policies and validated processes and procedures that ensure the quality of the blood, blood components, and services. The BB/TS shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

5.1 General Elements



5.1.1 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods perform as expected. Chapter 9, Process Improvement Through Corrective and Preventive Action, applies.

5.1.1.1 Quality control failures shall be investigated before release of test results, products, or services.

5.1.2 Use of Materials

All materials (including containers and solutions used for collection, processing, preservation, and storage of blood and blood components, and all reagents used for tests) shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements. Standards 3.6 and 4.1.3.1 apply.

5.1.3 Sterility

Aseptic methods shall be employed to minimize the risk of microbial contamination of blood and blood components. Equipment and solutions that come into direct contact with blood or blood components shall be sterile and pyrogen-free. Single-use equipment shall be used whenever possible.

5.1.4 Identification and Traceability

5.1.4.1 Use of Materials

All materials (including containers and solutions used for collection, processing, preservation, and storage of blood and blood components, and all reagents used for tests) shall be stored and used in accordance with the manufacturer’s written instructions and shall meet specified requirements.



5.1.4.2 Process or Procedure Steps

For each critical step in collection, processing, compatibility testing, and transportation of blood and blood components, there shall be a mechanism to identify who performed the step and when it was performed. Standard 6.2.4 applies.



5.1.4.3 Traceability

The BB/TS shall ensure that all blood, blood components, and critical materials used in their processing, as well as laboratory samples and donor and patient records, are identified and traceable.

5.1.4.4 General Labeling Requirements

The BB/TS shall have a labeling process. This process shall include all steps taken to:

- 1) Identify the original unit, any components, and any component modifications;
- 2) Complete the required reviews;
- 3) Attach the labels.

5.1.4.4.1 The following requirements shall apply:

- 1) Labeling of blood and blood component containers shall be standardized.
- 2) The original label and added portions of the label shall be affixed or attached to the container, and shall include the applicable items required in Reference Standard 5.1.4A, Requirements for Labeling Blood and Blood Components.
- 3) Handwritten additions or changes shall be legible and applied with permanent, moisture-proof ink.
- 4) All modifications to component labels shall be specified and controlled.
- 5) If a component is modified and new labels are applied, the labeling process shall include a method to ensure the accuracy of all labels, including the donation identification number, ABO/Rh, expiration date (as appropriate), and product name.
- 6) The labeling process shall include a second check to ensure the accu-