§ 640.10 Red Blood Cells

The proper name of this product shall be Red Blood Cells. The product is defined as red blood cells remaining after separating plasma from human blood.

(a) One or more segments shall be provided with each unit of Whole Blood or Red Blood Cells when issued or re-issued.
(b) Before they are filled, all segments shall be marked or identified so as to relate them to the donor of that unit of red cells.
(c) All segments accompanying a unit of Red Blood Cells shall be filled at the time the blood is collected or at the time the final product is prepared.

§ 640.11 General requirements.

(a) Storage. Immediately after processing, the Red Blood Cells shall be placed in storage and maintained at a temperature between 1 and 6 °C.
(b) Inspection. The product shall be inspected immediately after separation of the plasma, periodically during storage, and at the time of issue. The product shall not be issued if there is any abnormality in color or physical appearance or if there is any indication of microbial contamination.

§ 640.12 Suitability of donor.

The source blood for Red Blood Cells shall be obtained from a donor who meets the criteria for donor suitability prescribed in §640.3.

§ 640.13 Collection of the blood.

(a) The source blood shall be collected as prescribed in §640.4.
(b) Source blood may also be derived from Whole Blood manufactured in accordance with applicable provisions of this subchapter.

§ 640.14 Testing the blood.

Blood from which Red Blood Cells are prepared shall be tested as prescribed in §610.40 of this chapter and §640.5 (a), (b), and (c).

§ 640.15 Segments for testing.

Segments collected in integral tubing shall meet the following standards:

(a) Red Blood Cells Frozen: A cryoprotective substance may be added to the Red Blood Cells for extended manufacturers’ storage at −65 °C or colder, provided the manufacturer submits data considered by the Director, Center for Biologics Evaluation and Research, as adequately demonstrating