ANNEX

Quality system standards and specifications

6. BLOOD COLLECTION, TESTING AND PROCESSING

6.2. Collection of blood and blood components

1. The blood collection procedure shall be designed to ensure that the identity of the donor is verified and securely recorded and that the link between the donor and the blood, blood components and blood samples is clearly established.

2. The sterile blood bag systems used for the collection of blood and blood components and their processing shall be CE-marked or comply with equivalent standards if the blood and blood components are collected in third countries. The batch number of the blood bag shall be traceable for each blood component.

3. Blood collection procedures shall minimise the risk of microbial contamination.

4. Laboratory samples shall be taken at the time of donation and appropriately stored prior to testing.

5. The procedure used for the labelling of records, blood bags and laboratory samples with donation numbers shall be designed to avoid any risk of identification error and mix-up.

6. After blood collection, the blood bags shall be handled in a way that maintains the quality of the blood and at a storage and transport temperature appropriate to further processing requirements.

7. There shall be a system in place to ensure that each donation can be linked to the collection and processing system into which it was collected and/or processed.