Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments (Text with EEA relevance)

Article 1	Definitions
Article 2	Quality system standards and specifications
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ANNEX

Quality system standards and specifications

1. INTRODUCTION AND GENERAL PRINCIPLES

- 1.1. Quality system
 - 1. Quality shall be recognised as being the responsibility of all...
 - 2. The quality system encompasses quality management, quality assurance, continuous quality...
 - 3. The quality system shall ensure that all critical processes are...
- 1.2. Quality assurance
 - 1. All blood establishments and hospital blood banks shall be supported...
 - 2. All procedures, premises, and equipment that have an influence on...

2. PERSONNEL AND ORGANISATION

- 1. Personnel in blood establishments shall be available in sufficient numbers...
- 2. All personnel in blood establishments shall have up to date...
- 3. All personnel in blood establishments shall receive initial and continued...
- 4. The contents of training programmes shall be periodically assessed and...
- 5. There shall be written safety and hygiene instructions in place...

3 PREMISES

- 3.1. General
- 3.2. Blood donor area
- 3.3. Blood collection area
- 3.4. Blood testing and processing areas
- 3.5. Storage area
 - 1. Storage areas shall provide for properly secure and segregated storage...
 - 2. Provisions shall be in place in the event of equipment...
- 3.6. Waste disposal area

4. EQUIPMENT AND MATERIALS

- 1. All equipment shall be validated, calibrated and maintained to suit...
- 2. Equipment shall be selected to minimise any hazard to donors,...
- 3. Only reagents and materials from approved suppliers that meet the...

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- 4. Inventory records shall be retained for a period acceptable to...
- 5. When computerised systems are used, software, hardware and back-up procedures...

5. DOCUMENTATION

- 1. Documents setting out specifications, procedures and records covering each activity...
- 2. Records shall be legible and may be handwritten, transferred to...
- 3. All significant changes to documents shall be acted upon promptly...

6. BLOOD COLLECTION, TESTING AND PROCESSING

- 6.1. Donor eligibility
 - 1. Procedures for safe donor identification, suitability interview and eligibility assessment...
 - 2. The donor interview shall be conducted in such a way...
 - 3. The donor suitability records and final assessment shall be signed...
- 6.2. Collection of blood and blood components
 - 1. The blood collection procedure shall be designed to ensure that...
 - 2. The sterile blood bag systems used for the collection of...
 - 3. Blood collection procedures shall minimise the risk of microbial contamination....
 - 4. Laboratory samples shall be taken at the time of donation...
 - 5. The procedure used for the labelling of records, blood bags...
 - 6. After blood collection, the blood bags shall be handled in...
 - 7. There shall be a system in place to ensure that...

6.3. Laboratory testing

- 1. All laboratory testing procedures shall be validated before use.
- 2. Each donation shall be tested in conformity with the requirements...
- 3. There shall be clearly defined procedures to resolve discrepant results...
- 4. There shall be data confirming the suitability of any laboratory...
- 5. The quality of the laboratory testing shall be regularly assessed...
- 6. Blood group serology testing shall include procedures for testing specific...

6.4. Processing and validation

- 1. All equipment and technical devices shall be used in accordance...
- 2. The processing of blood components shall be carried out using...

6.5. Labelling

- 1. At all stages, all containers shall be labelled with relevant...
- 2. The labelling system for the collected blood, intermediate and finished...
- 3. For autologous blood and blood components, the label also shall...

6.6. Release of blood and blood components

- 1. There shall be a safe and secure system to prevent...
- 2. Before release, blood and blood components shall be kept administratively...
- 3. In the event that the final component fails release due...

7. STORAGE AND DISTRIBUTION

- 1. The quality system of the blood establishment shall ensure that,...
- 2. Procedures for storage and distribution shall be validated to ensure...
- 3. Autologous blood and blood components as well as blood components...
- 4. Appropriate records of inventory and distribution shall be kept.
- 5. Packaging shall maintain the integrity and storage temperature of blood...

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- 6. Return of blood and blood components into inventory for subsequent...
- 8. CONTRACT MANAGEMENT
- 9. NON-CONFORMANCE
 - 9.1. Deviations
 - 9.2. Complaints
 - 9.3. Recall
 - 1. There shall be personnel authorised within the blood establishment to...
 - 2. An effective recall procedure shall be in place, including a...
 - 3. Actions shall be taken within pre-defined periods of time and...
 - 9.4. Corrective and preventive actions
 - 1. A system to ensure corrective and preventive actions on blood...
 - 2. Data shall be routinely analysed to identify quality problems that...
 - 3. All errors and accidents shall be documented and investigated in...

10. SELF-INSPECTION, AUDITS AND IMPROVEMENTS

- 1. Self-inspection or audit systems shall be in place for all...
- 2. All results shall be documented and appropriate corrective and preventive...

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- (1) OJ L 33, 8.2.2003, p. 30.
- (2) OJ L 203, 21.7.1998, p. 14.
- (3) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).
- (4) OJ L 262, 14.10.2003, p. 22.
- **(5)** OJ L 91, 30.3.2004, p. 25.