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)

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...

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...

(**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.