

Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (Text with EEA relevance)

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ANNEX I
DEFINITIONS

1. 'Autologous donation' means blood and blood components collected from an...
2. 'Allogeneic donation' means blood and blood components collected from an...
3. 'Validation' means the establishment of documented and objective evidence that...
4. 'Whole blood' means a single blood donation.
5. 'Cryopreservation' means prolongation of the storage life of blood components...
6. 'Plasma' means the liquid portion of the blood in which...
7. 'Cryoprecipitate' means a plasma component prepared from plasma, fresh-frozen, by...
8. 'Washed' means a process of removing plasma or storage medium...
9. 'Red cells' means the red cells from a single whole...
10. 'Red cells, buffy coat removed' means the red cells from...
11. 'Red cells, leucocyte-depleted' means the red cells from a single...
12. 'Red cells in additive solution' means the red cells from...
13. 'Additive solution' means a solution specifically formulated to maintain beneficial...

14. 'Red cells, buffy coat removed, in additive solution' means the...
15. 'Buffy coat' means a blood component prepared by centrifugation of...
16. 'Red cells, leucocyte-depleted, in additive solution' means the red cells...
17. 'Red cells, apheresis' means the red cells from an apheresis...
18. 'Apheresis' means a method of obtaining one or more blood...
19. 'Platelets, apheresis' means a concentrated suspension of blood platelets obtained...
20. 'Platelets, apheresis, leucocyte-depleted' means a concentrated suspension of blood platelets,...
21. 'Platelets, recovered, pooled' means a concentrated suspension of blood platelets,...
22. 'Platelets, recovered, pooled, leucocyte-depleted' means a concentrated suspension of blood...
23. 'Platelets, recovered, single unit' means a concentrated suspension of blood...
24. 'Platelets, recovered, single unit, leucocyte-depleted' means a concentrated suspension of...
25. 'Plasma, fresh-frozen' means the supernatant plasma separated from a whole...
26. 'Plasma, cryoprecipitate-depleted for transfusion' means a plasma component prepared from...
27. 'Granulocytes, apheresis' means a concentrated suspension of granulocytes obtained by...
28. 'Statistical process control' means a method of quality control of...

ANNEX II

INFORMATION REQUIREMENTS

PART A

Information to be provided to prospective donors of blood or blood components

1. Accurate educational materials, which are understandable for members of the...
2. For both allogeneic and autologous donations, the reasons for requiring...
3. Information on the protection of personal data: no unauthorised disclosure...
4. The reasons why individuals are not to make donations which...
5. Specific information on the nature of the procedures involved either...

6. Information on the option for donors to change their mind...
7. The reasons why it is important that donors inform the...
8. Information on the responsibility of the blood establishment to inform...
9. Information why unused autologous blood and blood components will be...
10. Information that test results detecting markers for viruses, such as...
11. Information on the opportunity for donors to ask questions at...

PART B

Information to be obtained from donors by blood establishments at every donation

1. Identification of the donor
2. Health and medical history of the donor
3. Signature of the donor

ANNEX III

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

1. ACCEPTANCE CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS...
 - 1.1. Age and body weight of donors
 - 1.2. Haemoglobin levels in donor's blood
 - 1.3. Protein levels in donor's blood
 - 1.4. Platelet levels in donor's blood
2. DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS...
 - 2.1. Permanent deferral criteria for donors of allogeneic donations
 - 2.2. Temporary deferral criteria for donors of allogeneic donations
 - 2.2.1. Infections
 - Duration of deferral period
 - 2.2.2. Exposure to risk of acquiring a transfusion-transmissible infection
 - 2.2.3. Vaccination
 - 2.2.4. Other temporary deferrals
 - 2.3. Deferral for particular epidemiological situations
 - 2.4. Deferral criteria for donors of autologous donations

ANNEX IV

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

1. STORAGE
 - 1.1. Liquid storage

- 1.2. Cryopreservation
2. TRANSPORT AND DISTRIBUTION
3. ADDITIONAL REQUIREMENTS FOR AUTOLOGOUS DONATIONS
 - 3.1. Autologous blood and blood components must be clearly identified as...
 - 3.2. Autologous blood and blood components must be labelled as required...

ANNEX V

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

1. THE BLOOD COMPONENTS
2. QUALITY CONTROL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS
 - 2.1. Blood and blood components must comply with the following technical...
 - 2.2. Appropriate bacteriological control of the collection and manufacturing process must...
 - 2.3. Member States must take all necessary measures to ensure that...
 - 2.4. For autologous donations, the measures marked with an asterisk (*)...

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (1) [OJ L 33, 8.2.2003, p. 30.](#)
- (2) [OJ L 203, 21.7.1998, p. 14.](#)