Pharmaceuticals Policy and Law 7 (2005,2006) 311–327
IOS Press

Appendix 3

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*)

(*Official Journal of the European Union, L91, pp. 25–39, 30.3.2004*)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, [1] and in particular points (b) to (g) of the second paragraph of Article 29 thereof,

Whereas:

(1) Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements.

(3) This Directive lays down those technical requirements, which take account of Council Recommendation 98/ 463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community, [2] certain recommendations of the Council of Europe, the opinion of the Scientific Committee for Medicinal Products and Medical Devices, the monographs of the European Pharmacopoeia, particularly in respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products and recommendations of the World Health Organisation (WHO), as well as international experience in this field.

[1] OJ L 33, 8.2.2003, p. 30.
[2] OJ L 203, 21.7.1998, p. 14.

(4) Blood and blood components imported from third countries, including those used as starting material/raw material for the manufacture of medicinal products derived from human blood and human plasma, should meet the quality and safety requirements set out in this Directive.
(5) With regard to blood and blood components collected for the sole purpose of, and exclusive use in, autologous transfusion (autologous donation), specific technical requirements should be laid down, as required by Article 2(2) of Directive 2002/98/EC. Such donations should be clearly identified and kept separate from other donations to ensure that they are not used for transfusion to other patients.
(6) It is necessary to determine common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.
(7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

For the purposes of this Directive, the definitions set out in Annex I shall apply.

Article 2

Provision of information to prospective donors

Member States shall ensure that blood establishments provide prospective donors of blood or blood components with the information set out in Part A of Annex II.

Article 3

Information required from donors

Member States shall ensure that upon agreement of willingness to commence the donation of blood or blood components, donors provide the information set out in Part B of Annex II to the blood establishment.

Article 4

Eligibility of donors

Blood establishments shall ensure that donors of whole blood and blood components comply with the eligibility criteria set out in Annex III.

Article 5

Storage, transport and distribution conditions for blood and blood components

Blood establishments shall ensure that the storage, transport and distribution conditions for blood and blood components comply with the requirements set out in Annex IV.

Article 6

Quality and safety requirements for blood and blood components

Blood establishments shall ensure that the quality and safety requirements for blood and blood components comply with the requirements set out in Annex V.

Article 7

Autologous donations

1. Blood establishments shall ensure that autologous donations comply with the requirements set out in Directive 2002/98/EC and the specific requirements set out in this Directive.
2. Autologous donations shall be clearly identified as such and shall be kept separate from allogeneic donations.

Article 8

Validation

Member States shall ensure that all testing and processes referred to in Annexes II to V are validated.

Article 9

Transposition

1. Without prejudice to Article 7 of Directive 2002/98/EC, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 8 February 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.
2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 10

Entry into force

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 11

Addressees

This Directive is addressed to the Member States.
Done at Brussels, 22 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

DEFINITIONS
(as referred to in Article 1)

1. 'Autologous donation' means blood and blood components collected from an individual and intended solely for subsequent autologous transfusion or other human application to that same individual.
2. 'Allogeneic donation' means blood and blood components collected from an individual and intended for transfusion to another individual, for use in medical devices or as starting material/raw material for manufacturing into medicinal products.
3. 'Validation' means the establishment of documented and objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
4. 'Whole blood' means a single blood donation.
5. 'Cryopreservation' means prolongation of the storage life of blood components by freezing.
6. 'Plasma' means the liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh-frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion. It may be used for the manufacture of medicinal products derived from human blood and human plasma or used in the preparation of pooled platelets, or pooled, leucocyte-depleted platelets. It may also be used for re-suspension of red cell preparations for exchange transfusion or perinatal transfusion.
7. 'Cryoprecipitate' means a plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and re-suspension of the precipitated proteins in a small volume of the plasma.

8. 'Washed' means a process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed and replaced following further centrifugation of the suspension. The centrifugation, decanting, replacing process may be repeated several times.

9. 'Red cells' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed.

10. 'Red cells, buffy coat removed' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed.

11. 'Red cells, leucocyte-depleted' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed.

12. 'Red cells in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. A nutrient/preservative solution is added.

13. 'Additive solution' means a solution specifically formulated to maintain beneficial properties of cellular components during storage.

14. 'Red cells, buffy coat removed, in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed. A nutrient/preservative solution is added.

15. 'Buffy coat' means a blood component prepared by centrifugation of a unit of whole blood, and which contains a considerable proportion of the leucocytes and platelets.

16. 'Red cells, leucocyte-depleted, in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed. A nutrient/preservative solution is added.

17. 'Red cells, apheresis' means the red cells from an apheresis red cell donation.

18. 'Apheresis' means a method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.

19. 'Platelets, apheresis' means a concentrated suspension of blood platelets obtained by apheresis.

20. 'Platelets, apheresis, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by apheresis, and from which leucocytes are removed.

21. 'Platelets, recovered, pooled' means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation.

22. 'Platelets, recovered, pooled, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling

the platelets from the units during or after separation, and from which leucocytes are removed.

23. 'Platelets, recovered, single unit' means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood.

24. 'Platelets, recovered, single unit, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leucocytes are removed.

25. 'Plasma, fresh-frozen' means the supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored.

26. 'Plasma, cryoprecipitate-depleted for transfusion' means a plasma component prepared from a unit of plasma, freshfrozen. It comprises the residual portion after the cryoprecipitate has been removed.

27. 'Granulocytes, apheresis' means a concentrated suspension of granulocytes obtained by apheresis.

28. 'Statistical process control' means a method of quality control of a product or a process that relies on a system of analysis of an adequate sample size without the need to measure every product of the process.

ANNEX II

INFORMATION REQUIREMENTS
(as referred to in Articles 2 and 3)

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 general public, about the essential nature of blood, the blood donation procedure, the components derived from whole blood and apheresis donations, and the important benefits to patients.

2. For both allogeneic and autologous donations, the reasons for requiring an examination, health and medical history, and the testing of donations and the significance of 'informed consent'. For allogeneic donations, self-deferral, and temporary and permanent deferral, and the reasons why individuals are not to donate blood or blood components if there could be a risk for the recipient. For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individual whether as donor or recipient of the autologous blood or blood components.

3. Information on the protection of personal data: no unauthorised disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed.

4. The reasons why individuals are not to make donations which may be detrimental to their health.

5. Specific information on the nature of the procedures involved either in the allogeneic or autologous donation process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements.

6. Information on the option for donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during the donation process, without any undue embarrassment or discomfort.

7. The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion.

8. Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show any abnormality of significance to the donor's health.

9. Information why unused autologous blood and blood components will be discarded and not transfused to other patients.

10. Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents, will result in donor deferral and destruction of the collected unit.

11. Information on the opportunity for donors to ask questions at any time.

PART B

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

1. Identification of the donor

Personal data uniquely, and without any risk of mistaken identity, distinguishing the donor, as well as contact details.

2. Health and medical history of the donor

Health and medical history, provided on a questionnaire and through a personal interview performed by a qualified healthcare professional, that includes relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves.

3. Signature of the donor

Signature of the donor, on the donor questionnaire, countersigned by the health care staff member responsible for obtaining the health history confirming that the donor has:

(a) read and understood the educational materials provided;
(b) had an opportunity to ask questions;
(c) been provided with satisfactory responses to any questions asked;

(d) given informed consent to proceed with the donation process;
(e) been informed, in the case of autologous donations, that the donated blood and blood components may not be sufficient for the intended transfusion requirements; and
(f) acknowledged that all the information provided by the donor is true to the best of his/her knowledge.

ANNEX III

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS
(as referred to in Article 4)

1. ACCEPTANCE CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Under exceptional circumstances, individual donations from donors who do not comply with the following criteria may be authorised by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions in Articles 11, 12, and 13 of Directive 2002/98/EC.

The following criteria do not apply to autologous donations.

1.1. Age and body weight of donors

Age	18 to 65 years	
	17 to 18 years	– unless classified as a minor by law, or with written consent of parent or legal guardian in accordance with law
	First time donors over 60 years	– at the discretion of the physician in the blood establishment
	Over 65 years	– with permission of the physician in the blood establishment, given annually
Body weight	$\geqslant$ 50 kg for donors either of whole blood or apheresis blood components	

1.2. Haemoglobin levels in donor's blood

Haemoglobin	for females $\geqslant$ 125 g/l	for males $\geqslant$ 135 g/l	*Applicable to allogeneic donors of whole blood and cellular components*

1.3. Protein levels in donor's blood

Protein	$\geqslant$ 60 g/l	*The protein analysis for apheresis plasma donations must be performed at least annually*

1.4. Platelet levels in donor's blood

Platelets	Platelet number greater than or equal to $150 \times 109/l$	*Level required for apheresis platelet donors*

2. DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

The tests and deferral periods indicated by an asterisk (*) *are not required when the donation is used exclusively for plasma for fractionation.*

2.1. Permanent deferral criteria for donors of allogeneic donations

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure
Central nervous system disease	A history of serious CNS disease
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy
Repeated episodes of syncope, or a history of convulsions	Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions
Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases	Prospective donors with serious active, chronic, or relapsing disease
Diabetes	If being treated with insulin
Infectious diseases	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune Hepatitis C HIV-1/2 HTLV I/II Babesiosis (*) Kala Azar (visceral leishmaniasis) (*) Trypanosomiasis cruzi (Chagas' disease) (*)
Malignant diseases	Except *in situ* cancer with complete recovety
Transmissible spongiform encephalopathies (*TSEs*), (*e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease*)	Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jacob disease, further precautionary measures may be recommended.
Intravenous (*IV*) *or intramuscular* (*IM*)*drug use*	Any history of non-prescribed IV or IM drug use, including bodybuilding steroids or hormones
Xenotransplant recipients	
Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood

2.2. Temporary deferral criteria for donors of allogeneic donations

2.2.1. Infections

Duration of deferral period

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

However, the following deferral periods shall apply for the infections listed in the table:

Brucellosis (*)	2 years following the date of full recovery
Osteomyelitis	2 years after confirmed cured
Q fever (*)	2 years following the date of confirmed cured
Syphilis (*)	1 year following the date of confirmed cured
Toxoplasmosis (*)	6 months following the date of clinical recovery
Tuberculosis	2 years following the date of confirmed cured
Rheumatic fever	2 years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever $>°$C	2 weeks following the date of cessation of symptoms
Flu-like illness	2 weeks after cessation of symptoms
Malaria (*)	
– individuals who have lived in a malarial area within the first five years of life	3 years following return from last visit to any endemic area, provided person remains symptom free; may be reduced to 4 months if an immunologic or molecular genomic test is negative at each donation
– individuals with a history of malaria	3 years following cessation of treatment and absence of symptoms. Accept thereafter only if an immunologic or molecular genomic test is negative
– asymptomatic visitors to endemic areas	6 months after leaving the endemic area unless an immunologic or molecular genomic test is negative
– individuals with a history of undiagnosed febrile illness during or within six months of a visit to an endemic area	3 years following resolution of symptoms; may be reduced to 4 months if an immunologic or molecular test is negative
West Nile Virus (WNV) (*)	28 days after leaving an area with ongoing transmission of WNV to humans

2.2.2. Exposure to risk of acquiring a transfusion-transmissible infection

–Endoscopic examination using flexible instruments, –mucosal splash with blood or needlestick injury, –transfusion of blood components, –tissue or cell transplant of human origin, –major surgery, –tattoo or body piercing, –acupuncture unless performed by a qualified practitioner and with sterile single-use needles, –persons at risk due to close household contact with persons with hepatitis B.	Defer for 6 months, or for 4 months provided a NAT test for hepatitis C is negative

Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests

2.2.3. Vaccination

Attenuated viruses or bacteria	4 weeks
Inactivated/killed viruses, bacteria or rickettsiae	No deferral if well
Toxoids	No deferral if well
Hepatitis A or hepatitis B vaccines	No deferral if well and if no exposure
Rabies	No deferral if well and if no exposure If vaccination is given following exposure defer for one year
Tick-borne encephalitis vaccines	No deferral if well and if no exposure

2.2.4. Other temporary deferrals

Pregnancy	6 months after delivery or termination, except in exceptional circumstances and at the discretion of a physician
Minor surgery	1 week
Dental treatment	Minor treatment by dentist or dental hygienist – defer until next day (NB: Tooth extraction, root-filling and similar treatment is considered as minor surgery)
Medication	Based on the nature of the prescribed medicine, its mode of action and the disease being treated

2.3. Deferral for particular epidemiological situations

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation (These deferrals should be notified by the competent authority to the European Commission with a view to Community action)

2.4. Deferral criteria for donors of autologous donations

Serious cardiac disease	Depending on the clinical setting of the blood collection
Persons with or with a history of – hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune – hepatitis C – HIV-1/2 – HTLV I/II Active bacterial infection	Member States may, however, establish specific provisions for autologous donations by such persons

ANNEX IV

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS
(as referred to in Article 5)

1. STORAGE

1.1. Liquid storage

Component	Temperature of storage	Maximum storage time
Red cell preparations and whole blood (if used for transfusion as whole blood)	+ 2 to + 6°C	28 to 49 days according to the processes used for collection, processing and storage
Platelet preparations	+ 20 to + 24°C	5 days; may be stored for 7 days in conjunction with detection or reduction of bacterial contamination
Granulocytes	+ 20 to + 24°C	24 hours

1.2. Cryopreservation

Component	Storage conditions and duration
Red blood cells	Up to 30 years according to processes used for collection, processing and storage
Platelets	Up to 24 months according to processes used for collection, processing and storage
Plasma and cryoprecipitate	Up to 36 months according to processes used for collection, processing and storage
Cryopreserved red blood cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after thawing to depend on the method used.	

2. TRANSPORT AND DISTRIBUTION

Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product.

3. ADDITIONAL REQUIREMENTS FOR AUTOLOGOUS DONATIONS

3.1. Autologous blood and blood components must be clearly identified as such and stored, transported and distributed separately from allogeneic blood and blood components.

3.2. Autologous blood and blood components must be labelled as required by Directive 2002/98/EC and in addition the label must include the identification of the donor and the warning ‘FOR AUTOLOGOUS TRANSFUSION ONLY’.

ANNEX V

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS
(as referred to in Article 6)

1. THE BLOOD COMPONENTS

1. Red cell preparations	The components listed in points 1.1 to 1.8 may be further processed within blood establishments and must be labelled accordingly
1.1	Red cells
1.2	Red cells, buffy coat removed
1.3	Red cells, leucocyte-depleted
1.4	Red cells, in additive solution
1.5	Red cells, buffy coat removed, in additive solution
1.6	Red cells, leucocyte-depleted, in additive solution
1.7	Red cells, apheresis
1.8	Whole blood
2. Platelet preparations	The components listed in points 2.1 to 2.6 may be further processed within blood establishments and must be labelled accordingly
2.1	Platelets, apheresis
2.2	Platelets, apheresis, leucocyte-depleted
2.3	Platelets, recovered, pooled
2.4	Platelets, recovered, pooled, leucocyte-depleted
2.5	Platelets, recovered, single unit
2.6	Platelets, recovered, single unit, leucocyte-depleted
3. Plasma preparations	The components listed in 3.1 to 3.3 may be further processed within blood establishments and must be labelled accordingly.
3.1	Fresh-frozen plasma
3.2	Fresh-frozen plasma, cryoprecipitate-depleted
3.3	Cryoprecipitate
4.	Granulocytes, apheresis
5. New components	Quality and safety requirements for new blood components must be regulated by the competent national authority. Such new components must be notified to the European Commission with a view to Community action

2. QUALITY CONTROL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

2.1. Blood and blood components must comply with the following technical quality measurements and meet the acceptable results.

2.2. Appropriate bacteriological control of the collection and manufacturing process must be performed.

2.3. Member States must take all necessary measures to ensure that all imports of blood and blood components from third countries, including those used as starting material/raw material for the manufacture of medicinal products derived from human

blood or human plasma, shall meet equivalent standards of quality and safety to the ones laid down in this Directive.

2.5. For autologous donations, the measures marked with an asterisk (*) are recommendations only.

Component	**Quality measurements required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measurements**
Red cells	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, buffy coat removed	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, leucocytedepleted	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Leucocyte content	Less than 1×106 per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, buffy coat removed, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life

Component	**Quality measurements required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measurements**
Red cells, leucocyte-depleted, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Leucocyte content	Less than 1×106 per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Whole blood	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis 450 ml $+/-$ 50 l For paediatric autologous whole blood collections – not to exceed 10.5 ml per kg body weight
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Platelets, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within limits that comply with validated preparation and preservation conditions
	pH	6.4–7.4 corrected for 22°C, at the end of the shelf life
Platelets, apheresism, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1×106 per unit
	pH	6.4–7.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, pooled	Volume	Valid for storage characteristics to maintain product within specifications for pH

Component	**Quality measurements required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measurements**
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 0.2 × 109 per single unit (platelet-rich plasma method) Less than 0.05 × 109 per single unit (buffy coat method)
	pH	6.4–7.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, pooled, leucocytedepleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1 × 106 per pool
	pH	6.4–7.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, single unit	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 0.2 × 109 per single unit (platelet-rich plasma method) Less than 0,05 × 109 per single unit (buffy coat method)
	pH	6.4–7.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, single unit, leucocytedepleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leukocyte content	Less than 1 × 106 per unit
	pH	6.4–7.4 corrected for 22°C, at the end of the shelf life
Plasma, fresh-frozen	Volume	Stated volume +/− 10%
	Factor VIIIc (*)	Average (after freezing and thawing): 70% or more of the value of the freshly collected plasma unit

Component	**Quality measurements required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measurements**
	Total protein (*)	Not less than 50 g/l
	Residual cellular content (*)	Red cells: less than 6.0 × 109/l Leucocytes: less than 0.1 × 109/l Platelets: less than 50 × 109/l
Plasma, fresh-frozen, cryoprecipitate-depleted	Volume	Stated volume: +/− 10%
	Residual cellular content (*)	Red cells: less than 6.0 × 109/l Leucocytes: less than 0.1 × 109/l Platelets: less than 50 × 109/l
	Cryoprecipitate Fibrinogen content (*)	Greater than or equal to 140 mg per unit
	Factor VIIIc content (*)	Greater than or equal to 70 international units per unit
Granulocytes, apheresis	Volume	Less than 500 ml
	Granulocyte content	Greater than 1 × 1010 granulocytes per unit