L.N. 7 of 2016

HUMAN BLOOD AND TRANSPLANTS ACT (CAP. 483)

Blood (Quality and Safety) (Amendment) Regulations, 2016

BY virtue of article 16 of the Human Blood and Transplants Act the Parliamentary Secretary for Health, after consultation with the Licensing Authority, has made the following regulations:

Title and scope.

1. (1) The title of these regulations is the Blood (Quality and Safety) (Amendment) Regulations, 2016 and these regulations shall be read and construed as one with the Blood (Quality and Safety) Regulations, hereinafter referred to as the "principal regulations".

S.L. 483.02

(2) The scope of these regulations is to amend the principle regulations and transpose Commission Directive 2014/110/EU of 17th December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donation.

Amends regulation 3 of the principal regulations.

2. In regulation 3 of principal regulations for the "Annex I to Directive 2002/98/EC and any amendments thereto", there shall be substituted the words "Schedule I".

Amends regulation 5 of the principal regulations.

3. Regulation 5 of the principal regulations shall be amended as follows:

(a) sub-regulation (1) thereof shall be amended as follows:

(i) in paragraph (b) thereof for the words "Annexes to Directive 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and the Council as regards Community Standards and specification relating to a quality system for Blood Establishments;" there shall be substituted the words "Schedule IX"; and

(ii) in paragraph (c) thereof for the words "Annexes II and V to Directive 2004/33/EC" there shall be substituted the words "Schedules V and VIII".

(b) sub-regulation (2) thereof shall be amended as follows:

(i) in paragraph (a) thereof for the words "Annex II to Directive 2004/33/EC and any amendments

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thereto" there shall be substituted the words "Schedule V";

(ii) in paragraph (b) thereof for the words "Annex II to Directive 2004/33/EC and any amendments thereto" there shall be substituted the words "Schedule V"; and

(iii) in paragraph (d) thereof for the words "Annex III to Directive 2004/33/EC and any amendments thereto" there shall be substituted the words "Schedule VI".

(c) sub-regulation (3) thereof shall be amened as follows:

(i) in paragraph (a) thereof for the words "Annex IV to Directive 2002/98/EC and any amendments thereto" there shall be substituted the words "Schedule IV";

(ii) in paragraph (b) thereof for the words "Annex IV to Directive 2004/33/EC and any amendments thereto" there shall be substituted the words "Schedule VII"; and

(iii) in paragraph (c) thereof for the words "Annex V to Directive 2004/33/EC and any amendments thereto." there shall be substituted the words "Schedule VIII.";

(d) in sub-regulation (4) thereof for the words "Annexes II and IV to Directive 2002/98/EC and Annexes II Part A and Part B and Annex III to Directive 2004/33/EC" there shall be substituted the words Schedules II, IV, V and VI".

Amends regulation 6 of the principal regulations.

4. In sub-regulation (1) of regulation 6 of the principal regulations for the words "Annex III to Directive 2002/98/EC" there shall be substituted the words "Schedule III".

Amends regulation 7 of the principal regulations.

5. Regulation 7 of the principal regulations shall be amended as follows:

(a) paragraph (c) thereof for the words the words "Annex IV to Directive 2004/33/EC and any amendments thereto" there shall be substituted the words "Schedule VII"; and

(b) paragraph (h) thereof for the words the words "Annex IV to Directive 2004/33/EC and any amendments thereto" there shall be substituted the words "Schedule VII".

Adds new Schedules to the principal regulations.

6. Immediately after regulation 9 of the principal regulations, there shall be added the following new Schedules:

SCHEDULE I

INFORMATION TO BE PROVIDED BY BLOOD ESTABLISHMENT TO THE COMPETENT AUTHORITY FOR THE PURPOSES OF DESIGNATION, AUTHORISATION, ACCREDITATION OR LICENSING

(Regulation 3)

Part A

General Information:

- Identification of the blood establishment;
- Name, qualification and contact details of responsible persons;
- A list of hospital blood banks which it supplies.

Part B

- A description of the quality system, to include:
- Documentation, such as an organisation chart, including responsibilities of responsible persons and reporting relationships;
- Documentation such as site master file or quality manual describing the quality system in accordance with Schedule IX;
- Number and qualification of personnel;
- Hygiene provisions;
- Premises and equipment;

- List of standard operating procedures for recruitment, retention and assessment of donors, for processing and testing, distribution and recall of blood components and for the reporting and recording of serious adverse reactions and events.

SCHEDULE II

REPORT OF THE BLOOD ESTABLISHMENT'S PRECEDING YEAR'S ACTIVITY

The annual report will include:

- Total number of donors who give blood and blood components;
- Total number of donations;
- An updated list of the hospital blood banks which it supplies;
- Total number of whole donations not used;
- Number of each component produced and distributed;
- Incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components;
- Number of product recalls;
- Number of serious adverse events and reactions reported.

SCHEDULE III

LABELLING REQUIREMENTS

The label on the component must contain the following information:

- The official name of the component;
- The volume or weight or number of cells in the component (as appropriate);
- The unique numeric or alphanumeric donation

identification;

- The name of producing blood establishment;

- The ABO Group (not required of plasma intended only for fractionation);

- The Rh D Group, either Rh D positive or Rh D negative (not required for plasma intended only for fractionation);

- The date or time of expiry (as appropriate);

- The temperature of storage;

- The name, composition and volume of anticoagulant and/ or additive solution (if any).

SCHEDULE IV

BASIC TESTING REQUIREMENTS OR WHOLE BLOOD AND PLASMA DONATIONS

The following tests must be performed for whole blood and apheresis donations including autologous predeposit donations:

- ABO Group (not required for plasma intended only for fractionation);

- Rh D Group (not required for plasma intended only for fractionation);

Testing for the following infections in the donors:

- Hepatitis B (HBs-Ag)

- Hepatitis C (Anti-HCV)

- HIV 1 and 2 (Anti-HIV 1 and 2)

Additional tests may be required for specific components or donors or epidemiological situations.

SCHEDULE V
INFORMATION REQUIREMENTS

(Regulation 5)

Part A

Information to be provided to prospective donors of blood and 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.

SCHEDULE VI

ELIGIBITITY CIRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

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

Under exceptional circumstances, individual donations from donors who do not comply with the following criteria may be authorised to donate blood by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions in accordance with regulation 5.

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 of legal curator

	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	≥ 50 kg for doors either for whole blood or apheresis blood components	

1.2 Haemoglobin levels in donor's blood

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

1.3 Protein levels in donor's blood

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

1.4 Platelet level in donor's blood

Platelets	Platelet number greater than or equal to 150 x 10^9/ l	Level required for apheresis platelet donor

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 donor 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 and 2
	HTLV I/II
	Babesiosis (*)
	Kala Azar (visceral leishmaniasis) (*)
	Trypanosomiasis cruzi (Chagas' disease)(*)
Malignant diseases	Except *in situ* cancer with complete recovery
Transmissable spongiform Encephalapathies (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 medicine made from human pituitary glands. For variant Creutzfeld Jacob diseases, further precautionary measures may be recommended.
Intravenous (IV) or intramuscular (IM) drug use	Any history of non-prescribed IV or IM drug use, including body-building 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 donor 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 recover
Osteomyelitis	2 years after confirmed cured
Q fever (*)	2 years following the date of confirmed cure
Syphilis (*)	1 year following the date of confirmed cure
Toxoplasmosis (*)	6 months following the date of clinical recovery
Tuberculosis	2 years following the date of confirmed cure
Rheumatic fever	2 weeks following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever > 0C	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 immunological or molecular genomic test is negative
- asymptomatic visitors of 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 o 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 a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative'

2.2.2 Exposure to risk of acquiring a transfusion-transmissible infection

- Endoscopic examination using flexible instruments, - Mucosal splash with blood or needle stick 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 or with sterile single- use needles, - person 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 who behaviour or activity places them at risk of acquiring 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 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 deferral should be notified by the competent authority to the European Commission with a view to Community action)

2.4 Deferral criteria for donor of autologous donations

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

SCHEDULE VII
STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

(Regulations 3 and 7)

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^{0}C	**28** to **49** days according to the process used for collection, processing and storage
Platelet preparations	+ 20 to + 24^{0}C	**5** days; may be stored for 7 days in conjunction with detection or reduction of bacterial contamination
Granulocytes	+ 20 to + 24^{0}C	**24** hours

1.2 Cryopreservation

Components	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
Cyropreserved red blood cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after having to depend on the method used.	

2. TRANSPOSRT 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 Schedules I, II, III, IV and in addition the label must include the identification of the donor and the warning 'FOR AUTOLOGOUS TRANSFUSION ONLY'.

SCHEDULE VIII

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

(Regulation 3)

1. THE BLOOD COMPONENTS

1. Red cell preparations	The components listed in points 1.1 to 1.8 may be further processed within blood establishment 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, depleted
2.5	Platelets, recovered, single unit
2.6	Platelets, recovered, single unit, leucocyte-depleted
3.Plasma preperations	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

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

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

2.3 The competent authority 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 these regulations.

2.4 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 specification 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 specification of 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, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40g per unit
	Luecocyte content	Less than 1×10^6 per unit
	Haemolysis	Less than 0,8% of red cell mass at the end of the shelf life
Red cells, in additive soution	Volume	Valid for storage characteristics to maintain product within specification 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

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, buffy coat removed, in additive solution	Volume	Valid for storage characteristics to maintain product within specification for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43g per unit
	Haemolysis	Less than 0,8% of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted, in additive solution	Volume	Valid for storage characteristics to maintain product within specification for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40g per unit
	Leucocyte content	Less than 1×10^6 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 specification 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 ml 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

Component	**Quality measurements required** ***The required frequency of sampling for all measurements shall be determined using statistical process control***	**Acceptable results for quality measurements**
Platelets, apherisis	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 22^0C, at the end of the shelf life
Platelets, apheresis, 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 1×10^6 per unit
	pH	6,4 – 7,4 corrected for 22^0C, at the end of the shelf life
Platelets, recovered, pooled	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
	Leukocyte content	Less than $0,2 \times 10^9$ per single unit (platelet-rich plasma method) Less than $0,05 \times 10^9$ per single unit (buffy coat method)
	pH	6,4 – 7,4 corrected for 22 °C, 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**
Platelets, recovered, pooled leukocyte-depleted	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 1×10^6 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 $0,2 \times 10^9$ per single unit (platelet-rich plasma method) Less than $0,05 \times 10^9$ 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, leukocyte-depleted	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 1×10^6 per unit
	pH	6, 4 -7,4 corrected for 22 °C, 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**
Plasma, fresh-frozen	Volume	Stated volume +/- 10%
	Factor VIII c(*)	Average (after freezing and thawing): 70% or more of the value of the freshly collected plasma unit
	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 × 10^9/l Leucocytes: less than 0,1 × 10^9/l Platelets: less than 50×10^9/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, aphaeresis	Volume	Less than 500 ml
	Granulocyte content	Greater than 1 × 10^{10} granulocytes per unit

SCHEDULE IX
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 persons involved in the processes of the blood establishment with management ensuring a systematic approach towards quality and the implementation and maintenance of a quality system.

2. The quality system encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection.

3. The quality system shall ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications set out in this Schedule. Management shall review that system at regulation intervals to verify its effectiveness and introduce corrective measures if deemed necessary.

1.2 Quality assurance

1. All blood establishments and hospital blood banks shall be supported by a quality assurance function, whether internal or related, in fulfilling quality assurance. That function shall be involved in all quality-related matters and review and approve all appropriate quality related documents.

2. All procedures, premises, and equipment that have an influence on the quality and safety of blood and blood components shall be validated prior to introduction and re-validated at regular intervals determined as a result of these activities.

2. PERSONNEL AND ORGANISATION

1. Personnel in blood establishments shall be available in sufficient numbers to carry out the activities related to the collection, testing, processing, storage and distribution of

blood and blood components and be trained and assessed to be competent to perform their tasks.

2. All personnel in blood establishments shall have up to date job descriptions which clearly set out their tasks and responsibilities. Blood establishments shall assign the responsibility for processing management and quality assurance to different individuals and who function independently.

3. All personnel in blood establishments shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained, Training programmes shall be in place and shall include good practice.

4. The contents of training programmes shall be periodically assessed and the competence of personnel evaluated regularly.

5. There shall be written safety and hygiene instructions in place adapted to the activities to be carried out and are in compliance with Council Directive 89/391/EEC and Directive 2000/54/EC of the European Parliament and the Council.

3. PREMISES

3.1 General

Premises including mobile sites shall be adapted and maintained to suit the activities to be carried out. They shall enable the work to proceed in a logical sequence so as to minimise the risk of errors, and shall allow for effective cleaning and maintenance in order to minimise the risk of contamination.

3.2 Blood donor area

There shall be an area for confidential personal interviews with assessment of individuals to assess their eligibility to donate. This area shall be separated from all processing areas.

3.3 Blood collection area

Blood collection shall be carried out in an area intended for the safe withdrawal of blood from donors,

appropriately equipped for the initial treatment of donors experiencing adverse reactions or injuries from events associated with blood donation, and organised in such a way as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure.

3.4. Blood testing and processing area

There shall be a dedicated laboratory area for testing that is separate from the blood donor and blood components processing area with access restricted to authorised personnel.

3.5 Storage area

1. Storage areas shall provide secure and segregated storage of different categories of blood and blood components and materials including quarantine and units of blood or blood components collected under special criteria (e.g. autologous donation).

2. Provisions shall be in place in the event of equipment or power failure in the main storage facility.

3.6. Waste disposal area

An area shall be designated for the safe disposal of waste, disposal items used during the collection, testing and processing and for rejected blood or blood components.

4. EQUIPMENT AND MATERIALS

1. All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.

2. Equipment shall be selected to minimise any hazard to donors, personnel or blood components.

3. Only reagents and materials from approved supplies that meet the documented requirements and specifications shall be used. Critical materials shall be released by a person qualified to perform this task. Where relevant materials, reagents and equipment shall meet the requirements of Council Directive 93/42/EEC for medical devices and Directive 98/79/EC of the European Parliament and of the Council for in vitro diagnostic

medical devices or comply with equivalent standards in the case of collection in third countries.

4. Inventory records shall be retained for a period acceptable to and agreed with the competent authority.

5. When computerised systems are used, software, hardware and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Hardware and software shall be protected against unauthorised use or unauthorised changes. This back-up procedure shall prevent loss of or damage to data at expected and unexpected down times or function failures.

5. DOCUMENTATION

1. Documents setting out specifications, procedures and records covering each activity performed by the blood establishment shall be in place and kept up to date.

2. Records shall be legible and may be handwritten, transferred to another medium such as microfilm or documented in a computerised system.

3. All significant changes to documents shall be acted upon promptly and shall be reviewed, dated and signed by a person authorised to perform this task.

6. BLOOD COLLECTION, TESTING AND PROCESSING

6.1 Donor eligibility

1. Procedures for safe donor identification, suitability interview and eligibility assessment shall be implemented and maintained. They shall take place before each donation and comply with requirements set out in Schedule V and Schedule VI.

2. The donor interview shall be conducted in such a way as to ensure confidentiality.

3. The donor suitability records and final assessment shall be signed by a qualified health professional.

6.2 Collection of blood and blood component

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 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.

6.3. Laboratory testing

1. All laboratory testing procedures shall be validated before use.

2. Each donation shall be tested in conformity with requirements laid down in Schedule IV.

3. There shall be clearly defined procedures to resolve discrepant results and ensure that blood and blood components that have a repeatedly reactive result in a serological screening test for infection with the viruses mentioned in Schedule IV shall be excluded from therapeutic use and be stored separately in a dedicated environment. Appropriate confirmatory testing shall take place. In case of confirmed positive results, appropriate donor management shall take place including the

provision of information to the donor and follow-up procedures.

4. There shall be data confirming the suitability of any laboratory reagents used in the testing of donor samples and blood component samples.

5. The quality of the laboratory testing shall be regularly assessed by the participation in a formal system of proficiency testing, such as an external quality assurance programme.

6. Blood group serology testing shall include procedures for testing specific groups of donors (e.g. first time donors, donors with a history of transfusion).

6.4 Processing and validation

1. All equipment and technical devices shall be used in accordance with validated procedures.

2. The processing of blood components shall be carried out using appropriate and validated procedures including measures to avoid the risk of contamination and microbial growth in the prepared blood components.

6.5 Labelling

1. At all stages, all containers shall be labelled with relevant information of their identity. In the absence of a validated computerised system for status control, the labelling shall clearly distinguish released from non-released units of blood and blood components.

2. The labelling system for the collected blood, intermediate and finished blood components and samples must unmistakably identify the type of content, and comply with the labelling and traceability requirements referred to in regulation 6. The label for a final blood component shall comply with the requirements of Schedule III.

3. For autologous blood and blood components, the label shall comply with Schedules I, II and III and the additional requirements for autologous donations specified in Annex VII.

6.6. Release of blood and blood components

1. There shall be a safe and secure system to prevent each single blood and blood component from being released until all mandatory requirements have been fulfilled. Each blood establishment shall be able to demonstrate that each blood or blood component has been formally released by an authorised person. Records shall demonstrate that before a blood component is released, all current declaration forms, relevant medical records and test results meet all acceptance criteria.

2. Before release, blood and blood components shall be kept administratively and physically segregated from released blood and blood components. In the absence of a validated computerised system for status control the label of a unit of blood or blood component shall identify the release status in accordance with 6.5.1.

3. In the event that the final component fails release due to a confirmed positive infection test result, in conformity with the requirements set out in section 6.3.2 and 6.3.3, a check shall be made to ensure that other components from the same donation and components prepare from previous donations given by the donor are identified. There shall be an immediate update of the donor card.

7. STORAGE DISTIRBUTION

1. The quality system of the blood establishment shall ensure that, for blood and blood components intended for the manufacture of medical products, the storage and distribution requirements shall comply with the Medicines Act.

2. Procedures for storage and distribution shall be validated to ensure blood and blood component quality during the entire storage period and to exclude mix-ups of blood components. All transportation and storage actions including receipt and distribution, shall be defined by written procedures and specifications.

3. Autologous blood and blood components as well as blood components collected and prepared for specific purposes shall be stored separately.

4. Appropriate records of inventory and distribution shall be

kept.

5. Packaging shall maintain the integrity and storage temperature of blood and blood components during the distribution and transportation.

6. Return of blood and blood components into inventory for subsequent reissue shall only be accepted when all quality requirements and procedures laid down by the blood establishment to ensure blood component integrity are fulfilled.

8. CONTRACT MANAGEMENT

Tasks that are performed externally shall be defined in a specific written contract.

9. NON-CONFORMANCE

9.1 Deviations

Blood components deviating from required standards set out in Schedule VIII shall be released for transfusion only in exceptional circumstances and with the recorded agreement of the prescribing physician and the blood establishment physician.

9.2 Complaints

All complaints and other information, including serious adverse reactions and serious adverse events, which may suggest that defective blood components have been issued, shall be documented, carefully investigated for causative factors of the defect and, where necessary followed by recall and the implementation of corrective actions to prevent recurrence. Procedures shall be in place to ensure that the competent authorities are notified as appropriate of serious adverse reactions or serious adverse events with regulatory requirements.

9.3 Recall

1. There shall be personnel authorised with the blood establishment to assess the need for blood and blood component recall and to initiate and coordinate the necessary actions.

2. An effective recall procedure shall be in place, including

a description of the responsibilities and actions to be taken. This shall include notification to the competent authority.

3. Actions shall be taken with pre-defined periods of time and shall include tracing all relevant blood components and, where applicable, shall include trace-back. The purpose of the investigations is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from that donor, as well as to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk.

9.4 Corrective and preventive actions

1. A system to ensure corrective and preventive actions on blood component non-conformity and quality problems shall be in place.

2. Data shall be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action.

3. All errors and accidents shall be documented and investigated in order to identify system problems for correction.

10. SELF-INSPECTION, AUDITS AND IMPORVEMENTS

1. Self-inspection or audit systems shall be in place for all parts of the operations to verify compliance with the standards set out in this Schedule. They shall be carried out regularly by trained and competent persons in an independent way according to approved procedures.

2. All results shall be documented and appropriate corrective actions shall be taken in a timely and effective manner.

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