SCHEDULE

Regulations 4(4)(b), 7(1)(c), 2(a), (b) and (d), and (3)(b) and (c), 9(1)(c) and (h) and 13.

PART 1

Definitions

The following definitions apply for the purposes of this Schedule.

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 or raw material for manufacturing into medicinal products.

3. "Whole blood" means a single blood donation.

4. "Cryopreservation" means prolongation of the storage life of blood components by freezing.

5. "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.

6. "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.

7. "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.

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

9. "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.

10. "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.

11. "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 or preservative solution is added.

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

13. "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 or preservative solution is added.

14. "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.

15. "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 or preservative solution is added.

16. "Red cells, apheresis" means the red cells from an apheresis red cell donation.

17. "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.

18. "Platelets, apheresis" means a concentrated suspension of blood platelets obtained by apheresis.

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

20. "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.

21. "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.

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

23. "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.

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

25. "Plasma, cryoprecipitate-depleted for transfusion" means a plasma component prepared from a unit of plasma, fresh-frozen. It comprises the residual portion after the cryoprecipitate has been removed.

26. "Granulocytes, apheresis" means a concentrated suspension of granulocytes obtained by apheresis.

27. "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.

PART 2

INFORMATION REQUIREMENTS FOR DONORS

Part A – Information to be provided to prospective donors of blood or blood components

1. Accurate educational materials, which are written in terms which can be understood by 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 and health and medical history, and the testing of donations, and the significance of "informed consent".

3. For allogeneic donations, the criteria for 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.

4. 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.

5. Information on the protection of personal data, including confirmation that there will be no disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed, other than in accordance with the requirements of these Regulations.

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

7. 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.

8. 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.

9. 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.

10. 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.

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

12. 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.

13. 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

Identification of the donor

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

Health and medical history of the donor

15. Health and medical history, provided on a questionnaire and through a personal interview performed by a qualified health 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.

Signature of the donor

16. Signature of the donor, on the donor questionnaire, countersigned by the qualified health professional 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 knowledge.

PART 3

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Acceptance criteria for donors of whole blood and blood components

1.

Under exceptional circumstances, individual donations from donors who do not comply with 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 criteria in this paragraph do not apply to autologous donations.

1.1. Age and body weight of donors

Age	**18 to 65 years**	
	17 years	Where, in the opinion of a qualified health professional, the donor has sufficient knowledge and understanding of what is involved in the process of blood donation to give their informed consent, or otherwise with the written consent of a person with parental responsibility.

	First time donors over 60 years	— at the discretion of the doctor in the blood establishment
	Over 65 years	— with permission of the doctor in the blood establishment, given annually
Body weight	≥ 50 kg for donors either of 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 levels in donor's blood

Platelets	Platelet number greater than or equal to 150 x 10^9 /1	*Level required for apheresis platelet donors*

DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Deferral criteria for donors of whole blood and blood components

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 and 2
	HTLV I/II
	Babesiosis (*)
	Kala Azar (visceral leishmaniasis) (*)
	Trypanosomiasis cruzi (Chagas' disease) (*)
Malignant diseases	Except in situ cancer with complete recovery
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 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 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 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 years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever >38°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. Donations may be accepted thereafter only if an immunologic or molecular genomic test is negative
— asymptomic 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, — mocusal 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 6 months, or 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 an the disease being treated

2.3. Deferral for particular epidemiological situations

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation

2.4. Deferral criteria for donors of autologous donations

Serious cardiac disease	Depending on the clinical setting of the blood collection
Active bacterial infection	

PART 4

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

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.	

TRANSPORT AND DISTRIBUTION

2. 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.

ADDITIONAL REQUIREMENTS FOR AUTOLOGOUS DONATIONS

3.

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 regulation 8, and, in addition, the label must include the identification of the donor and the warning "FOR AUTOLOGOUS TRANSFUSION ONLY".

PART 5

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

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

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

Component	***Quality measures required*** ***The required frequency of sampling for all measurements shall be***	***Acceptable results for quality measures***

	determined using statistical process control	
Red cells	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45g per unit
	Haemolysis	Less than 0.8% of red cell mass at 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, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications 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, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45g per unit
	Haemolysis	Less than 0.8% of red cell mass at 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 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 specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40g per unit
	Leucocyte content	Less than 1 x 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 specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40g 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 450ml +/- 50ml For paediatric autologous whole blood collections – not to exceed 10.5ml per kg body weight
	Haemoglobin (*)	Not less than 45g 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 the 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, 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 the 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°C, 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
	Leucocyte content	Less than 0.2×10^9 per single unit (platelet-rich plasma method) Less than 0.05×10^9 per single unit (buffy coat method)
	pH	6.4-7.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, pooled, leucocyte-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 x 10^9 per single unit (platelet-rich plasma method) Less than 0.05 x 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, leucocyte-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
	Leucocyte content	Less than 1 x 10^6 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
	Total protein	Not less than 50g/l
	Residual cellular content(*)	Red cells: less than 6.0 x 10^9/l Leucocytes: less than 0.1 x 10^9/l Platelets: less than 50 x 10^9/l
Plasma, fresh-frozen, cryoprecipitate-depleted	Volume	Stated volume +/-10%
	Residual cellular content(*)	Red cells: less than 6.0 x 10^9/l Leucocytes: less than 0.1 x 10^9/l Platelets: less than 50 x 10^9/l
Cryoprecipitate	Fribrinogen content(*)	Greater than or equal to 140mg per unit
	Fractor VIIIc content (*)	Greater than or equal to 70 international units per unit
Granulocytes, apheresis	Volume	Less than 500ml

	Granulocyte content	Greater than 1 x 10^{10} granulocytes per unit

[F1PART 6

RECORD OF DATA ON TRACEABILITY

Textual Amendments

F1 Sch. Pts. 6-8 inserted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **15**

A. BY BLOOD ESTABLISHMENTS

1. Blood establishment identification
2. Blood donor identification
3. Blood unit identification
4. Individual blood component identification
5. Date of collection (year/month/day)
6. Facilities to which blood units or blood components are distributed, or subsequent disposition.

B. BY FACILITIES

1. Blood component supplier identification
2. Issued blood component identification
3. Transfused recipient identification
4. For blood units not transfused, confirmation of subsequent disposition
5. Date of transfusion or disposition (year/month/day)
6. Lot number of the component, if relevant.

PART 7

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

SECTION A

Rapid notification format for suspected serious adverse reactions

Reporting establishment
Report identification
Reporting date (year/month/day)
Date of transfusion (year/month/day)
Age and sex of recipient
Date of serious adverse reaction (year/month/day)
Serious adverse reaction is related to
— Whole blood
— Red blood cells
— Platelets
— Plasma
— Other *(specify)*
Type of serious adverse reaction(s)
— Immunological haemolysis due to ABO incompatibility
— Immunological haemolysis due to other allo-antibody
— Non-immunological haemolysis
— Transfusion-transmitted bacterial infection
— Anaphylaxis/hypersensitivity
— Transfusion related acute lung injury
— Transfusion-transmitted viral infection (HBV)
— Transfusion-transmitted viral infection (HCV)
— Transfusion-transmitted viral infection (HIV-1/2)
— Transfusion-transmitted viral infection, other (specify)
— Transfusion-transmitted parasitical infection (Malaria)
— Transfusion-transmitted parasitical infection, other (specify)
— Post-transfusion purpura
— Graft versus host disease
— Other serious reaction(s) *(specify)*

Imputability level (NA, 0-3)

SECTION B

Serious adverse reactions – imputability levels

Imputability levels to assess serious adverse reactions

Imputability level		*Explanation*
NA	Not assessable	When there is insufficient data for imputability assessment
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes.
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

SECTION C

Confirmation format for serious adverse reactions

Reporting establishment
Report identification
Confirmation date (year/month/day)
Date of serious adverse reaction (year/month/day)
Confirmation of serious adverse reaction (Yes/No)
Imputability level (NA, 0-3)
Change of type of serious adverse reaction (Yes/No)
If Yes, *specify*
Clinical outcome (if known) — Complete recovery — Minor sequelae — Serious sequelae — Death

SECTION D

Annual notification format for serious adverse reactions

Reporting establishment							
Reporting period							
This Table refers to [ ] Whole blood [ ] Red blood cells [ ] Platelets [ ] Plasma [ ] Other *(use separate table for each component)*		Number of units issued (total number of units issued with a given number of blood components)					
		Number of recipients transfused (total number of recipients transfused with a given number of blood components) *(if available)*					
		Number of units transfused (the total number of blood components (units) transfused over the reporting period) *(if available)*					
		Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Section A of Part 7)				
		Number of deaths					
			not assessable	Level 0	Level 1	Level 2	Level 3
Immunological Haemolysis	Due to ABO incompatibility	Total					
		Deaths					
	Due to other allo-antibody	Total					
		Deaths					
Non-immunological haemolysis		Total					
		Deaths					
Transfusion-transmitted bacterial infection		Total					
		Deaths					
Anaphylaxis/hypersensitivity		Total					
		Deaths					
Transfusion related acute lung injury		Total					
		Deaths					
Transfusion-transmitted viral infection	HBV	Total					
		Deaths					
	HCV	Total					
		Deaths					
	HIV-1/2	Total					
		Deaths					
	Other *(specify)*	Total					
		Deaths					
Transfusion-transmitted parasitical infection	Malaria	Total					
		Deaths					
	Other *(specify)*	Total					
		Deaths					
Post-transfusion purpura		Total					
		Deaths					
Graft versus host disease		Total					
		Deaths					
Other serious reactions *(specify)*		Total					
		Deaths					

PART 8

NOTIFICATION OF SERIOUS ADVERSE EVENTS

SECTION A

Rapid Notification Format for Serious Adverse Events

Reporting establishment				
Report identification				
Reporting date (year/month/day)				
Date of serious adverse event (year/month/day)				
Serious adverse event, which may affect quality and safety of blood component due to a deviation in:	**Specification**			
	Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection				
Apheresis collection				
Testing of donations				
Processing				
Storage				
Distribution				
Materials				
Others *(specify)*				

SECTION B

Confirmation Format for Serious Adverse Events

Reporting establishment
Reporting identification
Confirmation date *(year/month/day)*
Date of serious adverse event *(year/month/day)*
Root cause analysis (details)
Corrective measures taken (details)

SECTION C

*Annual Notification Format for Serious Adverse Events***]**

Reporting establishment					
Reporting period		**1 January-31 December *(year)***			
Total number of blood and blood components processed:					
Serious adverse event, affecting quality and safety of blood component due to a deviation in:	Total number	**Specification**			
		Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection					
Apheresis collection					
Testing of donations					
Processing					
Storage					
Distribution					
Materials					
Others *(specify)*					

Status:
Point in time view as at 31/08/2006.

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005, SCHEDULE.