STATUTORY INSTRUMENTS

2005 No. 50

HEALTH AND SAFETY

The Blood Safety and Quality Regulations 2005

Made - - - -	*13th January 2005*
Laid before Parliament	*18th January 2005*
Coming into force	
For all purposes other than regulation 25(1)	*8th February 2005*
For the purposes of regulation 25(1)	*8th November 2005*

THE BLOOD SAFETY AND QUALITY REGULATIONS 2005

1. Citation, commencement and interpretation
2. Designation of the competent authority and scope of the Regulations
3. Requirement for authorisation
4. Authorisation of a blood establishment
5. Suspension or revocation of authorisation
6. The responsible person for a blood establishment
7. Blood establishment requirements
8. Labelling of blood and blood components and traceability
9. Hospital blood bank requirements
10. Requirement for hospital blood banks to provide information to the Secretary of State
11. Service of notices relating to hospital blood banks
12. Objections to suspensions, revocations etc
13. Import of blood and blood components into the United Kingdom
14. Disclosure of information by blood establishments and hospital blood banks
15. Inspections, etc.
16. Records to be kept by the Secretary of State
17. Powers of entry, etc.
18. Criminal offences
19. Penalties
20. Defence of due diligence
21. Offences by bodies corporate and Scottish partnerships
22. Fees
23. Specific epidemiological situations

24. Transitional provisions
25. Consequential amendments
Signature

SCHEDULE —
PART 1
Definitions
PART 2 — INFORMATION REQUIREMENTS FOR DONORS
Part A – Information to be provided to prospective donors of blood or blood components
1. Part A – Information to be provided to prospective donors of blood or blood components
2. For both allogeneic and autologous donations, the reasons for requiring...
3. For allogeneic donations, the criteria for self-deferral, and temporary and...
4. For autologous donations, the possibility of deferral and the reasons...
5. Information on the protection of personal data, including confirmation that...
6. The reasons why individuals are not to make donations which...
7. Specific information on the nature of the procedures involved either...
8. Information on the option for donors to change their mind...
9. The reasons why it is important that donors inform the...
10. Information on the responsibility of the blood establishment to inform...
11. Information as to why unused autologous blood and blood components...
12. Information that test results detecting markers for viruses, such as...
13. Information on the opportunity for donors to ask questions at...
Part B – Information to be obtained from donors by blood establishments at every donation
14. ***Identification of the donor***
15. ***Health and medical history of the donor***
16. ***Signature of the donor***
PART 3 — ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS
1. Acceptance criteria for donors of whole blood and blood components
1.1 Age and body weight of donors Age 18 to 65...
1.2 Haemoglobin levels in donor’s blood Haemoglobin For females ≥ 125...
1.3 Protein levels in donor’s blood Protein ≥ 60 g/l The...
1.4 Platelet levels in donor’s blood Platelets Platelet number greater than...
Deferral criteria for donors of whole blood and blood components
2.1 **Deferral criteria for donors of whole blood and blood components**
2.2 Temporary deferral criteria for donors of allogeneic donations
2.2.1 Infections
Duration of deferral period
2.2.2 **Duration of deferral period**
2.2.3 Vaccination Attenuated viruses or bacteria 4 weeks Inactivated/killed viruses, bacteria...
2.2.4 Other temporary deferrals Pregnancy 6 months after delivery or termination,...
2.3 Deferral for particular epidemiological situations Particular epidemiological situations (e.g. disease...
2.4 Deferral criteria for donors of autologous donations Serious cardiac disease...

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...
1.2 Cryopreservation Component Storage conditions and duration Red blood cells Up...
2. TRANSPORT AND DISTRIBUTION
3. ADDITIONAL REQUIREMENTS FOR AUTOLOGOUS DONATIONS
3.1 Autologous blood and blood components must be clearly identified as...
3.2 Autologous blood and blood components must be labelled as required...
PART 5 — QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS
1. THE BLOOD COMPONENTS 1. Red cell preparations The components listed...
2. QUALITY CONTROL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS
2.1 Blood and blood components must comply with the following technical...
2.2 Appropriate bacteriological control of the collection and manufacturing process must...
2.3 For autologous donations, the measures marked with an asterisk (*)...

Explanatory Note