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STATUTORY INSTRUMENTS

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**2005 No. 50**

**HEALTH AND SAFETY**

**The Blood Safety and Quality Regulations 2005**

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

**THE BLOOD SAFETY AND QUALITY REGULATIONS 2005**

1. Citation, commencement and interpretation
- 1A Modification of provisions of the Annex to Commission Directive 2005/62/EC
- 1B References to the requirements set out in the Annex to Commission Directive 2005/62/EC
2. Designation of the competent authority for Northern Ireland 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
- 12A Requirement that facilities retain certain data
- 12B Requirement to report serious adverse reactions and events
13. Import of blood and blood components into Great Britain
- 13A Import of blood and blood components into Northern Ireland
14. Disclosure of information by blood establishments and hospital blood banks
15. Inspections, etc.

*Changes to legislation:* There are currently no known outstanding effects for the *The Blood Safety and Quality Regulations 2005*. (See end of Document for details)

- 16. Records to be kept by the Secretary of State
- 16A Requirement that the Secretary of State communicate certain information in respect of Northern Ireland to other competent authorities
- 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 in relation to Great Britain
- 23ZA Specific epidemiological situations in relation to Northern Ireland
- 23A Regulations relating to the quality and safety of blood and blood components
- 23B Scope and nature of powers
- 23C Scrutiny of regulations made by the Secretary of State
- 23D Scrutiny of regulations made by the Welsh Ministers
- 23E Scrutiny of regulations made by the Scottish Ministers
- 23F . . . . .
- 24. Transitional provisions
- 25. Consequential amendments
- Signature

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SCHEDULE —  
PART 1

Definitions

- 1. “Autologous donation” means blood and blood components collected from an...
- 2. “Allogeneic donation” means blood and blood components collected from an...
- 3. “Whole blood” means a single blood donation.
- 4. “Cryopreservation” means prolongation of the storage life of blood components...
- 5. “Plasma” means the liquid portion of the blood in which...
- 6. “Cryoprecipitate” means a plasma component prepared from plasma, fresh-frozen, by...
- 7. “Washed” means a process of removing plasma or storage medium...
- 8. “Red cells” means the red cells from a single whole...
- 9. “Red cells, buffy coat removed” means the red cells from...
- 10. “Red cells, leucocyte-depleted” means the red cells from a single...
- 11. “Red cells in additive solution” means the red cells from...
- 12. “Additive solution” means a solution specifically formulated to maintain beneficial...
- 13. “Red cells, buffy coat removed, in additive solution” means the...
- 14. “Buffy coat” means a blood component prepared by centrifugation of...
- 15. “Red cells, leucocyte-depleted, in additive solution” means the red cells...
- 16. “Red cells, apheresis” means the red cells from an apheresis...
- 17. “Apheresis” means a method of obtaining one or more blood...
- 18. “Platelets, apheresis” means a concentrated suspension of blood platelets obtained...
- 19. “Platelets, apheresis, leucocyte-depleted” means a concentrated suspension of blood platelets,...

20. "Platelets, recovered, pooled" means a concentrated suspension of blood platelets,...
21. "Platelets, recovered, pooled, leucocyte-depleted" means a concentrated suspension of blood...
22. "Platelets, recovered, single unit" means a concentrated suspension of blood...
23. "Platelets, recovered, single unit, leucocyte-depleted" means a concentrated suspension of...
24. "Plasma, fresh-frozen" means the supernatant plasma separated from a whole...
25. "Plasma, cryoprecipitate-depleted for transfusion" means a plasma component prepared from...
26. "Granulocytes, apheresis" means a concentrated suspension of granulocytes obtained by...
27. "Statistical process control" means a method of quality control of...
  - 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...
    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  $\geq 125$ ...
      - 1.3 Protein levels in donor's blood Protein  $\geq 60$  g/l The...
      - 1.4 Platelet levels in donor's blood Platelets Platelet number greater than...
    - 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  
However, the following deferral periods shall apply for the infections...
        - 2.2.2 Exposure to risk of acquiring a transfusion-transmissible infection —  
Endoscopic...
        - 2.2.3 Vaccination Attenuated viruses or bacteria 4 weeks Inactivated/killed  
viruses, bacteria...

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- 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 (\*)...
  - PART 6 — RECORD OF DATA ON TRACEABILITY

#### 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,...

#### 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*

SECTION B

*Serious adverse reactions – imputability levels*

SECTION C

*Confirmation format for serious adverse reactions*

SECTION D

*Annual notification format for serious adverse reactions*

PART 8 — NOTIFICATION OF SERIOUS ADVERSE EVENTS

SECTION A

*Rapid Notification Format for Serious Adverse Events*

SECTION B

*Confirmation Format for Serious Adverse Events*

SECTION C

*Annual Notification Format for Serious Adverse Events*

Explanatory Note

**Changes to legislation:**

There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005.