STATUTORY INSTRUMENTS

# 2005 No. 50

# HEALTH AND SAFETY

## The Blood Safety and Quality Regulations 2005

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| *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

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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 ≥ 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...

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...

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.

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.