The Blood Safety and Quality Regulations 2005

UK Statutory Instruments 2005 No. 50 **Regulation 1**

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Status: This is the original version (as it was originally made).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Blood Safety and Quality Regulations 2005.

(2) Except for regulation 25(1), which shall come into force on 8th November 2005, these Regulations shall come into force on 8th February 2005.

(3) In these Regulations—

"autologous transfusion" means a transfusion in which the donor and the recipient are the same person and in which pre-deposited blood or blood components are used;

"blood" means whole human blood collected from a donor and processed either for transfusion or for further manufacturing;

"blood component" means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods;

"blood component release" means a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

"blood establishment" means any person, other than a person responsible for management of a hospital blood bank, which carries out any of the activities listed in regulation 3(2);

"blood product" means any therapeutic product derived from human blood or plasma;

"Commission" means the European Commission;

"deferral" means suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary;

"the Directive" means Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(1);

"distribution" means the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood products, other than the issuing of blood or blood components for transfusion;

"doctor" means a registered medical practitioner;

"donor carer" means a person who has passed both the written and practical examinations of the National Blood Authority(2), the Scottish National Blood Transfusion Service(3), the Northern Ireland Blood Transfusion Service(4) or the Welsh Blood Service(5) in the care of blood donors and who holds a current certificate of competence, awarded by that body, in the care of blood donors;

"health service hospital" has the same meaning as in section 128 of the National Health Service Act 1977(6);

"haemovigilance" means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

"health service body" means—

(a) a Strategic Health Authority, Special Health Authority, Primary Care Trust or Local Health Board established under the National Health Service Act 1977,

(b) a Health Board or Special Health Board established under the National Health Service (Scotland) Act 1978,

(c) a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972(7),

(d) a special health and social services agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990(8),

(e) the Common Services Agency for the Scottish Health Service established under the National Health Service (Scotland) Act 1978,

(f) the Northern Ireland Central Services Agency for the Health and Social Services established under the Health and Personal Social Services (Northern Ireland) Order 1972,

(g) a National Health Service trust established under the National Health Service and Community Care Act 1990(9), or the National Health Service (Scotland) Act 1978,

(h) an NHS foundation trust within the meaning of section 1(1) of the Health and Social Care (Community Health and Standards) Act 2003(10), or

(i) a Health and Social Services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991(11);

"hospital" means a health service hospital or an independent hospital;

"hospital blood bank" means any unit within a hospital which stores and distributes, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

"independent hospital" has the same meaning as in section 2 of the Care Standards Act 2000(12);

"inspection" means formal and objective control to identify problems in accordance with standards adopted to assess compliance with these Regulations;

"inspector" means a person appointed by the Secretary of State to carry out inspections pursuant to regulation 15(10);

"nurse" means a registered nurse or registered midwife;

"person responsible for management of a hospital blood bank" means—

(a) in the case of hospital blood bank located in a hospital managed by a health service body, that body, and

(b) in the case of an independent hospital, the registered person;

"qualified health professional" means—

(a) a doctor;

(b) a nurse, or

(c) a donor carer;

"registered person" means the person registered as the manager of an independent hospital following an application to be registered as such pursuant to section 12(3) of the Care Standards Act 2000;

"reporting year" means the period of twelve months ending on 31st March;

"responsible person" in relation to a blood establishment means the person who has been designated pursuant to regulation 8 as the responsible person for that blood establishment,

"serious adverse event" means any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity;

"site", in relation to a blood establishment, means any premises at which the blood establishment carries out any of the activities listed in regulation 3(2), but shall not include any premises not owned or managed by the blood establishment at which blood is collected, or any mobile blood collection unit;

"validation" means the establishment of documented and objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

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(1) O.J. No. L33, 8.2.2003, p.30.

(2) The National Blood Authority was established by the National Blood Authority (Establishment and Constitution) Order (S.I. 1993/585), as amended by S.I. 1994/589 and 2001/1745.

(3) The Scottish National Blood Transfusion Service is managed by the Common Services Agency established by section 10 of, and Schedule 5 to, the National Health Service (Scotland) Act 1978 (c. 29). The Common Services Agency was designated for this purpose by the NHS (Functions of the Common Services Agency) (Scotland) Order (S.I. 1974/467)

(4) The Northern Ireland Blood Transfusion Service was established under Article 10(1)(d) of the Health and Personal Social Services (Northern Ireland) Order (S.I. 1972/1265) (N.I. 14).

(5) The Welsh Blood Service is provided and managed by the Velindre National Health Service Trust. The Velindre NHS Trust was established, and designated for this purpose by the Velindre National Health Service Trust (Establishment) Order (1993/2838), as amended by S.I. 1999/826 and 2002/442 and 2199.

(6) 1977 c. 49; the definition of "health service hospital" has been amended by sections 1 and 2 of, and paragraph 77(d) of Schedule 1 to, the Health Services Act 1980 (c. 53), section 26(2)(c) of the National Health Service and Community Care Act 1990, section 65 of, and paragraphs 4 and 38(1) and (2)(a) of Schedule 4 to, the Health Act 1999 (c. 9) and by section 34 of, and paragraphs 23 and 42 of Schedule 4 to, the Health and Social Care (Community Health and Standards) Act 2003 (c. 43).

(7) S.I. 1972/1265 (N.I. 14).

(8) S.I. 1990/247 (N.I.3).

(9) 1990 c. 19.

(10) 2003 c. 43.

(11) S.I. 1991/194 (N.I.1).

(12) 2000 c. 14.

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