STATUTORY INSTRUMENTS

2005 No. 50

The Blood Safety and Quality Regulations 2005

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;

[F1"biomedical research institution" means any body which carries out biomedical research;**]**

"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;

[F2"blood establishment" means any person who carries out any of the activities specified in regulation 3(2) which require an authorisation by virtue of that regulation;**]**

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

[F1"care home"—

(a) in England F3..., has the same meaning as in section 3 of the Care Standards Act 2000,

(b) in Scotland, **[**F4means a care home service within the meaning of paragraph 2 of schedule 12 to the Public Services Reform (Scotland) Act 2010**]**, F5...

(c) in Northern Ireland, has the same meaning as in article 2 of the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003 **[**F6, and

(d) in Wales, means a place at which a care home service, within the meaning of Paragraph 1 of Schedule 1 of the Regulation and Inspection of Social Care (Wales) Act 2016, is provided wholly or mainly to persons aged 18 or over**];]**

"Commission" means the European Commission;

[F1"Commission Directive 2005/62/EC" means Commission Directive 2005/62/EC of 30th September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments F7;**]**

"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 [M1];

"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 **[**[F8]NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG)**]** , the Scottish National Blood Transfusion Service [M2], the Northern Ireland Blood Transfusion Service [M3] or the Welsh Blood Service [M4] in the care of blood donors and who holds a current certificate of competence, awarded by that body, in the care of blood donors;

[[F1]"facility" means—

(a) a hospital,

(b) any other facility or service owned or managed by a health service body,

(c) a care home,

(d) an independent clinic,

(e) a manufacturer, or

(f) a biomedical research institute;**]**

[[F9]"health service hospital" means a hospital owned or managed by a health service body;**]**

"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 [F10]... Special Health Authority [F10]... 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 [M5],

(d) a special health and social services agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990 [M6],

(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 [M7], 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 [M8], or

(i) a Health and Social Services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991 [M9];

"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;

[F1"imputability" means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused, or that a serious adverse reaction in a donor can be attributed to the donation process;**]**

[F11"independent clinic"—

(a) in Wales, has the same meaning as in section 2 of the Care Standards Act 2000;

(b) in Scotland, has the same meaning as in **[**F12section 10F(2) of the National Health Service (Scotland) Act 1978**]**;

(c) in Northern Ireland, has the same meaning as in article 2 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003; and

(d) in England, means an establishment of the following kind—

(i) a walk-in centre, in which one or more medical practitioners provide services of a kind which, if provided in pursuance of the National Health Service Act 2006, would be provided as primary medical services under Part 4 of that Act; or

(ii) a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the National Health Service Act 2006 provides medical services of any kind (including psychiatric treatment), except where such medical services are provided only under arrangements made on behalf of the patients by—

(aa) their employer;

(bb) a government department or any executive agency of a government department;

(cc) a prison or other establishment in which patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983; or

(dd) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity

and where two or more medical practitioners use different parts of the same premises as a surgery or consulting room, or use the same surgery or consulting room at different times, each of the medical practitioners shall be regarded as carrying on a separate independent clinic unless they are in practice together.**]**

[F13"independent hospital"—

(za) **[**F14in England, means a hospital as defined by section 275 of the National Health Service Act 2006 that is not a health service hospital as defined by that section,

(a) in Wales, has the same meaning as in section 2 of the Care Standards Act 2000,**]**

(b) in Scotland, has the same meaning as in **[**F12section 10F(2) of the National Health Service (Scotland) Act 1978**]**, and

(c) in Northern Ireland, has the same meaning as in article 2 of the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003**]**

"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);

[F1"issue" means the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient;**]**

[F1"manufacturer" means a person who—

(a) holds a licence under section 8(2) of the Medicines Act 1968 to manufacture medicinal products;

(b) holds an authorisation to manufacture an investigational medicinal product granted pursuant to regulation 36 of the Medicines for Human Use (Clinical Trials) Regulations 2004; or

(c) falls within the definition of "manufacturer" in paragraph (1) of regulation 2 of the Medical Devices Regulations 2002;**]**

"nurse" means a registered nurse or registered midwife;

[F1"person responsible for the management of a facility" means—

(a) in the case of a hospital, facility or service which is owned or managed by an NHS body, that body,

(b) in the case of an independent hospital, an independent clinic or a care home, the registered person,

(c) in the case of a manufacturer or a biomedical research institution, the manufacturer or biomedical research institution;**]**

"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;

[F1"person responsible for the management of a reporting establishment" means a blood establishment, the person responsible for the management of a facility or the person responsible for the management of a hospital blood bank;**]**

"qualified health professional" means—

(a) a doctor;

(b) a nurse, or

(c) a donor carer;

[F15"quality system" means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management and, for this purpose, "quality management" means the co-ordinated activities to direct and control an organisation with regard to quality at all levels within the blood establishment or hospital blood bank;**]**

[F1"recipient" means a person who has been transfused with blood or blood components;**]**

[F16"registered person" means—

(a) in England, the person registered as manager under Chapter 2 of Part 1 of the Health and Social Care Act 2008 in respect of regulated activities (within the meaning of that Part) carried on in an independent hospital, a care home or an independent clinic; F17...

(b) in F18... Scotland or Northern Ireland, the person registered as the manager of an independent hospital, a care home or an independent clinic following an application to be registered as such pursuant to—

(i) section 12(3) of the Care Standards Act 2000,

(ii) **[**F19section 10P of the National Health Service (Scotland) Act 1978, or section 59 of the Public Services Reform (Scotland) Act 2010 as appropriate;**]**

(iii) article 13(1) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003; **[**F20and

(c) in Wales,—

(i) the person registered with Social Care Wales as the manager of a place at which a care home service, within the meaning of Paragraph 1 of Schedule 1 of the Regulation and Inspection of Social Care (Wales) Act 2016, is provided wholly or mainly to persons aged 18 or over, or

(ii) the person registered as the manager of an independent hospital or independent clinic following an application to be registered as such pursuant to section 12(3) of the Care Standards Act 2000;**]]**

[F1"reporting establishment" means the blood establishment, the hospital blood bank or the facility where the transfusion takes place;**]**

"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 6 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;

[F21"third country" means—

(a) in relation to the import of blood or blood components into Great Britain, a country other than the United Kingdom; and

(b) in relation to the import of blood or blood components into Northern Ireland, a country other than Northern Ireland or a member State;**]**

[F1"traceability" means the ability to trace each individual unit of blood or blood component from the donor to its final destination (whether this is a recipient, a manufacturer of medicinal products or disposal) and from its final destination back to the donor;**]**

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

Textual Amendments

F1 Words in reg. 1(3) inserted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **2(d)**

F2 Words in reg. 1(3) substituted (8.11.2005) by The Blood Safety and Quality (Amendment) (No. 2) Regulations 2005 (S.I. 2005/2898), regs. 1(1), **2**

F3 Words in reg. 1(3) omitted (1.4.2018) by virtue of The Blood Safety and Quality Regulations and the Care and Support (Business Failure) Regulations (Consequential Amendments) Order 2018 (S.I. 2018/231), arts. 1, **2(a)(i)**

F4 Words in reg. 1(3) substituted (28.10.2011) by The Public Services Reform (Scotland) Act 2010 (Consequential Modifications of Enactments) Order 2011 (S.I. 2011/2581), art. 1(2)(b), **Sch. 2 para. 44(a)**

F5 Word in reg. 1(3) omitted (1.4.2018) by virtue of The Blood Safety and Quality Regulations and the Care and Support (Business Failure) Regulations (Consequential Amendments) Order 2018 (S.I. 2018/231), arts. 1, **2(a)(ii)**

F6 Words in reg. 1(3) inserted (1.4.2018) by The Blood Safety and Quality Regulations and the Care and Support (Business Failure) Regulations (Consequential Amendments) Order 2018 (S.I. 2018/231), arts. 1, **2(a)(iii)**

F7 O.J. L 256 1.10.2005 p 14.

F8 Words in reg. 1 substituted (E.W.) (1.10.2005) by The National Blood Authority and United Kingdom Transplant (Abolition) Order 2005 (S.I. 2005/2532), art. 1(1), **Sch. 2 para. 7**

F9 Words in reg. 1(3) substituted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **2(a)**

F10 Words in reg. 1(3) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 77**

F11 Words in reg. 1(3) substituted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **16(a)**

F12 Words in reg. 1(3) substituted (28.10.2011) by The Public Services Reform (Scotland) Act 2010 (Consequential Modifications of Enactments) Order 2011 (S.I. 2011/2581), art. 1(2)(b), **Sch. 2 para. 44(b)**

F13 Words in reg. 1(3) substituted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **2(b)**

F14 Words in reg. 1(3) substituted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **16(b)**

F15 Words in reg. 1(3) inserted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), **reg. 3(a)** (as substituted by S.I. 2020/1304, regs. 1, 3); 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 1(3) substituted (1.10.2010) by The Health and Social Care Act 2008 (Miscellaneous Consequential Amendments) Order 2010 (S.I. 2010/1881), arts. 1(1), **16(c)**

F17 Word in reg. 1(3) omitted (1.4.2018) by virtue of The Blood Safety and Quality Regulations and the Care and Support (Business Failure) Regulations (Consequential Amendments) Order 2018 (S.I. 2018/231), arts. 1, **2(b)(i)**

F18 Word in reg. 1(3) omitted (1.4.2018) by virtue of The Blood Safety and Quality Regulations and the Care and Support (Business Failure) Regulations (Consequential Amendments) Order 2018 (S.I. 2018/231), arts. 1, **2(b)(ii)**

F19 Words in reg. 1(3) substituted (28.10.2011) by The Public Services Reform (Scotland) Act 2010 (Consequential Modifications of Enactments) Order 2011 (S.I. 2011/2581), art. 1(2)(b), **Sch. 2 para. 44(c)**

F20 Words in reg. 1(3) inserted (1.4.2018) by The Blood Safety and Quality Regulations and the Care and Support (Business Failure) Regulations (Consequential Amendments) Order 2018 (S.I. 2018/231), arts. 1, **2(b)(iii)**

F21 Words in reg. 1(3) substituted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), **reg. 3(b)** (as substituted by S.I. 2020/1304, regs. 1, 3); 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M1 O.J. No. L33, 8.2.2003, p.30.

M2 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).

M3 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).

M4 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.

M5 S.I. 1972/1265 (N.I. 14).

M6 S.I. 1990/247 (N.I.3).

M7 1990 c. 19.

M8 2003 c. 43.

M9 S.I. 1991/194 (N.I.1).

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005, Section 1.