STATUTORY INSTRUMENTS

# 2006 No. 2013

# The Blood Safety and Quality (Amendment) Regulations 2006

**Amendment of regulation 1 of the principal Regulations**

**2.** In regulation 1 of the principal Regulations (citation, commencement and interpretation), in paragraph (3)—

(a) for the definition of "health service hospital", substitute—

""health service hospital" means a hospital owned or managed by a health service body;";

(b) for the definition of "independent hospital", substitute—

""independent hospital"—

(a) in England and Wales, has the same meaning as in section 2 of the Care Standards Act 2000(**1**),

(b) in Scotland, has the same meaning as in section 2 of the Regulation of Care (Scotland) Act 2001(**2**), 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(**3**)

(c) for the definition of "registered person", substitute—

""registered person" means 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—

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

(b) section 7(1) of the Regulation of Care (Scotland) Act 2001, or

(c) article 13(1) of the Health and Personal Social Services (Quality, Improvement and Regulation)(Northern Ireland) Order 2003"; and

(d) insert, in the appropriate alphabetical places, the following definitions—

""biomedical research institution" means any body which carries out biomedical research;

"care home"—

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

(b) in Scotland, has the same meaning as in section 2 of the Regulation of Care (Scotland) Act 2001, and

(**1**) 2000 c.14.
(**2**) 2001 asp. 8.
(**3**) 2003 N. 431( N.I).

(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;

"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(**4**);

"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;

"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;

"independent clinic"—

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

(b) in Scotland, has the same meaning as in section 2 of the Regulation of Care (Scotland) Act 2001, and

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

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

"manufacturer" means a person who—

(a) holds a licence under section 8(2) of the Medicines Act 1968(**5**) 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(**6**); or

(c) falls within the definition of "manufacturer" in paragraph (1) of regulation 2 of the Medical Devices Regulations 2002(**7**);

"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,

(**4**) O.J. L 256 1.10.2005 p 14.
(**5**) 1968 c. 67, relevant amendments to section 8 have been made by S.I. 2004/1031, 2005/50 and 2789.
(**6**) S.I. 2004/1031.
(**7**) S.I. 2002/618 relevant amending instruments are S.I. 2003/1697 and 2005/2759.

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

"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;

"recipient" means a person who has been transfused with blood or blood components;

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

"third country" means any country other than a Member State; and

"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;".