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STATUTORY INSTRUMENTS

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**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;

“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<sup>(1)</sup>;

“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<sup>(2)</sup>, the Scottish National Blood Transfusion Service<sup>(3)</sup>, the Northern Ireland Blood Transfusion Service<sup>(4)</sup> or the Welsh Blood Service<sup>(5)</sup> in the care of

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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).

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);

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- (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](#).

“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 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;

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

## **Designation of the competent authority and scope of the Regulations**

2.—(1) The Secretary of State is designated the competent authority for the purpose of the Directive.

(2) Subject to the following paragraphs, the requirements of these Regulations apply to the collection and testing of blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when they are intended to be used for transfusion.

(3) These Regulations apply without prejudice to the Medical Devices Regulations 2002(13).

(4) These Regulations do not apply to blood stem cells.

## **Requirement for authorisation**

3.—(1) Subject to paragraph (3), no person may carry on any of the activities listed in paragraph (2) otherwise than in accordance with an authorisation granted under regulation 4.

(2) The activities referred to in paragraph (1) are—

- (a) the collection and testing of blood or blood components, whatever their intended purpose; and
  - (b) the processing, storage and distribution of blood and blood components when they are intended to be used for transfusion.
- (3) The restriction in paragraph (1) shall not apply to—
- (a) the storage and distribution of, and the performance of compatibility tests on, blood and blood components exclusively for use within hospital facilities, including transfusion activities where such activities are performed by a hospital blood bank; or
  - (b) any person carrying out any of the activities referred to in paragraph (2), where that person carries out that activity on behalf of, and pursuant to a contractual arrangement with—
    - (i) a blood establishment which is authorised under these regulations to carry out the activity in question; or
    - (ii) a person responsible for management of a hospital blood bank.

#### **Authorisation of a blood establishment**

4.—(1) The Secretary of State may grant an authorisation to a blood establishment to carry out any of the activities referred to in regulation 3(2).

- (2) An application for authorisation under paragraph (1) shall be made to the Secretary of State.
- (3) An application must—
  - (a) include the information set out in paragraph (4); and
  - (b) be accompanied by a fee of the amount prescribed in regulation 22(2)(a).
- (4) The information referred to in paragraph (4) is—
  - (a) the name and address of the blood establishment and general information about its activities which shall include—
    - (i) details of each site at which it wishes to carry out any of the activities referred to in regulation 3(2),
    - (ii) a description of the activities which it wishes to carry out at each site,
    - (iii) where it has or intends to enter into a contractual arrangement with any person to carry out any of the services in respect of which it is seeking authorisation, the name and address of that person and of the services which he will carry out,
    - (iv) the name, qualifications and contact details of the responsible person for the establishment,
    - (v) the list of hospital blood banks which it supplies; and
  - (b) a description of the quality system in place at each site for each activity in respect of which the application for authorisation is made, which shall include the following information—
    - (i) documentation, such as an organisation chart, setting out the responsibilities of responsible persons and reporting relationships,
    - (ii) documentation, such as a site master file or quality manual, describing the quality system and explaining how it meets the requirements of Part 5 of the Schedule,
    - (iii) details of the number and qualifications of personnel,
    - (iv) details of hygiene provisions,
    - (v) details of premises and equipment, and
    - (vi) a list of standard operating procedures for—
      - (aa) recruitment, retention and assessment of donors,

- (bb) processing, testing, distribution and recall of blood and blood components, and
  - (cc) the reporting and recording of serious adverse reactions and events.
- (5) The Secretary of State may—
- (a) grant or refuse any application for authorisation made under paragraph (3); and
  - (b) grant such application—
    - (i) in respect of particular sites or activities only, and
    - (ii) subject to conditions.
- (6) Where the Secretary of State grants an application for authorisation, he shall give notice in writing to the blood establishment specifying—
- (a) the activities which the blood establishment may undertake under these Regulations at each site in respect of which authorisation is granted; and
  - (b) the conditions which apply to the undertaking of those activities.
- (7) Subject to the requirements of paragraph (8), the Secretary of State may at any time remove or vary any of the conditions referred to in paragraph (5)(b)(ii), or may impose additional conditions.
- (8) Where the Secretary of State removes or varies any condition or imposes any additional condition pursuant to paragraph (7), he shall serve a notice on the blood establishment in question which shall—
- (a) give details of the conditions which he proposes to remove, or of the variation which he proposes to make to any existing conditions, or of any additional condition which he proposes to impose;
  - (b) give the reasons for his decision; and
  - (c) specify the date, which shall be not less than 14 days from the date on which the notice is served, from which the removal or variation of any condition, or the imposition of any additional condition shall apply.
- (9) A blood establishment may not make any substantial change in the activities which it undertakes without the prior written approval of the Secretary of State.
- (10) Any application for approval to make a substantial change in its activities shall be made in writing to the Secretary of State, and shall be accompanied by a fee of the amount prescribed in regulation 22(2)(b).
- (11) For the purpose of this regulation, a substantial change in a blood establishment's activities is any change—
- (a) to the sites from which the blood establishment operates or to the activities to be carried out at each site;
  - (b) which would result in breach of these regulations or of any condition specified by the Secretary of State pursuant to this regulation; or
  - (c) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the activities which the blood establishment has been authorised to undertake pursuant to this regulation.

### **Suspension or revocation of authorisation**

- 5.—(1) The Secretary of State may suspend or revoke the authorisation of a blood establishment on one or more of the following grounds—
- (a) that the blood establishment has failed, in any material respect, to comply with the requirements of these regulations;

- (b) that the collection, testing, processing, storage or distribution of blood or blood components by the establishment cannot be carried out safely;
- (c) that any blood or blood components cannot be supplied to hospital blood banks in such a state that they could be safely administered for transfusion; or
- (d) that the information given by the blood establishment pursuant to regulation 4(3) was false or incomplete in any material respect.

(2) Subject to paragraph (3), before suspending or revoking the authorisation of a blood establishment, the Secretary of State shall serve a notice on the blood establishment stating that he intends to suspend or revoke its authorisation with effect from the date specified in the notice, which date shall be not less than 7 days from the date on which the notice is served.

(3) Where the Secretary of State considers that it is necessary in the interests of safety, he may, by a notice served on a blood establishment, suspend or revoke its authorisation with immediate effect.

(4) Where—

- (a) the blood establishment has failed, in any material respect, to comply with the requirements of these regulations; or
- (b) the information given by the blood establishment pursuant to regulation 4(4) was false or incomplete in any material respect,

and the Secretary of State considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the authorisation of the blood establishment in the first instance, he may serve a notice on the responsible person of the blood establishment in accordance with paragraph (5).

(5) A notice served under this paragraph shall—

- (a) identify the requirements of the regulations of which the blood establishment is in breach or, in the case of false and incomplete information, the further information which is required;
- (b) identify the action which the blood establishment is required to take; and
- (c) give the timescale within which the blood establishment shall take the action identified in sub-paragraph (b).

(6) If the blood establishment fails to comply with the requirements set out in the notice within the specified timescale, the Secretary of State may, by a notice served on the blood establishment, suspend or revoke the authorisation of the blood establishment.

(7) A suspension or revocation pursuant to paragraph (6) shall take effect—

- (a) in a case where the Secretary of State considers that it is necessary in the interests of safety, immediately; or
- (b) in all other cases, from a date specified in the notice.

(8) Any suspension pursuant to paragraphs (1) or (6) shall be for such period as the Secretary of State shall consider necessary having regard to the reasons for the suspension.

(9) The suspension or revocation of an authorisation under paragraph (1) or paragraph (6) may be total, or may be limited to a particular activity or to one or more activities carried out at a particular site or sites, or to a particular blood component.

### **The responsible person for a blood establishment**

6.—(1) A blood establishment shall designate a person who is responsible for the following tasks—

- (a) ensuring that every unit of blood or blood component that has been collected or tested for any purpose has been collected and tested in accordance with the requirements of these Regulations;

- (b) ensuring that every unit of blood or blood components intended for transfusion has been processed, stored and distributed in accordance with the requirements of these Regulations;
  - (c) providing information to the Secretary of State relating to the authorisation of the blood establishment for the purposes of regulation 4; and
  - (d) the implementation in the blood establishment of the requirements of regulations 7, 8 and 14.
- (2) A blood establishment shall not designate a person under paragraph (1) unless that person has—
- (a) a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of—
    - (i) a university course of study, or
    - (ii) a course recognised as an equivalent course by the Secretary of State; and
  - (b) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these Regulations for at least 2 years, in an establishment (or more than one establishment) authorised in any Member State in to undertake activities related to the collection or testing (or both) of blood and blood components, or to their preparation, storage and distribution.
- (3) The Secretary of State shall from time to time publish details of courses recognised by him for the purpose of paragraph (2)(a)(ii).
- (4) The responsible person may delegate any of the tasks specified in paragraph (1) to other persons who shall be qualified by training and experience to perform them.
- (5) Blood establishments shall notify the Secretary of State of the name of any persons to whom tasks have been delegated by the responsible person under paragraph (4), and the specific tasks which have been delegated to such persons.
- (6) Where the responsible person or a person to whom tasks have been delegated under paragraph (4) is permanently or temporarily replaced, the blood establishment shall without delay provide the Secretary of State with the name of the replacement, details of his qualifications and the date on which the replacement began his duties.
- (7) If the Secretary of State considers that the responsible person does not meet the requirements of paragraph (2), he may serve a notice to that effect on the blood establishment.
- (8) If, within 14 days of receiving a notice in accordance with paragraph (7), a blood establishment is not able to demonstrate to the reasonable satisfaction of the Secretary of State that the responsible person does meet the requirements of paragraph (2), it shall, without delay—
- (a) relieve him of the duties of responsible person in respect of the establishment;
  - (b) appoint a new responsible person in his place; and
  - (c) notify the Secretary of State that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

### **Blood establishment requirements**

7.—(1) A blood establishment shall—

- (a) ensure that the personnel directly involved in the collection, testing, processing, storage and distribution of human blood and blood components for the blood establishment are qualified to perform those tasks and are provided with timely, relevant and regularly updated training;

- (b) establish and maintain a quality system for blood establishments based on the principles of good practice;
  - (c) ensure that all testing and processes of the blood establishment which are referred to in Parts 2 to 5 of the Schedule are validated;
  - (d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection under regulation 15;
  - (e) notify the Secretary of State of—
    - (i) any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components by the blood establishment which may have an influence on their quality and safety, and
    - (ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components collected, tested, processed, stored or distributed by the blood establishment; and
  - (f) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in paragraph (e).
- (2) A blood establishment shall, in relation to the donation of blood—
- (a) give all prospective donors of blood or blood components information in accordance with Part A of Part 2 of the Schedule;
  - (b) obtain from all persons who are willing to provide blood or blood components, information in accordance with Part B of Part 2 of the Schedule;
  - (c) put and keep in place procedures for the evaluation of donors;
  - (d) apply eligibility criteria for all donors of blood and blood components in accordance with Part 3 of the Schedule;
  - (e) maintain records of the results of donor evaluations and report to donors any relevant abnormal findings from the evaluations;
  - (f) ensure that—
    - (i) an examination of the donor, including an interview, is carried out before any donation of blood or blood components,
    - (ii) a qualified health professional is responsible for giving to and gathering from donors the information which is necessary to assess their eligibility to donate, and
    - (iii) on the basis of that information, a qualified health professional assesses the eligibility of all donors to donate; and
  - (g) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are, in so far as possible, provided from such donations, in particular, by—
    - (i) disseminating information about blood donation, and
    - (ii) advertising for blood donors.
- (3) A blood establishment shall ensure that, in relation to the blood and blood components which it collects, processes, stores or distributes—
- (a) each donation of blood and blood components (including blood and blood components which are imported into the European Community) is tested in conformity with—
    - (i) the basic testing requirements for whole blood and apheresis donations, specified in paragraph (7), and



- (ii) any additional tests which may be necessary for specific components, types of donors or epidemiological situations;
  - (b) the storage, transport and distribution conditions of blood and blood components comply with the requirements of Part 4 of the Schedule; and
  - (c) quality and safety requirements for blood and blood components meet the standards specified in Part 5 of the Schedule.
- (4) A blood establishment shall, in relation to the activities specified in regulation 3(2) for which it is responsible, maintain records, for a minimum period of 15 years, of—
- (a) the information specified in paragraphs (5) and (6),
  - (b) the conduct of the tests referred to in paragraph (3)(a).
- (5) The information specified in this paragraph is—
- (a) the total number of donors who give blood and blood components;
  - (b) the total number of donations;
  - (c) an updated list of the hospital blood banks which it supplies;
  - (d) the total number of whole donations not used;
  - (e) the number of each component produced and distributed;
  - (f) the incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components;
  - (g) the number of product recalls; and
  - (h) the number of serious adverse events and serious reactions reported;
- (6) The information specified in this paragraph is—
- (a) information provided to donors by the blood establishment in accordance with paragraph (2)(a);
  - (b) information obtained from donors by the blood establishment in accordance with paragraph (2)(b); and
  - (c) information relating to the suitability of blood and plasma donors in accordance with the eligibility criteria specified in Part 3 of the Schedule.
- (7) The basic testing requirements with which blood establishments must ensure compliance pursuant to paragraph (3)(a)(i) are—
- (a) testing to establish ABO Group, except in respect of plasma intended only for fractionation;
  - (b) testing to establish Rh D Group, except in respect of plasma intended only for fractionation; and
  - (c) testing for the following infections of donors—
    - (i) Hepatitis B (HBs-Ag);
    - (ii) Hepatitis C (Anti-HCV);
    - (iii) HIV 1 and 2 (Anti-HIV 1 and 2).
- (8) The Secretary of State may issue guidance as to the additional tests referred to in paragraph (3)(a)(ii) which are necessary in relation to specific components, types of donor or epidemiological situations and blood establishments shall have regard to such guidance.
- (9) As soon as practicable after the end of the reporting year, each blood establishment shall provide to the Secretary of State a report specifying—
- (a) the information referred to in paragraph (3) for that year; and

- (b) details of the steps it has taken during that year to comply with paragraph (2)(g).

### **Labelling of blood and blood components and traceability**

8.—(1) A blood establishment shall ensure that the label on each unit of blood or blood component supplied by it, or imported by it from outside the European Community, shall contain the following information—

- (a) the official name of the component;
- (b) the volume or weight or number of cells in the component, as appropriate;
- (c) a unique numeric or alphanumeric donation indication;
- (d) the name of the producing blood establishment;
- (e) the ABO Group, except in the case of plasma intended only for fractionation;
- (f) the Rh D Group, either Rh D positive or Rh D negative, except in the case of plasma intended only for fractionation;
- (g) the date or time of expiry, as appropriate;
- (h) the temperature of storage;
- (i) the name, composition and volume of any anticoagulant and any additive solution.

(2) A blood establishment shall keep such records of the information referred to in paragraph (1) above and such additional records as are necessary—

- (a) for the identification of each single blood donation and each single blood unit and its components (including blood and blood components which are imported into the European Community); and
- (b) to ensure full traceability to the point of delivery to a hospital,

for a period of not less than 30 years.

### **Hospital blood bank requirements**

9.—(1) The person responsible for the management of a hospital blood bank shall—

- (a) ensure that personnel directly involved in the testing, storage and distribution of human blood and blood components for the hospital blood bank are qualified to perform those tasks and are provided with timely, relevant and regularly updated training;
- (b) establish and maintain a quality system for the hospital blood bank which is based on the principles of good practice;
- (c) ensure that all processes referred to in Part 4 of the Schedule which are applicable to activities carried out by the hospital blood bank, are validated;
- (d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection under regulation 15;
- (e) maintain, for not less than 30 years, the data needed to ensure full traceability of blood and blood components, from the point of receipt of the blood or blood component by the hospital blood bank;
- (f) notify the Secretary of State of—
  - (i) any serious adverse events related to the testing, storage and distribution of blood and blood components by the hospital blood bank which may have an influence on their quality and safety, and

- (ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components issued for transfusion by the hospital blood bank;
- (g) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in paragraph (f); and
- (h) ensure that the storage, transport and distribution conditions of blood and blood components by the hospital blood bank comply with the requirements of Part 4 of the Schedule.

#### **Requirement for hospital blood banks to provide information to the Secretary of State**

**10.—**(1) As soon as practicable after the end of the reporting year, the person responsible for management of a hospital blood bank shall submit an annual report to the Secretary of State, which shall—

- (a) include a declaration that the hospital blood bank has in place appropriate systems to ensure compliance with the requirements of these Regulations; and
- (b) provide details of the systems which it has in place to ensure such compliance.

(2) The person responsible for management of a hospital blood bank shall without delay notify the Secretary of State of any changes to the matters in respect of which evidence has been supplied pursuant to paragraph (1) which might affect compliance with the requirements of these Regulations.

#### **Service of notices relating to hospital blood banks**

**11.—**(1) If the Secretary of State is of the opinion that—

- (a) the person responsible for management of a hospital blood bank has failed, in any material respect, to comply with the requirements of these regulations; or
- (b) the testing, storage or distribution of blood or blood components by the hospital blood bank is such that any blood or blood components cannot be safely administered for transfusion; or
- (c) the information given by the person responsible for management of a hospital blood bank pursuant to regulation 10 was false or incomplete in any material respect,

he may serve a notice on the person responsible for management of the hospital bank requiring that the hospital ceases to conduct any of the activities specified in the notice, or refrains from administering to patients any blood or blood components specified in the notice, until the requirements of paragraph (4) are met.

(2) Subject to paragraph (3), any notice served by the Secretary of State pursuant to paragraph (1) shall specify the date from which the prohibition specified in the notice shall take effect, which shall be not less than 7 days from the date on which the notice is served.

(3) Where the Secretary of State considers that it is necessary in the interests of safety, he may specify in the notice that the prohibition takes immediate effect.

(4) The requirements of this paragraph are, as may be applicable in each case, that—

- (a) that the person responsible for management of the hospital blood bank is no longer in breach of the requirements of these regulations;
- (b) that the hospital blood bank is able to show that the activity or product referred to in the notice given pursuant to paragraph (1)(b) may be safely carried out or, as the case may be, administered; or
- (c) that all necessary information has been supplied to the Secretary of State.

**Objections to suspensions, revocations etc**

12.—(1) A blood establishment or a person responsible for the management of a hospital blood bank who—

- (a) objects to any suspension or revocation of authorisation, or to any notice served pursuant to regulation 4(8), 5 or 11; or
- (b) objects to the refusal of authorisation or the imposition of any condition pursuant to regulation 4(5),

may notify the Secretary of State of its desire to make written representations to, or be or appear before and be heard by, a person appointed by the Secretary of State for that purpose.

(2) Any notification of an objection pursuant to paragraph 1 shall be made within 14 days of service on the blood establishment or the person responsible for the management of the hospital blood bank of the notice to which the notification pursuant to paragraph (1) relates.

(3) Where the Secretary of State receives a notification pursuant to paragraph (1), he shall appoint a person to consider the matter.

(4) The person appointed pursuant to paragraph (3) shall determine the procedure to be followed with respect to the consideration of any objection.

(5) The person appointed pursuant to paragraph (3) shall consider any written or oral objections made by the blood establishment or the person responsible for management of the hospital blood bank in support of its objection, and shall make a recommendation to the Secretary of State.

(6) A recommendation made pursuant to paragraph (5) shall be made in writing to the Secretary of State, and a copy of it shall be sent to the blood establishment or the person responsible for the management of the hospital blood bank concerned, or to its nominated representative.

(7) The Secretary of State shall take into account any recommendation made pursuant to paragraph (5).

(8) Within 14 days of receipt of any recommendation made pursuant to paragraph (5), the Secretary of State shall inform the blood establishment or the person responsible for the management of the hospital blood bank whether he accepts the recommendation and, if he does not accept it, of the reasons for his decision.

(9) Where the Secretary of State is notified of an objection pursuant to paragraph (1)(a) before the date upon which the suspension or revocation or the notice is due to take effect, the suspension or revocation or notice in respect of which the objection is made shall not take effect until—

- (a) the person appointed pursuant to regulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and
- (b) the Secretary of State has informed the blood establishment or the person responsible for the management of the hospital blood bank concerned of his decision with regard to the recommendation pursuant to paragraph (8),.

(10) Subject to paragraph (11), where the Secretary of State is notified of an objection pursuant to paragraph (1)(a), within the period specified in paragraph (2), to a suspension, revocation or other notice which has already taken effect on the date the notification was made, the suspension, revocation or notice in respect of which the objection is made shall cease to have effect until—

- (a) the person appointed pursuant to regulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and
- (b) the Secretary of State has informed the blood establishment or the person responsible for the management of the hospital blood bank concerned of his decision with regard to the recommendation pursuant to paragraph (8).

(11) Paragraph (10) shall not apply—

- (a) in relation to a suspension or revocation, or a notice served pursuant to regulation 11, which takes immediate effect in accordance with regulation 5(3) or 11(3); or
- (b) in any other case, where the Secretary of State determines that it is necessary in the interests of public safety for the suspension, revocation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the blood establishment or person responsible for management of the hospital blood bank concerned.

### **Import of blood and blood components into the United Kingdom**

**13.** No person shall import into the United Kingdom any blood or blood components (including blood or blood components intended for use as a starting material or raw material in the manufacture of medicinal products) from a country or territory outside the European Community which does not meet standards of quality and safety equivalent to those laid down in Part 5 of the Schedule.

### **Disclosure of information by blood establishments and hospital blood banks**

**14.—(1)** A blood establishment and the person responsible for management of a hospital blood bank shall ensure that all information which is collected for the purposes of these Regulations is held securely so that it is—

- (a) available for the purpose of, tracing donations;
- (b) not disclosed except—
  - (i) in accordance with one or more of the requirements of paragraph (2), or
  - (ii) where they have been rendered anonymous so that donors are no longer identifiable;
- (c) subject to safeguards against unauthorised additions, deletions or modifications.

(2) The requirements of this paragraph are—

- (a) the disclosure is made in accordance with an order of a court or is otherwise required by law;
- (b) the disclosure is to an inspector appointed by the Secretary of State in accordance with regulation 15(10); or
- (c) the disclosure is for the purpose of tracing a donation from donor to recipient or recipient to donor.

(3) Where a disclosure is made to an inspector pursuant to paragraph (2)(b), the inspector shall not further disclose the information received unless—

- (a) the disclosure is made in accordance with an order of a court or is otherwise required by law;
- (b) the disclosure is to another officer of the Secretary of State where this is necessary for the proper performance of the inspector or officer's duties; or
- (c) the information has been rendered anonymous so that that donors are no longer identifiable.

(4) Where a disclosure is made by an inspector to another officer of the Secretary of State pursuant to paragraph (3), that person shall not further disclose the information he receives other than in accordance with the requirements of that paragraph.

(5) The responsible person of the blood establishment and the person responsible for management of the hospital blood bank shall ensure that they put in place a procedure to ensure that any discrepancies relating to data which are brought to their attention are resolved without delay.

**Inspections, etc.**

**15.**—(1) The Secretary of State shall conduct a regular inspection of each site of a blood establishment, not less than once every two years, for the purpose of ensuring that—

- (a) blood establishments comply with the requirements of these Regulations; and
- (b) problems relating to compliance with those requirements are identified.

(2) The Secretary of State may conduct such additional inspections of blood establishments sites as he considers necessary for the purpose of ensuring compliance with the requirements of these Regulations.

(3) The Secretary of State may also serve a notice on a blood establishment requiring that it furnish him with such information concerning its compliance with these Regulations as shall be specified in the notice within such period as shall be specified in the notice.

(4) Any blood establishment which receives a request or information in accordance with paragraph (3) shall provide the information requested within the period specified in the notice.

(5) The Secretary of State may inspect hospital blood banks with a view to ensuring that—

- (a) hospital blood banks and persons responsible for the management of such blood banks comply with the requirements of these Regulations; and
- (b) problems relating to compliance with those requirements are identified.

(6) The Secretary of State may also serve a notice on the person responsible for managing a hospital blood bank requiring that he furnish him with such information concerning the compliance of the blood bank with these Regulations as shall be specified in the notice within such period shall be specified in the notice.

(7) Any person responsible for management of a hospital blood bank who receives a request for information in accordance with paragraph (6) shall provide the information requested within the period specified in the notice.

(8) In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, the Secretary of State shall request such information or conduct such inspections in accordance with this regulation as he shall consider appropriate.

(9) Any reference to an inspection of a site which the Secretary of State is required or empowered to conduct by virtue of this regulation, shall be construed so as to include an inspection of premises within the UK at which any of the activities listed in regulation 3(2) are carried out by any person on behalf of, and pursuant to a contractual arrangement with, a blood establishment or, as the case may be, a person responsible for management of a hospital blood bank.

(10) The Secretary of State may appoint such persons to be inspectors as he thinks necessary for the proper discharge by them of his functions set out in these Regulations, and he may appoint such persons upon such terms and conditions (including conditions as to remuneration, benefits, allowances and reimbursement for expenses) as he thinks fit.

**Records to be kept by the Secretary of State**

**16.**—(1) The Secretary of State shall keep such records of information which he receives from, or relating to, blood establishments as he considers appropriate and shall, in particular, keep records relating to—

- (a) authorisations under regulation 4;
- (b) the designation of responsible persons under regulation 6;
- (c) notification of serious adverse events and serious adverse reactions by such establishments pursuant to regulation 7(1)(e);
- (d) inspections or requests for information under regulation 15;

- (e) the operation, during the period from 8<sup>th</sup> February 1005 to 7<sup>th</sup> November 2005, of blood establishments licensed under section 8 of the Medicines Act 1968.

(2) The Secretary of State shall keep such records of information which he receives from persons responsible for management of hospital blood banks, or otherwise or relating to hospital blood banks, as he considers appropriate and shall, in particular keep records relating to—

- (a) notification of serious adverse events and serious adverse reactions pursuant to regulation 9(1)(f);
- (b) the information supplied by hospital blood banks pursuant to regulation 10;
- (c) inspections or requests for information under regulation 15.

### **Powers of entry, etc.**

17.—(1) For the purposes of enforcing compliance with these Regulations or conducting inspections pursuant to regulation 15, an inspector appointed in accordance with regulation 15(10) shall, upon production of evidence that he is so authorised, have the right—

- (a) at any reasonable hour to enter any premises, other than premises used only as a private dwelling house, which he has reason to believe it is necessary for him to visit, including—
  - (i) any premises owned or managed by a blood establishment or person responsible for management of a hospital blood bank, or at which the blood establishment or person responsible for management of a hospital blood bank carries out any of the activities referred to in regulation 3;
  - (ii) any premises of any person who carries out any of the activities referred to in regulation 3(2) on behalf of, and pursuant to a contractual arrangement with, a blood establishment or a person responsible for management of a hospital blood bank; and
  - (iii) where any facilities for donor evaluation and testing are in the premises of any person other than a blood establishment or hospital blood bank, those facilities in that person's premises;
- (b) to carry out at those premises during that visit inspections, examinations, tests and analyses as he considers necessary;
- (c) to require the production of, and inspect any article or substance at, the premises;
- (d) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record (in whatever form it is held) at, or (in the case of computer data or records) accessible at the premises;
- (e) subject to paragraph (6), to take possession of any samples for examination and analysis and any other article, substance, book, document, data, record (in whatever form they are held) at, or (in the case of computer data or records) accessible at, the premises;
- (f) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;
- (g) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities;
- (h) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him;

but nothing in this paragraph shall be taken to compel the production by any person of a document of which he would on grounds of legal professional privilege be entitled to withhold production on an order for disclosure in an action in the High Court or, as the case may be, on an order for production of documents in an action in the Court of Session.

(2) If a justice of the peace is satisfied by any written information on oath that there are reasonable grounds for entry into any premises, other than premises used only as a private dwelling house, for any purpose mentioned in paragraph (1), and—

- (a) admission to the premises has been refused or is likely to be refused and notice of intention to apply for a warrant under this sub-paragraph has been given to the occupier;
- (b) an application for admission, or the giving of such notice, would defeat the object of the entry; or
- (c) the premises are unoccupied or the occupier is temporarily absent and it might defeat the object of the entry to await his return,

the justice may, by warrant signed by him, which shall continue in force for a period of one month, authorise an inspector to enter the premises, if need be by force.

(3) An inspector entering premises by virtue of paragraph (1) or of a warrant under paragraph (2) may take with him when he enters those premises such equipment as may appear to him necessary and any person who is authorised by the Secretary of State to accompany him on that visit.

(4) On leaving any premises which an inspector is authorised to enter by a warrant under paragraph (2), he shall, if the premises are unoccupied, or the occupier is temporarily absent, leave the premises as effectively secured against trespassers as he found them.

(5) Where, pursuant to paragraph (1)(e), an inspector takes possession of any article, substance, book, document, data or record, he shall leave at the premises with a responsible person, or if there is no such person present on the premises, leave in the premises in a prominent position, a statement giving particulars of the article, substance, book, document, data or record sufficient to identify it and stating that he has taken possession of it.

(6) Where, pursuant to paragraph (1)(e) an inspector takes a sample for analysis, the Secretary of State may, subject to the requirements of paragraph (7), make such arrangements for analysis of that sample as he considers appropriate.

(7) The requirements of this paragraph are—

- (a) that the Secretary of State shall inform the responsible person of the blood establishment or person responsible for the management of the hospital blood bank from which the sample was taken that he intends to make arrangements for analysis of the sample, and of the tests which he intends should be made; and
- (b) that if the responsible person or person responsible for the management of the hospital blood bank so requests, the Secretary of State shall divide the sample of which an analysis is to be made into three equal parts and deal with those parts in accordance with the requirements of paragraph (8).

(8) The requirements of this paragraph are—

- (a) that the Secretary of State shall make arrangements for the testing of one part of the sample;
- (b) that one part of the sample shall be sent to the responsible person of the blood establishment or person responsible for the management of the hospital blood bank; and
- (c) that one part of the sample shall be retained by the Secretary of State for a reasonable period in case of dispute.

### **Criminal offences**

**18.—**(1) Any person who contravenes any of the following provisions—

- (a) regulation 3(1)
- (b) regulation 7;
- (c) regulation 9;



- (d) regulation 13;
- (e) regulation 23(2),

shall be guilty of an offence.

(2) Any person who contravenes any of the following provisions—

- (a) regulation 4(9);
- (b) regulation 6, other than regulation 6(3);
- (c) regulation 8;
- (d) regulation 10;
- (e) regulation 15(4) and (7),

shall be guilty of an offence

(3) Any person who fails to comply with a notice of suspension or revocation of his authorisation served pursuant to regulation 5, save where the operation of that notice has been suspended pursuant to regulation 12, or has been withdrawn or revoked by the Secretary of State, shall be guilty of an offence.

(4) Any person who knowingly sells or supplies blood or any blood component which is not labelled in accordance with the requirements of regulation 8, shall be guilty of an offence.

(5) Any person who contravenes the requirements of any notice served by the Secretary of State under regulation 11(1), shall be guilty of an offence.

(6) Any person who—

- (a) contravenes regulation 14; or
- (b) discloses any information referred to in regulation 14(1) to which they have access by virtue of these regulations, otherwise than in accordance one or more of the requirements specified in regulation 14(2) and (3),

shall be guilty of an offence.

(7) Subject to paragraph (5)—

- (a) any person who—
  - (i) intentionally obstructs an inspector, or;
  - (ii) without reasonable cause fails to comply with any requirements made of him by an inspector, in circumstances where that inspector is acting in pursuance of any of his functions under these Regulations; or
  - (iii) any person who, in purported compliance with any such requirement as is mentioned in sub-paragraph (a)(ii), intentionally or recklessly furnishes information which is false or misleading in a material respect,

shall be guilty of an offence.

(8) Nothing in paragraph (7)(a)(ii) shall be construed as requiring any person to answer any question or give any information if to do so might incriminate him or, in the case of a person who is married, his spouse.

## **Penalties**

**19.**—(1) A person guilty of an offence under regulation 18(1), (3), (5) or (7) shall be liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding 6 months, or to both; or
- (b) on conviction on indictment, to a fine, or to imprisonment for a term not exceeding 2 years, or to both.

(2) A person guilty of an offence under regulation 18(2), (4) or (6) shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale, or to imprisonment for a term not exceeding 6 months, or to both.

### **Defence of due diligence**

**20.**—(1) In any proceedings for an offence under any of the preceding provisions of these Regulations, it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid commission of the offence.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond all reasonable doubt that it is not.

### **Offences by bodies corporate and Scottish partnerships**

**21.** Where an offence under these Regulations is committed by a body corporate or a Scottish partnership and is proved to have been committed with the consent or connivance of, or to be attributable to, any neglect on the part of—

- (a) any director, manager, secretary, partner or similar officer of the body corporate or Scottish partnership; or
- (b) any person who was purporting to act in any such capacity,

he, as well as the body corporate or Scottish partnership, shall be deemed to be guilty of that offence and he shall be liable to be proceeded against and punished accordingly.

### **Fees**

**22.**—(1) Blood establishments shall pay to the Secretary of State such fees as are payable in accordance with paragraphs (2) and (3).

(2) The fees payable pursuant to paragraph (1) by blood establishments in relation to authorisation under regulation 3 are—

- (a) in respect of an application for authorisation pursuant to regulation 3, the sum of £2,444;
- (b) in respect of an application for approval of a substantial change pursuant to regulation 4(10), the sum of £400; and
- (c) in connection with the holding of an authorisation under regulation 3, an annual fee of the sum of £304.

(3) Where the Secretary of State carries out an inspection at a site of a blood establishment he may charge the establishment and that establishment shall, if so charged, pay to the Secretary of State a fee calculated in accordance with the following sub-paragraphs—

- (a) for a regular inspection of a major site, the sum of £8,729;
- (b) for a regular inspection of a standard site, the sum of £5,557;
- (c) for a regular inspection of a minor site, the sum of £2,698;
- (d) for any other inspection, where the inspector spends at least two hours but no more than one day at the site, £1,518;
- (e) for any other where an inspector spends more than one day but less than three days at the inspection site, £4,048; or
- (f) for any other inspection where the inspector spends three days or more at the site, £7,590.

(4) Where the Secretary of State carries out an inspection of a hospital blood bank he may charge the person responsible for management of the hospital blood bank and that person shall, if so charged, pay to the Secretary of State a fee calculated in accordance with paragraph (5).

(5) The fees payable by hospital blood banks in respect of inspections are—

- (a) where an inspector spends at least two hours but no more than one day at the inspection site, £759;
- (b) where an inspector spends more than one day but less than three days at the inspection site, £2024; or
- (c) where the inspector spends three days or more at the inspection site, £3795.

(6) In this regulation—

“major site” means a site at which 60 or more persons are involved in processing and quality assurance of blood or blood components;

“minor site” means a site at which fewer than 10 persons are involved in processing and quality assurance of blood or blood components;

“regular inspection” means an inspection of blood establishment pursuant to regulation 15(1);

“standard site” means a site at which at least 10 but fewer than 60 people are involved in processing and quality assurance of blood or blood components.

(7) Any fee payable under this regulation shall be payable at the following times—

- (i) the fee payable pursuant to paragraph (2)(a) in respect of an application for authorisation to operate a blood establishment, and the fee payable pursuant to paragraph (2)(b) in respect of an application to make a substantial change, shall, in each case, be payable at the time the application is made;
- (ii) the periodic fee payable pursuant to paragraph (2)(c) shall be payable on the first anniversary of the grant by the Secretary of State of authorisation to operate as a blood establishment, and whilst the blood establishment continues to be authorised to operate as such pursuant to these Regulations, annually thereafter;
- (iii) any other fee payable under this regulation shall be payable within fourteen days following written notice from the Secretary of State requiring payment of the fee.

(8) All unpaid sums due by way of, or on account of, any fees payable under this regulation shall be recoverable as debts due to the Crown.

(9) The Secretary of State may in exceptional circumstances where it appears to him to be in the interests of safety or otherwise appropriate to do so—

- (a) waive any fee or reduce any fee or part of a fee otherwise payable under this regulation; or
- (b) refund the whole or part of any fee paid pursuant to this regulation.

### **Specific epidemiological situations**

**23.**—(1) Where the Secretary of State is aware of a specific epidemiological situation, such as an outbreak of a disease, which may affect the safety of blood donations, and as a result of which he considers that specific deferral criteria for the collection of blood donations should be adopted, he shall—

- (a) notify blood establishments that those criteria must be adopted; and
- (b) notify the Commission of—
  - (i) the epidemiological situation; and
  - (ii) the additional deferral criteria which blood establishments are required to adopt in relation to it pursuant to sub-paragraph (a).

(2) A blood establishment shall adopt and comply with any criteria for additional tests notified to them by the Secretary of State pursuant to paragraph (1).

### Transitional provisions

**24.**—(1) Subject to paragraph (2), these Regulations, other than regulations 13 and 16, shall not apply before 8th November 2005 in relation to—

- (a) any blood establishment licensed under section 8 of the Medicines Act 1968<sup>(14)</sup>;
- (b) any hospital blood bank.

(2) From the date these Regulations come into force, a blood establishment licensed under section 8 of the Medicines Act 1968 may apply for, and the Secretary of State may grant, an authorisation under regulation 4 to have effect as from 8th November 2005.

### Consequential amendments

**25.**—(1) The Medicines Act 1968 shall be amended as follows—

- (a) in section 7 (general provisions as to dealing with medicinal products) omit paragraph (a) of subsection (6A)<sup>(15)</sup>;
- (b) in section 8 (provisions as to manufacture and wholesale dealing), omit paragraph (a) of subsection (4)<sup>(16)</sup>;
- (c) in section 130 (meaning of “medicinal product” and related expressions) in subsection (5), after paragraph (b), insert the following new paragraph—  
“*(ba)* whole human blood and human blood components;”.
- (d) In section 130, after subsection (5A) insert the following new subsection—  
“(5B) For the purposes of this section, “human blood component” means any of the following constituents of human blood: red cells, white cells, platelets and plasma.”.

(2) The Medicines (Standard Provisions for Licenses and Certificates) Regulations 1971 shall be amended as follows—

- (a) in regulation 2 (interpretation), after the definition of “BCG vaccine” insert the following definitions—  
““blood” means whole human blood;  
“blood component” means a therapeutic constituent of blood (red cells, white cells, platelets and plasma);”; and

(b) in Schedule 2 insert the following new paragraph—

“**5C.** The licence holder shall ensure that any blood or blood component imported into the United Kingdom and used by him as a starting material or raw material in the manufacture of a medicinal product, shall meet equivalent standards of quality and safety to those laid down in Commission Directive [2004/33/EC](#), implementing Directive [2003/98/EC](#) of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.”.

(3) In the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994<sup>(17)</sup>, in regulation 1 (citation, commencement and interpretation), in paragraph (2), in the definition of “the 2001 Directive”, after “as amended by” insert—

<sup>(14)</sup> 1968 c. 67.

<sup>(15)</sup> Subsection (6A) was inserted by S.I. [1992/604](#) and amended by S.I. [1994/276](#).

<sup>(16)</sup> Subsection (4) was substituted by S.I. [1992/604](#) and amended by S.I. [1994/276](#).

<sup>(17)</sup> S.I. [1994/3144](#); relevant amending instruments are S.I. [2001/795](#), [2002/236](#), [2003/2321](#) and [2004/3224](#).

“Directive [2002/98/EC](#) of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive [2001/83/EC](#)”.

Signed by authority of the Secretary of State for Health

12th January 2005

*Melanie Johnson*  
Parliamentary Under Secretary of State,  
Department of Health

We consent,

13th January 2005

*Joan Ryan*  
*Nick Ainger*  
Two of the Lords Commissioners' of Her  
Majesty's Treasury