PUBLIC HEALTH (BLOOD SAFETY AND QUALITY) ACT 2007

Principal Act

Act. No. 2007-06	*Commencement (LN. 2008/003)*	31.1.2008
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Amending enactments	Relevant current provisions	Commencement date
LN. 2011/157	Sch. 4	22.9.2011

Transposing:
Directive 2002/98/EC
Directive 2004/33/EC
Directive 2005/61/EC
Directive 2005/62/EC
Directive 2011/38/EU

ARRANGEMENT OF SECTIONS

Section

SCHEDULE 4
QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

SCHEDULE 5
NOTIFICATION OF SERIOUS ADVERSE REACTIONS

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QUALITY SYSTEM STANDARDS AND SPECIFICATIONS

Public Health (Blood Safety and Quality)

AN ACT TO TRANSPOSE INTO THE LAW OF GIBRALTAR DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 JANUARY 2003 SETTING OUT THE STANDARDS OF QUALITY AND SAFETY FOR THE COLLECTION, TESTING, PROCESSING, STORAGE AND DISTRIBUTION OF HUMAN BLOOD AND BLOOD COMPONENTS AND COMMISSION DIRECTIVE 2004/33/EC OF 22 MARCH 2004 IMPLEMENTING DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS CERTAIN TECHNICAL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS, AND COMMISSION DIRECTIVE 2005/61/EC OF 30 SEPTEMBER 2005 IMPLEMENTING DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS TRACEABILITY REQUIREMENTS AND NOTIFICATION OF SERIOUS ADVERSE REACTIONS AND EVENTS, AND COMMISSION DIRECTIVE 2005/62/EC OF 30 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; AND FOR CONNECTED PURPOSES.

Title and commencement.

1. This Act may be cited as the Public Health (Blood Safety and Quality) Act 2007 and comes into operation on the day appointed by the Minister for Health by notice in the Gazette and different days may be appointed for different purposes.

Interpretation.

2.(1) In this Act, unless the context otherwise requires–

"additive solution" means a solution specifically formulated to maintain beneficial properties of cellular components during storage;

"allogeneic donation" means blood and blood components collected from an individual and intended for transfusion to another individual, for use in medical devices or as starting material or raw material for manufacturing into medicinal products;

"apheresis" means a method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process;

"authorised person" means a person appointed under section 22(1);

"autologous donation" means blood and blood components collected from an individual and intended solely for subsequent autologous transfusion or other human application to that same individual;

"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;

"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;

"blood establishment" means a person who carries out any of the activities specified in section 4(2) which requires an authorisation under section 5;

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

"buffy coat" means a blood component prepared by centrifugation of a unit of whole blood, and which contains a considerable proportion of the leucocytes and platelets;

"clinic" means an establishment or a facility that is devoted to the diagnosis and care of patients and in which services are provided by qualified health professionals;

"Commission" means the European Commission;

"competent authority" means the competent authority designated under section 3(1);

"computerised system" means a system including the input of data, electronic processing and the output of information to be used either for reporting, automatic control or documentation.

"Cryopreservation" means prolongation of the storage life of blood components by freezing;

"Cryoprecipitate" means a plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and re-suspension of the precipitated proteins in a small volume of the plasma;

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

"dentist" means a person who is registered as a dentist under the Medical and Health Act 1997;

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

"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 person who is a registered medical practitioner within the meaning of the Medical and Health Act 1997;

"donor carer" means a nurse who by virtue of training and experience in the care of donors is awarded a certificate of competence by the Gibraltar Health Authority;

"facilities" means–

(a) a hospital,

(b) any other facility or service owned or managed by the Gibraltar Health Authority;

(c) a clinic;

(d) a manufacturer; or

(e) a biomedical research institution;

"Gibraltar Health Authority" means the Authority established by section 3 of the Medical (Gibraltar Health Authority) Act, 1987;

"good practice" means all elements in established practice that collectively will lead to final blood or blood components that consistently meet predefined specifications and compliance with defined regulations;

"granulocytes, apheresis" means a concentrated suspension of granulocytes obtained by apheresis;

"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;

"hospital" means any hospital run by the Gibraltar Health Authority or any other hospital in Gibraltar;

"hospital blood bank" means a 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;

"implementing Directives" means Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components, and Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events, and Commission Directive 2005/62/EC of 30 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;

"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;

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

"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 or an entity that manufactures medicinal products or medical devices;

"medical device" means medical device as defined in Article 1(2)(a) of Council Directive 1993/42/EEC of 14 June 1993 concerning medical devices;

"medicinal product" means medicinal products as defined in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;

"midwife" means a person who is registered as a midwife under the Medical and Health Act 1997;

"Minister" means the Minister with responsibility for Health;

"mobile site" means a temporary or movable place used for the collection of blood and blood components which is in a location outside of but under the control of the blood establishment;

"nurse" means a person who is registered as a nurse under the Medical and Health Act 1997;

"person responsible for management of a hospital blood bank" means a person designated by the Gibraltar Health Authority for management of a hospital blood bank and in the case of a private clinic or hospital, the owner;

"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 the Gibraltar Health Authority, the Gibraltar Health Authority ;

(b) in the case of a clinic, the owner or manager of the clinic;

(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;

"Plasma" means the liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh-frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion. It may be used for the manufacture of medicinal products derived from human blood and human plasma or used in the preparation of pooled platelets, or pooled, leucocyte-depleted platelets. It may also be used for re-suspension of red cell preparations for exchange transfusion or perinatal transfusion;

"plasma, fresh-frozen" means the supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored;

"plasma, cryoprecipitate-depleted for transfusion" means a plasma component prepared from a unit of plasma, fresh-frozen. It comprises the residual portion after the cryoprecipitate has been removed;

"platelets, apheresis" means a concentrated suspension of blood platelets obtained by apheresis;

"platelets, apheresis, leucocyte-depleted" means a concentrated suspension of blood platelets, obtained by apheresis, and from which leucocytes are removed;

"platelets, recovered, pooled" means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation;

"platelets, recovered, pooled, leucocyte-depleted" means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation, and from which leucocytes are removed;

"platelets, recovered, single unit" means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood;

"platelets, recovered, single unit, leucocyte-depleted" means a concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leucocytes are removed;

"processing" means any step in the preparation of a blood component that is carried out between the collection of blood and the issuing of a blood component;

"qualification", as part of validation, means the action of verifying that any personnel, premises, equipment or material works correctly and delivers the expected results;

"qualified health professional" means–

(a) a doctor;

(b) a dentist;

(c) a midwife;

(d) a nurse; or

(e) a donor carer;

"quality assurance" means all the activities from blood collection to distribution made with the object of ensuring that blood and blood components are of the quality required for their intended use;

"quality control" means part of a quality system focussed on fulfilling quality requirements;

"quality management" means the co-ordinated activities to direct and control an organisation with regard to quality at all levels within the blood establishment;

"quality system" means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management;

"quarantine" means the physical isolation of blood components or incoming materials or reagents or both over a variable period of time while awaiting acceptance, issuance or rejection of the blood components or incoming materials or reagents or both;

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

"red cells" means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed;

"red cells, buffy coat removed" means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed;

"red cells, leucocyte-depleted" means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed;

"red cells in additive solution" means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. A nutrient or preservative solution is added;

"red cells, buffy coat removed, in additive solution" means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed. A nutrient or preservative solution is added;

"red cells, leucocyte-depleted, in additive solution" means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed. A nutrient or preservative solution is added;

"red cells, apheresis" means the red cells from an apheresis red cell donation;

"relevant thing" means–

(a) any blood, blood component or blood product; or

(b) any article or substance used in the manufacture, processing or storage of any blood, blood component or blood product;

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

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

"responsible person" in relation to a blood establishment means the person who has been designated under section 7 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 section 4(2) or any mobile blood collection unit, but shall not include any premises not owned or managed by the blood establishment at which blood is collected;

"specification" means a description of the criteria that must be fulfilled in order to achieve the required quality standard;

"statistical process control" means a method of quality control of a product or a process that relies on a system of analysis of an adequate sample size without the need to measure every product of the process;

"standard" means the requirements that serve as the basis for comparison;

"third country" means a country or territory outside the European Community;

"traceability" means the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa;

"trace-back" means the process of investigating a report of a suspected transfusion-associated adverse reaction in a recipient in order to identify a potentially implicated donor;

"validation" means the establishment of documented and objective evidence that the particular or pre-defined requirements for a

specific procedure or process or specific intended use can be consistently fulfilled;

"washed" means a process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed and replaced following further centrifugation of the suspension. The centrifugation, decanting, replacing process may be repeated several times;

"whole blood" means a single blood donation;

"written procedures" means controlled documents that describe how specified operations are to be carried out.

(2) Any term used in this Act, but not defined, shall be construed in accordance with the provisions of the principal Directive and the implementing Directives.

Designation of the competent authority and application of the Act.

3.(1) The Minister is designated the competent authority for the purposes of this Act.

(2) The competent authority may enter into a contractual arrangement with a person for the purposes of the person assisting the competent authority to perform his functions under this Act.

(3) Subject to subsection (4), the requirements of this Act 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.

(4) This Act does not apply to blood stem cells.

Requirement for authorisation.

4.(1) Subject to subsection (3), no person shall carry on any of the activities listed in subsection (2) otherwise than in accordance with an authorisation granted under section 5.

(2) The activities referred to in subsection (1) are–

(a) the collection and testing of blood or blood components, whatever their intended purpose;

(b) the processing, storage and distribution of blood and blood components when they are intended to be used for transfusion; and

(c) the import of blood or blood components from a third country.

(3) The restriction in subsection (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 subsection (2), where that person carries out that activity on behalf of, or pursuant to a contractual arrangement with–

(i) a blood establishment which is authorised under this Act to carry out the activity in question, or

(ii) a person responsible for management of a hospital blood bank; and

(c) the import of blood and blood components from a third country when undertaken by–

(i) a manufacturer, or

(ii) a person acting on behalf of and pursuant to a contractual arrangement with a manufacturer,

for the purposes of manufacturing a medicinal product or medical devices.

Authorisation of a blood establishment.

5.(1) The competent authority may grant an authorisation to a blood establishment to carry out any of the activities referred to in section 4(2).

(2) An application for authorisation under subsection (1) shall be made to the competent authority.

(3) An application shall–

(a) include the information set out in subsection (4); and

(b) be accompanied by a fee of the amount prescribed by Regulations.

(4) The information referred to in subsection (3) 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 section 4(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 Schedule 4,

(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 competent authority may–

(a) grant or refuse any application for authorisation made under subsection (2); and

(b) grant such application–

(i) in respect of particular sites or activities only, and

(ii) subject to conditions.

(6) Where the competent authority 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 this Act 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 subsection (8), the competent authority may at any time remove or vary any of the conditions referred to in subsection (5)(b)(ii), or may impose additional conditions.

(8) Where the competent authority removes or varies any condition or imposes any additional condition under subsection (7), the competent authority shall serve a notice on the blood establishment in question that 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 shall not make any substantial change in the activities that it undertakes without the prior written approval of the competent authority.

(10) Any application for approval to make a substantial change in its activities shall be made in writing to the competent authority, and shall be accompanied by a fee of the amount prescribed by Regulations.

(11) For the purposes of this section, 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) that would result in breach of this Act or of any condition specified by the competent authority under this section; 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 under this section.

Suspension or revocation of authorisation.

6.(1) The competent authority 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 this Act;

(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 under section 5(3) was false or incomplete in any material respect.

(2) Subject to subsection (3), before suspending or revoking the authorisation of a blood establishment, the competent authority 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 competent authority 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 this Act; or

(b) the information given by the blood establishment under section 5(3) was false or incomplete in any material respect,

and the competent authority 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 subsection (5).

(5) A notice served under this subsection shall–

(a) identify the requirements of the sections 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 paragraph (b).

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

(7) A suspension or revocation under subsection (6) shall take effect–

(a) in a case where the competent authority 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 under subsections (1) or (6) shall be for such period as the competent authority shall consider necessary having regard to the reasons for the suspension.

(9) The suspension or revocation of an authorisation under subsection (1) or subsection (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.

7.(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 this Act;

(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 this Act;

(c) providing information to the competent authority relating to the authorisation of the blood establishment for the purposes of section 5; and

(d) the implementation in the blood establishment of the requirements of sections 8, 9 and 15.

(2) A blood establishment shall not designate a person under subsection (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 competent authority; and

(b) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under this Act for at least 2 years, in an establishment (or more than one establishment) authorised in any Member State 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 competent authority shall from time to time publish details of courses recognised by him for the purposes of subsection (2)(a)(ii).

(4) The responsible person may delegate any of the tasks specified in subsection (1) to other persons who shall be qualified by training and experience as prescribed by this section to perform them.

(5) Blood establishments shall notify the competent authority of the name of any persons to whom tasks have been delegated by the responsible person under subsection (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 subsection (4) is permanently or temporarily replaced, the blood establishment shall without delay provide the competent authority with the name of the replacement, details of his qualifications and the date on which the replacement began his duties.

(7) If the competent authority considers that the responsible person does not meet the requirements of subsection (2) or that he is failing to carry out the tasks specified in subsection (1) adequately or at all, he may serve a notice to that effect on the blood establishment.

(8) If, within 14 days of receiving a notice in accordance with subsection (7), a blood establishment is not able to demonstrate to the reasonable satisfaction of the competent authority that the responsible person does meet the requirements of subsection (2) or that he is carrying out the tasks specified in subsection (1) adequately, 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 competent authority that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

Blood establishment requirements.

8.(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, which complies with the Community standards and requirements set out in Schedule 7;

(c) ensure that all testing and processes of the blood establishment which are referred to in Schedules 1 to 4 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 section 21;

(e) 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 section 18;

(f) ensure that autologous donations comply with the requirements of this Act; and

(g) retain, for a period of at least 15 years, a record of any serious adverse events which may affect the quality or safety of blood and blood components.

(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 Schedule 1;

(b) obtain from all persons who are willing to provide blood or blood components, information in accordance with Part B of Schedule 1;

(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 Schedule 2;

(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 subsection (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 Schedule 3; and

(c) quality and safety requirements for blood and blood components meet the standards specified in Schedule 4.

(4) A blood establishment shall, in relation to the activities specified in section 4(2) for which it is responsible, maintain records, for a minimum period of 15 years, of–

(a) the information specified in subsections (5) and (6);

(b) the conduct of the tests referred to in subsection (3)(a).

(5) The information specified in this subsection 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 subsection is–

(a) information provided to donors by the blood establishment in accordance with subsection (2)(a);

(b) information obtained from donors by the blood establishment in accordance with subsection (2)(b); and

(c) information relating to the suitability of blood and plasma donors in accordance with the eligibility criteria specified in Schedule 2.

(7) The basic testing requirements with which blood establishments shall ensure compliance under subsection (3)(a)(i) are testing–

(a) to establish ABO Group, except in respect of plasma intended only for fractionation;

(b) to establish Rh D Group, except in respect of plasma intended only for fractionation; and

(c) 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 competent authority may issue guidance as to the additional tests referred to in subsection (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 competent authority a report specifying–

(a) the information referred to in subsection (3) for that year; and

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

Labelling of blood and blood components.

9.(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 maintain, in relation to all blood and blood components collected or prepared by it (including blood and blood components which are imported by it into the European Community)–

(a) records of the information referred to in subregulation (1);

(b) the records referred to in section 10(3)(a); and

(c) such other records as are necessary to ensure full traceability of blood and blood components and identification of each single donation, unit and component.

(3) The records referred to in subsection (2)(a) shall be maintained–

(a) in an appropriate and readable storage medium; and

(b) for a period of not less than 30 years.

Traceability.

10.(1) A blood establishment shall ensure that–

(a) the labelling system established under this Act is adequate or appropriate for the purpose of traceability of blood and blood components;

(b) the traceability system in place enables the tracing of blood components to their location and processing stage.

(2) Every blood establishment shall ensure that it has–

(a) a system in place to uniquely identify each donor, each blood unit collected, and each blood component prepared, whatever its intended purpose, and the facilities to which a given blood component has been delivered; and

(b) a unique identifier that enables it to be precisely linked to each unit of blood that it has collected and to each blood component that it has prepared.

(3) Every facility shall ensure that it has a system in place to record each blood unit or blood component received, whether or not locally processed, and the final destination of that received unit, whether transfused, discarded or returned to the distributing blood establishment.

(4) Every blood establishment, hospital blood bank and facility shall retain the data set out in subsection (5) for at least 30 years in an appropriate and readable storage medium in order to ensure traceability.

(5) The record of data on traceability required to be retained as referred to in subsection (4) are as follows–

(a) by blood establishments–

(i) blood establishment identification,

(ii) blood donor identification,

(iii) blood unit identification,

(iv) individual blood component identification,

(v) date of collection (year/month/day), and

(vi) facilities to which blood units or blood components are distributed, or subsequent disposition;

(b) by facilities–

(i) blood component supplier identification,

(ii) issued blood component identification,

(iii) transfused recipient identification,

(iv) for blood units not transfused, confirmation of subsequent disposition,

(v) date of transfusion or disposition (year/month/day), and

(vi) lot number of the component, if relevant.

(6) A blood establishment shall ensure, when it issues a unit of blood or blood components for transfusion, that the facility to which the unit of blood is issued has in place a procedure to verify that each unit of blood issued has been transfused to the intended recipient or, if not transfused, to verify its subsequent disposition.

Verification procedure for issuing blood or blood components.

11. No blood establishment or hospital blood bank shall issue any units of blood or blood components for transfusion, unless it has in place a procedure to verify that each unit issued has been transfused to the intended recipient or if not transfused to verify its subsequent disposition.

Hospital blood bank requirements.

12.(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 that complies with the Community standards and requirements set out in Schedule 7 insofar as they are applicable to the activities carried out by the hospital blood bank;

(c) ensure that all processes referred to in Schedule 4 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 section 21;

(e) maintain in an appropriate and readable storage medium and for a period of not less than 30 years–

(i) the data set out in section 10(5) (insofar as those data are applicable to the activities carried out by the hospital blood bank), and

(ii) such other data as are needed to ensure full traceability of blood and blood components and the unique

identification of each unit of blood and each blood component from the point of receipt of the blood or blood components by the hospital blood bank;

(f) retain, for a period of not less than 30 years, a record of any serious events which may affect the quality or safety of blood or blood components;

(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 section 18;

(h) ensure that the storage, transport and distribution conditions of blood and blood components by the hospital blood bank comply with the requirements of Schedule 3; and

(i) ensure that the traceability system in place in the hospital blood bank enables the tracing of blood components to their final destination; and

(j) where it delivers blood or blood components for transfusion at another facility, have in place a system to uniquely identify the facility to which a given unit of blood or blood component has been delivered.

(2) A person responsible for management of a hospital blood bank shall ensure that when a hospital blood bank issues a unit of blood for transfusion, that it has in place a procedure to verify that each unit of blood issued has been transfused to the intended "recipient, or if not transfused, to verify its subsequent disposition.

Requirement for hospital blood banks to provide information to the competent authority.

13.(1) On or before the date specified in subsection (2), the person responsible for management of a hospital blood bank shall submit a report to the competent authority, which shall–

(a) include a declaration that the hospital blood bank has in place appropriate systems to ensure compliance with the requirements of this Act; and

(b) provide details of the systems which it has in place to ensure such compliance.

(2) The date referred to in subsection (1) is–

(a) in relation to the reporting year ending on 31st March 2007, 31st December 2006;

(b) in relation to each subsequent reporting year, 30th April following the end of that year.

(3) The person responsible for management of a hospital blood bank shall without delay notify the competent authority of any changes to the matters in respect of which evidence has been supplied under subsection (1) which might affect compliance with the requirements of this Act.

Service of notices relating to hospital blood banks.

14.(1) If the competent authority 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 this Act; 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 under section 13 was false or incomplete in any material respect,

he may serve a notice on the person responsible for management of the hospital blood bank requiring that the hospital blood bank 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 subsection (4) are met.

(2) Subject to subsection (3), any notice served by the competent authority under subsection (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 competent authority 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 subsection are, as may be applicable in each case, that–

(a) the person responsible for management of the hospital blood bank is no longer in breach of the requirements of this Act;

(b) the hospital blood bank is able to show that the activity or product referred to in the notice given under subsection (1)(b) may be safely carried out or, as the case may be, administered; or

(c) all necessary information has been supplied to the competent authority.

Quality system standards and specifications.

15. Every blood establishment shall ensure that the quality system in place in it complies with the Community standards and specifications set out in Schedule 7.

Objections to suspensions, revocations etc.

16.(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 under section 5(8), 6 or 14; or

(b) objects to the refusal of authorisation or the imposition of any condition under section 5(5),

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

(2) Any notification of an objection under subsection (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 under subsection (1) relates.

(3) Where the competent authority receives a notification under subsection (1), he shall appoint a person to consider the matter.

(4) The person appointed under subsection (3) shall–

(a) determine the procedure to be followed with respect to the consideration of any objection;

(b) 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

(c) make a recommendation to the competent authority.

(5) A recommendation made under subsection (4)(c) shall be made in writing to the competent authority, 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.

(6) The competent authority shall take into account any recommendation made under subsection (4).

(7) Within 14 days of receipt of any recommendation made under subsection (5), the competent authority 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.

(8) Subject to subjection (10), where the competent authority is notified of an objection under subsection (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 under subsection (3) has considered the matter in accordance with the provisions of this section and made a recommendation; and

(b) the competent authority 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 under subsection (7).

(9) Subject to subsection (10), where the competent authority is notified of an objection under subsection (1)(a), within the period specified in subsection (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 under subsection (3) has considered the matter in accordance with the provisions of this section and made a recommendation; and

(b) the competent authority 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 under subsection (7).

(10) Subsections (8) and (9) shall not apply–

(a) in relation to a suspension or revocation, or a notice served under section 14, which takes immediate effect in accordance with section 6(3) or 14(3); or

(b) in any other case, where the competent authority 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.

Requirement that facilities retain certain data.

17. A person responsible for management of a facility shall ensure that the facility–

(a) retains the data set out in section 10(3)(b), in an appropriate and readable storage medium, for a period of at least 30 years; and

(b) has in place a system in place to record each unit of blood or blood component received, whether or not locally used, and the final destination of that received unit whether transfused, used in the manufacture of medicinal products, discarded or returned to the blood establishment or hospital blood bank.

Requirement to report serious adverse reactions and events.

18.(1) A person responsible for management of a reporting establishment shall ensure that the reporting establishment–

(a) has in place procedures to retain the record of transfusions for a period of at least 30 years**;**

(b) notifies blood establishments without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood or blood components; and

(c) notifies the competent authority as soon as is known all relevant information about suspected serious adverse reactions using the notification formats set out in Part A and Part B of the Schedule 6.

(2) A person responsible for management of a reporting establishment shall ensure that the reporting establishment–

(a) notifies the competent authority of all relevant information about serious adverse reactions of imputability level 2 and 3 as referred to in Part B of the Schedule 5, which may be attributable to the quality and safety of blood or blood components;

(b) notifies the competent authority, as soon as is known, of any case of transmission of infectious agents by blood or blood components;

(c) as part of the notification referred to in paragraph (a), describes the actions taken with respect to other implicated blood or blood components that have been distributed for transfusion or for plasma fractionation;

(d) as soon as is reasonably practicable after each suspected serious adverse reaction, evaluates that reaction according to the imputability levels set out in Part B of Schedule 5;

(e) completes the serious adverse reaction notification, upon conclusion of the investigation, using the format set out in Part C of Schedule 5; and

(f) submits a complete report to the competent authority on serious adverse reactions in any calendar year by no later than 1st April in the following calendar year, using the format set out in Part D of Schedule 5.

(3) A person responsible for management of a reporting establishment shall ensure that the reporting establishment notifies the competent authority as soon as is known, using the notification formats set out in Part A of Schedule 6, of all relevant information about serious adverse events which

may put in danger donors or recipients other than those directly involved in the event concerned.

(4) A person responsible for management of a reporting establishment shall ensure that the reporting establishment–

(a) as soon as is reasonably practicable after each serious adverse event, evaluates that serious adverse event to identify preventable causes within the process;

(b) upon completion of the investigation, completes the serious adverse event notification, using the format set out in Part B of Schedule 6; and

(c) submits a complete report to the competent authority on serious adverse reactions in any calendar year by no later than 1st April in the following calendar year, using the format set out in Part C of Schedule 6.

(5) A facility may make arrangements with a hospital blood bank for the hospital blood bank to submit to the competent authority or the blood establishment the reports required by subsection (1)(b) and (c), (2)(a),(b),(e) and (f) and (3)(b) and(c) on the facility's behalf, only if either the condition set out in subsection (6)(a), or the conditions set out in subsection (6)(b) and (c) are satisfied.

(6) The conditions referred to in subsection (5) are that–

(a) the person responsible for management of the hospital blood bank is the same person as the person responsible for management of the facility with which the arrangement is made; or

(b) the arrangements referred to in subsection (5) must be–

(i) evidenced by a written agreement, and

(ii) made with the person responsible for management of the hospital blood bank who supplied the blood or blood components to the facility for transfusion; and

(c) the facility must supply the information necessary to enable the hospital blood bank to make the reports within the timescale specified by this regulation in relation to that report.

Import of blood and blood components into Gibraltar.

19. Any person who imports blood or blood components into Gibraltar from a third country shall ensure that each unit of blood and each blood components which he imports–

(a) has been prepared in accordance with standards equivalent to the Community standards and requirements set out in Schedule 7; and

(b) meets standards of quality and safety equivalent to those laid down in Schedule 4.

Disclosure of information by blood establishments and hospital blood banks.

20.(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 this Act 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 subsection (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 subsection 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 authorised person appointed by the competent authority in accordance with section 22(1); 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 authorised person under subsection (2)(b), the authorised person 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 competent authority where this is necessary for the proper performance of the authorised person's 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 authorised person to another officer of the competent authority under subsection (3), that person shall not further disclose the information he receives other than in accordance with the requirements of that subsection.

(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 that are brought to their attention are resolved without delay.

Inspections, etc.

21.(1) The competent authority 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 this Act; and

(b) problems relating to compliance with those requirements are identified.

(2) The competent authority may conduct such additional inspections of blood establishments sites as he considers necessary for the purpose of ensuring compliance with the requirements of this Act.

(3) The competent authority may also serve a notice on a blood establishment requiring that it furnish him with such information concerning its compliance with this Act as shall be specified in the notice within such period as shall be specified in the notice.

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

(5) The competent authority may inspect hospital blood banks and facilities with a view to ensuring that–

(a) hospital blood banks and facilities, and persons responsible for the management of such blood banks and facilities comply with the requirements of this Act; and

(b) problems relating to compliance with those requirements are identified.

(6) The competent authority may also serve a notice on the person responsible for managing a hospital blood bank or a facility requiring that he furnish him with such information concerning the compliance of the blood bank or a facility with this Act 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 or a facility who receives a request for information in accordance with subsection (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 competent authority shall request such information or conduct such inspections in accordance with this section as he shall consider appropriate.

(9) Any reference to an inspection of a site which the competent authority is required or empowered to conduct by virtue of this section, shall be construed so as to include an inspection of premises within Gibraltar at which any of the activities listed in section 4(2) are carried out by any person on behalf of, and under a contractual arrangement with, a blood establishment or, as the case may be, a person responsible for management of a hospital blood bank.

Authorised persons.

22.(1) The Minister may–

(a) appoint such and so many persons as authorised persons as he thinks necessary for the proper discharge by them of his functions set out in this Act; and

(b) in appointing such persons, determine such terms and conditions (including conditions as to remuneration, benefits, allowances and reimbursement for expenses) as he thinks fit.

(2) For the purposes of enforcing compliance with this Act or conducting inspections under section 21, the competent authority, or in the case of an authorised person appointed under subsection (1) upon production of evidence that such person is so authorised, shall 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 section 4,

(ii) any premises of any person who carries out any of the activities referred to in section 4(2) on behalf of, or pursuant to a contractual arrangement with, a blood establishment or a person responsible for management of a hospital blood bank,

(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; and

(iv) any premises where transfusion of blood or blood components takes place, or which are owned or managed by a person responsible for management of a facility to which blood or blood components have been delivered;

(b) to carry out at those premises during that visit or 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) 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 subsection 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 Supreme Court or on an order for production of documents in an action in the Magistrates' court.

(3) Where the Stipendiary Magistrate or 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 subsection (2), 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 subsection 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 Stipendiary Magistrate or the justice of the peace may, by warrant signed by him, which shall continue in force for a period of one month, permit the authorised person to enter the premises, if need be by force.

(4) An authorised person entering premises by virtue of subsection (2) or of a warrant under subsection (3) may take with him when he enters those premises such equipment as may appear to him necessary and any other

person who is also authorised by the competent authority to accompany him on that visit.

(5) On leaving any premises which an authorised person is permitted to enter by a warrant under subsection (3), 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.

(6) Where, under subsection (2)(e), an authorised person takes–

(a) 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; and

(b) a sample for analysis, the competent authority may, subject to the requirements of subsection (7), make such arrangements for analysis of that sample as he considers appropriate.

(7) The requirements of this subsection are–

(a) that the competent authority shall inform the responsible person of the blood establishment or person responsible for the management of the hospital blood bank from which the sample of relevant thing 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 competent authority shall divide the sample of relevant thing of which an analysis is to be made into three equal parts and deal with those parts in accordance with the requirements of subsections (8), (9) and (10).

(8) Subject to subsection (10*)*, where an authorised person takes a sample of a relevant thing, he shall–

(a) divide the sample into 3 approximately equal parts;

(b) place each part into separate containers; and

(c) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by that authorised person.

(9) Where an authorised person has complied with subsection (1), he shall–

(a) offer one of the sealed containers to the owner or person for the time being in charge or possession of the relevant thing from which the sample concerned was taken;

(b) retain one of the sealed containers;

(c) forward or caused to be forwarded, one of the sealed containers for test, examination or analysis.

(10) Where a relevant thing is contained in a container and its division into parts under subsection (8) is, for whatever reason, not practicable, an authorised person, who wishes to take samples of such relevant things for the purposes of any test, examination or analysis, shall take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of subsection (8), and subsections (8) and (9) shall apply to it accordingly.

Records to be kept by the competent authority.

23.(1) The competent authority 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 section 5;

(b) the designation of responsible persons under section 7;

(c) notification of serious adverse events and serious adverse reactions by such establishments under section 8(1)(e);

(d) inspections or requests for information under section 21.

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

(a) notification of serious adverse events and serious adverse reactions under section 18;

(b) the information supplied by hospital blood banks under section 13;

(c) inspections or requests for information under section 21.

Requirement that the competent authority communicate certain information to other competent authorities.

24. The competent authority shall communicate to the competent authorities of Member States such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.

Offences and penalties.

25.(1) Any person who contravenes section 4(1), section 8, section 11, section 12, section 15, section 17, section 18, section 19 or section 26(2) shall be guilty of an offence.

(2) Any person who contravenes section 5(9), section 7 (other than section 7(3)), section 9, section 13 or section 21(4) or (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 under section 6, save where the operation of that notice has been suspended under section 16, or has been withdrawn or revoked by the competent authority, 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 section 9, shall be guilty of an offence.

(5) Any person who contravenes the requirements of any notice served by the competent authority under section 14(1), shall be guilty of an offence.

(6) Any person who contravenes section 20 or who discloses any information referred to in section 20(1) to which they have access by virtue of this Act, otherwise than in accordance one or more of the requirements specified in section 20(2) and (3), shall be guilty of an offence.

(7) Subject to subsection (5)–

(a) a person who–

(i) intentionally obstructs an authorised person; or

(ii) without reasonable cause fails to comply with any requirements made of him by an authorised person, in circumstances where that authorised person is acting in pursuance of any of his functions under this Act; or

(b) any person who, in purported compliance with any such requirement as is mentioned in paragraph (a), intentionally or recklessly furnishes information which is false or misleading in a material respect,

shall be guilty of an offence.

(8) Nothing in subsection (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.

(9) A person guilty of an offence under subsection (1), (3), (5) or (7) shall be liable–

(a) on summary conviction to a fine not exceeding level 5 on the standard scale or to imprisonment for a term not exceeding 3 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.

(10) A person guilty of an offence under subsection (2), (4) or (6) shall be liable on summary conviction to a fine not exceeding level 4 on the standard scale, or to imprisonment for a term not exceeding 3 months, or to both.

(11) Where an offence under subsection (1) or (2) is committed by a person who is employed by the Gibraltar Health Authority or by the Crown, the provisions of subsections (9) and (10) shall not apply, and that person shall be liable to such disciplinary action as the Minister may deem appropriate.

Specific epidemiological situations.

26.(1) Where the competent authority 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 European Commission of–

(i) the epidemiological situation; and

(ii) the additional deferral criteria which the blood establishments are required to adopt in relation to it under paragraph(a).

(2) A blood establishment shall adopt and comply with any criteria for additional tests notified to them by the competent authority under subsection (1).

Regulations.

27. The Minister may make Regulations–

(a) prescribing fees to be paid under this Act;

(b) giving effect to or implementing any International Convention, Protocol or Agreement or any European Union Directive or Regulations that relate to the subject-matter of this Act; or

(c) providing for generally carrying out the purposes of this Act.

SCHEDULE 1

Section 8(2)

INFORMATION REQUIREMENTS FOR DONORS

PART A

Information to be provided to prospective donors of blood or blood components.

1. Accurate educational materials, which are written in terms which can be understood by members of the general public, about the essential nature of blood, the blood donation procedure, the components derived from whole blood and apheresis donations, and the important benefits to patients.

2. For both allogeneic and autologous donations, the reasons for requiring an examination and health and medical history, and the testing of donations, and the significance of "informed consent".

3. For allogeneic donations, the criteria for self-deferral, and temporary and permanent deferral, and the reasons why individuals are not to donate blood or blood components if there could be a risk for the recipient.

4. For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individual whether as donor or recipient of the autologous blood or blood components.

5. Information on the protection of personal data, including confirmation that there will be no disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed, other than in accordance with the requirements of this Act.

6. The reasons why individuals are not to make donations which may be detrimental to their health.

7. Specific information on the nature of the procedures involved either in the allogeneic or autologous donation process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements.

8. Information on the option for donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-

deferring at any time during the donation process, without any undue embarrassment or discomfort.

9. The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion.

10. Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show any abnormality of significance to the donor's health.

11. Information as to why unused autologous blood and blood components will be discarded and not transfused to other patients.

12. Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents, will result in donor deferral and destruction of the collected unit.

13. Information on the opportunity for donors to ask questions at any time.

PART B

Information to be obtained from donors by blood establishments at every donation

Identification of the donor

14. Personal data uniquely, and without any risk of mistaken identity, distinguishing the donor, as well as contact details.

Health and medical history of the donor

15. Health and medical history, provided on a questionnaire and through a personal interview performed by a qualified health professional, that includes relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves.

Signature of the donor

16. Signature of the donor, on the donor questionnaire, countersigned by the qualified health professional responsible for obtaining the health history confirming that the donor has–

(a) read and understood the educational materials provided;

(b) had an opportunity to ask questions;

(c) been provided with satisfactory responses to any questions asked;

(d) given informed consent to proceed with the donation process;

(e) been informed, in the case of autologous donations, that the donated blood and blood components may not be sufficient for the intended transfusion requirements; and

(f) acknowledged that all the information provided by the donor is true to the best of his knowledge.

SCHEDULE 2

Section 8(2)(d), (6)(c)

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

1. Acceptance criteria for donors of whole blood and blood components

Under exceptional circumstances, individual donations from donors who do not comply with following criteria may be authorised by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions of regulations 8 and 21 and Schedule 7 of these Regulations.

The criteria in this subsection do not apply to autologous donations.

1.1 Age and body weight of donors:

Age	18 to 65 years	
	17 years and over	Where, in the opinion of a qualified health professional, the donor has sufficient knowledge and understanding of what is involved in the process of blood donation to give their informed consent, or otherwise with the written consent of a person with parental responsibility.
	First time donors over 60 years	-at the discretion of the doctor in the blood establishment
	Over 65 years	-with permission of the doctor in the blood establishment, given annually
Body weight	≥ 50 kg for donors either of whole blood or apheresis blood components	

1.2 Haemoglobin levels in donor's blood

Haemoglobin	For females ≥	For males	*Applicable to*

	125 g/1	≥ 135 g/1	*allogeneic donors of whole blood and cellular components*

1.3 **Protein levels in donor's blood**

Protein	≥ 60 g/1	*The protein analysis for apheresis plasma donations must be performed at least annually*

1.4 **Platelet levels in donor's blood**

Platelets	Platelet number greater than or equal to 150 x 10^9 /1	*Level required for apheresis platelet donors*

DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

The tests and deferral periods indicated by an asterisk (*) are not required when the donation is used exclusively for plasma for fractionation.

2.1 **Permanent deferral criteria for donors of allogeneic donations**

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure
Central nervous system disease	A history of serious CNS disease
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy
Repeated episodes of syncope, or a history of convulsions	Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions
Gastrointestinal,	Prospective donors with serious active,

Genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases	chronic, or relapsing disease
Diabetes	If being treated with insulin
Infectious diseases	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune
	Hepatitis C
	HIV - 1 and 2
	HTLV I/II
	Babesiosis (*)
	Kala Azar (visceral leishmaniasis) (*)
	Trypanosomiasis cruzi (Chagas' disease) (*)
Malignant diseases	Except in situ cancer with complete recovery
Transmissible spongiform encephalopathies (TSEs) (e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease)	Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jacob disease, further precautionary measures may be recommended.
Intravenous (IV) or intramuscular (IM) drug use	Any history of non-prescribed IV or IM drug use, including body-building steroids or hormones
Xenotransplant recipients	
Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood

2.2 Temporary deferral criteria for donors of allogeneic donations

2.2.1 Infections

Duration of deferral period

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

However, the following deferral periods shall apply for the infections listed in the table:

Brucellosis (*)	2 years following the date of full recovery
Osteomyelitis	2 years after confirmed cured
Q fever (*)	2 years following the date of confirmed cure
Syphilis (*)	1 year following the date of confirmed cure
Toxoplasmosis (*)	6 months following the date of clinical recovery
Tuberculosis	2 years following the date of confirmed cure
Rheumatic fever	2 years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever >38°C	2 weeks following the date of cessation of symptoms
Flu-like illness	2 weeks after cessation of symptoms
Malaria (*)	
- individuals who have lived in a malarial area within the first five years of life	3 years following return from last visit to any endemic area, provided person remains symptom free; may be reduced to 4 months if an immunologic or molecular genomic test is negative at each donation.
- individuals with a history of malaria	3 years following cessation of treatment and absence of symptoms. Donations may be accepted thereafter only if an immunologic or molecular genomic test is negative
- asymptomic visitors to endemic	6 months after leaving the endemic area unless an immunologic or molecular genomic test is

areas	negative
- individuals with a history of undiagnosed febrile illness during or within six months of a visit to an endemic area	3 years following resolution of symptoms; may be reduced to 4 months if an immunologic or molecular test is negative
West Nile Virus (WNV) (*)	28 days after leaving an area with ongoing transmission of WNV to humans

2.2.2 ***Exposure to risk of acquiring a transfusion-transmissible infection***

- Endoscopic examination using flexible instruments, - mocusal splash with blood or needlestick injury, - transfusion of blood components, - tissue or cell transplant of human origin, - major surgery, - tattoo or body piercing, - acupuncture unless performed by a qualified practitioner and with sterile single-use needles, - persons at risk due to close household contact with persons with hepatitis B.	Defer 6 months, or 4 months provided a NAT test for hepatitis C is negative
Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests.

2.2.3 ***Vaccination***

Attenuated viruses or bacteria	4 weeks
Inactivated/killed viruses, bacteria or rickettsiae	No deferral if well

Toxoids	No deferral if well
Hepatitis A or hepatitis B vaccines	No deferral if well and if no exposure
Rabies	No deferral if well and if no exposure. If vaccination is given following exposure defer for one year
Tick-borne encephalitis vaccines	No deferral if well and if no exposure

2.2.4 ***Other temporary deferrals***

Pregnancy	6 months after delivery or termination, except in exceptional circumstances and at the discretion of a physician
Minor surgery	1 week
Dental treatment	Minor treatment by dentist or dental hygienist - defer until next day (NB: Tooth extraction, root-filling and similar treatment is considered as minor surgery)
Medication	Based on the nature of the prescribed medicine, its mode of action and the disease being treated

2.3 **Deferral for particular epidemiological situations**

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation

2.4 **Deferral criteria for donors of autologous donations**

Serious cardiac disease	Depending on the clinical setting of the blood collection

Active bacterial infection	

SCHEDULE 3

Sections 8(3)(b), 12(1)(h)

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

1. STORAGE

1.1 **Liquid storage**

Component	*Temperature of storage*	*Maximum storage time*
Red cell preparations and whole blood (if used for transfusion as whole blood)	+2 to +6°C	28 to 49 days according to the processes used for collection, processing and storage
Platelet preparations	+20 to +24°C	5 days, may be stored for 7 days in conjunction with detection or reduction of bacterial contamination
Granulocytes	+20 to +24°C	24 hours

1.2 **Cryopreservation**

Component	*Storage conditions and duration*
Red blood cells	Up to 30 years according to processes used for collection, processing and storage
Platelets	Up to 24 months according to processes used for collection, processing and storage
Plasma and cryoprecipitate	Up to 36 months according to processes used for collection, processing and storage
Cryopreserved red blood cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after thawing to depend on the method used.	

2. TRANSPORT AND DISTRIBUTION

Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product.

3 ADDITIONAL REQUIREMENTS FOR AUTOLOGOUS DONATIONS

3.1 Autologous blood and blood components must be clearly identified as such and stored, transported and distributed separately from allogeneic blood and blood components.

3.2 Autologous blood and blood components must be labelled as required by section 9, and, in addition, the label must include the identification of the donor and the warning “FOR AUTOLOGOUS TRANSFUSION ONLY”.

SCHEDULE 4

Sections 5(4)(b), 8(3)(c) and 19

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

1. **THE BLOOD COMPONENTS**

1. Red cell preparations	The components listed in points 1.1 to 1.8 may be further processed within blood establishments and must be labelled accordingly
1.1	Red cells
1.2	Red cells, buffy coat removed
1.3	Red cells, leucocyte-depleted
1.4	Red cells, in additive solution
1.5	Red cells, buffy coat removed, in additive solution
1.6	Red cells, leucocyte-depleted, in additive solution
1.7	Red cells, apheresis
1.8	Whole blood
2. Platelet preparations	The components listed in points 2.1 to 2.6 may be further processed within blood establishments and must be labelled accordingly
2.1	Platelets, apheresis
2.2	Platelets, apheresis, leucocyte-depleted
2.3	Platelets, recovered, pooled
2.4	Platelets, recovered, pooled, leucocyte-depleted
2.5	Platelets, recovered, single unit
2.6	Platelets, recovered, single unit,

	leucocyte-depleted
3. Plasma preparations	The components listed in 3.1 to 3.3 may be further processed within blood establishments and must be labelled accordingly
3.1	Fresh-frozen plasma
3.2	Fresh-frozen plasma, cryoprecipitate-depleted
3.3	Cryoprecipitate
4.	Granulocytes, apheresis

2. QUALITY CONTROL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

2.1 Blood and blood components must comply with the following technical quality measurements and meet the acceptable results.

2.2 Appropriate bacteriological control of the collection and manufacturing process must be performed.

2.3 For autologous donations, the measures marked with an asterisk (*) are recommendations only.

Component	*Quality measures required* *The required frequency of sampling for all measurements shall be determined using statistical process control*	*Acceptable results for quality measures*
Red cells	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45g per unit

	Haemolysis	Less than 0.8% of red cell mass at end of the shelf life
Red cells, buffy coat removed	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40g per unit
	Leucocyte content	Less than 1 x 10^6 per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45g

		per unit
	Haemolysis	Less than 0.8% of red cell mass at end of the shelf life
Red cells, buffy coat removed, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40g per unit
	Leucocyte content	Less than 1×10^6 per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Red cells, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis

	Haemoglobin (*)	Not less than 40g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Whole blood	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis 450ml +/- 50ml For paediatric autologous whole blood collections - not to exceed 10.5ml per kg body weight
	Haemoglobin (*)	Not less than 45g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
Platelets, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within the limits that comply with validated preparation and

		preservation conditions
	pH	Minimum 6.4 corrected for 22°C, at the end of the shelf life
Platelets, apheresis, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within the limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1 x 10^6 per unit
	pH	Minimum 6.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, pooled	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and

		preservation conditions
	Leucocyte content	Less than 0.2 x 10^9 per single unit (platelet-rich plasma method) Less than 0.05 x 10^9 per single unit (buffy coat method)
	pH	Minimum 6.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, pooled, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1 x 10^6 per pool
	pH	Minimum 6.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, single unit	Volume	Valid for storage characteristics to maintain product within specifications for

		pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 0.2 x 10^9 per single unit (platelet-rich plasma method) Less than 0.05 x 10^9 per single unit (buffy coat method)
	pH	Minimum 6.4 corrected for 22°C, at the end of the shelf life
Platelets, recovered, single unit, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1 x 10^6 per unit
	pH	Minimum 6.4

		corrected for 22°C, at the end of the shelf life
Plasma, fresh-frozen	Volume	Stated volume +/- 10%
	Factor VIIIc(*)	Average (after freezing and thawing): 70% or more of the value of the freshly collected plasma unit
	Total protein	Not less than 50g/l
	Residual cellular content(*)	Red cells: less than 6.0 x 10^9/l Leucocytes: less than 0.1 x 10^9/l Platelets: less than 50 x 10^9/l
Plasma, fresh-frozen, cryoprecipitate-depleted	Volume	Stated volume +/- 10%
	Residual cellular content(*)	Red cells: less than 6.0 x 10^9/l Leucocytes: less than 0.1 x 10^9/l Platelets: less than 50 x 10^9/l
Cryoprecipitate	Fribrinogen content(*)	Greater than or equal to 140mg per unit
	Fractor VIIIc content (*)	Greater than or equal to 70 international units per unit

Granulocytes, apheresis	Volume	Less than 500ml
	Granulocyte content	Greater than 1 x 10^{10} granulocytes per unit

SCHEDULE 5

Section 18

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

PART A
Rapid notification format for suspected serious adverse reactions

Reporting establishment
Report identification
Reporting date (year/month/day)
Date of transfusion (year/month/day)
Age and sex of recipient
Date of serious adverse reaction (year/month/day)
Serious adverse reaction is related to- (a) Whole blood (b) Red blood cells (c) Platelets (d) Plasma (e)Other *(specify).*
Type of serious adverse reaction(s)- (a) Immunological haemolysis due to ABO incompatibility (b) Immunological haemolysis due to other allo-antibody (c) Non-immunological haemolysis (d) Transfusion-transmitted bacterial infection (e) Anaphylaxis/hypersensitivity (f) Transfusion related acute lung injury

(g)Transfusion-transmitted viral infection (HBV) (h) Transfusion-transmitted viral infection (HCV) (i)Transfusion-transmitted viral infection (HIV-1/2) (j) Transfusion-transmitted viral infection, Other *(specify)* (k) Transfusion-transmitted parasitical infection (Malaria) (l) Transfusion-transmitted parasitical infection, Other *(specify)* (m) Post-transfusion purpura (n) Graft versus host disease (o)Other serious reaction(s) *(specify)*
Imputability level (NA, 0-3)

PART B
Serious adverse reactions — imputability levels

Imputability levels to assess serious adverse reactions.

Imputability level	Explanation	
NA	Not assessable	When there is insufficient data for imputability assessment.
0	Unlikely	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes.
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

PART C
Confirmation format for serious adverse reactions

Reporting establishment
Report identification
Confirmation date (year/month/day)
Date of serious adverse reaction (year/month/day)
Confirmation of serious adverse reaction (Yes/No)
Imputability level (NA, 0-3)
Change of type of serious adverse reaction (Yes/No)
If Yes, *specify*
Clinical outcome (if known)- (a) Complete recovery (b) Minor sequelae (c) Serious sequelae (d) Death

PART D

Annual notification format for serious adverse reactions

_____

Reporting establishment

_____

Reporting period

This Table refers to [] Whole blood [] Red blood cells [] Platelets [] Plasma [] Other *(use separate table for each component)*		Number of units issued (total number of units issued with a given number of blood components)				
		Number of recipients transfused (total number of recipients transfused with a given number of blood components) (*if available)*				
		Number of units transfused (the total number of blood components (units) transfused over the reporting period) (*if available)*				
	Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Part A of this Schedule)				
	Number of deaths					
		not assessable	Level 0	Level 1	Level 2	Level 3
Immunological Haemolysis	Due to ABO incompatability	Total				
		Deaths				
	Due to other allo-antibody	Total				
		Deaths				
Non-immunological haemolysis		Total				
		Deaths				
Transfusion-transmitted bacterial infection		Total				
		Deaths				
Anaphylaxis/hypersensitivity		Total				
		Deaths				
Transfusion related acute lung injury		Total				
		Deaths				
Transfusion-transmitted viral infection	HBV	Total				
		Deaths				
	HCV	Total				
		Deaths				
	HIV-1/2	Total				
		Deaths				
	Other (specify)	Total				
		Deaths				
Transfusion-transmitted parasitical infection	Malaria	Total				
		Deaths				
	Other (specify)	Total				
		Deaths				
Post-transfusion purpura		Total				
		Deaths				
Graft versus host disease		Total				
		Deaths				
Other serious reactions (*specify)*		Total				
		Deaths				

SCHEDULE 6

Section 18

NOTIFICATION OF SERIOUS ADVERSE EVENTS

PART A

Rapid notification Format for Serious Adverse Events

_____

Reporting establishment

_____

Reporting identification

_____

Reporting date (year/month/day)

_____

Date of serious adverse event (year/month/day)

Serious adverse event, which may affect quality and safety of blood component due to a deviation in:	Specification			
	Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection				
Aspheresis collection				
Testing of donations				
Processing				
Storage				
Distribution				
Materials				
Others *(specify)*				

PART B

Confirmation Format for Serious Adverse Events

Reporting establishment

Reporting identification

Confirmation date (year/month/day)

Date of serious adverse event (year/month/day)

Root cause analysis (details)

Corrective measures taken (details)

PART C

Annual Notification Format for Serious Adverse Events

Reporting establishment					
Reporting period	1 January – 31 December (*year)*				
Total number of blood components processed:					
Serious adverse event, which may affect quality and safety of blood component due to a deviation in:	Total number	Specification			
		Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection					
Apheresis collection					
Testing of donations					
Processing					
Storage					
Distribution					
Materials					
Others *(specify)*					

SCHEDULE 7

Sections 12(1)(b) and 15

QUALITY SYSTEM STANDARDS AND SPECIFICATIONS

1. INTRODUCTION AND GENERAL PRINCIPLES

1.1. Quality system

1. Quality shall be recognised as being the responsibility of all persons involved in the processes of the blood establishment with management ensuring a systematic approach towards quality and the implementation and maintenance of a quality system.

2. The quality system encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, nonconformance and self-inspection.

3. The quality system shall ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications set out in this Schedule. Management shall review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.

1.2. Quality assurance

1. All blood establishments and hospital blood banks shall be supported by a quality assurance function, whether internal or related, in fulfilling quality assurance. That function shall be involved in all quality-related matters and review and approve all appropriate quality related documents.

2. All procedures, premises, and equipment that have an influence on the quality and safety of blood and blood components shall be validated prior to introduction and be re-validated at regular intervals determined as a result of these activities.

2. PERSONNEL AND ORGANISATION

1. Personnel in blood establishments shall be available in sufficient numbers to carry out the activities related to the collection, testing, processing, storage and distribution of blood

and blood components and be trained and assessed to be competent to perform their tasks.

2. All personnel in blood establishments shall have up to date job descriptions which clearly set out their tasks and responsibilities. Blood establishments shall assign the responsibility for processing management and quality assurance to different individuals and who function independently.

3. All personnel in blood establishments shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice.

4. The contents of training programmes shall be periodically assessed and the competence of personnel evaluated regularly.

5. There shall be written safety and hygiene instructions in place adapted to the activities to be carried out and are in compliance with section 6 of the Factories Act and the Management of Health and Safety at Work Regulations 1996 and the Factories (Protection of Workers from Risks Related to Exposure to Biological Agents at Work) Regulations 2006.

3. PREMISES

3.1. General

Premises including mobile sites shall be adapted and maintained to suit the activities to be carried out. They shall enable the work to proceed in a logical sequence so as to minimise the risk of errors, and shall allow for effective cleaning and maintenance in order to minimise the risk of contamination.

3.2. Blood donor area

There shall be an area for confidential personal interviews with and assessment of individuals to assess their eligibility to donate. This area shall be separated from all processing areas.

3.3. Blood collection area

Blood collection shall be carried out in an area intended for the safe withdrawal of blood from donors, appropriately equipped for the initial treatment of donors experiencing adverse reactions or injuries from events associated with blood donation, and organised in such a way as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure.

3.4. Blood testing and processing areas

There shall be a dedicated laboratory area for testing that is separate from the blood donor and blood component processing area with access restricted to authorised personnel.

3.5. **Storage area**

1. Storage areas shall provide for properly secure and segregated storage of different categories of blood and blood components and materials including quarantine and released materials and units of blood or blood components collected under special criteria (e.g. autologous donation).

2. Provisions shall be in place in the event of equipment or power failure in the main storage facility.

3.6. **Waste disposal area**

An area shall be designated for the safe disposal of waste, disposable items used during the collection, testing, and processing and for rejected blood or blood components.

4. **EQUIPMENT AND MATERIALS**

1. All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.

2. Equipment shall be selected to minimise any hazard to donors, personnel, or blood components.

3. Only reagents and materials from approved suppliers that meet the documented requirements and specifications shall be used. Critical materials shall be released by a person qualified to perform this task. Where relevant, materials, reagents and equipment.

4. Inventory records shall be retained for a period acceptable to and agreed with the competent authority.

5. When computerised systems are used, software, hardware and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Hardware and software shall be protected against unauthorised use or unauthorised changes. The back-up procedure shall prevent loss of or damage to data at expected and unexpected down times or function failures.

5. **DOCUMENTATION**

1. Documents setting out specifications, procedures and records covering each activity performed by the blood establishment shall be in place and kept up to date.

2. Records shall be legible and may be handwritten, transferred to another medium such as microfilm or documented in a computerised system.

3. All significant changes to documents shall be acted upon promptly and shall be reviewed, dated and signed by a person authorised to perform this task.

6. BLOOD COLLECTION, TESTING AND PROCESSING

6.1. Donor eligibility

1. Procedures for safe donor identification, suitability interview and eligibility assessment shall be implemented and maintained. They shall take place before each donation and comply with the requirements set out in Part B of Schedule 1 and Schedule 2 of this Act.

2. The donor interview shall be conducted in such a way as to ensure confidentiality.

3. The donor suitability records and final assessment shall be signed by a qualified health professional.

6.2. Collection of blood and blood components

1. The blood collection procedure shall be designed to ensure that the identity of the donor is verified and securely recorded and that the link between the donor and the blood, blood components and blood samples is clearly established.

2. The sterile blood bag systems used for the collection of blood and blood components and their processing shall be CE-marked or comply with equivalent standards if the blood and blood components are collected in third countries. The batch number of the blood bag shall be traceable for each blood component.

3. Blood collection procedures shall minimise the risk of microbial contamination.

4. Laboratory samples shall be taken at the time of donation and appropriately stored prior to testing.

5. The procedure used for the labelling of records, blood bags and laboratory samples with donation numbers shall be designed to avoid any risk of identification error and mix-up.

6. After blood collection, the blood bags shall be handled in a way that maintains the quality of the blood and at a storage and transport temperature appropriate to further processing requirements.

7. There shall be a system in place to ensure that each donation can be linked to the collection and processing system into which it was collected and/or processed.

6.3. **Laboratory testing**

1. All laboratory testing procedures shall be validated before use.

2. Each donation shall be tested in conformity with the requirements specified in section 8(7) of this Act.

3. There shall be clearly defined procedures to resolve discrepant results and ensure that blood and blood components that have a repeatedly reactive result in a serological screening test for infection with the viruses mentioned in section 8(7) of this Act shall be excluded from therapeutic use and be stored separately in a dedicated environment. Appropriate confirmatory testing shall take place. In case of confirmed positive results, appropriate donor management shall take place including the provision of information to the donor and follow-up procedures.

4. There shall be data confirming the suitability of any laboratory reagents used in the testing of donor samples and blood component samples.

5. The quality of the laboratory testing shall be regularly assessed by the participation in a formal system of proficiency testing, such as an external quality assurance programme.

6. Blood group serology testing shall include procedures for testing specific groups of donors (e.g. first time donors, donors with a history of transfusion).

6.4. **Processing and validation**

1. All equipment and technical devices shall be used in accordance with validated procedures.

2. The processing of blood components shall be carried out using appropriate and validated procedures including measures to

avoid the risk of contamination and microbial growth in the prepared blood components.

6.5. **Labelling**

1. At all stages, all containers shall be labelled with relevant information of their identity. In the absence of a validated computerised system for status control, the labelling shall clearly distinguish released from non-released units of blood and blood components.

2. The labelling system for the collected blood, intermediate and finished blood components and samples must unmistakably identify the type of content, and comply with the labelling and traceability requirements referred to in sections 9 and 10 of this Act. The label for a final blood component shall comply with the requirements of section 9(1) of this Act.
3. For autologous blood and blood components, the label also shall comply with section 8(1)(g) and Schedule 1 of this Act and the additional requirements for autologous donations specified in Schedule 3 of this Act.

6.6. **Release of blood and blood components**

1. There shall be a safe and secure system to prevent each single blood and blood component from being released until all mandatory requirements set out in this Act have been fulfilled. Each blood establishment shall be able to demonstrate that each blood or blood component has been formally released by an authorised person. Records shall demonstrate that before a blood component is released, all current declaration forms, relevant medical records and test results meet all acceptance criteria.

2. Before release, blood and blood components shall be kept administratively and physically segregated from released blood and blood components. In the absence of a validated computerised system for status control the label of a unit of blood or blood component shall identify the release status in accordance with paragraph 6.5.1 of this Schedule.

3. In the event that the final component fails release due to a confirmed positive infection test result, in conformity with the requirements set out in paragraphs 6.3.2 and 6.3.3 of this Schedule, a check shall be made to ensure that other components from the same donation and components prepared from previous donations given by the donor are identified. There shall be an immediate update of the donor record.

7. STORAGE AND DISTRIBUTION

1. The quality system of the blood establishment shall ensure that, for blood and blood components intended for the manufacture of medicinal products, the storage and distribution requirements shall comply with Directive 2003/94/EC.

2. Procedures for storage and distribution shall be validated to ensure blood and blood component quality during the entire storage period and to exclude mix-ups of blood components. All transportation and storage actions, including receipt and distribution, shall be defined by written procedures and specifications.

3. Autologous blood and blood components as well as blood components collected and prepared for specific purposes shall be stored separately.

4. Appropriate records of inventory and distribution shall be kept.

5. Packaging shall maintain the integrity and storage temperature of blood or blood components during distribution and transportation.

6. Return of blood and blood components into inventory for subsequent reissue shall only be accepted when all quality requirements and procedures laid down by the blood establishment to ensure blood component integrity are fulfilled.

8. CONTRACT MANAGEMENT

Tasks that are performed externally shall be defined in a specific written contract.

9. NON-CONFORMANCE

9.1. Deviations

Blood components deviating from required standards set out in Schedule 4 shall be released for transfusion only in exceptional circumstances and with the recorded agreement of the prescribing physician and the blood establishment physician.

9.2. Complaints

All complaints and other information, including serious adverse reactions and serious adverse events, which may suggest that defective blood components have been issued, shall be documented, carefully investigated for causative factors of the defect and, where necessary, followed by recall

and the implementation of corrective actions to prevent recurrence. Procedures shall be in place to ensure that the competent authorities are notified as appropriate of serious adverse reactions or serious adverse events in accordance with regulatory requirements.

9.3. **Recall**

1. There shall be personnel authorised within the blood establishment to assess the need for blood and blood component recall and to initiate and coordinate the necessary actions.

2. An effective recall procedure shall be in place, including a description of the responsibilities and actions to be taken. This shall include notification to the competent authority.

3. Actions shall be taken within pre-defined periods of time and shall include tracing all relevant blood components and, where applicable, shall include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from that donor, as well as to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk.

9.4. **Corrective and preventive actions**

1. A system to ensure corrective and preventive actions on blood component non-conformity and quality problems shall be in place.

2. Data shall be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action.

3. All errors and accidents shall be documented and investigated in order to identify system problems for correction.

10. **SELF-INSPECTION, AUDITS AND IMPROVEMENTS**

1. Self-inspection or audit systems shall be in place for all parts of the operations to verify compliance with the standards set out in this Schedule. They shall be carried out regularly by trained and competent persons in an independent way according to approved procedures.

2. All results shall be documented and appropriate corrective and preventive actions shall be taken in a timely and effective manner.