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European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005

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I, Mary Harney, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2002/98/EC[1] of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC[2], and Commission Directive 2004/33/EC[3] of 22 March 2004 implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components, hereby make the following Regulations:

PART 1

PRELIMINARY

Citation.

1. These Regulations may be cited as the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005.

[1] OJ L33 of 8.2.2003, p. 30
[2] OJ L311 of 28.11.2001, p. 67
[3] OJ L91 of 30.3.2004, p. 25

Interpretation.

2. (1) In these Regulations, unless the context otherwise requires -

"allogeneic donation" means blood and blood components collected from an individual and intended -

(a) for transfusion to another individual,

(b) for use in medical devices, or

(c) as a starting material or raw material in the manufacture of medicinal products;

"appropriate fee" means the fee concerned charged pursuant to *Regulation 29(1)*;

"authorised officer" means a person appointed under *Regulation 19(1);*

"autologous transfusion" means a transfusion in which -

(a) the donor and the recipient are the same person, and

(b) pre-deposited blood or blood components are used;

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

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

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

“blood establishment” means any person, other than a person responsible for the management of a hospital blood bank, which carries out any prescribed activity;

“blood product” means any therapeutic product derived from blood or human plasma;

“Commission” means the European Commission;

“Commission Directive 2004/33/EC” 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;

“Council Directive 2001/83/EC” means Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use;

“deferral” means the suspension, whether permanent or temporary, of the eligibility of an individual to donate blood or blood components;

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

"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;

"functions" includes powers and duties, and references to the performance of functions include, with respect to powers and duties, references to the exercise of powers and the carrying out of the duties;

"haemovigilance" means -

(a) a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and

(b) the epidemiological follow-up of donors;

"hospital blood bank" -

(a) 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, and

(b) includes hospital based transfusion services;

"IMB" means the Irish Medicines Board established by section 3 of the Irish Medicines Board Act 1995 (No. 29 of 1995);

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

"Irish Blood Transfusion Service" means the body established by the Blood Transfusion Service Board (Establishment) Order 1965 (S.I. No. 78 of 1965) as amended by the Blood Transfusion Service Board (Establishment) Order 1965 (Amendment) Order 2000 (S.I. No. 22 of 2000);

"Minister" means the Minister for Health and Children;

"National Haemovigilance Office" means the service set up by the Irish Blood Transfusion Service pursuant to its function under Article 4(k) of the Blood Transfusion Service Board (Establishment) Order 1965 (S.I. No. 78 of 1965) as amended by the Blood Transfusion Service Board (Establishment) Order 1965 (Amendment) Order 2000 (S.I. No. 22 of 2000);

"person responsible for the management of a hospital blood bank" means -

(a) in the case of a hospital blood bank located in a publicly funded hospital provided and maintained by the Health Service Executive, the Health Service Executive,

(b) in the case of a hospital blood bank located in any other hospital (whether or not publicly funded), the person operating or managing the hospital;

"prescribed activity" means any activity consisting of any aspect of -

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

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

"qualified health professional" means -

(a) a medical practitioner whose name is entered in the General Register of Medical Practitioners established under the Medical Practitioners Acts 1978 to 2000, or

(b) a nurse whose name is entered in the register of nurses maintained under section 27 of the Nurses Act 1985 (No. 18 of 1985),

"reporting year" means the period of 12 months ending on 31 December;

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

"serious adverse event" means any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components -

(a) that might lead to death or life-threatening, disabling or incapacitating conditions for patients, or

(b) which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response in a donor or a patient associated with the collection or transfusion of blood or blood components -

(a) that is fatal, life-threatening, disabling or incapacitating, or

(b) 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 prescribed activities, but shall not include any premises not owned or managed by the blood establishment at which blood is collected;

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

(2) In these Regulations -

(a) words and expressions which are also used in the Directive have the same meaning as in the Directive,

(b) a reference to any other enactment, EC Directive or Regulation shall be construed as a reference to that enactment, EC Directive or Regulation as amended or extended by any other enactment, EC Directive or Regulation, including a Regulation of these Regulations,

(c) a reference to a Regulation is a reference to a Regulation of these Regulations, and

(d) a reference to a paragraph, subparagraph, clause or subclause is a reference to a paragraph, subparagraph, clause or subclause of the provision in which the reference occurs.

Application.

3. (1) Subject to *paragraph (2)*, the requirements of these Regulations shall 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.

(2) These Regulations shall not apply to blood stem cells.

(3) These Regulations shall apply without prejudice to -

(a) the European Communities (Medical Devices) Regulations 1994 (S.I. No. 252 of 1994),

(b) the Data Protection Acts 1988 and 2003 in so far as those Acts transpose Directive 95/46/EC[4] of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and

(c) the European Communities (*In Vitro* Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001).

[4] OJ L281 of 23.11.1995, p. 31

Competent Authority, etc.

4. (1) The IMB is designated as the competent authority in the State for the purposes of the Directive.

(2) The Irish Blood Transfusion Service and the National Haemovigilance Office shall each render to the IMB such assistance as the IMB may reasonably require of each of them for the purposes of assisting the IMB to perform its functions under these Regulations.

(3) The IMB may enter into a contractual arrangement with a person for the purposes of the person assisting the IMB to perform its functions under these Regulations.

PART 2

PROVISIONS APPLICABLE TO BLOOD ESTABLISHMENTS

Requirement for authorisation.

5. (1) Subject to *paragraph (2),* no person may carry on any prescribed activity otherwise than in accordance with an authorisation granted under *Regulation 6* (including any conditions to which the authorisation is subject).

(2) The restriction in *paragraph (1)* shall not apply to -

(a) the storage and distribution of, and the performance of compatibility tests on, blood and blood components exclusively for use within hospital facilities, including transfusion activities where such activities are performed by a hospital blood bank, or

(b) any person carrying out any prescribed activity where that person carries out that activity on behalf of, and pursuant to a contractual arrangement with -

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

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

Authorisation of blood establishment.

6. (1) The IMB may grant an authorisation to a blood establishment to carry out any prescribed activity.

(2) An application for authorisation under *paragraph (1)* shall be made to the IMB.

(3) An application must -

(a) include the information set out in *paragraph (4)*, and

(b) be accompanied by the appropriate fee.

(4) The information referred to in *paragraph (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 prescribed activity,

(ii) a description of the prescribed 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 the person and of the services which the person will carry out,

(iv) the name, qualifications and contact details of the responsible person for the establishment, and

(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 prescribed 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 Annex V to Commission Directive 2004/33/EC,

(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 -

(I) recruitment, retention and assessment of donors,

(II) processing, testing, distribution and recall of blood and blood components, and

(III) the reporting and recording of serious adverse reactions and events.

(5) The IMB may -

(a) grant or refuse any application for authorisation made under *paragraph (3)*, and

(b) grant such application -

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

(ii) subject to conditions.

(6) Where the IMB grants an application for authorisation, it shall give notice in writing to the blood establishment specifying -

(a) the prescribed activities which the blood establishment may undertake under these Regulations at each site in respect of which authorisation is granted, and

(b) the conditions which apply to the undertaking of those activities.

(7) Subject to the requirements of *paragraph (8)*, the IMB may at any time remove or vary any of the conditions referred to in *paragraph 5(b)(ii)*, or may impose additional conditions.

(8) Where the IMB removes or varies any condition or imposes any additional condition pursuant to *paragraph (7)*, it shall serve a notice on the blood establishment concerned which shall -

(a) give details of the conditions which it proposes to remove, or of the variation which it proposes to make to any existing conditions, or of any additional condition which it proposes to impose,

(b) give the reasons for its 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 prescribed activities which it undertakes without the prior written approval of the IMB.

(10) Any application by a blood establishment for approval to make a substantial change in its activities must be -

(a) made in writing to the IMB, and

(b) accompanied by the appropriate fee.

(11) For the purpose of this Regulation, a substantial change in a blood establishment's activities is any change -

(a) to the sites from which the blood establishment operates or to the prescribed activities to be carried out at each site,

(b) which would result in a failure to comply with the requirements of these Regulations, 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 prescribed

activities which the blood establishment has been authorised to undertake pursuant to this Regulation.

Suspension or revocation of authorisation.

7. (1) Subject to *paragraph (2)*, the IMB may suspend or revoke the authorisation of a blood establishment on one or more of the following grounds -

(a) that the blood establishment has failed, in any material respect, to comply with the requirements of these Regulations,

(b) that the collection, testing, processing, storage or distribution of blood or blood components by the establishment cannot be carried out safely,

(c) that any blood or blood components cannot be supplied to hospital blood banks in such a state that they could be safely administered for transfusion, or

(d) that the information given by the blood establishment pursuant to *Regulation 6(3)* and *(4)* was false or incomplete in any material respect.

(2) Subject to *paragraph (3)*, before suspending or revoking the authorisation of a blood establishment, the IMB shall serve a notice on the blood establishment stating that it 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 IMB considers that it is necessary in the interests of safety, it may, by a notice served on a blood establishment, suspend or revoke its authorisation with immediate effect.

(4) Where -

(a) the blood establishment has failed, in any material respect, to comply with the requirements of these Regulations, or

(b) the information given by the blood establishment pursuant to *Regulation 6(3)* and *(4)* was false or incomplete in any material respect,

and the IMB 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, it may serve a notice on the responsible person of the blood establishment in accordance with *paragraph (5)*.

(5) A notice served under this paragraph shall -

(a) identify the requirements of these Regulations in respect of which the blood establishment has failed to comply with or, in the case of false or 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 *subparagraph (b)*.

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

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

(a) in a case where the IMB considers that it is necessary in the interests of safety, immediately, or

(b) in all other cases, from a date specified in the notice.

(8) Any suspension pursuant to *paragraph (1)* or *(6)* shall be for such period as the IMB shall consider necessary having regard to the reasons for the suspension.

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

Responsible person for blood establishment.

8. (1) Subject to *paragraph (2),* a blood establishment shall designate a person who is responsible for the following functions -

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

(b) ensuring that every unit of blood or blood component intended for transfusion has been processed, stored and distributed in accordance with the requirements of these Regulations,

(c) providing information to the IMB relating to the authorisation of the blood establishment for the purposes of *Regulation 6*, and

(d) the implementation in the blood establishment of the requirements of *Regulations 9, 10* and *15*.

(2) A blood establishment shall not designate a person under *paragraph (1)* unless that person has -

(a) a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of -

(i) a university course of study, or

(ii) a course recognised as an equivalent course by the IMB, and

(b) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these Regulations for at least 2 years, in an establishment (or more than one establishment) in any Member State lawfully undertaking activities related to the collection or testing (or both) of blood and blood components, or to their preparation, storage and distribution.

(3) The IMB shall from time to time publish details of courses recognised by it for the purpose of *paragraph (2)(a)(ii)*.

(4) The responsible person may delegate any of the functions specified in *paragraph (1)* to other persons who shall be qualified by training and experience to perform them.

(5) Blood establishments shall notify the IMB of the name of any persons to whom functions have been delegated by the responsible person under *paragraph (4)*, and the specific functions which have been delegated to such persons.

(6) Where the responsible person or a person to whom functions have been delegated under *paragraph (4)* is permanently or temporarily replaced, the blood establishment shall without delay provide the IMB with the name of the replacement, details of his or her qualifications and the date on which the replacement began his or her duties.

(7) If the IMB considers that the responsible person does not meet the requirements of *paragraph (2)*, it may serve a notice to that effect on the blood establishment.

(8) If, within 14 days of receiving a notice in accordance with *paragraph (7)*, a blood establishment is not able to demonstrate to the reasonable satisfaction of the IMB that the responsible person does meet the requirements of *paragraph (2)*, it shall, without delay -

(a) relieve him or her of the duties of responsible person in respect of the establishment,

(b) appoint a new responsible person in his or her place, and

(c) notify the IMB that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

Blood establishment requirements.

9. (1) A blood establishment shall -

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

(b) establish and maintain a quality system for blood establishments based on the principles of good practice,

(c) ensure that all testing and processes of the blood establishment which are referred to in Annexes II to V to Commission Directive 2004/33/EC are validated,

(d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection under *Regulation 16*,

(e) notify the IMB of -

(i) any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components by the blood establishment which may have an influence on their quality and safety, and

(ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components collected, tested, processed, stored or distributed by the blood establishment,

(f) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in *subparagraph (e)*, and

(g) ensure that in particular epidemiological situations (such as disease outbreaks) criteria for deferral are put in place which are consistent with the epidemiological situation concerned,

(h) notify the IMB of -

(i) criteria referred to in *subparagraph (g)* not later than 7 days after the criteria have been put in place, and

(ii) the epidemiological situation to which the criteria relate,

(i) adopt and comply with any criteria for additional tests notified to it pursuant to *Regulation 28(a)*, and

(j) ensure that an autologous donation -

(i) complies with the specific requirements set out in Annexes II to V of Commission Directive 2004/33/EC applicable to an autologous donation, and

(ii) is clearly identified as an autologous donation and is kept separate from any allogeneic donation.

(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 Annex II to Commission Directive 2004/33/EC,

(b) obtain from all persons who are willing to provide blood or blood components information in accordance with Part B of Annex II to Commission Directive 2004/33/EC,

(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 Annex III to Commission Directive 2004/33/EC,

(e) maintain records of the results of donor evaluations and report to donors any relevant abnormal findings from the evaluations, and

(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.

(3) A blood establishment shall ensure that, in relation to the blood and blood components which it collects, processes, stores or distributes -

(a) each donation of blood and blood components (including blood and blood components which are imported into the European Community) is tested in conformity with -

(i) the basic testing requirements for whole blood and apheresis donations, specified in *paragraph (7)*, and

(ii) any additional tests which may be necessary for specific components, types of donors or epidemiological situations,

(b) the storage, transport and distribution conditions of blood and blood components comply with the requirements of Annex IV to Commission Directive 2004/33/EC, and

(c) quality and safety requirements for blood and blood components meet the standards specified in Annex V to Commission Directive 2004/33/EC.

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

(a) the conduct of the tests referred to in *paragraph (3)(a)*, and

(b) the information specified in *paragraphs (5)* and *(6)*.

(5) The information specified in this paragraph is -

(a) the total number of donors who give blood and blood components,

(b) the total number of donations,

(c) an updated list of the hospital blood banks which it supplies,

(d) the total number of whole donations not used,

(e) the number of each component produced and distributed,

(f) the incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components,

(g) the number of product recalls, and

(h) the number of serious adverse events and serious adverse reactions reported.

(6) The information specified in this paragraph is -

(a) information provided to donors by the blood establishment in accordance with *paragraph (2)(a)*,

(b) information obtained from donors by the blood establishment in accordance with *paragraph (2)(b)*, and

(c) information relating to the suitability of blood and plasma donors in accordance with the eligibility criteria specified in Annex III to Commission Directive 2004/33/EC.

(7) The basic testing requirements with which blood establishments must ensure compliance pursuant to *paragraph (3)(a)(i)* are -

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

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

(c) testing for the following infections of donors -

(i) Hepatitis B (HBs-Ag),

(ii) Hepatitis C (Anti-HCV), and

(iii) HIV 1 and 2 (Anti-HIV 1 and 2).

(8) The IMB may issue guidance as to the additional tests referred to in *paragraph (3)(a)(ii)* which are necessary in relation to specific components, types of donor or epidemiological situations and blood establishments shall have regard to such guidance.

(9) As soon as practicable after the end of the reporting year, each blood establishment shall provide to the IMB a report specifying the information referred to in *paragraph (3)* for that year.

Labelling of blood and blood components and traceability.

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

(a) the official name of the component,

(b) the volume or weight or number of cells in the component, as appropriate,

(c) a unique numeric or alphanumeric donation indication,

(d) the name of the producing blood establishment,

(e) the ABO Group, except in the case of plasma intended only for fractionation,

(f) the Rh D Group, either Rh D positive or Rh D negative, except in the case of plasma intended only for fractionation,

(g) the date or time of expiry, as appropriate,

(h) the temperature of storage,

(i) the name, composition and volume of any anticoagulant and any additive solution.

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

(a) for the identification of each single blood donation and each single blood unit and its components (including blood and blood components which are imported into the European Community), and

(b) to ensure full traceability to the point of delivery to a hospital,

for a period of not less than 30 years.

PART 3

PROVISIONS APPLICABLE TO HOSPITAL BLOOD BANKS

Hospital blood bank requirements.

11. 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 blood and blood components for the hospital blood bank are qualified to perform those tasks and are provided with timely, relevant and regularly updated training,

(b) establish and maintain a quality system for the hospital blood bank which is based on the principles of good practice,

(c) ensure that all processes referred to in Annex IV to Commission Directive 2004/33/EC which are applicable to activities carried out by the hospital blood bank are validated,

(d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection under *Regulation 16*,

(e) maintain, for not less than 30 years, the data needed to ensure full traceability of blood and blood components, from the point of receipt of the blood or blood component by the hospital blood bank,

(f) notify the IMB of -

(i) any serious adverse events related to the testing, storage and distribution of blood and blood components by the hospital blood bank which may have an influence on their quality and safety, and

(ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components issued for transfusion by the hospital blood bank,

(g) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in *subparagraph (f)*, and

(h) ensure that the storage, transport and distribution conditions of blood and blood components by the hospital blood bank comply with the requirements of Annex IV to Commission Directive 2004/33/EC.

Requirement for hospital blood banks to provide information to IMB.

12. (1) As soon as practicable after the end of the reporting year, the person responsible for management of a hospital blood bank shall submit an annual report to the IMB, which shall -

(a) include a declaration that the hospital blood bank has in place appropriate systems to ensure compliance with the requirements of these Regulations, and

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

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

Service of notices relating to hospital blood banks.

13. (1) If the IMB is of the opinion that -

(a) the person responsible for management of a hospital blood bank has failed, in any material respect, to comply with the requirements of these Regulations,

(b) the testing, storage or distribution of blood or blood components by the hospital blood bank is such that any blood or blood components cannot be safely administered for transfusion, or

(c) the information given by the person responsible for management of a hospital blood bank pursuant to *Regulation 12* was false or incomplete in any material respect,

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

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

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

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

(a) the person responsible for management of the hospital blood bank is no longer in contravention of the requirements of these Regulations,

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

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

PART 4

PROVISIONS APPLICABLE TO BLOOD ESTABLISHMENTS AND HOSPITAL BLOOD BANKS

Objections to suspension, revocation, etc.

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

(a) objects to the refusal of authorisation or the imposition of any condition pursuant to *regulation 6(5)*, or

(b) objects to any suspension or revocation of authorisation, or to any notice served, pursuant to *regulation 6(8), 7* or *13*,

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

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

(3) Where the IMB receives a notification pursuant to *paragraph (1)*, it shall appoint a person to consider the matter.

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

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

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

(7) The IMB shall take into account any recommendation made pursuant to *paragraph (5)*.

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

(9) Subject to *paragraph (11)*, where the IMB is notified of an objection pursuant to *paragraph (1)(b)* before the date upon which the suspension or revocation or the notice is due to take effect, the suspension or revocation or notice in respect of which the objection is made shall not take effect until -

(a) the person appointed pursuant to *paragraph (3)* has considered the matter in accordance with the provisions of this Regulation and made a recommendation, and

(b) the IMB has informed the blood establishment or the person responsible for the management of the hospital blood bank concerned of its decision with regard to the recommendation pursuant to *paragraph (8)*.

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

(a) the person appointed pursuant to *paragraph (3)* has considered the matter in accordance with the provisions of this Regulation and made a recommendation, and

(b) the IMB has informed the blood establishment or the person responsible for the management of the hospital blood bank concerned of its decision with regard to the recommendation pursuant to *paragraph (8)*.

(11) *Paragraphs (9)* and *(10)* shall not apply -

(a) in relation to a suspension or revocation, or a notice served pursuant to *Regulation 13*, which takes immediate effect in accordance with *Regulation 7(3)* or *13(3),* or

(b) in any other case, where the IMB 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.

Disclosure of information by blood establishments and hospital blood banks.

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

(a) available for the purpose of tracing donations,

(b) not disclosed except -

(i) in accordance with one or more of the requirements of *paragraph (2)*, or

(ii) where they have been rendered anonymous so that donors are no longer identifiable, and

(c) subject to safeguards against unauthorised additions, deletions or modifications.

(2) The requirements of this paragraph are -

(a) the disclosure is made in accordance with an order of a court or is otherwise required by law,

(b) the disclosure is to an authorised officer, 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 officer pursuant to *paragraph (2)(b)*, the authorised officer 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 authorised officer or an officer of the IMB where this is necessary for the proper performance of any function of any such officer, or

(c) the information has been rendered anonymous so that the donors are no longer identifiable.

(4) Where a disclosure is made pursuant to *paragraph (3)*, the person to whom the disclosure is made shall not further disclose the information he or she receives other than in accordance with the requirements of that paragraph.

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

Inspections, etc.

16. (1) The IMB shall conduct a regular inspection of each site of a blood establishment, not less than once every 2 years, for the purpose of ensuring that -

(a) blood establishments comply with the requirements of these Regulations, and

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

(2) The IMB may conduct such additional inspections of blood establishment sites as it considers necessary for the purpose of ensuring compliance with the requirements of these Regulations.

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

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

(5) The IMB may inspect hospital blood banks with a view to ensuring that -

(a) hospital blood banks and persons responsible for the management of hospital blood banks comply with the requirements of these Regulations,

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

(c) not later than 8 November 2008, the hospital blood banks operate to International Standard ISO 15189 (Medical laboratories - Particular requirements for quality and competence) of the International Organisation for Standardisation.

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

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

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

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

(10) For the avoidance of doubt, it is hereby declared that the IMB's functions under this Regulation in relation to a blood establishment are also applicable in the case of a blood establishment seeking authorisation under *Regulation 6*.

Records to be kept by IMB.

17. (1) The IMB shall keep such records of information which it receives from, or relating to, blood establishments as it considers appropriate and shall, in particular, keep records relating to -

(a) authorisations under *Regulation 6*,

(b) the designation of responsible persons under *Regulation 8*,

(c) notification of serious adverse events and serious adverse reactions by blood establishments pursuant to *Regulation 9(1)(e)*, and

(d) inspections or requests for information under *Regulation 16*.

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

(a) notification of serious adverse events and serious adverse reactions pursuant to *Regulation 11(1)(f)*,

(b) the information supplied by hospital blood banks pursuant to *Regulation 12*, and

(c) inspections or requests for information under *Regulation 16*.

PART 5

AUTHORISED OFFICERS AND TESTING, ETC. OF SAMPLES, ETC.

Interpretation *(Part 5)*.

18. In this Part -

"inspect" includes search;

"premises" means any place, ship or other vessel, aircraft, railway wagon or other vehicle, and includes a container used to transport relevant things;

"record" includes, in addition to a record in writing -

(a) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable (with or without the aid or some other instrument) of being reproduced in legible or audible form,

(b) a film, tape or other device in which visual images are embodied so as to be capable (with or without the aid or some other instrument) of being reproduced in visual form, and

(c) a photograph,

and any reference to a copy of a record includes -

(d) in the case of a record to which *paragraph (a)* of this definition applies, a transcript of the sounds or signals embodied therein,

(e) in the case of a record to which *paragraph (b)* of this definition applies, a still reproduction of the images embodied therein, and

(f) in the case of a record to which *paragraphs (a)* and *(b)* of this definition apply, such a transcript together with such a still reproduction;

"relevant thing" means -

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

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

Authorised officers.

19. (1) The IMB -

(a) may appoint such and so many persons as the IMB thinks fit to be authorised officers for the purposes of these Regulations, and

(b) shall furnish each authorised officer appointed by it with a warrant of the authorised officer's appointment.

(2) An authorised officer shall, when performing a function imposed under these Regulations on an authorised officer, produce his or her warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of enforcing compliance with these Regulations or conducting inspections pursuant to *Regulation 16*, an authorised officer may -

(a) subject to *paragraph (5)*, enter (if necessary by the use of reasonable force), at all reasonable times, any premises at which he or she has reasonable grounds to believe that it is necessary 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 prescribed activities,

(ii) any premises of any person who carries out any prescribed activities on behalf of, and 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 at which books, records or other documents (including documents stored in non-legible form) relating to any prescribed activities are stored or kept,

(b) at such premises inspect and take copies of, any books, records, other documents (including documents stored in non-legible form) or extracts therefrom, which he or she finds in the course of his or her inspection,

(c) remove any such books, records or other documents from such premises and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(d) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of -

(i) the premises,

(ii) any relevant thing at the premises, or

(iii) any equipment, machinery or plant at the premises,

as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(e) require any person at the premises or the owner or person in charge of the premises and any person employed there to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as he or she may reasonably require for the purposes of his or her functions under these Regulations,

(f) without payment, take samples of any relevant thing found at the premises for the purposes of any test, examination or analysis,

(g) direct that such relevant thing found at the premises as he or she, upon reasonable grounds, believes does not comply with the requirements of these Regulations not be sold or distributed or moved from the premises, without his or her consent,

(h) secure for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under these Regulations,

(i) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations,

(j) without payment, take samples of any relevant thing, detained pursuant to *subparagraph (i)*, for the purposes of any test, examination, or analysis, or

(k) where the taking of samples of any relevant thing pursuant to *subparagraph (f)* or *(j)* is, for whatever reason, not practicable, without payment take the relevant thing concerned for the purposes of any test, examination or analysis.

(4) When performing a function under these Regulations, an authorised officer may, subject to any warrant under *subsection (6)*, be accompanied by such number of -

(a) other authorised officers,

(b) members of the Garda Síochána, or

(c) persons with expertise relating to any relevant thing,

as he or she considers appropriate in the circumstances of the case.

(5) An authorised officer shall not enter a dwelling, other than -

(a) with the consent of the occupier, or

(b) in accordance with a warrant issued under *paragraph (6)*.

(6) Upon the application of an authorised officer, a judge of the District Court, if satisfied that there are reasonable grounds for believing that -

(a) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling,

(b) books, records or other documents (including documents stored in non-legible form) referred to in *paragraph (3)(a)(iv)* are being stored or kept in any dwelling, or

(c) a dwelling is occupied in whole or in part by an undertaking carrying out any prescribed activity,

may issue a warrant authorising a named authorised officer accompanied by such other authorised officers, members of the Garda Síochána, or persons with expertise relating to any relevant thing, as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under *paragraph (3)(b)* to *(k)*.

(7) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under these Regulations, he or she may require that person to provide him or her with his or her name and the address at which he or she ordinarily resides.

(8) A statement or admission made by a person pursuant to a requirement under *paragraph (3)(e)* shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under *Regulation 22(7)*).

(9) Nothing in this Regulation shall be taken to compel the production by any person of a document of which he or she would be exempt from production in proceedings in a court on the ground of legal professional privilege.

Taking of samples, etc. by authorised officers.

20. (1) Subject to *paragraph (3)*, where an authorised officer takes a sample of a relevant thing, he or she 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 officer.

(2) Where an authorised officer has complied with *paragraph (1)*, he or she 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, and

(c) forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by a person mentioned in *Regulation 21(1)(a),(b)* or *(c)*.

(3) Where a relevant thing is contained in a container and its division into parts pursuant to *paragraph (1)* is, for whatever reason, not practicable, an authorised officer, 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 *paragraph (1)*, and the provisions of *paragraphs (1)* and *(2)* shall apply thereto accordingly.

(4) Where an authorised officer takes a relevant thing pursuant to *Regulation 19(3)(k)*, he or she shall -

(a) place the relevant thing in a container,

(b) forthwith seal and mark the container in such a manner as to identify it as a relevant thing taken pursuant to that section, and

(c) forward, or cause to be forwarded, the sealed container for test, examination or analysis of the relevant thing by a person mentioned in *Regulation 21(1)(a)*, *(b)* or *(c)*.

Certificate of result of test, etc. of sample, etc.

21. (1) In any proceedings for an offence under these Regulations, a certificate in the form specified in the Schedule to these Regulations signed by -

(a) either -

(i) the State Chemist, or

(ii) another chemist employed or engaged at the State Laboratory and authorised by the State Chemist to sign the certificate,

(b) either -

(i) a public analyst appointed under section 10 of the Sale of Food and Drugs Act 1875 to 1936, or

(ii) another analyst authorised by such a public analyst to sign the certificate, or

(c) a chemist or analyst appointed by the IMB,

stating the result of any test, examination or analysis of a sample of any relevant thing, or of a relevant thing, as the case may be, forwarded under *Regulation 20(2)(c)* or *(4)(c)* shall, with regard to that sample of the relevant thing, or the relevant thing, as the case may be, be evidence of the matters stated in the certificate unless the contrary is proved.

(2) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that purports to bear the name of the manufacturer or importer of that thing, or of the person who placed that thing on the market, shall, unless the contrary is proved, be evidence that the relevant thing was manufactured or imported, or placed on the market, as the case may be, by the person so named.

(3) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that bears a trademark shall, unless the contrary is proved, be evidence that the thing was manufactured by the person who at the time of the alleged commission of the offence owned that trademark.

(4) In this section "trademark" has the same meaning as it has in the Trade Marks Act 1996 (No. 6 of 1996).

PART 6

OFFENCES, ETC.

Offences.

22. (1) A person who contravenes any of the provisions of *Regulation 5(1), 9 or 11* shall be guilty of an offence and liable on summary conviction to a fine not exceeding €2,000, or to imprisonment for a term not exceeding 6 months, or to both.

(2) A person who contravenes any of the provisions of *Regulation 6(9), 8 (except Regulation 8(3)), 10, 12 or 16(4) or (7)* shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to imprisonment for a term not exceeding 3 months, or to both.

(3) Any person who fails to comply with a notice of suspension or revocation of the person's authorisation served pursuant to *Regulation 7*, except where the operation of that notice has been suspended pursuant to *Regulation 14*, or has been withdrawn or revoked by the IMB, shall be guilty of an offence and liable on summary conviction to a fine not exceeding €2,000, or to a term of imprisonment not exceeding 6 months, or to both.

(4) Any person who knowingly sells or supplies blood or any blood component which is not labelled in accordance with the requirements of *Regulation 10* shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to a term of imprisonment not exceeding 3 months, or to both.

(5) Any person who contravenes the requirements of any notice served by the IMB under *Regulation 13(1)*, shall be guilty of an offence and liable on summary conviction

to a fine not exceeding €2,000, or to a term of imprisonment not exceeding 6 months, or to both.

(6) Any person who -

(a) contravenes *Regulation 15*, or

(b) discloses any information referred to in *Regulation 15(1)* to which he or she has access by virtue of these Regulations, otherwise than in accordance with the provision of *Regulation 15(2)* and *(3)*,

shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to a term of imprisonment not exceeding 3 months, or to both.

(7) Any person who -

(a) obstructs or interferes with an authorised officer, a member of the Garda Síochána, or a person with expertise relating to any relevant thing (within the meaning of *Regulation 18*), in the course of performing a function conferred on him or her by these Regulations or a warrant under *Regulation 19(6)*, or

(b) impedes the performance by the officer, member, or person with expertise, as the case may be, of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked

by, the officer, member, or person with expertise, as the case may be, pursuant to *Regulation 19*, or

(c) in purported compliance with such request or requirement or in answer to such question gives information to the officer, member, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect,

shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to imprisonment for a term not exceeding 3 months, or to both.

(8) A person who falsely represents himself or herself to be an authorised officer shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to imprisonment for a term not exceeding 3 months, or to both.

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

(10) On conviction for an offence under these Regulations (including an offence under *Regulation 23)*, the court may, in addition to any other penalty -

(a) order any relevant thing (within the meaning of *Regulation 18*) to which the offence relates to be forfeited to the IMB for destruction or other disposal as the IMB thinks fit,

(b) upon application made to it by or on behalf of the IMB, order the person convicted of the offence to pay to the relevant person all or part of the costs of such destruction or other disposal subject to such conditions, if any, as are specified in the order.

Offence to import below standard blood, etc. into State.

23. A person who imports into the State any blood components (including blood or blood components intended for use as a starting material or raw material in the manufacture of medicinal products) from a country or territory outside the European Community which does not meet standards of quality and safety equivalent to those laid down in Annex V to Commission Directive 2004/33/EC is guilty of an offence and liable on summary conviction to a fine not exceeding €2,000, or to imprisonment for a term not exceeding 6 months, or to both.

Offence by body corporate.

24. (1) Where an offence under these Regulations which is committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any person who, when the offence was committed, was a director, manager, secretary or other officer of the body or a person who was purporting to act in any such capacity, that person, as well as the body corporate, shall also be guilty of an offence and shall also be liable to be proceeded against and punished as if guilty of the offence committed by the body corporate.

(2) Where the affairs of a body corporate are managed by its members, *paragraph (1)* applies as if the reference to a director in that subsection were a reference to a member of the body corporate.

Defence of due diligence.

25. (1) In any proceedings for an offence under *Regulation 22* or *23*, or *Regulation 22* or *23* as read with *Regulation 24*, it shall be a defence for the person charged to prove that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to a defence under *paragraph (1)*, the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond all reasonable doubt that it is not.

Proceedings may be brought by IMB.

26. (1) Summary proceedings for an offence under these Regulations may be brought and prosecuted by the IMB.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851 (14& 15 Vict. c. 93), summary proceedings for an offence under these Regulations may be instituted within 2 years from the date of the offence.

PART 7

MISCELLANEOUS

Reports by IMB.

27. The IMB shall send to the Commission a report -

(a) before the end of 2006 and before the end of every 3 years thereafter, and

(b) on the activities undertaken in relation to the provisions of the Directive, including an account of the measures taken in relation to inspection and control.

Specific epidemiological situations.

28. Where the IMB is aware of a specific epidemiological situation (whether under *Regulation 9(1)(h)* or otherwise), such as an outbreak of a disease, which may affect the safety of blood donations -

(a) it may notify blood establishments of additional deferral criteria for the collection of blood donations that must be adopted by them, and

(b) it shall notify the Commission of -

(i) the epidemiological situation, and

(ii) the additional criteria, if any, which blood establishments are required to adopt in relation to it pursuant to *subparagraph (a)*.

Fees.

29. (1) The IMB may charge fees which shall be equal to the respective amounts which the IMB estimates it will incur in, or in connection with, performing the functions referred to in these Regulations to which the fees respectively relate.

(2) Where the costs incurred -

(a) are greater than the appropriate fee, then the difference between those costs and that fee shall be payable by the blood establishment concerned or its authorised representative, or the person responsible for the management of the hospital blood bank concerned or his or her authorised representative, as the case may be, to the IMB, and

(b) are less than the appropriate fee, the difference between those costs and that fee shall be repayable by the IMB to the blood establishment concerned or its authorised representative, or the person responsible for the hospital blood bank concerned or his or her authorised representative, as the case may be.

Transitional provisions.

30. (1) Subject to *paragraph (2)*, these Regulations, other than *Regulations 17* and *23*, shall not apply before 8 November 2005 in relation to -

(a) any blood establishment, and

(b) any hospital blood bank.

(2) From the commencement of this Regulation -

(a) a blood establishment may make an application under *Regulation 6(2)*, and

(b) authorisation under *Regulation 6(5)* may be granted to a blood establishment before 8 November 2005 but any such authorisation shall not have effect before that date.

SCHEDULE

Regulation 21

EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN BLOOD AND BLOOD COMPONENTS) REGULATIONS 2005

CERTIFICATE STATING RESULTS OF TEST, EXAMINATION OR ANALYSIS

This certificate is issued by me, the undersigned, for the purpose of *Regulation 21* of the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005, being -

[1] _____ .

I hereby certify that I received, on the ___ day of _____ _____, from

[2] _____ of _____ a sample of the relevant thing/the relevant thing*, being [3] _____for test, examination or analysis: which was undamaged, duly sealed and marked [4] _____ .

I further certify that the said sample/relevant thing* has been tested, examined or analysed by me or under my direction and that the results are as follows-

[5]

Signature _____

Date _____

Address _____

_____

_____

1. Here insert official title of person signing the certificate.
2. Here insert the name of the authorised officer who submitted the sample of the relevant thing, or the relevant thing, as the case may be.
3. Here insert the name or description of the relevant thing.
4. Here insert distinguishing mark on the sample of the relevant thing, or the relevant thing, as the case may be, and the date shown on its container as the date of sampling, or the date on which the relevant thing was taken into possession, as the case may be.
5. Here insert the relevant results as appropriate.

* Delete whichever is inapplicable.

LS

GIVEN under the Official Seal of the Minister for Health and Children, this 12th day of July, 2005.

_____
Mary Harney
Minister for Health and Children.

EXPLANATORY NOTE

These Regulations give effect to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, and Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components.

The Regulations may be cited as the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005.

The Regulations apply to the collection and testing of blood and blood components, whatever their intended purpose. The Directive also applies to the processing, storage and distribution of blood and blood components, but only when they are intended to be used for transfusion. The Regulations do not apply to stem cells.