STATUTORY INSTRUMENTS

2005 No. 50

The Blood Safety and Quality Regulations 2005

Blood establishment requirements

7.—(1) A blood establishment shall—

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

[F1(b) establish and maintain a quality system for blood establishments—

(i) in relation to Great Britain, that is based on the principles of good practice, which meets the standards and requirements set out in the Annex to Commission Directive 2005/62/EC and which gives effect to the Good Practice Guidelines for Blood Establishments Required to Comply with Directive 2005/62/EC published in the 20th edition of the Guide to the preparation, use and quality assurance of blood components;

(ii) in relation to Northern Ireland, that is based on the principles of good practice, which complies with the Community standards and requirements set out in the Annex to Commission Directive 2005/62/EC and which gives effect to the requirements in respect of the use of good practice guidelines set out in Article 2.2 of that Directive;**]**

(c) ensure that all testing and processes of the blood establishment which are referred to in Parts 2 to 5 of the Schedule are validated;

(d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection under regulation 15;

F2(e) . . . . . .

(f) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in paragraph (e) **[**F3; and**]**

[F4(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.**]**

[F5(1A) In relation to Great Britain, for the purposes of paragraph (1)(b), references to the competent authority or to competent authorities in the Annex to Commission Directive 2005/62/EC must be read as references to the Secretary of State.**]**

(2) A blood establishment shall, in relation to the donation of blood—

(a) give all prospective donors of blood or blood components information in accordance with Part A of Part 2 of the Schedule;

(b) obtain from all persons who are willing to provide blood or blood components, information in accordance with Part B of Part 2 of the Schedule;

(c) put and keep in place procedures for the evaluation of donors;

(d) apply eligibility criteria for all donors of blood and blood components in accordance with Part 3 of the Schedule;

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

(f) ensure that—

(i) an examination of the donor, including an interview, is carried out before any donation of blood or blood components,

(ii) a qualified health professional is responsible for giving to and gathering from donors the information which is necessary to assess their eligibility to donate, and

(iii) on the basis of that information, a qualified health professional assesses the eligibility of all donors to donate; and

(g) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are, in so far as possible, provided from such donations, in particular, by—

(i) disseminating information about blood donation, and

(ii) advertising for blood donors.

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

(a) each donation of blood and blood components (including blood and blood components which are imported **[**F6from a third country**]**) is tested in conformity with—

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

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

(b) the storage, transport and distribution conditions of blood and blood components comply with the requirements of Part 4 of the Schedule; and

(c) quality and safety requirements for blood and blood components meet the standards specified in Part 5 of the Schedule.

(4) A blood establishment shall, in relation to the activities specified in regulation 3(2) for which it is responsible, maintain records, for a minimum period of 15 years, of—

(a) the information specified in paragraphs (5) and (6),

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

(5) The information specified in this paragraph is—

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

(b) the total number of donations;

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

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

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

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

(g) the number of product recalls; and

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

(6) The information specified in this paragraph is—

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

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

(c) information relating to the suitability of blood and plasma donors in accordance with the eligibility criteria specified in Part 3 of the Schedule.

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

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

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

(c) testing for the following infections of donors—

(i) Hepatitis B (HBs-Ag);

(ii) Hepatitis C (Anti-HCV);

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

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

(9) As soon as practicable after the end of the reporting year, each blood establishment shall provide to the Secretary of State a report specifying—

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

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

Textual Amendments

F1 Reg. 7(1)(b) substituted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), regs. 1, **7(a)** (as substituted by S.I. 2020/1304, regs. 1, 7(a)); 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 7(1)(e) omitted (31.8.2006) by virtue of The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **4(1)(b)**

F3 Word in reg. 7(1)(f) inserted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **4(1)(c)**

F4 Reg. 7(1)(g) inserted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **4(1)(d)**

F5 Reg. 7(1A) inserted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), regs. 1, **7(b)** (as amended by S.I. 2020/1304, regs. 1, 7(b)); 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 7(3)(a) substituted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), regs. 1, **7(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Modifications etc. (not altering text)

C1 Reg. 7 modified (temp. until 30.6.2010) (16.12.2009) by The Blood Safety and Quality (Modification) Regulations 2009 (S.I. 2009/3307), regs. 1(1), **2**

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005, Section 7.