STATUTORY INSTRUMENTS

2005 No. 50

The Blood Safety and Quality Regulations 2005

Hospital blood bank requirements

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

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

[[F1](b) establish and maintain a quality system for the hospital blood bank—

(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 processes referred to in Part 4 of the Schedule which are applicable to activities carried out by the hospital blood bank, are validated;

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

[[F2](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 Part 6 of the Schedule (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;**]**

[[F3](f) 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;**]**

(g) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in paragraph (f); [F4]...

(h) ensure that the storage, transport and distribution conditions of blood and blood components by the hospital blood bank comply with the requirements of Part 4 of the Schedule **[**[F5]; and**]**

[F6(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.**]**

[F7(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 that Directive must be read as references to the Secretary of State.**]**

[F8(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.**]**

Textual Amendments

F1 Reg. 9(1)(b) substituted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), regs. 1, **9(a)** (as substituted by S.I. 2020/1304, regs. 1, 8(a)); 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 9(1)(e) substituted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **6(2)(b)**

F3 Reg. 9(1)(f) substituted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **8**

F4 Word in reg. 9(1)(g) omitted (31.8.2006) by virtue of The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **6(2)(d)**

F5 Word in reg. 9(1)(h) inserted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **6(2)(e)**

F6 Reg. 9(1)(i)(j) inserted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **6(2)(f)**

F7 Reg. 9(1A) inserted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), regs. 1, **9(b)** (as amended by S.I. 2020/1304, regs. 1, 8(b)); 2020 c. 1, Sch. 5 para. 1(1)

F8 Reg. 9(2) inserted (31.8.2006) by The Blood Safety and Quality (Amendment) Regulations 2006 (S.I. 2006/2013), regs. 1(1), **6(3)**

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005, Section 9.