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STATUTORY INSTRUMENTS

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**2006 No. 2013**

**The Blood Safety and Quality (Amendment) Regulations 2006**

**Amendment of regulation 9 of the principal Regulations**

6.—(1) Regulation 9 of the principal Regulations (hospital blood bank requirements), is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (b), for “good practice;”, substitute “good practice, which complies with the Community standards and requirements set out the Annex to Commission Directive [2005/62/EC](#) insofar as these are applicable to hospital blood banks;”;

(b) for sub-paragraph (e), substitute—

“(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;”.

(c) for sub-paragraph (f), substitute the following sub-paragraph—

“(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;”;

(d) in paragraph (g), at the end, omit “and”;

(e) in paragraph (h), at the end, insert “; and”; and

(f) after paragraph (h), insert the following paragraphs—

“(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.”.

(3) After paragraph (1), insert the following paragraph—

“(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.”.