
STATUTORY INSTRUMENTS

2005 No. 50

The Blood Safety and Quality Regulations 2005

The responsible person for a blood establishment

6.—(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 these Regulations;
- (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 these Regulations;
- (c) providing information to the Secretary of State relating to the authorisation of the blood establishment for the purposes of regulation 4; and
- (d) the implementation in the blood establishment of the requirements of regulations 7, 8 and 14.

(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 Secretary of State; 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) authorised in any Member State in 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 Secretary of State shall from time to time publish details of courses recognised by him for the purpose of paragraph (2)(a)(ii).

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

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

(7) If the Secretary of State considers that the responsible person does not meet the requirements of paragraph (2), he 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 Secretary of State that the responsible person does meet the requirements of paragraph (2), 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 Secretary of State that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.