

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

CHAPTER III

**PROVISIONS FOR BLOOD ESTABLISHMENTS**

*Article 9*

**Responsible person**

- 1 Blood establishments shall designate a person (responsible person), responsible for:
  - ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State,
  - providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures as required in Article 5,
  - the implementation of the requirements of Articles 10, 11, 12, 13, 14 and 15 in the blood establishment.
- 2 The responsible person shall fulfil the following minimum conditions of qualification:
  - a he/she shall possess a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;
  - b he/she shall have practical post-graduate experience in relevant areas for at least two years, in one or more establishments which are authorised to undertake activities related to collection and/or testing of human blood and blood components, or to their preparation, storage, and distribution.
- 3 The tasks specified in paragraph 1 may be delegated to other persons who shall be qualified by training and experience to perform such tasks.
- 4 Blood establishments shall notify the competent authority of the name of the responsible person referred to in paragraph 1 and other persons referred to in paragraph 3 together with information on the specific tasks for which they are responsible.
- 5 Where the responsible person or such other persons referred to in paragraph 3 are permanently or temporarily replaced, the blood establishment shall provide immediately the name of the new responsible person and his or her date of commencement to the competent authority.

*Article 10*

**Personnel**

Personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components shall be qualified to perform those tasks and be provided with timely, relevant and regularly updated training.