Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (Text with EEA relevance)

Article 1

Definitions

For the purposes of this Directive, the definitions set out in Annex I shall apply.

Article 2

Provision of information to prospective donors

Member States shall ensure that blood establishments provide prospective donors of blood or blood components with the information set out in Part A of Annex II.

Article 3

Information required from donors

Member States shall ensure that upon agreement of willingness to commence the donation of blood or blood components, donors provide the information set out in Part B of Annex II to the blood establishment.

Article 4

Eligibility of donors

Blood establishments shall ensure that donors of whole blood and blood components comply with the eligibility criteria set out in Annex III.

Article 5

Storage, transport and distribution conditions for blood and blood components

Blood establishments shall ensure that the storage, transport and distribution conditions for blood and blood components comply with the requirements set out in Annex IV.

Article 6

Quality and safety requirements for blood and blood components

Blood establishments shall ensure that the quality and safety requirements for blood and blood components comply with the requirements set out in Annex V.

Article 7

Autologous donations

1 Blood establishments shall ensure that autologous donations comply with the requirements set out in Directive 2002/98/EC and the specific requirements set out in this Directive.

2 Autologous donations shall be clearly identified as such and shall be kept separate from allogeneic donations.

Article 8

Validation

Member States shall ensure that all testing and processes referred to in Annexes II to V are validated.

Article 9

Transposition

1 Without prejudice to Article 7 of Directive 2002/98/EC, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 8 February 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 10

Entry into force

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 11

Addressees

This Directive is addressed to the Member States.