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 VI

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

CHAPTER VII

DATA PROTECTION

CHAPTER VIII

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

CHAPTER IX

COMMITTEES

CHAPTER X

FINAL PROVISIONS

ANNEX I

INFORMATION TO BE PROVIDED BY BLOOD ESTABLISHMENT TO THE COMPETENT AUTHORITY FOR THE PURPOSES

OF DESIGNATION, AUTHORISATION, ACCREDITATION OR LICENSING IN ACCORDANCE WITH ARTICLE 5(2)

Part A:

General information:

Part B:

A description of the quality system, to include:

ANNEX II

REPORT OF THE BLOOD ESTABLISHMENT'S PRECEDING YEAR'S ACTIVITY

This annual report will include:
total number of donors who give blood and blood components...

ANNEX III

LABELLING REQUIREMENTS

The label on the component must contain the following information:...
the official name of the component the volume or weight...

ANNEX IV

BASIC TESTING REQUIREMENTS FOR WHOLE BLOOD AND PLASMA DONATIONS

The following tests must be performed for whole blood and...
ABO Group (not required for plasma intended only for fractionation)...
Additional tests may be required for specific components or donors...

(**1**) OJ C 154 E, 29.5.2001, p. 141 and
OJ C 75 E, 26.3.2002, p. 104.

(**2**) OJ C 221, 7.8.2001, p. 106.

(**3**) OJ C 19, 22.1.2002, p. 6.

(**4**) Opinion of the European Parliament of 6 September 2001 (OJ C 72 E, 21.3.2002, p. 289), Council Common Position of 14 February 2002 (OJ C 113 E, 14.5.2002, p. 93) and Decision of the European Parliament of 12 June 2002 (not yet published in the Official Journal). Decision of the European Parliament of 18 December 2002 and Decision of the Council of 16 December 2002.

(**5**) OJ L 311, 28.11.2001, p. 67.

(**6**) OJ C 164, 30.6.1995, p. 1.

(**7**) OJ C 374, 11.12.1996, p. 1.

(**8**) OJ C 268, 4.10.1993, p. 29.

(**9**) OJ C 329, 6.12.1993, p. 268.

(**10**) OJ C 249, 25.9.1995, p. 231.

(**11**) OJ C 141, 13.5.1996, p. 131.

(**12**) OJ L 281, 23.11.1995, p. 31.

(**13**) OJ L 203, 21.7.1998, p. 14.

(**14**) OJ L 184, 17.7.1999, p. 23.