Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events (Text with EEA relevance)

ANNEX I

Record of data on traceability as provided for in Article 4

BY BLOOD ESTABLISHMENTS

1. Blood establishment identification
2. Blood donor identification
3. Blood unit identification
4. Individual blood component identification
5. Date of collection (year/month/day)
6. Facilities to which blood units or blood components are distributed,...

BY FACILITIES

1. Blood component supplier identification
2. Issued blood component identification
3. Transfused recipient identification
4. For blood units not transfused, confirmation of subsequent disposition
5. Date of transfusion or disposition (year/month/day)
6. Lot number of the component, if relevant.

ANNEX II

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

PART A

Rapid notification format for suspected serious adverse reactions

PART B

PART C

Confirmation format for serious adverse reactions

PART D

Annual notification format for serious adverse reactions

ANNEX III

NOTIFICATION OF SERIOUS ADVERSE EVENTS

PART A

Rapid Notification Format for Serious Adverse Events

PART B

Confirmation Format for Serious Adverse Events

PART C

Annual Notification Format for Serious Adverse Events

(**1**) OJ L 33, 8.2.2003, p. 30.

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

(**3**) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(**4**) OJ L 91, 30.3.2004, p. 25.