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)

Article 5

Notification of serious adverse reactions

1 Member States shall ensure that those facilities where transfusion occurs have procedures in place to retain the record of transfusions and to notify blood establishments without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood and blood components.

2 Member States shall ensure that reporting establishments have procedures in place to communicate to the competent authority as soon as known all relevant information about suspected serious adverse reactions. The notification formats set out in Part A and Part C of Annex II shall be used.

3 Member States shall ensure that reporting establishments:

a notify to the competent authority all relevant information about serious adverse reactions of imputability level 2 or 3, as referred to in Part B of Annex II, attributable to the quality and safety of blood and blood components;

b notify the competent authority of any case of transmission of infectious agents by blood and blood components as soon as known;

c describe the actions taken with respect to other implicated blood components that have been distributed for transfusion or for use as plasma for fractionation;

d evaluate suspected serious adverse reactions according to the imputability levels set out in Part B of Annex II;

e complete the serious adverse reaction notification, upon conclusion of the investigation, using the format set out in Part C of Annex II;

f submit a complete report on serious adverse reactions to the competent authority on an annual basis using the format set out in Part D of Annex II.