ANNEX IV

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

(as referred to in Article 5)

1. STORAGE

1.1. Liquid storage

Component	Temperature of storage	Maximum storage time
Red cell preparations and whole blood (if used for transfusion as whole blood)	+ 2 to + 6 °C	*28* to *49* days according to the processes used for collection, processing and storage
Platelet preparations	+ 20 to + 24 °C	*5* days; may be stored for *7* days in conjunction with detection or reduction of bacterial contamination
Granulocytes	+ 20 to + 24 °C	*24* hours

1.2. Cryopreservation

Component	Storage conditions and duration
Red blood cells	Up to *30* years according to processes used for collection, processing and storage
Platelets	Up to *24* months according to processes used for collection, processing and storage
Plasma and cryoprecipitate	Up to *36* months according to processes used for collection, processing and storage
Cryopreserved red blood cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after thawing to depend on the method used.	

2. TRANSPORT AND DISTRIBUTION

Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product.

3. ADDITIONAL REQUIREMENTS FOR AUTOLOGOUS DONATIONS

3.1. Autologous blood and blood components must be clearly identified as such and stored, transported and distributed separately from allogeneic blood and blood components.

3.2. Autologous blood and blood components must be labelled as required by Directive 2002/98/EC and in addition the label must include the identification of the donor and the warning ‘FOR AUTOLOGOUS TRANSFUSION ONLY’.