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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
(2) OJ C 221, 7.8.2001, p. 106.
   Common Position of 14 February 2002 (OJ C 113 E, 14.5.2002, p. 93) and Decision of the European