Annexure: R

BLOOD BANK INSPECTION CHECK LIST
(use separate sheets ,if necessary)

(Collect specimen forms, documents, labels, record copies whenever necessary)

Name of Institution			Date of Inspection	
Address of the Institution				
Telephone No.: Fax No.: E-mail:				
Licence number and date of issue				
Inspected By				
Institution represented by				
Purpose of inspection				
Type of Institution	Government	Charitable	Red Cross	Others (specify) Registered Society & attached with Hospital.
Constitution Details				
Product(s)				

Technical staff *(Attach sheet, if reqd.)*	Name	Qualification *(check documents*)	Experience *(check testimonials)*
Doctor			
Registered Nurse			
Technician			

A	Total Collection *(Last two calendar years)*	Year	New Case	
		Voluntary		
		Replacement		
		Professional		
		Total		
	Distribution	Used in own hospital		
		Issued to others		
		Discarded		
B	**Premises**	Total area		
	Details of areas		**Comments**	
1	Registration and Medical Examination	nn		
2	Blood Collection (A/C ?)			
3	Refreshment & Rest Room (A/C ?)			
4	Serology Lab. (A/C ?)			
5	Transmissible diseases Lab. (A/C ?)			
6	Sterilization & washing			
7	Stores and Records			

	General comments on Area		
1	Standard Books? (obtain list)		
2	Blood Bank Manual		
3	Standard operating procedures		
a	Criteria to determine donor suitability	Yes/No/NA	
b	Method of donor selection	Yes/No/NA	
c	Preparation of phlebotomy site	Yes/No/NA	
d	Product to Donor traceabllity	Yes/No/NA	
e	Collection procedures, precautions etc.	Yes/No/NA	
f	Method of components preparation	Yes/No/NA	
g	Test methods	Yes/No/NA	
h	Pre-transfusion testing	Yes/No/NA	
i	Adverse reaction management	Yes/No/NA	
j	Storage temperature & its control	Yes/No/NA	
k	Expiry date assignment	Yes/No/NA	
l	Returned Blood management	Yes/No/NA	
m	QC for reagents & supplies	Yes/No/NA	

n	Maintenance, calibration & validation of equipment	Yes/No/NA	
o	Labeling procedures	Yes/No/NA	
p	Apheresis procedures	Yes/No/NA	
q	Any other SOPs	Yes/No/NA	
D	Procedure for disposal of blood (expired, clotted, improperly collected, HIV + etc.	Yes/No/NA	
E	Donor education/ motivation material	Yes/No/NA	
F	Donor selection	Yes/No/NA	
1	Donor record	Yes/No/NA	
2	Selection/rejecti on manual	Yes/No/NA	
3	**Donor record details:**		
a	Age	Yes/No/NA	
b	Interval between donations	Yes/No/NA	
c	Last pregnancy/delivery/ abortion	Yes/No/NA	
d	Immunization details	Yes/No/NA	
e	Recent drug intake	Yes/No/NA	
f	Major surgery	Yes/No/NA	
g	Malaria	Yes/No/NA	
h	Jaundice	Yes/No/NA	
i	Other viral infection	Yes/No/NA	
j	Fever & common cold	Yes/No/NA	

k	History-cancer, TB, Diabetes, Drug addiction, etc.	Yes/No/NA	
l	Alcohol intake	Yes/No/NA	
m	Transfusion history	Yes/No/NA	
4	Donor Examination	Yes/No/NA	
a	Weight	Yes/No/NA	
b	Venipuncture site	Yes/No/NA	
c	haemoglobin	Yes/No/NA	
d	Blood pressure	Yes/No/NA	
e	Pulse	Yes/No/NA	
f	Temperature	Yes/No/NA	
G	**Collection of Blood**		
a	Preparation of phlebotomy site	Yes/No/NA	
b	Type and amount of anti-coagulant used	Yes/No/NA	
c	Amount of blood collected (random wt.)	Yes/No/NA	
d	Blood collected in bags/bottles	Yes/No/NA	
e	Pediatric Bags?	Yes/No/NA	
f	Is mixing done during collection? How?	Yes/No/NA	
g	Is new bag used in case of 2^{nd} puncture?	Yes/No/NA	
h	How is sample tubes labelled?	Yes/No/NA	
i	Emergency kit available?	Yes/No/NA	
H	**Storage of blood**		
a	Temperature recording graph preserved?	Yes/No/NA	
b	Alarm system checks done?	Yes/No/NA	
c	Physical Verification done? Frequency?	Yes/No/NA	
d	How is blood transported? Outside, to wards?	Yes/No/NA	

I	**Blood Testing**		
a	Sterility Testing	Yes/No/NA	
b	Haemoglobin estimation-method	Yes/No/NA	
c	Method for ABO grouping	Yes/No/NA	
d	Procedure for grouping	Yes/No/NA	
e	Method of pooled cell preparation	Yes/No/NA	
f	Du test done on D-samples?	Yes/No/NA	
g	Test for unexpected antibodies done?	Yes/No/NA	
H	Hepatitis test done? Describe method and Name of kit manufacturer	Yes/No/NA	
I	Syphilis test done? Describe method and Name of kit manufacturer	Yes/No/NA	
J	HIV test done? Describe method and Name of kit manufacturer	Yes/No/NA	
K	HCV test done? Describe method and Name of kit manufacturer	Yes/No/NA	
L	Malaria test done? Describe method	Yes/No/NA	
M	Donor informed in case of +ve results?	Yes/No/NA	
N	In case of HbsAg/HIV +ve results Donor debarred permanently	Yes/No/NA	
O	Are HbsAg/HIV +ve donors followed up?	Yes/No/NA	
P	Cross matching. (Describe method)	Yes/No/NA	
J	**Testing of reagents etc.**		
a	Antisera tested?	Yes/No/NA	

b	Method of Antisera testing	Yes/No/NA	
c	CPDA solution testing	Yes/No/NA	
K	**General equipment and Instruments**		
a	Refrigerators for Blood Storage Type, capacity and number		Yes / No / NA
b	Temperature recorder in refrigerator		
c	Audible alarm system in refrigerator		
d	Balance for bag weighing		
e	Autoclave with temp. & pressure display		
f	Incinerator		
g	Emergency power supply (generator)		
h	Donor beds, chairs, tables		
i	Bedside table		
j	Sphygmomanometer & stethoscope		
k	Recovery bed for donors		
l	Donor weighing scale		
L	**Emergency equipment**		
a	Oxygen cylinder, mask, gauge and pressure regulator		
b	5% Dextrose or Normal Saline Inj.		
c	Sterile Disposable Syringes and needles (various sizes)		
d	Sterile disposable I.V.sets		
e	Adrenaline. Noradrenaline, Mephentin, Betamethasone (or dexamethasone),Metochlorpropamide injections		
M	**Accessories**		
a	Blankets, emesis basins, haemostats, set clamps, sponge forceps, gauze, dressing jars, waste cans etc.		
b	Medium cotton balls, 1.25 cm adhesive tapes		
c	Denatured spirit, Tinc. Iodine, green or liquid soap		
d	Paper napkins or towels		

N	Laboratory Equipment	
a	Refrigerator for kits and reagents storage Refrigerator make and Capacity Temperature display provided	
b	Compound microscope with low & high power objectives	
c	Table centrifuge	
d	Water bath- 37□& 57□	
e	Rh viewing box	
f	Incubator with thermostat	
g	Mechanical shakers for serological test of syphilis test	
h	Hand lens	
i	Serological graduated pipettes of various sizes	
j	Pasteur pipettes	
k	Glass slides	
l	Test tubs of various sizes/ microplates	
m	Precipitating tubes (6x50 mm) of various sizes	
n	Test tube racks	
o	Interval timer	
p	Material and equipment for glassware cleaning	
q	Blood transporting containers	
r	Wash bottles	
s	Filter papers	
t	Dielectric tube sealer	
u	Plain and EDTA vials	
v	Chemical balance	
w	Elisa reader with printer, washer and micro-pipettes	
x	Colorimeters / haemoglobinometer (strike off which is not applicable) for haemoglobin determination.	

O	**Records and Reports**		
			Comments on records, if any
a	Blood Stock/master Register	Yes / No / NA	
b	Blood donor record	Yes / No / NA	
c	Issue register	Yes / No / NA	
d	Record of Blood bags	Yes / No / NA	
e	Cross matching records	Yes / No / NA	
f	Register of diagnostic reagents and kits	Yes / No / NA	
g	Adverse reaction records	Yes / No / NA	
h	Stock register of other consumable articles	Yes / No / NA	
i	Are records destroyed?	Yes / No / NA	
j	Labels of Blood containers as per Schedule F of the d & C act	Yes / No / NA	
P	**Outdoor camps**		
a	Eligible to hold outdoor camps	Yes / No / NA	
b	Average number of camps held per month	Yes / No / NA	
c	Vehicle available?	Yes / No / NA	
d	How are blood bags transported	Yes / No / NA	
f	Proof sanitary conditions of camps	Yes / No / NA	
g	Detailed statement of blood collected in camps	Yes / No / NA	

PROCESSING OF BLOOD COMPONENTS FROM WHOLE BLOOD.

Q.	ACCOMMODATION/ PREMISES		COMMENTS
1.	Area provided for component preparation.		
2.	Does an additional 10-sq. meter area provided for aphaeresis procedures .	**YES/NO/NA**	
(a)	Is Blood component room Air-conditioned?	**YES/NO/NA**	
(b)	Is Blood component room well lighted?	**YES/NO/NA**	
(c)	Are walls and floors are smooth & washable?	**YES/NO/NA**	
(d)	Is overall hygienic conditions maintained in the premises.	**YES/NO/NA**	
(h)	Comments on Area		

R	PERSONNEL Whether Technical Supervisor with adequate basic qualification and experience is available with the blood bank.	**YES/NO**	**Comments**
	Name, Qualifications & Experience		

S1	**Equipment** **(As per GSR 245(E)** **dt.05.08.99)**		**Make/Model/** **Capacity**
(i)	Air Conditioner.	YES/NO/NA	
(ii)	Laminar air flow bench.	YES/NO/NA	

(iii)	Suitable refrigerated centrifuge.	YES/NO/NA	
(iv)	Plasma expresser	YES/NO/NA	
(v)	Clipper and clips and or dielectric sealer.	YES/NO/NA	
(vi)	Weighing device.	YES/NO/NA	
(vii)	Dry rubber balancing material.	YES/NO/NA	
(viii)	Artery forceps, scissors.	YES/NO/NA	
(ix)	Refrigerator maintaining a temperature between 2 degree centigrade to 6 degree centigrade, a digital dial thermometer with recording thermograph and alarm device, with provision for continuous power supply.	YES/NO/NA	
(x)	Platelet agitator with incubator (wherever necessary)	**YES/NO/NA**	
(xi)	Deep freezers maintaining a temperature between minus 30 degree centigrade to minus 40	YES/NO/NA	

	degree centigrade and minus 75 degree centigrade to minus 80 degree centigrade.		
(xii)	Refrigerated water bath for plasma Thawing.	YES/NO/NA	
(xiii)	Insulated blood bag containers with provisions for storing at appropriate temperature for transport purposes.	YES/NO/NA	
(xiv)	Whether components are prepared only in a closed system using single double triple or quadruple plastic bags.	YES/NO/NA	
S2	**EQIPMENT (GMP)**		**COMMENTS**
1.	Are equipment located in logical sequence and permit effective cleaning?	YES/NO/NA	
2.	Are equipment calibrated/validated periodically?	YES/NO/NA	

T	**PREPARATION OF BLOOD COMPONENTS.**		
1.	**Concentrated Human RBC's** **(Packed Red Blood Cells)**		**COMMENTS**
a	**Whether SOP is available for preparation of PRC?** ***Specify: Source material*** Method RCF Speed Time	**YES/NO/NA**	
b	**Is blood collected from suitable donor?** **(check the donor record).**	**YES/NO/NA**	
c	**Are the packed red cells confirmed to the standard of I.P.1996**	YES/NO/NA	
d	**How the Pilot tubes / samples are numbered?**	YES/NO/NA	
e	**Whether pilot tube is attached in a tamper proof manner to the unit?**	YES/NO/NA	
f	**Who is responsible for filling of pilot samples?**	YES/NO/NA	
g	**Whether pilot samples are filled immediately after** **the blood is collected or at the time the final product** **is prepared?**	YES/NO/NA	
h	**Whether expiry is assigned as per norms?** **(specify the period)**	YES/NO/NA	
2	Platelets concentrates		COMMENTS

a	**Whether SOP is available for preparation of Platelets concentrates?** ***Specify: Source material*** Method RCF Speed **Time**	YES/NO/NA	
b	**Whether the whole Blood / source material is stored at 20 degree to 24 degree centigrade after collection, before processing to platelet concentrates?**	YES/NO/NA	
c	**Whether Platelet Concentrates are separated within 6 hours after the time of collection whole blood /source material**	**YES/NO/NA**	
d	**Whether platelet concentrates are tested: Platelet count (Note the count)** **pH (not less then 6)** **measurement of Plasma volume** **sterility (1% of total platelets prepared shall be tested for sterility, 'functional viability'** **(swirling movement)**	**YES/NO/NA**	
e	**Whether compatibility test prepared on every unit before issue**	**YES/NO/NA**	

f	**Whether platelet yield is calculated (1% of total platelets prepared shall be tested of which 75% of units shall confirm to standards)**	**YES/NO/NA**	
3.	FRESS FROZEN PLASMA		COMMENTS
a	**Whether SOP is available for preparation of FFP?** ***Specify: Source material*** Method RCF Speed **Time**	**YES/NO/NA**	
b	**Whether deep freezers capable of maintaining temp between 75^{0}c to 80^{0}c and minus 30^{0} c to** **minus 40^{0} c are available**	YES/NO/NA	
c	**Whether the source material/human blood stored at 4^{0} c till processed**	YES/NO/NA	
d	**Whether thawing facilities are provided (note the thawing temperature)**	YES/NO/NA	

e	**Lag time between collecting of blood and processing of FFP (check records)**	YES/NO/NA	
4.	CRYOPRECIPITATE		COMMENTS
a	**Whether SOP is available for preparation of CRYOPRECIPITATE?** ***Specify: Source material*** Method ***RCF*** Speed **Time**	**YES/NO/NA**	
b	**Whether thawing facilities are available (note the temperature)**	YES/NO/NA	
c	**Whether anti-hemophiliac factor activity is tested. (NLT 80 units/bag), (1% of total cryo prepared shall be tested of which 75% shall conform to specification)**	YES/NO/NA	
5.	APHERESIS PROCEDURE		*COMMENTS*
a	**Whether cell separator facility is provided?**	YES/NO/NA	
b	**Whether donor is certified fit for apheresis (check the record)**	YES/NO/NA	
c	**Time allowed between successive aphaeresis on a single donor**	YES/NO/NA	

d	**Whether protein estimation of donor carried out if serial apheresis is to be conducted.**	YES/NO/NA	
e	**Whether inquiries about aspirin intake made before platelet apheresis.**	YES/NO/NA	
f	**Whether RBC's are re- transfused during platelet apheresis or leucopheresis. If not, what precautions are taken.**	YES/NO/NA	
g	**Whether following tests are carried out before apheresis procedures** Name of the test Acceptance criteria		
	(i) Hemoglobin/Hea matocrit **(ii) Platelet count** **(iii) WBC count** **(iv) Differential count** **(v) Serum protein**		**COMMENTS**
h	How much quantity of plasma is to be collected (Plasma apheresis)		
	DURATION (I) single sitting (II) Per months	LIMIT Not exceeding 500 ml./1 sitting Not exceeding 1000 ml./1 months)	***COMMENTS***

U	STORAGE OF BLOOD COMPONENTS		
S.No.	BLOOD COMPONENT	**TEMPERATIRE**	**DURATION/EXPIRY PERIOD**
1.	**FFP**		
2.	**Cryoprecipitate**		
3.	**Platelets concentrate**		
4.	**Red Cell concentrate**		
5.	**Granulocytes concentrate**		
V	**RECORDS AND LABELS**		**COMMENTS**
1.	Whether details of quantity supplied, compatibility report, details of receipts and signature of issuing person mentioned in the component record.	**YES/NO/NA**	
2.	Whether master record for component and issue register is mentioned as per norms (GSR 245 E dated 05.04.1999)	**YES/NO/NA**	
3.	Whether labels for components are prepared as per norms (GSR 245 E dated 05.04.1999)	**YES/NO/NA**	
4.	Whether all details on labels are filled by the responsible person on the final container	**YES/NO/NA**	

Observations, irregularities and Recommendations
Signature and Designations of Inspecting Persons

Name of Technical Personnel to be Endorsed on the Licence Copy:-

Personnel	Name	Qualification	Experience	Testimonials
Medical Officer In-Charge(s)				
Registered Nurse (s)				
Blood Bank Technician(s)				
Technical Supervisor(s)				

Sign of Inspection Team Members