Manual of Standards for Blood Service Facilities

Published in the Philippines by the Department of Health - National Voluntary Blood Services Program (DOH-NVBSP) with support from the Global Fund Round 6 HIV Project

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Foreword

It is a known fact that blood is vital for humans to survive. Crucial as it is, the demand for human blood has always been greater than the supply available in blood service facilities. Apart from the fact that the increasing blood supply failed to meet the demand, blood transmissible infectious diseases and blood transfusion adverse reactions have been growing over the years as well. In addition, other factors such as improper handling and storage cause the limited supply of blood to go to waste.

With the vision of providing SAFE BLOOD FOR ALL, the National Voluntary Blood Services Program (NVBSP) has aimed on achieving its vision and mission by giving the highest priority on health of Voluntary Non-Remunerated Blood Donors (VNRBD), patients, laboratory personnel and the community; achieving and maintaining a 100% voluntary blood donation; executing safe, reliable and cost-effective processing of blood; and creating a work environment that promotes integrity, caring for people and teamwork.

To set standards and define principles for professional practice for safe and effective blood banking and blood transfusion that will help the NVBSP see the vision and accomplish its mission. The Standards for Blood Service Facilities in the Philippines was updated and revised by the Department of Health (DOH), in collaboration with Global Fund Round 6-HIV Project (GFR6), Philippine Blood Coordinating Council (PBCC), Philippine Blood Center (PBC) and the Philippine Red Cross (PRC), representatives from the different specialty societies and various partner agencies.

May this manual serve as an instrument of change that will convey an improved blood banking service for the betterment of the Filipino and other stakeholders.

ENRIQUE T. ONA, MD
Secretary of Health

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INTRODUCTION

The Manual of Standards for Blood Service Facilities is patterned after the current and acceptable international standards that can be applied locally and put into actual practice. This will promote quality and competence among the blood transfusion service personnel, and will ensure adequate supply of safe blood.

Standards are classified into:

1. Mandatory: These are requirements for licensing. Each describes the single acceptable activity or method. Failure to meet the specified requirement will constitute a deficiency and will serve as a reason for a license not to be granted. The word **"shall"** is used to signal these mandatory requirements. These are in bold print for emphasis.

2. Recommended: These are standards which have several acceptable alternatives or range of acceptable values. These are indicated by the word "may".

All existing standards issued by the Department of Health regarding blood banking, blood transfusion, blood donor selection and counseling, etc., were reviewed and utilized as references for this new edition.

Section II

General Instructions

Section 1
General Principles

1.1 All Blood Service Facilities (BSF) **shall** place highest priority on the health and safety of Voluntary Non-Remunerated Blood Donors (VNRBD), patients, personnel and the community.

1.2 All BSFs **shall** achieve and maintain 100% voluntary blood donation.

1.3 Inspection and licensing **shall** take into account the capability and commitment of the BSF to continuously improve the safety and quality of its services and products.

1.4 Every person involved in every aspect of the blood service – from advocacy to blood product processing and transfusion of blood - **shall** be responsible for the quality of his/ her work.

1.5 All BSFs **shall** endeavor to gain and sustain the public confidence, support and commitment through consistent high quality services and products.

1.6 All BSFs **shall** mutually support and assist each other to attain and maintain these Standards. These Standards **shall** be regarded as performance goals to be attained and maintained by each BSF.

Section 2

Quality System Requirements

Section 2
Quality System Requirements

2.1 Quality Policies, Guidelines and Objectives

2.1.1 Policies and Guidelines

There **shall** be a series of related or tiered documents, consistent with each other, describing the systems in each BSF, each tier becoming progressively more detailed. These documents **shall** cover essential policies, guidelines, procedures and specific work instructions, forms and records.

2.1.2 Defining Organizational Objectives

The management of each BSF **shall** define organizational objectives pertaining to good manufacturing practices, quality services and blood products and legal requirements. These **shall** indicate how the Standards herein can be complied with.

2.1.3 Administrative Procedures

A Quality System Manual which puts together the policies, job delineation, task delegation and coordination including the flow of authority and responsibility **shall** be required at each BSF.

2.2 Organization

2.2.1 Classification of Blood Service Facility

2.2.1.1. Ownership

2.2.1.1.1 Government – operated and maintained partially or wholly by a national, provincial, city or municipal government or other political unit, by any department, division, board or agency thereof or by a government owned or controlled corporation.

2.2.1.1.2 Private – privately owned established and operated with funds through donation, capital or other means, by an individual, corporation, association or organization.

2.2.1.2 Institutional Character

2.2.1.2.1 Hospital-based – a BSF located within the premises of the hospital.

2.2.1.2.2 Non-hospital-based – a government-owned or Philippine Red Cross (PRC)-owned BSF located outside the premises of a hospital consistent with the National Voluntary Blood Services Program (NVBSP) Strategic Plan.

2.2.1.3 Service Capability

2.2.1.3.1 Blood Station (BS)

a) Advocacy and promotion of voluntary blood donation and healthy lifestyle;
b) Provision of whole blood and packed red cells;
c) Storage, issuance, transport and distribution of whole blood and packed red blood cells;
d) Compatibility testing of red cell units, if hospital-based.

2.2.1.3.2 Blood Collection Unit (BCU)

a) Advocacy and promotion of voluntary blood donation and healthy lifestyle;
b) Recruitment, retention and care of VNRBD;
c) Screening and selection of VNRBD;
d) Conduct of health education and counseling services;
e) Collection of blood (mobile or facility-based) from qualified VNRBD;
f) Transport of blood to Blood Center (BC) for testing and processing.

2.2.1.3.3 Blood Collection Unit/ Blood Station – all services stipulated under BCU and BS.

2.2.1.3.4 Blood Bank (BB)

a) Advocacy and promotion of voluntary blood donation and healthy lifestyle;

b) Storage and issuance of whole blood and blood components obtained from a BC;

c) The following services **shall** also be provided:
   i. Compatibility testing of red cell units;
   ii. Direct Coombs test;
   iii. Red cell antibody screening;
   iv. Investigation of transfusion reactions;

v. Assist the Hospital Blood Transfusion Committee (HBTC) in the conduct of post-transfusion surveillance (hemovigilance).

d. Hospital Blood Banks (Level 3 & 4): the following services may be provided:
   i. Recruitment, retention and care of VNRBD;
   ii. Collection of blood (mobile or facility based) from qualified VNRBD;
   iii. Conduct health education and counseling;
   iv. Testing of units of blood for Transfusion Transmitted Infections (TTIs);
   v. Processing and provision of Whole Blood andblood components.

2.2.1.3.5 Blood Center (BC)
   a) Advocacy and promotion of voluntary blood donation and healthy lifestyle;
   b) Recruitment, retention and care of VNRBD;
   c) Collection of blood (mobile or facility-based) from qualified VNRBD;
   d) Conduct health education and counseling;
   e) Testing of units of blood for Transfusion Transmitted Infections (TTIs);
   f) Processing and provision of WB and blood components;
   g) Storage, issuance, transport and distribution of units of whole blood (WB) and/or blood component to hospitals and other health facilities.

2.3 Technical Procedure Manual (TPM)

Each BSF staff **shall** develop and maintain clear, well-documented, updated and detailed Standard Operating Procedure (SOP) to cover all activities performed within the BSF and whenever applicable activities outside the BSF like in a mobile collection site.

2.3.1 Accessibility and Use of TPM

The TPM **shall** be made available to all staff within their easy reach. All BSF staff **shall** have read and understood all the procedures and shall thereafter sign the document review form.

2.3.2 Control of Copies and Revisions

The TPM **shall** be legibly printed, neatly filed, signed and dated by the authorized BSF Head. Document numbers **shall** be assigned to facilitate cross-references and review.

The TPM **shall** be regularly reviewed and updated at least once a year and initialed by the reviewer. Such review, updates and changes with involvement of the whole staff **shall** be well-documented, approved and signed by the BSF Head.

Master copies of obsolete TPM **shall** be archived in a secure area and made readily available for reference or verification whenever necessary.

2.4 Quality Control, Quality Assessment and Quality Audit

Quality Control refers to the evaluation and monitoring of the technical aspects of the laboratory, such as the reagents, equipment and the performance of the laboratory personnel. Internal Quality Control (IQC) utilizes the running of control samples together with the blood specimens to monitor the performance of and the inputs into the laboratory procedure.

Quality Assessment is a generic term in which an inspection or survey is carried out to verify if an institution complies with a set of standards. However, External Quality Assessment in the laboratory field has a special context as this refers to the performance of laboratory examinations by clinical laboratories on samples distributed by an External Quality Assessment Schemes (EQAS) provider. The results from the laboratories are statistically analyzed to determine the quality of performance (Standard Deviation Index –SDI, Coefficient of Variation –COV) of the participating laboratories.

Quality Audit is a form of Quality Assessment. Assessment through document review, observations and interview is conducted to determine if the standards selected have been complied with. Different types of Quality Audit include Internal Quality Audit, Second Party Audit, and External Third Party Audit.

2.4.1 Quality Control of Equipment and Materials

2.4.1.1 All equipment **shall** be carefully examined for quality and performance and shall be standardized. Equipment **shall** be regularly checked, calibrated and maintained. (Refer to Section 4)

2.4.1.2 All materials **shall** be examined for physical defects and evidence of contamination or deterioration.

2.4.1.3 Reagents **shall** be tested for quality before acceptance or use.

2.4.1.4 Use of control tests **shall** be routinely performed.

2.4.1.5 Records of internal quality control **shall** be maintained. Documentation of the above, refer to Section 9 (Quality Records)

2.4.2 Process Control

Reliability of a testing method is assured only by using dependable and verified materials required for the method, by following exactly the specific and previously defined and validated manufacturing procedures for test kits and by following the accepted standard technical procedures.

A system **shall** be established to detect and document any deviation from normal processes and procedures. This **shall** include the action and corrective action instituted.

2.4.3 Change Control

Any proposed changes on the product, systems and processes or procedures **shall** be clearly identified, documented, justified, reviewed and approved before these are implemented. The revisions **shall** also be systematically instituted and disseminated to concerned staff.

2.4.4 Audits

Audits **shall** be performed by trained personnel who do not have direct responsibilities for the procedures being audited.

2.4.4.1 Internal Audit – Internal auditing **shall** be done by designated **auditors**

2.4.4.2 External Audit – External auditing **shall** be done by the **DOH designated auditing body**.

All BSF **shall** establish an internal quality control program and **shall** participate in an External Quality Assessment Schemes (EQAS) instituted by DOH designated National Reference Laboratories (NRLs).

The BSF **shall** document and record all the results of quality assessment program audits and execute corrective and preventive actions on deficiencies identified.

2.5 Quality Record

Each BSF **shall** have procedures to maintain all records related to all the activities within the BSF. These records are stated and elaborated in Section 9 (Quality Records). Personnel **shall** not be permitted to sign **or initial a document requiring signatures unless they have been trained in the task and in the significance of the signature**. A Registry of signatories with their signatures and initials **shall** be maintained.

Section 3

The Blood Products

Section 3
The Blood Products

Only dependable and acceptable materials (supplies and equipments) **shall** be used in the preparation and processing of blood products. This starts with the collection of blood from qualified, healthy VNRBD.

Table 3.1 Blood Product Specifications

Cellular Blood Products	Description*	Volume *	Quality* Requirements	Storage and Expiration
Whole Blood (WB)	Unprocessed blood containing all cellular and plasma components of donor blood	450ml ± 45ml (in 63ml anticoagulant solution)	Hemoglobin: minimum 45g/ unit Hematocrit: 0.35 – 0.45 Potassium: <27mmol/ L Plasma hemoglobin: <0.04g/ dL pH: >6.5 Sterility: no growth	+2°C to +6°C CPD: 21 days CPDA-1:35 days (with Additive solution: 42 days) Irradiated: 28 days from irradiation or original expiration whichever comes first
Packed Red Blood Cells (PRBC)	Component obtained by removal of most of plasma from WB by sedimentation or centrifugation without further processing	280ml ± 50ml	Hemoglobin: minimum 45g/ unit Hematocrit: 0.65 – 0.75 Potassium: <78mmol/ L Plasma hemoglobin: 0.65g/ dL pH: >6.5 Sterility: no growth	+2°C to +6°C CPD: 21 days CPDA-1:35 days (with Additive solution: 42 days) Open system: 24 hours.Irradiated: 28 days from irradiation or original expiration whichever comes first
Buffy Coat Poor Red Cells (BCP – PRBC)	A component prepared by the separation of plasma and buffy coat from the red	250ml ± 50ml	Hemoglobin: minimum 43g/ unit Hematocrit: 0.65 – 0.75 Potassium: <78 mmol/L	+2°C to +6°C CPD: 21 days CPDA-1:35 days

Cellular Blood Products	Description*	Volume *	Quality* Requirements	Storage and Expiration
	cells. Buffy coat removal decreases formation of microaggregates		Plasma Hemoglobin: <0.65g/ dL Leucocyte/ unit:1.2 x 10^9 pH: >6.5 Sterility: no growth	(with Additive solution: 42 days)
Washed Red Cells	A red cell suspension prepared by removal of plasma by centrifugation with subsequent washing of red cells with pre-cold Normal Saline Solution (NSS)	250ml ± 50ml	Hemoglobin: minimum 40g/ unit Hematocrit: 0.65 – 0.75 Protein content: <0.5g/unit	+2°C to +6°C Usem within 6 hours after washing
Leukocyte-reduced PRBC	Red cell preparation where majority of leukocytes are removed. Pre-storage filtration, preferably within 48 hours after donation, is recommended.	270ml ± 50ml	Hemoglobin: minimum 40g/ unit Hematocrit: 0.50 – 0.70 Residual leukocytes: <1.0 x 10^6 per unit by count	+2°C to +6° C CPD: 21 days CPDA-1:35 days (with Additive solution: 42 days) Open system: 24 hours
Fresh Frozen Plasma (FFP)	The non-cellular fluid portion of anti-coagulated blood which has been extracted from a single donor unit within 6 hours post-collection and	200ml ± 50ml	Factor VIIIc level: >70 IU/ 100ml Residual red cells:<6.0 x 10^9/ L; leukocytes: 0.1 x 10^9/ L; platelets: <50 x 10^9/ L	-20°C to -65°C varies from 4 months to 7 years depending on storage temperature (refer to Table 3.2)

Cellular Blood Products	Description*	Volume *	Quality* Requirements	Storage and Expiration
	rapidly frozen to 30°C or colder.		No leakage, No abnormal color or visible clots	
Cryoprecipitate (Cryo)	Component that contains the cryoglobulin fraction of plasma obtained by further processing of FFP prepared from hard-spun cell free plasma	≤15ml	Factor VIIIc: >70 IU per unit Fibrinogen: > 140 mg per unit Von Willebrand Factor: >100 IU per unit	-20°C to -65°C varies from 4 months to 7 years depending on storage temperature (refer to Table 3.2)
Platelet Concentrate (PC) or Random Donor Platelets (RDP)	Platelets suspended in a small quantity of plasma prepared by centrifugation of WB within 6 hours post-collection before refrigeration	60ml ± 10ml	Platelet Count: At least $5.5x10^{10}$ platelets single unit equivalent Residual leukocytes before depletion:a) from PRP: <0.2 x 10^9/ single unit equivalent) from buffy coat: <0.05 x 10^9/ single unit equivalent pH: 6.4	+20°C to +24°C in continuous agitation (Shelf life: 3-5 days; 5 days if using platelet incubator)
Cryosupernate	A component that is prepared from plasma from which cryoprecipitate has been removed. Its content of albumin, immunoglobulins	190ml – 210ml		

Cellular Blood Products	Description*	Volume *	Quality* Requirements	Storage and Expiration
	and coagulation factors, except that of Factors V and VIII, is the same as FFP.			
Platelet Pheresis Product or Apheresis Platelets or Single Donor Platelets (SDP)	Platelets suspended in a small quantity of plasma prepared by automated instrumentation	250ml to 300ml	Platelet Count: At least $3.0x10^{11}$ platelets single unit equivalent: Residual leukocytes <0.12 x 10^9/ single unit equivalent pH: 6.4 – 7.4	+20°C to +24°C in continuous agitation (Shelf life: 3-5 days; 5 days if using platelet incubator)
Fresh Frozen Plasma (FFP), Pheresis derived	The non-cellular fluid portion of anti-coagulated blood which has been extracted from a single donor unit within 6 hours post-collection and rapidly frozen to 30°C or colder.	200ml ± 50ml	Factor VIIIc level: >70 IU/ 100ml Residual red cells: <6.0 x 10^9/ L; leukocytes: 0.1 x 10^9/ L; platelets: <50 x 10^9/L No leakage, No abnormal color or visible dots	-20°C to -65°C varies from 4 months to 7 years depending on storage temperature (refer to Table 3.2)
Red Blood Cell Pheresis Product or Apheresis Red Blood Cells	Red blood cells suspended in a small quantity of plasma prepared by automated instrumentation.	280ml ± 50ml	Hemoglobin: minimum 45g/ unit Hematocrit: 0.85, Residual leukocytes <0.12 x 10^9/ single unit equivalent Potassium: <78mmol/ L Plasma hemoglobin:	+2°C to +6°C CPD: 21 days CPDA-1: 35 days (with Additive solution: 42 days) irradiated: 28 days from irradiation or original expiration which ever comes first.

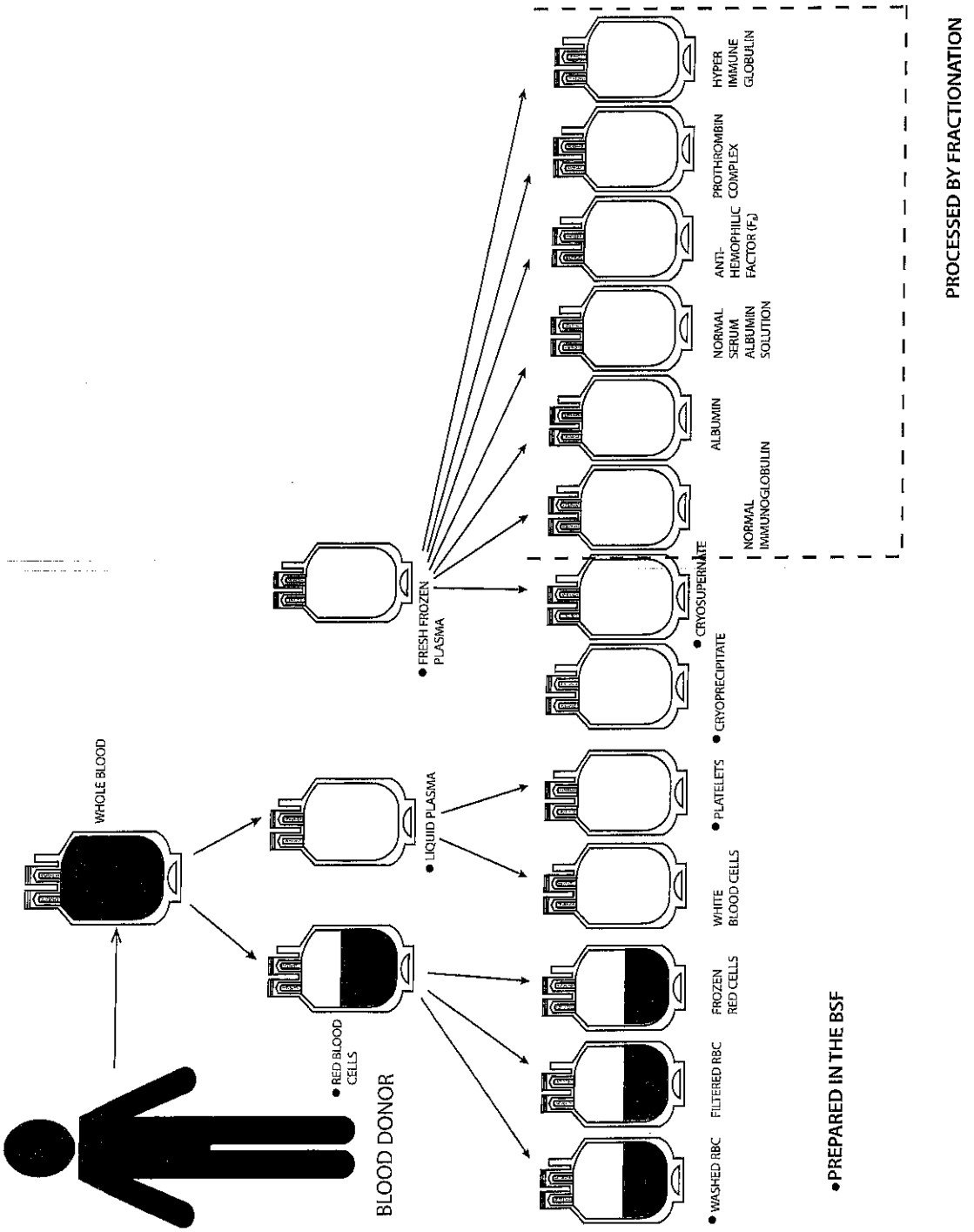
Cellular Blood Products	Description*	Volume *	Quality* Requirements	Storage and Expiration
			0.65g/ dL, pH: >6.5, Sterility: no growth	
Granulocyte Concentrate, Granulocyte Pheresis Product or Apheresis Ganulocyte	Granulocyte collected through an automated instrumentation	Variable volume depending on the harvested product	Variable quantities ranging from 55 to 300x10 leukocytes	+20°C to +24°C in continuous agitation until immediate transfusion. Maybe be subjected to irradiation

From: 1) Guide to the Preparation, Use and Quality Assurance of Blood Components – 12th edition Council of Europe
2) Standards for Blood Bank and Transfusion Services – 24th edition American Association of Blood Banks
3) Quality Procedure (2001) – National Blood Center of Malaysia (Kuala Lumpur)

Table 3.2
Maximum storage time of Frozen Plasma Products According to Storage Temperature

Product	Storage temperature	Maximum storage time
FFP	-65°C or below	7 years
FFP or Cryoprecipitate	-40 °C to -64 °C	24 months
FFP or Cryoprecipitate	-30 °C to -39 °C	12 months
FFP or Cryoprecipitate	-25 °C to -29 °C	6 months
FFP or Cryoprecipitate	-20 °C to -24°C	3 months

3.2 Diagrammatic Description of Blood Component



3.3 Special Blood Product

3.3.1 Irradiated Blood Products

Irradiation utilizes gamma radiation to inactivate all potentially proliferative cells (T lymphocytes) in WB, PRBC and PC in order to prevent Transfusion-Associated Graft versus Host Disease (TA-GVHD). These are subjected to Cobalt 60 or Cesium 137 isotopes using a licensed blood irradiator. Dosage of irradiation 25gy.

Section 4

The Physical Plant: Equipment and Materials

Section 4
The Physical Plant, Equipment and Materials

Building and Facilities

Buildings and facilities **shall** be located, designed, constructed and utilized so as to ensure both quality and safety of blood products and services as well as the safety and comfort of VNRBD and personnel.

4.1 Building Design and Maintenance

Buildings **shall** be designed, constructed and maintained so as to protect against the effects of weather, ground seepage, flooding, fire, and the entry of vermin, insects, pests and stray animals.

4.2 Restriction of Entry of Unauthorized Person

Selected rooms **shall** be secured against entry of unauthorized persons.

4.3 Construction Materials and Work Surfaces

Construction materials **shall** be sturdy and resistant to strong and abrasive cleaning agents. Concrete materials **shall** be used for construction and support.

Building materials in the processing areas **shall** be free from cracks or open joints and **shall** be non-porous.

Floors **shall** be non-slip and easy to clean. Work areas **shall** have coated surfaces resistant to chipping.

4.4 Clear Demarcation and Smooth Flow of Work and Activities

The physical arrangement **shall** allow for the smooth and orderly flow of activities and movement of people and supplies.

Work areas for blood donor selection and screening, collection, testing, processing, validation, packaging, issuance or transport and special procedures like apheresis when applicable, **shall** be separated and well-demarcated.

4.5 Adequacy of Space

The BSF **shall** provide adequate space for the different activities applicable to the services provided:

4.5.1 VNRBD Reception and Refreshment Areas

This shall be equipped with comfortable waiting facilities as well as clean and convenient hand washing and toilet facilities with adequate water supply. Educational and promotional materials on blood donation and other interesting health issues **shall** be available. Audio-visual facilities are encouraged.

4.5.2 VNRBD Assessment Area

The assessment area **shall** provide auditory and visual privacy to assure confidentiality of VNRBD -related information. This will also promote accuracy of medical and social history.

4.5.3 Hemoglobin Determination Area

The area for hemoglobin determination **shall** be clean and organized to avoid errors and mislabeling.

4.5.4 Blood Collection, Testing and Processing Areas

These areas shall be suitable, adequate and appropriately equipped and organized to ensure minimal risk of contamination and errors.

4.5.5 Areas for Packaging, Validation, Labeling and Other Documentation Operations

There shall be a space for counterchecking, validating, packaging, computer work, and other documentation operations.

4.6 Storage

Storage areas **shall** provide adequate space, suitable lighting, easy access and organized to allow dry, clean and orderly placement of stored material under controlled temperature conditions.

4.6.1 Blood Products

There shall be clear demarcation of stored blood products under controlled temperature required for each type of products. Cold rooms **shall** be encouraged in large blood centers.

4.6.2 Reagents and Other Supplies and Materials

There **shall** be temperature-controlled storage areas for reagents and adequate dry areas for other materials and supplies.

4.6.3 Records, SOP Manuals and References

Records, manuals and references **shall** be orderly arranged in a readily accessible area.

4.7 Lighting and Ventilation

There **shall** be adequate lighting and ventilation in all work areas.

4.8 Safety and Cleanliness

4.8.1 Eating, Drinking and Smoking

Eating, drinking and smoking **shall** not be permitted in any area where activities might adversely influence product quality or where staff may be exposed to potentially harmful agents. There **shall** be areas designated for eating, drinking and rest of personnel.

4.8.2 Toilet and Washing Facilities and Lockers for Personnel

There **shall** be adequate, clean and convenient handwashing and toilet facilities with adequate water for personnel. Secure lockers **shall** also be provided.

4.8.3 Doors and Fire Exits

Access to temperature-controlled rooms and areas shall be from corridors and other processing areas. Where internal doors are a barrier to avoid contamination, they **shall** be kept closed when not in use.

There **shall** be accessible and clearly demarcated Fire Exits.

Doors that lead from processing areas directly to the outside, e.g. fire exits, **shall** be secured in such a way that they may be used only as emergency exits.

4.8.4 Daily Cleaning Maintenance

Floors shall be cleaned daily with appropriate cleansing agent. When grossly contaminated, walls **shall** be cleaned and decomtaminated regularly. Work areas **shall** be neat and tidy at all times.

4.8.5 Drains

Drains shall be of adequate size and, where connected directly to a sewer, **shall** be equipped with traps to prevent back-siphoning.

4.8.6 Pest Control

Where pest control is needed, as in the case of storage of papers and records, it **shall** be carried out in such a way as to ensure that the chemicals used do not contaminate BSF materials.

4.9 Equipment

Equipment which is technically suitable, properly located, easy to clean, and well maintained is essential for accurate testing, prevention of contamination and ensuring the quality of the blood products.

4.9.1 Appropriate and Adequate Equipment

4.9.1.1 Recommended Equipment, Furniture and Instruments

Each BSF **shall** have appropriate and adequate equipment, furniture and instruments for blood bank and transfusion service. The quantity of equipment needed depends on the number of blood units collected and processed, the methods used, and the existing infrastructure. In situations where there are no back-up equipment, a contingency plan **shall** be in place.

4.9.1.2 Procurement Plan and Specifications of Basic Equipment

A comprehensive equipment procurement plan shall be prepared by each BSF with consideration as to specifications and quality of equipment to be procured.

There **shall** be provisions for training of staff on new equipment and service maintenance agreements **shall** be required when procuring equipment.

4.9.1.3 Quality of Equipment and Instruments

Equipment shall meet the approved requirement set by the Food and Drugs Administration (FDA) - Bureau of Health Devices and Technology (BHDT) or Department of Trade and Industry (DTI).

New equipment shall be capable of achieving the performance required and comply with specifications relevant to the examinations and procedures concerned.

4.9.1.4 Proper Use of Equipment

Equipment Operational Manual shall be available to all staff at all times. Equipment shall be operated only by authorized and properly trained personnel.

4.9.1.5 Equipment Maintenance and Calibration

All equipment shall be regularly monitored, calibrated and properly maintained with proper documentation.

Please refer to table 4.9.1.5.

Table 4.9.1.5
Calibration and Preventive Maintenance of Equipment

I. Refrigirators/ Freezers/ Platelate Incubators	
A. Refrigirators	
1. Recorder	Daily
2. Manual temperature	Daily
3. Alarm system board (if applicable)	Daily
4. Temperature charts (rewiew daily)	Weekly
5. Alarm activation	Quarterly
B. Freezers	
1. Recorder	Daily
2. Manual Temperature	Daily
3. Alarm system board (if applicable)	Daily
4. Temperature charts (rewiew daily)	Weekly
5. Alarm activation	Quarterly
C. Platelate Incubators	
1. Recorder	Daily
2. Manual Temperature	Daily
3. Temperature charts (rewiew daily)	Weekly
4. Alarm activation	Quarterly
D. Ambient platelate storage area	Every 4 hours
II. Laboratory Equipment	
A. Centrifuges/ cell washers	
1. Speed	Quarterly
2. Timer	Quarterly
3. Funtion	Yearly
4. Tube fill level (serologic)	Day of use
5. Saline fill volume (serologic)	Weekly
6. Volume of antihuman globulin dispensed (if applicable)	Monthly
7. Temperature check (refrigirated centrifuge)	Day of use
6. Temperature verification (refrigirated centrifuge)	Monthly
B. Heating blocks/ Waterbaths/ View boxes	
1. Temperature	Day of use
2. Quadrant/ area checks	Periodically
C. Component thawing devices	Day of use
D. pH meters	Day of use
E. Blood indicators	
1. Calibration	Yearly
2. Turntable (visual each time of use)	Yearly
3. Timer	Monthly/ Quarterly
4. Source of decay	Dependent on source type
5. Leak test	Twice yearly
6. Dose delivery check (with indicator	Each indicator use
7. Dose verification system	
a. Cesium-137	Yearly
b. Cobalt-60	Twice yearly
c. Other source	As specified by manufacturer

Each item of equipment **shall** be labeled with the following details:

1. Identity of the equipment
2. Serial Number
3. Manufacturer's name
4. Dates of acquisition and installation
5. Location of the equipment
6. Inventory number (optional)
7. Company service engineer contact number

4.9.1.6 Temperature Monitoring and Alarm Systems

All blood storage equipment and room temperature **shall** be monitored and recorded every four (4) hours or at least every eight (8) hours. Temperature monitoring charts **shall** be posted strategically. Monitoring chart **shall** be reviewed and validated every end of the month by the Quality Officer or the Blood Bank Head.

All blood storage equipment **shall** be equipped with a system for continuous temperature monitoring and an audible alarm in the event that storage temperature goes out-of-range. The alarm **shall** be set at temperature that will allow proper action to be taken before the blood product reaches undesirable temperatures. Authorized personnel **shall** reset the alarm.

4.9.1.7 Thrawer for Frozen Components

Warming devices such as plasma thawers shall be equipped with a temperature sensing device and a warning system to detect malfunctions. Depending on the frequency of use, the plasma thawer **shall** be tested for bacterial contamination at least once a month.

4.9.1.8 Equipment Malfunction

Equipment found to be defective shall be taken out of service, properly labeled and appropriately stored until it has been repaired and re-calibrated to meet specified acceptance criteria.

BSF shall follow prescribed protocols in case of equipment malfunction.

4.9.1.9 Computer System

a. All BSF **shall** subscribe to the integrated blood bank information system (National Blood Bank Network System or NBBNetS) to manage data on VNRBD, collection, processing, testing, storage, dispensing and generating reports. If the information system is unavailable in the area, the process flow **shall** be consistent with that of the NBBNetS.
b. Data security and integrity **shall** be ensured at all times.
c. Data backup mechanism and co-location of database **shall** be in place.
d. Computer hardware and peripherals **shall** conform to the prescribed specification set by the information system provider.
e. Computer software, including that bundled with the hardware **shall** have valid and updated license.

4.9.1.10 Record Keeping

Each BSF **shall** maintain a Master list of Equipment and Calibration schedule for each unit. Preventive Maintenance and Service reports **shall** also be maintained. ***Refer to Table under 6.5.1.5***

Documented reports of corrective maintenance done in defective equipment **shall** be kept.

These records shall be maintained and shall be readily available for the equipment's lifespan or as required by DOH local or international accrediting body.

4.10 Reagents and Supplies

All BSFs **shall** ensure the provision of adequate and suitable reagents and supplies for the preparation and testing of blood. All BSFs **shall** have enough reagents and supplies for testing.

4.10.1 Quality of Reagents and Supplies

4.10.1.1 BSF **shall** only procure reagents, blood bags and other supplies registered with FDA- Philippines and evaluated by the NRL.

4.10.1.2 Any product such as reagents, blood bags and other supplies found to be defective and sub-standard **shall** be properly documented and reported to the National Voluntary Blood Services Program (NVBSP).

4.10.1.3 The Quality Manual **shall** contain quality control process on the proper transport and storage of reagents and supplies to ensure potency and integrity.

4.10.2 Glassware

Glassware **shall** be inspected for breakages or scratches prior to use. Disposables (e.g. test tube) **shall** not be reused.

4.10.3 Inventory of Reagents and Supplies

BSF **shall** maintain a stock card or its equivalent to ensure proper monitoring of reagents and supplies. Strict Inventory management principles **shall** be observed.

4.10.4 Manufacturer's Instructions

Operational manual of equipment and Product inserts of supplies and reagents **shall** be strictly followed and kept for reference.

4.10.5 Suppliers

The BSF shall have policies, processes and procedures to evaluate the capability and track record of suppliers of materials, equipment and services to consistently meet standard requirements.

4.10.5.1 Suppliers **shall** be accredited by the FDA, BHDT and DTI.

*4.10.6 There **shall** be procedures and criteria for acceptance and rejection of suppliers.*

4.11 Duty-Free Importation

Only BSF actively participating in the NVBSP may be recommended for duty-free importation.

4.12 Personnel

4.12.1 The BSF **shall** have an organizational chart, with job descriptions that define qualifications and duties for all personnel

4.12.2 The BSF **shall** have records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. This information **shall** be readily available to relevant personnel, and may include the following:

a. Professional license relevant to the position
b. references from previous employment;
c. job description;
d. records of continuing education and certifications;
e. achievements and awards;
f. competency evaluations

Other records relating to personnel health may include records of exposure to occupational hazards and records of immunization status.

4.12.3 The BSF **shall** be headed by duly certified pathologist or hematologist having management or administrative skills and the competence to assume responsibility for the services provided. Non-hospital based BCU shall be headed by a duly licensed physician with at least three (3) months formal training in blood banking recognized by DOH-NVBSP or with one(1) year experience in a Blood Bank/ Center that performs blood collection activities recognized by DOH-NVBSP.

4.12.4 The responsibilities of the BSF head or his/ her deputies **shall** include professional, scientific, consultative or advisory organizational, administrative and educational matters. These shall be relevant to the services offered by the laboratory.

The BSF head or his/her deputies for each task should have the appropriate training and background to be able to discharge the following responsibilities:

a. Relate and function effectively (including contractual arrangement, if necessary), with
   i. Application accrediting and regulatory agencies,
   ii. Appropriate administrative officials,
   iii. The healthcare community,
   iv. The patient population served;

b. Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

c. Implement the quality management system (the laboratory head and professional laboratory personnel should participate as members of the various quality improvement committees of the institution, if applicable);

d. Monitor all work performed in the BSF to determine that reliable data are being generated;

e. Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the BSF;

f. Plan, set goals develop and allocate resources appropriate to the medical environment;

g. Provide effective and efficient administration of the medical laboratory services, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities;

h. Provide educational programs for the medical and laboratory staff and participate in educational programs of the institution.

i. Implement a safe laboratory environment in compliance with good practice and applicable regulations;

j. Address any complaint, request or suggestion from users of BSF;

k. Ensure good staff morale.

The BSF Head need not perform all responsibilities personally. However, it is the BSF Head who remains responsible for the overall operation and administration of the BSF, for ensuring that quality services are provided for donors, patients and staff.

4.12.5 There **shall** be staff resources adequate to the undertaking of the work required and the carrying out of the functions of the quality management system.

4.12.6 Personnel **shall** have training specific to quality assurance and quality management for services offered.

4.12.7 BSF management **shall** authorize personnel to perform particular tasks such as sampling, examination and operation of particular

types of equipment, including use of computers in the laboratory information system.

4.12.8 Policies **shall** be established which define who may access the information system,

4.12.9 There **shall** be a continuing education program and updates available to staff at all levels.

4.12.10 Employees **shall** be trained to prevent, manage and contain the effects of adverse incidents.

4.12.11 The competency of each person to perform tasks **shall** be assigned following training and periodically thereafter. Retraining and reassessment shall occur when necessary.

4.12.12 The personnel making professional judgment with reference to examinations **shall** have the applicable theoretical and practical background as well as recent experience.

4.12.13 Confidentiality of information regarding donors and patients **shall** be maintained by all personnel at all times.

4.13 Manpower Requirement

4.13.1 Qualification and Minimum Number Requirements

The establishment, implementation and maintenance of a quality assurance system in the BSF including the correct preparation of blood components rely upon competent people. For this reason, personnel **shall** have the education, training, experience and skills to ensure that they can perform assigned duties. In addition, there **shall** be a sufficient number of qualified and experienced personnel with at least six (6) months on-the-job training in blood banking to carry out the required services and provide the necessary blood products.

4.13.2 Job Descriptions and Functions

Each position in a BSF shall have a written job description which **shall** contain the following: duties, functions and responsibilities, measurable standards of performance for the tasks, hours of work, qualifications, immediate supervisor with whom the employee frequently works and communicates. Staff **shall** be required to sign their specific job description forms which **shall** be filed in their individual personnel records.

Personnel **shall** likewise be required to document the fact that they have read the required manual that apply to their tasks.

4.13.3 Levels of Responsibility and Delegation

The levels of responsibility, delegation and limitations **shall** be formally defined for each group or individual members of the staff. The degree of authority, especially to evaluate problems and recommend, initiate or provide corrective actions **shall** be determined. Functional organizational charts **shall** be used to define the flow of work and responsibilities.

There **shall** be adequate overall supervision by the blood center over BCU, BS, BCU/BS regarding the quality of services.

4.13.4 Evaluation of Staff Competency

The competency level of each staff **shall** be periodically evaluated. Validation can be done through external certification, formal evaluation or regular internal assessment at various levels. This **shall** be defined in the BSF manual.

4.13.5 Program for Continuing Education and Consultation

There **shall** be a program for continuing education of staff and a system of consultation and communication with the personnel. The program **shall** be prepared in consultation with the concerned staff. A yearly staff development plan **shall** be prepared at the beginning of each year.

The Voluntary Non-Remunerated Blood Donors

Section 5
The Voluntary Non-Remunerated Blood Donors (VNRBD)

The VNRBDs are the foundation for an adequate and safe blood supply. The quality and safety of the blood products **shall** be the responsibility of the BSFs.

5.1 Types of Blood Donation

5.1.1 Whole Blood Donation

The VNRBD can give about 450 ml of blood every three (3) months provided he/ she meets the eligibility criteria. (***Refer to Manual on Blood Donor Selection and Counseling***)

5.1.2 Apheresis Donation

Platelets, leucocytes, red blood cells or plasma are selectively collected using the apheresis machine. (***Refer to Manual on Blood Donor Selection and Counseling for the eligibility criteria***)

5.1.3 Autologous Donation

A patient donates his/her own blood at a pre-defined period prior to the elective surgery. (***Refer to the Manual on Blood Donor Selection and Counseling for the eligibility criteria***)

5.1.4 Directed Donation, includes Dedicated Donation

Under special circumstances, it may be important to use blood or blood components from a specific VNRBD for transfusion to a specific patient (e.g. patients with rare blood types or atypical red cell antibodies). The repeated use of a single VNRBD to supply components needed for a single patient is allowed provided it is requested by the patient's physician and approved by the BC/ BCU physician.

5.2 Target Groups for Blood Donation

Healthy men and women with the qualification presented below **shall** be considered as potential "Voluntary Non-Remunerated Blood Donors". They **shall** be encouraged to donate blood regularly in licensed/ authorized BSFs.

5.2.1 VNRBD Qualification

5.2.1.1 Allogeneic VNRBD Qualification

The potential VNRBD **shall** meet the VNRBD qualification requirements contained in the Blood Donor Selection and Counseling Manual.

5.2.1.2 Autologous VNRBD Qualification

Autologous blood transfusion may not require the rigid criteria for VNRBD selection.

The alternate requirements shall be defined (refer to Blood ***Donor Selection and Counseling Manual***) and documented by the BC physician.

5.2.1.3 Apheresis VNRBD Qualification

With the exception of the donation interval, the standards that apply to allogeneic VNRBD qualification **shall** apply to the selection of apheresis VNRBDs (***refer to Blood Donor Selection and Counseling Manual***). VNRBD s who do not meet allogeneic VNRBD requirements **shall** undergo apheresis only when the blood components are expected to be of particular value to an intended recipient and only when approved by the BC or Apheresis facility physician

5.3 VNRBD Temporary and Permanent Deferral

5.3.1 For the protection of VNRBDS and recipients, VNRBDs with any of the conditions in the Deferral Lists (***see A-Z Guide to Medical Assessment of Blood Donors, Blood Donor Selection and Counseling Manual, Appendix C***) **shall** not be allowed to donate for the stated duration. VNRBDs whose blood has been implicated in Transfusion Related Acute Lung Injury (TRALI) **shall** be evaluated regarding their continued eligibility to donate. Each potential VNRBD **shall** be evaluated and examined immediately prior to phlebotomy.

5.4 Pre-Donation Education, Notification and Counseling

5.4.1 Objectives

5.4.1.1 To maintain safety of blood supply and quality of blood products

5.4.1.1.1 Enable high-risk persons to defer themselves

5.4.1.1.2 Identify persons with medical condition/ s or medications that may affect the quality of the blood product

5.4.1.2 To protect the health of the VNRBD

5.4.1.3 To fulfill ethical requirement

The blood service facility **shall** have procedures to ensure that the following requirements are met for all potential VNRBDs:

a. VNRBDs **shall** be informed of donation process, transfusion transmitted infections (TTIs) and the VNRBD's responsibility in blood safety, whether written or oral, or *both* before donation to allow for informed consent and self-exclusion. This **shall** be a routine step in VNRBD selection *in every blood donation*.

b. VNRBDs **shall** be informed of the risk-factors associated with HIV, hepatitis B, hepatitis C, malaria and syphilis (TTIs).

c. VNRBDs **shall** be informed of the importance of honesty in providing information.

d. VNRBDs **shall** be informed of the importance of refraining from blood donation if they believe that their blood is not suitable for transfusion. As such, they **shall** notify the concerned BSF even after they have already donated blood.

e. VNRBDs **shall** acknowledge (in writing) that they have read the abovementioned information.

5.4.2 *Informed Consent by VNRBD*

Written informed consent for donation is a legal and ethical requirement. This implies one's willingness to donate blood given by a mentally competent person "who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence, or intimidation". The information given to the VNRBD **shall** include the donation process, and risks involved. The VNRBD **shall** be encouraged to ask questions and have them answered and be allowed to give or refuse consent for donation.

For potential VNRBDs 16 to 17 years old, written informed assent of the VNRBD and written informed consent of the parents or legal guardians have to be obtained before donation.

5.4.3 *Notification of Abnormal Findings and Test Results of VNRBD*

The BSF **shall** establish the procedure of notifying all VNRBDs (including pre-surgery autologous donors with medically significant abnormality detected during screening, or as a result of laboratory testing, or blood recipient follow-up. It **shall** have a system and procedure for managing information regarding VNRBD's

suitability, either from the VNRBD him/herself and/or from another party.

For autologous donors who are deferred, both the VNRBD and the referring physician **shall** be notified.

All deferred VNRBDs **shall** be counseled by the designated trained personnel.

5.5 Care of Voluntary Non-Remunerated Blood Donors

5.5.1 The BSF **shall** institute policies and procedures of maintaining privacy and confidentiality of information obtained during VNRBD screening and blood testing.

5.5.2 During blood donation, the VNRBD **shall** be attended on a one-on-one basis and observed closely for adverse reactions.

The BSF **shall** have guidelines and procedures for managing donation related adverse reactions and be capable of providing immediate medical care both in the facility and in the MBD site.

These adverse events **shall** be documented, assessed, investigated and monitored.

5.5.3 Post-donation Counseling

All VNRBDs **shall** receive post-donation counseling and instructions on post-phlebotomy self-care.

Section 6

Blood collection, testing, processing, storage, transportation

Section 6

Blood Collection, Testing, Processing, Storage, Issuance and Transport

The Blood Service Facility is ultimately responsible for the correct and safe procedures for collection, testing, preparation, handling, storage, issuance and transport of all blood products. Blood **shall** be collected, tested, and processed using Good Manufacturing Practices (GMP) guided by Quality Manual and Work Instructions.

6.1. Blood Collection

6.1.1 Training of Phlebotomists

Medical and paramedical personnel and volunteers **shall** undergo basic blood donor phlebotomy training recognized by the Philippine Blood Coordinating Council (PBCC).

6.1.2 Phlebotomy

Prepare all materials needed before phlebotomy. Make sure that all materials used are sterile. Each Blood Bag **shall** be inspected visually for damage or evidence of contamination prior to its use and immediately after filling. Such examination **shall** include inspection for breakage of seals and abnormal discoloration. Where any defect is observed, the container **shall** not be used, or if defective after filling, **shall** be properly handled and disposed of.

Defective supplies shall be immediately labeled "DEFECTIVE MATERIAL" and separated from the rest of the supplies in a designated place prior to proper disposal.

The Work Instruction shall describe in detail the phlebotomy technique with special attention to skin disinfection and preparation. To prevent bacterial contamination, reinsertion of a needle is not allowed. A new blood bag, therefore, **shall** be used if the first attempt is unsuccessful.

6.1.3 Labeling and Recording

Proper labeling of blood bags must be done during blood collection using the barcode stickers of the NVBSP information system. The following information **shall** be captured in the NVBSP information system:

1. Unique Blood Donation number

2. Date and Time of collection
3. Name or Initial of Phlebotomist

The said information is linked to a set of barcode stickers containing identical donation numbers which **shall** be placed on the DHQ, sample tubes, and blood bags, including satellite bags. All unused barcode stickers from each set of stickers are attached to the DHQ for accounting. In the absence of IBBIS, labeling **shall** be done using ball point pen containing the abovementioned information.

6.1.4 Duration of Donation

The duration of whole blood donation shall be noted. A whole blood donation longer than 15 minutes **shall** not be processed into platelet concentrate and cryoprecipitate or Anti Hemophilic Factor (AHF)-rich plasma.

6.1.5 Blood Samples for Testing

Blood sample for serologic screening shall be collected from the donor bag into the sample tube or sample pouch, if available. Evacuated tube **shall** be used in the collection of specimen so as not to comprimise the sterility of the blood units.

The identity of the sample tubes shall be ensured through barcoding.

6.1.6 Volume of Whole Blood Collection

The volume of blood collected shall be 450 ± 10% plus anticoagulant. For BSFs with pediatric transfusions, blood maybe collected using quadruple packs (50ml x 4).

6.1.7 Submission and Processing of Blood from Blood Collection Units

Specimen for testing and appropriate form/s together with the blood unit/s collected from the BCU **shall** be sent to the Blood Center, while observing the Blood Cold Chain.

6.2. Testing of Blood Donor Units

6.2.1 Determination of ABO Blood Group

The ABO grouping **shall** be determined for all blood units. Forward and Reverse Typing **shall** use the tube method or the method acceptable to NVBSP. The slide method is not acceptable.

All blood units with discrepant blood types **shall** be quarantined in a designated blood bank refrigerator until the discrepancy is resolved. An integrally attached segment of the blood bag **shall** be retested which **shall** be compared to the VNRBD's previous donation record, if available.

6.2.2 *Determination of Rh (D) Blood Group*

Rh (D) typing shall use the tube method or the method accpetable to NVBSP. If initially (D) negative, test for weak D antigens (Du) shall be performed. Appropriate negative Rh (D) control (6% albumin) **shall** be performed. Testing for additional Rh (D) factors and other antigens is optional.

6.2.3 *Red Cell Antigen and Antibody Screen*

Blood units may be tested for atypical red blood cell antibody.

6.2.3.1 Antigen - Red cell phenotyping may be determined for blood donor units.

6.2.3.2 Antibody - It is highly recommended that blood donor units be tested for clinically significant antibodies.

6.2.4 *Transfusion-Transmissible Infections (TTIs)*

All blood units from healthy VNRBD shall test negative for the following: HBsAg, HCV antigen and/or HCV antibody, HIV 1 and 2 antigen and antibody, Syphilis and Malaria methods as recommended by the National Council for Blood Services (NCBS) Technical Committee (NCBSTC). Rapid diagnostic platforms **shall** not be used for screning of blood units for TTIs.

Blood units tested non-reactive for HBsAg, HCV antigen and/or HCV antibody, and HIV 1 and 2 antigen and antibody may undergo Nucleic Acid Testing (NAT) if available.

A BSF in a locality may do additional screening tests for prevalent infections if technical skills are available and/or if the epidemiologic situation warrants.

6.2.5 *Introduction of New Mandatory Tests for Other Infectious Agents*

The NCBS or DOH authority shall require new mandatory tests only after a systematic study and evaluation of the following important factors: the prevalence of the disease, the risk of transmission through blood transfusion, and cost benefit of such introduction.

6.2.6 *Issuance of Untested or Partially Tested Blood Unit*

No untested or partially tested blood unit **shall** be issued by the BSF, except in cases of extreme emergency. Blood centers may be liable if they do not follow standard procedures.

6.2.7 *Testing Methods and Kits*

BSF **shall** procure reagents, blood bags and other supplies which are registered with FDA, evaluated by designated NRL and recommended by NCBSTC.

6.2.8 *Control Reagents*

Control reagents supplied by the manufacturer and/or a third party control **shall** be used as required. All test results **shall** be validated by the Quality Officer or his/her designate.

6.2.9 *Confirmation of the Test Results*

Blood units found to be reactive in any of the TTIs **shall** be labeled 'NOT FOR TRANSFUSION AND FOR CONFIRMATORY TESTING' and **quarantined** in a separate cold storage area.

All blood units reactive for the above tests (TTI) **shall** be referred to NRL-NVBSP in Research Institute for Tropical Medicine (RITM) for confirmatory testing subject to guidelines issued by the DOH. These blood units **shall** be transported properly at the required range of temperatures of +2°C to +10°C.

The NRL-NVBSP in RITM shall inform the referring BSF of the test results within five (5) working days and shall properly dispose these blood units.

Quality Procedures **shall** clearly state the manner of informing the blood collecting facility, the donor, the AIDS Registry, NEC.

6.2.10 *Issuance of Test Results*

Results of serological tests are for BSF use only. No printed or written results, whether positive or negative, **shall** be issued by any BSF.

6.3 *Blood Component Preparation*

The type and quantity of blood components which **shall** be supplied by the lead Blood Service Facilities, designated hospital blood banks with blood center capabilities and blood centers **shall** depend on the requirements of hospitals, dialysis centers and other end user facilities.

All blood components shall be prepared under strict aseptic technique using sterile pyrogen-free equipment and solutions. The use of sterile connecting device that allows transfer of components without breakage of the seal is recommended.

6.3.1 Handling and Storage of Blood Components ***(Refer to Tables 3.1 and 3.2 under Section 3-The Blood Products Specification)***

The BSF **shall** have a process to ensure that blood components, samples and critical materials are handled, stored and transported in a manner that prevents damage, limits deterioration and meets requirements contained in reference standards.

6.3.1.1 Segregation of Blood Components

The BSF **shall** ensure the appropriate segregation of blood and components according to these categories: untested, tested, cross matched, quarantined, and for disposal. Under each category the units of blood are separated according to type of component (whole blood or packed red blood cells) and blood type (ABO and Rh). These categories and blood types **shall** be clearly labeled.

6.3.1.2 Access to storage areas and authorization to remove contents **shall** be controlled according to SOP/ Work Instructions of the BSF.

6.3.2 List of Blood Components and Description

6.3.2.1 Whole Blood and Red Blood Cell Components

1. Whole Blood (WB): WB is collected in an anticoagulant/ preservative solution and is not further processed. This **shall** not be used as a source of platelets or labile coagulation factors.

2. Packed Red Blood Cell (Red Blood Cell Concentrate): are Red cells concentrated by the removal of most of the plasma from sedimented or centrifuged WB.

3. Leukocyte Reduced Red Blood Cells (Leuko-reduced packed RBC): RBCs prepared by a method known to retain at least 85% of the original red cells and reduce the leukocyte number in the final component to $<5x10^6$.

4. Washed Red Blood Cells (RBC Washed): RBCs remaining after washing with a volume of 0.9 NSS using a method known to remove almost all of the plasma. Depending on the method used, the preparation may contain variable quantities of leukocytes and platelets from the original unit.

5. Apheresis Red Blood Cells Leukocyte Reduced (Red Blood Cells Pheresis, Leukocyte-Reduced): RBCs in anticoagulant or in anticoagulant and storage solution that have been prepared by automated cytapheresis that have been leukocyte reduced by a method known to retain at least 85% of the original red cells and to reduce the leukocyte number in the final component to $<5x10^6$.

6.3.5.2 Plasma Components

1. Fresh Frozen Plasma (FFP): Plasma separated from whole blood of an individual VNRBD collected within 15 minutes and placed at (-30)°C or colder within 6 to 8 hours of collection from the VNRBD.

2. Cryoprecipitated AHF (Cryoprecipitate): The cold insoluble portion of plasma processed from FFP thawed at +2°C to +6°C overnight, centrifuged, precipitate is collected and stored at (-30)°C or colder and **shall** be re-frozen within 1 hour.

6.3.5.3 Platelet Components

1. Platelet Concentrate (Plt Conc): A suspension of platelets in plasma prepared by centrifugation of whole blood from a VNRBD and placed at +20°C to +24°C within 6 to 8 hours of collection and stored at +20°C to +24°C with constant agitation.

2. Pooled Platelets (Platelets Pooled): Two or more units of platelet concentrate that have been combined into one unit depending on the patient's requirement.

3. Platelets Leukocyte-Reduced (Platelets Leukocyte-Reduced): Platelets Leukocyte-Reduced are prepared by a method known to reduce the leukocyte number to $< 8.3 \times 10^5$ in at least 95% of the components sampled.

4. Pooled Platelets Leukocyte-Reduced (Platelets Leukocyte-Reduced Pooled): A suspension of platelets in plasma that has been leukocyte-reduced. The leukocyte reduction process can take place either before or after the pooling process.

5. Apheresis Platelets (Platelets Pheresis): A suspension of platelets in plasma prepared by cytapheresis. WB undergoes centrifugation in a cell separator, with the return to the donor of components not collected.

6. Apheresis Platelets Leukocyte-Reduced (Platelets Pheresis Leukocyte-Reduced): Platelets collected by apheresis that is prepared by a method known to reduce the residual leukocyte number to $<5 \times 10^6$ in 95% of the components sampled.

7. Apheresis Granulocytes (Granulocytes Pheresis): A suspension of granulocytes in plasma prepared by cytapheresis with the return to the donor of components not collected.

8. Apheresis Granulocytes/ Platelets (Granulocytes/ Platelets Pheresis): A suspension of granulocytes in plasma prepared by cytapheresis, with the concurrent collection of platelets.

6.3.5.4 Irradiated Blood Components

Irradiated blood components are those that have been exposed to 25gã gamma irradiation to inactivate T lymphocytes which are responsible for Graft versus Host transfusion reaction. These **shall** include the following:

1. APHERESIS GRANULOCYTES, IRRADIATED (Granulocytes Pheresis, Irradiated)

2. APHERESIS GRANULOCYTES/PLATELETS, IRRADIATED (Granulocytes/ Platelets Pheresis, Irradiated)

3. PLATELETS, IRRADIATED (Platelets, Irradiated)

4. POOLED PLATELETS, IRRADIATED (Platelets Pooled, Irradiated)

5. APHERESIS PLATELETS, IRRADIATED (Platelets Pheresis, Irradiated)

6. APHERESIS PLATELETS, IRRADIATED LEUKOCYTE-REDUCED (Platelets Pheresis, Leukocyte-Reduced, Irradiated)

7. RED BLOOD CELLS, IRRADIATED (Red Blood Cells, Irradiated)

8. RED BLOOD CELLS, IRRADIATED LEUKOCYTE-REDUCED (Red Blood Cells Leukocyte-Reduced, Irradiated)

9. APHERESIS RED BLOOD CELLS, IRRADIATED (Red Blood Cells Pheresis, Irradiated)

10. WHOLE BLOOD, IRRADIATED (Whole Blood, Irradiated)

6.4 Issuance and Transport of Blood Units

6.4.1 Quarantine

There **shall** be a system to clearly identify and quarantine the following products:

- Blood units with discrepant ABO/Rh grouping **shall** be quarantined until the inconsistency is resolved.
- Blood units found reactive to any disease screening test **shall** be labeled "FOR CONFIRMATORY TESTING AND NOT FOR TRANSFUSION" and quarantined until results of confirmatory testing from NRL-RITM determine their true results.

6.4.2 Validation of Blood Units prior to Issuance

The following information requires validation before the blood or blood component is cleared for issuance:

- Results of TTI screening tests
- Results of ABO and Rh grouping
- Complete data on the blood unit label
- Confirmation, if for autologous transfusion, when applicable

The two authorized Medical Technologists on duty **shall** validate the above information by crosschecking the laboratory forms with the appropriate logbooks.

6.4.3 Packing and Issuance

- Blood and blood components **shall** be inspected before packing with special attention to signs of contamination or significant hemolysis, change in color, presence of blood clots, or leakage. Blood units exhibiting these changes **shall** not be packed or issued.

6.4.4 Issuance Process

- There **shall** be a system to document the approval of issuance with specific personnel in charge.
- There **shall** be a list of details which has to be verified by the personnel approving the issuance of the blood unit.
- There **shall** be a system for a second verification before issuance

6.4.5 Packaging, Issuance and Transport

Each blood unit for packaging, issuance and transport to requesting hospital(s) or BSF **shall** carry with it the instruction material with clear and brief instructions on how the product **shall** be used.

This brief instruction **shall** include the following:

- Name of blood product
- Volume and required storage temperature
- Specific content/ s
- Procedures for thawing or warming (when applicable)

6.4.6 Records of Collection and Distribution

The BSF **shall** have policies and procedures to ensure that documents are identified, reviewed, approved, retained and that records are created, stored and archived in accordance with record retention policies. ***(Refer to Annex 6)***

6.4.7 Distribution and Payment for Blood Products

Blood products **shall** be distributed directly to hospitals and other end user facilities. Only BSF or hospital personnel **shall** be authorized to deliver or receive the blood units. Payments, when necessary, **shall** be paid by the hospital directly to the issuing BSF.

6.4.8 Transport of Blood Products

Blood units **shall** be inspected thoroughly before they are packed for distribution.

Cold chain **shall** be followed during transport and distribution of the blood products *(Table 3.1, page 9)*. Components ordinarily stored at room temperature (+20°C to +24°C) **shall** be transported also at +20°C to +24°C Blood products stored at +2°C to +6°C **shall** be transported at +2°C to +10°C. Frozen components **shall** be transported with dry ice to maintain their frozen state.

Blood units **shall** be packed and distributed using blood transport boxes.

6.4.9 Reissue and Re-designation

Blood units which have been returned to the issuing or releasing BSF within 30 minutes may be reissued provided that the following conditions are met and documented in the appropriate logbooks and records by the personnel-in-charge:

- The sterility of the blood product is maintained
- The product has been stored in the proper temperature
- At least two sealed segments of the integral donor tubing remained intact
- The records clearly document the return and reissue in appropriate logbooks

The BSF personnel **shall** inspect the product prior to its reissue

6.4.10 Unsuitable Blood Products

All blood products which have been found unsuitable for transfusion **shall** be labeled, documented and be disposed of as follows:

- Blood units found reactive to serological tests
  These **shall** be labeled "FOR CONFIRMATORY TESTING AND NOT FOR TRANSFUSION" and **shall** be sent to NRL-NVBSP .

- Blood units confirmed positive for TTIs
  These **shall** be labeled 'NOT FOR TRANSFUSION - FOR OTHER SCIENTIFIC PURPOSES' and **shall** be utilized by RITM for appropriate scientific purposes.

- Wasted and Outdated blood products
  Hemolyzed, contaminated or punctured blood units **shall** be labeled "NOT FOR TRANSFUSION - FOR DISPOSAL" and **shall** be sterilized prior to disposal as waste products ***(Refer to Section 8, Waste Management)***

6.5 Labeling

Each BSF **shall** have a labeling process or system that **shall** include steps taken to identify the original unit, any component and component modifications; complete the required reviews; and attach the appropriate labels.

6.5.1 Unique Blood Donation Identification Number/Barcode

In each BSF, every donation **shall** be assigned a unique blood donation ID number/ bar code. This **shall** be permanently attached during blood collection to:

6.5.1.1 Donor History Questionnaire
6.5.1.2 All blood units including their satellite bag/ s
6.5.1.3 All blood sample tubes

6.5.2 Content of each Label

6.5.2.1 Unique blood donation number, barcode
6.5.2.2 Name of blood center/ BSF
6.5.2.3 Type and volume of the blood product
6.5.2.4 ABO and Rh group
6.5.2.5 Type and volume of anticoagulant
6.5.2.6 Required storage temperature
6.5.2.7 Date of collection
6.5.2.8 Date of expiration
6.5.2.9 Additional information: irradiated, etc. (if appropriate)

6.5.3 Additional Labels

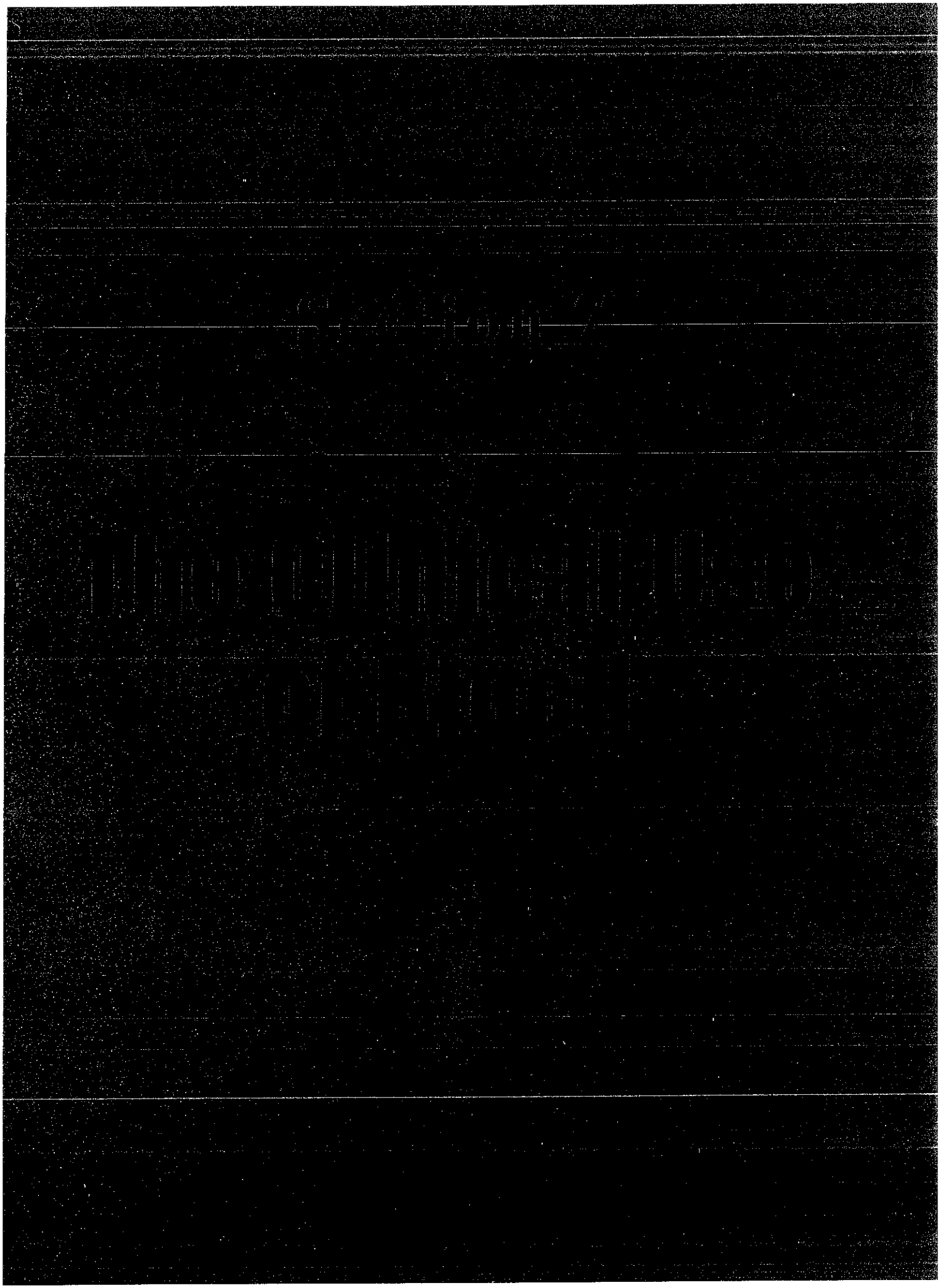
The following label **shall** be attached to these specific blood products:

6.5.3.1 Products modified by open method systems **shall** be labeled "TRANFUSE WITHIN 24 HOURS"

6.5.3.2 Products found reactive to disease screening tests **shall** be labeled "FOR CONFIRMATORY TESTING AND NOT FOR TRANSFUSION"

6.5.6.5 Products found unsuitable for transfusion such as in outdated units or damaged bags **shall** be labeled "NOT FOR TRANSFUSION - FOR OTHER SCIENTIFIC PURPOSES"; and properly disposed accordingly.

6.5.6.5 Products for Autologous transfusion **shall** bear the patient's name & labeled "FOR AUTOLOGOUS USE ONLY"



Section 7

The Clinical Use of Blood

Transfusion of a blood product, no matter how carefully it has been collected and prepared, always carries some risk to the recipient. Blood transfusion, therefore, **shall** be given only when absolutely necessary for specific clinical indications. Only the specific blood component needed **shall** be transfused. (***Refer to Philippine Clinical Practice Guideline for the Rational Use of Blood and Blood Products and Strategies for Implementation***).

7.1 Clinical Indications for Specific Blood Products

Table 7.1 Indications for Transfusion of Blood and Blood Products

Blood and Blood Products	Composition	Indications
1. Whole Blood (WB)	All cellular and plasma components. Deficient in active platelets, granulocytes and labile clotting factors (VIII, vWF, and Factor V)	Actively bleeding patient (more than 25-30% blood loss or about 2 liters) with symptomatic deficit in oxygen-carrying capacity and shock WB (less than 5 days old in CPDA, or less than 4 days old in CPD) used mainly in neonatal exchange transfusion.
2. Packed Red Blood Cells (PRBC)	RBC which has been depleted of much plasma Leucocytes can be further reduced using leukocyte filters	Patients with symptomatic deficit of oxygen-carrying capacity e.g. severe or chronic anemia not corrected by iron, vitamin B12 or folic acid. For Exchange Transfusion in neonates use RBC (less than 5 days old in CPDA, or less than 4 days old CPD. If volume expansion also is needed, may use with isotonic saline. If coagulation factors are also needed, may use with FFP or specific component.

Blood and Blood Products	Composition	Indications
3. Washed Red Cells	RBC, no plasma; no plasma proteins; minimal platelets. 70-80% WBC removed if manual wash; 90% WBC removed if automated wash.	Use only for those requiring repeated transfusions who develop febrile or allergic transfusion reactions
4. Platelet Concentrate (PC)	At least $5.5x10^{10}$ platelets in 50-70 ml plasma; depending on centrifugation rate, may contain many lymphocytes or some red cells.	Treatment or prevention of bleeding due to deficient platelet number ($<20x10^9$/ L); Abnormal platelet function or both Example: sepsis, DIC, renal failure, coagulation, splenomegaly Patients about to undergo major surgery with platelets $<50x10^9$/ L Long term supportive treatment of conditions with bone marrow depression

7.2 Samples and Requests for Blood Products

The recipient and his/her blood sample **shall** be positively identified at the time of sample extraction for blood typing and compatibility testing. A complete, accurate and legibly filled-in blood request form(s) **shall** be submitted to the blood bank at least 24 hours before anticipated need. In case of emergency need of blood, the request **shall** be sent immediately.

The prescribing practice for elective surgical procedures which will require blood transfusion **shall** be based on the Maximum Blood Ordering Schedule (MBOS) as agreed upon by the Hospital Blood Transfusion Committee (HBTC).

7.3 Pre-Transfusion testing of Patient's Blood

Blood sample submitted for compatibility testing **shall** be tested for ABO and Rh blood group. Screening for unexpected or atypical antibodies to red cell antigens is highly recommended.

Selection of compatible blood product(s) for transfusion **shall** be based on the Philippine Clinical Practice Guidelines. Recipients **shall** receive ABO group-specific whole blood or ABO group-compatible red cell products. The HBTC **shall** have a policy for the use of Rh-positive red cell products in Rh negative recipients.

Before issue, recipient's serum or plasma **shall** be tested compatible against a sample of donor cells from an integrally attached segment of the blood product. The crossmatch **shall** use tube method or a method acceptable to NVBSP that demonstrate ABO compatibility and detects clinically significant antibodies to red cell antigens. The crossmatch **shall** be performed in all three phases (saline, albumin or Low Ionic Strength Solution, thermal phase, and anti-human globulin) including an auto control. Slide method is not acceptable.

7.4 Blood Issuance and Handling

Blood **shall** be issued from the hospital blood bank only when the patient is ready for transfusion. Any preparation and verification steps **shall** be performed according to the source facility and policies and procedures of the hospital.

Blood **shall** not be allowed in the ward refrigerator at any time. From time of issue to the ward, a 30-minute period is acceptable for any returned, intact blood and blood product.

Blood **shall** be transported in appropriate containers with proper temperature-monitoring devices.

7.5 Minimizing Adverse Blood Transfusion Reactions (BTR)

7.5.1 Careful clerical check of the information on the blood unit label and the patient's identification to ensure that the "right" blood unit is administered to the "right" patient

7.5.2 Careful inspection of the safety of blood product packaging

7.5.3 Close monitoring of patient undergoing transfusion, with mandatory presence of medical or trained nursing staff for the first 15 minutes.

7.5.4 Use of appropriately stored blood product

*7.5.5 Elective transfusion **shall** be done during hours when there is full complement of medical staff*

7.6 Management of Adverse BTRs

The BSF **shall** have written standard operating procedures (SOPs) for the identification, management, investigation and reporting of suspected transfusion reactions and other transfusion-related adverse events.

7.7 Hospital Blood Transfusion Committee (HBTC)

The establishment of an active HBTC **shall** be the responsibility of the Medical Director or Chief of Hospital. The members **shall** be committed to the function of HBTC as stated in the Implementing Rules and Regulations of RA 7719.

7.8 Hemovigilance

Involves surveillance of the entire comprehensive process from the collection of blood from the VNRBDs to transfusion to the recipients. This **shall** collate information on VNRBDs and recipients into an integrated NVBSP information system which **shall** provide monitoring trends to factors affecting transfusion safety.

Any deviations from the accepted blood component indications and established MSBOS in the blood requisition and utilization **shall** be reported and investigated by the HBTC.

Reporting systems on the transfusion related diseases, accidents, errors, near misses, transfusion reactions and any complications of transfusions **shall** be in place so that risks and trends are identified and appropriately managed.

Section 8

Environmental Management and Blood Safety

Section 8
Environmental Management and Biosafety

Each BSF **shall** institutionalize a system of Environmental Management and Biosafety to ensure the protection of the environment and safety of the staff, clients and community.

8.1 Management of the Environment and Biosafety

8.1.1 *The BSF Head or supervisor **shall** be responsible for the protection* and safety of *the environment, staff, clients and community. A system shall be designed which provides for sanitation and cleanliness, orderliness and labeling, waste management, fire safety, and accident & emergency preparedness.*

8.1.2 *It **shall** be the management's responsibility to identify or designate an individual as Biosafety Officer of the BSF.*

8.2 Responsibility of the Biosafety Officer (BO)

8.2.1 *The BO **shall** institute compliance to the established policies, guidelines and procedures set by the management to ensure safety and protection of the environment, staff, clients and community.*

8.2.2 *He/She **shall** be responsible in bringing to the management's attention BSF's unsafe working conditions and identify opportunities to minimize biohazards in the BSF.*

8.3 Sanitation and Cleanliness

There **shall** be written procedures and safe work practices of the staff which are documented in maintaining cleanliness, sanitation and safety in the BSF. The documented procedures and safe work practices **shall** be reviewed periodically by the Hospital Biosafety Committee (HBC).

8.4 Orderliness and Labeling

The BSF **shall** sort, label, arrange and store all materials being used in the BSF according to order and frequency of use. These procedures **shall** be contained in a manual and **shall** be available at the workstations for dissemination to all the staff.

8.5 Solid Waste Management

The BSF **shall** develop, establish and implement a system for proper solid waste management. There **shall** be step by step procedures for the proper disposal of solid wastes and **shall** conform with the guidelines set by the DOH and Department of Environment and Natural Resources (DENR).

8.6 Liquid Waste Management

The BSF **shall** develop, establish and implement a system for proper liquid waste management. There **shall** be procedures in the disposal of liquid wastes and **shall** conform with the guidelines set by the DOH and Department of Environment and Natural Resources (DENR).

8.7 Fire Safety

The BSF **shall** establish and implement a system to address the hazards and consequences of fires. There **shall** be procedures in the prevention, management and safety in case of fire.

8.8 Accidents and Emergency Preparedness

The BSF **shall** establish and implement a contingency plan for dea ling with laboratory accidents, emergencies, natural, man-made disasters, and other type of emergencies.

The BSF **shall** record in the Accident Book all laboratory accidents and **shall** be analyzed periodically to determine the need to modify laboratory SOP's, to prevent similar incidents from occurring and to reduce risks to the staff.

Section 9

Documents and Records

Section 9
Documents and Records

The BSF **shall** have policies, processes, and procedures to ensure that documents are identified, reviewed, approved, and retained and that records are created, stored, and archived in accordance with record retention policies.

9.1 Documents

The BSF **shall** have a process for document control that includes the following elements:

9.1.1 *A master list of documents, including policies, processes, procedures, labels, and forms that relate to the requirements of this Manual of Standards for BSF.*

9.1.2 *Use of standardized formats for all policies, processes, and procedures.*

9.1.3 *Review and approval of new and revised documents before use.*

9.1.4 *Annual review of each policy, process, and procedure by an authorized individual.*

9.1.5 *Use of only current and valid documents. Appropriate and applicable documents* ***shall*** *be available at all locations where activities essential to meeting the requirements of this Manual of Standards for BSF are performed.*

9.1.6 *Identification, appropriate recall and archival of obsolete documents.*

9.2 Records

The BSF **shall** ensure identification, collection, indexing, access, filing, storage, and disposition of records as required by ***Reference Standards in, Annex 5, Retention of Blood Service Facility (BSF) Records.***

9.2.1 Facility Records

Records **shall** be complete, properly stored, retrievable in a period of time, appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.

9.2.1.1 Copies of Records

Before the destruction of the original records, the BSF **shall** have a process to ensure that copies of records are identified as such. Copies of records **shall** be verified as containing the original content and **shall** be legible, complete, and accessible.

*9.2.2 A system designed to prevent unauthorized access and ensure confidentiality of records **shall** be established and followed.*

*9.2.3 The record system **shall** make it possible to trace any unit of blood, and blood products from its source to final disposition; to review the records applying to the specific component; and to investigate adverse events manifested by the recipient.*

9.2.3.1 The system **shall** ensure that the donor number and donation identification number are unique and **shall** match with each other.

*9.2.4 The actual result of each test observed **shall** be recorded immediately and the final interpretation **shall** be recorded upon completion of testing.*

9.2.5 Electronic Records

There **shall** be processes and procedures to support the management of computer systems.

9.2.5.1 There **shall** be a process in place for routine back up of all critical data.

9.2.5.1.1 Procedures **shall** be in place to ensure that data are retrievable and usable.

9.2.5.1.2 If possible, back up data **shall** be stored in an off-site location.

APPENDIX

Department of Health

NATIONAL VOLUNTARY BLOOD SERVICES PROGRAM

(BSF Name and Address)

Blood Donor History Questionnaire

Date : _____ Venue : _____

Name : _____ _____ _____

Date of Birth : ___ /____ /_____ Age : _____

Gender : ❑ Male ❑ Female Civil Status : _____

Contact number: _____ E-mail address : _____

Nationality : _____ Occupation : _____

Preferred Mailing Address

❑ Home Address : _____ _____
Number, Street and Subdivision Barangay

_____ _____ Zip Code : _____
Town/District City/Province

❑ Office Address : _____ _____ _____
Floor Building Name Number and Street

_____ _____ _____ Zip Code : _____
Barangay Town/District City/Province

Type of Donor : ❑ Volunteer ❑ Others _____

Method of Collection : ❑ Whole Blood (Conventional) ❑ Apheresis _____

Instructions: All donors must read the donor educational materials provided by the Blood Service Facility staff before answering.

	Yes	No
Are you		
1. Feeling healthy today?		
2. Currently taking medication?		
Have you taken any medication from the deferral list?		
3. Have you received any vaccination?		
In the past three days		
4. Have you taken aspirin or anything that has aspirin in it?		

	Yes	No
QUESTION No. 5, FOR FEMALE DONORS: **In the past 1 and ½ months (6 weeks)** 5. Have you been pregnant or are you pregnant now? Last Menstrual Period: _____		
In the past 12 weeks have you 6. Donated blood, platelet or plasma?		
In the past 12 months have you		
7. Had a blood transfusion?		
8. Had surgical operation, dental extraction?		
9. Had a tattoo, ear or body piercing, accidental contact with blood, needle-stick, and acupuncture?		
10. Had sexual contact with high risk individuals?		
11. Had sexual contact with anyone in exchange for material or monetary gain?		
12. Had sexual contact with a person who has worked abroad?		
13. Engaged in casual sex?		
14. Lived with a person who has hepatitis?		
15. Have you been imprisoned?		
16. Have any of your relatives had Creutzfeldt-Jakob (Mad Cow) disease?		
Have you ever		
17. Lived outside your place of residence?		
18. Lived outside the Philippines?		
19. Used needles to take drugs, steroids, or anything not prescribed by your doctor?		
20. Used clotting factor concentrates?		
21. Had a positive test for the HIV virus, Hepatitis virus, Syphilis or Malaria?		
22. Had Hepatitis?		
23. Had malaria?		
24. Been told to have or treated for genital wart, syphilis, gonorrhea or other Sexually Transmissible Infections?		
25. Had any type of cancer, for example Leukemia?		
26. Had any problems with your heart and lungs?		
27. Had a bleeding condition or a blood disease?		
28. Are you giving blood because you wanted to be tested for HIV or Hepatitis virus?		
29. Are you aware that if you have the HIV/Hepatitis virus, you can give it to someone else though you may feel well and have a negative HIV/ Hepatitis test?		
BSFs may choose to add local questions here.		

_____

Donor's Signature

Donor's Informed Consent

I certify that I am the person referred to in all the entries, which were read and well understood by me. It is my free and voluntary act to donate my blood, aware of its risks during and after extraction. The same have been explained to me in understandable language and dialect that I speak.

I am voluntarily giving my blood through (**name of BSF**). I understand that my blood will be tested for Blood Type, Hemoglobin, Malaria, Syphilis, Hepatitis B, Hepatitis C and HIV* and no official result will be issued to me. If found reactive, I agree to be referred to the appropriate facility for counseling and further management.

I certify that I have to the best of my knowledge, truthfully answered the above questions.

Donor's Signature

**Note: You may include other specific tests done in your BSF*

CONFIDENTIAL UNIT EXCLUSION (CUE):

If at any point during or after your blood donation your blood is not suitable for transfusion, please inform the Blood Service Facility staff. Please use your Blood Donation ID Number and the Segment Number written below in identifying your blood donation.

Contact number of Blood Service Facility : _____

Segment Number : _____

Place Barcode Sticker of
Donation ID No. here:

For Blood Bank Use Only

Physical Examination

Body weight : _____ (kg) Blood Pressure : _____/_____ Pulse Rate : _____ Temp: _____

General Appearance : _____ Skin : _____

HEENT : _____ Heart and Lungs : _____

Remarks

- ☐ Accepted Volume _____ mL
- ☐ Temporarily Deferred
- ☐ Permanently Deferred

Reason for Deferral

_____

_____

Place Barcode Sticker of **Donation ID No. here:**

_____

Blood Bank Officer

For Phlebotomist use only:
Blood Bag: (S) Single / (D) Double / (T) Triple
Segment Number:
Time Started:
Time Ended:
Phlebotomist:

Test	Result	Screened by:
Blood Type		
Hemoglobin		

Name of Blood Service Facility

REQUEST FOR BLOOD COMPATIBILITY TESTING

(BSF Form No. _____)

Name of Recipient: _____Ward/ Room No.: _____ Date: _____

Recipient's Identification No.: _____ Health Record No. (HRN) (If any): _____

Age: _____ Gender: _____ Diagnosis/ Procedure: _____

If emergency, please check appropriate box or boxes as needed.

( ) Cross matched – 3 phases and fully screened blood (at least 3 hours)

Because of the extreme need of blood, I hereby direct the blood bank to issuance the following:

( ) Group "O" blood UNCROSSMATCHED
( ) ABO Type specific blood UNCROSSMATCHED
( ) Crossmatched blood SALINE PHASE ONLY
( ) Crossmatched blood SALINE AND ALBUMIN PHASE ONLY
( ) Blood NOT SCREENED for malaria, VDRL, HIV Ab, HBsAg and HCV Ab
( ) Blood NOT SCREENED for HIV Ab, HBsAg and HCV Ab
( ) Blood NOT SCREENED for HIV Ab and HCV Ab
( ) Crossmatched and screened blood with MINOR INCOMPATIBILITY

Justification for emergency issuance of blood

_____

_____

_____, M.D.

Attending Physician

Name of Healthcare Facility

BLOOD TRANSFUSION FORM

(BSF Form No. _____)

Name of Patient: _____ _____ _____
Lastname First Name Middle Name

Health Record No. (HRN) / Identification No.: _____

Age: _____ Sex: _____ Blood Type: _____ Ward/ Room/ Bed: _____

Blood Unit Serial Number : _____ Expiry Date : _____

Blood Type (ABO/ RH) : _____ Issued by : _____

Type of Component:

( ) Whole Blood ( ) Platelet Concentrate
( ) Red Blood Cells ( ) Cryoprecipitate
( ) Plasma ( ) Others: _____

Result of Blood Crossmatching: _____

Cross matching Done By: _____ Date/ Time: _____
Name/ Signature and Title

( ) Emergency Testing
( ) Uncrossmatched
( ) Crossmatched
( ) Saline Phase Only
( ) Saline and Albumin Phase Only
( ) Saline, Albumin and Antiglobulin Phase
( ) ABO/ Rh Compatible

Blood Unit Received By: _____ Date/ Time: _____
Name/ Signature and Title

Appearance of Unit Checked By:

_____, RN (Staff Nurse)
_____, RN (Head Nurse)
_____, RN (Nurse Supervisor)
_____, MD (Physician-on-Duty) Date/ Time: _____

BLOOD TRANSFUSION RECORD

Patient's Vital Signs: BP: _____ PR: _____ RR: _____ Temp: _____

Transfusion Started By: _____ Date/ Time: _____
Name/ Signature and Title

Transfusion Completed/ Stopped: _____ Date/ Time: _____
Name/ Signature and Title

Transfusion Set Removed By: _____ Date/ Time: _____
Name/ Signature and Title

Remarks:

( ) Transfusion completed without immediate transfusion reactions noted

( ) Transfusion stopped with transfusion reactions noted

( ) Fever ( ) Nausea ( ) Flushes

( ) Chills ( ) Vomiting ( ) Rashes

( ) Others: Vital Signs: BP_____ PR_____ RR _____Temp_____

( ) For transfusion reaction studies

Prepared by:

_____
Signature over Printed Name, Title/ Designation
Date: _____

Name of Healthcare Facility

ALPHABETICAL LIST OF EQUIPMENT/ INSTRUMENTS

BSF Form No. _____

Equipment/ Instruments	Activity Number (S)	Activities
1. Agglutination viewer 1.1 For ABO/ Rh grouping and compatibility testing	3.3 – 3.4, 9.2, 10.2.21	1. Advocacy and health education and counseling: One-on-one or in group (s)
2. Air conditioning unit	1-10	2. Medical history and physical examination
3. #Apheresis machine with AVR		3. Pre-donation donor screening 3.1 Hemoglobin determination 3.1.1 $CuSO_4$ method 3.1.2 Cyanmethemoglobin method 3.2 Hematocrit determination 3.2.1 Microhematocrit method 3.3 ABO grouping (tube method) 3.3.1 Forward grouping 3.3.2 Reverse grouping 3.4 Rh grouping (tube method)
4. Autoclave	3, 4, 6, 7, 9.2, 10	
5. Balance 5.1 Analytical balance 5.2 Rough balance, top loading	3.1.1 3.1.1	
6. Barcoding machine	4.2	
7. Blood collection set 7.1 Blood collection couch or bed 7.2 Spring scale for blood units 7.3 Surgical instruments: forceps, scissors 7.4 Tube sealer 7.5 Tray carrier for blood units 7.6 Mechanical device for agitation of blood bags	4.1	4. Blood collection 4.1 Phlebotomy 4.2 Labeling 4.3 Post-donation care 5. Storage and transport of blood to testing blood bank/ center 5.1 Temporary storage of blood prior to transport 5.2 Packaging of blood units
8. Computer with printer, UPS, AVR, internet access	2, 6, 9, 10	
9. Centrifuge 9.1 Clinical centrifuge	3.3-3.4, 6.1-6.2, 6.3.2, 6.3.5, 10.2.2, 10.3	6. Post-donation testing 6.1 Repeat ABO grouping (forward and reverse, tube method)

Equipment/ Instruments	Activity Number (S)	Activities
9.2 Microhematocrit centrifuge with reader	3.2	6.2 Rh typing (tube method)
9.3 Refrigerated centrifuge with AVR	7.1	6.3 Tests for transfusion-transmissible diseases
		6.3.1 Malaria parasite
10. Freezer		6.3.1.1 Quantitative buffy coat method
10.1 Plasma freezer (-30°C) with AVR	7.1.3	6.3.1.2 Thick and thin smear
10.2 Ultralow freezer (-80°C) with AVR	7.1.4-7.1.5	6.3.2 Syphilis
10.3 Blast Freezer (-50°C)	7.1.3	6.3.2.1 RPR card test
		6.3.2.2 VDRL slide test
11. EIA equipment set with AVR	6.3.3-6.3.5	6.3.3 Hepatitis B surface antigen
11.1 Reader		6.3.3.1 Enzyme immuno-assay (EIA)
11.2 Washer		6.3.3.2 Immuno-chromatography assay
11.3 Incubator (including heating block)		6.3.4 Hepatitis C antibody
11.4 Printer		6.3.4.1 Particle agglutination (PA)
12. Generator (power)	4, 5, 6, 7, 10	6.3.4.2 Enzyme immuno-assay (EIA)
13. Laboratory oven (dry heat sterilizer)	6, 7, 10	6.3.5 HIV antibody
14. Microscope (binocular) equipped with:		6.3.5.1 Particle agglutination (PA) test
14.1 Oil immersion objective (OIO)	6.3.1.1	6.3.5.2 Enzyme immuno-assay (EIA)
15. Pipettor	6.3, 9.2, 10.2	
16. Plasma extractor	7.1.1, 7.1.3	
17. Plasma thawer	7.1.3	
18. Photometer		
18.1 Blood hemoglobin photometer (portable)	3.1.2	
18.2 Spectrophotometer	3.1.2	

Equipment/ Instruments	Activity Number (S)	Activities
19. Pyconometer for $CuSO_4$ method	3.1.1	7. Provision of whole blood and components
20. Red cell washer	3.3-3.4, 9.2, 10.2.2.1, 10.3	7.1 Preparation of components from whole blood by manual procedure, open or close system
21. Refrigerator	5, 7, 10	7.1.1 Red blood cell
21.1 Blood bank refrigerator controlled at 1-6 °C, with temperature recorder, alarm system and AVR		7.1.2 Platelet concentrate
		7.1.3 Fresh frozen plasma
		7.1.4 Cryoprecipitate
		7.1.5 Cryosupernate
		7.2 Collection of blood components by apheresis
21.2 Reagent refrigerator with laboratory thermometer and AVR	3, 6, 9.2, 10	7.3 Collection of blood for directed donations
22. Rotator		8. Validation and packaging
22.1 Serologic rotator (RPR or VDRL)	6.3.3-6.3.5	8.1 Counterchecking
		8.2 Packaging
22.2 Platelet rotator or agitator	7.1.2	9. Transport and issuance
23. Serofuge	3.3-3.4, 9.2, 10.2.2.1, 10.3	9.1 Computerization or documentation
24. Shaker for PA	6.3.3-6.3.5	9.2 Compatibility testing
		9.2.1 ABO grouping, tube method
25. Sphygmomanometer	2, 4	9.2.2 Rh typing, tube method
26. Spring scale	4.1	9.2.3 Cross matching, three phases
27. Stethoscope	2, 4	
		10. Special services for category B hospital-based BB/ BC only
28. Stopwatch or timer	9.2	10.1 Preparation of components
29. Tachometer	6.3, 7, 10	10.1.1 Washed RBC
		10.1.2 Leucocyte reduced RBC by filtration
30. Thermometer		
30.1 Clinical thermometer	2, 10.2.1	10.2 Investigation of transfusion reaction
30.2 Laboratory thermometer	5, 7	10.2.1 Clinical assessment
30.3 Room thermometer	1, 7, 10	10.2.2 Laboratory work-up

Equipment/ Instruments	Activity Number (S)	Activities
31. *TV monitor with video cassette player	1, 4	10.2.2.1 Repeat compatibility testing
32. Incubator		
32.1 Set at 56 °C for VDRL	6.3.2	10.2.2.2 Free hemoglobin and bilirubin determination in serum
32.2 Set at 37 °C for EIA	6.3.3-6.3.5	
32.3 Set at 37 °C for cross matching	9.2.3, 10.2.2.1, 10.3	
33. Weighing scale		
33.1 Calibrate up to 500 kilograms for donors	2	10.2.2.3 Free hemoglobin and hemosiderin determination in urine
33.2 Calibrated up to 500 grams for blood units	4.1	
		10.2.2.4 Bacteriologic examination of donor unit and recipient blood samples
		10.3 Antibody screening/ detection
		10.3.1 Direct and indirect antiglobulin tests
		10.3.2 Antibody identification

LEGEND

* Optional

\# Only for BB/ BC with component collection by aphresis

Retension of Blood Service Facility (BSF) Records

All records relevant to the operation of the Blood Service Facility (BSF) shall be kept for a minimum of 5 years or as required by law.

A. Records that should be retained for indefinite period include:

1. Blood Donor Session Records

1.1 Donor's identifying information
1.2 Medical history and physical examination
1.3 Written consent
1.4 Interpretations of laboratory screening tests
1.5 Status of deferral or notification to donors of permanent deferral

2. Blood Processing Records

2.1 Information to identify facilities that carry out any part of the preparation of blood components and functions performed
2.2 Information from any intermediate facility if it retains the units and identification of the collecting facility

3. Records of Blood and Components Received from Outside Facilities

3.1 Numeric or alphanumeric identification of blood units and identification of the collecting facility

4. Records of Disposition of Blood and Blood Components

4.1 Names, signatures, initials or identification code of those authorized to sign or initial or review reports and records

5. Therapeutic Apheresis Procedures and Donor Hemapheresis Clinical Records

6. Records of Issue for Transfusion

6.1 Notification to recipients of potential exposure to disease transmissible by blood
6.2 Record of notification to transfusing facility of previous receipt of units from donors subsequently found positive for HIV

7. Records of Patient with Adverse Transfusion rection

7.1 ABO and Rh types
7.2 Sever adverse reactions to donation transfusion

7.3 Compatibility test interpretation and clinically significant unexpected antibodies found in patients

B. Records that should be retained for five (5) years include:

1. Standard operating procedures

1.1 Technical manuals, procedures and publications done by the facility

1.2 Biosafety manual including procedures for biological, chemical safety and monitoring records of training and compliance

1.3 Documentation of staff qualifications and competency

2. Records of storage and inspection of blood and blood components

2.1 Blood and blood component inspection during storage and prior to issue

2.2 Storage temperatures and control testing

3. Records of quality control and quality assessment

3.1 Proficiency testing surveys and any corrective actions taken

3.2 Control testing of reagents and calibration of equipment and instruments

4. Records of voluntary blood donors who have been temporarily deferred for the protection of the potential recipient

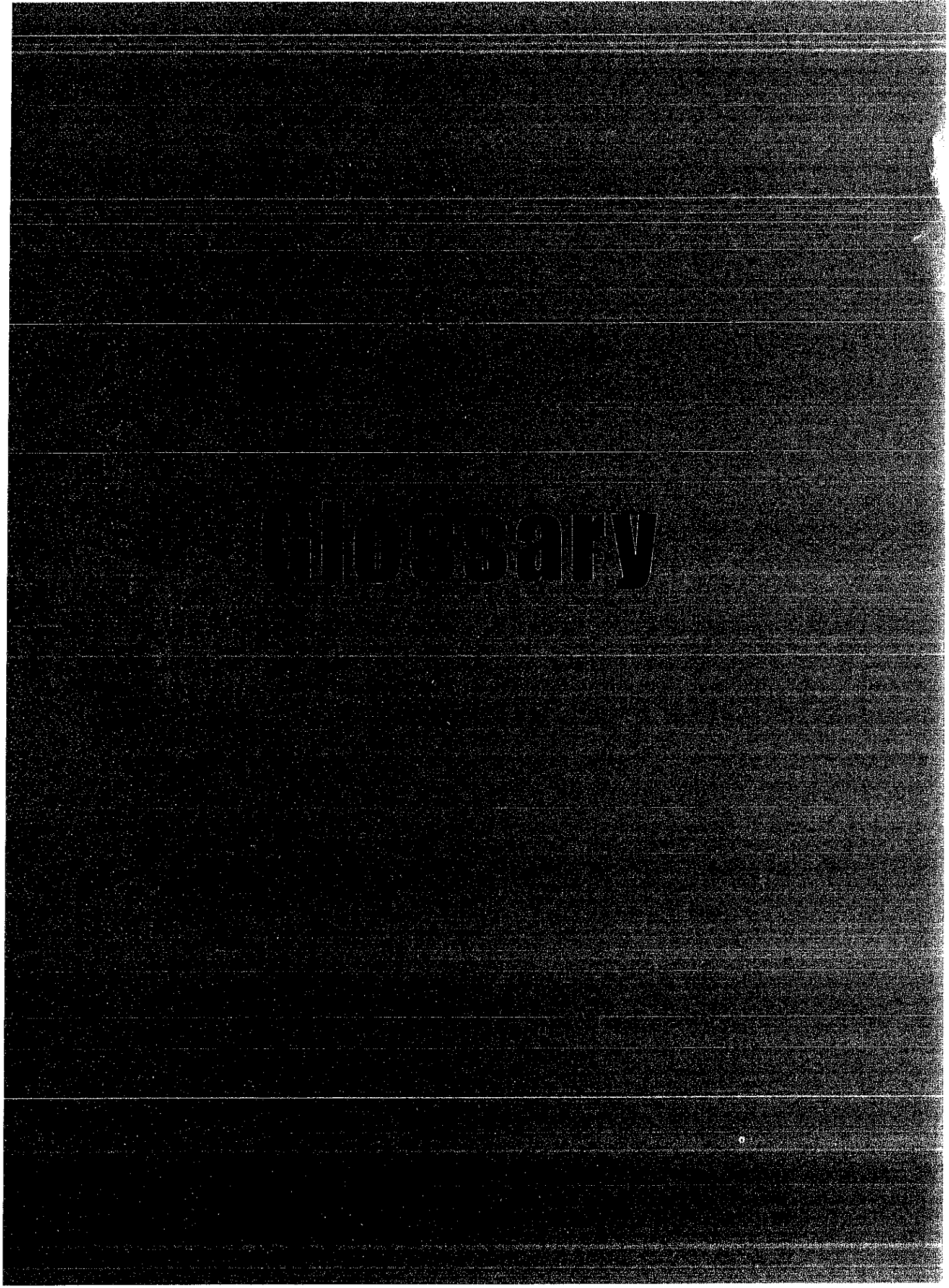
5. Records of all laboratory screening tests on blood samples of donors who are temporarily deferred

Abbreviations

Ab	Antibody
Ag	Antigen
ABD	Autologous Blood Donation
AIDS	Acquired Immune Deficiency Syndrome
AHF	Anti-Hemophilic Factor
AHG	Anti-Human Globulin
Anti-HBc	Hepatitis B Core Antibody
Anti-HBs	Hepatitis B Surface Antibody
A.O.	Administrative Order
AVR	Automatic Voltage Regulator
BB/ BC	Blood Bank / Blood Center
BCU	Blood Collection Unit
BP	Blood Pressure
BRL	Bureau of Research and Laboratory
BS	Blood Station
BSF	Blood Service Facility
CMV	Cytomegalovirus
CPD	Citrate Phosphate Dextrose anticoagulant
CPDA-1	Citrate Phosphate Dextrose Adenine-1 anticoagulant
CPDA-2	Citrate Phosphate Dextrose Adenine-2 anticoagulant
DAPE	Diploma in Applied Parasitology and Entomology
DOH	Department of Health
DMM	Diploma in Medical Microbiology
DTMH	Diploma in Tropical Medicine and Hygiene
D^u	D variant (weak D)
DPDP	Diplomate, Philippine Society of Pathologists
DTI	Department of Trade and Industry
EIA	Enzyme Immunoassay
ELISA	Enzyme-linked Immunosorbent Assay
EVF	Erythrocyte Volume Fraction
FASCP	Fellow, American Society of Clinical Pathology
FDA	Food and Drugs Administration
FPCP	Fellow, Philippine College of Physicians
FPSHBT	Fellow, Philippine Society of Hematology and Blood Transfusion
FPSP	Fellow Philippine Society of Pathologists
FFP	Fresh Frozen Plasma

GMP	Good Manufacturing Practices
GVHD	Graft-Venous-Host Disease
HBIg	Hepatitis B Immunoglobulin
HBV	Hepatitis B Virus
HBsAg	Hepatitis B Surface Antigen
HBTC	Hospital Blood Transfusion Committee
Hct	Hematocrit
HCV	Hepatitis C Virus
HCV Ab	Hepatitis C Virus Antibody
HIV	Human Immunodeficiency Virus
HIV Ab	Human Immunodeficiency Virus Antibody
Hgb	Hemoglobin
HLA	Human Lymphocyte Antigen
IEC	Information Education Communication
IgG	Immunoglobulin
IRR	Implementing Rules and Regulations
ITP	Immune Thrombocytopenic Purpura
KVA	Kilovolt Amperes
MBOS	Maximum Blood Ordering Schedule
MGM	Master in Government Management
NCBSTC	Nationa Council for Blood Services Technical Committee
NCR	National Capital Region
NKTI	National Kidney and Transplant Institute
NRL	National Reference Laboratory
NVBSP	National Voluntary Blood Services Program
OHFSR	Office for Health Facilities, Standards and Regulation
PA	Particle Agglutination Test
PAMET	Philippine Association of Medical Technologists
PBCC	Philippine Blood Coordinating Council
PBHBT	Philippine Board of Hematology and Blood Transfusion
PC	Platelet Concentrate
PRC	Philippine Red Cross
PRC	Professional Regulation Commission
PSHBT	Philippine Society of Hematology and Blood Transfusion
PSP	Philippine Society of Pathologists, Inc.
QA	Quality Assurance

QBC	Quantitative Buffy Coat
QC	Quality Control
R.A.	Republic Act
RBC	Red Blood Cells
RITM	Research Institute for Tropical Medicine
RMT	Registered Medical Technologist
RN	Registered Nurse
RPM	Revolutions per Minute
RPR	Rapid Plasma Reagin Card Test
SAG-M	Sodium Adenine Glucose-Mannitol anticoagulant
SLMC	St. Luke's Medical Center
SPPS	Stable Plasma Protein Solution
SOP	Standard Operating Procedure
STD	Sexually Transmitted Diease
SY	Syphillis
TB	Tuberculosis
TTI	Transfusion Transmitted Infections
UPS	Uninterrupted Power Source
VDRL	Venereal Disease Research Laboratory Slide Test
VNRBD	Voluntary Non-Remunerated Blood Donors
vWF	von Willerband Factor
WB	Whole Blood
WHO	World Health Organization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ADDITIVE SOLUTION. A solution added to whole blood used to extend its shelf life; usually contains adenine, dextrose and other nutritional components

ACT. Republic Act 7719 otherwise known as the ***"National Blood Services Act of 1994"***.

AGGLUTINATION. Visible clumping as evidence of the interaction of red blood cells with antibody directed towards the antigen on the red blood cells.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS). A set of serious clinical ailments resulting from severe immune dysfunction caused by infection with the human immunodeficiency virus (HIV)

ANTIGLOBULIN TEST. Detects antibody or complements bound to the red cell. Direct antiglobulin test is used to diagnose conditions in which the patient's red cells have been sensitized in vivo as in the hemolytic disease of the newborn, autoimmune hemolytic anemia, drug induced hemolytic anemia and transfusion reactions. The **Indirect antiglobulin method** is used to detect in vitro sensitization; and is used in antibody screening, phenotyping and crossmatching.

ANTIBODY. Proteins produced by the immune system in response to the presence of a foreign substance, an antigen or immunogen, with the capability to react specifically with the inducing antigen or immunogen.

ANTICOAGULANT. A substance used to prevent coagulation or clotting of blood

ANTIGEN. Foreign substance that may induce the immune system to produce antibodies. These antibodies specifically react with the antigen.

APHERESIS. Blood collection procedure in which whole blood is removed, a selected component separated and the remainder returned to the donor.

ANTI-HEMOLYTIC FACTOR. Also known as ***Factor VIII***, the coagulation factor deficient in Hemophilia A, usually prepared from plasma or pools of plasma and packaged in lyophilized form.

ATYPICAL ANTIBODY. Antibody to red cell antigens other than the natural or expected group ABO antibodies.

AUTOLOGOUS DONATION. A blood donation in which the donor and the recipient are the same person.

BAR CODE. A series of marks on preprinted packaging or labeling materials that may be visually inspected or read by an optical scanning device.

BIOHAZARD. Substance derived from biological sources such as blood or body fluid, capable of transmitting pathogenic organisms.

BLOOD. Refers to whole blood (WB) and not processed into products/ components.

BLOOD BAGS. Sterile, sturdy plastic bags containing anticoagulants which are especially designed for blood collection and transfusion. Blood bags can either be single or multiple types and have an integral sterile needle and collection tubing.

BLOOD BANK/ CENTER. A blood service facility with capability to recruit and screen blood donors, collect, process, store, transport and issue blood for transfusion and provide information and/ or education on blood transmissible diseases.

BLOOD BANKING EQUIPMENT. Essential laboratory machines, instruments and their accessories used in the different steps in the blood banking process such as those used to centrifuge blood or separate blood into its various components; preserve blood or blood components in cold storage or freezer; and perform blood tests such as hemoglobin tests and screening tests for blood transmissible diseases. These equipment also include those used in specific supportive processes such as sterilization and sanitary disposal of blood and blood products.

BLOOD COLLECTION UNIT. A blood service facility duly authorized by the Department of Health to recruit and screen donors and collect blood.

BLOOD COMPONENTS. Specific cellular or liquid products of human blood. The components are obtained by processing in the blood bank, such as centrifugation, precipitation, etc. Examples are red blood cells, FFP, cryoprecipitate, platelet.

BLOOD DERIVATIVES. Refer to blood products which are obtained from fractionation of plasma (Albumin, protein fractions, immunoglobulin, Factor VIII, etc.)

BLOOD COLLECTION COUCH. Blood collection couch is another term for Blood collection table or bed. It is a furniture upon which the donor sits or reclines during blood collection.

BLOOD PRODUCT. Any therapeutic substance prepared from human blood, includes both blood components and derivatives.

BLOOD SERVICE FACILITY (BSF). Any unit, office, institution providing any of the blood transfusion services, which can be a blood bank/ center category A and B (non-hospital and hospital-based), a blood collection unit or a blood station.

BLOOD TRANSFUSION SERVICES. A set of activities and functions related to blood transfusion such as, but not limited to, motivation and recruitment of

donors, blood collection, testing and screening of donor blood, preparation of blood products, storage and distribution of blood and products, inventory control and quality assurance.

BLOOD TRANSMISSIBLE DISEASES. Diseases which may be transmitted through blood transfusion, including, but not limited to HIV Infection, Hepatitis B, Hepatitis C, Malaria and Syphilis.

BLOOD STATION. A blood services facility which can be sited in either a government of private hospital or a Philippine Red Cross Chapter which has not been licensed as a blood bank/ center but has been authorized by the Department to store and issue blood and blood products, and whenever necessary perform compatibility testing, as in emergency blood transfusion.

CALIBRATION. A comparison of a measurement of a parameter on a piece of equipment with a standard measurement prescribed to ensure the proper function of the equipment.

CITRATE. Component of anticoagulant composed of citric acid and a base. Citrate binds calcium and prevents coagulation.

CITRATE PHOSPHATE DEXTROSE. Anticoagulant that is used in routine blood collection; allows a 21-day storage period.

CITRATE PHOSPHATE DEXTROSE ADENINE. Anticoagulant used in the routine blood collection; allows a 35-day storage period.

CLOSED SYSTEM. A mechanism in which the blood units are processed in plastic bags connected to satellite bag and sealed from the external environment preventing contamination.

COMPATIBILITY TESTING. Although this term is frequently used synonymously with crossmatching, it includes selecting the proper ABO group and Rh type and eliminating incompatible immunologic reactions through crossmatching.

COMPETENT. Capable to do a certain task or job according to set standards and standard procedures.

COMPETENCY ASSESSMENT. A method which documents the performance abilities of the personnel performing the various tasks within the blood service facility. Competency assessment/ testing programs should test technical skills and knowledge.

CONTROL. A device, compound or solution which has one or more accurately known characteristics and which is used for the purpose of verifying the accuracy and precision of measurements of these characteristics in unknown similar objects by being treated in the same manner as the unknown.

CROSSMATCHING. A test for blood group incompatibility in which the serum of the recipient is tested with the red blood cells of the perspective donor.

CRYOPRECIPITATE. The cold insoluble portion of fresh frozen plasma that is frozen and thawed under controlled condition.

CRYOSUPERNATE. A residual plasma refrozen after the removal of cryoprecipitate.

CYTAPHERESIS. The collection of specific blood cells, requiring an instrument capable of processing sufficiently large volumes of whole blood for a satisfactory yield of the desired component.

D (Rh_0). The major antigen in the Rh group system.

DECONTAMINATION. A procedure that eliminates or reduces microbial contamination to a safe level with respect to the transmission of infection.

DEPARTMENT. The Department of Health.

DIASTOLIC BLOOD PRESSURE. The blood pressure in a large artery during the period when the cavities of the heart dilate and fill with blood. This is the lower number in a blood pressure reading.

DISINFECTANT. An agent that kills microorganisms capable of producing an infection.

DISINFECTION. A procedure that kills pathogenic microorganisms but not necessarily their spores. Chemical germicides formulated as disinfectants are used on inanimate surfaces (medical devices, etc.) and should not be used on skin, tissue or any part of the body.

DISPOSAL. The act of eliminating or sequestering indefinitely or permanently either treated or untreated waste.

DONATION NUMBER. The unique identification number that is issued in advance for each blood donor which must be linked to the donor's name on the register, the donor's form, all blood bags, including satellite blood packs and all blood sample containers.

D^u. A weak phenotype of Rh_0(D) antigen of the Rh blood group system.

ELISA. An assay in which the antigen of antibody is bound to a solid support and unknown antibody or antigen in the specimen is then specifically bound and detected by an enzyme-substrate system.

ENDEMIC. A disease that is prevalent in a particular geographic area throughout the year.

ENZYME. An organic catalyst in a biochemical reaction. In the ELISA test, the enzyme acts upon a specific substrate to create a colored end product that is measured, and reflects the amount of enzyme bound in the reaction.

ERYTHROPOIESIS. The process of red blood cell production in the bone marrow.

EXTERNAL CONTROL. Control sera, with known values or reactivity, derived from source other than the test kit. These controls are included in test runs to monitor performance such as lot-to-lot variation, etc.

FRESH FROZEN PLASMA (FFP). The liquid portion of whole blood after separation from the cellular components which is frozen within 6 to 8 hours from blood collection to maintain viability of clotting factors. The product usually is about 250 ml in volume and is used to treat multiple clotting factor deficiencies.

FORWARD GROUPING. Test in which unknown red blood cells are mixed with antisera of known specificity to determine the presence or absence of antigens on the red blood cells. Agglutination with the reagent indicated the presence of the antigen.

HEMOLYSIS. The disruption of the red blood cell membrane resulting in a issuance of hemoglobin into the plasma or cell suspension medium.

HEMOVIGILANCE. Defined as the detection, gathering and analysis of information regarding untoward and unexpected effects of blood donation and transfusion

HEPARIN. An anticoagulant but not preservative; used when blood is to be filtered for the removal of lymphocytes.

HIGH-RISK BEHAVIOR. Refers to a particular behavior and lifestyle predisposing to the occurrence of a particular condition or illness.

HIV-1. Human Immunodeficiency Virus type 1, the causative agent of AIDS. Initially called HTLV-III or LAV

HIV-2. Human Immunodeficiency Virus Type 2, also associated with AIDS and sharing parial homology with HIV-1.

HIV POSITIVE. Refers to laboratory evidence of exposure to human immunodeficiency virus. Such people have had repeatedly reactive screening tests for HIV antibody and confirmed by supplemental tests for HIV antibody or persons positive for HIV antigen.

IMMUNE RESPONSE. The reaction of the body following an exposure to an antigen. This can result in either cellular response or the formation of antibody or both.

IMMUNOCOMPROMISED. Defect in immune system resulting in decreased resistance to infection or diminished immune response.

INCINERATION. Use of high temperature to convert combustible solid waste material into residual ash and gases, which are vented to the atmospheres. It is utilized as a treatment technique for almost all types of infectious waste.

INFORMED CONSENT. Refers to an agreement to testing which is obtained after informing the blood donors of processes involved in blood donation, including testing and reporting of positive test results. This is required by ethical rules and legal issuances.

IgG-SENSITIZED RED BLOOD CELLS. These are red blood cells coated with IgG used to confirm any negative antiglobulin test ant to evaluate the antiglobulin reagent.

IN-HOUSE CONTROL. Control sera of defined reactivity prepared in the investigator's own laboratory. In-house controls are often prepared by pooling several specimens together, determining the test result, and aliquoting for routing use as a control.

INTERNAL CONTROL. The positive and negative control sera included in a test kit.

INTERNAL QUALITY ASSESSMENT. Assessment of performance done by the staff within the BSF.

LEUCOCYTE-REDUCED BLOOD COMPONENT. A blood component that has a reduced number of leucocytes either by filtration, deglycerolization of frozen red cells, washing or centrifugation.

MALARIA. A parasitic disease caused by Plasmodia that can be transmitted by transfusion.

MEAN. In ELISA, the average value of a set of optical density (OD) readings or absorbance values and cut-off values (COV).

MOBILE BLOOD DONATION (MBD). A blood donation session conducted in a temporary site away from the location of the Blood Collection Unit or Blood Bank/ Center.

NORMAL SALINE SOLUTION (NSS). 0.9% Sodium Chloride solution.

OPTICAL DENSITY. The units expressed by a spectrophotometer or an ELISA reader representing the quantity of light adsorbed by the colored end product of the reaction.

OD/ COV RATIO. The test optical density (O.D.) reading divided by the cut-off (C.O.) value of that run.

OPEN SYSTEM. A procedure in which the transfer container, not integrally attached to the blood pack is used to obtain a component from the blood pack. The blood pack is breached resulting in potential or actual contamination. The shelf life is 24 hours after the procedure.

PACKED RED BLOOD CELLS (PRBC). Blood component consisting mainly of red cell mass produced when most of the plasma is removed following sedimentation or centrifugation.

PARALLEL TESTING. A comparison of performance of new lots of kits with the previous lots done at the same time and utilizing common control material. Parallel testing is also performed on serial samples to obtain results on the same run for comparison.

PHENOTYPE. The detectable or expressed characteristics of genes.

PHERESIS. See Apheresis.

PHLEBOTOMY. The process of withdrawing blood from the circulatory system from a vein.

PLASMA. The fluid component of uncoagulated blood after cells are removed.

PLASMA DERIVATIVE. Human plasma proteins prepared under pharmaceutical manufacturing conditions, such as: albumin, coagulation factor concentrates, and immunoglobulins.

PLAMAPHERESIS. A pheresis procedure in which plasma is removed from whole blood with the cellular elements returned to the donor.

PLATELET CONCENTRATE. A blood component which contains platelets as the major cellular element. It is prepared from plasma by differential centrifugation or obtained direct from the donor by apheresis.

PREDEPOSIT AUTOLOGOUS DONATION. Donation of one or more units of blood prior to an elective surgical procedure by a person for his or her use during or after the procedure.

PROFICIENCY TESTING. External evaluation of performance by the use of unknown test samples.

PYCNOMETER. A device used to measure the specific gravity of Copper Sulfate solution.

PYROGEN-FREE. Free from fever-producing protein substances of antibodies.

QUALITY. The consistent and reliable performance of services and manufacture of blood products in conformity with the specified standards.

QUALITY ASSURANCE (QA). The combination of activities necessary for every blood service facility to ensure quality blood products and quality blood services for their patients, donors, fellow employees, hospitals, doctors, the community, and the regulatory agencies. It is a part of the broader and continuous quality improvement process which ensures that quality will benefit the organization and its end-users.

QUALITY CONTROL (QC). Part of the quality assurance system which consists of retrospective tests or other measures that should provide satisfactory results before proceeding further in a given process and which demonstrates compliance to certain defined limits and specifications.

QUARANTINE. The sequestration of materials and blood products, whether physically or by a system, while awaiting a decision on their suitability for further processing or use.

REAGENTS. Substances employed to detect or measure another substance or convert one substance to another by means of the reaction that it causes. In blood banking, the reagents used are those necessary to measure hemoglobin; screen for blood transmissible diseases such as HIV, hepatitis, malaria, syphilis, among other; identify blood groupings; and perform crossmatching and other immunohematologic examinations.

RECIPIENT. The person or a patient who receives a transfusion of whole blood or its products.

Rh FACTOR. A blood group antigen, named after Rhesus monkey, originally identified because and antibody agglutinated the erythrocytes of all rhesus monkeys, 85% of Caucasians and over 99% of Asians.

Rh NEGATIVE. A blood type characterized by the absence of D (Rh_o) antigen and its variant D^U from the surface of red blood cells.

Rh POSITIVE. A blood type characterized by the presence of D (Rh_o) antigen and its variant D^U from the surface of red blood cells.

RETROVIRUS. Virus that uses an enzyme reverse transcriptase to transcribe an RNA genome into DNA.

REVERSE GROUPING. Serologic test in which serum containing unknown ABO antibody(les) is tested with red blood cells or known ABO group A, B and sometimes A_2 red blood cells are used.

SECRETARY OF HEALTH. The Secretary of Health or any other person to whom the Secretary delegates the responsibility of carrying out the provisions of this Act.

SENSITIVITY. The capacity of a procedure to diagnose a positive case as postitive (very low false positive); also the ability of the reagent or test to detect very small amounts of analyte, or the ability of a reagent or test to detect all or most infected individuals correctly.

SERUM. The straw-colored fluid remaining when blood has clotted and cellular components are separated.

SPECIFICITY. The ability of a procedure or reagent to identify all negative correctly (very low false postitive).

SPECTROPHOTOMETER. The instrument used to measure absorbance of light at a specific wavelength.

SPHYGMOMANOMETER. An instrument used to obtain a person's systolic and diastolic blood pressure.

STANDARD OPERATING PROCEDURES. The enumeration of steps in a procedure. A set of documents or detailed protocols of procedures performed within the laboratory / blood bank which should be compiled in a Manual.

STARTING MATERIAL. The starting material for component preparation is whole blood or the products of apheresis collected from donors.

STERILE. Free from viable microorganisms.

STERILIZATION. A procedure that effectively kills all microorganisms including bacterial spores.

SYMPTOM. A subjective complaint by the patient usually indicating a disturbance of body function, a disorder or disease.

SYSTOLIC BLOOD PRESSURE. The blood pressure in a large artery during which the heart is contracting to propel blood to the circulatory system. The upper number of a blood pressure reading.

TEST RUN. A group of specimens processed together with the reagent and in-house controls in one batch.

THERAPEUTIC PHLEBOTMY. Removal of blood from a vein for treatment purposes, as in the case of polycythemia.

TRANSFUSION. The administration of blood or blood component to person through the intravenous route.

TRANFUSION REACTION/ COMPLICATION. Any adverse reaction following the infusion of blood or blood component.

VACCINE. Any preparation intended for active immunological prophylaxis.

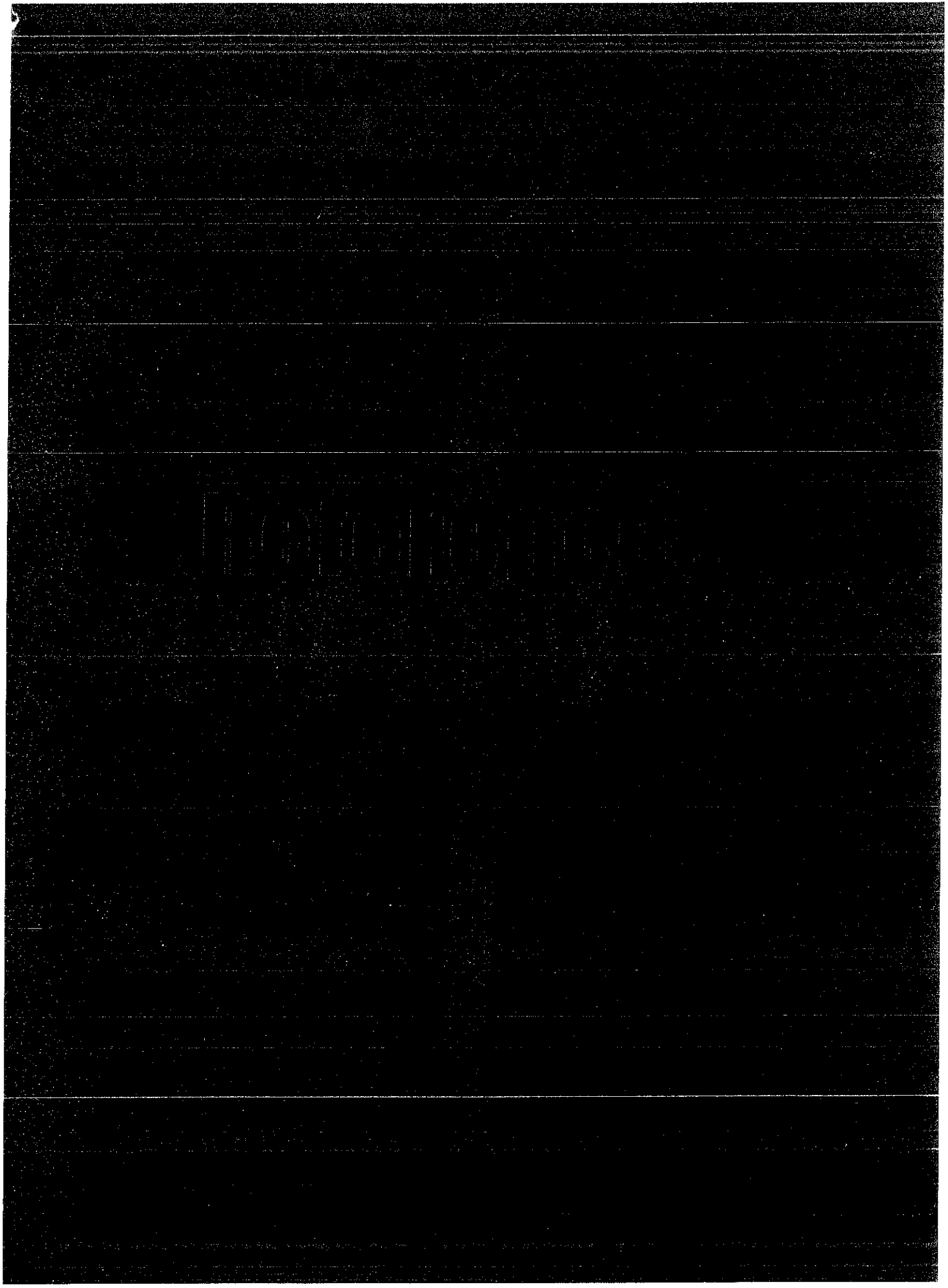
VALIDATION. A procedure that shows a piece of equipment of process does what it is supposed to do. It assures that a process will consistently procedure a product according to requirements.

VENIPUNCTURE. See Phlebotomy.

VOLUNTARY NON-REMUNERATED BLOOD DONOR (VNRBD). An individual who donates blood on one's own volition or initiative and not induced, directly or indirectly, in any manner whatsoever, by any monetary compensation nor blood relations/ obligations.

WASTE. A useless or worthless byproduct, as from a manufacturing process. This refers to waste generated by the BSF, and are classified into hazardous and non-hazardous.

WHOLE BLOOD. A unit of blood not further processed, containing all the cellular and liquid components, collected into an approved container containing an anticoagulant-preservative solution. See Blood.



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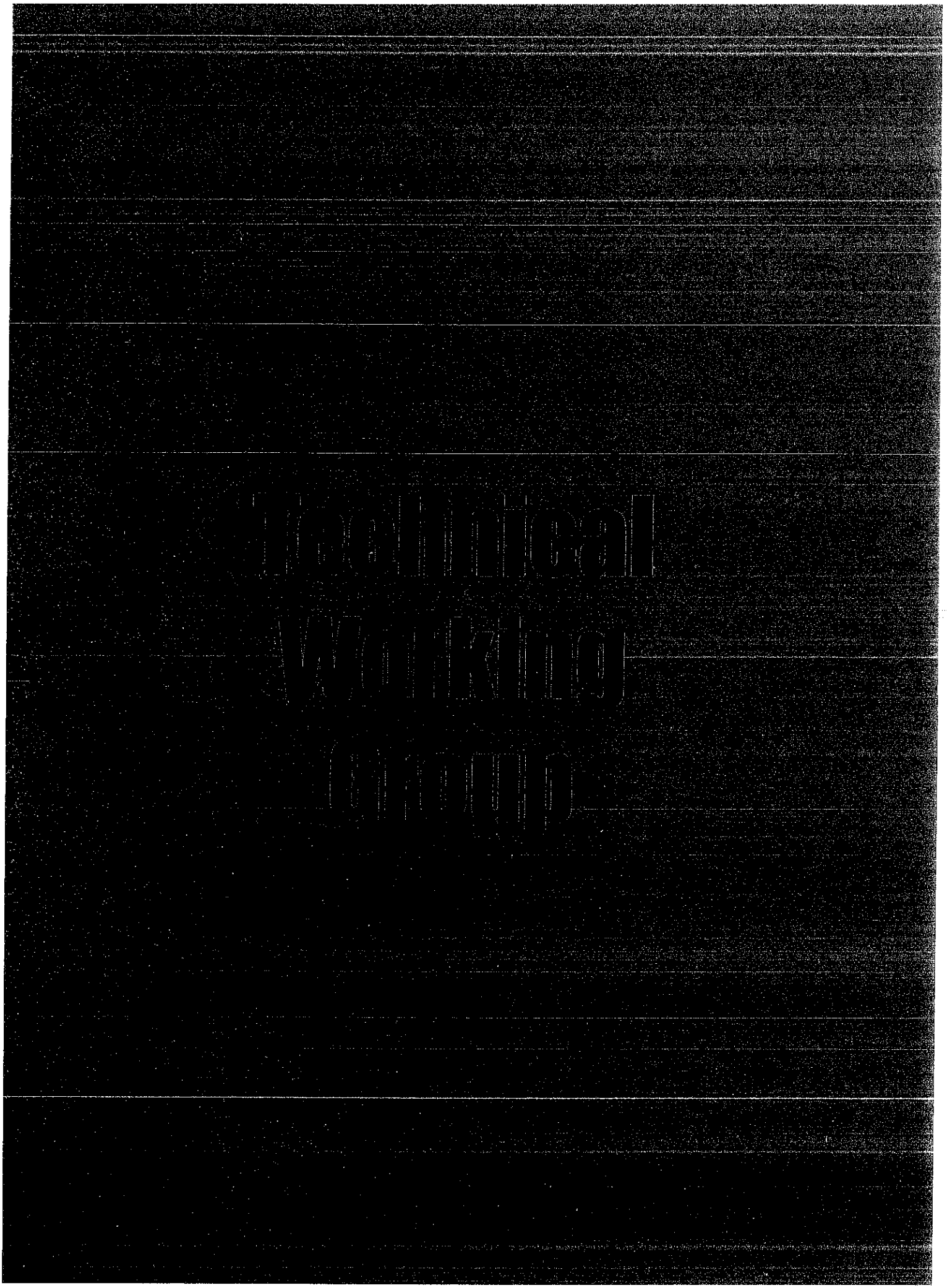

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