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TECHNICAL STANDARDS GOVERNING COLLECTION, PROCESSING, AND OPERATION OF BLOOD BANKS

BRL BUREAU ORDER NO. 5, S. 1990, January 15, 1990

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Pursuant to the provisions of Section 8 of Administrative Order No. 57, s. 1989, otherwise known as "Revised Rules and Regulations Governing the Collection, Processing and Provision of Human Blood and the Establishment and Operation of Blood Banks", approved on January 3, 1989 and which took effect on February 14, 1989, the following Technical Standards are hereby adopted:

SECTION 1. Title — These requirements shall be known as the "Technical Standards Governing the Collection, Processing and Operation of Blood Banks in the Philippines".

SECTION 2. Authority — These Technical Standards are issued to implement R.A. 1517, (Blood Bank Law) with its Revised Rules and Regulations (A.O. 57, s. 1989) consistent with E.O. 119, s. 1987 (Reorganization Act of the Ministry of Health).

SECTION 3. Purpose — These Standards are promulgated to enable the Bureau of Research and Laboratories, DOH, to evaluate compliance with such technical standards as requirements for the issuance of a license and to prevent the operation and maintenance of sub-standard, improperly managed and poorly equipped Blood Banks and evaluate the quality of blood banking services and blood products.

SECTION 4. Scope — These Standards embodied herein shall apply to Primary, Secondary and Tertiary Category of Blood Banks, non-hospital (free-standing) and those in all government and private hospitals in the Philippines.

SECTION 5. Service Capabilities — These Standards are the minimum services required for each respective category of blood banks, hospital and free standing, and shall be:

Primary Category

1. Donor screening and selection
2. Collection and processing of blood
3. Storage of blood
4. Transport and issuance of blood
5. Compatibility testing (for hospital-based blood banks)

Secondary Category

1. Services required for Primary Category
2. Provision for packed red cells, plasma, and platelet rich plasma
3. Investigation of transfusion reactions (for hospital-based blood banks)

Tertiary Category

1. Services required for Primary Category
2. Services required for Secondary Category

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3. Provisions for blood components, products, or derivatives not included in Secondary Category
4. Investigation of incompatible crossmatches (for hospital-based blood banks)

SECTION 6. Technical Requirements to Show Compliance with the Standards

I
Head

The Blood Bank shall be under the competent supervision and management of a physician, licensed and duly registered with the Board of Medicine (Professional Regulation Commission or PRC) and duly authorized by the Undersecretary of Health for Standards and Regulation.

1. For all categories of Blood Banks, the Head shall be a licensed physician certified by the Philippine Board of Pathology in Clinical Pathology or Blood Banking, or by the Philippine Board of Hematology and Blood Transfusion in Blood Banking provided that:

1.1

This shall be mandatory for all categories of free-standing Blood Banks and all secondary and tertiary categories of hospital Blood Banks.

1.2

This shall be voluntary for all primary category hospital Blood Banks. Blood Banks unable to comply with the above requirements may be headed by a licensed physician who has completed at least three (3) months of training in Blood Banking including quality control and laboratory management in an acceptable institution and passed an examination given by the Bureau of Research and Laboratories.

2. A certified Clinical Pathologist or Hematologist may be authorized to head and manage not more than two (2) blood banks.

3. A Physician under Sec. 6 paragraph 1.2. may be authorized to head only one (1) hospital blood bank (primary category).

II
Personnel

The Blood Bank shall be adequately staffed by qualified and trained personnel, with at least one (1) Medical Technologist registered with the Board of Medical Technology (PRC).

1. Primary category hospital-based and free-standing Blood Banks shall have at least one full time qualified Medical Technologist licensed and registered with the Board of Medical Technology, competent in performing phlebotomy, compatibility, and serology testing.

2. Secondary and tertiary category Blood Banks shall employ in addition to this Medical Technologist, at least one more personnel who shall be limited to performing non-technical activities.

3. The Head of the Blood Bank shall employ more than the above minimum depending on the requirements and needs of the laboratory with at least one more set of minimum required personnel in numbers 1 and 2 [above] for every additional 100 “U” of blood serviced or additional 500 blood typing, collection, screening and cross-matching examinations for month.

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4. There shall be at least one qualified Medical Technologist available at all hours of laboratory operation. During blood collection there shall be at least two (2) Blood Bank staff in attendance.

5. Work assignments shall be consistent with the qualifications of the personnel.

6. An orientation shall be provided for each new laboratory personnel, whose participation shall be documented.

III
Physical Facilities

The physical plant shall be housed in well-lighted and ventilated, dust-free areas with an adequate supply of water. The space shall be sufficient to accommodate the various activities of the Blood Bank.

1. The minimum working or technical area of the Blood Bank shall be:

Hospital

Free-standing

Primary Category

20 sq. m

30 sq. m.

Secondary Category

30 sq. m.

40 sq. m.

Tertiary Category

40 sq. m.

50 sq. m.

2. It shall be solely for the use of the Blood Bank and its related activities.

IV
Equipment Furniture

The Blood Bank shall have the equipment and furniture needed to undertake the required services.

Primary Category

Blood Pressure apparatus Stethoscope

Weighing scale for blood donors Thermometer,

Centrifuge, clinical, or serofuge clinical, and

Microscope laboratory (0-100ºC)

Blood Collection Equipment/ instruments Emergency medical kit

- Bleeding table Refrigerator,

- Spring scale for blood units thermostatically

- Tube sealer controlled at 4º to 6ºC

For Primary Category Hospital - Blood Banks:

- Water bath or dry incubator controlled at 37ºC

Secondary Category

Blood Pressure apparatus Stethoscope

Weighing scale for blood donors Thermometer, clinical and laboratory (0-100ºC)

Microscope Emergency medical kit

Blood Collection equipment/ instruments Centrifuge, clinical Serofuge

- Bleeding table Refrigerator, thermostatically

- Spring scale for blood units controlled at 4ºC to 6ºC

- tube sealer Rh viewer or test tube agglutination viewer

Water bath or dry bath incubator controlled at 37ºC Plasma extractor

Tertiary Category

Blood Pressure apparatus Stethoscope

Weighing scale for blood donors Thermometer, clinical and laboratory (0-100ºC)

Microscope Emergency medical kit

Blood Collection Equipment/ Centrifuge, clinical

instruments Serofuge

- Bleeding table Refrigerator, thermostatically

- Spring scale for blood units controlled at 4ºC to 6ºC with sensor Blood

- tube sealer Bank refrigerator

Water bath or dry bath Rh viewer or test tube agglutination viewer

incubator controlled at 37ºC Plasma extractor

Refrigerated centrifuge Storage freezer (-70ºC)

V
Glasswares/Reagents/Supplies

The Blood Bank shall have the glasswares, plastic blood bags, reagents and other supplies needed to undertake the required services.

1. All containers and anti-coagulants used for the preservation and storage of blood and blood components and all required reagents used for testing of blood samples shall at least meet the standards prescribed by the BRL or BFAD as appropriate.

2. The glasswares, reagents, and supplies shall be according to the type of services offered and the volume of work of the Blood Bank.

VI
Donor Requirements (Screening)

Determination of the suitability of the donor shall be the responsibility of the Head of the Blood Bank and shall be done by him or under his supervision with the assistance of the necessary trained personnel.

Blood donors shall be in good physical condition and free of diseases transmissible by blood transfusion as far as can be determined from the donor's personal history and from such physical examination and laboratory tests as prescribed by the Bureau of Research and Laboratories.

1. Procedures to be used for donor screening shall include a problem oriented history, physical examination, routine and other necessary laboratory tests required by the BRL or deemed necessary by the Head of the Blood Bank.

2. A potential blood donor may give blood provided the donor has/is:

2.1 Male or female in good heath
2.2 a body weight of 45 kgs (100 lbs.) or over
2.3 16-65 years old
2.4 A blood pressure below 160/100
2.5 A body temperature below 37.5ºC

2.6 No history of contagious diseases like hepatitis, malaria, tuberculosis, etc.

3. Prospective Donor conditions precluding donation of blood at the time of evaluation:

a. One or more of the following conditions shall preclude donation at the time of evaluation

- Known existing pregnancy

- History of viral hepatitis

- History of close contact with a person with viral hepatitis during the preceding six (6) months

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- History of having received blood or blood components or derivatives in the preceding six (6) months known to be possible sources of hepatitis

- Positive history, clinical symptoms, or positive serologic test for syphilis

- Infection with Human Immunodeficiency Virus (HIV)

- Admission in confidence by prospective donor of unsuitability of blood to be collected for transfusion

- Pulse rate of more than 100 beats/minute or less than 40 per minute (in a non-athlete) taken for two minutes

- Temperature 37.5ºC (99.5ºF) and above taken orally

- Unexplained weight loss of more than 4.5 kg. or 10 lbs. within preceding three months

- Presence of skin lesions at venipuncture site

- Persons with obvious stigmata of narcotic or alcohol habituation or intoxication

- Hemoglobin less than 125 gms/1 (by fingerprick) or venipuncture

- Reactive test for Hepatitis-B Surface Antigen (HbsAg)

b. The following conditions preclude donation until after a definite time interval:

- Within one (1) week after pheresis

- Within two (2) weeks after poliomyelitis, measles, mumps and yellow fever immunization

- Within two (2) weeks after diphteria, pertussis, tetanus and typhoid immunization

- Within eight (8) weeks after immunization against diphtheria or German measles

- Within twelve (12) weeks (3) three months of donation of full unit (500 ml) of blood

- Within six (6) months following full term or third trimester delivery

- Within six (6) months after undergoing a major operation

- Within six (6) months after sojourn in an area considered endemic for malaria by DOH provided that:

    a. Prospective donor was a permanent resident of NON-ENDEMIC area.

    b. He has been asymptomatic for the preceding six (6) months

    c. He has not taken anti-malarial prophylaxis for the preceding six (6) months.

- Within six (6) months of an emergency transfusion

- Within six (6) months of tattooing of skin and ear piercing (non-medical ear-holing)

- Within twelve (12) months or one (1) year after rabies vaccination

- Within twelve (12) months or one (1) year after Hepatitis B Immunoglobulin injection

- Within three (3) years after clinical malaria in a prospective donor who has become asymptomatic

- Within three (3) years after permanent residency in an ENDEMIC AREA and having no anti-malarial prophylaxis and symptoms

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c. The following conditions or findings need further evaluation by the Head or a qualified Physician:

- History and physical examination evidence of probable cardiac and pulmonary malignant disease or blood dyscrasia

- Current drug (i.e. digitalis, beta blockers, antibiotics or anticoagulant) therapy known to have deleterious effect on either donor or recipient

- Donors older than sixty five (65) years old or younger than sixteen (16) years old

- Donors who have a high exercise tolerance with a slow pulse rate (athlete)

- Blood pressure reading above 160/100 or below 90/60 mm. Hg

- Donors weighing less than fifty (50) kg. but not less than 45 kg. shall be bled 300 ml

- Persons at risk of contracting AIDS (Acquired Immunodeficiency Syndrome)

d. Donor requirements for preparation of blood components.

- Restrictions in 3.b.9 and 3.b.15 are not necessary when donation [above] is to be used for the preparation of plasma components or derivatives devoid of RBC.

- Ingestion of acetylsalicylic acid — containing medication within three (3) days of donation shall preclude use of a donor as the source of platelet preparation for a patient.

4. Information to the Donor

a. The donor shall sign the Consent Form provided by the blood bank.

b. Minors below 18 years old need the written consent of a parent/guardian before donating blood.

c. Significant abnormalities detected during pre-donation evaluation or laboratory testing precluding actual blood donation shall be communicated by a responsible member of the blood bank's staff to the donor.

d. Any donor found to be positive during pre- and post-donation evaluation and screening should be informed or properly advised and counselled to seek evaluation by a physician.

e. Donor must be instructed on the precautions to be observed after blood donation.

VII
Collection of Blood/Labeling

A. Collection of Blood — Blood shall be aseptically collected by a trained Phlebotomist under the supervision of a licensed, qualified Physician.

1. Methods The removal of blood from the donor shall be by aseptic methods using a sterile, closed system and a single venipuncture.

2. Protection against contamination

2.1

The donor as well as the future recipient shall be protected by proper preparation of the skin at the site of the venipuncture. If more than one skin puncture is needed, another set and container must be used.

2.2

At the time of collection the integral donor tubing must be filled with anticoagulant blood and sealed in such a manner that it will be available for subsequent tests for serologic incompatibility and infectious diseases.

2.3

The integral donor tubing segments must be separable from the container without breaking the sterility of the container.

3. Donor reactions

3.1

Specific instructions concerning procedures to be followed for prevention and treatment of donor reactions, together with the necessary equipment and supplies shall be available.

3.2

There shall be provisions for medical care for donors who sustain adverse reactions.

4. Anticoagulants and additives

4.1

Anticoagulants and additives shall be in the prescribed amounts in relation to the volume of blood to be collected:

4.1.1 If 300 to 405 ml. have been collected into an anticoagulant volume calculated for 450 ml., the Red Blood Cells may be used for the transfusion if a label is affixed stating:

> "Low Volume Unit", ____ml. Red Blood Cells. Computed from:
>
> vol. of blood in bag x hematocrit = ___ ml. red blood cells

4.1.2 If less than 300 ml. of blood is collected, it may be used for transfusion purposes if collected in a proportionately reduced volume of anticoagulant.

4.2

Other blood components shall not be made from low volume units.

5. Temperature

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5.1

Immediately after collection, the blood shall be placed in storage at a temperature between 4o C to 6o C, unless it is to be used as a source of platelets.

5.2

If the blood will be used as a source of platelets, it shall be placed in storage at a temperature of about 20o C to 24o C until the platelets are separated, but for no more than six (6) hours.

6. Reissued Blood. Blood that has been returned to the Blood Bank shall not be reissued unless conditions set by the BRL as enumerated in the App. E Reissuing of Blood.

B. Labeling — The original label and added portions of the label shall be attached firmly to the container and shall be in clear, readable type.

- Labeling requirements do not preclude the use of a single facility label that includes the applicable information on:

a. Labeling at Collection or Preparation
b. Labeling prior to Issue
c. Special Requirements for Component Labels

Hand-written additions or changes shall be legible and in permanent moisture-proof ink.

- Before the final label is applied, records must be examined to ensure that blood and component from unsuitable donors will not be distributed.

1. Blood Unit Identification: a numeric or alphanumeric system shall be used that will make it possible to trace any unit of blood or component from the source to final disposition and to recheck records applying to the specific unit, including investigation of reported adverse reactions.

- The unique numeric or alphanumeric identification must be affixed by the collecting facility to each unit of blood, its components and attached containers. THIS NUMBER SHALL NOT BE OBSCURED, ALTERED, OR REMOVED BY SUBSEQUENT FACILITIES.

- The transfusing facility may assign or affix a local numeric or alphanumeric identification of the unit of blood or components when it so desires. THIS MUST NOT OBSCURE OR ALTER THE IDENTIFICATION FROM THE COLLECTING FACILITY.

2. Labeling at collection or preparation: At the time of the collection of the blood or the preparation of a blood component the label shall have at least the following information:

- Name of whole blood or component

- The numeric or alphanumeric identification

- Except for components made by hemapheresis, the name of the anticoagulant and the approximate amount of blood collected

- The approximate volume of the components in platelets, low volume red blood cells, fresh frozen plasma, liquid plasma, pooled components and components made by hemapheresis

3. Labeling prior to issue. The final label must indicate at least the following information:

- Temperature of storage

- Expiration date

- Identification of the collecting facility or of the facility preparing the final component

- ABO or Rh types

- Instructions to the transfusionist, i.e.
— "See Circular of Information for the Use of Human Blood and Blood Components"
— "Properly Identify Intended Recipients"

4. Special Requirements for Component Labels

1. The label for pooled components must comply with requirements in B-3, Labeling Prior to Issue, and have the following information:

1.1

Name of the pooled component

1.2

Unique numeric or alphanumeric identification of the pool. Identification of each unit in the pool must be part of the record.

1.3

Number of units in the pool must be indicated on the label or attached tie-tag

1.4

ABO and Rh types, if all units in the pool are the same type or when a pool contains more than one type, the label indicates the types contained in the mixture

1.5

Final volume of the pooled component.

2. Rh type is not required for Liquid Plasma, Plasma, Fresh Frozen Plasma or Cryoprecipitated AHF.

3. Anticoagulant need not be named on Cryoprecipitated AHF label.

4. The labels for frozen, deglycerolized, rejuvenated Washed Red Cells need not indicate the type of anticoagulant in the original whole blood unit.

VIII
Screening of Donor

Blood/Storage of Blood

A. Screening Test for Donor Blood — The following screening tests should be performed on donor blood by each Blood Bank.

ABO Grouping, Tests for Syphilis, Hepatitis B Surface Antigen, Human Immunodeficiency Virus (HIV) antibody and detection of malarial parasites.

1. ABO group

1.1 ABO Group determined by:

— testing the red blood cells with anti-A and anti-B sera which meet BFAD standards and,

— testing the serum or plasma with a pool of known group A cells (or a mingle subgroup A) and known B cells.

1.2 The blood shall not be labelled unless the tests are in agreement and all discrepancies are resolved.

2. Test for syphilis

2.1 An acceptable serologic test for syphilis shall be done.

2.2 Serologic reactive blood must not be issued for transfusion.

3. Test for Hepatitis B Surface Antigen (HbsAg)

- All donor blood shall be tested for HbsAg using acceptable technique and reagents.

- No HbsAg reactive blood or component must be issued for transfusion.

4. Test for Human Immunodeficiency Virus (HIV) Antibody

4.1 Blood shall be screened for HIV antibody as prescribed by the Bureau of Research and Laboratories using one of the following:

1. Enzyme Immunoassay (EIA)

2. Particle Agglutination (PA)

3. Other BFAD approved screening tests for HIV Antibody

4.2 Seropositive samples are handled in accordance with the Rules and Regulations governing the Accreditation

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of Laboratories Performing HIV Testing (A.O. #55-A, s. 1989)

4.2.1 All serum samples reactive in screening tests (EIA or PA) by private laboratories shall be referred to the Research Institute for Tropical Medicine for confirmation.

4.2.2 All serum samples reactive in screening tests (EIA or PA) by government laboratories shall be referred to the Bureau of Research and Laboratories for confirmation.

4.2.3 The names, age, sex, and address of persons confirmed to be seropositive (by WB/IF/RIPA) shall be reported to the AIDS Registrar, Health Intelligence Service, DOH, in accordance with Department Circular No. 11, s. 1987 dated March 11, 1987.

4.2.4 Such person shall be informed of the implication of a seropositive test and the requirement of a confidential report to the AIDS Registry.

4.3

No sero-reactive unit of blood/product must be issued for transfusion.

5. Test for Malarial Parasites

5.1

Screening for and identification of malarial parasites shall be done using thick and thin blood smears.

5.2

Experienced and trained personnel are necessary for the proper identification of parasites in Wright's or Giemsa stained specimens.

6. Repeat Testing

6.1

The Blood Bank performing the compatibility test must confirm the ABO Group of Donor Cells obtained from the integral segment of all units of whole blood or red blood cells and the Rh type (D and Du) of all (D) negative units of whole blood or red blood cells.

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6.2

Discrepancies shall be resolved before the unit is issued for transfusion.

6.3

Repeat testing for atypical antibodies, HbsAg, or Syphilis is not required.

7. Rh Type

ROUTINE TESTING FOR Rh (D) ANTIGEN IS NOT MANDATORY.

8. IN AN EMERGENCY, BLOOD OR BLOOD COMPONENTS MAY BE ISSUED BEFORE TESTING FOR THE ABOVE-MENTIONED TESTS FOR SYPHILIS, HbsAg, HIV AND MALARIAL PARASITES ARE PERFORMED, PROVIDED THAT THE REQUESTING PHYSICIAN SIGNS AN EXPLICIT REQUEST AND ASSUMES THE RESPONSIBILITY FOR NECESSITY OF THE EMERGENCY TRANSFUSION. IF TEST IS SUBSEQUENTLY REACTIVE, THE RECIPIENT'S PHYSICIAN MUST BE NOTIFIED IMMEDIATELY.

9. Previous Records: a donor's previous record or ABO group and Rh type shall not serve for identification of units of blood subsequently given by the same donor. Determination of ABO and Rh type shall be made after each collection.

10. Retention of Blood Samples: processing samples shall be stored at 4º to 6ºC for at least seven (7) days after transfusion. When the unit of blood is discarded, the processing sample need not be saved.

11. Laboratory Records. All actual results of various screening and compatibility tests, as well as the final interpretation shall be recorded.

B. Storage of Blood and Components — Blood shall be stored properly in order to maintain hemoglobin function and viability of the stored red blood cell mass. The following are the requirements to be observed by the Blood Banks. There should be written standard operating policies, procedures and instructions for record keeping for monitoring storage and transport conditions.

1. Whole Blood

1.1

The blood shall be primarily collected into an appropriate sterile anticoagulant-preservative solution that prevents the blood from clotting and provides proper nutrients for continuing metabolism in the red blood cells.

1.2

Whole blood and stored liquid red blood cells shall be stored at a temperature of 4º — 6º C in order to maintain the delicate biochemical balance of the elements of blood.

1.3

During transport, it shall be refrigerated at 4º to 6ºC.

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1.4.

To ensure the continued sterility of blood during storage, procedures for routine inspection of stored blood for bacteriologic studies of blood in an open system and for the re-issuance of blood shall be written and instituted.

1.5.

Expiration

1.5.1.

When stored in a blood bank refrigerator:

ACD (Acid Citrate Dextrose)
CPD (Citrate Phosphate Dextrose) 21 days after phlebotomy
CPDA (Citrate Phosphate Dextrose with Adenosine) 28 days after phlebotomy

1.5.2.

When stored in an ordinary household refrigerator properly controlled and monitored between 4º to 6ºC:

ACP (Acid Citrate Dextrose)
CPD (Citrate Phosphate Dextrose) 10 days after phlebotomy
CPDA (Citrate Phosphate Dextrose)
with Adenosine) 14 days after phlebotomy

1.5.3

Red blood cell components shall have the same expiration as the whole blood from which it was derived.

2. Platelet/s concentrate. If stored in an air-conditioned room or environment (20-24ºC), continuous gentle agitation of the platelets shall be maintained throughout the storage period.

Expiration: 72 hours when kept in an air-conditioned room with continuous gentle agitation if prepared in a closed system (20º-24ºC). 6 hours if kept at ordinary room temperature.

3. Cryoprecipitate. This component, if maintained constantly in the frozen state at -30ºC shall be stored no longer than twelve (12) months from the date of phlebotomy.

4. Plasma: Liquid Plasma. Liquid plasma may be stored between 4º and 6ºC for no more than five (5) days

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following expiration of whole blood from which it was processed. Plasma may be stored at -30oC for not more than five (5) years from the date of phlebotomy, except that if it is processed from Fresh Frozen Plasma it may not be refrozen when thawed.

IX
Specifications for Whole Blood
and Blood Products

In processing blood components it is necessary to maintain its sterility with the use of aseptic methods and sterile pyrogen-free equipment and solutions. Equipment that allows transfer of components without breakage of the seal is preferred.

A. The following Requirements/Precautions Must Be Observed

1. Seal

1.1 If the seal is not broken, the storage period is limited only by the viability and stability of the components.

1.2 If the seal is broken during processing which includes pooling:

1.2.1 Components stored between 4º to 6º must be transfused within 24 hours

1.2.2 Components stored between 20º to 24ºC must be transfused as soon as possible but not beyond six (6) hours after seal is broken. When components are thawed, they must be transfused:

1.2.2.1. Within six (6) hours after thawing if stored between 20º to 24ºC

1.2.2.2. Within 24 hours after thawing if stored between 4º and 6ºC

2. Aliquot of blood or components and pooled components must comply with the foregoing requirements.

B. Specifications for Blood Components/Products

1. Red Blood Cell Components

1.1 Red blood cells — The proper name of this component is: ACD (state the name of the anticoagulant/preservative) Red Blood Cells.

1.1.1

Red Blood Cells may be separated from plasma following either centrifugation or undisturbed sedimentation at any time before the expiration date of the blood.

1.1.2

Red blood cells separated as in 1.1.1. should have a final hematocrit not less than 70 + 5% and stored between 4-6ºC.

1.2 Washed red blood cells

1.2.1

These are the Red Blood Cells remaining after washing with a volume of compatible solution using a method known to remove almost all the plasma.

1.2.2

Depending on the method used, the preparation may contain variable quantities of leukocytes and platelets from the original unit.

1.2.3

At the time of preparation of the final component intended for transfusion, the integrally connected tubing must be filled with an aliquot of the component and sealed in such manner it will be available for subsequent compatibility testing.

1.2.4

Washed RBC shall be stored between 4-6ºC and used within 12 hours.

1.3. Leukocyte-Poor Red Blood Cells

1.3.1

These are Red Blood Cells prepared by a method known to remove at least 70% of the original leukocytes and to retain at least 70% of the original red blood cells. sufficient plasma should be returned to the red cells to achieve 80% hematocrit if the unit will be stored.

1.3.2

At the time of preparation of the final component intended for transfusion, the integrally connected component is sealed in such manner that it will be available for subsequent compatibility testing.

1.3.3

Proper names include:

— Red Blood Cells leukocytes Removed by Filtration
— Red Blood Cells leukocytes Removed by Centrifugation
— Red Blood Cells leukocytes Removed by Washing

1.3.4

Expiration:

Open system — 24 hours
Closed system — 21 days

2. Plasma and Plasma Components

2.1. Liquid Plasma:

2.1.1.

This is plasma from a single donor that is separated from Whole Blood at any time up to five (5) days after the expiration date applicable to the Whole Blood.

2.1.2

Alternatively the product may be made from Fresh Frozen Plasma that is either outdated or has had cryoprecipitate removed.

2.1.3

Requirements/precautions stated in IX A-1, 1.1. to 1.2. on Seal are to be observed.

2.1.4

Liquid Plasma is stored at 4ºC to 6ºC Frozen Plasma is stored at -30ºC or colder.

2.1.5

Heparin is not an acceptable anticoagulant.

2.2 Fresh frozen plasma

2.2.1

This is plasma separated from the blood of an individual donor placed at -30ºC or lower within six (6) hours of collection from the donor.

2.2.2

If a liquid freezing bath is used, the plastic container must be protected from chemical alteration.

2.2.3

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Heparin is not an acceptable anticoagulant.

2.3 Cryoprecipitated anti-hemophilic factor (AHF)

2.3.1

This is the cold-insoluble portion of plasma from fresh frozen plasma.

— The Fresh Frozen Plasma should be thawed between 4ºC to 6ºC.
— Immediately after completion of the thawing and prompt centrifugation in the cold (4ºC to 6ºC) the plasma should be separated from the cold-insoluble material under sterile conditions.
— Cryoprecipitated AHF shall be frozen within one (1) hour. If maintained constantly in the frozen state at -30ºC or below, it should be stored no longer than twelve (12) months from the date of phlebotomy.

2.3.2

The component should contain an average of 80-120 international units of Factor VIII per container in at least 75% of units tested.

3. Platelets: platelet pheresis

3.1

This is a suspension of platelets in plasma prepared by centrifugation of whole blood collected aseptically using a sterile closed system and a single venipuncture or by cytopheresis.

3.2

Platelets from whole blood should contain a minimum of 5.5. x 10 platelets in at least 75% of the units tested at the maximum storage time or the time of use.

3.3

Plateletpheresis prepared by cytopheresis should contain a minimum of 3 x 10 platelets in at least 75% of units tested.

3.4 Platelets to be stored should be suspended in sufficient plasma so that the pH determined at the temperature of storage shall be 6.0 or greater in the units tested at the end of the allowable storage interval. there shall be no grossly visible platelet aggregates after storage.

3.5 Platelet preparation should be stored at 20-26ºC or in an air-conditioned room with constant gentle agitation. Shelf life: 72 hours.

4. Granulocyte pheresis

4.1 This is a suspension of granulocytes in plasma prepared by cytopheresis.

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4.2 The component should contain a minimum of 1.0 x 10 granulocyte in at least 75% of the units tested.

5. Whole blood cryoprecipitate removed/whole blood leukocytes removed

5.1 This is blood from which cryoprecipitate and/or leukocytes have been removed.

5.2 The method used must be one known to ensure sterility and allow for proper storage of the red blood cells during the processing.

5.3 The component should be stored at 4º - 6ºC shelf life: same as whole blood

X
Records
There shall be a provision for accurate recording to ensure proper care of donors and recipients, the production of quality blood products and the accuracy and completeness of data when necessary for medico-legal purposes.

1. This shall be accomplished in the formats suggested by the Bureau of Research and Laboratories.

2. Records shall be stored in a readily available place that will protect them against loss or damage. Records that are discarded must be destroyed.

3. Records like all medical information should not be released or made available to unauthorized persons.

4. Each Blood Bank shall establish Donor Registries of Rare Blood Types for supply of rare blood and donor Registries of Hazardous Donors for protection of recipient.

XI
Reporting
Each Blood Bank shall report annually to the Bureau of Research and Laboratories in a standard prescribed format prescribed by the BRL which shall include but not be limited to the following:

Any request for additional or special reports of activities/accomplishments from the BRL shall be complied with.

XII
Quality Control
All Blood Banks shall have a Written Program of quality control that is sufficiently comprehensive to ensure that reagents, equipments and methods function as expected and hence will help to maintain and upgrade standards of laboratory practices. There shall be DOCUMENTED EVIDENCE OF IMPLEMENTATION of the quality control program. The program shall consist of an internal and external Quality Control Program.

1. Internal Quality Control

1.1. Personnel. The selection and maintenance of appropriate, qualified and competent personnel for various services in the Blood Bank.

1.2. Equipment and Supplies Management: There shall be a program to properly maintain and monitor the status of all equipment and supplies.

1.3. Reagents. Each Blood Bank must confirm that each reagent, on each day of use is suitably reactive when used according to manufacturer’s instructions. Records of quality assurance testing must include identification of the personnel involved, the source and identification numbers of all reagents tested, date of testing, and the source and nature of positive and negative controls.

1.4. Donor Selection. There shall be adequate and up to-date documentation of donors being medically fit and

blood being suitable and safe.

1.5. Storage, transport and processing of Blood and Blood Components shall be performed and handled according to requirements prescribed by BRL.

2. External Quality Control — All Blood Banks shall participate in the Quality Assurance Program conducted periodically by the BRL. This shall include proficiency testing and testing of blood products. Any refusal to participate shall be a basis for suspension or revocation of the license of the Blood Bank.

XIII
Donor Registries
Donor Registries for donors with rare blood type shall be established.

1. A Rare Donor File should be maintained by the Bureau of Research and Laboratories to contain blood grouping information on rare types of donors throughout the Philippines.

2. Any Blood Bank with rare blood types should submit their names and blood grouping to the BRL Rare Donor File.

3. To maintain confidentiality, the Blood Bank providing the donor's name makes all contacts with the donors. It is their responsibility to obtain the donor's agreement to participate in the program.

4. Should the donor's blood be needed, the requesting Blood Bank is referred to the appropriate Blood Bank.

XIV
Blood Bank Rates
The Blood Bank shall be operated on a non-profit basis i.e. blood shall be sold at cost. The regular charges shall not be less or more than that set from time to time by the BRL in consultation with the appropriate Specialty Societies and professional organizations.

XV
Safety and Sanitation/Disposal of
Infectious or Toxic Laboratory Wastes
There shall be written policies, guidelines, procedures for maintenance of sanitation and safety standards and disposal of infectious or toxic laboratory wastes through facilities such as sewers and incinerators disposal system or other approved methods for the disposal of contaminated materials and wastes shall be provided for use within the Blood Banks premises.

1. Before disposal, all laboratory specimens or materials CONSISTING OF OR CONTAINING/CONTAMINATED WITH BLOOD, PLASMA, SERUM OR HUMAN/ANIMAL TISSUES, FLUIDS OR POTENTIALLY INFECTIVE MATERIALS MUST BE EITHER:

1.1 Incinerated or sterilized by autocalving following the procedures prescribed by the Bureau of Research and Laboratories, or

1.2 In cases where autoclaving is not feasible, it shall be decontaminated with the use of a chemical disinfectant.

2. All glasswares, pipettes, slides, etc. used in the different activities of blood banking must be autoclaved or chemically disinfected before being discarded or prepared for re-use.

3. Single-use bottles, tubes, vials and other biological specimen containers shall be placed in biohazard containers and decontaminated before disposal and not be placed in waste baskets customarily emptied by the janitorial personnel.

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4. Rejected blood products positive on serologic screening tests that will be used for research or for purification of viral antigen shall be transported in accordance with the system prescribed by the Bureau of Research and Laboratories.

5. Used needles and syringes shall be discarded into puncture-resistant containers for disposal. Needles should not be re-capped, bent, broken or removed from disposable syringes after use.

This BUREAU ORDER takes effect immediately and supersedes other issuances inconsistent hereof.

Adopted: 15 Jan. 1990

(SGD.) TOMAS P. MARAMBA, JR.
Undersecretary of Health for
Standards and Regulation

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