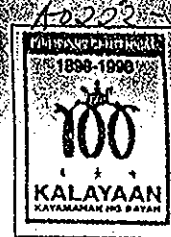


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May 12, 1998

ADMINISTRATIVE ORDER
No. 17-A s. 1998

SUBJECT : *Amendment to Sections 26 to 32 of Administrative Order No. 9 s. 1995 to be known as Requirements and Procedures for a License to Operate a Blood Bank / Blood Center in the Philippines*

Provisions of Chapter VIII Section 26 to 32 of the Administrative Order No. 9 series of 1995 dated April 28, 1995: Rules and Regulations Implementing Republic Act 7719, otherwise known as the "National Blood Services Act of 1994" dated August 1994, are hereby amended to be known as the "Requirements and Procedures for a License to Operate a Blood Bank / Blood Center (BB/BC) in the Philippines".

Section 1. TITLE

This Administrative Order shall be known as "Requirements and Procedures for a License to Operate a Blood Bank / Blood Center (BB / BC) in the Philippines".

Section 2. REGULATORY AUTHORITY

This Administrative Order is issued pursuant to Republic Act 7719 (National Blood Services Act of 1994) and its Implementing Rules and Regulations (A.O. #9 s. 1995) consistent with E.O. 119 (Reorganization Act of the Ministry of Health). The licensing and regulatory functions of the Department of Health for Blood Service Facilities shall be exercised through the Bureau of Research and Laboratories (BRL) under the Office for Health Facilities, Standards and Regulation (OHFSR). As such, it is hereby authorized to issue orders and circulars providing for the implementation details and specific technical and administrative requirements related to licensing and regulation.

Section 3. PURPOSE

This Administrative Order is being issued to enforce RA 7719 to protect and promote the health of the people by preventing the operation and maintenance of sub-standard Blood Bank / Blood Center in the country.

Section 4 SCOPE

These requirements and procedures shall apply to all establishments, owned and operated by the government and non-government agencies, and private individuals engaged in blood banking and transfusion services within the geographical boundaries of the Philippines.

Section 5 SERVICE CAPABILITIES OF BLOOD BANK / BLOOD CENTER

Category A (Non Hospital-Based)

1. Recruitment and retention of voluntary blood donors
2. Health education and counselling
3. Donor screening and selection
4. Blood collection
5. Blood testing for blood transmissible diseases
6. Provision of whole blood and packed red blood cells
7. Storage of whole blood and packed red blood cells
8. Issuance, transport and distribution of whole blood and packed red blood cells

Category A (Hospital-Based)

1. All of the above (Category A -Non Hospital-Based)
2. Compatibility Testing

Category B (Non Hospital-Based)

1. Recruitment and retention of voluntary blood donors
2. Health education and counselling
3. Donor screening and selection
4. Blood collection
5. Blood testing for blood transmissible diseases
6. Provision of whole blood, packed red blood cells and other blood components
7. Storage of whole blood and blood products
8. Issuance, transport and distribution of whole blood and blood products

Category B (Hospital-Based)

1. All of the above (Category B -Non Hospital-Based)
2. Compatibility testing
3. Preliminary investigation of transfusion reactions
4. Resolution of incompatible crossmatches

7.1.2.1 Documents

- a. Duly accomplished and notarized Petition / Application Form (BRL- BSF (BB/BC) Form No. 1),
- b. Blood Services Network Documents (Administrative Order #9 s. 95, Chapter 8, Sec. 28, Item 10):
 - b.1 Certificate of Inclusion in the Official Blood Services Network of the National Voluntary Blood Services Program Unit (NVBSP),
 - b.2 Lists of Blood Collection Units and Blood Stations within their network to include names of their respective personnel,
- c. Certificate of Registration
 - c.1 If Corporation /Foundation Proprietorship / Ownership-Certified True Copy of (SEC) Securities and Exchange Commission Registration
 - c.2 If Single Proprietorship / Ownership Certified True Copy of (DTI) Domestic Trade and Industry Registration
- d. Photocopies of PRC Certificates of Personnel of the Blood Service Facilities,
 - d.1 Additional requirement for the Head of the Blood Bank / Blood Center
 - If Pathologist, Specialty Board Certificate issued by the Philippine Board of Pathologist ;
 - If Hematologist, Specialty Board Certificate issued by the Philippine Board of Hematology and Blood Transfusion ,
- e. Location map of the Blood Bank / Blood Center,
- f. Floor diagram of the Blood Bank / Blood Center and its premises,
- g. List of Equipment - to include serial number, brand, date of purchase, number of units and operational status,
- h. List of glasswares and supplies, and

7.1.2.2 Human Resource Requirements

The minimum number of staff with their corresponding qualification for each category of Blood Banks / Blood Centers shall be as follows:

A. HEAD (for both Category A & B Hospital-Based & Non-Hospital-Based):

The overall supervision and management shall be under a registered Physician duly licensed by the Professional Regulation Commission Certified in Clinical Pathology by the Philippine Board of Pathology or Blood Banking by the Philippine Board of Hematology and Blood Transfusion.

B. TECHNICAL STAFF

Medical Technologists

The Blood Bank / Blood Center shall have Medical Technologists who shall work on a shifting basis to cover a 24 - hour service. Medical Technologists must be duly registered by the PRC with valid professional license (PRC ID Card) and with at least one (1) year on the job training or experience in blood banking services.

For Blood Bank Category A - at least Four (4) RMTs based on :

One (1) RMT in every shift (Morning, Afternoon and Night) and One (1) RMT on off-duty.

For Blood Bank Category B - at least Five (5) RMTs based on :

Two (2) RMT in morning shift , one (1) RMT in afternoon and night shift, and one (1) RMT on off-duty.

Donor Recruitment Officer (For both Category A & B Blood Bank/ Center)

The Blood Bank / Blood Center shall also have at least one (1) designated Donor Recruitment Officer who is either a Registered MD / RMT / RN.

7.1.2.3 Physical Plant

The physical plant shall be housed in a well-lighted and well-ventilated area with an adequate supply of water.

The space shall be sufficient to accommodate the various activities of the blood bank / center with provisions for accessible and clearly demarcated fire exits.

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

The technical or working area shall be exclusively for the use of the blood bank/center and its other related activities.

7.1.2.4 Equipments, Reagents, Glassware & Supplies

The blood bank / center shall have the equipment, reagents, glassware, blood bags, and other supplies needed to properly undertake the required services.

Table 1, 2 & 3 presents the minimum requirements respectively for equipment / instruments, reagents, glassware and supplies necessary to undertake the required services.

7.2 Requirements for Renewal of License

The license of a Blood Bank/ Center to operate may be renewed only if it shall have complied with all of the requirements for a new license with the following additions or modifications:

7.2.1 Documents

- a. Duly accomplished Application Form for Renewal of License (BRL- BSF (BB/BC) Form No. 2),
- b. Changes in the list of authorized Blood Collection Units and Blood Station (deletions or additions only) within their network,
- c. Names, qualifications and proofs of qualification of new staff and any staff development (e.g. additional trainings or qualifications for existing staff, resignations),

- d. Changes in location or address, if applicable,
- e. Changes in existing physical facilities and equipment and facilities,
- f. Newly acquired equipment and facilities,
- g. Annual Accomplishment Report on Blood Services of the previous year,
- h. Names and addresses of blood donors with rare blood types,
- i. Documented changes in Blood Banking Standard Operating Procedures,
- j. Passed Rating in the External Quality Assessment or Proficiency Testing of the previous year,
- k. Documented accomplishment of at least 70% of the staff development plan targets for the previous year.

Section 8 LICENSE FEES AND CHARGES

- 8.1 The license fees and charges shall be uniform for both government and non-government blood banks / centers and shall be adjusted only by the BRL through appropriate official issuances as the need arises.
- 8.2 All fees / charges shall be payable to the Bureau of Research & Laboratories.
- 8.3 **License Fee**
 - a. A non-refundable license fee of six hundred pesos (**P600.00**) shall be charged for every accepted application for a new license to operate a blood bank / blood center.
 - b. A non-refundable fee of four hundred pesos (**P400.00**) shall be charged for every accepted application for renewal of license.
 - c. The license fee shall cover the cost of inspection and printing of license certificates and other required forms and documents. Subsequent or separate issuances shall cover other allowable fees and charges (e.g. proficiency testing fee, blood service fee, etc.).

8.4 Charges

- a. A penalty of five thousand pesos (P 5000.00) for blood banks / blood centers which fail to submit the application for renewal of license to the BRL within two (2) months prior to the expiration of the existing license. (Administrative Order No.9 s. 1995, Chapter X, Section 47, Item 5.a)
- b. Blood Banks/ Blood Centers which fail to submit an application for renewal within the two (2) months period shall be considered as "BLOOD BANKS / BLOOD CENTERS OPERATING WITHOUT A LICENSE" when their current license expires and shall be subject to the penalties for such violation. (Administrative Order No. 9 s. 1995 , Chapter X, Sec. 47, Item 2)

Section 9 TERMS AND CONDITIONS OF LICENSING

A license is granted on the basis of compliance to certain requirements as established during the inspection and defined in the issuance of the license.

The following are the terms and conditions of the License:

- 9.1 A license to operate a Blood Bank / Center shall be signed by the Undersecretary of Health for Health Facilities, Standards and Regulation. It shall be issued to persons, agencies, corporations who have successfully complied with all of the standards and requirements.
- 9.2 The license is valid for a maximum of one (1) year from the date of issue. The exact date of expiration of the license shall be printed on the license.
- 9.3 The license, as well as the rights under the license, is non-transferable, directly or indirectly.
- 9.4 The license of the Blood Bank / Blood Center shall be displayed in a conspicuous place within the Blood Bank / Blood Center. A notice shall be posted informing the public that complaints about the services may be addressed to the Chief of Hospital (if Hospital-Based) or to the Head of the Blood Bank / Blood Center (if Non-Hospital-Based) or to the Director of the Bureau of Research & Laboratories.
- 9.5 Blood Collection Unit(s) and Blood Station(s) linked within the Blood Bank / Center Blood Services Network will function under the license of their parent Blood Bank / Blood Center.

Section 10 LICENSING PROCEDURE

10.1 Filing of Application

The following are procedures to be followed when applying for a license:

- a. A duly accomplished and notarized Petition/ Application Form (BRL- BSF (BB/BC) Form No. 1), or Application for Renewal of License (BRL- BSF (BB/BC) Form No. 2) together with all the required supporting documents shall be addressed and submitted to the Bureau of Research and Laboratories (BRL)- Division of Laboratory Regulation and Development (DLRD).
- b. Applications for new license may be submitted anytime.
- c. Applications for renewal of license should be submitted within 2 months prior to the expiration of the current license.

10.2 Document Screening and Approval

- a. DLRD screens and evaluates the documents for completeness and authenticity. If complete, application is accepted and approved. A charge slip is issued and the applicant pays the corresponding license fee at the BRL Cashier Section.
- b. If documents are incomplete, a letter is sent to the applicant informing him / her of items for compliance and with a directive to complete said items for compliance within such period of time as may be warranted under the circumstances.

10.3 Inspection

- a. Assessment of a Blood Bank / Blood Center for new license to operate and renewal of license shall involve an actual inspection of the facility and evaluation of documents by authorized BRL- Blood Bank Inspectors at least once a year or as may be ordered by the Director.
- b. Only Inspectors who have satisfactorily completed the BRL Training Course for Blood Bank Inspectors are qualified to inspect Blood Bank/Centers and other blood service facilities.
- c. Inspection shall be done only if applicants have complied all the basic requirements.

- d. Each Blood Bank /Center shall be visited by an authorized BRL Blood Bank Inspectors at least once before initial licensing and once a year for the renewal of license. Those who failed to apply for renewal of license within the prescribed period shall also be visited within the year to confirm that blood operations have ceased.
- e. Inspection of licensed blood bank/center shall be done unannounced while its activities are going on.
- f. Each licensee shall make available all records and documents as may be required by the authorized BRL Blood Bank Inspectors upon presentation of a valid inspection mission order signed by the Secretary or its authorized representative.
- g. Applicants for license to operate who, upon inspection, did not meet all of the prescribed standards shall receive a letter from the BRL stating the requirements which the Blood Bank / Center failed to meet. These Blood Bank / Centers shall be revisited at least once after release of the order for confirmation of compliance with the order.

10.3.1 Documents Required on Inspection

- a. Copies of Manual of Standards for Blood Banks/Centers, Blood Collection Units, Blood Stations in the Philippines
- b. Donor Forms:
 - 1. Donor History and Physical Examination
 - 2. Donor Medical Declaration Form
- c. Staff Development Plan for at least one (1) year
- d. Book of Accounts or Cash Books or official Receipts showing collection of allowable service fee for each blood unit dispensed
- e. Minutes of Meetings of the Hospital Blood Transfusion Committee
- f. Manuals /Logbooks on:
 - 1. Quality System Manual (Administrative SOPs Manual)

1.1 BB//BC Organizational Objectives, Policies and Guidelines which will include the following :

- a. Guidelines for provision of Health Education, Pre & Post-Donation Counselling Services for blood donors (AO #9 s. 1995 , Chapter VIII, Sec. 28, Item 9)
- b. Guidelines for referrals of blood donors for further medical evaluation (AO #9 s. 1995 , Chapter VIII, Sec. 28, Item 9)
- c. Blood Distribution and Transport Guidelines (AO #9s. 1995 , Chapter VIII, Sec. 28, Item 7)

1.2 BB / BC Organization and Personnel Job Delineation, Level of Responsibility, Task Delegation and Coordination

1.3 Personnel Development and Competency Evaluation

2. Technical Procedures Manual (Technical SOPs)

3. Biosafety and Waste Management Manual

4. Equipment Maintenance & Repair Logbook / Record

5. Quality Management Records

6. Records of Blood Donations

6.1 Donor Session Record

6.2 Blood Collection Record

7. Laboratory Processing of Donor Blood

7.1 Records of Tests on Donor Blood Sample

7.2 Labelling

7.3 Records of Component Preparation

8. Records of Blood Transfusion

8.1 Records of Blood Transfusion Requests

8.2 Records of Compatibility Tests

8.3 Records of Issue for Transfusion

8.4 Records of Transfusion Complications

- 9. Storage, Transport and Issue of Blood
 - 9.1. Records for Blood Storage
 - 9.2. Records of Transport and Issue of Blood and Blood Components
 - 9.3. Records of Emergency Issue of Blood
 - 9.4. Transport Records
 - 9.5. Records of Blood and Components Received from Other Facilities
- 10. Records of Errors and Accidents
- 11. Summary Records
 - 11.1. Annual Blood Collection and Utilization

10.3.2 External Quality Assessment

The BRL shall conduct a yearly External Quality Assessment / Proficiency Testing to all licensed blood bank / center. A blood bank / center who got a satisfactory rating will be given a Quality Assurance Citation Certificate. Supervisory visits will be conducted as necessary to blood banks / centers who failed in the External Quality Assessment.

Section 11 ISSUANCE OF LICENSE

Immediately after approval and evaluation, license is prepared and issued directly to the Head of the Blood Bank or his representative (personally or by mail).

Section 12 VALIDITY OF LICENSE

Each license shall expire on its anniversary date of the year stated.

Section 13 TRANSITION PERIOD FOR CONFIRMATION OF LICENSES

May 28, 1998 to July 31, 1998 shall be the transition period for confirmation of compliance to the new licensure requirements of existing Blood Banks / Blood Centers following the new BSF categorization. The BRL-DLRD shall issue certificates to existing blood service facilities based on the NVBSP -Blood Services Network Guidelines to continue operation until confirmation of licenses / certificates of authority to operate.

Section 14 PUBLICATION OF THE LIST OF LICENSED BLOOD BANKS/ CENTERS

An annual updated list of licensed blood banks/ centers shall be published at least once a year in a newspaper of general circulation.

Section 15 PENALTIES FOR VIOLATIONS

Non-compliance to these requirements shall be regarded as a violation under R.A. 7719 and thus is subject to the penalties as provided for in said law as implemented by Department of Health. (A.O. No. 9 s. 1995, Chapter X, Section 47)

15.1 In addition to A.O. No. 9 s. 1995, Chapter X, Sec. 47, Item 1, Documented blood collection from paid donors; blood collection without the supervision of a physician; non-performance of the required blood testing; and disposal of blood units to unauthorized persons shall be a cause for the cancellation, revocation or suspension of the license.

Section 16 APPEALS AND REPORTS ON VIOLATIONS

Reports on violation of RA7719 and these Rules and Regulations shall be addressed to the Secretary of Health and the Director of the Bureau of Research and Laboratories.

The Secretary or the Director of BRL may request for Police Assistance and the National Bureau of Investigation and/or the Philippine National Police for the effective enforcement of RA 7719 and these Implementing Rules and Regulations.

Section 17 REPEALING CLAUSE

These requirements and procedures shall supersede Sections 26-32, Chapter VIII of Administrative Order No. 9 s. 1995, and related Bureau Orders and Circulars of the Department. The provisions of any of these issuances inconsistent with this administrative order are hereby repealed or modified accordingly.

Section 18 EFFECTIVITY CLAUSE

These requirements and procedures shall take effect May 28, 1998. A Transition period of 60 days from date of effectivity of this order shall be the transition period for confirmation of compliance to these licensing requirements and procedure.



CARMENCITA NORIEGA-REODICA, M.D., MPH, CESO I
Secretary of Health

Table 1 - BB / BC

MINIMUM REQUIREMENTS FOR EQUIPMENTS / INSTRUMENTS

BLOOD BANK / CENTER CATEGORY A		BLOOD BANK / CENTER CATEGORY B	
I. Non-Hospital - Based		I. Non-Hospital - Based	
<p>Blood Bank Refrigerator controlled at 1-6 C with temperature recorder, alarm system, & automatic voltage regulator</p> <p>Agglutination viewer for ABO/RH grouping (tube method)</p> <p>Blood donation couch or bed</p> <p>Surgical instruments: forceps, scissors</p> <p>For Hemoglobin Determination</p> <p>1. by Cyanmethemoglobin Method: Spectrophotometer / Hemocue</p> <p>2. by Copper Sulfate Method</p> <p>Pycnometer</p> <p>Laboratory Oven (for Instrument Drying Purposes)</p> <p>Sphygmomanometer</p> <p>Stethoscope</p> <p>Thermometers</p> <p>Room Thermometer</p> <p>Laboratory Thermometer</p> <p>Clinical Thermometer</p> <p>Weighing Scales</p> <p>for Blood Donors</p> <p>for Blood Units</p> <p>Autoclave</p> <p>Emergency Generator power unit (at least 20 KVA)</p> <p>Microplate Tray Viewer for PA Method</p> <p>Clinical centrifuge</p> <p>Centrifuge for Quantitative Buffy Coat Method for Malaria detection</p>		<p>Blood Bank Refrigerator controlled at 1-6 C with temperature recorder, alarm system, & automatic voltage regulator</p> <p>Agglutination viewer for ABO/RH grouping (tube method)</p> <p>Blood donation couch or bed</p> <p>Surgical instruments: forceps, scissors</p> <p>For Hemoglobin Determination</p> <p>1. by Cyanmethemoglobin Method: Spectrophotometer / Hemocue</p> <p>2. by Copper Sulfate Method</p> <p>Pycnometer</p> <p>Laboratory Oven (for Instrument Drying Purposes)</p> <p>Sphygmomanometer</p> <p>Stethoscope</p> <p>Thermometers</p> <p>Room Thermometer</p> <p>Laboratory Thermometer</p> <p>Clinical Thermometer</p> <p>Weighing Scales</p> <p>for Blood Donors</p> <p>for Blood Units</p> <p>Autoclave</p> <p>Emergency Generator power unit (at least 20 KVA)</p> <p>Microplate Tray Viewer for PA Method</p> <p>Clinical centrifuge</p> <p>Centrifuge for Quantitative Buffy Coat Method for Malaria detection</p> <p>Refrigerated Centrifuge w/ AVR</p> <p>Plasma Freezer / 300</p>	

Table 1 - BB / BC MINIMUM REQUIREMENTS FOR EQUIPMENTS / INSTRUMENTS

BLOOD BANK / CENTER CATEGORY A	BLOOD BANK / CENTER CATEGORY B
I. Non-Hospital - Based	I. Non-Hospital - Based
<p>EIA Equipment set w/ AVR EIA reader with printer EIA washer Incubator including heating block Microdiluter w/ Go-no-Go tester set Microscope, Binocular with Oil Immersion Objective and with UV Paralens adapter for Malaria Parasite Detection Pipettor, 10-100ul Plasma Extractor Platelet Rotator Reagent Refrigerator w/ AVR & Thermometer Rotator for RPR/VDRL Stopwatch or Timer Waterbath w/ thermometer (10-100C)</p>	<p>EIA Equipment set w/ AVR EIA reader with printer EIA washer Incubator including heating block Microdiluter w/ Go-no-Go tester set Microscope, Binocular, with UV Paralens adapter with Oil Immersion Objective for Malaria Parasite Detection Pipettor, 10-100ul Plasma Extractor Platelet Rotator Reagent Refrigerator w/ AVR & Thermometer Rotator for RPR/VDRL Stopwatch or Timer Waterbath w/ thermometer (10-100C)</p>
II. Hospital - Based	II. Hospital - Based
<p>All those stated above plus the following: Serologic Centrifuge Waterbath controlled at 37C (for crossmatching) Water or Dry bath</p>	<p>All those stated above plus the following: Serologic Centrifuge Waterbath controlled at 37C (for crossmatching) Water or Dry bath</p>

Table 2 - BB /BC MINIMUM REQUIREMENTS FOR REAGENTS

BLOOD BANK / CENTER CATEGORY A	BLOOD BANK / CENTER CATEGORY B
1. Non-Hospital - Based	1. Non-Hospital - Based
For Hemoglobin Determination - by CuSO ₄ Method CuSO ₄ Solution, Sp. Gr. of 1.053 Distilled Water - by Cyanmethemoglobin Method Drabkins Reagent Hemoglobin Standard	For Hemoglobin Determination - by CuSO ₄ Method CuSO ₄ Solution, Sp. Gr. of 1.053 Distilled Water - by Cyanmethemoglobin Method Drabkins Reagent Hemoglobin Standard
For ABO Grouping -Forward Typing (slide/tube method) Anti-A Typing sera Anti-B Typing sera -Reverse Typing (tube method) Known A cells Known B cells	For ABO Grouping -Forward Typing (slide/tube method) Anti-A Typing sera Anti-B Typing sera -Reverse Typing (tube method) Known A cells Known B cells
For Rh Typing (tube method) Anti-D with appropriate control	For Rh Typing (tube method) Anti-D with appropriate control
For Infectious Disease Testing A. Malaria (either of the following) -Thick & Thin Smear Giemsa - Wright's Stain Buffer water - Quantitative Buffy Coat Method QBC Reagent kit	For Infectious Disease Testing A. Malaria (either of the following) -Thick & Thin Smear Giemsa - Wright's Stain Buffer water - Quantitative Buffy Coat Method QBC Reagent kit

Table 2 - BB/BC MINIMUM REQUIREMENTS FOR REAGENTS
BLOOD BANK / CENTER CATEGORY A

BLOOD BANK / CENTER CATEGORY A	BLOOD BANK / CENTER CATEGORY B
<p>B. Screening Test for Syphilis</p> <p>VDRL Test Kit or RPR Card Test Kit</p>	<p>B. Screening Test for Syphilis</p> <p>VDRL Test Kit or RPR Card Test Kit</p>
<p>C. Screening Test for HIV-Ab</p> <p>HIV 1& 2 PA Test Kit or HIV 1& 2 EIA Kit</p>	<p>C. Screening Test for HIV-Ab</p> <p>HIV 1& 2 PA Test Kit or HIV 1& 2 EIA Kit</p>
<p>D. Screening Test for HBsAg</p> <p>EIA Test Kit or Immunochromatography</p>	<p>D. Screening Test for HBsAg</p> <p>EIA Test Kit or Immunochromatography</p>
<p>E. Screening Test for HCV-Ab</p> <p>EIA Test Kit or PA Test Kit</p>	<p>E. Screening Test for HCV-Ab</p> <p>EIA Test Kit or PA Test Kit</p>
<p>II. Hospital - Based</p>	<p>II. Hospital - Based</p>
<p>All those stated above plus the following:</p> <p>For Compatibility Testing -Crossmatching</p> <p>Known A Cells Known B Cells 22%BovineSerumAlbumin Anti-Human Globulin Reagent</p>	<p>All those stated above plus the following:</p> <p>For Compatibility Testing -Crossmatching</p> <p>Known A Cells Known B Cells 22%BovineSerumAlbumin Anti-Human Globulin Reagent</p>

Table 2 - BB/BC MINIMUM REQUIREMENTS FOR REAGENTS
BLOOD BANK / CENTER CATEGORY A

BLOOD BANK / CENTER CATEGORY A	BLOOD BANK / CENTER CATEGORY B
<p>B. Screening Test for Syphilis</p> <p>VDRL Test Kit or RPR Card Test Kit</p>	<p>B. Screening Test for Syphilis</p> <p>VDRL Test Kit or RPR Card Test Kit</p>
<p>C. Screening Test for HIV-Ab</p> <p>HIV 1& 2 PA Test Kit or HIV 1& 2 EIA Kit</p>	<p>C. Screening Test for HIV-Ab</p> <p>HIV 1& 2 PA Test Kit or HIV 1& 2 EIA Kit</p>
<p>D. Screening Test for HBsAg</p> <p>EIA Test Kit or Immunochromatography</p>	<p>D. Screening Test for HBsAg</p> <p>EIA Test Kit or Immunochromatography</p>
<p>E. Screening Test for HCV-Ab</p> <p>EIA Test Kit or PA Test Kit</p>	<p>E. Screening Test for HCV-Ab</p> <p>EIA Test Kit or PA Test Kit</p>
<p>II. Hospital - Based</p>	<p>II. Hospital - Based</p>
<p>All those stated above plus the following:</p> <p>For Compatibility Testing -Crossmatching</p> <p>Known A Cells Known B Cells 22%BovineSerumAlbumin Anti-Human Globulin Reagent</p>	<p>All those stated above plus the following:</p> <p>For Compatibility Testing -Crossmatching</p> <p>Known A Cells Known B Cells 22%BovineSerumAlbumin Anti-Human Globulin Reagent</p>

Table 2 - BB/BC MINIMUM REQUIREMENTS FOR REAGENTS

BLOOD BANK / CENTER CATEGORY A	BLOOD BANK / CENTER CATEGORY B
	<p>For Preliminary Investigation of Transfusion Reactions</p> <p>Compatibility Testing</p> <p>1. ABO Grouping</p> <p>-Forward Typing (slide/tube method)</p> <p>Anti-A Typing sera</p> <p>Anti-B Typing sera</p> <p>-Reverse Typing (tube method)</p> <p>Known A cells</p> <p>Known B cells</p> <p>2. Rh Typing (tube method)</p> <p>Anti-D with appropriate control</p> <p>3. Crossmatching</p> <p>Known A Cells</p> <p>Known B Cells</p> <p>22% Bovine Serum Albumin</p> <p>Anti-Human Globulin Reagent</p> <p>4. Bacterial Culture (c/o Clinical Laboratory)</p> <p>For Complete Investigation of Transfusion Reactions (refer to Reference Laboratory)</p> <p>1. Antibody Identification</p>

For Preliminary Investigation of Transfusion Reactions

Compatibility Testing

1. ABO Grouping

-Forward Typing (slide/tube method)

Anti-A Typing sera

Anti-B Typing sera

-Reverse Typing (tube method)

Known A cells

Known B cells

2. Rh Typing (tube method)

Anti-D with appropriate control

3. Crossmatching

Known A Cells

Known B Cells

22% Bovine Serum Albumin

Anti-Human Globulin Reagent

4. Bacterial Culture (c/o Clinical Laboratory)

For Complete Investigation of Transfusion Reactions (refer to Reference Laboratory)

1. Antibody Identification

Table 3 - BB / BC MINIMUM REQUIREMENTS FOR SUPPLIES

BLOOD BANK / CENTER CATEGORY A	
I. Non-Hospital - Based	
<p>IEC (Information, Education, & Campaign) Materials:</p> <ul style="list-style-type: none"> Posters Leaflets Brochures <p>Health Education & Counselling IEC Materials</p> <ul style="list-style-type: none"> Posters Leaflets Brochures <p>Donor Selection and Screening</p> <ul style="list-style-type: none"> Donor Declaration Form Donor Medical History & Physical Examination Forms <p>Hemoglobin Determination</p> <ul style="list-style-type: none"> Lancet Tourniquet Isopropyl Alcohol, 70% Syringes w/ needles, disposables Pipette, disposable, plastic Pipette tips <p>ABO Grouping (Slide Method)</p> <ul style="list-style-type: none"> Applicator Sticks Normal Saline Solution (NSS, Sterile) <p>Proper Waste Disposal</p> <ul style="list-style-type: none"> Sodium Hypochlorite Solution Biohazard Plastic Bags Color-coded Plastic Disposable Trash Bags 	
BLOOD BANK / CENTER CATEGORY B	
I. Non-Hospital - Based	
<p>IEC (Information, Education, & Campaign) Materials:</p> <ul style="list-style-type: none"> Posters Leaflets Brochures <p>Health Education & Counselling IEC Materials</p> <ul style="list-style-type: none"> Posters Leaflets Brochures <p>Donor Selection and Screening</p> <ul style="list-style-type: none"> Donor Declaration Form Donor Medical History & Physical Examination Forms <p>Hemoglobin Determination</p> <ul style="list-style-type: none"> Lancet Tourniquet Isopropyl Alcohol, 70% Syringes w/ needles, disposables Pipette, disposable, plastic Pipette tips <p>ABO Grouping (Slide Method)</p> <ul style="list-style-type: none"> Applicator Sticks Normal Saline Solution (NSS, Sterile) <p>Proper Waste Disposal</p> <ul style="list-style-type: none"> Sodium Hypochlorite Solution Biohazard Plastic Bags Color-coded Plastic Disposable Trash Bags 	

Table 3 - BB /BC MINIMUM REQUIREMENTS FOR SUPPLIES

BLOOD BANK / CENTER CATEGORY A	BLOOD BANK / CENTER CATEGORY B
Biosafety Personnel protection Laboratory gown Gloves, disposable, latex Emergency Medical Kit ood Collection Skin Preparation & Disinfection Cotton / Gauze Isopropyl Alcohol, 70% Phlebotomy Tourniquet Surgical Tape Blood Bags w/ Anticoagulant 250 ml Single 450 ml Double Triple Quadruple Labelling Stick-on Labels for ABO / Rh Group Stick-on Labels for Expiration Dates Moisture-Proof Pens Screening Tests for Blood Transmissible Diseases Absorbent Papers Distilled Water Ethyl Alcohol, 30% Forceps Laboratory Mat or its equivalent Lens paper Microplates w/ "U" concavity Needles w/o bevel (G18, 19, & 23) Pipette Tips	Biosafety Personnel protection Laboratory gown Gloves, disposable, latex Emergency Medical Kit Blood Collection 1. Skin Preparation & Disinfection Cotton / Gauze Isopropyl Alcohol, 70% 2. Phlebotomy Tourniquet Surgical Tape Blood Bags w/ Anticoagulant 250 ml Single 450 ml Double Triple Quadruple 3. Labelling Stick-on Labels for ABO / Rh Group Stick-on Labels for Expiration Dates Moisture-Proof Pens Screening Tests for Blood Transmissible Diseases Absorbent Papers Distilled Water Ethyl Alcohol, 30% Forceps Laboratory Mat or its equivalent Lens paper Microplates w/ "U" concavity Needles w/o bevel (G18, 19, & 23) Pipette Tips

Table 3 - BB / BC MINIMUM REQUIREMENTS FOR SUPPLIES

BLOOD BANK / CENTER CATEGORY A	BLOOD BANK / CENTER CATEGORY B
<p>Slide Carrier Syringes, 1-2 ml Test Tube Racks</p> <p>Provision of Whole Blood & Red Blood Cells</p> <p>Transfer bags</p> <p>Transport, Issuance & Distribution of Whole Blood & Blood Cells</p> <p>Cold Box with cold packs or ice bags</p> <p>Logbooks / Record books</p> <p>Hospital - Based</p> <p>those stated in above plus the following :</p> <p>Biosafety</p> <p>Personnel protection</p> <p>Laboratory gown</p> <p>Gloves, disposable, latex</p> <p>Compatibility Testing</p> <p>Test Procedure</p> <p>Pipette, Pasteur, disposable</p> <p>Test Tube racks</p> <p>Normal Saline Solution (NSS, Sterile)</p> <p>Forms / Records</p> <p>Request Forms for Blood & Compatibility Testing</p> <p>Result Forms of Compatibility Testing</p> <p>Transfusion Forms</p> <p>Worksheets</p> <p>Logbooks</p>	<p>Slide Carrier Syringes, 1-2 ml Test Tube Racks</p> <p>Provision of Whole Blood & Blood Components</p> <p>Transfer bags</p> <p>Transport, Issuance & Distribution of Whole Blood & Blood Product</p> <p>Cold Box with cold packs or ice bags</p> <p>Logbooks / Record books</p> <p>II. Hospital - Based</p> <p>All those stated in above plus the following :</p> <p>1. Biosafety</p> <p>Personnel protection</p> <p>Laboratory gown</p> <p>Gloves, disposable, latex</p> <p>For Compatibility Testing</p> <p>1. Test Procedure</p> <p>Pipette, Pasteur, disposable</p> <p>Test Tube racks</p> <p>Normal Saline Solution (NSS, Sterile)</p> <p>2. Forms / Records</p> <p>Request Forms for Blood & Compatibility Testing</p> <p>Result Forms of Compatibility Testing</p> <p>Transfusion Forms</p> <p>Worksheets</p> <p>Logbooks</p>

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