



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
Manila



October 14, 2003

ADMINISTRATIVE ORDER
NO. 101-A s. 2003

SUBJECT: Rules and Regulations Governing Authorization of Blood Collection Unit and Blood Station

I. BACKGROUND/RATIONALE

Republic Act 7719 otherwise known as the "National Blood Services Act of 1994" was enacted to promote safe and efficient blood banking and transfusion practices in the Philippines through the creation of the National Voluntary Blood Services Program. To carry out the provisions of Republic Act 7719, Administrative Order No.9 s. 1995 'Rules and Regulations Implementing Republic Act 7719' was formulated. Under Sections 36 and 37, the Regional Health Directors shall authorize Blood Collection Units and Blood Stations according to the prescribed standards and procedures.

To strengthen the systems and procedures in the regulation of Blood Collection Units and Blood Stations, Sections 36 and 37 of Administrative Order No. 9 s. 1995 is hereby amended.

II. OBJECTIVE

These rules and regulations are promulgated to protect and promote the health of the people by ensuring available authorized Blood Collection Units and Blood Stations with adequate staff, equipment and resources to perform all the required functions safely, efficiently and effectively.

III. SCOPE

These rules and regulations shall apply to all government and private Blood Collection Units and Blood Stations.

IV. DEFINITION OF TERMS

Act – R. A. 7719 also known as the National Blood Services Act of 1994, unless herein specified.

Authority to Operate - a formal permit issued by the DOH-Center for Health Development to an individual, partnership, corporation or association which has complied with all the technical requirements as prescribed in this issuance and in the Manual of Standards for Blood Collection Units/Blood Stations in the Philippines.

BHFS – refers to the Bureau of Health Facilities and Services.

Blood - refers to human blood for transfusion.

Blood Component – refers to whole blood, red cells, granulocytes, plasma, platelets, cryoprecipitate and cryosupernate.

Blood Derivative or Plasma Fraction – partially purified plasma protein made under pharmaceutical manufacturing conditions, including coagulation factors, immunoglobulin and albumin.

Blood Product – a therapeutic substance derived from whole blood or plasma.

Blood Transfusion Services – set of activities related to blood transfusion such as but not limited to, motivation and recruitment of donors, blood collection, testing and screening of donor blood, compatibility testing, preparation of blood components, storage, distribution, administration of blood components, investigation of blood transfusion reactions, inventory control, and quality assurance.

BSF – refers to Blood Service Facility

CHD – refers to the Center of Health Development, which is the DOH Regional Field Office.

DOH – refers to the Department of Health.

NVBSP- refers to the National Voluntary Blood Services Program.

PNRC-refers to the Philippine National Red Cross.

Secretary – refers to the Secretary of Health.

Voluntary Non-remunerated Blood Donor – a donor who gives blood freely and voluntarily without receiving money or any form of payment.

V. CLASSIFICATION OF BLOOD COLLECTION UNITS AND BLOOD STATIONS

Blood Collection Units and Blood Stations shall be classified as follows:

1. Ownership:

1.1 Government – operated and maintained partially or wholly by a national, provincial, city or municipal government or other political

unit or by any department, division, board, agency or instrumentality thereof;

1.2 Private – privately owned, established and operated hospital based Blood Collection Unit/Blood Station with funds through donation, capital or other means, by an individual, corporation, association or organization.

2. Institutional Character:

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

2.2 Non hospital-based –located outside the premises of a hospital consistent with the NVBSP Strategic Plan.

3. Service Capability:

3.1 Blood Station - a BSF authorized by the CHD to perform the following:

- Provision of whole blood and packed red cells.
- Storage, issuance, transport and distribution of whole blood and packed red cells.
- Compatibility testing of red cell units, if hospital based.

3.2 Blood Collection Unit – a BSF authorized by the CHD to perform the following:

- Recruitment and retention of voluntary blood donors.
- Screening and selection of voluntary blood donors.
- Conduct of health education and counseling services.
- Collection of blood.
- Transport of blood to Referral Blood Center for testing and processing.
- Compatibility testing of red cell units, if hospital based.

VI. TECHNICAL REQUIREMENTS

All Blood Collection Units and Blood Stations are required to comply with the requirements for authorization that are stated in the Annex.

VII. PROCEDURAL GUIDELINES

A. Application for Initial/Renewal of Authority to Operate

A.1 Applicant requests for relevant information and prescribed form from the CHD under whose jurisdiction the proposed Blood Collection Unit/Blood Station is located, in person, on internet or through mail.

A.2 Applicant accomplishes the required documents and submits them to the CHD.

Documentary Requirements -

A.2.1 Initial Authority to Operate

A.2.1.1 Certificate of inclusion in the Regional Blood Services Network approved by the Regional Director upon the recommendation of the designated lead BSF of the Zonal/Regional Blood Services Network.

A.2.1.2 Duly accomplished and notarized Application Form for Authority to Operate.

A.2.1.3 DTI/SEC registration (for private Blood Collection Unit/Blood Station)

A.2.1.4 Photocopies of Professional Regulation Commission Certificates of personnel

A.2.2.5 Location map of Blood Collection Unit/Blood Station

A.2.2.6 Floor diagram of the Blood Collection Unit/Blood Station and its premises

A.2.2.7 List of equipment to include serial number, brand, date of purchase, number of units and operational status.

A.2.2.8 List of glasswares and supplies

A.2.2.9 Composition of Hospital Blood Transfusion Committee (for hospital based only)

A.2.2. Renewal of Authority to Operate

A.2.2.1 Duly accomplished application Form for Renewal of Authority to Operate

A.2.2.2 List of personnel

A.2.2.3 Change in location, address, if applicable

A.2.2.4 List of equipment

A.2.2.5 Annual accomplishment report (previous year) utilizing the NVBSP standardized monitoring forms.

A.2.2.6 Recommendation from the lead BSF of the Zonal/Regional Blood Services Network.

A.3 The CHD reviews the documents for completeness, authenticity and compliance with authorization requirements.

B. Payment of Fees

- B.1 The CHD prepares the order of payment.
- B.2 The applicant pays the corresponding fees to the Cashier of the CHD in person or through postal money order.
- B.3 The authorization fees shall follow the current prescribed DOH schedule of fees.

C. Survey

- C.1 The CHD together with the lead BSF of the Zonal/Regional Blood Services Network surveys the Blood Collection Unit/Blood Station to determine compliance with standards and technical requirements.
- C.2 The CHD prepares official summary of findings and recommends approval or disapproval after survey.
- C.3 The Director of the CHD approves or disapproves the issuance of authority to operate.
 - C.4.1 If approved, the CHD registers the Blood Collection Unit/Blood Station and issues an authority to operate to the applicant.
 - C.4.2 If disapproved, the CHD sends the findings and recommendations to the applicant. The applicant makes necessary corrections in the Blood Collection Unit/Blood Station within fifteen (15) days from the time of survey. Failure to comply within fifteen (15) days shall be a ground for denial of application for initial and suspension/revocation of authority to operate.

D. Monitoring

The BHFS with the lead BSF of the Zonal/Regional Blood Services Network shall conduct on site monitoring visits of Blood Collection Unit and Blood Station. The monitoring visits shall document the overall quality of Blood Collection Unit and Blood Station.

VIII. TERMS AND CONDITIONS

1. The authority to operate is granted in compliance with the requirements of this Administrative Order. Any deficiencies incurred during the validity of the authority shall be immediately corrected otherwise authority shall be considered null and void.
2. An authority to operate as herein granted as well as any right under the authority cannot be assigned or otherwise transferred directly or indirectly to any party.
3. The CHD shall be notified of any change in management, name or ownership. In cases of transfer of location, a new application authority to operate shall be required.
4. Failure to report in writing within fifteen (15) days of any substantial change in the condition of the authority may be a basis for the suspension or revocation of the authority to operate.
5. A separate authority to operate shall be required for each Blood Collection Unit/Blood Station or branch maintained in separate premises even if operated by the same management.
6. Each Blood Bank shall be responsible for and conduct close supervision of the Blood Collection Unit/Blood Station affiliated with the Blood Service Network. It shall guarantee their compliance with prescribed documentary and technical requirements.
7. The head of the Blood Bank or his designated staff shall conduct on site visits of each satellite Blood Collection Unit/Blood Station at least four (4) times a year or whenever necessary, such as when a problem arises.
8. The authority to operate and the prescribed maximum allowable fees shall be placed in an area readily seen by the public. A copy of these rules and regulations and other relevant Administrative Orders and DOH issuances shall be readily available for guidance of all personnel of Blood Collection Unit/Blood Station.
9. Authority to operate shall be renewed every year.
10. Application for renewal of authority to operate shall be filed ninety (90) days before the expiry date to the CHD under which jurisdiction it is located.
11. The authority to operate may be renewed only if it shall comply with the requirements for authorization.

IX. VALIDITY OF AUTHORITY TO OPERATE

The authority to operate shall be valid for a period of one (1) year.

X. MAXIMUM ALLOWABLE SERVICE FEES

The Blood Collection Unit and Blood Station shall be operated and maintained on a non-profit basis. Hence,

1. The Blood Collection Unit/Blood Station may collect a reasonable service fee for every blood/blood product issued, which shall not be greater than the maximum fees prescribed by the DOH. The maximum allowable service fees shall be adjusted from time to time specifying the basic requirements and special tests covered by the service fees.
2. The BHFS through the NVBSP shall determine the basic donor screening and blood testing procedures through analysis of research information such as disease prevalence studies and risk estimates, consultation with the technical experts and careful evaluation of the optimum benefits from the expected cost of these tests.
3. The maximum allowable service fee shall be calculated by the NVBSP based on a study of the direct and indirect costs of running a standard Blood Collection Unit/Blood Station with basic minimum staffing, facilities and corresponding maximum workload. Direct costs shall include expenses incurred in collecting and processing blood from donor recruitment, blood collection and screening, storage and distribution, with allowance for spoilage, and professional services. These shall not include cost of cross-matching and other special screening and complete compatibility testing. Indirect costs shall include reasonable expenses needed to maintain and upgrade services such as salary of staff and repair of equipment.
4. The direct and indirect cost shall be estimated for every unit of blood collected, processed and distributed.

XI. VIOLATIONS

Violation of the National Blood Services Act or the rules and regulations issued in pursuance thereto, including the commission of the following acts by individual, corporation, association, or organization operating the Blood Collection Unit/Blood Station, or persons under their authority:

1. Any material false statement in the application.
2. Misrepresentation of facts or falsification of documents or records.
3. Change of location, management, name or ownership without informing the CHD in writing.
4. Refusal to allow survey of a Blood Collection Unit/Blood Station by the Regional Blood Center Assessment Team at an appropriate time.
5. Refusal to make available its books, accounts and records of operation to an authorized person from the BHFS/CHD.
6. Charging of blood service fees above the maximum fees set by the DOH.

7. Collection of blood from paid or remunerated donor whether payment comes from the hospital or from the patient/relatives.
8. Dispensing or transfusing unscreened, incompletely tested and/or contaminated blood.
9. Failure to dispose contaminated blood within appropriate time.
10. Any act which is contrary to the accepted blood banking practices.

XII. INVESTIGATION AND HEARING OF CHARGES OR COMPLAINTS

Upon filing of charges or complaints duly sworn to by any individual, corporation, association, or organization against any Blood Collection Unit/Blood Station or any of its personnel who has violated or is violating the provisions of R. A. 7719 or any of these rules and regulations, the DOH-Legal Division/BHFS for Blood Collection/Blood Station respectively shall investigate and verify if the facility concerned or any of its personnel is guilty of the charges or complaints. If upon investigation and hearing, the Blood Collection Unit/Blood Station concerned or any of its personnel is found violating the provisions of R.A.7719 or any of these rules and regulations, the Director of the CHD shall suspend the authority to operate for a definite or indefinite period of time, or revoke the authority to operate without prejudice to taking the case to judicial authorities for criminal action.

XIII. APPEAL

Any Blood Collection Unit/Blood Station or any of its personnel aggrieved by the decision of the DOH Legal Division/BHFS/CHD may within thirty (30) days after receipt of notice of the decision, file a notice of appeal with the Office of the Secretary, and serve a copy of the notice of appeal to the DOH Legal Division/BHFS/CHD. Thereupon, the DOH Legal Division/BHFS/CHD shall promptly certify and file a copy of the decision, including the transcript of the hearings on which the decision is based, with the Office of the Secretary for review. The decision of the Office of the Secretary shall be final and executory.

XIV. ADMINISTRATIVE LIABILITIES

The Director of the DOH Legal Division/BHFS/CHD may impose the following administrative liabilities:

1. Penalty of three thousand pesos (P3, 000) for any Blood Collection Unit/Blood Station that operates without securing an authorization from the CHD.
2. Recommendation to the Professional Regulation Commission to revoke the certificate of registration or to invalidate the authority of any health professional found violating the provisions of R. A. 7719 or of these rules and regulations.
3. Suspension/revocation of authority to operate upon violation of the National Blood Services Act or its rules and regulations.

XV OPERATING WITHOUT AN AUTHORITY TO OPERATE

The CHD shall immediately close all Blood Collection Unit/Blood Station without an authority to operate and may seek assistance of any government agency to effectively enforce the closure.

XVI. PUBLICATION

A list of authorized Blood Collection Unit/Blood Station shall be published by the CHD periodically at the local newspaper (not necessarily a publication of nationwide circulation) by the respective CHDs.

XVII. SEPARABILITY CLAUSE

In the event that any section, paragraph, sentence, clause or word of this order is declared invalid for whatever, any reason, other provisions thereof shall not be affected thereby.

XVIII. REPEALING CLAUSE

These rules and regulations shall repeal and supersede all administrative orders and other issuance inconsistent thereof.

XIX. EFFECTIVITY

These rules and regulations shall take effect upon approval and publication in a newspaper of general circulation.

Signed AO
Received in the Records
Section on 12-18-03


MANUEL M. DAYRIT, M.D., M.Sc.
Secretary of Health

TECHNICAL REQUIREMENTS FOR AUTHORITY TO OPERATE**I. PROMOTION OF VOLUNTARY BLOOD DONATION**

1. Blood shall be collected from healthy voluntary non-remunerated blood donors only.
2. There shall be a documented system of recruitment, retention, screening and selection of voluntary non-remunerated blood donors (for Blood Collection Units).

II- STAFFING

1. Head (Minimum Requirement)

BLOOD SERVICE FACILITY	HOSPITAL BASED	NON HOSPITAL BASED
Blood Collection Unit	Authorized physician certified in Clinical Pathology by the Philippine Board of Pathology In areas where pathologists are not available, the authorized physician authorized to head the clinical laboratory of that particular hospital may head the Blood Collection Unit.	Authorized physician with a formal training of at least three (3) months in blood banking recognized by the NVBSP. or authorized physician with at least one (1) year experience in a Blood Bank/Center that performs blood collection activities recognized by the NVBSP
Blood Station	Authorized physician certified in Clinical Pathology by the Philippine Board of Pathology In areas where pathologists are not available, the authorized physician authorized to head the clinical laboratory of that particular hospital may head the Blood Collection Unit.	Authorized physician with at least three (3) months training in basic blood banking services recognized by the NVBSP or authorized physician with at least one (1) year on the job experience in a Blood Bank/Center recognized by the NVBSP.

2. Medical Technologist

The Blood Collection Unit/Blood Station shall have Medical Technologists who shall work on shifts to cover a 24- hour service. Such Medical Technologists may be part of the clinical laboratory in a hospital-based Blood Collection Unit or Blood Station. The Medical Technologists must be duly registered with the PRC, have a valid professional authority and at least one (1) year on-the-job training/experience in blood banking services.

3. Donor Recruitment Officer

The Blood Collection Unit shall employ one (1) qualified and trained Donor Recruitment Officer. Such training shall be recognized by the NVBSP.

4. Quality Assurance Officer

The Blood Collection Unit/Blood Station shall designate and train at least one (1) of its medical technologists as a Quality Assurance Officer. The Quality Assurance Officer of the Blood Bank/Center to which it is affiliated in the Blood Services Network shall recognize such training.

III. STAFF DEVELOPMENT PLAN

1. There shall be an staff development plan for all personnel.

IV. PHYSICAL FACILITIES

1. The physical plant shall be housed in a well-lighted and well-ventilated area with adequate supply of water.
2. The space shall be sufficient to accommodate the various activities of the Blood Collection Unit/Blood Station with provisions for accessible and clearly demarcated fire exits.
3. The physical arrangement shall allow for the smooth and orderly flow of activities and movements of people and supplies.
4. The technical working area shall be exclusively for the use of the Blood Collection Unit/Blood Station and its other related activities.
5. The physical plant shall be well maintained.

V. EQUIPMENT:

BLOOD STATION	BLOOD COLLECTION UNIT
<p>NON HOSPITAL-BASED</p> <ol style="list-style-type: none"> 1.Refrigerator, Blood Bank controlled at 2-6 ° C with Temperature recorder and alarm system 2.Laboratory thermometer 0-100°C 	<p>NON HOSPITAL-BASED</p> <p>All those stated for Blood Station plus:</p> <ol style="list-style-type: none"> 1. Agglutination viewer for ABO/Rh grouping tube method. 2. Rough balance top loading 3. Blood collection set <ol style="list-style-type: none"> 3.1 Blood donor couch or bed 3.2 Spring scale for blood unit 3.3 Surgical instruments: forceps, scissors 3.4 Tube sealer 3.5 Tray carrier for blood units 3.6 Mechanical device for agitation of blood units during blood collection

<p>HOSPITAL-BASED</p> <p>All those stated above plus:</p> <p>1. Agglutination viewer for compatibility testing. 2. Water bath at 37° C</p>	<p>4. Hemoglobin determination 4.1 Hemoglobinometer or 4.2 Photometer or 4.3 Pycnometer 5. Sphygmomanometer 6. Needle destroyer or its equivalent 7. Stethoscope 8. Thermometer 8.1 Clinical thermometer 8.2 Laboratory thermometer 9. Weighing scale calibrated up to 300 kilograms 10. Generator capacity of at least 10 KVA</p> <p>HOSPITAL-BASED</p> <p>All those stated above plus:</p> <p>1. Agglutination viewer for compatibility testing 2. Water bath at 37° C</p>
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Note: AVR as needed

1. There shall be a regular schedule and a written record of maintenance and service of all equipment and instruments.
2. There shall be written and available contingency program in case an equipment or instrument becomes incapacitated or unavailable.
3. There shall be adequate supplies of good quality to perform the expected services.

VI. QUALITY ASSURANCE/CONTROL

1. There shall be a QA Program including Internal Quality Control of Procedures and Products. Hence, a Quality Assurance Officer shall be designated to plan and implement the QA Program.
2. The Blood Bank/Center to which they are affiliated in the Blood Services Network shall monitor the quality of the services of the Blood Collection Unit or Blood Station.

VII. BIOSAFETY

1. Safety precautions shall be observed at all times.

VIII. RECORDING, REPORTING AND DOCUMENTATION

1. Standard recording, reporting and documentation format, procedures and other documentation requirements of the NVBSP shall be followed.

For Blood Collection Unit only.

2. It shall submit its schedule of bleeding and target area of donor recruitment that clearly follows geographical area agreements with other Blood Collection Unit within the catchment of the relevant Blood Bank/Center.
3. The Blood Collection Unit shall express agreement to submit the blood collected and the list of donors to its attached Blood Bank/Center at the end of the collection day.