

**[DOH ADMINISTRATIVE ORDER NO. 101-A, S.
2003, October 14, 2003]**

**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.2.1.5 Location map of Blood Collection Unit/Blood Station

A.2.1.6 Floor diagram of the Blood Collection Unit/Blood Station and its premises

A.2.1.7 List of equipment to include serial number, brand, date of purchase, number of units and operational status.

A.2.1.8 List of glasswares and supplies.

A.2.1.9 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. Payments 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.3.1 If approved, the CHD registers the Blood Collection Unit/Blood Station and issues an authority to operate to the applicant.

C.3.2 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