

**[ DOH ADMINISTRATIVE ORDER NO. 2008-0008,  
May 02, 2008 ]**

**RULES AND REGULATIONS GOVERNING THE REGULATION OF  
BLOOD SERVICE FACILITIES**

**I. BACKGROUND/RATIONALE**

Republic Act 7719 otherwise known as the "National Blood Services Act or was passed to ensure safe and efficient Blood Banking and transfusion practices is the Philippines. To carry out the provisions of Republic Act 7719, Administrative Order No. 9 1995 "Rules and Regulations Implementing Republic Act 7719" was formulated. Chapter VIII of the said Administrative Order addresses the regulation of blood services by the Bureau of Research and Laboratories. This was amended by Administrative Order No. 17 As. 1998 otherwise known as the "Requirements and Procedures for a License to Operate a BB/BC in the Philippines" The Rules and Regulations Governing Authorization of BCU and BS was formulated and approved in 2003.

In January 2005, Administrative Order No. 2005-0002 "Rules and Regulations for the Establishment of the Philippine National Blood Services Amending Pertinent Provisions of Administrative Order No. 9, s. 1995" was formulated pursuant to Sections 5 and 6 of RA 77-19 This Administrative Order established the National Council for Blood Services and the Philippine National Blood Services. It also defined the new functions and/or service capabilities of the different blood service facilities, including hospital BBs and BCs, as well as those of the end-user hospitals and other health facilities. With these newly delineated functions and service capabilities of blood service facilities. It is imperative that relevant provisions of A.O. No. 9 s. 1995 and A.O. 17-A s. 1998 be revised.

Regulation is one of the main thrusts of current health sector reforms under FOURmula One (F1) for health. The main objective of regulatory reforms is to ensure access to quality and affordable health products, devices, facilities and services, especially those commonly used by the poor. It is the responsibility of the state to provide the public with safe and adequate blood through an efficient blood services network. With the separation of the regulatory functions from the programming functions, it is envisioned that the goals of the national voluntary blood services program shall be better achieved.

**II. OBJECTIVE**

These rules and regulations are promulgated to protect and promote the health of the people by ensuring available licensed blood service facilities with adequate staff, equipment and resources to perform all the required functions safely, efficiently and effectively.

### III. SCOPE

The rules and regulations embodied herein shall apply to all government and private blood service facilities engaged in blood banking and transfusion services.

### IV. DEFINITION OF TERMS

A. Act - Republic Act (R.A.) 7719, also known as the National Blood Services Act of 1994, unless herein specified.

B. ATO - refers to the Authority to Operate. It is a format permit issued by the DOH-CHD to an individual, partnership, corporation or association to a BCU/BS.

C. BB refers to the Blood Bank

D. BC - refers to the Blood Center

E. BHFS - refers to the Bureau of Health Facilities and Services

F. Blood- refers to the human blood for transfusion

G. Blood Component - refers, but not limited to whole blood, red cells, granulocytes plasma, platelets, cryoprecipitate and cryosupernate prepared in a BC.

H. BCU - refers to the Blood Collection Unit

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

J. BS - refers to the Blood Station

K. BSF - refers to the blood service facility. It is a unit, agency or institution providing blood products. The types of BSF are BS, BCU, Hospital BB and BC (Regional, Sub-national and National).

L. Blood Services Network - an organization composed of the designated BCs, hospital BBs, BCUs, BSs, end-user hospitals, and other health facilities established to provide for the blood needs of a specific geographical area.

M. CHD - refers to the Center for Health Development which is the DOH Regional Field Office.

N. DOH-refers to the Department of Health.

O. End-User Hospital - a hospital with a licensed clinical laboratory capable of red cell typing and cross-matching and which does not have any BSF but only receives blood and blood components for blood transfusion as needed.

P. End-User Non-hospital Health Facility - a licensed/accredited non-hospital health facility without a licensed clinical laboratory but administers blood transfusion such as a dialysis clinic and birthing home under the supervision of a licensed physician/s.

Q. EQAS - refers to the External Quality Assessment Scheme

R. HBTC - refers to the Hospital Blood Transfusion Committee

S. LTO - refers to the License to Operate. It is a formal authority issued by the DOH to an individual, partnership, corporation or association to operate a BB/BC.

T. NCBS - refers to the National Council for Blood Services.

U. NVBSP- refers to the National Voluntary Blood Services Program

V. PNRC- refers to the Philippine National Red Cross

W. TTI- refers to the Transfusion-Transmitted Infections

X. Voluntary, Non-Remunerated Blood Donor - a donor who gives blood freely voluntarily without receiving money or any form of payment.

## V. POLICIES AND GUIDELINES

### A. General Guidelines

1. EVERY BSF shall be an integral part of a blood services network and guided by administrative issuances governing the establishment and operation of blood services networks.

a. Each BC shall have responsibility for and authority over the conduct and close supervision of the BCU/BS affiliated with its Blood Service Network.

b. The head of the BC or his designated staff shall conduct on site periodic evaluation of each affiliated BB, BCU and BS.

2. All BSF are required to comply with the standards and technical requirements embodied in the inspection tools. It shall be posted at the DOH website [www.doh.gov.ph](http://www.doh.gov.ph)

3. Blood shall be collected from qualified healthy voluntary non-remunerated blood donors only.

4 Testing forTTIs shall be based on the DOH prescribed methodology. The number of infections to be screened as well as the method for their detection shall be determined and reviewed periodically by the NCBS.

5. Testing for TTIs shall be done at the National, Sub-national and designated Regional BCs including PNRC BCs. Such designation shall be determined by the NCBS pursuant to AO 2005-0002.

6. All units of blood issued by the Philippine BC, Sub-national BCs, Regional BCs, and PNRC under the Philippine Blood Services Network shall not be retested for TTIs by the end-user hospitals and other health facilities. It is the responsibility of the issuing BCs to ensure that all units of blood issued have been tested and found to be

negative to TTIs.

7. Blood and blood products for transfusion shall be obtained from licensed and authorized BSF only.

## B. Specific Guidelines

### 1 Classification of BSF

#### a. Ownership

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

2. Private - (for hospital-based BSF only) - privately owned, established and operated with funds through donation, capital or other means, by an individual, corporation, association, or organization.

#### b. Institutional Character

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

2. Non-hospital-based - a government-owned or PNRC-owned BSF located outside the premises of a hospital consistent with the NVBSP Strategic Plan

#### c. Service Capability

##### 1. BS

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

b. Provision of whole blood and packed red cells;

c. Storage, issuance, transport and distribution of whole blood and packed red cells;

d. Compatibility testing of red cell units, if hospital based.

##### 2. BCU

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

b. Recruitment, retention, and care of voluntary blood donors;

c. Screening and selection of voluntary blood donors;

d. Conduct of health education and counselling services;

e. Collection of blood (mobile or facility-based) from qualified voluntary

blood donors;

f. Transport of Blood to BC for testing and processing;

g. Compatibility testing of red cell units, if hospital based.

3. BCU/BS - all services stipulated under BCU and BS

4. BB -

a. Advocacy and promotion of voluntary blood donation and healthy life;

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

c. The following services shall also be provided:

i. Compatibility testing and red cell units;

ii. Direct Coombs Test;

iii. Red cell antibody screening;

iv. Investigation of transfusion reactions;

v. Assist the HBTC in the conduct of post-transfusion surveillance (hemovigilance)

5. BC

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

b. Recruitment, retention and care of voluntary blood donors;

c. Collection of blood (mobile or facility-based) from qualified voluntary blood donors;

d. Conduct health education and counselling;

e. Testing of units of blood for TTIs;

f. Processing and provision of blood components;

g. Storage, issuance, transport and distribution of units of whole blood and/or blood products to hospitals and other health facilities.

2. Standards and Technical Requirements

a. The BSF appoints and allocates personnel who are suitably qualified, skilled and/or trained to assume the responsibilities, authority, accountability and functions of the position.