Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
2/F Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila
Trunk Line 743-83-01 Direct Line: 711-9501; Fax: 743-1829;743-1829; 743-1786
URL: http://www.doh.gov.ph; e-mail: osec@doh.gov.ph

May 2, 2008

ADMINISTRATIVE ORDER
No. 2008 - 0008

SUBJECT: Rules and Regulations Governing the Regulation of Blood Service Facilities

I. BACKGROUND/RATIONALE

Republic Act 7719 otherwise known as the "National Blood Services Act of 1994" was passed to ensure safe and efficient Blood Banking and transfusion practices in the Philippines. To carry out the provisions of Republic Act 7719, Administrative Order No. 9 s. 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-A s. 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 R.A. 7719. 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. No. 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 formal 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 and 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

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

4. Testing for TTIs 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 National 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 counseling 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 of 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 counseling;
   - **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.

b. Services are provided in an environment that promotes safety, has adequate space, meets the needs of clients, service providers and other stakeholders, and conforms to the current Manual of Standards issued by the DOH.

c. All equipment and instruments necessary for the safe and effective provision of services are available and are properly maintained.

d. All reagents and glassware to be used by the BSF shall be based on the minimum requirement for sensitivity and specificity of testing reagents as well as the testing procedures as recommended by the technical committee of the NVBSP.

e. There shall be a system of reporting and recording of results of BSF examinations.

f. The BSF shall put into practice a quality assurance program.

1) There shall be a policy on quality assurance program and continuous quality improvement.
2) The BSF shall participate in an External Quality Assessment Program administered by the designated National Reference Laboratories (NRL) or other external assessment program approved by the DOH-NVBSP.

g. There shall be a system in outsourcing of examinations and blood components.

h. All hospital-based BB, BCU and/ or BS shall establish a HBTC.

i. All BSF shall comply with policies and guidelines of the NVBSP.

3. LTO/ ATO

a. Hospital based BBs, BCUs, BS shall be licensed or authorized to operate through the One-Stop-Shop Licensure for Hospitals and are therefore not required to obtain a separate LTO or ATO. The required documents for the licensure of the BB or the authorization of the BCU or BS shall be submitted to the CHD, along with other documentary requirements for the hospital LTO.

b. The LTO/ ATO shall be granted in accordance with prescribed documentary and technical requirements and on the basis of specific conditions and limitations established during inspection.

c. The LTO/ ATO as well as any right under the license/authorization cannot be assigned or otherwise transferred directly or indirectly to any party.

d. The LTO/ ATO must be displayed at all times at a prominent place within the premises.

e. The CHD shall be notified within fifteen (15) calendar days of any change in management, name or ownership. In cases of transfer of location, a new application for LTO/ ATO shall be required.

f. A separate LTO/ ATO shall be required for each BSF or branch maintained in separate premises even if operated by the same management.

4. Maximum Allowable Service Fees

a. The BSF 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 NVBSP shall periodically review the maximum allowable service fee specifying the basic requirements and special tests covered by the service fee.

b. The prescribed maximum allowable fees shall be placed in an area readily seen by the public.

c. The basic donor screening and blood testing procedures shall be determined by the NVBSP 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.

VI. PROCEDURAL GUIDELINES

A. Application for LTO for BCs and BBs and ATO for BCU and BS

1. Applicant requests for relevant information and prescribed form from the CHD under whose jurisdiction the proposed BSF is located, in person or through mail, email or Internet.

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

   Documentary requirements for the issuance of LTO/ ATO:
   a. Certificate of inclusion in the Regional Blood Services Network approved by the identified Lead Blood Center in the region
   b. Duly accomplished and notarized Application Form
   c. DTI/ SEC registration (initial)
   d. List of personnel with photocopy of valid PRC card
   e. Location map (initial)
   f. Floor diagram
   g. List of equipment – with serial number, brand, date of purchase, number of units and operational status
   h. NVBSP Annual Blood Report (renewal)
   i. Certificate of participation in EQAS in previous year (renewal)

3. The CHD Director or his authorized representative/s reviews documents for completeness, authenticity and compliance with the requirements.

4. The applicant pays the appropriate fees, based on the current prescribed DOH schedule of fees, to the CHD Cashier in person or through postal money order. BSF operating as BCU/ BS shall be charged the corresponding fee for BCU.

B. Inspection

1. The CHD Director or his authorized representative(s) inspects the BSF within thirty (30) calendar days from the time of application to determine compliance with standards and technical requirements.

2. The CHD inspection team prepares official summary of findings and recommends approval or disapproval after inspection.

C. Issuance of LTO/ ATO

1. The CHD Director approves or disapproves the issuance of LTO/ ATO.

   a. If approved, the BSF is registered and an LTO/ ATO is issued to the applicant within fifteen (15) calendar days.

   b. If disapproved, a copy of inspection findings and recommendations is provided to the applicant within fifteen (15) calendar days from the time of inspection.

   c. An application for an LTO/ ATO that is not processed within the thirty (30) calendar day period is considered approved.

D. Renewal of LTO/ ATO

1. The LTO/ ATO shall be renewed every three (3) years. All hospital BSF shall renew their LTO/ ATO annually as part of the One-Stop-Shop licensure for hospitals.

2. Application for renewal of LTO/ ATO shall be filed on the first day of October until the last day of November on the last year of the LTO validity period to the CHD under which jurisdiction the BSF is located.

3. The LTO/ ATO may be renewed only if it complies with the prescribed standards and technical requirements.

VII. VALIDITY OF LICENSE TO OPERATE

The LTO/ ATO to operate a BSF shall be valid for a period of three (3) years, beginning on January 1 of the first year of the validity period to December 31 of the third year of the validity period.

As part of the hospital license to operate, the license to operate/ authority to operate a BB/ BCU/ BS shall be valid for a period of one (1) year, beginning January 1 to December 31.

VIII. MONITORING

The BHFS/ CHD Director or his authorized representative/s is authorized to monitor and conduct on-site visits to the BSF at any given time. The BSF shall make available to the monitoring team all pertinent records to determine the level of compliance with the National Blood Services Act and these rules and regulations.

IX. VIOLATIONS

Violations of the National Blood Services Act or the rules and regulations issued in pursuance thereto, include the commission of the following acts by individual, corporation, association, or organization operating the BSF, or persons under their authority:

A. Any material false statement in the application.

B. Misrepresentation of facts or falsification of documents or records.

C. Refusal to make available its books, accounts and records of operation to an authorized person from the BHFS/CHD.

D. Charging of blood service fees above the maximum fees set by the DOH.

E. Collection of blood from paid or remunerated donor whether payment comes from the hospital or from the patient/relatives.

F. Refusal to participate in EQAS conducted by the designated National Reference Laboratories

X. TRANSITORY PROVISIONS

All previously licensed hospital based and PNRC BCs already performing the blood testing and processing shall be allowed to operate as such until December 31, 2009. By 2010, there shall be a nationally coordinated blood service network with only the designated BCs performing the centralized testing and processing.

XI. 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 BSF 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 BHFS/ CHD Director or his authorized representative/s shall investigate and verify if the BSF concerned or any of its personnel is guilty of the charges or complaints. If upon investigation and hearing, the BSF concerned or any of its personnel is found violating the provisions of R. A. 7719 or any of these rules and regulations, the CHD Director shall suspend the LTO/ ATO for a definite or indefinite period of time, or revoke the LTO/ ATO without prejudice to taking the case to judicial authorities for criminal action.

XII. SUSPENSION REVOCATION OF LICENSE/AUTHORITY TO OPERATE

A LTO/ ATO shall be suspended or revoked by the CHD Director upon violation of the National Blood Services Act or the rules and regulations issued in pursuance thereto. The CHD Director shall notify the BSF concerned or any of its personnel by registered mail the particular reasons for the denial or revocation of LTO/ ATO.

XIII. APPEAL

Any BSF or any of its personnel aggrieved by the decision of the CHD Director may, within thirty (30) calendar days after receipt of notice of the decision, file a notice of appeal with the Office of the Secretary through the BHFS, and serve a copy of the notice of appeal to the CHD. Thereupon, the CHD Director 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. CLOSURE

The CHD Director or his authorized representative/s shall immediately close all BSF without an LTO/ ATO, and may seek assistance of any government agency to effectively enforce the closure.

XV. PENAL PROVISION

A. Upon conviction, any BSF that collects service fees greater than the maximum prescribed by the DOH shall have its LTO/ ATO suspended or revoked by the CHD Director. Any individual, corporation, association, or organization who is responsible for the above violation shall suffer the penalty of imprisonment of not less than one (1) month but not more than six (6) months, or a fine of not less than five thousand pesos (P5,000) but not more than fifty thousand pesos (P50,000), or both at the discretion of the judicial authority.

B. Any individual, corporation, association, or organization who establishes and manages a BSF without securing the necessary LTO/ ATO from the CHD, or violates any provision of these rules and regulations shall suffer the penalty of imprisonment of not less than twelve (12) years but not more than twenty (20) years, or a fine of not less than fifty thousand pesos (P50,000) but not more than five hundred thousand pesos (P500,000), or both at the discretion of the judicial authority.

C. The head of the BSF and the personnel responsible for dispensing or transfusing unscreened, incompletely tested and/ or contaminated blood or failing to dispose within forty-eight (48) hours blood that is contaminated with transfusion transmissible infections after receipt of confirmatory testing result from the Research Institute for Tropical Medicine National Reference

Laboratory shall be imprisoned for ten (10) years. This shall be without prejudice to the filing of criminal charges under the Revised Penal Code.

D. The CHD Director, after due notice and hearing, and upon approval of the Secretary, may impose the following administrative sanctions:

1. Penalty of five thousand pesos (P5,000) for any BSF that fails to submit the application for renewal of LTO/ ATO to the CHD within three (3) months prior to the expiration of the existing license;

2. Recommendation to the PRC to revoke the certificate of registration or to invalidate the license of any health professional found violating the provisions of R. A. 7719 or of these rules and regulations.

XVI. PUBLICATION

A list of licensed/ authorized BSF according to their classification shall be published or posted at the DOH website annually.

XVII. SEPARABILITY CLAUSE

In the event that any provision or part of this Order be declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

XVIII. REPEALING CLAUSE

These rules and regulations shall repeal and supersede all administrative orders and previous issuances inconsistent thereof.

XIX. EFFECTIVITY

These rules and regulations shall take effect fifteen (15) days after publication in a newspaper of general circulation.

FRANCISCO T. DUQUE III, M.D., MSc.
Secretary of Health