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Department of Health
OFFICE OF THE SECRETARY

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28 April 1995

ADMINISTRATIVE ORDER
No. 9 s. 1995

SUBJECT: Rules and Regulations Implementing Republic Act No. 7719 otherwise known as the "NATIONAL BLOOD SERVICES ACT of 1994"

Pursuant to Section 11 of Republic Act. No. 7719, otherwise known as the National Blood Services Act of 1994, passed by the Senate and the House of Representatives on 28 April 1994 which took effect on 12 May 1994, the following Rules and Regulations are hereby adopted.

Chapter I
TITLE AND APPLICATION

Section 1 TITLE.

These Rules shall be known as the "Rules and Regulations Implementing Republic Act No. 7719 otherwise known as the NATIONAL BLOOD SERVICES ACT OF 1994".

Section 2 PURPOSE.

These Rules and Regulations are adopted prescribing the principles, guidelines, procedures and standards for the implementation of R.A. 7719 to facilitate compliance therewith and achieve the objectives thereof.

Section 3 SCOPE.

These Rules shall apply to all hospitals, entities, establishments or institutions, government owned and operated or private, engaged in blood transfusion services in the Philippines, whether full time or part time, local or foreign.

Section 4 **DEFINITION OF TERMS.**

As used in these Rules and Regulations, the terms below shall be defined as follows:

1. **ACT** - Republic Act 7719 otherwise known as the "National Blood Services Act of 1994", unless herein specified;

2. **DEPARTMENT** - the Department of Health;

3. **SECRETARY OF HEALTH** - the Secretary of Health or any other person to whom the Secretary delegates the responsibility of carrying out the provisions of this Act;

4. **BLOOD/BLOOD PRODUCT** - refers to human blood, processed or unprocessed and includes blood components, its products and derivatives;

5. **BLOOD TRANSFUSION SERVICES** - a set of activities and functions related to blood transfusion such as, but not limited to, motivation and recruitment of donors, blood collection, testing and screening of donor blood, preparation of blood components, storage and distribution of blood and components, inventory control and quality assurance;

6. **BLOOD BANK/CENTER** - a laboratory or institution with the capability to recruit and screen blood donors, collect, process, store, transport and issue blood for transfusion and provide information and/or education on blood transmissible diseases;

7. **HOSPITAL-BASED BLOOD BANK/CENTER** - a blood bank/center which is located and performing blood bank services within the premises of a hospital and which can perform compatibility testing of blood;

8. **NON-HOSPITAL-BASED BLOOD BANK/CENTER** - a blood bank/ center which is not located and not performing blood bank services within the premises of a hospital and is not part of a hospital;

9. **COMMERCIAL BLOOD BANK** - a blood bank that exists for profit, money or any material gain earned out of sale of, or exchange for, blood or blood products which profit, money or any material gain are not used solely for the operation and maintenance of the blood bank service;

10. **BLOOD COLLECTION UNIT** - an institution or facility duly authorized by the Department of Health to recruit and screen donors and collect blood;

11. **BLOOD STATION** - a government or private hospital or a Philippine National Red Cross chapter which has not been licensed as a blood center but has been authorized by the Department to store and issue blood and blood products, and perform compatibility testing, when necessary, according to specific regulations in Section 40 hereby;

12. **BLOOD SERVICE FACILITY** - any unit, office, institution providing any of the blood transfusion services, which can be a Blood Bank/Center, a Blood Collection Unit or a Blood Station;

13. **VOLUNTARY BLOOD DONOR** - an individual who donates blood on one's own volition or initiative and not induced, directly or indirectly, in any manner whatsoever, by any monetary compensation;

14. **WALKING BLOOD DONOR** - an individual who has been screened by history and physical examination, found to be fit to donate blood, and included in the list of qualified voluntary donors referred to in Section 4, paragraph (e) of R.A. No. 7719, who is ready to donate blood when needed in his or her community;

15. **BLOOD TRANSFUSION TRANSMISSIBLE DISEASES** - diseases which may be transmitted through blood transfusion, including, but not limited to, Acquired Immune Deficiency Syndrome (AIDS), hepatitis B, hepatitis C, malaria and syphilis;

16. **BLOOD BANKING EQUIPMENTS** - essential laboratory machines, instruments and their accessories used in the different steps in the blood banking process such as those used to centrifuge blood or separate blood into its various components; preserve blood or blood products in cold storage or freezer; and perform blood tests such as hemoglobin tests and screening tests for blood transmissible diseases. These equipments also include those used in specific supportive processes such as sterilization and sanitary disposal of blood and blood products.

17. **BLOOD BAGS** - sterile, sturdy plastic bags containing anti-coagulants which are especially designed for blood collection and transfusion. Blood bags can either be single or multiple types and have an integral sterile needle and collection tubing.

18. **REAGENTS** - substances employed to detect or measure another substance or convert one substance to another by means of the reaction that it causes. In blood banking, the reagents used are those necessary to measure hemoglobin; screen for blood transmissible diseases such as HIV, hepatitides, malaria, syphilis, among others; identify blood groupings; and perform cross-matching and other immunohematologic examinations.

Chapter II
NATIONAL VOLUNTARY BLOOD SERVICES PROGRAM

Section 5 NATIONAL PROGRAM COMMITTEE.

1. *Composition.* A National Voluntary Blood Services Program Committee is hereby created and shall be chaired by the Secretary of Health. It shall be composed of, but not limited to, the Heads of the following Offices and associations:

   - Department of Education, Culture and Sports
   - Department of Interior and Local Government
   - Department of Finance
   - Department of Social Welfare and Development
   - Professional Regulation Commission
   - Philippine National Red Cross
   - Philippine Blood Coordinating Council
   - Philippine Society of Hematology and Blood Transfusion
   - Philippine Society of Pathologists
   - Philippine Medical Association
   - Philippine Hospital Association
   - Philippine Association of Medical Technologists, and
   - representatives from other societies and cooperating or donor agencies.

2. *Functions.* The National Voluntary Blood Services Program Committee shall be responsible for the following:

   a) Formulation of a five-year Directional/Strategic Plan of the National Voluntary Blood Services Program taking into consideration the 1992 National Blood Services Program Directional Plan of the Department;

   b) Operationalization and institutionalization of the National Voluntary Blood Services Program including budgetary allocation for program activities;

   c) Monitoring and evaluation of the National Voluntary Blood Services Program activities;

   d) Creation of multi-sectoral sub-committees such as, but not limited to, advocacy and promotion, programming, monitoring and evaluation and curriculum development;

   e) Generation of multi-sectoral and inter-disciplinary support for national activities focused on blood services including the organization of the National Blood Congress.

3. *Meetings.* The National Voluntary Blood Services Program Committee shall meet at least quarterly. Unscheduled or emergency meetings shall be called upon the discretion of the chairperson.

Section 6 **FIELD REPRESENTATIVE OF THE NATIONAL COMMITTEE.**

The Regional Health Director shall be the field representative of the National Voluntary Blood Services Program Committee, and as such shall coordinate the Voluntary Blood Services Program activities in the region.

Section 7 **DOH PROGRAM MANAGEMENT.**

1. *National Voluntary Blood Services Unit.* The Secretary of Health shall institutionalize a National Voluntary Blood Services Unit within the organizational structure of the Office of Health Facilities Standards and Regulation of the Department.

2. *Functions.* The unit, as the program management arm of the Department, shall be responsible for the following:

a) Integration and coordination of all voluntary blood service program efforts such as, but not limited to, integration of blood service facilities operations and upgrading ;

b) Development of training, information, education and communication (IEC) materials, program guidelines and standards especially on preventive services, and pre- and post-donation counseling for blood transfusion transmissible diseases in coordination with other health programs and units in the Department ;

c) Provision of technical assistance and training in designing and implementing a voluntary blood donation program in private hospitals;

d) Preparation of the blood services operational plan incorporating the activities and needs of the other Department units and services involved in the blood services programs such as, but not limited to, the Bureau of Licensure and Regulation, and Hospital Operation and Management Service;

e) Provision of secretariat services to the National Voluntary Blood Service Program Committee and as such shall:

(1) Collate and review all annual operational plans, proposed budgets of the different sub-committees at the national and sub-national levels ;

(2) Propose priorities for budgetary allocation;

(3) Prepare the consolidated annual National Voluntary Blood Services Program Plan which shall be submitted during the first quarter meeting of the National Program Committee for approval;

(4) Coordinate and document all National Voluntary Blood Services Program Committee and Sub-committee meetings and activities.

Section 8 **PROGRAM FUNDING.**

1. The funds for the National Voluntary Blood Services Program shall be provided by:

   a) The budgetary allocation of the Department;

   b) The Philippine Charity Sweepstakes Office with the initial amount of at least twenty-five million pesos (P 25,000,000.00);

   c) The Philippine Amusement and Gaming Corporation with the initial amount of at least twenty-five million pesos (P 25,000,000.00);
   d) The trust liability account of the Duty Free Shop with the initial amount of at least twenty million pesos (P 20,000,000.00)

   e) The contributions of other agencies such as civic and charitable organizations.

2. The National Voluntary Blood Services Program Committee shall work out a plan with the Philippine Charity Sweepstakes Office, Philippine Amusement and Gaming Corporation and Duty Free Shop and similar civic and charitable organizations for continued funding and material support.

3. The utilization of the fund shall be based on the consolidated and approved National Voluntary Blood Services Program Committee Plan.

4. The Department shall allocate an annual budget for personnel, capital outlay, infrastructure, maintenance, operating and other expenses to be used by the program.

5. A trust fund shall be established for the National Voluntary Blood Services Program at the national level and at the level of the different blood service facilities of the Department out of the donations generated by the office and/ or the facility. Use of funds shall be based on the operational plan of the different sub-committees and blood service facilities concerned.

Chapter III
PROMOTION OF VOLUNTARY BLOOD DONATION

Section 9 PUBLIC INFORMATION AND EDUCATION.

1. *Composition.* The National Advocacy and Promotion Sub-committee shall be composed of, but not limited to, representatives of the Department of Health, the Philippine National Red Cross (PNRC), the Philippine Blood Coordinating Council (PBCC), the Philippine Information Agency, and other similar organizations whose activities are related to advocacy and promotion of voluntary blood donation.

2. *Functions.* The National Advocacy and Promotion Sub-committee shall be responsible for the following:

   a) Preparation of a five-year advocacy and promotion plan based on the National Voluntary Blood Services Program five-year directional/ strategic plan which shall be submitted to the Secretary of Health for approval;

   b) Formulation of designs for non-monetary or non- profit oriented incentives for voluntary blood donors such as, but not limited to, Blood Assurance Plans;

   c) Planning, coordination, monitoring and evaluation of the national advocacy and promotion activities;

3. *Regional Counterpart.* The Regional Advocacy and Promotion Sub-committee shall be created in each region of the country with similar corresponding composition as that of the National Advocacy and Promotion Sub-committee but may be expanded to include other organizations. In turn, the Regional Advocacy and Promotion Sub-committee shall encourage the creation of similar committees at the provincial and city levels.

   The Regional Advocacy and Promotion Sub-committee shall be chaired by the representative of the Department of Health and shall have the following responsibilities:

   a) Formulation of the regional advocacy and promotion operational plan which shall be submitted to the Regional Health Director for approval and endorsement to the National Voluntary Blood Services Program Committee;

   b) Implementation, monitoring and evaluation of the regional advocacy and promotion activities;

Section 10 **PROMOTION IN SCHOOLS AND COMMUNITIES.**

1. *Composition.* The National Voluntary Blood Services Program Sub-committee on Curriculum Development shall be chaired by the Secretary of Education and shall be composed of members including, but not limited to, the representatives from the:

   - Department of Health
   - Philippine Society of Hematology and Blood Transfusion
   - Philippine Society of Pathologists
   - Philippine Association of Medical Technologists
   - Philippine Association of Schools of Medical Technology and Public Health
   - Philippine Nursing Association
   - Association of Philippine Medical Colleges
   - Philippine Medical Association
   - Philippine National Red Cross

2. *Functions.* This Sub-committee shall be responsible for the following:

   a) Development, printing and distribution of instructional materials and methods focused on voluntary blood donation for integration into the health subjects of all schools, public or private, and at all levels of education, formal or non-formal;

   b) Orientation and/or training of teachers on the utilization of such materials and methods;

   c) Monitoring of the use and effectiveness of such materials and methods in terms of process and product, and continuing revision of such as necessary;

   d) Preparation and submission to the National Voluntary Blood Services Unit of the annual budgetary requirements for the promotion of voluntary blood services in the schools.

3. *Training Programs and Technical Assistance.* The Department shall likewise provide training programs and technical assistance to enable communities, schools, industrial and business sectors, barangays, military groups and local government units to implement their own voluntary blood donation programs.

Section 11 **PROFESSIONAL EDUCATION AND RATIONAL USE OF BLOOD AND BLOOD PRODUCTS.**

1. *Role of the PRC.* The Professional Regulation Commission (PRC) shall encourage all medical and other health professional associations and societies especially those accredited by the PRC to conduct trainings on

rational use of blood and blood products including the benefits of voluntary blood donation for their respective members as part of the continuing professional education.

The PRC shall provide equivalent continuing professional education units for all training courses on rational use of blood and blood products.

2. ***Role of Professional Societies and Associations.*** **All medical and other health professional associations and societies whose activities are related to professional education and blood transfusion shall be encouraged to conduct trainings and seminars on the rational use of blood and blood products including the dangers of commercial blood and the benefits of voluntary blood donation for their respective members as part of their continuing professional education activities and residency programs.**

Through Sub-committees created by the National Voluntary Blood Services Program Committee, technical manuals and training modules for health professionals on the "Rational Use of Blood and Blood Products and Blood Transfusion Medicine" shall be developed involving various professional societies and associations.

3. ***Role of the Department of Health.*** **The Secretary of Health shall ensure the conduct of trainings on rational use of blood and blood products, on the practice of blood transfusion medicine, and on the merits of voluntary blood donation for the health personnel.**

The Department shall require training hospitals to conduct continuing professional education programs and trainings on the rational use of blood and blood products and the merits of voluntary blood donation as one of the prerequisite for licensure of hospitals. It shall also provide guidelines for the inclusion of the rational blood and blood product use and the merits of voluntary blood donation in the examination for residency training admission and the monitoring of such activities in hospitals.

The Department shall require the establishment of a hospital Blood Transfusion Committee as a prerequisite for licensure of teaching/ training hospitals and hospitals with blood banks/centers.

4. ***Composition and Functions of the Hospital Blood Transfusion Committee.*** **The Hospital Blood Transfusion Committee shall be composed of, but not limited to:**

- **physicians from the Department of Pediatrics, Medicine, Surgery, Obstetrics and Gynecology, and Pathology**
- **the Hematology consultant**
- **representatives from the nursing service**
- **the Hospital Medical Training Officer and**
- **the Blood Service Quality Assurance Officer**

The Hospital Blood Transfusion Committee shall be primarily responsible for the establishment of hospital policies and guidelines for blood transfusion therapy and monitoring and audit of the use of blood and blood products within the facility according to the Standard Operating Manual on Blood Services of the BRL (Section 38).

Chapter IV
BLOOD SERVICES NETWORK AND BLOOD DONOR RECRUITMENT

Section 12 **ESTABLISHMENT OF BLOOD SERVICES NETWORK.**

There shall be established, in coordination with the local PNRC, a Regional Blood Services Network which shall be chaired by the Regional Health Director. The Regional Blood Services Network shall be the venue for the following:

1. Review of the existing linkages among blood service facilities and requirements for blood within their respective regions;

2. Formulation of a design for a blood collection and distribution scheme for the region;

3. Designation and authorization of different blood service facilities according to geographic location, to complementary tasks and other related undertakings;

4. Review of the annual consolidated Regional Blood Services Operational Plan which will be recommended for funding to the National Program Committee.

Section 13 **BLOOD DONOR RECRUITMENT.**

The Department shall adopt a system of procedures or programs to promote blood donor recruitment and ensure the increase in the number and retention of voluntary blood donors as follows:

1. The Department shall coordinate with heads of agencies, institutions, offices, organizations, business establishments and communities, be they government or non-government, and encourage them to actively participate in donor recruitment in order to secure commitments to regular blood donations in their particularly designated blood services facility;

2. The Department in collaboration with the Philippine National Red Cross shall be the lead agency in the celebration of the Blood Donor's Week which shall be held annually on the second week of July. During the Blood Donor's Week, the Department, in coordination with other agencies, shall adopt a program or system of awards, rites, ceremonies or activities in special recognition of the voluntary blood donors;

3. The Department shall coordinate the professionalization of voluntary blood donors, health educators and donor recruiters through organized training activities;

4. The Department shall encourage and convince local government units to pass ordinances or resolutions that will promote the walking blood donor concept such as, but not limited to, the mandatory keeping of a list of qualified voluntary blood donors in the government hospitals, rural health units, health centers and barangays, and the conduct of mass blood typing activities in areas where there are no adequate blood service facilities.

Chapter V
UPGRADING OF SERVICES AND FACILITIES

Section 14 **MONITORING AND EVALUATION SUB-COMMITTEE.**

1. *Composition.* The Monitoring and Evaluation Sub-committee shall be composed of, but not limited to, representatives from the:

   - Department of Health
   - Department of Education
   - Philippine National Red Cross
   - Philippine Blood Coordinating Council
   - Other agencies, professional organizations and societies

   This Sub-committee may require status reports, when deemed appropriate, from various agency units such as, but not limited to, the Hospital Operation and Management Service, the Bureau of Licensure and Regulation and the Bureau of Research and Laboratories of the Department.

2. *Functions.* The Monitoring and Evaluation Sub-committee shall:

   a) Design an upgrading and development plan to ensure, at all times, better quality blood services;

   b) Set a criteria of indicators to monitor the progress or success in meeting the requirements of upgrading of blood service facilities;

   c) Monitor all continuing professional education activities;

   d) Coordinate all studies and reviews related to the upgrading of blood service facilities.

   e) Review the non-monetary incentives for voluntary blood donors and recommend changes when necessary.

Section 15 **DEPARTMENT OF HEALTH REGIONAL HOSPITALS AND MEDICAL CENTERS.**

As much as possible, all regional hospitals and medical centers of the Department shall be upgraded to Hospital-Based Category B Blood Banks/ Centers in accordance with the requirements of sections 28 and 29 of these Implementing Rules and Regulations.

Section 16 **PROVINCIAL AND DISTRICT HOSPITALS.**

The Department shall assist in the upgrading of provincial and district hospitals to meet the blood transfusion services requirement in the area especially by providing technical assistance, training and mobilizing resources.

Section 17 **BLOOD BANKS/CENTERS WITH SPECIAL FUNCTIONS.**

Strategically located Blood Banks/Centers shall be identified as follows:

1. **One Blood Bank/Center shall be designated as the National Blood Center and shall be developed to be able to perform more specialized functions such as, but not limited to:**

   a) **preparation of special plasma derivatives;**
   b) **performance of special confirmatory and reference blood tests;**
   c) **conduct of highly technical specialist on-the-job training courses;**
   d) **conduct of research and special studies.**

2. **At least one Blood Bank/Center in every geographical region shall be designated as the Regional Blood Center and shall be developed to perform special functions such as, but not limited to:**

   a) **preparation and distribution of blood components for other hospitals within the region;**

   b) **training and supervisory functions over the other Blood Banks/Centers within the region;**

   c) **research.**

Section 18 **LICENSING OF PRIVATE HOSPITALS.**

The Department, through the Bureau of Licensure and Regulation, shall require private hospitals to submit their Voluntary Blood Donation Program Plan.

Section 19 **LICENSING OF GOVERNMENT HOSPITALS.**

The Department, through the Bureau of Licensure and Regulation, shall require all government hospitals to submit a Voluntary Blood Donation Program Plan. The application for renewal of their licenses shall be accompanied by the following:

1. Preceding year's voluntary blood donation program report according to the format designed by the Monitoring and Evaluation Sub-committee.

2. Bureau of Licensure and Regulation monitoring visit report for the preceding year.

Section 20 **PHILIPPINE NATIONAL RED CROSS.**

The Department shall assist the PNRC in mobilizing resources and in upgrading their facilities or chapters by facilitating linkages with private or government hospitals with laboratory facilities and trained personnel.

Section 21 **PREVENTIVE SERVICES.**

All blood service facilities shall provide preventive health services such as education and pre- and post-donation counseling on blood transfusion transmissible diseases in line with the guidelines and standards of the National Voluntary Blood Services Unit.

Section 22 **RECOGNITION AWARDS.**

The Department, in coordination with the PNRC, shall grant seals of excellence in recognition of outstanding service of blood service facilities to be awarded in a formal ceremony as part of the Blood Donors' Week.

Chapter VI
PHASE-OUT OF COMMERCIAL BLOOD BANKS

Section 23 **PROCESS OF PHASING-OUT.**

The Department shall effect the phasing-out of all commercial blood banks over a period of two (2) years, extendable for a maximum period of (2) years after the effectivity of R.A. 7719. The decision to extend shall be based on the result of a careful study and review of the blood supply and demand and public safety.

Section 24 **OPTIONS FOR COMMERCIAL BLOOD BANKS.**

The Department shall encourage and assist existing commercial blood banks to convert to solely clinical laboratories in order to ensure job security of their personnel and allow a reasonable return on their investment on training and equipment.

Chapter VII
NON-PROFIT OPERATION

Section 25 OPERATION AND MAINTENANCE OF BLOOD SERVICE FACILITIES.

The operation and maintenance of all blood service facilities and any other entities, agencies, establishments engaged in blood services and covered by these Rules shall be non-profit, provided that, service fees may be collected, but not greater than the amount prescribed by the Department, which shall be limited to the necessary expenses entailed in the collection and processing of blood and reasonable fees for maintaining and upgrading facilities and services. Blood shall be collected from healthy voluntary donors only.

The BRL Director shall issue Bureau Orders on the schedule of standard fees as stated in section 35.

Chapter VIII
REGULATION OF BLOOD SERVICES

Section 26 REGULATORY AUTHORITY.

The licensing and regulatory functions of the Department of Health regulating blood services shall be exercised through the Bureau of Research and Laboratories (BRL) in the Office for Health Facilities Standards and Regulations, and as such, it is hereby authorized to issue orders and circulars providing for implementation details and specific technical requirements related to licensing and regulation.

Section 27 CATEGORIES OF BLOOD SERVICE CAPABILITIES.

Blood service capabilities shall be classified into categories as follows:

A. **BLOOD BANK/CENTER:** A Blood Bank/Center may either be hospital-based or non-hospital-based and may be licensed as Category A or B when it meets the minimum required service capabilities set forth hereunder:

1. A blood bank/center shall be considered non-hospital Based Category A when it can and is performing the following:

   a) Recruitment of voluntary donors
   b) Health education and counselling
   c) Donor screening and selection
   d) Blood collection
   e) Basic blood screening and testing
   f) Provision of whole blood and packed RBC
   g) Issuance, transport and distribution of blood/ blood products
   h) Storage of blood/ blood products

2. Non-hospital Based Category B when, in addition to those performed under the Non-hospital Based Category A, it is capable of providing, in addition to whole blood, all blood products and components.

3. Hospital-Based Category A when, in addition to those performed under the Non-hospital Based Category A, it is capable of performing compatibility-testing.

4. Hospital-Based Category B when, in addition to those performed under the Hospital-Based Category A, it is capable of providing, in addition to whole blood, all blood products and components; and of performing investigation of transfusion reactions and resolution of incompatible cross-matching results.

B. **BLOOD COLLECTION UNITS.** In coordination with other related or appropriate agencies, the Blood Banks/Centers shall organize and establish Blood Collection Units (BCU) which are authorized to perform the following:

1. Recruitment of voluntary blood donors
2. Screening of blood donors
3. Provision of health education and counselling
4. Collection and transport of blood to Blood Banks/Centers

C. **BLOOD STATION.** All other hospitals and PNRC chapters rendering blood services not classified as a Blood Bank/Center or Blood Collection Unit may be allowed by these rules to store blood and blood products, subject to regulation by the BRL. Further, duly-authorized Blood Stations (BS) shall be properly identified and specified for each Blood Bank/Center.

Section 28 **REQUIREMENTS FOR NEW LICENSE.**

A Blood Bank/Center may be granted a license to operate only if it shall have complied with the following minimum requirements:

1. **MINIMUM NUMBER AND QUALIFICATION OF PERSONNEL:** The minimum number of staff with their corresponding qualifications for each category of Blood Bank/Center shall be as follows:

a) **Category A Hospital and Non-hospital Based Blood Bank/Center:** The overall supervision and management shall be under a competent physician duly registered by the Professional Regulation Commission (PRC) with a valid certificate of registration and a valid professional license, who has at least six (6) months training in blood banking services under an institution or agency recognized by the BRL.

The Blood Bank/Center shall have at least one (1) Trained Medical Technologist duly registered by the PRC with a valid certificate and a valid professional license, who has at least one (1) year on-the-job training or experience in blood banking services under an institution or agency recognized by the BRL.

The Blood Bank/Center shall also have at least one other (1) Medical Technologist or Medical Laboratory Technician duly registered by the PRC with a valid certificate and a valid professional license. Pursuant to the Medical Technology Law (RA No. 005527), the Medical Laboratory Technician shall be under the responsibility of the Trained Medical Technologist.

b) **Category B Non-hospital Based Blood Bank/Center:** The minimum personnel requirements for Category A Blood Banks/Centers (Section 28[2a]) shall also be required of Category B Non-hospital Based Blood Banks/Centers.

In addition to the foregoing, the laboratory and blood processing section of the Category B Non-hospital Based Blood Bank/Center shall be managed by and under the direct and regular supervision and of a PRC-registered and licensed physician certified by the Philippine Board of Pathology in Clinical or Anatomical Pathology with at least 6 months additional training in blood banking from a training institution recognized by the BRL, and/or the Philippine Board of Hematology and Blood Transfusion in Blood Banking. However, if the overall supervisor of the Blood Bank/Center is already a pathologist trained in blood banking or a hematologist, this additional requirement will not be necessary.

c) **Category B Hospital Based Blood Bank/Center:** The overall supervision and management shall be under a PRC-registered and licensed physician with a valid certificate in Clinical or Anatomical Pathology from the Philippine Board of Pathology with at least 6 months additional training in blood banking from a training institution recognized by the BRL, and/or a certificate in Blood Banking from the Philippine Board of Hematology.

The Blood Banks/Centers in this category shall also have one (1) Trained Medical Technologist and one (1) other Medical Technologist or Medical Laboratory Technician with the same qualifications as those required for a Category A Blood Bank/Center.

2. **STAFF DEVELOPMENT PLAN:** The Blood Bank/Center shall prepare a one (1) year staff development plan for all categories of personnel.

3. **PHYSICAL FACILITIES, EQUIPMENT AND SUPPLIES:**

a) All Blood Banks/Centers shall operate and maintain blood bank services under good physical conditions and with adequate physical facilities, equipments and supplies. Specifications for these shall be defined in appropriate BRL Bureau Orders and shall be included in the Manual on Standard Operating Procedures on Blood Services of the BRL (Section 38).

b) All Blood Banks/Centers, Blood Collection Units and Blood Stations shall have a regular schedule, and a written record, of maintenance and service of all equipments and instruments used in blood bank services.

c) There shall also be a written and readily available contingency program in case an instrument or equipment becomes incapacitated or unavailable.

4. **BIOSAFETY:** Safety precautions shall be followed in all Blood Banks/Centers at all times. This shall include, but shall not be limited to, prominent display of easily understandable posters on safety procedures; wearing of protective clothing and gadgets such as laboratory gowns, gloves, masks, and eye protectors; and adherence to clear and acceptable procedures and physical arrangements for decontamination and disposal of contaminated materials such as blood, equipment, clothing and other supplies.

5. **QUALITY CONTROL:** All the technical staff of the Blood Bank/ Center shall have satisfactorily passed the minimum proficiency test given by the BRL or any of its certified proficiency testing agencies.

Adequacy of quality control procedures of each Blood Bank/Center shall be assessed based on their compliance with quality control standards set by the BRL, including but not limited to, the use of quality reagents, techniques and equipments; the presence of an adequately trained and competent Quality Assurance Officer; the acceptability of procedures and arrangements for internal and external quality control monitoring activities; the acceptability of equipment calibration and maintenance procedures; the adequacy of documentation of accountability in key steps and procedures; and the acceptability of procedures for reporting errors and instituting remedial action.

6. **RECORDING, REPORTING AND DOCUMENTATION REQUIREMENTS:** All Blood Banks/Centers shall follow standard recording, reporting and documentation formats and procedures and other documentation requirements of the BRL which shall be described in appropriate BRL Bureau Orders and included in the SOP Manual on Blood Services of the BRL (Section 38).

All the entries in the application forms, logbooks, reports and other written documents should be true and correct.

7. **BLOOD DISTRIBUTION AND TRANSPORT REQUIREMENTS:** Blood shall be distributed to the hospitals, not to individuals or patients.

   The blood distribution scheme of each Blood Bank/Center shall be clearly described and shall include the complete list of authorized Blood Stations strategically located to provide maximum equitable distribution of blood to its catchment area and the names and qualifications of the persons authorized to handle, transport or issue blood.

   Blood shall be issued only to authorized Blood Stations except during emergency conditions such as disasters and major accidents, breakdown of equipments or facilities in other Blood Banks/Centers, and other similar circumstances.

   The Blood Bank/Center shall have adequate facilities and arrangements for keeping blood and blood products under appropriate refrigeration during transport and storage following the principles of an unbroken cold storage chain.

   No untrained person shall be allowed to handle, transport or issue blood and blood products.

8. **BLOOD TRANSFUSION COMMITTEE:** Blood Banks/Centers shall have organized Blood Transfusion Committees. The names of committee members, their corresponding qualifications and tasks and functions shall be submitted upon application for license.

9. **PREVENTIVE SERVICES:** All Blood Banks/Centers shall have adequate and effective health education and counselling services and materials. Health education should cover the benefits of blood donation; the social behaviors that increase the risk of acquiring blood-borne diseases; and the effective measures of preventing disease transmission.

   Counselling of donors found to have infectious blood-borne diseases should include advice on the nature of the disease, the basic treatment and management options and referral to clinics, hospitals or physicians for continuing treatment and clinical management. The principle of confidentiality, especially for AIDS patients, shall be upheld.

10. **NETWORKING:** Blood Banks/Centers shall have clear arrangements for continuing staff training on blood banking and rational blood use, sharing of manpower and other resources, geographical coordination of donor recruitment, complete list of authorized strategically-located Blood Collection Units and laboratory referral arrangements.

Section 29 **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:

1. All the technical staff of the Blood Bank/Center shall have passed the basic proficiency tests the previous year.

2. The Blood Bank/Center shall have achieved at least 70% of the staff development plan targets.

3. The Blood Bank/Center shall have bled only voluntary blood donors the previous year, including those bled in its authorized Blood Collection Units.

4. The complete annual report of the preceding year's operations shall have been submitted on or before January 31 of the succeeding year, following the required format (BRL Blood Services Form No. 3).

5. The inspection visit shall have confirmed that the Blood Bank/Center has continued to operate under good physical conditions and according to prescribed technical and operating standards.

6. The Blood Bank/Center has been shown to collect only the allowable service fee for each blood unit dispensed.

Section 30 **TERMS AND CONDITIONS OF LICENSING.**

The following are the terms and conditions of licensing:

1. In regions outside the National Capital Region, the Regional Health Director shall be the designated representative of the Director of the BRL in the licensing and regulation of Blood Banks/Centers.

2. Applications for new license shall be addressed and submitted to the Director of the BRL. Applications for renewal of license shall be officially addressed to the Director of the BRL and submitted, for Blood Banks/Centers in Metro Manila, directly to the BRL; or, for Blood Banks/Centers in other regions, to the Regional Health Directors.

3. A license to operate a Blood Bank/Center shall be valid for one year from the date of issue and shall be signed by the Undersecretary of Health for Health Facilities Standards and Regulations and issued to persons, agencies or corporations who have successfully complied with all of the standards and requirements listed in Section 28 or 29, as appropriate.

4. The exact date of expiration of the license shall be printed on the license.

5. Assessment of a Blood Bank/Center for initial licensing and renewal of license shall involve evaluation of documents and at least once a year actual inspection of the facility by authorized BRL inspectors.

6. The license, as well as the rights under the license, is non-transferrable, directly or indirectly.

7. The license of the Blood Bank/Center shall be displayed in a conspicuous place within the Blood Bank/Center. A notice shall be posted informing the public that complaints about the services may be addressed to the Director of the Bureau of Research and Laboratories.

8. A non-refundable license fee of six hundred pesos (P 600) shall be charged on application for a license to open and operate a Blood Bank/Center and four hundred pesos (P 400) for renewal of license. The license fee shall cover the cost of inspection and printing of special license certificates and other required forms and documents.

   A non-refundable proficiency testing fee shall also be charged to cover for the cost of materials and supplies especially reagents used during the proficiency testing. The proficiency test fee shall be two thousand pesos (P 2,000) per bank/center.

   The fees shall be uniform for both government and private Blood Banks/Centers and shall be adjusted by the BRL through appropriate Bureau Orders as necessary. All fees shall be payable to the Bureau of Research and Laboratories.

Section 31 **THE LICENSING PROCESS.**

The following shall be the process of licensing:

1. **INITIAL APPLICATION.** Any person, agency, or corporation desiring to operate a Blood Bank/Center shall submit to the BRL a duly-accomplished and notarized BRL Blood Services Form No. 1 (Application for New Blood Center License) together with the following supporting documents:

   a) Certified true copy of Securities and Exchange Commission registration (if a corporation or a foundation);

   b) Names and qualifications of proposed staff, including certified true copies of PRC certificate of registration and professional license; PSP or PSHBT certification; results of proficiency tests, and other certificates of training, as appropriate and applicable;

c) Floor diagram of proposed premises;

d) List of equipments for blood services;

e) Biosafety and Quality Control arrangements and procedures;

f) List of Blood Collection Units (Names of heads, qualifications and complete addresses);

g) List of Blood Stations (Names of medical technologist in-charge and complete addresses);

h) Names and tasks of the members of the BTC (hospital-based only);

2. **APPLICATION FOR RENEWAL OF LICENSE.** Any person, agency, or corporation desiring to renew its license to operate a Blood Bank/Center shall submit to the BRL or the Regional Health Director, as appropriate, a duly-accomplished and notarized BRL Blood Services Form No. 2 (Application for Renewal of Blood Center License) together with the following supporting documents:

a) Names, qualifications and proofs of qualifications of new staff and any staff changes (eg. resignations, additional trainings or qualifications for existing staff);

b) Changes (improvements or deterioration) in existing physical facilities and functioning of facilities and equipments;

c) Newly acquired equipments and facilities;

d) Annual Report on Blood Services for the previous year (BRL Blood Services Form No. 3);

e) Certified true copy of hospital license for preceding year (hospital-based only);

f) Names and addresses of regular blood donors who donate at least twice a year;

g) Any changes in the list of authorized Blood Collection Units and Blood Stations (deletions or additions only);

h) Any other changes in blood banking operations and services;

3. **INSPECTION.**

a) Each Blood Bank/Center shall be visited by an authorized BRL inspector 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.

b) Only inspectors who have satisfactorily completed the BRL Course for Blood Bank/Center Inspectors are qualified to inspect Blood Banks/Centers and other blood service facilities. A productivity incentive pay of fifty pesos (P50) for every blood bank/center inspected properly and thoroughly may be allowed subject to the usual auditing and accounting procedures and to availability of funds of the agency where the inspector comes from.

c) For applicants desiring to open a Blood Bank/Center (i.e. new license), inspection shall be done only of applicants who have fulfilled all the basic written requirements.

d) Inspection of licensed blood bank/center shall be done while its activities are going on and shall be unannounced. Each licensee shall make available all records and documents as may be required by the authorized BRL inspectors upon presentation of a valid inspection mission order signed by the Secretary or his authorized representative.

4. **TIMETABLE FOR APPLICATION AND INSPECTION.**

a) Applications for new license may be submitted any time.

b) Applications for renewal of license should be submitted within the two (2) months prior to the expiration date of the current license. Blood Banks/Centers which fail to submit an application for renewal within the prescribed two-month period shall be considered as "Blood Banks/Centers operating without a license" when their current license expires and shall be subject to the penalties for such violation.

5. **RELEASE.**

a) Licenses shall be released only to the heads of the Blood Bank/Center or their officially designated representatives not later than two (2) weeks after the completion of the inspection visit.

b) Applicants for new license who, upon inspection, did not meet all of the prescribed standards shall receive a letter from the Director of the BRL or the Regional Health Director stating the requirements which the Blood Bank/Center failed to meet.

c) Applicants for renewal of license who, upon inspection, did not meet all of the prescribed standards shall receive, aside from the letter stating their deficiencies, an order signed by the BRL Director or respective Regional Health Director, to cease blood banking operations immediately. These blood centers shall also be revisited within one month after release of the order to stop operations for confirmation of compliance with the order.

Section 32 **TRANSITION PERIOD FOR CONFIRMATION OF LICENSES.**

The years nineteen ninety-five to nineteen ninety-six (1995-1996) shall be the transition years for confirmation of compliance to the new licensure requirements of existing Blood Banks/Centers. During this transition period, the documents, forms and process for renewal of licenses shall follow the procedures for new licenses.

Existing Blood Banks/Centers which will fail to meet all of the new or additional requirements may still be allowed to operate within this two-year period provided such banks/centers submit a plan to upgrade their services and facilities according to the prescribed standards.

Starting January 1, 1997, all licensure requirements will be imposed without exemption.

Section 33 **PHASE OUT OF COMMERCIAL BLOOD BANKS.**

No new license shall be issued for a commercial blood bank.

Renewal of license of existing commercial blood banks beginning January 1, 1995 shall be upon compliance with the new requirements under these Rules and Regulations subject to the provisions of Section 32 hereof.

Section 34 **APPEALS AND REPORTS ON VIOLATIONS.**

Reports on violations of R.A. 7719 and these Rules and Regulations shall be addressed to the Secretary of Health and the National Director of the Bureau of Research and Laboratories.

The Secretary or the National Director of the BRL may request for police assistance from 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 35 **ALLOWABLE SERVICE FEES.**

1. The blood service facility may collect a reasonable service fee for every blood or blood product issued which shall not be greater than the maximum prescribed by the Department of Health and implemented through an appropriate BRL Bureau Order issued by the Director of the BRL. The maximum allowable service fee shall be adjusted from time to time specifying the basic requirements and special tests not covered by the service fee.

2. The BRL shall determine the basic required donor and blood screening tests and procedures through a thorough analysis of research information such as disease prevalence studies and risk estimates, consultation with 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 BRL based on a study of the direct and indirect costs of running a standard blood bank with basic, minimum staffing and facilities and corresponding maximum workload.

   Direct costs shall include those expenses incurred in collecting and processing blood - from donor recruitment, blood collection, blood screening, component preparation, storage and distribution, with allowance for spoilage, and professional services. These shall not include cost of cross-matching and other special screening and compatibility testing. Indirect costs shall include reasonable expenses needed to maintain and upgrade services such as salary of staff and repair of equipments.

4. The direct and indirect costs shall be estimated for every unit of blood collected, processed and distributed.

Section 36 **AUTHORIZATION OF BLOOD COLLECTION UNITS.**

The Regional Health Directors, including the Regional Health Director of the National Capital Region, shall authorize Blood Collection Units (BCU) according to the following standards and procedures:

1. A Blood Collection Unit shall have at least one PRC-registered physician and one PRC-registered medical technologist, both with valid certificate of registration and valid professional license. Both should have had at least one (1) month training on voluntary donor recruitment and screening; voluntary donor holding and motivation; health education and counselling; blood collection, handling and transport; and management of blood collection activities and problems. Such training shall be done by an agency duly recognized by the BRL.

2. A Blood Collection Unit shall have adequate and proper equipments and supplies of good quality to be able to perform donor recruitment and screening; health education and counselling; blood collection, handling and transport; and management of any reactions according to the BRL standards described in the SOP Manual on Blood Services (Section 38).

   There shall be a written and readily available contingency plan for all Blood Collection Units in case of problems such as instrument or equipment breakdown.

   All Blood Collection Units shall have a regular schedule, and a written record, of maintenance and service of all equipments and instruments used in blood bank services.

3. A Blood Collection Unit may be static or mobile. Physical arrangements for both kinds during collection shall be comfortable, clean and adequate.

4. The Blood Collection Unit shall be clearly attached to a network of one Blood Bank/Center which has confirmed its recognition of the coordination and cooperation arrangements with the BCU. Such confirmation may be contained in an appropriate certificate.

5. The BCU shall submit its schedule of bleeding and target area of donor recruitment that clearly follows geographical area agreements with other BCUs within the catchment of the relevant Blood Bank/Center.

6. The BCU shall express agreement to submit the blood bags collected and the list of donors to its attached Blood Bank/Center at the end of the collection day. Authorization can be withdrawn if the BCU fails to execute this agreement.

7. Each BCU shall be visited at least once a year by the head of the Blood Bank/Center it coordinates with or by a duly designated Blood Bank/Center health staff.

8. Authorization as a BCU shall be renewed yearly, signed by the Regional Health Director, and issued to the head of the BCU.

9. The authority to operate the BCU shall be revoked by the Regional Health Director should the procedures and services be found to be below the standards set by the BRL in its Standard Operating Procedures Manual on Blood Services (Section 38).

Section 37 **AUTHORIZATION OF BLOOD STATIONS.**

The Regional Health Directors, including the Regional Health Director of the National Capital Region, shall authorize Blood Stations according to the following standards and procedures:

1. Blood Stations may be located only within hospital premises, government or private; or within the premises of the Philippine National Red Cross chapters.

2. A Blood Station shall be under the responsibility of a PRC-registered medical technologist with a valid certificate of registration and a valid professional license.

3. A Blood Station shall have at least one properly functioning blood refrigerator with twenty-four (24) hours power supply.

4. There shall be a written and readily available contingency plan for all Blood Stations in case of problems such as instrument or equipment breakdown.

5. All Blood Stations shall have a regular schedule, and a written record, of maintenance and service of all equipments and instruments used in blood bank services.

6. Blood shall be issued only to patients confined within the hospital that houses the station or to hospitals within the area, unless called for by emergency conditions as listed in Section 28 (6).

7. The authority to operate a Blood Station shall be renewed yearly, signed by the Regional Health Director and issued to the agency that operates the Blood Bank/Center that will distribute the blood bags to the station, with a copy furnished to the chief of the hospital where the Blood Station is located and the medical technologist-in-charge.

8. Each Blood Station shall be visited at least once a year by the head of the Blood Bank/Center that distributes blood to the station or by a duly designated Blood Bank/Center health staff. A record of such visit shall be open for inspection by the BRL or its duly authorized representative.

9. The authority to operate the Blood Station shall be revoked by the Regional Health Director should blood storage, handling, issuance, distribution or disposal be found to be below the standards set by the BRL in its Standard Operating Procedures Manual on Blood Services (Section 38).

Section 38 **STANDARD OPERATING MANUAL.**

Standards for donor recruitment and screening; for all laboratory and blood processing tests and procedures; for handling and disposal of blood and other biosafety procedures; for inventory and recording procedures; for networking, blood collection and distribution; and all quality assurance/ quality control measures shall follow international guidelines promoted by the World Health Organization and the International Society of Blood Transfusion. Such guidelines shall be adapted to the Philippine situation through a Standard Operating Procedures Manual (SOP Manual) on Blood Services which shall be developed, pretested and printed by the BRL within six (6) months after the effectivity of these Implementing Rules and Regulations. The Manual shall be formally signed and dated by the Director of the BRL. This manual shall then be incorporated as an integral part of these Rules and Regulations.

Until the time when the updated SOP manual is available, the procedures and standards incorporated in AO 57 s. 1989 (Sections 10, 11, 12 & 13), BO No. 5 s. 1990 (Section 6), AO 122 s. 1992, Bureau Circulars No. 2 s. 1990, No. 2 s. 1991, and No. 4 s. 1994, of the BRL which are not in conflict with these Rules and Regulations shall continue to be in effect.

Such a manual shall be reviewed and revised periodically. In its revisions, the previous editions shall be collected back by the BRL and precautions taken to ensure that all relevant key persons are informed of the changes and the effectivity of these changes.

Section 39 **QUALITY ASSURANCE OFFICER.**

A Quality Assurance Officer recognized for his/her integrity and organizational abilities shall be assigned or designated and trained for each blood service facility by the BRL. He/she shall organize all documents relating to quality assurance and, in coordination with the head of the blood service facility, shall make sure that the required, recognized standards are instituted and followed according to national specifications. He/ she shall periodically review quality control procedures and monitor compliance with standard procedures. He/ she shall initiate investigation and remedial action when errors occur, in cooperation with the head of the units affected.

Section 40 **CONFIRMATION OF VOLUNTARY DONORS.**

1. Paid blood donors who are usually brought in by relatives of patients should be carefully selected out and blacklisted from the roster of donors. This can be done through careful history and physical examination of donors. Donors which show multiple needle punctures on the arms and those whose complete names and relations to the

patient are unknown to the patient or his relatives should be immediately rejected.

2. The Quality Assurance Officer shall countercheck donors who regularly donate to the Blood Bank/Center as part of his/her regular monitoring of Blood Bank/Center operations.

Section 41 **EMERGENCY BLOOD TRANSFUSION.**

Blood collection and immediate transfusion in hospitals without a license as a Blood Bank/Center may be allowed in an emergency situation subject to the following conditions:

1. That the medical/ surgical condition poses an immediate threat to the patient's life;

2. That the collection and transfusion is done under the direct supervision and with the full responsibility of the attending physician;

3. That the existing standards and specifications for donor screening including history and physical examination, on asepsis and biosafety, and on the use of proper and good quality equipments and materials or supplies, are complied with;

4. That the required tests for hemoglobin, syphilis, HIV, hepatitis and for presence of malarial parasites and compatibility testing including cross-matching are also performed before transfusion.

Chapter IX
IMPORTATION OF BLOOD BANK EQUIPMENT AND SUPPLIES

Section 42 **CERTIFICATION OF IMPORTATION PRIVILEGES.**

An annual list of Blood Banks/Centers and hospitals participating actively in the National Voluntary Blood Services Program shall be prepared by the National Voluntary Blood Services Unit. This list, duly approved and certified by the Undersecretary of Health for Health Facilities Standards and Regulations and duly noted by the Directors of the Bureau of Research and Laboratories and the Bureau of Licensing and Regulation of the Department, shall be submitted to the Department of Finance and the Bureau of Customs before January 31 of every year.

Section 43 **EQUIPMENT AND MATERIALS COVERED.**

The BRL, in consultation with the Department of Finance and Bureau of Customs, shall enumerate in an appropriate Bureau Circular the detailed list of equipment, blood bags and reagents, with specifications as necessary, which may be allowed to be imported tax- and duty-free under the provisions of RA 7719. The list shall be modified by the BRL as necessary.

Section 44 **APPLICATION FOR TAX EXEMPTION.**

1. A letter of intent enclosing the list of equipment and materials with the necessary specifications and justification for their use shall be submitted to the Secretary of Health. The BRL Director shall certify that the list of equipments and materials requested are included in the list of allowable equipments and supplies and that these are necessary for the voluntary blood services program of the particular Blood Bank/Center or hospital. The Secretary of Health or his duly-authorized representative shall sign a recommendation for tax- and duty-free exemption addressed to the Secretary of Finance.

2. An application for exemption from customs duties and taxes shall then be filed with the Revenue Office, Department of Finance, Manila. The PNRC, blood banks/centers, hospitals and other institutions participating actively in the National Voluntary Blood Services Program may avail of the tax duty exemption mentioned herein, upon certification and appropriate endorsement by the Secretary of Health or his duly-authorized representative.

Section 45 **OTHER DOCUMENTATION REQUIREMENTS.**

For expeditious processing, the application shall also include a certification from the Department of Trade and Industry that the proposed importations are not locally available in sufficient quantity, comparable quality and reasonable price.

Section 46. **INSPECTION.**

The Department of Finance may conduct pre/post-inspection of the facilities and imported articles released duty- and tax-free in accordance with these Rules and Regulations in line with the monitoring functions of said office. Said findings/ report shall be furnished the Department of Health.

Chapter X
PENALTIES FOR VIOLATIONS

Section 47 PENALTIES.

1. Upon complaint of any person and after due notice and hearing, any blood bank/center which shall collect charges and fees greater than the maximum prescribed by the Department shall have its license suspended or revoked by the Secretary.

   Any person or persons who shall be responsible for the above violation shall suffer the penalty of imprisonment of not less than one (1) month nor more than six (6) months, or a fine of not less than Five thousand pesos (P5,000) nor more than Fifty thousand pesos (P50,000), or both at the discretion of the competent court.

2. Any person who shall establish and operate a Blood Bank/Center without securing a license to operate from the Department or who fails to comply with the standards prescribed by the Department refered to in Section 9 of RA No. 7719, shall suffer the penalty of imprisonment of not less than twelve (12) years and one (1) day nor more than twenty (20) years or a fine of not less than Fifty thousand pesos (P50,000) nor more than Five hundred thousand pesos (P500,000), or both at the discretion of the competent court.

3. The head of the Blood Bank/Center and the necessary trained personnel under the head's direct supervision found responsible for dispensing, transfusing and failing to dispose within forty-eight (48) hours blood which have been proven contaminated with blood transfusion transmissible diseases shall be imprisoned for ten (10) years. This without prejudice to the filing of criminal charges under the Revised Penal Code.

4. All importation accorded duty- and tax-free release pursuant to this Order shall not be transferred or disposed of in any manner whatsoever to any person or entity without prior approval of the Department of Finance. The penalty provided for under existing laws or any revenue laws shall be imposed in any violation of the provisions of this Order.

5. The Secretary or his duly-authorized representative, after due notice and hearing, may also impose the following administrative sanctions:

   a) Penalty of Five thousand pesos (P 5,000) for the head or owner of the Blood Bank/Center which fails to submit the application for renewal of license to the BRL or its designated offices within two (2) months prior to the expiration of the existing license;

b) Penalty of Three thousand pesos (P 3,000) for the head of a Blood Collection Unit or Blood Station which shall operate without securing authorization from the Department or its designated offices;

c) Revocation or suspension of Blood Bank/Center license or Blood Collection Unit or Blood Station authorization for:

- Misrepresentation of facts or falsification of documents or records
- Refusal of entry for inspection
- Refusal to make available its books, accounts and records of operations
- Failure to inform the BRL or its authorized representatives about changes in Blood Bank/Center, Blood Collection Unit or Blood Station location, facilities, services or operations;

d) Recommendation to revoke the certificate of registration or to suspend said certificate to practice the profession and to invalidate the professional license of any health professional involved in misrepresentation of facts or falsification of documents or records especially medical, laboratory or inspection results and certificates, or in violation of RA No. 7719 and the herein Rules, by the Professional Regulation Commission upon recommendation of the Secretary.

Section 48 **REPEALING CLAUSE.**

These Rules and Regulations shall supersede all previous Administrative and Bureau Orders and Circulars of the Department. The provisions of any Department or BRL order and circular, or other issuances inconsistent with these Rules and Regulations are hereby repealed or modified accordingly.

Section 49 **EFFECTIVITY CLAUSE.**

These Rules and Regulations shall take effect fifteen (15) days after its publication in the Official Gazette or in two (2) national newspapers of general circulation.

Section 50 Approved on this twenty-eighth day of April nineteen hundred and ninety-five.

JAIME Z. GALVEZ-TAN, MD, MPH
Acting Secretary of Health