Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

September 20, 1971

ADMINISTRATIVE ORDER
No. 156 series 1971

REVISED RULES AND REGULATIONS GOVERNING THE COLLECTION, PROCESSING AND SALE OF HUMAN BLOOD AND THE ESTABLISHMENT AND OPERATION OF BLOOD BANKS AND BLOOD PROCESSING LABORATORIES.

Sec. 1 - Purpose and Title - The Rules and Regulations promulgated as Department of Health Administrative Order No. 56 series 1959 pursuant to Section 5 of Republic Act No. 1517, approved on June 16, 1956, are hereby revised and shall be known as "REVISED RULES AND REGULATIONS GOVERNING THE COLLECTION, PROCESSING AND SALE OF HUMAN BLOOD AND THE ESTABLISHMENT AND OPERATION OF BLOOD BANKS AND BLOOD PROCESSING LABORATORIES IN THE PHILIPPINES", they are hereby promulgated for the purpose of safeguarding and promoting public health and welfare by preventing improper collection, processing and sale of human blood or its product to the public.

Sec. 2 - Scope - The regulations embodied herein shall apply to the collection, processing, and sale of human blood and the establishment and the operation of blood banks and blood processing laboratories in the Philippines, including those already in operation in all government or private hospitals.

Sec. 3 - Basic License Requirement - Any person desiring to establish or operate blood bank and/or Blood Processing Laboratory or desiring authority to collect, process and distribute, whether for free or for sale human blood, shall submit to the Bureau of Research and Laboratories, a sworn application in the form prepared by the said Bureau and containing, among others, the following data: the place, municipality, and province where it is to be established; the name of the establishment, the name or names of person or persons incharge; and the name, citizenship, and domicile of the owner, administrator, or manager. The application should be accompanied by a copy of the partnership or corporation papers if the applicant is a partnership or corporation. An inspector of the Bureau of Research and Laboratories shall, upon receipt of said application, inspect the establishment and verify if the applicant has complied with the requirements prescribed in these regulations. The application will then be forwarded by the Director of Bureau of Research and Laboratories to the Secretary of Health for approval and signature of the necessary license or for any other appropriate action.

Sec. 4 - A fee of one hundred pesos (₱100.00) shall be charged for every license issued by the Bureau of Research and Laboratories, to open or operate a blood bank or processing laboratory or

to distribute human blood whether for free or for sale. This license shall be subject to renewal within the last 2 months of each year upon payment of a renewal fee of fifty (₱50.00) pesos. A grace period of two (2) months is allowed subject to a levy of ten pesos (₱10.00) fine within the first two months of the next year. After this grace period the license will be considered to have lapsed and a new license shall be applied for.

Sec. 5 - No Blood Bank or Blood Processing Laboratory shall be allowed to operate nor any person allowed to collect, process and distribute human blood either for sale or for free without having secured the proper license from the Bureau of Research and Laboratories properly signed by the Secretary of Health, except in case of emergencies due to severe hemorrhage where there is an immediate danger to the patient's life, as provided for in Section 3 of R.A. No. 1517.

Sec. 6 - No blood is to be dispensed except upon the presentation of a proper prescription, or request from the attending physician or hospital authority or another blood bank, which shall be kept on file and subject or open to inspection.

Sec. 7 - No person is permitted to operate, manage or supervise a blood bank unless he or she is a licensed physician duly registered with the Board of Medical Examiners of the Republic of the Philippines to practice the medical profession in this country and must have had training in blood bank operations in accredited blood banking institutions.

Sec. 8 - Unless otherwise specified, the words hereinafter mentioned shall have the following meanings:

a. "Blood" - means human blood, processed or unprocessed and includes its products and derivatives.

b. "Persons" - includes individuals, corporations, associations, societies and organizations.

c. "Costs" - means the actual purchase price of unprocessed blood and its handling charges, such as those for its collection, processing, storage, transportation and sale and reasonable allowance for spoilage.

d. "Blood Bank" - Blood processing laboratory or service where any two or more of the following are done:

1. Solicitation and screening of blood donors.
2. Collection of blood for transfusion.
3. Processing and storage of blood.
4. Transport and issuance to hospitals, to clinics, and health centers.

e. "Closed System" - means a system which permits the transfer of material from one container to another entirely within the system, without contamination and exposure to outside air.

f. "Philippines" - When used in a geographical sense includes all the territories and possession of the Republic of the Philippines.

g. "Products and Derivatives" - Whole blood, concentrated red cells, plasma and its fractions, platelet concentrates, etc.

Sec. 9 - Interpretations - Except as specifically authorized by the Secretary of Health in writing no interpretation of the meaning of the regulations by any office or employee of the Office of the Secretary of Health other than a written interpretation by the Secretary of Justice will be recognized to be binding upon the Secretary of Health.

Sec. 10 - Application for Licenses

a. Application for license shall be filed in a form "Application for Blood and Processing Laboratory" with the Office of the Bureau of Research and Laboratories for screening and approval.

b. Each application shall be signed under oath or affirmation by the applicant or a person duly authorized to act for and on his behalf.

Sec. 11 - General Requirements for Issuance of License - An application for license will be approved if:

a. The application is for a non-profit basis, i.e. blood shall be sold at cost. The regular charge shall not be less or more than set by the Bureau of Research and Laboratories from time to time in consultation with the appropriate specialty societies.

b. The laboratory establishment satisfied the scientific standards as contained in Sections 13 and 14 thereof.

c. No material false statement ot mistatement of conditions verified on inspection have been made in the application.

Sec. 12 - Terms and Conditions of License

a. Meither the license as herein granted nor any right under the license shall be assigned or otherwise transferred to an unauthorized party in violation of the provisions of these regulations.

b. Any Blood Bank or Blood Processing Laboratory desiring to transfer to another place shall report this fact to the Bureau of Research and Laboratories, stating the new place and site of the establishment within ten (10) days after transfer subject to reinspection. Likewise, any blood bank or blood processing laboratory desiring to stop operation should notify the Bureau of Research and Laboratories of this fact stating the date it will or stopped operation.

c. Any blood bank physician who decides to terminate services or transfer supervision should

inform the Bureau of Research and Laboratories.

Sec. 13 - Requirements for a Blood Bank and/or Blood Processing Laboratory

a. Personnel - Blood Banks and Blood Processing Laboratories shall be under the direction and supervision of a licensed and qualified physician with training in blood processing and operation in an accredited Blood Bank. All technical assistants involved in the technical aspects of blood banking operation should be either registered physicians or registered Medical Technologists. No qualified physician will be given permits to operate more than four (4) geographically separate blood banks and/or clinical laboratories except in localities where other factors like lack of qualified physicians and the needs of public health have to be considered.

b. Physical Plant

(1) Work rooms must be housed in a permanent building constructed of strong materials, preferably concrete or semi-concrete. Flood must be concrete, tiled or linoleum finish. It must also have adequate drainage.

(2) Work rooms should be well-ventilated with adequate provisions for either natural or artificial lighting.

(3) Should be relatively dust-free, preferably air conditioned.

(4) Should have adequate supply of water for washing and cleaning facilities such as for scrubbing of hands, washing glass containers, utensils, and other glasswares used in the laboratory.

(5) A separate space must be provided for the bleeding or collection of blood which should be well lighted and well ventilated and situated on the cool portion of the building. The ideal temperature is from 75° - 80°F.

(6) The laboratory should likewise be clean and should be located just adjacent to the bleeding area.

c. Equipments

(1) For preliminary testing of donors:

(a) Blood pressure apparatus
(b) Stethoscope
(c) Weight scale
(d) Disposable or autoclaved lancets, needles for making punctures for collecting blood for hematologic examinations.
(e) Hemoglobin determination apparatus or hematocrit
(f) Miscellaneous glasswares, slides, etc.
(g) Clinical thermometer.

(2) For Bleeding Area:

(a) Bleeding tables or bed
(b) Blanket to cover donor when needed
(c) Bedside table with containers for sterile cotton, sponges, spirit of ammonia.
(d) Tourniquet
(e) Autoclaved or disposable syringes, needles.
(f) Special blood containers with measured anticoagulant, sterile and pyrogen free solutions.
(g) Disposable plastic blood donor sets
(h) Emergency tray containing vasopressor drugs, atropine, and cardio-respiratory stimulant and intravenous fluids and infusion set.
(i) Blood Collection Scale

(3) Storage Room

(a) Blood refrigerator, with automatic thermoregulator of adequate capacity. Temperature of refrigerator must be automatically maintained between 2° - 8°C. It must be provided with at least a laboratory thermometer which must be read and recorded every 12 hours. If possible, an alarm system must be incorporated to extreme temperature. The refrigerator must be used exclusively for storage of blood.

(4) For the Blood Processing Laboratory (Minimum required Equipments)

(a) Clinical centrifuge for serology work.
(b) Waterbaths for 37°C and 56°C with motoring thermometer.
(c) Microscope, compound
(d) Shaking machine for serological tests
(e) Miscellaneous laboratory glasswares, slides, etc.
(f) Close system for blood components.

(5) For Maintenance of Sterile Supplies - With the use of expendable blood containers, donor sets, transfusion sets and other expendable assemblies, the list of equipments mentioned above, under minimum equipments, are all that is required. However, if reusable equipments and supplies are to be used, the following additional facilities are required:

(a) Adequate washing facilities
(b) Autoclave and hot air sterilizer.

(6) For fractionation of blood components other than packed red cells and plasma, there should be a refrigerated centrifuge torsion balance.

d. Reagents

(1) ABO typing sera
(2) Rh typing sera
(3) Bovine albumin and/or Coomb's reagent or enzymes like Ficin or Papain, or trypsin etc.
(4) Antigen for the acceptable serological tests.
(5) Copper sulfate if there's no hematocrit or hemoglobinometer.
(6) Giemsa's or Wright's stains

Sec. 14 - Minimum Requirements for the Collection, Processing, and Disposal of Citrated Whole Blood (Human)

a. Donor requirement - Determination of the suitability of the donor shall be the responsibility of a physician-in-charge of the blood bank and shall be done by him or under his supervision with the assistance of the necessary trained attendants. Only those persons who are in physical condition to give blood may serve as blood donors. Donors shall be free of diseases past or present transmissible by blood transfusion (particularly malaria, other protozoal diseases, syphilis, infectious hepatitis and acute upper respiratory disease) as far as can be determined from donor's personal history and from such physical examination and laboratory tests as appear necessary for each donor on the day the blood is obtained.

b. Other requirements of donors:

(1) Age must be between 18 - 55 (18 - 20 written parental or guardian consent)
(2) Mouth temperature must not eceed 99.5°F or 37.3°C.
(3) Hemoglobin level must not be less than 12 gms/100ml. of blood or hematocrit of 36 or with $Cu2SO4$ at 1:053
(4) Systolic blood pressure must be between 100 to 160 mm. of mercury. Provided the distolic pressure is not over 100.
(5) Donor who is pregnant or who has delivered within the past year should not be accepted.
(6) Donors, male or female should weigh at least 110 lbs. to give one pint of blood.
(7) Donors may give ½ pint of blood every 3 to 4 weeks and 1 pint every 6 to 8 weeks provided they satisfy all other requirements.
(8) A history of viral hepatitis or any history of jaundice, malaria shall disqualify donors.
(9) Donors who have a history of the following diseases: diabetes, active tuberculosis, undulant fever, viral infection, filariasis, those under hypertensive therapy, those that show effects of alcohol, syphilis, those under treatment for rabies, should not be accepted.
(10) Persons who have had tooth extractions within 3 days should not be allowed to give blood.
(11) Persons who received blood transfusion within 6 months should not be allowed to give blood.
(12) Persons who have received within 2 weeks viral or bacterial vaccine immunizations should not be allowed to give blood.
(13) Persons who are receiving current penicillin therapy should not be allowed to give blood.
(14) Fasting is not a requirement for blood donation.

c. Collection of the Blood

(1) Bleeding of donors - Drawing blood from the donor shall be the responsibility of the licensed physician in-charge and shall be done by him or under his direct supervision with the assistance of the necessary trained attendants; the drawing shall be performed in a suitable bleeding area located in the licensed laboratory or blood bank.

Apparatus or instruments such as lancets needles, syringes or other blood letting device, capable of transmitting infection from one person to another shall be autoclaved for 30 minutes at 121.5°C (15 lb. pressure), or sterilized by dry heat for two hours at 170°C. The method employed for the removal of blood from the donor shall conform to the accepted standards of aseptic surgery and shall be made in a closed system.

(2) The Blood containers and Anticoagulant Solutions:

The blood letting device used for the removal of the blood and the receiving unit, whihc is commercially available in three sizes, shall contain a pyrogen free anticoagulant solution of either of the following:

(a) NIH-ACD Solution Formula A or B
(b) CPD Solution
(c) Heparin

(3) Collection and Storage of Blood

(a) Technic of Bleeding - should be in accordance with accepted standards. Please refer to addendum.
(b) Plastic Blood Containers - Plastic blood containers are preferred to bottles since it provides a closed sterile system, where the donor tubing, needle, and the blood container are integral parts of a set. It also allows multiple cross-matching without contamination of the main container. In addition, no pilot tubes are necessary.
(c) Precautions - If any sign of syncope develops during or after blood collection, constant direct medical attention of the donor is necessary until vasomotor stability of cardiac status is assessed as satisfactory.
(d) Labelling - The label of the blood container must contain the following:

1. Name and address of Blood Bank and permit number.
2. Contents of bottle - (Citrated whole blood or packed red cells).
3. Donor's name or serial number.
4. ABO type
5. Rh type when required.
6. Date of extraction
7. Date of expiration
8. Result of specific serological test.
9. Must contain a warning in bold type as follows: Caution: Keep continuosly at 2° - 8°C.
- Crossmatch before use

- A filter must be used in the administration.
- Do not add other medication to the bottle of blood.
When pilot tubes are used, labels must carry the same serial number as the main blood container.

(e) Storage - Blood should be stored in a refrigerator that is exclusively used for blood or any of its components at a temperature range of 2° to 8°C. If the refrigerator temperature exceeds 15°C for at least 8 hours, all blood stored at that time should be condemned for use. If at ay time, the temperature goes below the desired level and if there is any evidence of freezing of blood in the container, all such blood should be discarded.

Blood should never be heated nor allowed to freeze. - Blood should not be exposed to direct sunlight nor allowed to come in direct contact with dry ice or any other freezer object. Do not add anything to blood containers.

d. The Serological Test: At least a VDRL or any acceptable serological test for syphilis shall be made on the specimen of blood taken from the donor at the time of bleeding and the blood shall not be used for transfusion unless the result of the test is non-reactive. Specific serological test should follow the standard procedure required. Interpretation of the serological reaction should conform to that recognized by the Bureau of Research and Laboratories.

e. Determination of Blood Groups: Each donor's blood be securely attached to the donor's bottle and must not be detached until grouping and cross-matching tests have been done and recorded. A generally accepted technique must be used for each grouping test and with both Anti-A and Anti-B grouping serum of acceptable avidity and potency as defined by the Bureau of Research and Laboratories. Provisions for reverse typing should be available.

f. Determination of the Rh Type: - Typing the donor cells for the Rh factors may be carried out if desired using typing serum of satisfactory avidity and potency and with a technique designed for the test serum. The results of the tests must be recorded on the donor's personal history card and on the final container label.

g. Use of Group "O" Blood other than "O" Recipient:
Group specific blood must be the rule in transfusion. If Group "O" blood must be used for non-"O" recipients, low titer "O" blood should be used with titer of Anti-A and Anti-B to be not more than 1:100.

h. Expiration Date: - The expiration date for blood preserved in one of the Acid-Citrate Dextrose (ACD) anticoagulant solution, shall not exceed 21 days from the date of bleeding the donor and for containers with CPD shall not exceed 28 days.

i. The label for whole blood and packed Red Cells must provide for information as required in accordance with Sec. 14, subsection 4.

Colors to designate the various blood groups used internationally, may be used in the following

scheme:
A - Blue
B - Yellow
AB - Pink
O - White

j. Re-issue of Blood: - Blood, that has been removed from storage and sent to another bank or hospital, may be returned for re-issue only under the following conditions:

1. Blood collected in Bottles - Blood may be reissued provided:
(a) There is not evidence of punctures
(b) Re-issue after quarantine period of 24 hours and no evidence of hemolysis seen.
(c) Pilot tube is attached.

2. Blood Collected in Plastic Containers - May be re-issued under the following conditions:
(a) The seal must be unbroken
(b) Reissue after a quarantine period of 24 hours and no evidence of hemolysis seen.
(c) Sufficient integral donor tubing is left with the bag.

k. Records: - Blood banks and blood processing laboratories shall maintain a permanent record to show the donor's name, card number, and all data pertaining to the donor. It must show that the blood was stored under required condition of temperature, the result of blood grouping, blood typing, serologic and other tests. It must show for whom the blood was issued and the date of issue. Provisions must be made for recording reactions if any have occured. Records must be kept of the quantity of blood in storage, disposed or transferred.

Sec. 15 - Blood Banking facilities and processing laboratories shall be subject to regular inspections and records be made available to determine compliance with above regulations.

Sec. 16 - All existing Blood Banks and/or Blood Processing Laboratories shall comply with the requirements of these regulation within thirty (30) days, after receipt of notice.

Sec. 17 - Blood banks and/or blood processing laboratories whose license has been revoked under Sec. 23 hereof shall not be allowed to reopen without first securing a new permit which may be issued upon payment of a fee of One Hundred (₱100.00) Pesos and upon satisfactory evidence that such owner or administrator has already complied with the requirements prescribed in these regulations.

Sec. 18 - Expiration - Each specific license shall expire at the end of December of the year stated therein.

Sec. 19 - Renewal -

a. Application for renewal of license shall be filed in accordance with the preceding section 3

hereon.
b. In any case in which a licensee, prior to the expiration of an existing license, has filed an application in proper form for renewal or for a new license, such existing license shall not expire until the application for a renewal has been finally approved by the Secretary of Health.

Sec. 20 - Inalienability of License - No license issued or granted in accordance with these regulations shall be transferred, assigned or in any manner disposed of, either voluntary or involuntary, directly or indirectly, through transfer of control to any person, without the consent in writing of the Secretary of Health. The owner of the blood bank shall furnish the Secretary of Health the necessary and full information pertaining to the transfer.

Sec. 21 - Inspection -

a. Each license shall afford to give the Secretary of Health or his duly authorized representative at all reasonable time opportunity to inspect the premises and facilities wherein the blood is being processed or stored.

b. Each licensee shall make available to the Secretary of Health or his authorized representative for inspection, records kept by him pursuant to these regulations.

c. Directors of Regional Health regions, Provincial, City and Municipal Health Officers are hereby empowered to report the existence of unlicensed blood banks or any private party processing blood without proper permit or license to the Bureau of Research and Laboratories.

Sec. 22 - Tests - Each licensee shall perform or permit the Secretary of Health or his authorized representative to perform such tests as he deems appropriate or necessary for the administration of these regulations.

Sec. 23 - Modification and Revocation of License -

a. Any license may be revoked, or suspended in whole or in part, for any material false statement in the application or because of conditions revealed by such application or statement of fact or any report record of inspection which would warrant the Secretary of Health to refuse to grant a permit on an original application, or for a violation of, or failure to observe any of the terms and provisions of these regulations.

b. Except in cases of willfulness or those in which the public health interest, or safety requires otherwise, no permit shall be suspended or revoked unless, prior to the institution of proceeding therefore, facts or conduct which may warrant such action shall have been called to the attention of licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

Sec. 24 - Violations - Any person who violates any provision of the rules and regulations shall be punished by imprisonment for not less than one month and not more than one year or by a fine of

not less than one hundred pesos and not more than one thousand pesos or by both such fine and imprisonment in the discretion of the court.

Sec. 25 - Effectivity - Those regulations shall take effect immediately.

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