Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

ASSESSMENT TOOL FOR LICENSING A BLOOD BANK

Name of Blood Bank: _____

Address: _____
Number & Street Barangay/ Municipality

_____
Province/City Region

Contact No./Fax No./E-mail Address: _____

Application for: ☐ Initial
☐ Renewal License No: _____
DateIssued: _____
Expiry Date: _____

GENERAL INFORMATION:

Name of Owner or Institution: _____

Name of Head of Blood Bank: _____

Classification according to:

Ownership: ☐ Government ☐ Private

Instructions:
(1) Encircle (+) if item indicated is present, and (-) if item indicated is absent/ present but non-functional.
(2) All items with (*) shall be posted in a conspicuously designated area.
(3) This tool may serve as a guide for self-assessment of the facility in preparation for inspection/ monitoring visits.

STANDARDS AND REQUIREMENTS	REFERENCE	FINDINGS
Application Documents • **Documentary requirements complete (refer to application)** • **Certificates valid and required forms duly accomplished (refer to application)**		(+) (-) (+) (-)
1. MANAGEMENT REQUIREMENTS **1.1. Management Responsibility** **The Blood Bank shall be managed effectively and efficiently and in accordance with its vision, mission, and objectives.** **1.1.1. There shall be a continuing program on staff development and training.** 1.1.1.1. Proof of training through relevant certificates, memos, written reports, budgetary allocations, etc. **1.1.2. There shall be a policy for hiring, orientation and promotion for all levels of personnel.** 1.1.2.1. Documented procedure/ process on hiring, orientation and promotion of personnel at all levels **1.1.3. There shall be a policy for discipline, suspension, demotion and termination of personnel at all levels.** 1.1.3.1. Documented procedure/ process on discipline, suspension, demotion and termination of personnel at all levels		(+) (-) (+) (-) (+) (-)

STANDARDS AND REQUIREMENTS	REFERENCE	FINDINGS
1.2. <u>Manpower</u> **The Blood Bank appoints and allocates personnel who are suitably qualified, skilled and/ or trained to assume the responsibilities, authority, accountability and functions of the position.** **1.2.1. The organizational chart shall be clearly structured.** 1.2.1.1. Organizational chart* clearly structured indicating the names with pictures and designation, reflecting lines of authority, accountability, communication, inter-relationship, hierarchy of functions and flow of referrals **1.2.2. Duties and responsibilities shall be clearly spelled out.** 1.2.2.1. Documented duties and responsibilities of all Blood Bank personnel		(+) (-) (+) (-)
1.2.3. The Blood Bank is headed by a duly licensed physician and: Certified in Clinical Pathology or Blood Banking by the Philippine Society of Pathologists (PSP), and with experience of at least 1 year in the category of Blood Bank he/ she will head, **OR** Certified in blood transfusion by the Philippine Society of Hematology and Blood Transfusion (PSHBT), and with experience of at least 3 years in the category of Blood Bank he/ she will head, **OR** Certified in Anatomic Pathology by PSP or in Hematology by the PSHBT with additional training in blood banking for at least 6 months in a training institution accredited by the PSP or the PSHBT, with experience of at least 3 years in the category of Blood Bank he/ she will head.		(+) (-) (+) (-) (+) (-)
1.2.4. There shall be adequate number of qualified medical technologists who shall work on shifts to cover a 24-hour service proportional to the workload as determined by the head of the Blood Bank. 1.2.4.1. At least four (4) registered medical technologists distributed in shifts 1.2.4.2. At least 6 months on-the-job experience in blood banking service under an institution recognized by the DOH-NVBSP;		(+) (-) (+) (-)

STANDARDS AND REQUIREMENTS	REFERENCE	FINDINGS
1.2.5. The Blood Bank shall designate and train one (1) qualified and trained Donor Recruitment Officer (DRO). Such training shall be recognized by the DOH-NVBSP and shall include training on pre- and post-donation counseling. 1.2.5.1. Proof of training		(+) (-)
1.2.6. The Blood Bank shall designate and train one (1) of its senior medical technologists as a Quality Assurance Officer. Such training shall be recognized by the DOH-NVBSP. 1.2.6.1. Proof of training		(+) (-)
1.3. <u>PHYSICAL FACILITIES/ Work Environment</u> **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.** **1.3.1. The Blood Bank has adequate space for the conduct of its activities.** 1.3.1.1. Ocular inspection demonstrates adequate space for the equipment, furniture, storage of glassware, reagents and supplies and the activities of the of the Blood Bank staff 1.3.1.2. Work area accessible to Blood Bank personnel only		(+) (-) (+) (-)
1.3.2. The Blood Bank shall be adequately ventilated, well-lighted, clean, safe and functional based on the services it provides. 1.3.2.1. Ocular inspection demonstrates good ventilation, lighting, cleanliness with no risk of physical and chemical hazards		(+) (-)
1.3.3. There shall be a program of proper maintenance and monitoring of physical plant and facilities. 1.3.3.1. Documented program for the proper maintenance and monitoring of physical plant and facilities		(+) (-)

STANDARDS AND REQUIREMENTS	REFERENCE	FINDINGS
1.3.4. There shall be a policy on laboratory biosafety and biosecurity and for the proper disposal of waste and hazardous/ infectious substances.		
1.3.4.1. Documented procedure/ process on laboratory biosafety and biosecurity and for the proper disposal of waste and hazardous/ infectious substances		(+) (-)
1.4. <u>EQUIPMENT</u>		
All equipment and instruments necessary for the safe and effective provision of services are available and are properly maintained.		
1.4.1. There is an adequate number of operational equipment to provide the Blood Bank procedures the Blood Bank is licensed for.		
1.4.1.1. Equipment listed available in the Blood Bank		(+) (-)
1.4.1.2. Provision for a separate storage equipment/ properly labeled area for reactive units		(+) (-)
1.4.1.3. Provision for personal protective equipment		(+) (-)
1.4.2. There is a program for calibration, preventive maintenance and repair for the equipment.		
1.4.2.1. Record of schedule of calibration and maintenance of equipment		(+) (-)
1.4.2.2. Record of reports of preventive maintenance and repair		(+) (-)
1.4.3. There shall be a contingency plan in case of equipment breakdown, especially of Blood Bank cold storage equipment.		
1.4.3.1. Documented contingency plan in case of equipment breakdown		(+) (-)

STANDARDS AND REQUIREMENTS	REFERENCE	FINDINGS
1.5. <u>REAGENTS AND SUPPLIES</u> **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.** **1.5.1. There is an adequate supply of properly stored and inventoried reagents and supplies.** 1.5.1.1. Quality records of reagents/ supplies, their usage/ consumption and disposal are available		(+) (-)
1.5.2. There are adequate storage facilities such as refrigerators for perishable reagents and supplies. 1.5.2.1. Temperature monitoring records		(+) (-)
1.5.3. There is appropriate storage area/ technique for flammable, combustible and hazardous chemicals/ reagents. 1.5.3.1. NVBSP prescribed Materials Safety Datasheet (MSDS) available for all reagents/ supplies and accessible to all personnel at all times		(+) (-)
1.6. <u>REPORTING AND RECORDS MANAGEMENT</u> **There shall be a system of reporting and recording of results of blood bank (immunohematology) examinations.** **1.6.1. There shall be a documented procedure for reporting of results.** 1.6.1.1. Reports bearing the name and facsimile signature of the head 1.6.1.2. Reports signed by the medical technologists who performed the examinations **1.6.2. There shall be a documented procedure for retention of records which shall follow standards promulgated by the DOH and/ or competent professional organizations.** 1.6.2.1. File of retained records **1.6.3. There shall be a designated area for storage of records.** 1.6.3.1. Storage area adequate for record keeping		(+) (-) (+) (-) (+) (-) (+) (-)

STANDARDS AND REQUIREMENTS	REFERENCE	FINDINGS
2. <u>TECHNICAL REQUIREMENTS</u>		
2.1. Administrative/ Technical Procedures		
There shall be a system for the provision and proper issuance of safe and tested blood and blood products.		
2.1.1. There shall be a policy for the provision of blood products and blood banking services.		
2.1.1.1. Documented quality procedures for proper storage and provision of blood and blood products		(+) (-)
2.1.2. There shall be a policy for the proper issuance of compatible and tested blood products.		
2.1.2.1. Documented quality procedures for the proper issuance of blood products		(+) (-)
2.1.2.2. Logbook and records of blood/ blood products released		(+) (-)
2.1.3. There shall be a policy for the collection, preparation, storage and provision of apheresis-derived blood products, if the blood bank has the capability for this procedure.		
2.1.3.1. Documented quality procedures for the proper collection, preparation, storage and provision of apheresis-derived blood products		(+) (-)
2.1.3.2. Logbook and records of blood products collected, prepared, stored and issued		(+) (-)
2.1.4. There shall be a policy for specialized immunohematology examinations.		
2.1.4.1. Documented quality procedures such as red cell atypical antibody screening, identification, and phenotyping		(+) (-)
2.1.4.2. Logbooks/ records for red cell antibody screening, identification and phenotyping		(+) (-)
2.1.5. There shall be a policy for compatibility testing to provide safe blood components.		
2.1.5.1. Documented quality procedures for compatibility testing including ABO and Rh typing, red cell atypical antibody screening, identification and phenotyping		(+) (-)
2.1.5.2. Records for compatibility testing including ABO and Rh typing, red cell antibody screening, identification and phenotyping		(+) (-)

STANDARDS AND REQUIREMENTS	REFERENCE	FINDINGS
2.1.6. There shall be a policy for investigation of transfusion reactions.		
2.1.6.1. Documented quality procedure on detection and reporting of suspected transfusion reaction in the ward/ nursing unit		(+) (-)
2.1.6.2. Documented quality procedure for investigation and evaluation of a suspected transfusion reaction		(+) (-)
2.1.6.3. Documented quality procedure for reporting the result of the investigation and evaluation of the suspected transfusion reaction		(+) (-)
2.2. <u>QUALITY ASSURANCE PROGRAM</u> **The Blood Bank shall put into practice a quality assurance program.**		
2.2.1. There shall be a policy on Quality Assurance Program and Continuous Quality Improvement Program.		
2.2.1.1. Documented Internal Quality Assurance Program including Internal Quality Control and Continuous Quality Improvement		(+) (-)
2.2.1.2. Results/ findings of Quality Assurance audits/ assessments		(+) (-)
2.2.2. The Blood Bank shall participate in an External Quality Assessment Program (EQAP) administered by the designated National Reference Laboratories (NRL) or other EQAP approved by the DOH-NVBSP.		
2.2.2.1. Documented procedure in the actual performance of the EQAP activities administered by the NRLs.		(+) (-)
2.2.2.2. Certificate of participation of the Blood Bank in an EQAP administered by the NRLs		(+) (-)

STANDARDS AND REQUIREMENTS	REFERENCE	FINDINGS
2.3. <u>REFERRAL OF EXAMINATIONS FOR RARE BLOOD TYPES AND OUTSOURCING OF RARE BLOOD/ COMPONENTS</u> **There shall be a system in outsourcing of examinations and blood components.** **2.3.1. There shall be a policy on referral of examinations and outsourcing of rare blood/ components.** 2.3.1.1. Documented procedures on referral of examinations for rare blood types and outsourcing of blood components 2.3.1.2. Results and records of examinations performed 2.3.1.3. SOPs and records of outsourcing rare blood/ components		(+) (-) (+) (-) (+) (-)

LIST OF EQUIPMENT/ INSTRUMENTS
BLOOD BANK

1. Agglutination viewer for ABO/Rh grouping tube method.
2. Air-conditioning unit
3. Apheresis machine with AVR (refer to BCU requirements for BB with component collection by apheresis)
4. Autoclave
5. Automatic emergency light
6. Balance
   - 6.1. Analytical balance
   - 6.2. Rough balance, top loading
7. Centrifuge, serological
8. Computer with printer, UPS, AVR
9. Dispenser/ dispettes
10. Fire extinguisher
11. Freezer, plasma freezer (-30℃) with AVR
12. Generator with capacity of at least 20KVA
13. Microscope, binocular, equipped with oil immersion objective (OIO optional)
14. Pipettor
15. Plasma extractor (optional)
16. Plasma thawer
17. Platelet rotator/ agitator
18. Red Cell Antibody Screening System (optional)
19. Refrigerator
    - 19.1 Blood bank refrigerator controlled at 2-6 ^{0}C with temperature recorder and alarm system, and AVR
    - 19.2 Reagent refrigerator with laboratory thermometer and AVR
20. Spring scale for blood unit
21. Stopwatch or timer
22. Surgical forceps, scissors
23. Tachometer for calibration of centrifuge (optional)
24. Thermometer
    - 24.1 Laboratory thermometer
    - 24.2 Room thermometer
25. Water bath/ dry bath set at 37℃ for crossmatch ing
26. Water bath set at 56℃ for VDRL (optional)
27. Weighing scale calibrated up to 500 grams

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Name of Health Facility: _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process:

[ ] For issuance of License as Blood Bank.

Validity from _____ to _____

[ ] Issuance depends upon compliance to the recommendations given and submission of the following within _____ days from the date of inspection:

_____

_____

_____

_____

_____

[ ] Non-Issuance: Specify reason/s. _____

_____

_____

_____

_____

Inspected by:

Printed Name	Signature	Position/Designation

Received by:

Signature _____
Printed Name _____
Position/Designation _____
Date _____

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Name of Health Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:

B. For Monitoring Process:

[ ] Issuance of Notice of Violation

_____

_____

_____

[ ] Non-issuance of Notice of Violation

_____

_____

_____

_____

[ ] Others (Specify) _____

_____

_____

_____

Monitored by:

Printed Name	Signature	Position/Designation

Received by:

Signature _____
Printed Name_____
Position/Designation _____
Date _____