



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

February 15, 2018

**DEPARTMENT CIRCULAR**  
No. 2018 - 0039

**TO: ALL HEADS OF CENTRAL OFFICE BUREAUS, REGIONAL HEALTH OFFICES, SPECIALTY HOSPITALS/ MEDICAL CENTERS/ HOSPITALS/ SANITARIA, REGIONAL BLOOD PROGRAM COORDINATORS, BLOOD SERVICE FACILITIES HEADS, LEAD BLOOD SERVICE FACILITIES AND OTHERS CONCERNED**

**SUBJECT: Revised Assessment Tool for Licensing Blood Service Facilities**

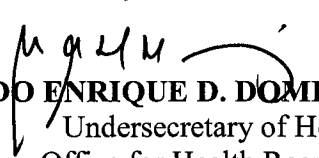
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The Department of Health (DOH) Administrative Order No. 2008-0008 dated May 2, 2008, has set the rules and regulations governing the licensure of Blood Service Facilities (BSFs). As part of the procedural guidelines, the BSFs shall strictly follow the minimum standard requirements prescribed in the Assessment Tool.

Relative thereto, a revision of the Assessment Tool has been made to be more consistent with the implementation guidelines. The revised Assessment Tool, once posted at the DOH and DOH-HFSRB website, shall be effective on ***February 26, 2018***.

For strict implementation.

By Authority of the Secretary of Health


  
**ROLANDO ENRIQUE D. DOMINGO, MD, DPBO**  
Undersecretary of Health  
Office for Health Regulation



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

**ASSESSMENT TOOL FOR LICENSING A BLOOD SERVICE FACILITY**

**INSTRUCTIONS:**

1. Check to make sure that you have the complete tool with a total of \_\_\_\_\_ pages with annex A\_\_\_\_\_ that serve as reference for Equipment, Reagents & Supplies per Category.
2. If the corresponding items are present, available or adequate, place ✓ on of the appropriate spaces under the FINDINGS column or space provided alongside each corresponding item. If not, put an X instead.
3. The REMARKS column shall document relevant observations for Quality Improvement.
4. Make sure to fill-in the blanks with the needed information. Do not leave any items blank; write (N/A) not applicable or —if needed.
5.  (Shaded cell) means that specific items are not applicable to the BSF category. With (\*) asterisk-policies incorporated in One Stop Shop facility are acceptable.

**GENERAL INFORMATION:**

Name of Facility: \_\_\_\_\_ Certificate of Inclusion No. \_\_\_\_\_ Exp. \_\_\_\_\_

Address: \_\_\_\_\_

(Number & Street) (Barangay/District) (Municipality/City) (Province & Region)

Telephone/ Fax No. \_\_\_\_\_ E-mail Address: \_\_\_\_\_

Initial: \_\_\_\_ Renewal: \_\_\_\_ License to Operate No.: \_\_\_\_\_ Authority to Operate No.: \_\_\_\_\_ Date Issued: \_\_\_\_ Expiry Date: \_\_\_\_\_

Name of Owner or Governing Body (if corporation): \_\_\_\_\_

Name of Head of Blood Service Facility: \_\_\_\_\_

Classification According to: Ownership: \_\_\_\_\_ Government \_\_\_\_\_ Private

Institutional Character: \_\_\_\_\_ Institution-based (specify) \_\_\_\_\_ Free-Standing

Category: \_\_\_\_\_ Blood Station \_\_\_\_\_ Blood Collection Unit \_\_\_\_\_ BCU/BS

\_\_\_\_\_ Blood Bank \_\_\_\_\_ Blood Bank with Additional Functions:

\_\_\_\_\_ Blood Center \_\_\_\_\_ Collection \_\_\_\_\_ Testing \_\_\_\_\_ Processing

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<b><u>Application Documents</u></b> <ul style="list-style-type: none"> <li>Documentary requirements complete (refer to application)</li> <li>Certificates valid and required forms duly accomplished (refer to application)</li> </ul>							
<b><u>1. MANAGEMENT REQUIREMENTS</u></b> <b><u>1.1. MANAGEMENT RESPONSIBILITY</u></b> <p>The Blood Service Facility (BSF) shall be managed effectively and efficiently and in accordance with its vision, mission, and objectives.</p> <p>1.1.1 Management shall formulate a vision, mission, objectives and values for the BSF.</p> <p>1.1.1.1 Mission, Vision, Objectives, Values</p> <p>1.1.2 There shall be an Annual Operational Plan</p> <p>1.1.2.1 Annual Operational Plan</p> <p>1.1.3 There shall be Management Review</p> <p>1.1.3.1 Management Review with Key Performance Indicators</p> <b><u>1.2 MANAGEMENT OF BLOOD SERVICE FACILITY</u></b> <p>The BSF shall be managed by qualified physicians with proper training.</p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<p><b>1.2.1 The BSF is headed by a duly licensed physician who is:</b></p> <p><b>For Hospital-based Blood Stations</b></p> <p>1.2.1.1 Certified in Clinical Pathology by the Philippine Board of Pathology of the PSP,  1.2.1.1.1. Specialty Board Certificate  1.2.1.1.2. Resume  1.2.1.1.3. Notarized Contract of Employment  1.2.1.1.4. Job Description</p> <p><b>For Non Hospital-based Blood Stations</b></p> <p>1.2.2.1 Physician with at least three (3) months formal training in basic blood banking provided by DOH recognized training provider.  1.2.2.1.1. PRC Board Certificate  1.2.2.1.2. Resume  1.2.2.1.3. Notarized Contract of Employment or Service Contract Agreement  1.2.2.1.4. Job Description  1.2.2.1.5. Training Certificate on Laboratory Management and Transfusion Medicine</p>							
<p><b>For Non hospital-based Blood Collection Unit</b></p> <p>1.2.3.1. Physician with formal training in basic blood banking provided by the DOH recognized training provider.  1.2.3.1.1. PRC Board Certificate  1.2.3.1.2. Resume  1.2.3.1.3. Notarized Contract of Employment or Service Contract Agreement  1.2.3.1.4. Job Description  1.2.3.1.5. Training Certificate on Laboratory Management and Transfusion Medicine</p>							
<p><b>For Non hospital-based Blood Station/ Blood Collection Unit</b></p> <p>1.2.4.1. Physician with formal training in basic blood banking provided by the DOH recognized training provider.  1.2.4.1.1. PRC Board Certificate</p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
1.2.4.1.2. Resume 1.2.4.1.3. Notarized Contract of Employment or Service Contract Agreement 1.2.4.1.4. Job Description 1.2.4.1.5. Training Certificate on Laboratory Management and Transfusion Medicine							
<b>For Blood Center, Hospital Blood Bank and Hospital Blood Bank with Additional Functions</b> 1.2.5.1 Certified in Clinical Pathology by Philippine Board of Pathology of the PSP, and with experience in a blood service facility 1.2.5.1.1. Specialty Board Certificate 1.2.5.1.2. Resume 1.2.5.1.3. Notarized Contract of Employment 1.2.5.1.4. Job Description							
<b>1.3. <u>MANAGEMENT OF HUMAN RESOURCES</u></b>  <b>The Blood Service Facility appoints and allocates personnel who are suitably qualified, skilled and/ or trained to assume the responsibilities, authority, accountability, and functions of the position.</b>  <b>1.3.1. There shall be an adequate number of qualified medical technologists proportional to the workload as determined by the head of the Blood Service Facility.</b>  1.3.1.1 Adequate number of personnel. As workload increases, the number of personnel increases. (refer to Annex A)  <b>1.3.2 There shall be a policy and procedure for hiring, orientation and promotion for all levels of personnel.</b>							

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<p>1.3.2.1 Policy and procedure for hiring, orientation and promotion of personnel at all levels.</p> <p>1.3.2.2 Records of hiring, orientation and promotion of personnel.</p> <p><b>1.3.3 Duties and responsibilities shall be clearly spelled out.</b></p> <p>1.3.3.1 Documented duties and responsibilities of all Blood Service Facility personnel.</p>							
<p><b>1.3.4 There shall be a program on staff development and training.</b></p> <p>1.3.4.1 Program for staff development and training</p> <p>1.3.4.2 Certificates or Records of Training</p> <p><b>1.3.5 There shall be a policy and procedure for discipline, suspension, demotion and termination of personnel at all levels.</b></p> <p>1.3.5.1 Policy and procedure on discipline, suspension, demotion and termination of personnel at all levels</p> <p>1.3.5.2 Records of discipline, suspension, demotion and termination of personnel</p> <p><b>1.3.6 The Blood Service Facility shall designate and train one (1) Registered Medical Technologist as a Quality Assurance Officer. Such training shall be recognized by the DOH.</b></p> <p>1.3.6.1 Designation of a Quality Assurance Officer</p> <p>1.3.6.2 Certificate of Training as Quality Assurance Officer</p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<p><b>1.3.7. The Blood Service Facility shall designate one (1) qualified and trained full-time Donor Recruitment Officer (DRO). Such training shall be recognized by the DOH and shall include training on pre- and post-donation counseling. As the workload increases, the number of DROs increases. See Annex A</b></p> <p>1.3.7.1 Designation as Donor Recruitment Officer</p> <p>1.3.7.2 Certificate of training as Donor Recruitment Officer DRO from Philippine Blood Coordinating Council (PBCC) or Philippine Red Cross (PRC)</p> <p><b>1.3.8 There shall be a structured organizational chart</b></p> <p>1.3.8.1 An Organizational chart* indicating the names with pictures and designation, reflecting lines of authority, accountability and, communication, inter-relationship, hierarchy of functions and flow of referrals</p> <p><b>1.3.9 Each Staff member shall read and sign his Duties and responsibilities</b></p> <p>1.3.9.1 Duties and responsibilities of each Staff member signed by Staff member.</p>							
<p><b>1.4. <u>PHYSICAL FACILITIES/Work Environment</u></b></p> <p>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.</p> <p><b>1.4.1 The Blood Service Facility has adequate space for the conduct of its activities.</b></p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
1.4.1.1 Ocular inspection demonstrates adequate space for the equipment, furniture, storage of glassware, reagents and supplies and the activities of the Blood Service Facility staff							
1.4.1.2 Work area accessible to Blood Service Facility personnel only							
<b>Areas for Blood Station – Designated area in the Clinical Laboratory</b> <ul style="list-style-type: none"> <li>• Storage blood bank refrigerator</li> <li>• Blood typing and Cross matching</li> <li>• Releasing of blood products</li> </ul>							
<b>Areas for BCU and BS/BCU</b> <ul style="list-style-type: none"> <li>• Reception / waiting area – 1.0 m<sup>2</sup> /person</li> <li>• Donor Counseling – 5.02 m<sup>2</sup></li> <li>• Physical Exam area for donor – 5.02 m<sup>2</sup></li> <li>• Donor extraction – 6 m<sup>2</sup> per bed or couch</li> <li>• Provision of sink for hand washing</li> <li>• Area for Refrigerator and supplies (at least 1.2 m<sup>2</sup> per storage unit)</li> <li>• Preparation Area – 5.02 m<sup>2</sup></li> <li>• Releasing of blood products</li> <li>• Administrative Office</li> </ul>							
<b>Area for Hospital Blood Bank – Area of at least 19 m<sup>2</sup></b> <ul style="list-style-type: none"> <li>• Areas for blood bank refrigerator, plasma freezer, platelet agitator, and supplies (at least 1.2 m<sup>2</sup> per storage unit)</li> <li>• Blood typing and Cross matching Work Counter</li> <li>• Releasing of blood products</li> </ul> <p>NOTE: Location of HBB must be adjacent or easily accessible to the main clinical laboratory.</p>							



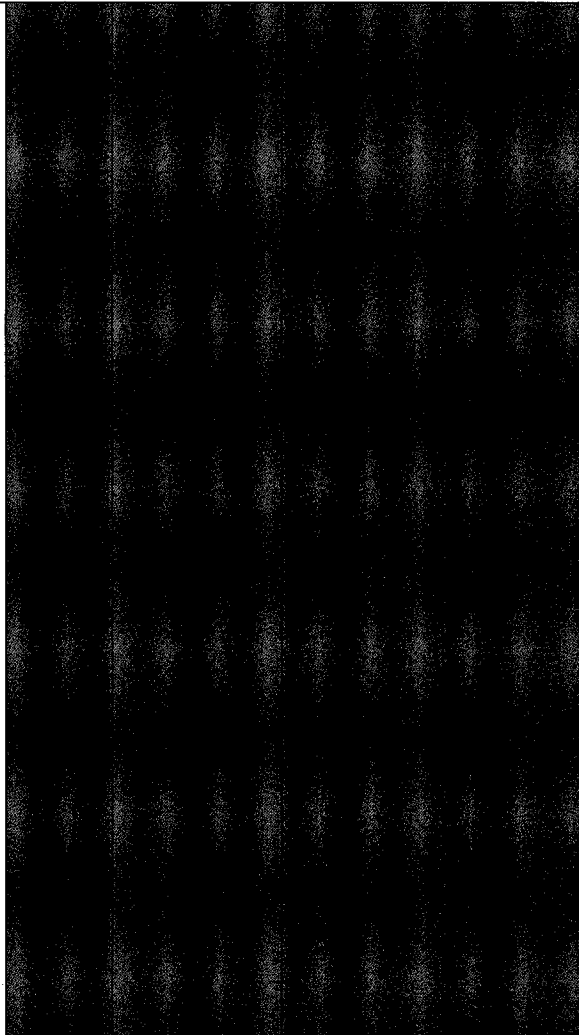
STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<b>Areas for Hospital Blood Bank with Additional Function</b> <ul style="list-style-type: none"> <li>• **Reception / waiting area – 1.0 m<sup>2</sup> /person</li> <li>• Donor Counseling – 5.02 m<sup>2</sup></li> <li>• Physical Exam area for donor – 5.02 m<sup>2</sup></li> <li>• Donor extraction – 6 m<sup>2</sup> per bed or couch</li> <li>• Provision of sink for hand washing</li> <li>• ***Blood screening for TTIs – 10 m<sup>2</sup></li> <li>• Blood typing and Cross matching Work Counter</li> <li>• Processing of blood into blood components 4.65 m<sup>2</sup> per equipment</li> <li>• Storage facility – 4.65 m<sup>2</sup> per storage unit</li> <li>• Releasing of blood products</li> <li>• Administrative Office</li> </ul> <p>**Reception/Waiting area for HBB++ can be located outside or can be a common area for clinical laboratory.</p> <p>***May be carried out within the clinical laboratory if the HBB++ is adjacent to the main clinical laboratory.</p>							
<b>Areas for Blood Center</b> <ul style="list-style-type: none"> <li>• Reception / waiting area – 1.0 m<sup>2</sup> /person</li> <li>• Donor Counseling – 5.02 m<sup>2</sup></li> <li>• Physical Exam area for donor – 5.02 m<sup>2</sup></li> <li>• Donor extraction – 6 m<sup>2</sup> per bed or couch</li> <li>• Blood screening for TTIs – 10 m<sup>2</sup></li> <li>• Processing of blood into blood components – 4.65 m<sup>2</sup> per equipment</li> <li>• Storage facility – 4.65 m<sup>2</sup> per storage unit</li> <li>• Releasing of blood products</li> <li>• Administrative Office</li> </ul>							
<b>1.4.2 The Blood Service Facility shall be adequately ventilated, well-lighted, clean, safe and functional</b>							

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<p><b>based on the services it provides.</b></p> <p>1.4.2.1 Ocular inspection demonstrates good ventilation, lighting, cleanliness with no risk of physical and chemical hazards.</p>							
<p><b>1.4.3 There shall be a program of proper maintenance and monitoring of physical plant and facilities.</b></p> <p>1.4.3.1 Program for the proper maintenance and monitoring of physical plant and facilities</p> <p>1.4.3.2 Records of the proper maintenance and monitoring of physical plant and facilities</p>							
<p><b>1.4.4 There shall be a policy and procedure on laboratory biosafety and biosecurity and for the proper disposal of waste and hazardous/ infectious substances that shall conform to the standards set by the DOH.</b></p> <p>1.4.4.1 Policy and procedure on laboratory biosafety and biosecurity and for the proper disposal of waste and hazardous/ infectious substances.</p> <p>1.4.4.2 Records on laboratory biosafety and biosecurity and for the proper disposal of waste and hazardous/ infectious substances.</p> <p><b>1.5. <u>EQUIPMENT</u></b></p> <p><b>All equipment and instruments necessary for the safe and effective provision of services are available and are properly maintained.</b></p> <p><b>1.5.1 There is an adequate number of functional equipment to provide the procedures the Blood Service Facility is authorized for.</b></p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<p>1.5.1.1 Equipment listed in Standards available in the Blood Station</p> <p>1.5.1.2 Records of monitoring of temperature of Refrigerator and other cold storage equipment, if any.</p> <p>1.5.1.3 Personal protective equipment available.</p> <p><b>1.5.2 There is a program for calibration, preventive maintenance and repair for the equipment.</b></p> <p>1.5.2.1 Program and schedule of calibration, preventive maintenance and repair of equipment</p> <p>1.5.2.2 Records of calibration, preventive maintenance and repair of equipment.</p>							
<p><b>1.5.3 There shall be a contingency plan in case of equipment breakdown, especially of Blood Service Facility cold storage equipment.</b></p> <p>1.5.3.1 Contingency plan in case of equipment breakdown</p> <p>1.5.3.2 Record of actions taken in case of equipment breakdown</p>							
<p><b>1.6. <u>REAGENTS AND SUPPLIES</u></b></p> <p><b>All reagents and glassware to be used by the Blood Service Facility 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.</b></p> <p><b>1.6.1 There is an adequate supply of properly stored and inventoried reagents and supplies.</b></p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
1.6.1.1 Records of inventory, usage/ consumption and disposal of reagents/ supplies.							
1.6.1.2 Materials Safety Data Sheet (MSDS) for all reagents/supplies accessible when needed							
<b>1.6.2 There are adequate storage facilities such as refrigerators for perishable reagents and supplies.</b>							
1.6.2.1 Refrigerator for storage of perishable reagents and supplies							
1.6.2.2 Records of monitoring of temperature of refrigerator							
<b>1.6.3 There is appropriate storage area/system for flammable, combustible and hazardous chemicals/ reagents.</b>							
1.6.3.1 Appropriate storage area for flammable, combustible, and hazardous chemicals/reagents.							
1.6.3.2 Appropriate system of storage for flammable, combustible, and hazardous chemicals/ reagents following safety (MSDS) requirements.							
<b><u>1.7. REPORTING AND RECORDS MANAGEMENT</u></b>							
<b>There shall be a system of reporting and recording of stored and issued blood and blood products.</b>							
<b>1.7.1 There shall be a policy and procedure for reporting of stored and issued blood and blood products.</b>							
1.7.1.1 Policy and procedure for reporting of stored and issued blood and blood products.							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<p>1.7.1.2 Monthly and annual reports on of stored and issued blood and blood products.</p> <p><b>1.7.2 There shall be a Policy and procedure for retention of records which shall follow standards promulgated by the DOH and/or competent professional organizations.</b></p> <p>1.7.2.1 Policy and procedure for retention of records.</p> <p>1.7.2.2 File of retained records.</p> <p>1.7.2.3 Inventory of disposed records</p> <p><b>1.7.3 There shall be a designated area for storage of records.</b></p> <p>1.7.3.1 Storage area adequate for records generated</p>							
<p><b>For Blood Center and Blood Bank with Additional Functions</b></p> <p><b>There shall be system of recording and reporting of results of immunohematology examinations and testing for infectious diseases and collection, storage and issuance of blood and blood products.</b></p> <p><b>1.7.4 There shall be a policy and procedure for recording and reporting of results of immunohematology examinations and testing for infectious diseases.</b></p> <p>1.7.4.1 Policy and procedure for recording and reporting of results of immunohematology examinations and testing for infectious diseases.</p> <p>1.7.4.2 Records of results of immunohematology examinations and testing for infectious diseases.</p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<p>1.7.4.3 Monthly and annual reports of immunohematology examinations and tests for infectious diseases.</p> <p><b>1.7.5 There shall be a policy and procedure for the recording and reporting of collection, storage, issued, and shared blood and blood products from voluntary donors.</b></p> <p>1.7.5.1 Policy and procedure for the recording and reporting of collection, storage, issued, and shared blood and blood products.</p> <p>1.7.5.2 Records of collection, storage, issued, and shared blood and blood products.</p> <p>1.7.5.3 Monthly and annual reports of collection, storage, issued, and shared blood and blood products.</p> <p><b>1.7.6 There shall be a policy and procedure to ensure blood safety by screening and testing for the five (5) TTIs namely: HIV 1/2, HBsAg, HCV, Malaria, Syphilis and other TTIs mandated for screening by the Technical Committee of the NCBS.</b></p> <p>1.7.6.1 Policy and procedure for testing for the five (5) TTIs, i.e, HIV 1/2, HBsAg, HCV, Malaria and Syphilis</p> <p>1.7.6.2 Records of results of Testing for the five (5) TTIs</p> <p>1.7.6.3 Monthly and Annual Reports of no. of units of Negative and Reactive Blood.</p> <p>1.7.6.4 Quarantine records for blood products that are reactive to any markers of TTI</p> <p><b>1.7.7 There shall be a policy and procedure for confirmation of blood/ blood products initially reactive to any of the</b></p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<p><b>5 TTI markers namely: HIV1/2, HBsAg, HCV, Malaria, and Syphilis.</b></p> <p>1.7.7.1 Policy and procedures for the referral to RITM TTI-NRL for confirmation of blood/ blood products initially reactive to any of the 5 TTI markers</p> <p>1.7.7.2 Records of referral for confirmation of blood/ blood products initially reactive to any of the 5 TTI markers.</p> <p>1.7.7.3 Records of receipt of results of confirmation testing of blood/ blood products initially reactive to any of the 5 TTI markers referred.</p> <p>1.7.7.4 Monthly and Annual Reports of results of confirmation testing of blood/ blood products initially reactive to any of the 5 TTI markers referred.</p> <p><b>1.7.8 There shall be a policy and procedure for the storage and distribution of whole blood/ components.</b></p> <p>1.7.8.1 Policy and procedure for the storage and distribution of whole blood/components.</p> <p>1.7.8.2 Records of storage and distribution of whole blood/ components.</p> <p>1.7.8.3 Monthly and annual reports of no. of units of whole blood/components stored and distributed.</p>							
<p><b>1.7.9 There shall be a policy and procedure for the management of inventory of blood products.</b></p> <p>1.7.9.1 Policy and procedure for the management of inventory of blood products</p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
1.7.9.2 Logbooks/ records of management of inventory of blood products.							
<b>FOR BLOOD STATION AND HOSPITAL BLOOD BANK</b>  There shall be system of recording and reporting of results of immunohematology examinations and collection, storage and issuance of blood and blood products.  1.7.10 There shall be a policy and procedure for recording and reporting of results of immunohematology examinations. 1.7.10.1 Policy and procedure for recording and reporting of results of immunohematology examinations.  1.7.10.2 Records of results of immunohematology examinations.  1.7.10.3 Monthly and annual reports of immunohematology examinations.  1.7.11 There shall be a policy and procedure for the storage and distribution of whole blood/ PRBC.  NOTE: For HBB, whole blood, PRBC, and other blood components.  1.7.11.1 Policy and procedure for the storage and distribution of whole blood/PRBC.  1.7.11.2 Records of storage and distribution of whole blood/ PRBC.  1.7.11.3 Monthly and annual reports of no. of units of whole blood/PRBC stored and distributed.							



STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<b>1.8 QUALITY ASSURANCE PROGRAM</b>  <b>The Blood Center shall put into practice a Quality Assurance Program.</b>  <b>1.8.1 There shall be policies and procedures on Quality Assurance Program and Continuous Quality Improvement.</b>  1.8.1.1. Policy and Procedure on Quality Assurance Program including Internal Quality Control  1.8.1.2 Records of Internal Quality Control and Quality Control of reagents  1.8.1.3 Policy and Procedure for Internal Quality Audit  1.8.1.4 Records of Internal Quality Audit.  1.8.1.5 Analysis of results of Internal Quality Audit and recommendations to improve the services.  1.8.1.6 Quality Improvement Studies for improvement of delivery of services.							
<b>1.8.2 The Blood Service Facility shall participate in an External Quality Assessment Program (EQAP) administered by the designated National Reference Laboratories (NRL) or other External Quality Assessment Program approved by the DOH.</b> 1.8.2.1 Policy and Procedures in the participation in NEQAS administered by the designated NRLs.  1.8.2.2 Certificate of participation of the Blood Center in the NEQAS administered by the designated NRLs.							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<p><b>For Hospital Based Blood Station and Blood Bank</b></p> <p><b>1.9 Hospital Blood Transfusion Committee:</b></p> <p><b>1.9.1 There shall be a policy and procedure for the establishment and operation of a Hospital Blood Transfusion Committee.</b></p> <p>1.9.1.1 Policy and procedure for the establishment and operation of a Hospital Blood Transfusion Committee.</p> <p>1.9.1.2 Letter, Memo or Order establishing the Hospital Blood Transfusion Committee providing for its composition and duties and responsibilities.</p> <p><b>1.9.2 The Hospital Blood Transfusion Committee (HBTC) shall meet and perform its duties and responsibilities.</b></p> <p>1.9.2.1 Minutes of meetings of HBTC, including Monthly reports of Blood Bank procedures, requests and issuance of blood and blood products.</p> <p>1.9.2.2 Memos or letters issued by HBTC to carry out recommended policies, procedures, sanctions, etc.</p> <p>1.9.2.3 Records of blood utilization reviewed and performed including corrective actions taken.</p> <p>1.9.2.4 Report on activities conducted in Blood Donors Month (July), if applicable</p> <p>1.9.2.5 Annual reports of activities including review of</p>							

STANDARDS AND REQUIREMENTS	Blood Station (BS)	Blood Collection Unit (BCU)	Blood Station / Blood Collection Unit (BS/BCU)	Hospital Blood Bank (HBB)	Hospital Blood Bank with Additional Function (HBB++)	Blood Center (BC)	Remarks
<p>policies, procedures and blood utilization.</p> <p><b>1.9.3 The HBTC shall conduct seminars to promote voluntary blood donation and the appropriate use of blood and blood products.</b></p> <p>1.9.3.1 Calendar of Seminars and other Training sessions on voluntary blood donation and the appropriate use of blood and blood products.</p> <p>1.9.3.2 Certificates or Records of Training on Seminars and other Training sessions voluntary blood donation and the appropriate use of blood and blood products conducted.</p>							

# ANNEX A. NUMBER OF PERSONNEL

BSF Category	Donor Recruitment/ Counselling	Pre-collection / Collection	Testing for TTIs	Component Processing	Compatibility Testing	Releasing	Transfusion Reaction Investigation	Inventory Management	Networking	Total Number of personnel /24 hrs
Hospital based Blood Station						1 designated RMT/shift				3 designated RMTs
Non-hospital based Blood Station (Not operating for more 8 hours)						1 RMT plus 1 reliever		Same personnel in Releasing		2 RMTs
Non-hospital base Blood Station / Blood Collection Unit (BS/BCU)	1 RN or RMT or under board MT trained by DOH recognized training provider	1 RMT 2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT 1 MD per activity				1 RMT plus 1 reliever		Same personnel in Releasing		1 MD 3 RMTs 2 Phlebotomists 1 RN/RMT
Blood Collection Unit	1 RN or RMT or under board MT trained by DOH recognized training provider	1 RMT 2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT 1 MD per activity							Same personnel in Donor Recruitment	1 MD 1 RMT 2 Phlebotomists 1 RN/RMT
Blood Bank	1 RN/RMT					1 RMT/shift plus 1 reliever 1 MD (on-call)				1 MD (on-call) 4 RMTs 1 RN/RMT
Blood Bank with additional functions	1 RN	1 RMT 2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT 1 MD per activity	*1 RMT/shift plus 1 reliever			1 RMT/shift Plus 1 reliever				1 MD 9 RMTs 2 Phlebotomists 1 RN
Blood Center	1 RN	1 RMT 2 phlebotomist which may be composed of RMTs, RNs or trained laboratory technician, or under board RMT 1 MD per activity	*1 RMT/shift plus 1 reliever			1 RMT/shift plus 1 reliever		Same RMT assigned in Releasing	Same RN assigned in donor recruitment	1 MD 9 RMTs 2 Phlebotomists 1 RN

## ANNEX B. EQUIPMENT

EQUIPMENT	BS	BCU	BC/BCU	HBB	HBB++	BC	REMARKS
1. Agglutination viewer							
2. Air-conditioning Unit in work area							
3. Apheresis Machine with AVR, for BSF with component collection by Apheresis					Optional	Optional	
4. Autoclave for sterilization before disposal of used blood bags if no outsourced waste disposal provide OR Bio-waste processor or proof of waste collection (MOA with a tertiary clinical laboratory for investigation of suspected contaminated blood units)							
5. Automatic Emergency Light							
6. Balance 6.1 Analytical Balance 6.2 Rough balance, top loading							
7. Blood Collection 7.1 Blood donor couch or bed 7.2 Spring scale for blood unit 7.3 Surgical forceps, scissors 7.4 Tube sealer 7.5 Blood mixer 7.6 Tube stripper							
8. Blood Transport box with non-mercurial thermometer and adequate cold packs (for mobile blood donation)							
9. Centrifuge 9.1 Serological centrifuge (>3400 rpm with minimum timer of 30 seconds) 9.3 Clinical Centrifuge 9.4 Refrigerated centrifuge with AVR - UPS							
10. Computer with printer, UPS, AVR							
11. Immunology Analyzer for TTIs: 11.1 Enzyme Immunoassay (EIA) equipment set with AVR 11.1.1 EIA reader 11.1.2 EIA washer microdiluter							

11.1.3 Incubator or heating block or its equivalent							
11.2 Chemiluminiscence (Optional)							
11.3 NAT testing (Optional for HBB++)							
12. Fire Extinguisher							
13. Freezer							
13.1 Plasma freezer (-30°C) with AVR							
13.2 Ultralow freezer (-70°C) with AVR							
13.3 Blast freezer (optional)							
14. Generator with capacity of at least 40 KVA							
15. Hematology Analyzer for QC of blood products							
16. Hemoglobin determination, <u>any one</u> of the following:							
16.1 Copper Sulfate for mobile blood donation							
16.2 Hemoglobinometer, or Photometer or Spectrophotometer							
17. Microscope, binocular, equipped with Oil Immersion Objective (OIO)							
18. Needle destroyer							
19. Pipettor							
20. Plasma Extractor							
21. Plasma Thawer or its equivalent, with regulated temperature							
22. Platelet Rotator/ Agitator with incubator							
23. Red Cell Antibody Screening System and phenotyping				Optional	Optional	Optional	
24. Refrigerator							
24.1 Blood Bank Refrigerator controlled at 2-6 °C with temperature recorder and alarm system, and AVR							
24.2 Reagent refrigerator with laboratory thermometer and AVR							
25. Rotator for RPR or VDRL					Optional	Optional	
26. Sphygmomanometer (Non-mercurial)							
27. Stethoscope							

28. Stopwatch or timer							
29. Tackle box / Phlebotomy box							
30. Thermometer							
30.1 Clinical Thermometer (non-mercurial)							
30.2 Laboratory Thermometer							
30.3 Room Thermometer							
31. Water bath/ dry bath set at 37°C for cross-matching and discrepant blood typing							
32. Clinical Weighing Scale							
32.1 Calibrated up to 200 kilograms – for blood donors							
32.2 Calibrated up to 500 grams – for blood units							



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

Name of Facility : \_\_\_\_\_  
Date of Inspection: \_\_\_\_\_

**RECOMMENDATIONS:**

**A. For Licensing Process:**

[ ] For issuance of License as \_\_\_\_\_  
**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 \_\_\_\_\_





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

Name of Facility : \_\_\_\_\_  
Date of Monitoring: \_\_\_\_\_

**RECOMMENDATIONS:**

**B. For Monitoring Process:**

☐ Issuance of Notice of Violation

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☐ Non-issuance of Notice of Violation

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☐ Others (Specify)

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**Monitored by:**

Printed Name

Signature

Position/Designation

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**Received by:**

Signature \_\_\_\_\_

Printed Name \_\_\_\_\_

Position/Designation \_\_\_\_\_

Date \_\_\_\_\_