Cabinet Resolution No. (28) of 2008
Regarding the Blood Transfusion Regulations

The Cabinet:

- Having reviewed the Constitution;
- Federal Law No. (1) of 1972 Regarding the Competences of Ministries and Powers of Minister as amended;
- Federal Law No. (7) of 1975 Regarding the Practice of Human Medicine Profession as amended;
- Federal Law No. (27) of 1981 Regarding the Prevention of Communicable Diseases;
- Federal Law No. (5) of 1984 Regarding the Practice of Certain Medical Professions by non-physicians and non-pharmacists, Non-Physicians and Non-Pharmacists;
- Federal Law No. (2) of 1996 Regarding Private Health Facilities;
- Cabinet Resolution No. (7) of 2008 Regarding the Medical Examination of Expatriates for Employment or Residency in the State;
- Cabinet Resolution No. (118/9) of 2008 Approving the Draft Cabinet Resolution Regarding Blood Transfusion; and
- Upon the proposal of the Minister of Health and the approval of the Cabinet,

Hereby resolves as follows:

Article (1)

The blood transfusion regulation attached to this Resolution is hereby approved. All government (federal and local) and private health facilities in the State shall be required to implement the measures, procedures, and rules prescribed therein.

Article (2)

The Ministry of Health shall monitor the implementation of this regulation. The local health authorities shall also monitor its implementation within the scope of their respective competence.

Article (3)

Without prejudice to criminal and civil liabilities, any violation of this regulation shall be deemed a disciplinary violation, and the disciplinary penalties prescribed by law shall apply thereto.

Article (4)

The Minister of Health may amend the attached regulation by addition or deletion whenever necessary.

Article (5)

This Resolution shall be published in the Official Gazette. All previous resolutions that contradict or conflict with the provisions of this Resolution shall be repealed. It shall enter into force from the date of its publication.

Mohamed bin Rashid Al Maktoum

Prime Minister

Issued by us in Abu Dhabi:
Dated: 3 Rajab 1429 A.H.
Corresponding to: 6 July 2008 A.D.

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Section One: Administrative Regulations for the Technical Aspects of Blood Transfusion Service Centers

Chapter One

Blood Transfusion Service

Definition:

Blood transfusion service center is the designation given to a center specialized in dealing with the public for the purpose of collecting blood, preserving it, conducting laboratory diagnostics, and dispensing it as per international regulations.

Blood Transfusion Service Centers shall be classified as follows:

1. Central blood transfusion service center
2. Satellite Blood Banks (located within hospital laboratory departments)
3. Semi-fixed mobile blood banks
4. Mobile blood bank

Main functions of blood transfusion service center:

1. Reception of blood donors, ensuring each donor is properly selected to exclude individuals with unsafe behavior, thereby monitoring the safety of the blood transfused to patients.
2. Verification of the donor's identity shall be conducted by means of personal identification. The individual must possess a UAE-issued personal identification document bearing the holder's photograph; no other form shall be accepted for blood donation. A Personal identification document refers to a passport, UAE health card, UAE Labour card, driving license issued within the state, or any other government

issued ID that includes the holder's photograph, UAE blood banks ID with photograph, or a work card issued by local departments.

3. The donor shall fill in the blood-donation questionnaire by providing accurate information for the items specified therein.
4. Inquiring about the donor via the computerized system, or from the blood center's records if the system is not available, to find all relevant information regarding the number of donations (donations shall not exceed four times per year with at least three months interval between donations), and to obtain all relevant information about the donor, to avoid collecting blood from donors suffering from diseases or from any donor who has donated within a period shorter than the specified donation interval, and other important information.
5. Collecting a blood sample from the donor to perform the necessary medical tests such as the hemoglobin test, white blood cells and platelets count, and conducting a blood-grouping test at each visit to prevent repeated errors in blood-group determination. Blood group identification shall be conducted using ABO or Rh systems.
6. A physician shall be continuously present at each centralized blood center. In satellite blood banks, if no physician is available on-site, the donor may, if necessary, be referred to an internist or an emergency physician.
7. The clinical examination shall consist of measuring blood pressure and pulse rate, and conducting a private personal interview with the donor to inquire about matters related to the donor's health condition as specified on the donation form.
8. After the physician approves the donation questionnaire, the donor is referred to blood collection halls or rooms, where the questionnaire is assigned a sequential number. The blood unit is then numbered, labeled, and prepared, and the donor undergoes psychological and physical preparation to ensure readiness for the blood-collection procedure. The volume collected is approximately 400-450 ml.
9. Measurement of blood pressure and pulse rate, and the personal interview shall be conducted by the physician, in the physician's absence, by the nurse; and if the nurse is also unavailable, by the technician, in descending order of precedence.
10. The physician and technicians shall immediately discontinue the blood collection

from the donor, if necessary, especially if the donor experiences fainting or any discomfort, or at the donor's request.

11. If blood collection is discontinued for any reason after more than 150 mL has been collected from the donor, it shall be considered a complete donation. The donor shall be treated as having donated 450 mL in terms of both the information recorded in the blood center's records and the utilization of the blood unit.
12. The donor shall be given a rest period of 5 -10 minutes after blood collection and shall be offered glucose-containing substances. The technician shall ensure the safety of the donor before departure from the blood center by enquiring about dizziness, vomiting, or nauseous. The technician should also put a medical bandit on the hand of the donor from the side where the needle pricked it after the end of the drawing process and before the donor exits the blood drawing hall or room.
13. The blood bank shall follow up with the donors (via phone, messages, and other means of communication) and extend thanks and appreciation to donors, especially those who have donated more than ten times, either through donor-appreciation ceremonies or via certificates of appreciation. Each blood center shall immediately contact any donor whose blood tests yield a positive result, to arrange retesting. If the confirmation test is also positive, the physician at the blood center (in central blood centers) and the center manager at satellite blood banks shall inform the donor via an official letter to whom it may concern, including all donor information and medical test results, for appropriate treatment and preventive measures for the donor's family.
14. After the collection of blood from donors, the blood units shall be transferred to the laboratory department at the central blood centers to conduct medical tests prior to being distributed to hospitals across the state. As for the satellite blood banks, the blood units are transferred to the hospital's laboratory department for preservation and, if available, for conducting medical tests. Alternatively, samples from these blood units may be sent to the central blood center for conducting the necessary tests in accordance with the prescribed regulations.
15. Comprehensive information shall be maintained in the electronic record systems for blood donors, including their laboratory test results, donation dates, hemoglobin

levels, blood pressure and other important information that is considered essential for each donor. This information shall be easily and promptly retrievable when needed.

16. A comprehensive monthly and annual statistics system shall be established covering the number of collected blood units and their components, the number of units dispensed to hospitals, and those discarded. It shall also include laboratory data related to the results for each donor and for each blood unit and its components.
17. A Quality Assurance and Quality Control program shall be established for all medical units and equipment.
18. A quarterly maintenance program shall be adopted for all the medical equipment used in the blood center to ensure its optimal performance and to avoid errors that could be fatal in blood centers. This maintenance program is known as Preventive Maintenance.
19. A proper program for preventing the transmission of infection during operations shall be established with a designated person responsible for its oversight. This system shall ensure continuous hygiene and sterilization of all used instruments, and require the use of plastic rather than glass tubes for blood samples to avert the risk of injury in the event of breakage.
20. Compatibility (X-matching) tests between the donor's blood unit and the patient's serum shall be conducted in accordance with the prescribed regulations as detailed on the blood-transfusion request questionnaires. The X-matching test shall be conducted on all blood units intended for transfusion, even in emergency situations where units are dispensed before compatibility results are available. Thereafter, the technician shall notify the entity to whom the blood was dispensed to recall any incompatible units, discontinue any incompatible blood already dispensed to the patient, and provide compatible replacement units.
21. The educational level of employees of the blood center shall be enhanced by participating in regular lectures and seminars, attending scientific conferences within and outside the state, and maintaining ongoing communication with international scientific societies specializing in blood centers and transfusion, to stay abreast of the latest developments in blood transfusion.

22. The competent administration shall provide blood centers with chemical solutions and supplies for blood transfusion operations, while maintaining a buffer stock sufficient to cover six months' requirements in advance, to avoid any shortages and cover any unexpected emergencies.

Competences of the Laboratory Department at the Central Blood Center:

1- Conducting Viral laboratory Diagnostics as follows:

No.	Test Name	Test Abbreviation
1-	Screening for antibodies to Human Immunodeficiency Virus, the causative agent of Acquired Immunodeficiency Syndrome (AIDS)	Anti-HIV 1+2
2-	Screening for protein 24 antigen of Human Immunodeficiency Virus type 1 (HIV-1)	HIV-1 P24 Antigen
3-	Screening for Hepatitis B surface antigen	HBsAg
4-	Screening for antibodies to Hepatitis C Virus	Anti-HCV
5-	Screening for antibodies to Human T-lymphotropic Virus types 1 and 2 (the causative agents of lymphotropic blood cell diseases)	Anti-HTLV 1+2
6-	Screening for syphilis (Venereal Disease)	Syphilis
7-	Screening for antibodies to Hepatitis B core antigen	Anti-Hbc
8-	Individual screening using nucleic acid testing (NAT) for Human Immunodeficiency Virus type 1 (HIV-1), the causative agent of Acquired Immunodeficiency Syndrome (AIDS), and for Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) during the window period	NAT

***With the possibility of adding any viral diagnostic test that health authorities may deem necessary to perform in the future.**

2- Blood components separation

1- Packed red cells
2- Concentrated platelets
3- Fresh frozen plasma
4- Cryoprecipitate
5- Repeat blood group testing on all blood units.
6- Perform blood component collection using apheresis, including plateletpheresis with plasma, plasmapheresis, or any device-specific procedures.

3- Storage of blood and blood components in refrigerators and freezers designated for this purpose

1- Maintain refrigerators at a temperature range of 1–6 °C (for blood units).
2- Maintain freezers at a temperature range of –35 °C to –30 °C (for plasma and cryoprecipitate).
3- Use automatic platelet agitators with an agitation speed of 8–10 cycles per minute at 22 °C (for blood platelets).

4- Monitor all medical equipment for temperature control and perform regular.

5- Preserve donor result records.

6- **Conducting confirmation tests for positive cases and for all tests via Enzyme-Linked Immunosorbent Assay (Elisa)**

No.	Confirmations Tests	Elisa
1-	W.B.	HIV 1+2
2-	Neutralization	HIV-1 P24 Antigen
3-	Neutralization	HBs Ag
4-	W.B.	Anti HCV
5-	W.B.	HTLV 1+2
6-	W.B.	Syphilis

Satellite Blood Bank (located within hospital laboratory departments)

These banks are located in hospitals across the UAE. They may be integrated into the Hematology Department or operate independently, subject to the direct supervision of the Head of the Laboratory Department or the supervising physician of the Hematology Department, with external regulatory oversight provided by the National Blood Transfusion Services Department.

Main functions of the Satellite blood bank

1. Reception of blood donors, ensuring each donor is properly selected to exclude individuals with unsafe behavior, thereby monitoring the safety of the blood transfused to patients.
2. Verification of the donor's identity shall be conducted by means of personal identification. The individual must possess a UAE-issued personal identification document bearing the holder's photograph; no other form shall be accepted for blood donation. A Personal identification document refers to a passport, UAE health card, UAE Labour card, driving license issued within the state, or any other government issued ID that includes the holder's photograph, UAE blood banks ID with photograph, or a work card issued by local departments.
3. Inquiring about the donor via the computerized system to find all relevant information

(donations shall not exceed 4 times per year), and ensuring that the donor's blood screening results are negative.

4. The donor shall fill in the questionnaire, answer all questions, and sign it upon completion, and the responsible staff member shall verify that.
5. Collecting a blood sample from the donor to perform the necessary medical tests such as the hemoglobin test, white blood cells and platelets count, and conducting a blood-grouping test at each visit to prevent repeated errors in blood-group determination. Blood group identification shall be conducted using ABO or Rh systems.
6. The donor shall be referred to a physician, if available in the laboratory department, for a clinical examination. If no physician is available on-site, the donor may, if necessary, be referred to an internist or an emergency physician.
7. The clinical examination shall consist of measuring blood pressure and pulse rate, and conducting a private personal interview with the donor to inquire about matters related to the donor's health condition as specified on the donation form, and investigating the donor's personal behaviors to avoid collecting blood from individuals with unsafe behaviors, thereby ensuring the safety of transfused blood for patients. individuals with bad behavior to ensure the safety of the transfused blood to patients.
8. After the physician approves the donation questionnaire, the donor is referred to blood collection halls or rooms, where the questionnaire is assigned a sequential number. The blood unit is then numbered, labeled, and prepared, and the donor undergoes psychological and physical preparation to ensure readiness for the blood-collection procedure. The volume collected is approximately 400-450 ml.
9. If the physician is unavailable for any reason, the technician shall measure blood pressure and pulse and conduct a personal interview. Preferably, a nurse shall perform these tasks if present in the blood bank; otherwise, the authorized technician shall conduct them.
10. Once it is confirmed that the donor meets all the requirements for blood donation, the blood collection site shall be sterilized. and the volume collected shall be approximately 400-450 ml. At the outset of blood collection, the initial blood drops shall be diverted into a small pouch dedicated to laboratory testing, to avoid the

potential transmission of bacterial contamination to the blood unit.

11. The physician and technicians should immediately discontinue the blood collection from the donor, if necessary, especially if the donor experiences fainting or any discomfort, or at the donor's request.
12. If blood collection is discontinued for any reason after more than 150 mL has been collected from the donor, it shall be considered a complete donation. The donor shall be treated as having donated 450 mL in terms of entitlements, the information recorded in the blood center's records, and the utilization of the blood unit. If less than 150 mL is collected, the blood unit shall be deemed unusable and the donation incomplete. Blood collection may resume immediately or at a later time, as determined by the donor's condition. In such cases, red blood cells shall be separated promptly and preserved in Citrate Phosphate Dextrose (CPD) solution at ≥50% of the original blood volume to maintain their therapeutic value. If separation is not performed, the unit shall be used within five days of collection.
13. The donor shall be given a rest period of 5 -10 minutes after blood collection and shall be offered glucose-containing substances. The technician shall ensure the safety of the donor. The technician should also put a medical bandit on the hand of the donor from the side where the needle pricked it after the end of the drawing process and before the donor exits the blood drawing hall or room.
14. The blood bank shall follow up with the donors (via phone, messages, fax, and other means of communication) and extend thanks and appreciation to donors, especially those who have donated more than ten times, either through donor-appreciation ceremonies or via certificates of appreciation.
15. Records shall be maintained to include comprehensive information on all blood units and their components that shall be dispensed to hospital departments. These records shall specify the patient's name, medical record number, nationality, age, gender, and the name of the department. The documentation shall be based on the blood transfusion request questionnaire submitted by the respective department. Additionally, any adverse reactions following the transfusion shall be recorded in dedicated records designated for this purpose.

16. There shall be continuous monitoring of the demand for blood units and blood components from the central blood center. Reserve quantities of blood units and its components from all blood groups shall be maintained to prevent shortages during emergencies. This shall be carried out in coordination with the nearest central blood center.
17. Cancellation of reservation shall be applied after 72 hours for any patient, upon coordination with the departments prior to cancellation.
18. In urgent and emergency cases, blood units that are not reserved for any patient shall be utilized. In case they are not sufficient, there shall be no hesitation in immediately contacting the central blood center. Blood units reserved for other patients shall be directly and promptly utilized to manage emergency cases. Subsequently, arrangements shall be made for the other patients whose medical conditions are not critical at that time.
19. Blood shall not be dispensed unless accompanied by a patient transfusion request questionnaire, duly signed by the attending physician and including all required information.
20. No blood transfusion shall be carried out for a patient except under the supervision of a physician.
21. It shall be mandatory for the nurse to sign the blood dispensing register at the blood bank upon receiving any blood unit and its components.
22. For any reason, if the closed system of a blood unit is opened, it shall be used within 24 hours only; otherwise, it must be discarded immediately.
23. In case blood is received from the blood bank and not dispensed to the patient for any reason within 30 minutes, it shall be returned to the blood bank immediately, and the reason for non-dispensation shall be clearly stated.

Semi-fixed mobile blood banks:

These banks take the form of mobile centers that move from one location to another for limited periods. Their main function is to collect blood from members of the public in

gathering places such as parks, in front of ministries, markets, mosques, or commercial centers. After completing the mission, this bank is relocated to other residential areas where it remains for a few days AT designated locations until donation activities are completed and then moves to other places. At the end of each day, the collected units are transferred to the main blood centers to carry out the necessary procedures.

Mobile blood banks:

These banks take the form of caravans pulled by large vehicles or specially equipped buses manufactured to serve as mobile blood banks. Each Bank includes all necessary equipment for blood collection and preservation, and for conducting some basic medical tests such as blood grouping and hemoglobin level measurement. They are equipped with beds for blood collection, a laboratory, a physician's room, refrigerators for storing collected blood, and another for preserving chemical solutions and refreshments, if needed. This bank shall operate under the supervision of a physician, and a nurse if available, and a laboratory or blood bank technician. Mobilization to specific entities shall be carried out following prior coordination with the relevant departments, ministries, or designated entities from which blood is to be collected.

The competent administration shall deliver advance lectures at the gathering location and distribute brochures on blood donation in advance, to prepare the donors before the mobile bank's arrival.

Chapter Two

Indications for the Optimal Use of Blood and Its Main Components

Blood:

It is an organic fluid containing hemoglobin that circulates through the blood vessels and the heart. Blood and its main components are highly valuable therapeutic substances of critical importance. It is a vital human resource that is difficult to attain. The collection and storage of blood shall be carefully regulated and subjected to thorough medical examinations. Specific and clear controls and regulations shall be established and implemented by the responsible personnel at all types of blood banks.

Blood fluid consists of two main parts:

1. Blood cells, which include three types (red blood cells, white blood cells, and platelets).
2. Plasma, which is the fluid in which the blood cells are suspended.

a- Blood Cells:

1. Red Blood Cells (RBCs):

They form the largest portion of the cellular components of blood. Their red color is due to the presence of hemoglobin pigment. The amount of hemoglobin in the blood can be measured by breaking down red blood cells using chemical substances and analysis. The normal levels of hemoglobin in humans are:

For men : 13-18 gram/liter

For women : 12-15 gram/liter

As for red blood cells in the body, they range as follows:

For men : 4.5-6.3 million per mm^3

For women : 2.5-5.4 million per mm^3

2. **White Blood Cells (WBCs):**

They are the cells responsible for protecting the body from bacterial infections. There are several types of white blood cells:

- Granulocytes: the largest among white blood cells.
- Monocytes: single-nucleus white blood cells that attack and engulf bacteria.
- Lymphocytes: responsible for recognizing foreign bodies, including bacteria and toxins and playing a key role in the immune response during infections or as a reaction to the invasion of these foreign bodies into the blood.

The count of white blood cells in a healthy human ranges from 4,000 to 10,000 cells per cubic millimeter.

An increase or decrease in this count may indicate a medical condition, and the count of certain types of white blood cells may point to specific infections.

3. **Platelets:**

Blood usually circulates in the blood vessels in a fluid state. If a blood vessel is punctured or wounded, platelets gather at the site to seal the wound and stop the bleeding, in coordination with other assisting substances in the blood plasma.

The normal platelet count in humans ranges from 150,000 to –450,000 per mm^3.

b- Plasma:

The blood cells mentioned above are present in a yellowish fluid known as plasma. This fluid transports blood cells and other substances such as glucose, fats, and other proteins, including clotting factors and antibodies, to all parts of the body. The main component of plasma is water, followed by various types of proteins.

Fresh plasma is separated by cryo-centrifugation within no more than 6 hours after donation. It shall be preserved at freezing temperatures between –30°C and –35°C, and used to compensate for clotting factor deficiencies in patients.

A unit of whole blood (450 cm^3) contains approximately 200 to 250 cm^3 of plasma.

c- Methods for preserving blood and its components:

Whole blood is preserved using anticoagulant substances that differ in their chemical compositions, which in turn affects the blood preservation period.

1- Chemical Substances Used for preserving Whole Blood and the preservation Duration:

- **CPD:**

It is identified by its components: Dextrose, Phosphate, and Citrate. Upon being mixed with blood, it preserves it for 21 days in sterile blood units. These blood units shall be preserved under controlled and sterile conditions to avoid bacterial or viral contamination, at a temperature between 2°C and 8°C.

- **CPDA:**

It is the same as the above substance, with the addition of Adenine. This extends the preservation time to 29 days under the previously described conditions.

- **CPDA-1:**

This substance preserves blood for up to 35 days. It differs from the previous substance by the increased use of Dextrose, which represents the latest chemical substance for the preservation of whole blood.

A volume of 63 cm^3 of the above three substances is added to a whole unit that accommodates 400-450 cm^3 of whole blood during donor blood collection. Blood is then preserved at a temperature between 2°C and 8°C in special refrigerators designated for blood preservation.

- **SAG-M (Saline Adenine Glucose – Mannitol) or ADSOL (adenine, dextrose, sorbitol, sodium chloride and mannitol)**

These substances differ in the concentrations of Dextrose and Citrate Acid used in each.

They are used to preserve red blood cells for up to 42 days at temperatures between 2°C and 8°C.

A volume of 100 cm^3 of SAG-M or ADSOL is added to a unit separate from the whole blood unit and attached to a sealed and sterile tube. Blood is collected from the donor and mixed with CPD as per standard procedure. Blood plasma is then separated by centrifugation into an adjacent empty unit, leaving behind packed red blood cells. An additional 100 cm^3 of SAG-M or ADSOL is then added to the packed red blood cells, enabling their preservation for up to 42 days.

- **Glycerol:**

Glycerol is used to preserve packed red blood cells for 5-10 years at temperatures between −65°C and −80°C. It prevents red blood cells from breaking and preserves their original size and shape.

This modern method is used to freeze packed red blood cells of rare or Rh-negative blood groups. The frozen blood is thawed when needed, and the red blood cells are washed with a glucose-saline solution to remove the glycerol from the blood. Red blood cells are then used for transfusion to patients.

If the blood is not used, it must be discarded, as it cannot be refrozen under the same system.

2- Biochemical Changes in Whole Blood and Its Components During Storage from Initial Collection up to 35 Days.

Characteristics of Whole Blood Stored for 35 Days (CPDA-1)

	Storage Time (Days)				
	0	7	14	21	35
Plasma dextrose (mg/dl)	432	374	357	324	282
Plasma sodium (mEq/L)	169	162	159	157	153
Plasma Potassium (mEq/L)	3.3	12.3	17.6	21.7	17.2
Plasma chloride (mEq/L)	84	81	79	77	79
Plasma bicarbonate ((mEq/L)	12.0	17.0	12.5	12.2	8.0
Whole - blood pH	7.16	6.94	6.93	6.87	6.73
Whole - blood lactate (mg/dl)	19	62	91	130	202
Plasma LDH (U/L)	296	1002	1222	1457	1816
Whole-blood ammonia (µg/dl)	82	280	423	521	703
Plasma hemoglobin (mg/dl)	0.5	13.1	24.7	24.7	45.6
WBC ($\times 10^3/\mu L$)	7.2	4.0	3.0	2.8	2.4
Hematocrit (%)	35	36	35	36	36
RBC hemoglobin (g/dl)	12	12	12	12	12
RBC ($\times 10^6/\mu L$)	4.0	4.0	3.9	3.9	3.9
Red Blood Cell 2,3-DPG (µmol/gHb)	13.2	-	-	-	0.7
Red Blood Cell ATP (µmol/gHb)	4.18	-	-	-	2.40

3- Laboratory diagnostic tests on blood unit after donation:

To ensure the safety of patients and confirm that the transfused blood is free of any bacteria or viruses, several laboratory diagnostic tests shall be conducted using highly sensitive methods. This has become especially important after the discovery of AIDS.

The tests are as follows:

No.	Test Name	Test Abbreviation

1.	Screening for the causative agent of Acquired Immunodeficiency Syndrome (HIV/AIDS)	-HIV 1+2 = Human Immuno Deficiency Virus Type 1+2 AIDS = Acquired Immuno Deficiency Syndrome
2.	Screening for protein 24 antigen of Human Immunodeficiency Virus type 1 (HIV-1)	HIV-1 P24 Antigen
3.	Screening for Hepatitis B surface antigen	HBSAG = Hepatitis B surface Antigen
4.	Screening for antibodies to Hepatitis C Virus	Anti-HCV = Anti Hepatitis C Virus
5.	Screening for antibodies to Human T-lymphotropic Virus types 1 and 2 (the causative agents of lymphotropic blood cell diseases)	HTLV 1+2 = Human T-Cells Lymphotropic Virus Type 1+2
6.	Screening for syphilis (Venereal Disease)	Syphilis
7.	Screening for antibodies to Hepatitis B core antigen	Anti-Hbc
8.	Individual screening using nucleic acid testing (NAT) for Human Immunodeficiency Virus type 1 (HIV-1), the causative agent of Acquired Immunodeficiency Syndrome (AIDS), and for Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) during the window period	NAT

***With the possibility of adding any viral diagnostic test that health authorities may deem necessary to perform in the future.**

d- Indications for the Optimal Use of Blood and Its Main Components:

This table outlines blood transfusion and its main components, detailing the contents of each component, its volume, and the indications for its optimal use.

Component	Content	Volume	Indications for Use and Effectiveness
Whole blood	Red and white blood cells, blood plasma and	500 cm^3	Increases the levels of both red blood cells and plasma volume.

	platelets		Not effective in compensating for deficiencies of white blood cells, platelets, and coagulation factors V and VIII. (Currently, there is no justified indication for the use of whole blood except in rare cases.)
Red blood cells	Red blood cells free of plasma, platelets and white blood cells	250 cm^3	Increases the level of red blood cells in cases of anemia. Not effective for platelets or white blood cells.
Fresh Frozen Plasma	Plasma containing all coagulation factors without platelets	220 cm^3	To treat and compensate for coagulation factor deficiencies, compensate lost bodily fluids in burns cases, and treat other medical conditions
Single unit platelet Concentrate (recovered)	Platelets Platelets: 5.5×10^{10}/ unit	50 cm^3	In cases of hemorrhaging and to compensate for lost platelets due to dysfunction in the body's platelet production mechanism.
Cryoprecipitate	Fibrinogen, Coagulation Factor VIII, and Von Willebrand factor	15 cm^3	In case of Factor VIII deficiency (hemophilia A), and for the treatment of Von Willebrand disease
Apheresis platelet Concentrate	Platelets: > $2.5–3 \times 10^{11}$/ unit. Each unit of platelets contains a few red or white blood cells and plasma	300 cm^3	Same indication as for single unit platelets, and in some cases for matching HLA

Saline washed red blood cells	Red blood cells with less than 0.5 gram of residual protein per unit.	180 cm^3	Increases the level of red blood cells and reduces the possibility of allergic reactions to protein plasma
Thawed Frozen Red Blood Cells	Red blood cells with white blood cell content less than 0.1×10^9 per unit.	180 cm^3	Increases the level of red blood cells and reduces the possibility of allergic and other transfusion-related reactions. Used to freeze red blood cells of rare groups for select cases.

e- <u>Use of Blood and its Components in Blood Group Incompatibility:</u>

Blood and blood components shall only be transfused if they match the blood group (ABO) and Rhesus (Rh) factor to avoid transfusion risks such as complications resulting from blood group incompatibility and the presence of antibodies that are - or were - not present in the person to whom blood is transfused.

No blood group shall be transfused except in accordance with the system and principles set out below:

1- <u>As per ABO system</u>

1/1-**Transfusion of packed red blood cells (PRBCs):**

Selection of the blood group and the alternative blood group:

a. Group "O" may be transfused to recipients with the same group "O" and to all other groups (A, B, AB) only within certain limits when using whole blood units.
b. Group "A" may be transfused to recipients with the same group "A" and to group "AB".
c. Group "B" may be transfused to recipients with the same group "B" and to group "AB".
d. Group "AB" may be transfused only to recipients with the same group "AB".

1/2-**Blood plasma transfusion:**

Selection of the blood group and alternative blood groups:

a. Group "O" may be transfused only to recipients with the same group "O".
b. Group "A" may be transfused to recipients with the same group "A" and group "O".
c. Group "B" may be transfused to recipients with the same group "B" and group "O".
d. Group "AB" may be transfused to recipients with all blood groups (O, A, B, AB).

1/3-**Platelet transfusion:**

Selection of the blood group and alternative blood group:

In non-chronic cases that do not require continuous platelet transfusion over the long term, platelets from any ABO group may be transfused to recipients of any other group where large quantities of concentrated platelet are.

However, when a permanently adequate supply of platelet concentrates is available, transfusion must be limited either to the same blood group or carried out in accordance with the red-blood-cell compatibility system outlined above.

2- <u>As per Rhesus (RH) system</u>

2/1-Transfusion of packed red blood cells:

Packed red blood cells shall be transfused only when the donor and recipient share the identical Rhesus (Rh) factor to prevent transfusion-related complications. In life-threatening emergencies where Rh-negative units are scarce or unavailable, a single Rh-positive unit may be given once to an Rh-negative male patient to save his life; this option is generally impracticable in women, especially younger women.

Approximately 70% of cases in which an Rh-positive unit is transfused to an Rh-negative patient, recipient develops anti-D antibodies (d-immunization) against the foreign antigen. In this case, after administering an Rh-positive unit to an Rh-negative recipient, the patient shall be screened for anti-D antibodies no sooner than 7—10 days after the transfusion.

2/2-Blood plasma transfusion:

When plasma with the identical Rhesus (Rh) factor is available, it shall be used for transfusion. If no such plasma is available, the transfusion may proceed without regard to the Rh factor.

For children, pregnant women, and young female patients who are Rh-negative, it is advisable to transfuse plasma with the identical Rh factor.

2/3-Transfusion of Platelet Concentrates:

Transfusion of platelet concentrates depends on whether the unit contains even trace amounts of red blood cells in the platelets. If no RBCs are present, Rh-positive platelet units may be transfused to Rh-negative patients.

If even a small amount of red blood cells is present, Rh-positive units shall be given only to Rh-positive patients, while Rh-negative units may be given to patients of either Rh type, because giving an Rh-positive component to an Rh-negative recipient carries a risk of D-IMMUNIZATION (anti-D allo-immunization).

Platelets shall also be tested before storage to ensure they are free of any bacterial contamination prior to transfusion to the patient.

It is essential to record every blood transfusion in patients' records, especially when the transfused unit's blood group, whether under the ABO or Rh system, differs from the patient's own.

f- <u>Role of blood banks in reducing the transmission of diseases:</u>

To safeguard patient safety and, using modern medical techniques, verify that blood to be transfused is free of any germs, viruses, or bacteria. It has therefore become imperative to carry out a battery of medical tests using highly sophisticated techniques—especially after the advent of the modern-age scourge, AIDS.

Various means and methods shall be employed to reduce the spread of this disease, as follows:

1. Continuous public education to prevent this disease, accompanied by clear information on its modes of transmission.
2. Complying with societal values and traditions, and religious teachings by refraining from illicit sexual relations.
3. Ensuring the continuous provision of adopted treatment across healthcare, especially in developing and poor countries.
4. Proper sexual hygiene, including condom use and thorough washing of genital organs after every sexual intercourse, may afford some protection.

This disease poses a serious danger to pregnant women and their fetuses, if the mother becomes infected during pregnancy, she can transmit the disease to her fetus which may lead to fetal death, miscarriage or congenital deformities.

g- Blood transfusion risks:

Although blood transfusion offers many benefits, most notably saving the lives of patients' lives, it also entails risks that are usually beyond the control of the competent authorities responsible for monitoring the patient's condition during the transfusion.

1. AIDS

Method:

HIV can be transmitted when contaminated blood is transfused during the window period, before anti-HIV antibodies become detectable, to a patient who needs blood.

Infection Probability:

Advanced modern tests have decreased the probability of being infected with HIV from 1 in 40,000 blood units to 1 in 153,000 blood units.

Result:

Becoming infected with AIDS.

2- Viral Hepatitis (types B or C):

Method:

The virus can be transmitted through an ordinary blood transfusion when medical screening fails to detect the virus during its window period, which is usually a long period.

Infection probability:

The risk of transmission through transfused blood is estimated at about one case per 100,000 units for hepatitis C virus (HCV) and about one case per 200,000 blood transfusions for hepatitis B virus (HBV).

Result:

Only a small proportion of recipients develop clinical signs of hepatitis, and in some of them the infection progresses to chronic hepatitis.

3- Syphilis:

Screening for this infection is one of the principal tests conducted on donated blood to prevent its transmission to patients. Any unit found to be contaminated is discarded, and the donors of such blood are retested and referred to the competent entities to receive proper treatment. Measures are also taken to prevent the infected persons from passing the infection to family members (his or her spouse, if married).

Some studies indicate that preserving the blood unit for more than 72 hours in dedicated blood refrigerators is sufficient to kill these spirochetes, thereby making the blood safe for use when the necessary chemical substances required for detecting the disease are unavailable.

4- Mad Cow Disease (bovine spongiform encephalopathy):

There is generally no laboratory test that can detect the disease-causing protein in blood. Therefore, appropriate precautions shall be taken to prevent collecting blood from persons who may have been exposed to this disease.

5- Transmission of diseases that are still unknown to date.

Chapter Three:

Principles for Handling Blood and Its Components

Introduction:

The primary purpose of blood donation centers is to ensure that all operations related to the collection, preparation, storage and transfusion of blood and its components are carried out to maximize the benefit for their recipient.

All the methods used shall prevent, or at least delay, any physical or chemical changes that may damage blood components and shall minimize microbial contamination or proliferation. Like other living cells, blood cells rely during storage on maintaining biochemical equilibrium for various substances, especially glucose, pH, and adenosine triphosphate (ATP). In addition, refrigeration and freezing processes slow the growth of bacteria that may have entered the container when the needle pierced the skin or that were already present in the donor's bloodstream.

Sterility:

1) Sterility of blood and its components shall be maintained throughout the preparation phase by employing sterilization methods and using sterile equipment and solutions free of pathogenic (infectious) agents. It is preferable to use devices that allow the transfer of blood components without breaking the seal (leak-proof).
2) Seal (leak-proof)
   - If the seal remains unbroken, the permissible storage period of blood and its components shall depend on their stability and viability as indicated on the plastic blood container.
   - If the seal is broken during the preparation of blood components, including pooling phase, the validity of the blood components stored at 2 – 8 °C is 24 hours, whereas the validity of blood components stored at 20 – 24 °C generally expire within 4 hours after the seal is broken.
   - If the seal is broken during the preparation phase and the blood components are to be frozen for storage, the components shall be frozen within 6 hours of the time the seal

is broken. After thawing, these components shall be used within 6 hours if held at 20 – 24 °C, or within twenty-four hours if held at 2 – 8 °C.

- All split blood bags, blood components, and pooled derivatives shall be subject to the general rules previously outlined in paragraphs (1) and (2).

3) When a sterile connector is used to join two sections of tubing while keeping the system closed (closed circuit), the following should be observed:
   - The connection site shall be inspected during the preparation of the components to verify their integrity and sterility.
   - If the connection is intact, the blood component shall retain its original validity period.
   - If the connection is not intact, the blood components shall be handled under open-system conditions (open circuit). In this case, the components shall be sealed and used within the validity period indicated in the following paragraphs (check sections w and x).

Gamma-Irradiation

1. The validated irradiation dose shall be 25 Gy (2 500 c Gy), taking into account the general operating guidelines for gamma-irradiation, provided that the minimum dose within the irradiation field shall be not less than 15 Gy (1 500 cGy).
2. Methods shall be employed to ensure that gamma irradiation has been carried out and is effective. For example, affixing indicator labels to the blood component that changes color when exposed to the required dose of gamma radiation.
3. Records shall be maintained to monitor the irradiation process:
   - Record of dose calculation for each irradiated blood component.
   - Record of the monthly and annual decay of the device's radioactive source.
   - Record of the quality procedures used to identify the irradiation field of the device.
   - Record of repairs and routine maintenance.

Blood and Blood Components

1- Whole blood

Whole blood contains red blood cells, white blood cells, platelets, and plasma. Blood shall be collected in sterile containers containing anticoagulant fluid.

1-1- Modified Whole blood

Modified whole blood is obtained after removal of the cryoprecipitate, which contains anti-hemophilic factor from the whole blood.

1-2- Irradiated Whole blood

Is whole blood exposed to gamma-irradiation to prevent the proliferation of lymphocytes.

1-3- Low volume whole blood

Each unit of whole blood may be divided into several smaller units for use in pediatric patients.

2- Red blood cells and their components

Securely connected segments of tubing shall be filled with small amounts of the blood component during the final preparation of components intended for transfusion to be used in compatibility testing.

2-1- Red blood cells

These are the remaining after removal of plasma from the whole blood. Red blood cells may be separated from plasma either by sedimentation or by centrifugation. This process may be performed at any time during the validity period of the blood.

2-2- Frozen red blood cells

- Frozen red blood cells are red blood cells preserved at optimal temperatures with an anticoagulant agent (glycerol). The cryoprotective agent shall be removed by washing before transfusion. The washing process shall ensure sufficient removal of the cryoprotective agent and preservation of at least 80% of the original red blood cells in the blood unit.

- In general, red blood cells shall be frozen within 6 days of donation, except for rejuvenated red blood cells (see section 2.5 below). Preservative and nutrient fluids for packed red blood cells may be used to extend storage period.

2-3- Washed red blood cells

These are the red blood cells remaining after being washed to remove most of the plasma (using a defined volume of compatible solution). The amount of white blood cells and platelets removed from the original unit depends on the washing method used.

2-4- Leucodepleted packed red cells

Leucodepleted packed red blood cells are those in which most white blood cells have been removed, resulting in a final product containing fewer than 1×10^6 white blood cells per unit. The leucodepletion process shall ensure retention of at least 85% of the original red blood cells in each unit.

2-5- Rejuvenated (activated) red blood cells

- These are red blood cells that have been rejuvenated after storage at 2–8°C for three days beyond their expiry date.
- The rejuvenation process shall restore ATP and 2,3-diphosphoglycerate (2,3-DPG) levels to normal or above.
- After rejuvenation, the red blood cells may be transfused, after (after washing) or frozen (after adding glycerol) within 24 hours.
- The use of rejuvenation solutions must be indicated on the unit label.

2-6- Irradiated red blood cells

As stated above.

2-7- Low volume red blood cells

These are units of whole blood collected in volumes of 300-400 ml, which is less than the standard volume.

- This unit may be used after labeling the blood unit as "Low-Volume" indicating the collected volume on the label.
- No other blood components shall be prepared from low volume units.

3- Plasma derivatives

3-1- Fresh Frozen Plasma (FFP)

This is plasma separated from the donor's blood and stored at –18°C or lower.

- Preparation shall be completed within a maximum of 8 hours from the time of donation if the anticoagulant used is CPD or CPDA-1.

It shall be noted that if the plasma is thawed in a water bath prior to transfusion, the plastic container must be protected from the surrounding liquid.

3-2- Cryoprecipitate (Antihemophilic Factors)

Cryoprecipitate is the cold, insoluble extract from fresh frozen plasma (FFP).

- While preparing cryoprecipitate, fresh frozen plasma shall be processed in a closed system and thawed at 2°C to 8°C.
- Plasma shall be separated immediately from the cryoprecipitate after complete thawing and centrifugation at 2°C to 8°C, and the cryoprecipitate shall be frozen within one hour of preparation.

3-3- Plasma frozen within 24 hours of donation

This is plasma separated from the donated blood and stored at –18°C or lower within 24 hours of donation. It contains reduced levels of coagulation factors V and VIII.

3-4- Liquid plasma

This is plasma separated from the donor's blood more than 24 hours after donation. It is not used for transfusion.

3-5- Cryoprecipitate-Poor Plasma

This is fresh frozen plasma (FFP) from which the cryoprecipitate has been removed.

4- Platelets

This is a suspension of blood platelets in plasma, prepared by centrifuging whole blood using a closed system and special containers.

Concentrated platelets prepared from whole blood units.

- Concentrated platelets prepared by automated blood cell separator.
- Leucodepleted concentrated platelets.

Irradiated platelets.

It shall be noted that the volume of plasma in platelets units may be reduced for use in neonates, provided this is done directly before usage.

Laboratory tests conducted on donated blood:

ABO group Testing

Blood group (ABO) shall be identified by testing red blood cells with anti-A and anti-B reagents, as well as through checking serum or plasma for the presence of antibodies using red blood cells of groups A, B, and O.

Blood shall not be used unless all results are compatible.

Rh type Testing

The Rh factor shall be determined using anti-D reagent. In case the result is negative, the blood shall be tested for the Weak-D factor.

- If either of the two previous tests is positive, it shall be stated on the label: "Rh Positive."
- If both of the two previous tests are negative, it shall be stated on the label: "Rh Negative."

Testing for additional blood group antigens is not routinely required.

Previous Blood Group Records

The donor's blood group and Rh shall be checked at each donation. Previous records shall not be relied on for this purpose.

Screening for Red Blood Cell Antibodies

The serum or plasma of the donor shall be screened for unexpected antibodies if there is a history of transfusion or pregnancy.

Screening for antibodies of clinical significance shall be performed.

Screening for Infectious Diseases Associated with Blood Transfusion

5-1- Each blood unit shall be screened for infectious diseases by performing the following tests: Anti-HIV I,II,O / HIV I-Ag (P24) / Anti-HTLV I-II / Anti-HBc, HBsAg. Anti-HCV / Syphilis.

Additional tests may be introduced upon approval, with a statement of test implications to be provided following a field study to establish the scientific rationale for implementation.

5-2- Whole blood or its components shall not be distributed or transfused unless all previous test results are negative (with the exception of the case described in 5.3).

5-3- In urgent situations, blood may be transfused before completion of all the previous tests and screenings (see 5.1). In this case, the transfused blood unit must be clearly labeled as "Incomplete Testing". All required tests shall be completed as soon as possible. If any test result is positive, the physician supervising the patient shall be informed immediately. Transfusion of untested blood shall be permitted only in the most exceptional cases and only with the approval of the treating specialist physician.

System for Disposal of Blood Units or Components Unsuitable for Transfusion:

- Rules and conditions shall be established for the storage and disposal of blood units or components unsuitable for transfusion.

Labeling process for blood and blood components

1- **General conditions**

The labeling process shall include all steps taken to identify the original unit and its components as well as any modifications made to components, to ensure the completion of

required references and the placement of appropriate labels.

The original and any added labels shall be affixed to the blood unit so that they are clearly legible to the naked eye (or by equipment, if available).

All handwritten additions and modifications shall be legible and written with moisture-resistant ink.

The labeling process shall include a second check procedure to ensure the accuracy of blood group information (ABO/Rh) and expiry date, as well as to confirm that labels are properly affixed to blood and blood component containers.

In case of any modification to any of the blood component and the affixation of a new label, the labeling process shall include a system to ensure the accuracy of ABO/Rh information, expiry date, and the correct affixation of the modified blood component.

2- **Identification of Blood Unit or its Components:**

2-1- A numeric or alphanumeric system shall be used to enable the traceability of any blood unit or blood component from the original source to the final destination, including checking all related records.

2-2- The collecting facility shall affix the numeric (or alphanumeric) identification to each blood unit, its components, and associated units. This number shall not be concealed, altered, or removed by other entities responsible for transferring or using them.

3- **Labeling during collection or preparation**

During the collection process of whole blood or blood components, or the preparation of blood components, the label affixed to the blood unit shall contain at least the following information:

3-1-1 Type of content (whole blood or blood component).

3-1-2 Identification number (numeric or alphanumeric) and the blood collecting entity.

3-1-3 Name of the anticoagulant used (this condition is not required for frozen red blood cells, deglycerolized red blood cells, activated, or washed red blood cells).

3-1-4 Date of blood collection from the donor.

3-1-5 Expiry date and validity of the blood component.

4- **Renewing blood component validity prior to the labeling process**

- A method should be put in place to ensure that all the steps of the preparation of blood, blood components, biological tissues, etc., have been followed prior to the final labeling process.
- The criteria for testing and acceptance should be specified. There should be evidence that the records for said bases have been reviewed prior to the final labeling process.
- In the case of prior donation, the results of the current blood group (ABO/Rh) should be compared to the existing records. In case of discrepancy in results, the blood component should not be used until the reason for said discrepancy is identified.

5- **Final Label prior to distribution**

5-1- The final label affixed to the container should include the following information:

5-1-1 Temperature of storage.

5-1-2 Expiry date for blood and blood components (and in some cases, expiry time).

Entity that prepared the final blood component in case of pooled components. Blood group and Rh factor (ABO/RH)

Unexpected present red cell antibodies (except for cryoprecipitate; or frozen, activated, washed or deglycerolized red blood cells).

Instructions for the person conducting the transfusion:

- Read the information related to the use of human blood and blood components.
- Identify the recipient.
- This product or blood component could transmit infectious agents.

6- **Cases for Special Labeling:**

1. In case gamma irradiation is applied to whole blood or blood components, a permanent label should be affixed to indicate this, and state the entity or center in which the process was carried out.
2. In case the whole blood or blood components are CMV-seronegative and are to be used for this purpose, a label to this effect should be affixed to the blood unit.

3. In case the whole blood or blood components are leukocreduced and are to be used for this purpose, a label to this effect should be affixed to the blood unit.
4. Red blood cells antigens.
5. In case of pooled components:

6-5-1 The label affixed to pooled components should include the information set forth in Paragraph (5), in addition to:

6-5-1-1 Type of pooled blood components.

6-5-1-2 Final volume of pooled blood.

6-5-1-3 Name of entity that prepared the pooled blood.

6-5-1-4 Identification number (numeric or alphabetical) of the pooled component.

6-5-2 The following information should be mentioned on the label or attached tag:

6-5-2-1 Number of units pooled.

6-5-2-2 The blood group and Rh factor for the pooled units.

6-5-3 The following information should be retained in the records of the entity preparing the pooled components:

6-5-3-1 Identification number of each of the pooled units.

6-5-3-2 Collecting entity for each of the pooled units.

Storage, Transport, Receipt and Expiry

Storage:

Blood banks and blood transfusion service centers should designate specific areas for the proper storage of blood and blood components. The blood bank manager shall specify the persons authorized to access these storage areas and handle their contents.

Blood, blood components and tissues prepared for transplantation should be stored separately and separated from laboratory materials and blood samples from donors and patients.

Devices designated for the storage of blood and blood components must comply with internationally approved standard specifications.

There should be specific steps and instructions to be followed in case of an alarm triggered by a power failure or any other malfunction in the devices.

Transport:

Blood, its derivatives, components, and tissues should be transported from one place to another in a manner that prevents damage or deterioration, while complying with the specific storage conditions applicable to each blood component.

Platelets should not remain stationary (without agitation) for more than 24 hours.

Blood and blood components should be inspected and their validity checked prior to transportation. In case the external appearance is abnormal, they should not be transported.

Receipt:

1- When a blood transfusion service center receives blood or blood components, each container should be inspected to ensure external intactness and the presence of a label including all the required information in a legible form. All information as to the appearance of the unit and its number, date and time of receipt, and the supplying entity should be recorded.

2- When receiving blood, blood components or tissue under unusual circumstances (such as emergencies or special releases), the blood bank or blood transfusion center must: (1) maintain the records of the receipt and the unusual circumstances, and (2) store said components in a separate storage area.

Expiry date:

The expiry date is the last day on which the blood, blood components and tissues are deemed suitable for transfusion to a patient and for the issuance of a release document.

5- Method of storage, transport and expiry

Item	Method of storage	Method of transport	Expiry	Additional criteria
1- Whole blood	1°C-6°C (except when preparing components at room temperature within 8 hours)	1°C-10°C (except after collection for components at room temperature, in which case 20°C-24°C)	21 days (PD/ACD) 35 days (CPDA-1)	
2- Irradiated whole blood	1°C-6°C	1°C-10°C	Original expiry date, or 28 days from irradiation date, whichever nearer	
3- Modified whole blood	1°C-6°C	1°C-10°C	21 days (CPD/ACD) 35 Days (CPDA-1)	
4- Red blood cells	1oC-6oC 1°C-6°C	1° C-10° C 1°C-10°C	21 days (CP2D/CPD /ACD) 35 days (CPDA-1) 24 hours (in case of open system)	
5- Red blood cells with additive solutions	1°C-6°C	1°C-10°C	42 days (SAG-M/ADSOL)	
6- Deglycerolized red blood cells	1°C-6°C	1°C-10°C	12 hours from the time	

			deglycerolization	
7- Frozen red blood cells with 40% Glycerol	<-65°C	Maintain frozen state	10 years	Freezing shall be performed within 6 hours of collection with the addition of a cryoprotective agent.
8- Frozen red blood cells with 20% Glycerol	<-120°C	Maintain frozen state	10 years	Freezing shall be performed within 6 hours of collection with the addition of cryoprotective agent.
9- Red blood cells frozen with liquid nitrogen	<-120°C	Maintain frozen state	10 years	
10- Frozen red blood cells prepared using open system	1°C-6°C	1°C-10°C	10 years, 24 hours after thawing	Freezing shall be performed within 6 hours of breaking the seal
11- Irradiated red blood cells	1°C-6°C	1°C-10°C	Original expiry date, or 28 hours after irradiation	

12- Red blood cells leukoreduced	1°C-6°C	1°C-10°C	21 days (CP2D/CPD/ACD) 35 days (CPDA-1) 42 days in case solutions are added (SAG-M/ADSOL) 24 hours (in case of open system)	
13- Rejuvenated red blood cells	1°C-6°C	1°C-10°C	24 hours	
14- Rejuvenated deglycerolized red blood cells	1°C-6°C	1°C-10°C	12 hours	
15- Irradiated and washed red blood cells	1°C-6°C	1°C-10°C	12 hours	
16- Rejuvenated and frozen red blood cells	<-65°C	Maintain frozen state	10 years	
17- Washed red blood cells	1°C-6°C	1°C-10°C	12 hours	
18- Blood platelets	20°C-24°C with continuous gentle agitation	20°C-24°C	5 days based on the collection system	Maximum period without agitation is 24 hours

19- Irradiated blood platelets	20°C-24°C with continuous gentle agitation	20°C-24°C	5 days based on the collection system	Maximum period without agitation is 24 hours
20- Blood platelets leukoreduced	20°C-24°C with continuous gentle agitation	20°C-24°C	5 days based on the collection system	Maximum period without agitation is 24 hours
21- Pooled platelets or platelets prepared using open system	20°C-24°C	20°C-24°C	4 hours	
22- Apheresis Platelets	20°C-24°C with continuous gentle agitation	20°C-24°C	5 days	Maximum period without agitation is 24 hours
23- Irradiated Apheresis Platelets	20°C-24°C with continuous gentle agitation	20°C-24°C	5 days	Maximum period without agitation is 24 hours
24- Apheresis Platelets Leukoreduced	20°C-24°C with continuous gentle agitation	20°C-24°C	5 days	Maximum period without agitation is 24 hours

25- White blood cells (Apheresis)	20°C-24°C	20°C-24°C	24 hours	
26- Cryoprecipitate	<-18°C	Maintain frozen state	12 months	
27- Solvent Cryoprecipitate	20°C-24°C	20°C-24°C	4 hours	
28- Fresh frozen plasma	<-18°C or <-65°C	Maintain frozen status	< 18°C, for 12 months < 65°C, for 7 years	
29- Thawed Fresh Frozen Plasma (Thawed FFP)	1°C-6°C	1°C-10°C	12 hours	Thawing to 30°C-37°C
30- Fresh frozen plasma prepared using open system	1°C-6°C	1°C-10°C	12 hours	Freezing within 6 hours from breaking the seal
31- Plasma Cryoprecipitate Reduced	<-18°C	Maintain frozen status	12 months	
32- Thawed Plasma Cryoprecipitate Reduced	1°C-6°C	1°C-10°C	24 hours	
33- Plasma frozen within 24 hours	<-18°C	Maintain frozen status	12 months	Freezing within 24 hours of collection
34- Thawed Plasma frozen within 24 hours	1°C-6°C	1°C-10°C	12 hours	Thawing to 30°C-37°C
35- Thawed Plasma	1°C-6°C	1°C-10°C	From 24 hours to 5 days	Prepared in a closed system

36- Solvent/ Detergent-treated plasma	<-18°C	Maintain frozen status	12 months from manufacturing date	The manufacturing source must specify the expiry date on the label

(d) <u>Documents and records of blood transfusion centers</u>

Blood transfusion services centers should maintain a system to ensure that all documents are reviewed, signed, approved, and stored. It should also be ensured that the records are organized and maintained in accordance with the policy of the Ministry of Health.

<u>Periodic reviewing:</u>

1- A periodic (annual) review of all policies and work methods should be conducted by an authorized qualified person.
2- All new and amended documents and work methods should be reviewed, audited, and approved prior to being used.
3- Documents and work methods (in use) should be made available in all the locations where these procedures are conducted and should be easily accessed.
4- All revoked documents and work methods should be segregated and stored systematically to prevent their use after the revocation date.
5- All documents, work methods, forms, templates, and labels should be organized and standardized as per the principles and standards of the Ministry of Health.
6- Records must be complete and accessible within a timeframe appropriate to the nature of work at the centers.
7- Records should be stored in a way that would prevent damage or tampering by unauthorized persons, and in a manner that would preserve the confidentiality of the information of donors and patients.
8- In case computers are used in record keeping, this should be conducted in a way that ensures the validity of the used system by providing training courses to personnel, conducting regular maintenance and inspections, protecting the system from modification or testing by unauthorized persons, protecting information and records, and

providing alternative means in case of temporary computer system failure.

- The computerized recordkeeping system must be capable of retrieving all the information related to blood units or blood component units from the source and until the final disposal of said units, reviewing the records of a specific blood unit, and investigate causes of suspected adverse reactions in recipient following the transfusion.
- The system used must be capable of providing a unique identifier to each patient.
- The results of each test should be recorded instantaneously, as well as the final results upon the completion of the testing process (Result entry should not be delayed until the final stage).
- A method should be indicated to identify the employee or technician conducting any of the major stages or specific steps during the collection, preparation, compatibility testing and distribution processes.

Blood Storage Policy:

The specified duration of blood storage is the retention duration of various records.

- Permanent records
- Records to be kept for a minimum of five years

- **Permanent records are:**
  1. Records confirming the identity and medical history of the donor.
  2. Records confirming the identity and medical history of the recipient (patient).
  3. Records of the blood units or blood component units received from external sources.
  4. Records identifying the centers preparing any blood components and related testing.
  5. Record identifying the final disposal of blood and blood component units.
  6. Records of informing donors of final deferral.
  7. Records of the tests conducted on donors who are permanently deferred, including those who presented to donate but did not.

8. Record of informing blood transfusion centers of the results of the final deferral of donors in case prior donations from the same donor were accepted.
9. Records of quarantining blood units deemed unsuitable for use, results of related tests, and method of disposal, and notifications sent to competent authorities concerned with these units.
10. Records of informing competent entities and the treating physician in case of suspicions as to the suitability of blood units transfused to a patient.
11. Records identifying employees authorized to sign blood bank records.

- **Records to be kept for a minimum of five years:**

1- Recipient records, including blood group, results of compatibility testing, and adverse reactions.
2- Donor records, including blood group, any difficulties in identifying blood type, and complications during the donation process.
3- Obsolete and canceled records.
4- Records of medical equipment, temperature control, and maintenance.
5- Records of quality assurance.
6- Records of employees including qualifications, training and competency.

e- Quality assurance requirements for blood and blood components:

1- Blood banks and centers should maintain the highest level of quality assurance requirements related to blood components.
2- Blood component quality assurance requirements:

Component	Characteristics	Criteria to be tested in each sample	Quality Requirements
Whole blood		▪ Tests conducted on donated blood as specified in chapter (C). ▪ Volume (all units must be tested). ▪ Hematocrit ▪ pH ▪ Sterility ▪ Potassium in plasma ▪ No signs of hemolysis	400-500 ml (without anti-coagulation factor) 35-45% 6.84-7.2 Negative bacterial test 21-3.9 millimoles/liter
Red blood cells	Containing red blood cells after centrifugating the donor's blood unit. No leukocyte or platelet removal has been performed.	▪ Tests conducted on donated blood as specified in chapter (C). ▪ Volume (3units/day to be tested). ▪ Hematocrit (3units/day to be tested). ▪ Hemoglobin (3 units/day to be tested)	+50/-280 ml 55-75% ≥ 45 gram/unit
Red blood cells after buffy coat removal	All the red blood cells present in the donated unit with the exception for 10-30 ml remaining after the centrifugation.	▪ Tests conducted on donated blood as specified in chapter (C). ▪ Volume (3units/day to be tested) ▪ Hematocrit (3units/day to be tested). ▪ Hemoglobin (3 units/day to be tested). ▪ White blood cells (3units/day to be tested) (75% of the tested units should be within the specified quantities). ▪ Platelets	-60/+280 ml 50-60% > 43 gram/unit $<10^9$ x1.2 cell/ unit $<10^9$x10 platelet/ unit

Red blood cells in additive solutions	All the red blood cells present in the donated unit after centrifugation, without the removal of leukocytes or platelets	▪ Tests conducted on donated blood as specified in chapter (C). ▪ Volume (1% of all units to be tested). ▪ (75% of the tested units should be within the specified results). ▪ Hematocrit. ▪ Hemoglobin.	420-280 ml 50-70% (depending on the nature of the additive solution, method of centrifugation and the amount of residual plasma) ≥45 gram/unit
Red blood cells in additive solutions after buffy coat removal	All red blood cells in the donated unit after centrifugation	▪ Tests conducted on donated blood as specified in chapter (C). ▪ Volume (3units/day to be tested) ▪ Hematocrit (3units/day to be tested). ▪ Potassium ▪ Sterility ▪ pH	-60/+280 ml 50-70% (depending on the nature of the additive solution, method of centrifugation and the amount of residual plasma) (in ≥ 75% of the tested units)

Frozen red blood cells		▪ Tests conducted on donated blood as specified in these regulations. ▪ Volume ▪ Hematocrit ▪ Hemoglobin. ▪ Osmolarity (1% of all units to be tested). ▪ White blood cells (1% of all units to be tested) (75% of all tested units, provided that they are within the specified results). Sterility (1% of all units to be tested)	 > 185 ml. 50-75% ≥ 36gram/unit < 340m or mmol/L <10^9x0.1 cell/unit Sterilized
Leukoreduced red blood cells	Through the use of filters	▪ Tests conducted on donated blood as specified in these regulations. ▪ Volume ▪ Residual white blood cells (100 units for each type of filters to be tested after filtration)	 60±280 ml < 10^6x5 cell/unit
Washed red blood cells	The amount of residual plasma depends on the washing method used	▪ Tests conducted on donated blood as specified in chapter (C). ▪ Volume ▪ Hematocrit ▪ Hemoglobin (3units/day to be tested). ▪ Residual protein in the final net product.	 -60/+280ml 50-75% ≥ 40gram/unit < 0.5 gram/unit (to ensure IgA content of less than 0.2 milligram/unit)

Platelets extracted from a single unit of red blood cells		▪ Tests conducted on donated blood as specified in chapter (C). ▪ Volume (units/day to be tested). ▪ Platelets content of 0 (1% of all units to be tested ≥ 10 units/month) (75% of all tested units, provided that they are within the specified quantities). ▪ Number of residual white blood cells: – Before leukoreduction process – After leukoreduction process (1% of all units to be tested 6 ≥ 10 units/month) (75% of all tested units, provided that they are within the specified quantities). pH (at the time of expiry) (1% of all units to be tested). Tissue compatibility HPA/HLA Sterility	40-60 ml of plasma/donation $\geq 10^9$x55 platelet/unit $< 10^9$x0.2/unit $< 10^6$x0.2/unit 4.6-7.4 Conducting necessary tests Sterile

Platelets collected by the Apheresis method Yield = >60 * 10^9/40ml >200*10^9/20ml	Platelets content depends on the method used. This also applies to the quantity of residual red and white blood cells. Standard unit = 5-6 Single units collected from red blood cells	▪ Tests conducted on donated blood as specified in these regulations. ▪ Volume ▪ Platelets content (testing all units) (75% of all tested units, provided that they are within the specified quantities). ▪ Number of residual white blood cells: – Before leukoreduction – After leukoreduction (all units to be tested) (90% of all tested units, provided that they are within the specified quantities). ▪ pH (testing all negative units with centrifuging test) ▪ Tissue compatibility HPA/HLA	 > 40 ml >10^9x240 platelet/donation < 10^9x1/standard unit < 106x1/ standard unit 6.5-7.4 Conducting the necessary tests (if requested)

Platelets from buffy coat		▪ Tests conducted on donated blood as specified in chapter (C). ▪ Volume ▪ Blood platelets content ▪ Number of residual white blood cells: – Before leukoreduction – After Leukoreduction – (1% of all units to be tested, or 10 units/month) (75% of all tested units, provided that they are within the specified quantities). ▪ pH ▪ Tissue compatibility HPA/HLA	Unstable 10^{11}x205 10^{9}x0.05/ equivalent to one unit 10^{6}x0.2/ equivalent to one unit 6.5-7.4 Conducting the necessary tests (if requested)
Fresh frozen plasma	Same content as normal plasma of stable coagulation factors, albumin, and immunoglobulins	▪ Tests conducted on donated blood as specified in chapter (C) (except where plasma is the source) ▪ Volume (3units/day to be tested). ▪ Volume (Aghersis) ▪ Physical appearance ▪ Red blood cells (all units to be tested) ▪ Blood characteristics ▪ Coagulation factor VIII	- 150 -300 ml with anti-coagulants 500-600 ml with anti-coagulants Clear < 6 x 10^{9} Less than 50x10^{9}/L <0.7 international unit/ milliliter

Cryoprecipitate (cold)	Contains the majority of the coagulation factor VIII, Von Willebrand factor, Fibrinogen, and coagulation factor XIII, in addition to fibronectin in separated fresh plasma	▪ Tests conducted on donated blood as specified in chapter (C) ▪ Volume ▪ Coagulation factor VIII (1% of units to be tested) 1_ (6) units of the different blood groups should be collected during the first month of storage. 2_ (6) units of the different blood groups should be collected during the last month of storage. 3_ Fibrinogen (1% of all units to be tested)	10-25 ml >70 international units/ unit >40 milligram/ unit
White blood cells collected through Apheresis	Main function is the phagocytosis of microbes	▪ Tests conducted on donated blood as specified in chapter (C) ▪ Volume ▪ Content of white blood cells	<500 ml $>10/10^9$/unit $\geq 10^{10}$ in 75% of all units
Plasma collected from Cryoprecipitate (CRP)	Content of albumin, immunoglobulin, and coagulation factors similar to that of fresh frozen plasma. Contains lower levels of coagulation factors V, VIII, and XIII, Von Willebrand factor, fibrinogen, and fibronectin	▪ Tests conducted on donated blood as specified in chapter (C) (except where plasma is the source) ▪ Volume (all units to be tested)	Specified volume +/- 10%

Section Two

Ensuring Safety of a Patient Receiving Blood Transfusion

The objective of blood and blood components transfusion is to provide effective treatment of high quality that complies with the highest possible safety limits after verifying the actual need of the patient for this treatment. This goal is achieved through the coordinated efforts of healthcare professionals supervising all stages of the blood and blood components transfusion process, from collection to administration.

1. In light of the human origin of blood and the scarcity of the available quantities, blood transfusion operations shall be organized at healthcare facilities authorized to perform blood transfusion operations. All necessary measures shall be taken to protect the interests of the donor and recipient and avoid misuse and squandering.
2. Despite the efforts exerted to prevent the transfer of infectious diseases, it is impossible to guarantee the safety of blood and blood component units from all known infectious diseases. The treating physician should, therefore, consider the risk and prioritize the principle of maximizing benefit over harm before taking a decision to transfuse blood or blood components.
3. Transfusion of blood and blood components may only be performed under the supervision and responsibility of the treating physician.
4. Patients should be allowed the opportunity to benefit from blood and blood components transfusion according to availability, regardless of the patients' financial capabilities or resources.
5. Treatment through blood components rather than whole blood transfusion should be broadened to be able to meet the increasing needs of patients, while at the same time protecting the recipient from additional risks.
6. To ensure the optimal use of blood and blood components, and protect patients from the risk of blood transfusion, the cooperation between treating physicians and physicians supervising blood banks should be organized. The required Therapeutic and regulatory policies should be developed and documented in all healthcare facilities authorized to perform blood transfusion.

Chapter One

Responsibilities of the Blood Bank

1. Ensuring the implementation of effective and safe policies when selecting donors, including temporary deferral or permanent exclusion of all donors suspected to be unfit for blood and blood component donation, and maintaining full and updated records of donors (see Chapter Two).
2. Blood banks should comply with the policy of screening all donor blood units for red blood cell antibodies and disposing of all units containing clinically significant antibodies.
3. Blood banks should provide appropriate quantities of blood and blood components (as available) necessary to provide care to patients in healthcare facilities they serve. The blood banks should implement the approved standard criteria in collecting, preparing, processing, storing and transporting blood and blood components, and conduct all the necessary tests to ensure the safety and validity of blood products as per the standards specified in these regulations.
4. Blood banks should conform to the policy prohibiting the release of any blood or blood components without conducting the infectious diseases tests specified by the Ministry of Health. Further, they shall not release blood units containing red blood cells (whole blood, concentrated red blood cells, concentrated white blood cells) without conducting blood group and compatibility testing.
5. Blood banks (Hospital-based branches) should conduct urgent compatibility testing (20-30 minutes) in cases of emergency and commit to simultaneously conducting the standard compatibility testing, and to inform the treating physician with the results of these tests as soon as they become available.
6. Blood banks (Hospital-based branches) shall adopt a compatibility label to be affixed to all blood and blood component units, whether standard or urgent compatibility testing has been conducted or not. The cards should indicate:
    a. Full name of patient/recipient (first name, middle name(s) and surname).
    b. Serial number of hospital file.
    c. Blood group of patient/recipient (ABO and Rh-D).

d. Serial number of blood unit.
e. Blood group of the unit (ABO and Rh-D).
f. Date of compatibility testing (if conducted).
g. Name and signature of technician conducting compatibility testing.

7. In case of the availability of other blood groups, Group (O) may only be used for a recipient of the same blood group for various reasons. Some of these reasons are related to the antibodies that may interact with the blood of the recipient, while others are related to the need of these units for Group (O) patients who can only receive this blood group.
8. Blood banks (Hospital-based branches) should comply with the policy stipulating that blood samples used in blood group and compatibility testing be retained for not less than three weeks from the date of blood transfusion, whenever possible, due to their importance in investigating any instantaneous or delayed blood reactions.
9. Blood banks should comply with the policy stipulating that used blood and blood component bags be retained for not less than 48 hours after the transfusion of blood and blood components before disposal, due to their importance in investigating any instantaneous blood reactions.
10. Blood banks must request a new blood sample from the patient and repeat compatibility testing if blood transfusion is delayed for more than 48 hours.
11. Blood banks shall ensure the implementation of effective, safe and approved policies when releasing, transporting and delivering blood and blood components to the location where the patient / recipient is present.
12. Blood banks should write the new expiry date on blood and blood component units when their specifications have changed or they have been combined.
13. Blood banks should apply the policy stipulating that white blood cells should be removed from blood and blood components through special filters. This applies for blood units that have not already undergone leukocyte removal.
14. Ensuring the validity of blood and blood component units returned to the blood bank before releasing said units to be used by another patient/recipient, and adopting a special policy in this regard.
15. Blood banks should apply a policy that stipulates maintaining records of blood group and

compatibility testing, names of patients/recipients of blood and blood components, donor records, infectious diseases tests, release logs, and disposal of blood and blood components whether in hard or electronic form for no less than 10 years.

16. Blood banks should investigate any incidents and reactions related to blood transfusion, identify causes thereof, and report them to the treating physician, the blood transfusion committee of the hospital, and all relevant entities. The banks should also keep the records of such investigations for no less than 10 years.
17. Blood banks should, in cooperation with other hospital departments and the administrations of the hospitals they serve, adopt documented policies to deal with major incidents and disasters (Disaster Plan) particularly for situations involving mass casualties within a short time. They should train as to the implementation of such a plan.

Chapter Two

Responsibilities of the Physician Ordering the Blood Transfusion

1. Making a responsible decision based on the actual need of the patient/recipient for blood or blood components. This decision should not be influenced by any other incentives, such as material or financial incentives offered to the physician or the institution in which the patient is being treated.
2. Clarifying and explaining the risks and complications that may result from the transfusion of blood or blood components to the patient, and ensuring that the patient/recipient has signed the treatment consent form approved by the Ministry of Health.
3. Determining the level of emergency for blood transfusion to the patient/recipient and providing clear instructions as to the type and quantity of blood component needed, and the rate of transfusion of blood or blood component.
4. Providing an appropriate sample of the blood of the patient/recipient for conducting the blood groups and compatibility testing, and ensuring that the sample meets the recipient identification requirements: name of patient/recipient including given, middle and surname; serial number of file; and date of collecting the sample. The documented and approved policies should be applied for the identification of the sample of the patient/recipient in all healthcare facilities authorized to conduct blood transfusions.
5. Cooperating with blood banks to identify the priorities for transfusion of blood and blood components to patients, especially when the blood bank is suffering from shortage. Physician should inform the bank when the patient/recipient no longer needs the reserved blood and blood component units, or when the prescribed treatment with blood or blood components is postponed so that such units may be used for other patients.
6. Ensuring that the approved blood transfusion form is completed and documented.
7. To identify and verify the identity of the patient/recipient, the following information should be included in the blood transfusion form:
    - Full name (first name, middle name(s), and surname).
    - Serial number of hospital file.

- Gender of patient.
- Date of birth or age.
- Patient's location in the hospital (department, unit, ward).
- Name of the attending physician.
- Blood group, if known.

8. It is preferable to use patient's identification labels available in their file, if available. Otherwise, the information should be written clearly and legibly.
9. Indicating the type of required treatment, whether by blood or blood component, in the form, along with the number of units required, transfused quantity, degree of urgency of blood or blood components transfusion, and the time of need of the patient of same.
10. Stating the medical condition or diagnosis and all relevant information, along with hemoglobin level, the number of blood platelets (if requesting concentrated platelets), and previous date of blood or blood components transfusion (date of last blood transfusion if known) or date of complications resulting from blood transfusion, if any. This information should be verified and stated in the blood transfusion form.
11. Informing the blood bank through the blood transfusion form of all medical information related to the condition of the patient/recipient, including diagnosis and all factors that may affect the safety of blood or blood components transfusion.
12. For adult female patients, the number of pregnancies, miscarriages, and instances of neonatal jaundice, must be recorded.
13. If the patient's need for blood or the duration of need is not certain, the physician should request blood group and antibodies screening, without requesting the compatibility testing.
14. The name of the physician ordering the transfusion of blood or blood components (or the stamp of said physician) should be clearly indicated on the form, together with their signature and date of the request for blood or blood components transfusion.

Chapter Three

Responsibilities of the Physician Supervising the Transfusion of Blood and Blood Components

1. Verifying the identity of the patient/recipient, date of expiry stated on the blood or blood component unit; and ensuring that the unit number, blood group, name of designated patient/recipient and their blood group match the information stated on the compatibility label affixed to the unit. Documented approved policies should be implemented in all healthcare facilities authorized to carry out blood transfusions to ensure and confirm the identity of the patient and blood and blood component units before commencing the blood transfusion process. A special policy should be adopted to identify an unconscious patient/recipient.
2. Performing the blood or blood components transfusion process shortly after receiving the units from the blood bank. In case of a delay of more than 30 minutes, the units should immediately be returned to the blood bank at all hours (within or outside working hours) to be properly preserved.
3. Selecting an appropriate place for injecting the patient/recipient with blood. The veins on the back of the hand or the inside of the arm are the best places for injecting blood and blood components. In case no suitable veins are found, the area in front of the elbow joint may be used. In this case, the elbow should be immobilized in a stretched position using a temporary cast. In children, the veins in the scalp are usually used. Veins in other areas, such as the leg, may only be used if no appropriately sized veins are found in the arms.
4. Using 14-17gauge needles or catheters for adults, and 18-20 gauge for children.
5. Using the appropriate blood transfusion equipment for this purpose with a standard filter (170 micrometer) to remove micro clots that result from the storage of blood. Leukocyte 20 micrometer filters may be used for this purpose (which are different from the filters used for leukoreduction). Unlike the 170 micrometer filters, the 20 micrometer filters are not suitable for the injection of leukocyte concentrates, platelets concentrates; and cryoprecipitates.
6. Blood transfusion equipment should be changed within 24 hours of use or after

transfusing 4 blood units.

7. Saline solution of 0.9% concentration may be used for priming blood transfusion equipment, and no other saline solutions may be used.
8. No therapeutic solutions may be mixed or added to the blood and blood component units. Equipment used previously to transfuse therapeutic solutions may not be used for blood transfusion.
9. Blood temperature should not be less than room temperature as the transfusion of cold blood may cause cardiac arrhythmias. If large volumes of blood are needed to be transfused quickly; it is advisable to use blood warmers.
10. The blood bank should be informed of any events that may affect blood or blood component units' safety during their time at the patient/recipient's bedside.
11. Ensuring the availability of equipment for treating transfusion reactions at the facility where the blood transfusion is being performed. These equipment should be placed near the patient/recipient directly before the transfusion of blood or blood components.
12. Fully supervising the blood or blood components transfusion until completion, especially during the first 30 minutes of the process.
13. Recording heart rate, blood pressure, respiratory rate, temperature, urine output, and central venous pressure CVP (if available) in the relevant approved form during the transfusion.
14. Repeatedly asking the patient/recipient about any feelings of pain, shortness of breath, hypotension, or skin itching during the transfusion of blood or blood components. Documented and approved policies must be implemented for monitoring the recipient during the transfusion of blood and its components in all healthcare facilities authorized to perform blood transfusion.
15. After the transfusion of blood or blood components, the injected site should be examined to ensure no inflammation or subcutaneous infiltration has occurred, and treated if necessary. In case signs of inflammation are observed, the needle should be sent to the laboratory for culture.
16. Removing the infusion needle and applying pressure to the injection site for a sufficient time to prevent bleeding, and covering the site with a sterilized medical dressing.

17. Patients prone to circulatory overload should be monitored for an extended period, which may range from 12 to 24 hours after the blood transfusion.
18. Blood or blood component transfusion should be discontinued in case of any unexpected reaction or any sign of a reaction to the blood transfusion. The patient/recipient should be slowly injected with 0.9% saline solution.
19. The appropriate treatment should be given to the patient/recipient in case of an unexpected reaction or reactance to the blood. A documented and approved policy should be applied for treating any patient/recipient at all healthcare facilities authorized to perform blood transfusion in case of any unexpected reaction or reactance to the blood or blood components.
20. Informing the blood bank of all reactions, reactance or complications that may result from blood or blood component transfusion, regardless of whether the transfusion was discontinued. The healthcare facility must cooperate with the blood bank to investigate the causes of these occurrences.
21. Recording all blood or blood components transfusions in the medical file of the patient/recipient using the approved treatment form, as is the case with all injection treatments. This should be kept permanently in the file that should include the following:
    a. Number of blood and blood components units transfused.
    b. Serial numbers of these units.
    c. Date of the blood transfusion.
    d. The start and end times of the blood transfusion.
    e. Name and signatures of person(s) who tested the blood units, identified the patient/recipient, and transfused the blood to the patient/recipient.
22. Recording all the incidents that occur during the transfusion of blood or blood components in terms of unexpected reactions, hemolytic reactions and septicemia, and the outcomes of the investigation into the causes of these incidents. All should be permanently kept in the medical file of the patient.
23. Returning used blood bags and blood transfusion devices to the blood bank after the completion of the blood transfusion.

Chapter Four

Rules and Regulations Governing Blood Transfusion Services

1. These rules and regulations shall apply to all healthcare facilities authorized to collect, test, prepare, store or dispense blood and blood components, hereinafter referred to as "Blood Banks".
2. These rules and regulations shall also apply to all healthcare facilities authorized to perform blood and blood components transfusion.
3. Blood banks in private hospitals may store, prepare and dispense of blood and blood components, and these hospitals may also perform blood and blood components transfusion if they are authorized by the Ministry of Health or by relevant local government health authorities.
4. All blood banks in the State are subject to the policies and regulations applied by the Ministry of Health.
5. Licensing private blood banks and private healthcare facilities to collect blood or trade therein for profit or to enter into any commercial relationship with blood donors is prohibited.
6. Blood banks shall implement these policies and regulations in order to ensure public confidence in the quality, safety, efficacy of blood and blood components and that they are free of infectious diseases.
7. Blood banks shall also comply with all the rules and regulations issued by the World Health Organization (WHO) and by other governmental and non-governmental organizations such as European Commission (EC), International Federation of Red Cross and Red Crescent Societies (IFRC) and the American Association of Blood Banks (AABB) after being accredited by the Ministry of Health.
8. There are many similarities between blood banks and clinical laboratories, but there are also clear differences, the most important of which are that blood banks produce therapeutic products and are involved in the storage, transport and distribution as well as the quality control and testing of such products. Therefore, in addition to implementing the policies regulating clinical laboratories, they also comply with being subject to many

regulations applied to the manufacturing of pharmaceutical and medical products, the most important of which are:

- Complying with Good Manufacturing Practice (GMP).
- Demonstrating the efficacy and safety of all blood bank products.

The Ministry of Health, and local government health authorities shall conduct periodic inspection tours for blood banks, which are subject to their supervision, to ensure their compliance with the policies and regulations governing the work of blood banks and the adequacy of facilities and equipment to their intended purpose.

If the bank violates the policies and regulations approved by the Ministry of Health, the Ministry of Health and the local health authorities may revoke its license and may also temporarily suspend the license until the blood bank remedies the violations.

Key regulatory requirements for the work of blood banks:

- The blood banks' basic and administrative regulation.
- Comprehensive quality system applied in blood banks.
- Hospitals Blood Transfusion Committees.

9- The import of blood and blood main components (red blood cells, frozen plasma and platelet concentrates) or any other components containing blood cells or human blood plasma from outside the State, as well as their transit through its ports, except by virtue of an official authorization from the Ministry of Health.

- **Blood Banks Basic and Administrative Regulation:**

1 The operation of blood banks must be regulated to enable them to fulfill the responsibilities assigned thereto. A basic and administrative regulation characterized by effectiveness and flexibility shall be adopted.

2 Determining the mission assigned to blood banks.

3 Determining the organizational chart and the administrative structure of the blood bank.

4 Determining the person in charge of managing the blood bank and the extent of their responsibilities and authorities.

5 Determining the system for selecting employees, including the requirement to obtain a license to practice.

6 Job description for every position in the blood bank.

7 Determining financial affairs and budgeting systems.

– **Comprehensive quality system applied in blood banks:**

1- A comprehensive quality system shall be applied to all the blood banks' activities and aspects.

2- A system for continuous training and maintaining the competency of the blood bank employees shall be adopted.

3- All blood bank activities shall be documented and a manual of standard operating procedures (SOPs) must be established.

4- The main activities for which policies and standard processes must be adopted are:

4.1 The information that must be provided to the donor about the process of blood and blood components donation.

4.2 The policies and methods applied for donor selection and pre-donation testing.

5- Policies of informing the donors of the results of positive infectious diseases tests, providing them with the necessary directives and guidelines to get the appropriate healthcare while maintaining the confidentiality of the information.

6- Policies for temporary and permanent donor deferral and reacceptance of deferred donors.

7- Approved standards of whole blood and the blood components produced by the blood bank.

8- Approved policies and methods of performing infectious diseases testing followed by the blood bank.

9- Policies followed by the blood bank regarding the blood quarantine and disposal of contaminated blood.

10- Policies for cards and labels used in the blood bank.

11- Policy for tracking the product from the donor to the recipient.

12- Standard operating procedures for all tests conducted for identifying blood groups and antibody screening, compatibility testing and other tests performed by the blood bank.

13- Policies for quality control and quality testing of blood and blood components.

14- Policies for releasing and transporting blood and blood components.

15- Equipment specifications, storage methods for blood and blood components and specifications of the primary products and reagents used by the blood bank.

16- Adopted policies and procedures for quality control and testing of equipment and reagents used by the blood bank.

17- Equipment preventive maintenance policies followed by the blood bank.

18- Policies for maintaining physical and electronic records, information management and information quality monitoring.

19- Policies of notifying the blood bank of unexpected reactions, blood reactions and the procedures of investigating the same.

20- Blood banks must be encouraged to introduce modern management tools, and continuous product quality improvement methods, including:

21- Introducing modern Information Technology (IT) systems and applying advanced statistical methods in blood banks.

22- Introducing process improvement strategies, error and accident review and control of nonconforming products.

23- Applying modern quality management tools, including process control, conducting internal quality audits and implementing continuous quality improvement measures.

24- Participating in external quality assessment programs accredited locally and internationally.

25- Obtaining internationally accredited quality application certificates, such as ISO 9000 series as well as CPA.

26- <u>Hospital Blood Transfusion Committees</u>

- A medical blood transfusion committee shall be established in all healthcare facilities authorized to perform blood transfusions.

- This committee shall be permanent and shall meet regularly once a month. It shall be chaired by a physician appointed by the hospital Director who may dissolve and restructure the committee.
- The hospital Director may call for an extraordinary meeting of the committee and refer to it all matters pertaining to blood and blood components transfusion for study and discussion.
- The hospital Director shall appoint the members of the committee who is responsible for overseeing all the aspects related to organizing and practicing blood and blood components transfusions in the hospital as well as the efficiency, preparation and ability of the blood bank in the hospital to fulfill the task assigned thereto.
- The person responsible for the blood bank must be appointed as a member of the committee, and the majority of the clinical departments and the nursing department must also be represented in the committee.
- A Policy and Procedure Guide (PPG) shall be prepared to regulate the work of the committee and to determine its duties, authorities and be approved by the hospital administration.

27-Tasks of Hospitals Blood Transfusion Committee:

- Enhancing the quality of blood and blood components transfusion services in the hospital.
- Developing the necessary policies to achieve standardization of blood transfusion practice in the hospital and monitoring the implementation of these policies through periodic transfusion practice reviews.
- Establishing and developing surgical blood ordering schedules to suit the hospital's needs.
- Contributing to continuous medical education programs and raising awareness regarding recent advancements in blood transfusion medicine.
- The committee shall discuss the reports of monthly blood utilization review prepared by the blood bank in the hospital.
- The committee shall submit its annual report to the hospital Director regarding the

status of blood transfusion services in the hospital, the levels of its staff, training and development needs, the adequacy of blood and blood components supplies in relation to hospital needs, and the changes occurred to blood and blood components transfusion practice in the hospital.

- The hospital administration shall send a copy of the annual report of the committee along with any comments it may have to the Ministry of Health or its local health authority.