I Introduction

1 These licensing terms and conditions set out the requirements for the provision of blood services, which comprise one or more of the following activities involving blood and blood products:
   (a) Collection 
   (b) Processing 
   (c) Storage 
   (d) Distribution

2 “Blood”, in the context of these licensing conditions, means whole blood or any blood component or product that is derived from the plasma, red blood cells, white blood cells and/or platelets of one or more persons. A list of blood component descriptions is presented in Annex A.

3 Under the PHMC Regulations, blood services are considered a form of specialised/special care service in:
   (a) private hospitals (Regulation 18, Second Schedule); and
   (b) medical clinics (Regulation 37, Third Schedule)
Licensees of hospitals and medical clinics are required to obtain prior approval from the Director of Medical Services under Regulation 18 and 37 respectively of the PHMC Regulations before commencing blood services. Approval may be granted subject to compliance with these licensing terms and conditions, which are imposed under section 6(2)(a) or section 6(5) of the PHMC Act, whichever the case may be.

4 A licensee of a hospital or medical clinic who has been given prior approval referred to in paragraph 3 is required to comply with the licensing terms and conditions as applicable. A breach of these licensing terms and conditions may attract potential consequences under the PHMC Act, including but not limited to:
   (a) Suspension or revocation of the approval to provide blood services;
   (b) Suspension or revocation of hospital licence or medical clinic licence;
   (c) Prosecution.
II Provision of blood services

5 No medical clinic (except Blood Services Group, HSA) or ambulatory surgery centre shall provide any blood service.

III Quality Assurance

6 The Licensee shall establish a documented Quality Assurance Programme, which shall be reviewed annually.

7 The Licensee of a healthcare institution shall appoint a committee under the Quality Assurance Programme to oversee the quality of any blood service that is provided.

8 Any healthcare institution that provides blood distribution, storage or transfusion services shall comply with the “GUIDELINES FOR THE TRANSPORT AND STORAGE OF BLOOD AND BLOOD PRODUCTS” (Annex B).

9 There shall be a framework for receiving, evaluating, investigating, documenting and reporting errors, adverse events and accidents relating to all blood services.

10 A report of the quality assurance activities regarding blood services shall be submitted to the Director of Medical Services at such time and in such form as the Director shall require.

IV Testing & Quarantine

11 Pre-transfusion testing of blood shall be done to determine the following at the minimum:
   (a) ABO Group
   (b) Rh type
   (c) Antibodies to red cell antigens
   (d) Compatibility with recipient’s blood
   (e) Human Immunodeficiency Virus (HIV) infection
   (f) Hepatitis B and C infection
   (g) Syphilis

   The possibility of other infections should also be tested and determined if the donated blood comes from a donor with known risks of having such other infections.

12 There shall be quarantine/inventory system in place to ensure that donated blood is quarantined until all the necessary tests are done and the blood is certified suitable for use. Blood that is not suitable for use shall be clearly labeled removed from inventory and disposed of appropriately.
V  Equipment & Supplies

13 All equipment shall be certified/licensed as safe or in good working condition by the relevant authorities or agencies.

14 All equipment shall be regularly scheduled for maintenance (including preventive maintenance), monitoring and calibration according to manufacturers’ recommendations. Records must be made available for licensing inspection.

15 There shall also be documented policies and procedures to:
   (a) select and validate supplies, reagents and equipment required to provide blood services with accepted standards of accuracy, precision, efficiency and safety; and
   (b) ensure supplies that come into contact with blood are single-use, sterile and pyrogen-free.

VI  Documentation

16 The Licensee shall ensure that documentation in relation to blood services is properly kept and secured. The documentation shall include the following at the minimum:

   Facility, staff and equipment
      (a) Job descriptions, qualification(s) and training records of personnel providing the blood services;
      (b) Preventive maintenance, monitoring and calibration records of equipment.

   Donor
      (c) Donor assessment (including eligibility criteria and outcomes);
      (d) Donor consent form;
      (e) Clinical management of donors who suffer adverse events from blood donation, if any;
      (f) Corrective and preventive actions taken, if any.

   Blood
      (g) Policies and records on collection, handling, processing, storing and transportation of blood;
      (h) Policies on labeling of blood
      (i) Results of screening tests of blood;
      (j) Quality control of tests and reagents;
      (k) Evidence of the suitability and safety of blood for its intended use;
      (l) Verification of blood prior to its issue;
      (m) Periodic review of quality control processes;
      (n) Policies and records of infection control and disposal of contaminated waste;
      (o) Evidence of compliance with relevant local biological, chemical and radiation safety requirements (e.g. National Environmental Agency requirements);
(p) Evidence of compliance with relevant local workplace safety and health requirements (e.g. Ministry of Manpower requirements).

17 Written SOPs on blood services shall be maintained, regularly reviewed, made available to all staff handling blood services.
ANNEX A

LIST OF BLOOD COMPONENT DESCRIPTIONS

Cryoprecipitated Antihemophilic Factor
The cold insoluble portion of plasma processed from Fresh Frozen Plasma.

Cryoprecipitated Antihemophilic Factor, Pooled
Two or more units of Cryoprecipitated Antihemophilic Factor combined into one bag. The total volume will be indicated on the label. To assist in the pooling process, 0.9% sodium chloride (USP) may be added.

Fresh Frozen Plasma
Plasma separated from the blood of an individual donor and placed at -18°C or colder within 6 to 8 hours of collection from the donor, depending upon the anticoagulant or collection device.

Granulocytes Pheresis (a.k.a Apheresis Granulocytes)
A suspension of granulocytes in plasma prepared by cytapheresis.

Granulocytes/Platelets Pheresis (a.k.a Apheresis Granulocytes/ Platelets)
A suspension of granulocytes in plasma prepared by cytapheresis, with the concurrent collection of platelets.

Irradiated Blood Components
Blood or blood component that has been exposed to gamma irradiation to prevent proliferation of T lymphocytes. Includes the following:
- Granulocytes Pheresis, Irradiated
- Granulocytes/Platelets Pheresis, Irradiated
- Platelets, Irradiated
- Platelets Pooled, Irradiated
- Platelets Pheresis, Irradiated
- Platelets Pheresis, Leukocytes Reduced, Irradiated
- Red Blood Cells, Irradiated
- Red Blood Cells Leukocytes Reduced, Irradiated
- Red Blood Cells Pheresis, Irradiated
- Whole Blood, Irradiated

Liquid Plasma
Plasma separated from the blood of an individual donor and not frozen.

Plasma Cryoprecipitate Reduced
Fresh Frozen Plasma from which cryoprecipitate has been removed.

Plasma for Manufacture (a.k.a Recovered Plasma)
Plasma for use in manufacturing and prepared from allogeneic donations. Plasma selected for manufacture that has been collected from whole blood or apheresis plasma collected for transfusion that has expired (non commercial plasma derived products).
Plasma Frozen Within 24 Hours of Collection
Plasma separated from the blood of an individual whole blood donor and placed at -18°C or colder within 24 hours of the collection.

Platelets
A suspension of platelets in plasma prepared by centrifugation of whole blood.

Platelets Pooled
Two or more units of platelets that have been combined into one bag.

Platelets Leukocytes Reduced
Platelets Leukocytes Reduced are prepared by a method known to reduce the leukocyte number to < 8.3 × 10^5 in at least 95% of the components sampled.

Platelets Leukocytes Reduced Pooled
A suspension of platelets in plasma that has been leukocyte reduced. The leukocyte reduction process can take place either before or after the pooling process.

Platelets Pheresis
A suspension of platelets in plasma prepared by cytapheresis. Whole Blood undergoes centrifugation in a cell separator, with the return to the donor of components not collected.

Platelets Pheresis Leukocytes Reduced
Platelets collected by apheresis that are prepared by a method known to reduce the residual leukocyte number to <5 × 10^6 in 95% of the components sampled.

Red Blood Cells
Red cells concentrated by the removal of most of the plasma from sedimented or centrifuged whole blood.

Red Blood Cells Deglycerolized
Red blood cells to which glycerol has been added (eg. as a cryoprotective agent) and subsequently removed by washing with successively lower concentrations of sodium chloride (USP).

Red Blood Cells Frozen
Red Blood Cells that have been stored in the frozen state at optimal temperatures in the presence of a cryoprotective agent.

Red Blood Cells Leukocytes Reduced
Red Blood Cells prepared by a method known to retain at least 85% of the original red cells and to reduce the leukocyte number in the final component to < 5 × 10^5.

Red Blood Cells Low Volume
When 300-404 mL of whole blood is collected into an anticoagulant volume calculated for 450 +/- 45 mL or 333-449 ml of whole blood is collected into an anticoagulant volume calculated for 500 +/- 50 ml of whole blood.
Red Blood Cells Pheresis
Red Blood Cells in anticoagulant or in anticoagulant and storage solution that have been prepared by automated cytapheresis.

Red Blood Cells Pheresis Leukocytes Reduced
Red Blood Cells in anticoagulant or in anticoagulant and storage solution that have been prepared by automated cytapheresis that have been leukocyte reduced by a method known to retain at least 85% of the original red cells and to reduce the leukocyte number in the final component to $< 5 \times 10^6$.

Red Blood Cells Rejuvenated
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above.

Red Blood Cells Rejuvenated Deglycerolized
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above, subjected to a cryoprotective agent and stored frozen at optimal temperatures. The cryoprotective agent is subsequently removed by washing with successively lower concentrations of sodium chloride (USP).

Red Blood Cells Rejuvenated Frozen
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above and then subsequently exposed to a cryoprotective agent and stored at optimal temperatures in a frozen state.

Red Blood Cells Washed
Red Blood Cells remaining after washing with a volume of compatible solution using a method known to remove almost all of the plasma. Depending on the method used, the preparation may contain variable quantities of leukocytes and platelets from the original unit.

Thawed Plasma
Thawed plasma prepared from Fresh Frozen Plasma or Plasma Frozen Within 24 Hours of Collection, that has been thawed and stored for up to 5 days.

Thawed Plasma Cryoprecipitate Reduced
Thawed plasma prepared from Plasma Cryoprecipitate Reduced.

Whole Blood
Whole Blood is collected in an anticoagulant/ preservative solution and is not further processed. This product should not be used as a source of platelets or labile coagulation factors.
ANNEX B

GUIDELINES FOR THE TRANSPORT AND STORAGE OF BLOOD AND BLOOD PRODUCTS

Transport of Blood and Blood Products

1. Each unit of blood and blood components should be inspected for haemolysis in plasma or discolouration of red cell mass immediately before issuing or packing for shipment. Units with abnormal appearance should be quarantined and returned.

2. Whole blood and all liquid Red Blood Cell components must be transported in sturdy, well-insulated containers with refrigerant that will ensure maintenance of a temperature of 1°C to 10°C.

3. The refrigerant recommended for transporting Whole Blood and Red Blood Cell Components is wet ice in leak-proof containers such as plastic bags; the volume of ice should be at least equal to the volume of the blood. During trips of more than 30 minutes, two extra bags of wet ice should be used, one to be placed below and one placed above the blood. Chemical Coolant Pouches proven to maintain a temperature of 1°C to 10°C can also be used.

4. Super-cooled cubed ice, canned ice and dry ice should not be used for shipping or storing Whole Blood or Red Blood Cell components because they can reduce local temperature to the extent that may cause haemolysis of red cells in the immediate vicinity.

5. During transport, frozen components must be maintained at or below the required storage temperature. This can be achieved with a suitable quantity of dry ice in well-insulated containers. All frozen containers must be kept in a separate container and should not be packed together with liquid components.

6. Platelets should be maintained at temperatures of 20°C to 24°C during shipment. Well-insulated containers without added ice are sufficient.

7. Blood transport containers should be sealed with 5 cm wide adhesive tape. All containers should be accompanied by a packing slip.

8. The temperature of each container should be checked on receipt. Temperatures can be considered to be in the 1°C to 10°C range as long as unmelted ice remains in the box and is in contact with the blood.

9. Upon receipt, blood should not be left in the insulated transport container. It should be stored in a properly monitored refrigerator or freezer immediately.
Storage of Blood and Blood Products

Storage of Whole Blood and Red Blood Cell Components

10. During transportation, Whole Blood and Red Blood Cell components should be stored between 1°C to 10°C.

11. Blood should be stored in a blood bank refrigerator which has been specially designed for the purpose. This includes blood that is kept in sites outside the blood bank, such as surgical or obstetric units.

12. Units should be arranged so that the oldest blood is easily at hand and is used first.

Storage of Fresh Frozen Plasma and Cryoprecipitate

13. Fresh Frozen Plasma and Cryoprecipitate should be stored at -18°C or lower as quickly as possible after preparation.

14. Stocks should be rotated so that the oldest product is used first.

15. Thawed Fresh Frozen Plasma used for the correction of labile coagulation factor deficiencies should be transfused immediately. Thawed units should not be re-frozen.

16. Reconstituted cryoprecipitate should be stored at room temperature until transfusion, and should be administered within 6 hours of thawing and 4 hours of pooling. Thawed units should not be re-frozen.

Storage of Platelets

17. Platelet concentrates are to be stored at 20°C to 24°C.

18. Continuous gentle agitation is essential.

19. If the hermetic seal of any bag is broken, the platelets must be transfused within 4 hours.

Refrigerators

20. The blood bank refrigerator must be kept under constant supervision by the officer in charge of the blood bank.

21. The blood bank refrigerator should not be used for the storage of food or laboratory specimens other than those being used in the blood bank.
22. Refrigerators for storage of blood should incorporate the following:

   (a) A fan-cooled cabinet in which the fan operates when all doors are closed.
   (b) A system to monitor the temperature continuously and to record the temperature at least every 4 hours.
   (c) An alarm system which is not dependant on the mains electrical power supply. This should give both a visual and auditory signal at a place where there is always staff on duty.

23. The temperature in all areas of the refrigerator must be maintained at between 2°C to 6°C. There should be a locking device on the thermostat to prevent alteration of the setting.

24. There should be no freezing compartment in a blood storage refrigerator.

25. The interior should be clean and adequately insulated and there should clear organisation of storage areas which are properly labelled and designated for crossmatched blood, labelled blood and outdated blood.

26. Domestic type refrigerators should not be used for the storage of blood.

Monitoring Temperatures

27. Recording thermometers and audible alarms are required for all blood storage refrigerators.

28. The sensor for these systems should be on a high shelf and must be in a liquid-filled container. These should contain water or other fluids to a volume no greater than the volume of the smallest component stored.

29. The alarm signals must be activated at a temperature that allows personnel to take proper action before the stored blood reaches undesirable temperatures. An acceptable range is 1°C to 6°C.

30. In a large refrigerator, it is advisable to have at least two independent thermometers, one immersed with the recording sensor and the other in a similar container on the lowest shelf where blood is stored.

31. In large walk-in refrigerators, several thermometers should be used, placed in appropriate areas to determine the possible range of temperature fluctuations.

32. At the end of each time period, temperature charts from mechanical recording devices should be changed, properly dated and labelled to identify the refrigerator and the person changing the charts. Any departure from normal temperature should be explained in writing on the chart beside the tracing.
33. Temperature records should be retained as part of blood bank records for at least 5 years.

Freezers

34. A freezer that can achieve a storage temperature of -20°C or lower is required for storing Fresh Frozen Plasma and Cryoprecipitate.

35. Freezers must be equipped with a system to monitor the temperature continuously and record the temperature at least every 4 hours.

36. Freezers should also have an alarm system with audible signals.

Refrigerator and Freezer Alarms

37. Refrigerator and freezer thermometers and alarms should be checked periodically to ascertain that they are functioning properly.

38. Freezers and refrigerators must have a source of electricity that operates independently of standard house circuits.

39. The electrical source for the alarm system must be separate from that of the refrigerator.

40. There must be written instructions for personnel to follow in the event of power failure or other disruption of refrigerators.