Blood Bank Inspection Checklist- Random

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
5	**STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES**				
5.7.	The health facility shall maintain charter of patients' rights and responsibilities posted at the entrance of the premise in two languages (Arabic and English).				
5.8.	Obtain accreditation within eighteen (18) months from the issuing date of the health facility license and Ensure maintaining valid accreditation (AABB or CAP).				
5.9.	The health facility shall ensure it has in place adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets and communications.				
6	**STANDARD TWO: HEALTH FACILITY REQUIREMENTS**				
6.1.4.	Medical laboratory				
b.	Screening tests:				
I.	ABO and Rh testing, Unexpected Red Cell antibody testing.				
II.	Infectious Disease testing that includes Serology and NAT according to National screening programme for donors and donor sample testing shall be separated from patient testing.				
c.	Waste storage including sharp safe				
d.	Equipment and critical items Storage				
6.3.2.	A comfortable working environment is considered 20 to 25 C with relative humidity of 35 to 50%.				
6.4.	The Blood Bank should install and operate equipment				

	required for provision of the proposed services in accordance to the manufacturer's specifications.				
6.5.3.	Collected blood units shall be handled or discarded in a manner that minimizes the potential for human exposure to infectious agents.				
6.6.	The Blood Banks shall provide documented evidence of the following; but not limited to:				
6.6.1.	Equipment maintenance services.				
6.6.2.	Laundry services.				
6.6.3.	Medical waste management as per Dubai Municipality (DM) requirements.				
6.6.4.	Housekeeping services.				
6.6.5.	The Blood Banks shall be designed to easily accommodate People of Determination and aligned with the Dubai Universal Design Code.				
7	**STANDARD THREE: HEALTHCARE PROFESSIONALS REQUIREMENTS**				
7.1.	All healthcare professionals in the Blood Banks must hold an active DHA professional license and work within their scope of practice.				
7.4.	All healthcare professionals should maintain a valid training/certification in basic Cardiopulmonary Resuscitation (CPR) or Basic Life Support (BLS) or Advanced Cardiac Life Support (ACLS), as required.				
7.8.	The Blood Banks shall have a Medical Director who is a full-time or part-time DHA licensed physician, qualified by training and experience and facility defined relevant training and continuing education.				
8	**STANDARD FOUR: MANAGEMENT RESPONSIBILITIES**				
8.7.	Maintain the recommended immunizations for health professionals working at the BDCS and BB.				
9	**STANDARD FIVE: MANAGEMENT OF EQUIPMENT**				

9.7.2.	Equipment used for Infectious disease screening for Blood donor sample shall not be used concurrently for testing patient samples.				
9.14.1.	Storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored.				
9.14.2.	For storage of blood and blood components, the temperature shall be monitored continuously and recorded at least every four (4) hours.				
9.15.	Alarm Systems				
9.15.1.	Storage devices for blood, blood components, tissue, derivatives, and reagents shall have alarms and shall conform to the following standards:				
a.	The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, derivatives, or reagents reach unacceptable conditions.				
b.	Activation of the alarm shall initiate a process for immediate action, investigation, and appropriate corrective action.				
9.16.	Information Systems				
9.16.1.	The Blood Bank shall use DHA Blood services software for donor's management to have unified donor's and donation data within the Emirate of Dubai.				
9.16.2.	An alternate system, including any required forms, shall be maintained and readily available for use to ensure continuous operation in the event that computerized data and Computer-assisted functions are unavailable. The alternate system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.				
9.16.4.	The system shall be designed to prevent unauthorized access to computers and electronic records shall be established and followed.				

10	STANDARD SIX: PROCESS CONTROL				
10.4.	Use of Materials				
10.4.1.	All materials (including containers and solutions used for collection, processing, preservation, and storage of blood and blood components, and all reagents used for tests) shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements and meet the accreditation requirements of AABB and/or CAP.				
10.5.	Sterility				
10.5.3.	The Blood Banks shall have methods to detect bacteria or use pathogen reduction technology in all platelet components stored at 20 – 24 0C.				
10.5.4.	Detection methods shall use devices cleared or approved by the FDA or Competent Authority. Pathogen reduction technologies shall be cleared or approved by the FDA or Competent Authority.				
10.7.	General Labelling Requirement				
10.7.1.	The labeling system shall make it possible to trace any unit of blood, from source to final disposition. The system shall allow recheck of records applying to the specific unit or tissue, including investigation of reported adverse events.				
10.8.	Donor Identification				
10.8.1.	Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.				
10.11.	Transportation				
10.11.2.	Containers (e.g., portable coolers) shall be qualified to transport blood to ensure that they maintain temperatures within the acceptable range for the expected duration of transport or shipping. (Refer to **appendix 1)**				
10.12.	Proficiency Testing				

10.12.1.	Blood Banks shall participate in an external proficiency-testing program, if available, for each analyte.				
10.12.2.	When an external proficiency-testing program is not available, there shall be a system for determining the accuracy and reliability of test results.				
10.12.3.	Proficiency testing shall include comparison of test results from an outside laboratory.				
10.12.4.	Results shall be reviewed and when expected results are not achieved, investigation and corrective action shall be taken where appropriate.				
11	**STANDARD SEVEN: DONOR EDUCATION, CONSENT, NOTIFICATION AND ELIGIBILITY**				
11.2.	Donor Consent				
11.2.5.	In the case of a minor or a legally incompetent adult, consent shall be addressed in accordance with applicable law.				
11.3.	Donor Notification of Abnormal Findings and Test Results.				
11.3.2.	Blood Banks qualified medical physician should notify the donor with any abnormal results found during pre-donation testing or screening.				
11.3.3.	Donor notification for abnormal infectious disease results must be done within eight (8) weeks from the date of collection.				
11.4.	Care of Donors				
11.4.2.	The donor shall be observed during the donation and for a length of time thereafter, as defined by the facility's policies and procedures				
11.6.	Allogeneic Whole Blood Donor Qualification				
11.6.1.	The prospective blood donor is a healthy individual between the age of 18 to 65 years, UAE/GCC national or UAE resident as per UAE Blood Transfusion Policy. Holders of transit or visit visa are not eligible to donate blood in UAE.				

11.6.3.	Donor eligibility criteria shall be unified in the Emirate of Dubai. (Refer to Appendix 7)				
11.6.4.	If the donor is deferred or if the donation is determined to be unsuitable, the donor's record will identify the donor as ineligible to donate and the donor will be notified of the reason for deferral.				
11.6.5.	Donors implicated in a transfusion-related acute lung injury (TRALI) event or associated with multiple events of TRALI shall be evaluated regarding their continued eligibility to donate.				
11.7.2.	Automated plasmapheresis donation				
a.	Infrequent plasmapheresis donor: Donors shall undergo plasmapheresis no more frequently than once every four (4) weeks.				
b.	Frequent plasmapheresis donor: Plasma is donated more frequently than once every 4 weeks, the FDA requirements for donor testing and evaluation by a physical exam will be followed:				
I.	Collection shall occur a maximum of two times in a seven (7) day period and the interval between two collections shall be at least two (2) days.				
c.	Plasmapheresis donors shall be weighed at each donation.				
11.7.3.	Automated Cytapheresis donation				
a.	The interval between procedures for platelet, granulocyte, and leukocyte donors shall be at least two (2) days, and the total volume of plasma collected shall not exceed the volume of plasma cleared by the FDA for the instrument. A donor shall undergo the procedure a maximum of two times in a 7-day period. When greater than or equal to 6 × 1011 platelet collection is performed, the donor shall undergo the procedure a maximum of once in seven (7) days. Procedures shall not exceed twenty-four (24) times in a rolling 12-				

	month period, except in unusual circumstances as determined by the Medical Director.				
b.	The interval between a Whole Blood donation and a subsequent Cytapheresis procedure shall be at least 8 weeks, unless the extracorporeal red cell volume of the apheresis machine is < 100 mL, in which case the interval shall be at least two (2) calendar days.				
c.	If it becomes impossible to return the donor's red cells during apheresis, at least 8 weeks shall elapse before a subsequent apheresis procedure, unless the red cell loss was < 200 ml.				
11.7.4.	Plateletpheresis donor's qualification: A blood sample shall be collected before each procedure for the determination of the donor's platelet count. The result shall be used as the platelet count to qualify the donor.				
a.	Plateletpheresis donors with a platelet count of < 200,000/µL shall be deferred from plateletpheresis donation until a subsequent platelet count is at least 200,000/µL.				
b.	If a donor has donated a single donor platelet (SDP) unit by aphaeresis and presents for whole blood donation allow a period of 15 days interval between them.				
c.	Validation and quality control of Apheresis Platelets shall demonstrate with 95% confidence that greater than 75% of units ≥ 3.0 × 1011 platelets and shall demonstrate with 95% confidence that > 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration. FDA criteria apply.				
d.	Plasma, apheresis platelets and whole blood for allogeneic transfusion shall be from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for				

	HLA antibodies.				
I.	The donor shall be deferred from all donations for 16 weeks following a 2-unit Red Blood Cell apheresis collection.				
11.9.2.	On the day of donation and before collection, the prospective donor's history shall be evaluated and the donor examined to minimize the risk of harm to the donor.				
11.10.	Autologous Donor Qualification				
11.10.3.	A medical order from the patient's physician or other authorized health professional to collect blood for autologous use.				
11.10.4.	The hemoglobin concentration of the autologous donor's blood shall be > 11 g/dL, or the hematocrit shall be > 33%.				
11.10.5.	All blood collections from the autologous donor shall be completed > 72 hours before the time of anticipated surgery or transfusion.				
11.10.6.	Autologous donors shall be deferred when they have a clinical condition for which there is a risk of bacteremia.				
11.10.7.	The unit shall be reserved for autologous transfusion.				
12	**STANDARD EIGHT: DONORS REGISTRATION, DHQ, MEDICAL ASSESSMENT**				
12.1.	Donors Registration				
12.1.1.	Licensed Blood Banks shall use the unified Blood Banks software system to have a single platform for donors and donations records at the level of Emirate of Dubai.				
12.1.2.	At registration, the donor is identified with a photo identity card using the emirates ID/GCC ID.				
12.3.3.	The following standard applies:				
a.	Blood shall be collected into a sterile closed system. Blood collection containers withdraw line (inlet) diversion pouches shall be used for any collection of platelets, including whole blood from which platelets are made.				
b.	The collection facility shall have a method to limit				

	introduction of bacteraemia during collection, processing and sampling.				
12.3.4.	Tubes for laboratory tests shall be properly labelled before the donation begins, shall accompany the blood container, and shall be re- identified with the blood container during or after filling and before the tubes and containers are separated.				
12.4.	Blood Units Storage and Transporting				
12.4.1.	If blood is to be transported from the collection site, it shall be placed in a qualified Container having sufficient refrigeration capacity to cool the blood continuously toward a temperature range of 1 to 10 C until it arrives at the processing site.				
12.4.2.	Whole blood intended for room temperature processing and apheresis platelets shall be transported and stored in a manner intended to cool the blood and apheresis platelets toward a temperature range of 20 to 24 C.				
13	**STANDARD NINE: PREPERATION AND PROCESSING OF COMPONENTS**				
13.2.	Seal				
13.2.1.	If the seal is broken during processing, components shall be considered to have been prepared in an open system and expiration times specified for such components (open system within 24 hrs for packed cells).				
13.3.	Weld				
13.3.1.	If a sterile connection device is used to produce sterile welds between two pieces of compatible tubing, the following requirements shall apply:				
a.	The weld shall be inspected for completeness.				
b.	If the integrity of the weld is complete, the component shall have an expiration date/time assigned in accordance with the FDA.				

c.	If the integrity of the weld is incomplete, the container shall be considered an open system and may be sealed and used with a component expiration as indicated in current Appendix 1; requirement for storage, transportation and Expiration				
d.	Regardless of the integrity of the weld, if no storage time limit is specified in the package insert or the package insert is not available, the component shall have an expiration time of four (4) hours after transfer from original container.				
e.	Cross Match Segment at the time of collection or component preparation, the integral donor tubing shall be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent compatibility testing. The tubing must be segmented to at least six to eight crossmatch segments at the tubing attached to the final PC bag using the heat sealer.				
13.4.	Leukoreduction Method:				
13.4.1.	The Blood Banks shall entirely implement pre-storage Leukocyte-reduced blood and blood components. Leukocyte-reduced blood and blood components shall be prepared by a method known to reduce the leukocyte number to < 5 x 10^6 for red cells, apheresis or pooled platelets, and to < 8.3 x 10^5 for whole drive platelets. Validation and quality control shall demonstrate that > 95% of units sampled meet this criterion				
13.5.	Irradiation:				
13.5.1.	Irradiated blood and blood components shall be prepared by a method known to ensure that irradiation has occurred. A method shall be used to indicate that irradiation has occurred with each batch. The intended dose of irradiation shall be a minimum of 25 Gy (2500 cGy) delivered to the central portion of the container. The minimum dose at any				

	point in the components shall be 15 Gy (1500 cGy). Alternate methods shall be demonstrated to be equivalent.				
13.6.	Pooled Components				
13.6.1.	The BB shall maintain records of the ABO/Rh, donation identification number, and collecting facility for each unit in the pool.				
13.7.1.	Red Blood Cells without additive solutions shall be prepared using method known to result in a final hematocrit of ≤ 80%.				
13.7.2.	Red Blood Cells Leucocyte Reduced: Red Blood Cells Leukocytes Reduced shall be prepared by a method known to retain at least 85% of the original red cells. The sampling plan shall confirm with 95% confidence that < 95% of units contain < 5 × 106 leukocytes.				
13.7.3.	Red Blood Cell, Low Volume: When 300 to 404 mL of whole blood is collected into an anticoagulant volume calculated for 450 ± 45 mL or when 333 to 449 mL of whole blood is collected into an anticoagulant volume calculated for 500 ± 50 mL, red cells prepared from the resulting unit shall be labeled Red Blood Cells Low Volume. No other components shall be made from a low volume collection.				
13.7.4.	Apheresis Red Blood Cells, Leukocyte reduced. Shall be prepared by a method known to ensure a final component containing a mean hemoglobin of ≥ 51g (or 153 mL cell volume). The sampling plan shall confirm with 95% confidence that more than 95% of units contain < 5 × 106 leukocytes. At least 95% of units sampled shall have > 42.5 g of hemoglobin (or 128 mL red cell volume). Validation and quality control shall demonstrate that these criteria or the criteria specified in the operator's manual are met.				
13.7.5.	Frozen Red Blood Cells shall be prepared by a method known to minimize post-thaw hemolysis. Red Blood Cells				

	shall be frozen within 6 days of collection, except when rejuvenated Rare units may be frozen without rejuvenation up to the date of expiration.				
13.8.	Plasma Preparation:				
13.8.2.	Fresh Frozen Plasma shall be prepared from a whole blood or apheresis collection and placed at −18oC or colder within the time frame required for the collection, processing, and storage system.				
13.8.3.	If a liquid freezing bath is used, the container shall be protected from chemical exposure.				
13.9.	Platelets				
13.9.1.	Validation and quality control of Platelets prepared from Whole Blood shall demonstrate that at least 90% of units sampled contain ≥ 5.5 × 1010 platelets and have a pH ≥ 6.2 at the end of allowable storage.				
13.9.2.	Apheresis Platelets				
a.	Validation and quality control of Apheresis Platelets shall demonstrate with 95% confidence that is > 75% of units contain ≥ to 3.0 × 1011 platelets and shall demonstrate with 95% confidence that > 95% of units have a pH ≥ 6.2 at the time of issue or within 12 hours after expiration.				
b.	Apheresis Platelets containing < 3.0 x 1011 platelets shall have the platelet content included on the label.				
13.9.3.	Platelets Leucocyte reduced validation and quality control of Platelets Leukocytes Reduced shall demonstrate that at least 75% of units sampled contain ≥ to 5.5 × 1010 platelets and at least 90% of units sampled have a pH ≥ 6.2 at the end of allowable storage. The sampling plan shall confirm with 95% confidence that more than 95% of units contain < 8.3 x 105 leukocyte.				
13.9.4.	Pooled Platelets Leucocyte Reduced shall be prepared by a method known to result in a 95% confidence that more				

	than 95% of units contain < 5 x 106 leukocyte and at least 90% of units sampled have a pH ≥ to 6.2 at the end of allowable storage.				
13.10.	Cryoprecipitate (Anti Haemophilic Factor) shall be prepared by a method known to separate the cold insoluble portion from Fresh Frozen Plasma and result in an average content of at least 150mg of fibrinogen and 80 IU of coagulation Factor VIII per container or unit.				
14	**STANDARD TEN: ROUTINE BLOOD SCREENING TESTS**				
14.1.	Determination of ABO Group for All Collections				
14.1.1.	Determination of ABO Group for All Collections: The ABO group shall be determined for each collection by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma for expected antibodies with A1 and B reagent red cells.				
14.2.	Determination of Rh Type for All Collections				
14.2.1.	The Rh type shall be determined for each collection with anti-D reagent. If the initial test with anti-D is negative, the blood shall be tested using a method designed to detect weak D. When either test is positive, the label shall read “Rh POSITIVE.” When the tests for both D and weak D are negative, the label shall read “Rh NEGATIVE.”				
14.3.	Detection of Unexpected Antibodies to Red Cell Antigens for Allogeneic Donors.				
14.3.1.	Serum or plasma from donors shall be tested for unexpected antibodies to red cell antigens. Methods for testing shall be those that demonstrate clinically significant red cell antibodies.				
14.4.	Tests Intended to Prevent Infectious Diseases Transmission (IDT) by Allogeneic Donations				
14.4.1.	Shall follow the UAE. National screening program for IDT. by a sample of blood from each allogeneic donation shall be				

	screened using Individual Donor nucleic acid amplification test (ID NAT) to detect HBV DNA, HCV RNA and HIV-1 RNA & serological tests for HBsAg, anti-HBc, anti-HCV, anti-HIV-1/2, anti-HTLV-I/II, and syphilis by an FDA approved serologic test.				
14.4.2.	Blood and blood components shall not be distributed or issued for transfusion unless the results of these tests are negative				
14.4.3.	Autologous blood or components that shall be screened using Individual Donor nucleic acid amplification test (ID NAT) to detect HBV DNA, HCV RNA and HIV- 1 RNA, & serological tests for HBsAg, anti-HBc, anti-HCV, anti-HIV-1/2, anti- HTLV-I/II, and syphilis by an FDA approved serologic test.				
a.	These tests shall be performed before shipping on at least the first unit collected during each 30-day period.				
b.	The patient's physician and the donor-patient shall be informed of any medically significant abnormalities discovered.				
15	**STANDARD ELEVEN: INVENTORY MANAGEMENT**				
15.2.	The Blood Banks shall ensure the appropriate segregation of all stored products, including autologous units. The blood components inventory must be arranged on accordance to the collection and expiry dates.				
15.3.	The Blood Banks shall set an appropriate inventory level for the blood components based on storage devices capacity.				
15.4.	Blood Banks shall ensure the handling of packed red blood cell product shall not be exposed to temperatures outside refrigeration specifications for longer than 30 minutes, and for frozen blood product to be kept on dry ice or frozen ballast within a container to prevent temperature changes.				
15.5.	The blood and blood product unit and/or packaging				

	integrity must be inspected before issuing and distribution.				
15.6.	The Blood Banks shall regularly provide the statistical data of blood and blood components utilization and wastage to the DHA Blood transfusion services.				
15.7.	Blood Banks inventory shall be viewed and accessed/connected to DHA Blood transfusion services to perform Blood Inter Hospital Transfer where necessary.				
15.8.	Blood Banks shall report all identified rare blood groups donors to the DHA Blood transfusion services.				
15.9.	Blood and Blood derivatives, and reagents shall be stored in accordance with the manufacturer's written instructions.				
15.10.	For storage of blood and blood components, the temperature shall be monitored continuously and recorded at least every 4 hours.				
15.11.	For open storage areas, the ambient temperature shall be monitored and recorded at least every four (4) hours.				
15.12.	Access to storage areas and authorization to remove contents shall be controlled.				
16	**STANDARD TWELVE: SAFETY AND INFECTION CONTROL PRACTICES**				
16.1.	General Safety Considerations				
16.1.2.	The environment is also at risk of being contaminated by hazardous materials used and wastes generated.				
16.1.3.	Safety therefore includes protection of both the staff and the environment from hazardous materials. General safety measures include:				
b.	All staff shall be aware about the laboratory safety policies and procedures and follow these at all times. Proper training from the beginning of employment is the key to a successful safety program. A properly conducted training program will ensure comprehension and understanding.				
c.	A comprehensive warning labelling system should be implemented to identify contaminated objects or objects				

	containing contaminated or hazardous materials. Labels exhibiting the universal biohazard sign should be placed on containers of regulated waste, refrigerators containing blood or other potentially infectious materials, sharps disposal containers, and any other spaces in which infectious materials are stored.				
d.	Eyewash stations shall be available and should be located within a 10- second walk (approximately 55 ft) from all locations in which hazardous chemicals are used or infectious materials are handled.				
e.	Emergency showers should be available in locations in which caustic and corrosive chemicals are used and in which the possibility of a large spill exists, and should be within a 10-second walk (approximately 55 ft).				
f.	Basic first aid kit needs to be available and restocked periodically. Unless otherwise specified, the minimally recommended contents of a first aid kit.				
g.	The Blood Collection site must be equipped with an Oxygen Cylinders, which must be maintained for emergency use.				
h.	Smoking should be prohibited in the technical work area by posting a no smoking sign.				
i.	Blood Collection site, blood processing, storage and supply site shall ensure proper preservation and security of blood units and samples.				
j.	Blood Collection, blood processing, storage and supply personnel shall be thoroughly trained in managing emergencies such as biohazard spillage etc. as applicable to the facility.				
k.	Periodic checking of all safety equipment and accessories shall be ensured.				
l.	Two-handed recapping of needles is strictly prohibited. Contaminated needles or other sharps must not be sheared,				

	bent, recapped, or removed from syringes or other devices unless it can be accomplished using a mechanical device (such as a haemostat) or by a one-handed technique.				
16.2.	Hand Hygiene				
16.2.2.	Handwashing basins, paper towels should be provided in areas that conduct a medical procedure such as phlebotomy.				
16.2.3.	Antiseptic hand sanitizers should be in single use, non-refillable pouches inserted into dispensers.				
16.3.	Use of Personal Protective Equipment (PPE)				
16.3.3.	These types of PPE such as gloves, masks, disposable coats must be always available and discarded in the Infectious waste bin.				
16.5.	Waste Management				
16.5.2.	Medical and/or Non-infectious wastes must be handled carefully and properly to prevent gross microbial contamination of the air, environment and all personnel handling and disposing the waste. Discard blood and sample tubes into a double- bagged yellow plastic bag.				
16.5.5.	Sharps (i.e., needles, syringes with attached needles, scalpel blades) must be placed in a stable, rigid, puncture-resistant “sharps” container labelled with a biohazard warning label. Slides, coverslips, and capillary tubes may be placed in a rigid, puncture-resistant container or red-bagged biohazard waste container.				
16.6.	Spillage Management				
16.6.1.	All spillages of blood or body fluid, chemical spill must be considered as potentially infectious/hazardous and must be dealt with immediately, utilizing appropriate and available spill kits. These kits such as Biological Spill Kits, Vomit Spill Kits and Chemical Spill Kits must be readily available in procedure areas and must be inspected periodically.				

16.6.2.	Requirement of conducting proper training to all healthcare providers and housekeeping services on the usage of the appropriate spill kits is essential.				
16.7.	Occupational Exposures and Percutaneous Injury				
16.7.3.	Accident/incident/injuries record of Healthcare workers should be maintained and reported to the designated authority.				
16.7.4.	The report should include description of the event, factors contributing to the event and information on first aid or other health care provided. This information can be analysed periodically towards effectively controlling and preventing future events. The Safety Officer should maintain the records.				
17	**STANDARD THIRTEEN: HEALTH RECORDS**				
17.1.	Laboratory data management includes recording details of the donor medical check-up details, laboratory screening results and archiving the data for future reference.				
17.3.	Equipment maintenance reports must be kept for future reference.				