Standards for

Blood Donation Services

Version 1

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Health Policies and Standards Department

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INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (6) of 2018 to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector.
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice.
- Managing patient complaints and assuring patient and physician rights are upheld.
- Managing health advertisement and marketing of healthcare products.
- Governing the use of narcotics, controlled and semi-controlled medications.
- Strengthening health tourism and assuring ongoing growth.
- Assuring management of health informatics, e-health and promoting innovation.

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts. HPSD would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

TABLE OF CONTENTS

INTRODUCTION 2

ACKNOWLEDGMENT 2

DEFINITIONS 7

ABBREVIATIONS 13

1. **BACKGROUND** 14
2. **SCOPE** 15
3. **PURPOSE** 15
4. **APPLICABILITY** 15
5. **STANDARD ONE:** REGISTRATION AND LICENSURE PROCEDURES 15
6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS 18
7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS 20
8. **STANDARD FOUR**: MANAGEMENT RESPONSIBILITIES 23
9. **STANDARD FIVE:** MANAGEMENT OF EQUIPMENTS 26
10. **STANDARD SIX:** PROCESS CONTROL 29
11. **STANDARD SEVEN:** DONOR INFORMATION, CONSENTS, AND NOTIFICATIONS 33
12. **STANDARD EIGHT:** DONORS REGISTRATION & SELECTION 38
13. **STANDARD NINE:** SAFETY & INFECTION CONTROL PRACTICES 43
14. **STANDARD TEN:** HEALTH RECORDS 49

REFERENCES 51

APPENDIX 56

APPENDIX 1: GUIDELINES ON STANDARD OPERATING PROCEDURES (SOPS) 56

APPENDIX 2: HEALTH CARE WORKERS RECOMMENDED IMMUNIZATION 59

APPENDIX 3: GUIDELINES ON QUALITY ASSURANCE 60

APPENDIX 4: RETENTION OF DONOR RECORDS 64

EXECUTIVE SUMMARY

The purpose of this document is to assure the provision of the highest levels of safety and quality during collection of blood from voluntary blood donors. This Standard has been developed to align with the evolving healthcare needs and international best practice. It includes several aspects which are required to provide effective, efficient, safe and high quality of blood and blood components. This standard includes the process of collecting blood from voluntary blood donors including and not limited to: blood donors' education, registration, eligibility criteria, questionnaire and consent, medical assessment pre-blood donation, blood donation and post blood donation care and instructions. In addition, to blood units and handling blood samples, temporary storage, transportation to DHA DBDC. Lab equipment use and maintenance, safety requirements, management of blood donor records and quality assurance. It also addresses the facility and healthcare professional requirements, staffing requirements, medical director responsibilities, staff training and competency assessment, infection control, quality control and reporting key performance data.

At the Blood Donation sites, a thorough assessment is required which includes and not limited to the donor eligibility criteria, a minimum physical examination, laboratory testing, providing utmost safety to the blood donors and collecting the highest quality blood for use for needy patients in hospitals. Blood Donation Site shall provide services such as but not limited to:

- Donor Education
- Donor Registration

- Filling of Donor History Questionnaire.
- Donor Medical Assessment (Screening)
- Phlebotomy
- Post Donation Care
- Temporary storage of collected units
- Transportation of whole blood unit and blood samples under pre-defined controlled temperature.
- Daily quality control procedures.

Blood donation process shall require a certified nurse to perform donor registration, assess eligibility and carry out medical assessment. While blood collection (phlebotomy) can be carried out by trained phlebotomist. The concerned technical team who are trained, competent, experienced and privileged by the Clinical Privileging Committee to perform specified tasks within the confinements of permitted licensure and specialisation.

This standard is aligned with the following Federal and DHA documents:

1. UAE. Blood Transfusion Policy (2008).
2. Law no. (4) of 2016 on Medical Liability and related cabinet decision (40) of 2019.
3. Law no. (4) of 2015 on Private Health Facilities and related ministerial decision (29) of 2020.
4. Unified National Standards for Hospitals (2018).
5. Unified Healthcare Professional Qualification Requirements (PQR).
6. National Guidelines for Biosafety 2020.
7. Federal: Unified National Standards for Hospitals.

8. Dubai Design Code.
9. DHA Health Facility Guidelines - Laboratory Unit Chapter 220.
10. DHA Clinical Laboratory Accreditation Policy.
11. DHA Facility Licensing Policy.
12. DHA Role and Responsibilities of Medical Director Policy.
13. DHA Communicable Disease Notification Policy.
14. Standards for Medical Advertisement Content on Social Media.
15. DHA Guidelines for Managing Health Records.

DEFINITIONS

Accreditation: is the process of officially evaluating clinical laboratory to maintain satisfactory standards, conducted by international accreditation organizations.

Adverse Event: is a complication in a donor or patient. Adverse events may occur in relation to a donation, a transfusion, or a diagnostic or therapeutic procedure.

Allogeneic Donor: is an individual from whom products (blood) intended for another person are collected.

Autologous Donor: is a person who acts as his or her own product donor.

Backup: is a digital data and/or physical storage containing copies of relevant data.

Blood Donation Collection Site (BDCS.): is a DHA licensed medical site, building or place in which procedures for collecting blood from eligible and voluntary donor is carried out, ensuring required pre and post donation care is performed by trained and skilled healthcare professional.

Blood Donation Service: is a service in which donated whole blood (collected and prepared from a healthy eligible and voluntary donor is administered to the recipient. This can take place in an independent/stand-alone service or as part of a DHA licensed health facility such as Hospital, Day Surgical Centre, Polyclinic, or Specialty Clinic.

Blood Donor: is any individual (age 18 to 65 years) who fulfils the eligibility criteria for whole blood donation, and is voluntarily willing to donate a unit of whole blood, without any remuneration.

Blood Bank: is a facility that performs, or is responsible for the performance of the collection, processing, storage, and/or distribution of human blood and/or blood components intended for transfusion and transplantation.

Blood Components: are therapeutic products prepared from a whole blood collection or produced through an automated collection, e.g., red cells, plasma, and platelets.

Clinical Audit: is a systematic examination to review and determine whether actual activities and results comply with standards of care.

Closed System: is a system of which the contents are not exposed to air or outside elements during collection, preparation, and separation of components.

Collection Facility: is a facility that collects blood and/or blood components from a donor.

Competence: is the ability of an individual to perform a specific task according to standardized procedures.

Conformance: Fulfilment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or laws.

Corrective Action: is an activity performed to eliminate the cause of an existing Non-conformance or other undesirable situation in order to prevent recurrence.

Critical Equipment/Materials/Tasks: is a piece of equipment, material, service, or task that can affect the quality of the facility's products or services.

Deviation: is a departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Health Care Worker: is an individual employed by the health facility, whether directly or by contract with another entity, who provides direct or indirect donor care, this includes but not limited, healthcare professionals, medical and nursing students, administrative staff and contract employees who either work at or come to the health facility site.

Healthcare professional: is a person who is authorized and licensed by the Dubai Health Authority (DHA) to practice any healthcare professions as per the unified prequalification's requirements for the United Arab Emirates.

Informed Consent: refers to an agreement and permission accompanied by full information on the nature and risks of whole blood donation procedure. Consent is taken in a written form. Informed consent also refers to the consent given by the parent or legal guardian, in case the donor is a minor (17 years).

ISBT 128: Is a standard for the identification, terminology, coding, and labelling for blood, cellular therapy, and tissue products. When linear bar codes are used, Code 128 symbology is utilized.

Label: is an inscription affixed or attached to a unit of blood or a blood component, an issue, a derivative, or a sample for identification.

Labelling : is information that is required or selected to accompany a unit of blood or a Blood component, a tissue, a derivative, or a sample, which may include content, Identification,

description of processes, storage requirements, expiration date, cautionary Statements, or indications for use.

Licensure: is issuing an official permission to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

Non-conformance: Failure to meet requirements.

Open System: is a system, the contents of which are exposed to air and outside elements during preparation and separation of components.

Permanent Deferral: is a deferral applied to a donor who will never be eligible to donate blood for someone else.

People of Determination: are people with special needs or disabilities, under the National Policy for Empowering People with Special Needs. The UAE law defines a person with special needs as someone suffering from a temporary or permanent, full or partial deficiency or infirmity in his physical, sensory, mental, communication, educational or psychological abilities to an extent that limits his possibility of performing the ordinary requirements as people without special needs.

Quality Control: is a testing, which is routinely performed on materials and equipment to ensure their proper function.

Quality Indicator Data: Information that may be collected and used to determine whether an organization is meeting its quality objectives as defined by top management in its quality policy.

Indicators are measured by data for movement or regression with regard to those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

Safety: the condition of being protected against physical, psychological, or other types or consequences of failure, error, or harm, which could be considered non-desirable. This can take the form of being protected from the event or exposure to something that causes health losses, such as using a drug, a procedure, or risk in the care environment.

Standard Operating Procedure (SOP): is a document, which contains detailed, written instructions for both operational and analytical procedures. It describes the stepwise process and technique of performing a test or procedure in the laboratory.

Supplier: An entity that provides an input material or service.

Supplier Qualification: An evaluation method designed to ensure that input materials and services (e.g. Materials, blood, blood components, tissue, derivatives, patient blood samples) obtained from a supplier meet specified requirements.

Temporary Deferral: A deferral placed on a donor who is not eligible to donate for a specified period.

Traceability: The ability to follow the history of a product or service by means of recorded identification.

Unit: A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.

ABBREVIATIONS

AABB	:	Association for the Advancement of Blood and Biotherapies.
BDCS	:	Blood Donation Collection Site
BDCC	:	Blood Donation Collection Centre
CAP	:	College of American Pathologist
DBDC	:	Dubai Blood Donation Centre
DHA	:	Dubai Health Authority
EQA	:	External Quality Assessment
FDA	:	Food & Drug Administration
GMP	:	Good Manufacturing Practice
GLP	:	Good Laboratory Practice
GCP	:	Good Clinical Practice
HRS	:	Health Regulation Sector
IQC	:	Internal Quality Control
QA	:	Quality Assurance
QAP	:	Quality Assurance Program
SOP	:	Standard Operating Procedures
UAE	:	United Arab Emirates

1. BACKGROUND

Blood transfusion is an essential part of patient care and life-saving support within the health care system. Unsafe blood transfusions have significantly contributed to the global burden of new hepatitis and HIV infections. An important part of blood safety is collecting blood from only voluntary non-remunerated blood donors fulfilling donation eligibility criteria. As per UAE. Blood transfusion standards, AABB and FDA, Blood donation centre are considered as pharmaceutical industry where GMP, GLP and GCP are applicable.

Blood collection, processing, screening and storage services are critical steps in manufacturing therapeutic blood and components. Blood donation services are committed to providing safe and adequate blood and blood product to all the needy patients in all the government and private hospitals. A Blood donation collection site (BDCS.) should be a DHA licensed site for whole blood collection from voluntary blood donors where the processes are performed according to UAE Blood transfusion Standards. Current DHA AABB standards should serve as a regulatory and auditing body for such service. DHA licensed BDCS shall provide services such as and not limited to registration, screening phlebotomy services and transportation of whole blood unit and blood samples under pre-defined controlled temperature to DHA Dubai Blood Donation Centre (DBDC) laboratory unit.

DBDC is responsible for formulating related policies and procedures pertaining to whole blood collection, transportation of whole blood units and blood sample units from the blood collection sites to lab units in DBDC.

New Blood Collection sites shall obtain accreditation within eighteen (18) months from the issuing date of the health facility license for whole blood collection.

NOTE: For further details, refer to the DHA Clinical Laboratory Accreditation Policy.

2. SCOPE

2.1. Management of blood donation services in DHA licensed health facilities for purpose of collection of whole blood units from voluntary blood donors.

3. PURPOSE

3.1. To ensure provision of the highest levels of safety and quality of whole blood donation services in DHA licensed health facilities.

3.2. To ensure a supply of safe whole blood donation services DHA licensed health facilities.

4. APPLICABILITY

4.1. All DHA licensed healthcare professionals and health facilities providing blood donation services.

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing Bloservices shall adhere to the all relevant United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. BDCS shall be:

5.2.1. Independent/Stand-alone service; OR

5.2.2. Part of a DHA licensed health facility such as Hospital, Day Surgical Centre, Polyclinic, or Specialty Clinic.

5.3. The health facility must obtain a license from DHA to operate as blood collection site in the Emirate of Dubai. This applies to governmental, semi-governmental, and private under DHA jurisdiction.

5.4. Health facilities aiming to provide Blood collection services shall comply with the DHA licensure and administrative procedures available on the DHA website Health Facilities Licensing.

5.5. Upon receipt of a completed applicant's file, the HRS will conduct a detailed review of the submitted material to determine suitability for further processing.

5.6. In case of rejection of the application a detailed list of issues will be provided for corrective action and the Blood collection site is required to re-submit the application with applicable fees.

5.7. The health facility shall develop the following policies and procedure; but not limited to:

5.7.1. Service Description and Scope of Services.

5.7.2. List of services performed in the Blood Collection site.

5.7.3. Donor eligibility management.

5.7.4. Blood Collection from allogenic and autologous blood donors.

5.7.5. Donor education, communication and Informed consent.

5.7.6. Donor data management.

5.7.7. Donor confidentiality & privacy.

5.7.8. Storage & transportation of collected whole blood units and blood samples under predefined controlled temperature.

5.7.9. Emergency action plan.

5.7.10. Incident reporting.

5.7.11. Infection control measures and hazardous waste management.

5.8. Based on the onsite assessment and after meeting the DHA requirements and recommendations, Health Regulation Sector (HRS) will issue a DHA license valid for one year.

5.9. At any time and upon reasonable cause, HRS, health inspectors may conduct random inspections to inspect the BDCS to determine compliance and take appropriate action if required.

5.10. The onsite inspections may be scheduled or un-announced.

5.11. After every inspection in which non-compliance is identified, the authorized health inspectors shall issue an onsite copy of the field inspection report followed by a letter stating the identified violations.

5.12. The BDCS management shall submit to the HRS, Clinical Audit and Control Department (CACD) a written plan of correction of violations cited within fifteen (15) days after receiving the noncompliance letter stating the identified violations.

6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS

6.1. The new BDCS should meet the health facility requirement as per the DHA Health facility Guidelines 2019 and specifically the Functional Planning Units. It provides specific design requirements for the following areas:

6.1.1. Waiting area

6.1.2. Donor registration

6.1.3. Donor history questionnaire

6.1.4. Donor medical assessment , maintaining confidentiality and privacy

6.1.5. Donor phlebotomy

6.1.6. Post donation care

6.1.7. Medical store

6.1.8. Support areas

a. Waste storage including sharp safe

b. Equipment and critical items Storage

c. Area for Administrative activities.

d. Refreshment storage

e. Offices and staff areas.

6.2. Special consideration should be given to the choice of fireproof construction for the buildings aligned to the building and design codes of DM and Dubai Civil Defence (DCD) requirements.

6.3. Special consideration should also be given to climate and ventilation control. The temperature and humidity within the Blood Collection site should be maintained within proper limits for effective performance of tests performed and maintained according to manufacturer's specifications. A comfortable working environment is considered 20 to 25°C with relative humidity of 35 to 50%.

6.4. The BDCS should install and operate equipment required for provision of the proposed services in accordance to the manufacturer's specifications.

6.5. Facilities and safety:

6.5.1. The BDCS shall have policies, processes, and procedures to ensure the provision of safe environmental conditions. The facility shall be suitable for the activities performed. Safety programs shall meet local, state, and federal regulations, where applicable.

6.5.2. The BDCS shall have processes to minimize and respond to environmentally related risks to the health and safety of employees, donors, volunteers, patients, and visitors. Suitable quarters, environment, and equipment shall be available to maintain safe operations.

6.5.3. Collected blood units shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

6.6. The BDCS 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.

6.7. The BDCS 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 BDCS must hold an active DHA professional license and work within their scope of practice.

7.2. Appropriate and adequate number of DHA licensed healthcare professionals shall be present on duty during the working hours of the BDCS to meet the functional program.

7.3. Management of the BDCS shall determine the number of DHA licensed healthcare professionals employed and assigned to each service, and shall be consistent with type the of services provided.

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.

7.5. For qualifications, training, experience and Continuing Professional Development (CPD) requirements of healthcare professionals employed by a DHA Clinical Laboratory refer to the Healthcare Professionals Licensing.

7.6. DHA and DBCS shall conduct periodical competency assessment for health care professionals working in BDCS as per DHA DBDC SOP QAU 012 Staff Competency Policy and Procedure.

7.7. To ensure compliance, the BDCS may refer to the detailed Standards Operating Procedures (SOPs) related to donors and patient safety, which is approved by DBDC.

7.7.1. Covering both analytical and operational procedures related to the scope of services described in the functional program of the BDCS.

7.8. Staff of the DBCS. shall follow the procedures described in the SOPs as mentioned in appendix , to ensure high quality results:

7.8.1. Licensed, professional, and competent health provider is required to perform the procedure.

7.8.2. Staff training, evaluation and assessment as per DBDC. Procedure.

7.9. Data management should ensure security and safety of data.

7.10. The Blood Donation Collection Centre (BDCC) shall maintain charter of patients' rights and responsibilities, customer happiness charter, and donor journey posted at the premise in two languages (Arabic and English).

7.11. The BDCS should 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. (Related AABB standards applied).

7.12. The medical director shall have responsibility and authority for all medical and technical policies, processes, and procedure including those that pertain to laboratory

personnel and test performance and for the consultative and support services that relate to the care and safety of donors and/or transfusion recipients.

7.13. The medical director may delegate these responsibilities to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.

7.14. To ensure safe and high-quality care is upheld within BDCS. the Medical Director/laboratory director shall abide by the DHA Policy for Role and Responsibilities of Medical Director.

7.15. Quality Control Manager or competent authorized person should review the quality control data and maintain records of evaluations.

7.16. Resources: The BDCS shall have policies, processes, and procedures to ensure the provision of adequate resources to perform, verify, and manage all activities in the Blood Collection site.

7.17. The BDCS shall have a process to ensure the employment of an adequate number of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.

7.18. Qualification: Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training, and/or experience.

7.19. Training: The Blood Collection site shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.

7.20. Competence: Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals. Action shall be taken when competence has not been demonstrated.

7.21. Personnel Records: Personnel records for each employee shall be maintained.

7.22. For those authorized to perform or review critical tasks, records of names, signatures initials or identification codes, and inclusive dates of employment shall be maintained.

8. **STANDARD FOUR**: MANAGEMENT RESPONSIBILITIES

8.1. To guarantee the smooth operation and ensure safe and quality services are provided in the BDCS, the management lead by the Medical Director has certain responsibilities which include, but not limited to the following:

a. Comply with all federal and local laws and regulations.

b. Apply UAE. Blood Transfusion Standards issued by minister's cabinet 28/2008 related to donors and donations.

c. Apply current AABB standards in daily work and to be accredited from AABB or CAP as BDCS within a maximum period of 18 months from operation.

d. Comply with DHA DBDC related SOPs to maintain the quality and safety of blood supply in UAE.

e. Take necessary measures to distribute new DHA circulars and announcements among all staff.

f. Ensure policies and procedures are in place for the safe and quality provision of care and appoint responsible staff for developing and reviewing the documents.

g. Assess the consistent performance of contract and reference laboratory services.

h. Management review. Management shall assess the effectiveness of the quality system through assessments and scheduled management reviews.

i. Ensure all healthcare professionals employed have a current DHA license, are privileges as per the Clinical Privileging Policy and work within their scope of practice.

j. Maintain the recommended immunizations for health professionals working at the BDCS.

k. Support Continuous Professional Development (CPD) of the staff members by allocation of time for these activities.

l. Designate a qualified person(s) or team for the following:

   i. Quality Control Manager or competent authorized person to ensure quality assurance (for details regarding quality assurance refer to **Appendix 3)**.

   ii. Fire Safety.

m. Document ongoing assessment activities including corrective action, effectiveness reviews, and policy and procedure revisions made to prevent recurrence of a problem and discuss assessment reviews with staff.

n. Cooperate with HRS inspectors and/or any duly authorized representative when they visit the health facility and/or request for any material.

o. Avoid giving misleading information and false statements, which may lead to legal action against any employed DHA, licensed healthcare professionals or the health facility.

p. Settle any violation fines related to employed healthcare professionals or the health facility.

q. Maintaining malpractice insurance for all licensed healthcare professionals as per article Cabinet Decision no. (40) of 2019 concerning UAE Federal Law concerning Medical Liability.

r. Use the DHA Infectious Diseases Notification Service to report communicable disease required by the Cabinet Decision no. (24) of 2020 concerning Publication and exchange of health information on communicable diseases and epidemics and misinformation related to human health, and keep a log of it, aligned with DHA Communicable Disease Notification Policy.

s. Submit to the Health Data and Information Analysis Department in DHA the required statistical data of the health facility.

t. Obtain prior approval from the Ministry of Health and Prevention (MOHAP) for media and advertisement materials, for further information regarding the media and advertisement materials approval procedures and requirements please visit the MOHAP website.

9. **STANDARD FIVE:** MANAGEMENT OF EQUIPMENTS

9.1. The Health facility management shall identify the equipment that is critical to the provision of blood, blood components and/or services in the BDCS. This includes policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conforms to these current AABB Standards.

9.2. Selection of Equipment

9.2.1. The BDCS shall have a process to define the selection criteria for equipment.

9.3. Qualification of Equipment

9.3.1. All equipment shall be qualified for its intended use.

9.3.2. Equipment repairs and upgrades shall be evaluated and equipment prequalified, as appropriate, based on the manufacturer recommendations and DBDC procedures.

9.4. Installation Qualification

9.4.1. Equipment shall be installed per the manufacturer's specifications

9.5. Operational Qualification

9.5.1. The functionality of each piece of equipment and each component of an information system shall be verified before actual use and shall meet the manufacturer's operational specifications.

9.6. Performance Qualification

9.6.1. The BDCS shall demonstrate that equipment performs as expected for its intended use. Performance specifications established by the manufacturer shall be met.

9.7. Use of Equipment

9.7.1. Equipment shall be used in accordance with the manufacturer's written instructions.

9.8. Unique Identification of Equipment

9.8.1. Equipment shall have unique identification.

9.9. Equipment Monitoring and Maintenance

9.9.1. The BDCS shall have a process for scheduled monitoring and maintenance of equipment that at a minimum is in accordance with manufacturer's written instructions. The process shall include frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.

9.10. Calibration of Equipment

9.10.1. Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be performed as described below, unless otherwise indicated by the manufacturer:

a. Before use.

b. After activities that may affect the calibration.

c. At prescribed intervals.

9.11. There shall be safeguards to prevent equipment from adjustments that would invalidate the calibrated setting.

9.12. Calibration procedures shall follow the manufacturer's written instructions and shall include:

a. Instructions for performing calibrations.

b. Acceptance criteria.

c. Actions to be taken when unsatisfactory results are obtained.

9.13. Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

a. Assessment of blood, blood components, tissue, derivatives, and services provided since the equipment was last known to be functioning per manufacturer's written instructions, or facility-defined specifications.

b. Assessment of the effect on donor eligibility and donor and patient safety.

c. Steps to ensure that the equipment is removed from service.

d. Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected.

e. Steps for requalification of the equipment.

f. Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.

9.14. Information Systems Records

9.14.1. The BDCS should use DBDC software for donor's management to have unified donor's data within the emirate of Dubai.

9.14.2. 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.

9.15. Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect their use.

9.16. The System shall be designed to prevent unauthorized access to computers and electronic records shall be established and followed.

10. STANDARD SIX: PROCESS CONTROL

10.1. The BDCS shall have policies and validated processes and procedures that ensure the quality of the services and shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

10.2. Quality Control

10.2.1. A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods perform as expected. Improvement through Corrective and Preventive Action, applies.

10.2.2. The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.

10.2.3. Quality control failures shall be investigated before release of test results, products, or services.

10.3. Use of Materials

10.3.1. 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.

10.4. Sterility

10.4.1. Aseptic methods shall be employed to minimize the risk of microbial contamination of blood and blood components. Equipment and solutions that come into direct contact with blood or blood components shall be sterile and pyrogen-free. Single-use equipment shall be used whenever possible.

10.5. Identification and Traceability

10.5.1. Process or Procedure Steps; for each critical step in collection and transportation of blood, there shall be a mechanism to identify who performed the step and when it was performed.

10.5.2. Traceability; The BDCC shall ensure that all blood and critical materials used in their processing, as well as laboratory samples and donor and patient records, are identified and traceable.

10.6. General Labelling Requirement

10.6.1. 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.

10.6.2. A unique identification shall be affixed by the collecting or pooling facility to each unit of blood, blood component, and attached container, or a tissue or lot. This identification shall not be obscured, altered, or removed by facilities that subsequently handle the unit.

10.7. Donor Identification

10.7.1. Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.

10.8. Inspection

10.8.1. The BDCS shall have a process to ensure that blood, blood components, tissue, derivatives, and services are inspected at facility-defined stages to verify that specified requirements are met.

10.9. Handling, Storage, and Transportation

10.9.1. The BDCS shall have a process to ensure that blood units, samples, and critical materials (including reagents) are handled, stored, and transported in a manner that prevents damage, limits deterioration, and meets AABB requirements for storage, transportation, and expiration.

10.10. Transportation

10.10.1. Blood units shall be inspected immediately before packing for shipment to DHA DBDC Lab unit only if specified requirements are met (refer to related SOP).

10.10.2. 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.

10.11. Proficiency Testing for Facilities not Subject to US Regulation

10.11.1. BDCS Facilities shall participate in an external proficiency-testing program, if available, for each analyte.

10.11.2. When an external proficiency-testing program is not available, there shall be a system for determining the accuracy and reliability of test results.

10.11.3. Proficiency testing shall include comparison of test results from an outside laboratory.

11. STANDARD SEVEN: DONOR INFORMATION, CONSENTS, AND NOTIFICATIONS

11.1. Donor Education

11.1.1. The BDCC shall have procedures to ensure that the following requirements are met for all donors before donation:

a. Donors are given educational materials regarding the donation process.

b. Donors are given educational materials regarding relevant transfusion-transmitted infections

c. Donors are informed of the importance of providing accurate information.

d. Donors are informed that they should not donate blood in order to obtain infectious disease testing services and that there are circumstances in which testing is not performed.

e. Donors are given education materials regarding the risks of post donation iron deficiency and mitigation strategies.

f. Donors are informed of the importance of withdrawing themselves from the donation process if they believe that their blood is not suitable for transfusion.

g. Donors acknowledge that the educational materials have been read.

11.1.2. When parental permission is required, the collection facility shall have a process to provide information to parent(s) or legally authorized representative(s) of the donor concerning the donation process, and potential adverse effects related to the donation.

11.2. Donor Consent

11.2.1. The consent of all donors shall be obtained on the day of donation and before collection.

11.2.2. Elements of the donation procedure shall be explained to the prospective donor in understandable terms.

11.2.3. The explanation shall include information about risks of the procedure, tests performed to reduce the risks of relevant transfusion-transmitted infections to the allogeneic recipient, and requirements to report donor information, including test results, to state or local health departments.

11.2.4. The donor shall have an opportunity to ask questions and have them answered and to give or refuse consent for donation.

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.

11.3.1. The medical director shall establish a process to notify all donors (including autologous donors) of any medically significant abnormality detected during the predonation evaluation or because of laboratory testing or

recipient follow-up. In the case of autologous donors, the referring physician shall also be notified. Appropriate education, counseling, and referral shall be offered.

11.3.2. BDCS qualified medical physician should notify the donor with any abnormal results found during pre donation testing or screening.

11.3.3. DHA. DBDC shall notify the donors with any abnormal results found post donation according to related AABB standards through a licensed and qualified physician.

11.4. Care of Donors

11.4.1. The collection facility shall have a policy to ensure that the donor qualification process is private and confidential.

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 (refer to DBDC related SOPPHL002 Random Donor Whole Blood Donation).

11.4.3. The collection facility shall have a process for treating donor adverse events and providing for emergency medical care as necessary. Immediate assistance and the necessary equipment and supplies shall be available. (Refer to DBDC related SOP MED007- Monitoring and Managing Blood Donor Reactions)

11.5. Post phlebotomy Instructions

11.5.1. The collection facility shall provide the donor with written instructions about Post phlebotomy care. (Refer to DBDC post donation instruction form).

11.5.2. The collection facility shall provide the donor with written instructions, including actions to take, about adverse events that may occur after donation.

11.6. Post donation Information.

11.6.1. The collection facility shall provide donors with written instructions on how to notify the collection facility with information relevant to the safety of the donation.

11.6.2. The facility shall have a process for managing post donation information about a donor's eligibility received from the donor or a third party.

11.7. Allogeneic Donor Qualification

11.7.1. The prospective blood donor is a healthy individual between the age of 18 to 65 years and meeting the donor qualification requirements contained in the "Donor Eligibility Criteria Requirements for Allogeneic Donor Qualification".(Refer to DBDC donor eligibility criteria form).

11.7.2. 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.

11.7.3. 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.

11.8. Protection of the Recipient

11.8.1. On the day of donation and before collection, the prospective donor's history shall be evaluated and the donor examined to exclude donation by a person with evidence of disease transmissible by blood transfusion or other conditions thought to compromise the suitability of the blood or blood component.

11.8.2. If the collection facility determines that additional clarification or information is needed to evaluate donor eligibility, this information shall be obtained within 24 hours of collection.

11.9. Protection of the Donor

11.9.1. The collection facility shall have processes to minimize the adverse effects of donation.

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.

11.9.3. The collection facility shall have a process to reduce the risk of adverse reactions in young donors. Refer to DBDC related SOP MED 001.

11.9.4. The collection facility shall ensure that donor red cell losses for all donations and samples collected during any rolling 12-month period do not exceed the loss of red cells permitted for whole blood collections.

11.10. Autologous Donor Qualification

11.10.1. Due to the special circumstances related to autologous blood transfusion, rigid criteria for donor selection are not required.

11.10.2. In situations where requirements for allogeneic donor selection or collection are not applied, alternate requirements shall be defined and documented by the medical director. Refer to DBDC related SOP MED006

12. STANDARD EIGHT: DONORS REGISTRATION & SELECTION

12.1. Donors Registration

12.1.1. The DHA main blood donation center (DBDC) has a modern and high quality software to manage donations. For licensed BDCS, authorization to use the same system will be given by DHA to have one platform for donors and donations records.

12.1.2. At registration, the donor is identified with a photo identity card like the emirates ID/police ID/GCC ID and verified by asking the full name and date of the birth and registered in the e-Delphyn system by the emirates ID/ Police ID/GCC ID.

12.1.3. The donor may also use the DHA app (Dammi Service) to read the educational material, fill the donor questionnaire, and then approach for registration with the QR code.

12.1.4. Donors registration to be conducted by qualified and trained health care provider according to DBDC related SOP MED 001.

12.1.5. The system generates a unique donor number for all first-time donors. Repeat donors are linked to existing donor records by the donor number, which is unique for each donor.

12.1.6. Licensed Blood Collection site may accept walk-in donors, subject to internal policies and procedures.

12.1.7. As per UAE. Blood Transfusion standards (28/2008); only UAE. National, national of GCC and official UAE. Residents are allowed to donate blood. Holders of transit or visit visa are not eligible to donate blood in UAE.

12.2. Donor History Questionnaire

12.2.1. It is an important step to ensure donors and patient safety.

12.2.2. The donor accesses the tablet with his/her donor number/emirates ID number/phone number. When the chosen number is entered, the system will verify by asking his/her name, the donor has to verify before he/she can proceed to the next step.

12.2.3. The donor first reads all the educational materials and then answers all the questions in the “Donor History Questionnaire”.

12.2.4. After answering all the questions in the questionnaire, the donor signs the consent at the end and clicks 'submit".

12.3. Donor Selection (Eligibility Criteria)

12.3.1. When donor comes to the screening nurse; the nurse will first confirm the donor identity with a photo identity card like the emirates ID/police ID/GCC ID (5.1.6.4) and verified by asking the full name and date of the birth and is then interviewed by the qualified staff nurse by reviewing the e-questionnaire in the DBDC donor's management software.

12.3.2. If the donor is a regular donor before and previous donation history to be reviewed. "Donor deferral list" for his/her eligibility.(Refer to DBDC related SOP MED001)

12.3.3. If the donor is eligible as per the donor deferral list, then proceed with the donation Process.

12.3.4. If the donor is not eligible for donation as per the donor deferral list, then reason for deferral to be explained to the donor and decision to be made if this deferral in temporary or permanent according to DBDC SOPS.

12.3.5. Donor screening shall be done by licensed, qualified and trained nurse as per AABB related standards and DHA.

12.4. Blood Collection (Refer to related DBDC SOP PHL002 and PHL019)

12.4.1. Blood donation is a standardized medical procedure that ensures safety of donor, and phlebotomy is performed such that the sterility of the collected unit is preserved.

12.4.2. Phlebotomy must be performed only after proper donor identification and the donor has been found to be eligible for blood donation.

12.4.3. Donor will not be accepted if the pre-donation duration interval is less than 8 weeks unless an exceptional approval from the Medical Director.

12.4.4. 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.

12.4.5. If a donor has donated double RBC units and presents for whole blood donation allow a period of 16 weeks interval between them.

12.4.6. The following standard applies-

a. Blood shall be collected into a sterile closed system. Blood collection containers with draw 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.

c. The venepuncture site shall be prepared to minimize risk of bacterial contamination.

12.4.7. 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.

12.4.8. Donor identification: Blood collection facilities shall confirm donor identity and link the repeat donor to existing donor records.

12.5. Blood Units Storage and Transporting (Refer to related DBDC SOP PHL027)

12.5.1. Whole blood after collection should be transported to Dubai Blood Donation Center within specified time and under controlled temperature condition.

12.5.2. Validated transport cool boxes are used along with frozen ice packs to maintain a cooler temperature and plastic shields to separate the ice packs from coming in direct contact with the blood to prevent haemolysis.

12.5.3. The temperature of the transport boxes are monitored regularly throughout the entire journey by validated and calibrated data loggers which is placed carefully between the blood bags.

12.5.4. The following standards applies:

a. Containers shall be qualified to transport blood to ensure that they maintain temperatures within the acceptable range for the expected duration of transport or shipping.

b. Handling, storage and transportation, the collection facility shall have a process to ensure that blood transported in a manner that meets the requirement of storage. Whole blood should be transported for cooling toward 20°C -28°C.

12.6. Ethical Consideration

12.6.1. Blood donation is voluntary. The blood collection site are strictly prohibited from giving any commission to the blood donors

12.6.2. Personnel working in the blood collection site shall be aware of their ethical responsibilities and comply with the DHA Code of Conduct for Healthcare Professionals.

12.6.3. Personnel working in the blood collection site shall maintain donor's information confidentiality at all times.

12.6.4. Healthcare Professionals working in the blood collection site shall not use expired reagents/kits during blood collection. Evidence of documented validation must be readily available for any inspection.

13. STANDARD NINE: SAFETY & INFECTION CONTROL PRACTICES

13.1. General Safety Considerations

13.1.1. Personnel working in Blood Collection site may be exposed to risks from various chemicals, infectious materials, fire hazard, gas leak etc.

13.1.2. The environment is also at risk of being contaminated by hazardous materials used and wastes generated.

13.1.3. Safety therefore includes protection of both the staff and the environment from hazardous materials. General safety measures include:

a. Documentation of Safety Policies and Procedures.

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 shall ensure proper preservation and security of blood units and samples.

j. Blood Collection site 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.

m. An updated list of hazardous materials used in the Blood Collection site shall be maintained. All hazardous materials shall be accounted for on a continuous basis.

n. For reasons of both safety and security, personal belongings (coats, bags, pocketbooks, etc.) must not be kept in the work areas of the laboratories. Personal belongings must be secured in employees' lockers or staff designated areas.

13.2. Hand Hygiene

13.2.1. Any Healthcare Provider, Nurses, Laboratory Technologist, Phlebotomist, Laboratory Attendant involved in direct/ indirect donor care needs to be concerned about hand hygiene and should be able to perform it correctly and at the right time.

13.2.2. Handwashing basins, paper towels should be provided in areas that conduct a medical procedure such as phlebotomy.

13.2.3. Antiseptic Hand Sanitizers should be in single use, non-refillable pouches inserted into dispensers.

13.3. Use of Personal Protective Equipment (PPE)

13.3.1. The mucous membranes of the mouth, nose and eyes are susceptible portals of entry for infectious agents, as well as skin if skin integrity is compromised. Therefore, use of PPE to protect these body sites is essential.

13.3.2. The selection of PPE should be based on the nature of the procedure/anticipated level of exposure and / or the mode(s) of transmission.

13.3.3. These types of PPE such as Gloves, Masks, Disposable coats must be always available and discarded in the Infectious waste bin.

13.4. Environmental Cleaning & Disinfection

13.4.1. Ensure that a good standard of cleanliness and hygiene in procedure areas is observed and maintained following consistent and correct cleaning procedure, using appropriate disinfectants.

13.4.2. Monitoring the cleaning and external surfaces is essential to accurately assess/ gauge the level of compliance, improvement or deterioration of cleaning processes.

13.4.3. The sanitation of equipment must be in accordance to the Manufacturer's Instructions.

13.5. Waste Management

13.5.1. Blood, blood components, tissue and derivatives shall be handled and discarded in a manner that minimizes the potential for human exposure to infectious agents.

13.5.2. 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 bags.

13.5.3. Proper collection, containment and transportation of wastes from the source of generation to central waste collection compound for final disposal must be strictly adhered to in order to minimize significant amount of environmental contamination with microorganisms.

13.5.4. Pre-disposal treatment of Laboratory wastes should be performed prior to disposing to a sanitary sewer line.

13.5.5. 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.

13.5.6. Sharps containers must not be overfilled. When a sharps container becomes two-thirds full, seal and discard it.

13.6. Spillage Management

13.6.1. 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.

13.6.2. Requirement of conducting proper training to all healthcare providers and Housekeeping Services on the usage of the appropriate spill kits is essential.

13.7. Occupational Exposures and Percutaneous Injury

13.7.1. Correct handling and disposal of sharps and proper use of Personnel Protective Equipment minimize the risks of percutaneous injuries and blood borne virus exposure to healthcare providers, donors, patients and visitors.

13.7.2. The blood collection site must adhere to the procedure of managing occupational exposures to percutaneous injuries (needle stick, and sharp injuries), splashes of blood and body fluids, secretions and excretions.

13.7.3. Accident/incident/injuries record of Blood Collection site personnel should be maintained and reported to the designated authority.

13.7.4. 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 Blood Collection site Safety Officer should maintain the records.

14. STANDARD TEN: HEALTH RECORDS

14.1. Laboratory data management includes recording details of the donor medical check-up details, laboratory screening results and archiving the data for future reference.

14.2. The format of recording and reporting results should be described in the SOPs.

14.3. Equipment maintenance reports must be kept for future reference.

14.4. Donor Result Records and materials shall be retained aligned to the Guidelines for Managing Health Records and related AABB standards.

14.5. An internal policy must be available concerning the time keeping of the donors and laboratory reports as either hard copy or soft copy according to the BDCS.

14.6. Internal policies, which should be based on AABB standards. For further information regarding retention of patient result, records and materials refer to **Appendix 4.**

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APPENDIX

APPENDIX 1: GUIDELINES ON STANDARD OPERATING PROCEDURES (SOPS)

1. Clinical Laboratories must develop detailed SOPs that cover both analytical and operational procedures according to the scope of services described in their functional program and provided by the health facility.
2. SOP is a document, which contains detailed, written instructions for both operational and analytical procedures. It describes the stepwise process and technique of performing a test or procedure in the laboratory.
3. SOPs should be simple and written in an easy language to understand.
4. It is important for Analytical SOP documents to be readily available in the working area and to be referred to as laboratory bench work manual.
5. SOPs may contain information on who can perform the test, how to carry out the test including pre-analytical, analytical and post-analytical stages of test/procedure, laboratory conditions required for the test/procedure, routine care and maintenance of equipment, precautions and safety instructions, troubleshooting measures, waste disposal and linkage with reference laboratories.
6. The procedure described in the SOPs must be followed exactly by all staff members to ensure high quality results
7. SOPs are controlled documents and can be changed only with approval of the clinical laboratory quality manager and/or Laboratory Director.

8. SOPs help to ensure uniformity, consistency and control over the processes carried out. They ensure that the procedures are done in exactly the same way each time irrespective of the operator.
9. The Laboratory Director shall ensure that the SOPs are current, titled along with version number, dated and signed.
10. The header of SOP may display the following information on all pages:
    - 10.1. Title of SOP and Document number
    - 10.2. Version number with dates of revision
    - 10.3. Issue number and date of issue of the document
    - 10.4. Page number/Number of pages
11. The Text Of Analytic SOP May Contain Information On:
    - 11.1. Name of test
    - 11.2. Scope of test
    - 11.3. Principle of the test
    - 11.4. Equipment and materials required
    - 11.5. Detailed test procedure including type, quantity and condition of specimen required, sample processing and preparation. Alternative procedure for test in case of breakdown of equipment should also be stated.
    - 11.6. Documentation of results including calculations
    - 11.7. Limit of detection (Analytical sensitivity)
    - 11.8. Analytical Measurement Range (AMR)

11.9. Reference range

11.10. Clinical significance, Inference and limitation of the test

11.11. Critical alert values (shall be reported immediately to the referring physician)

11.12. References of test procedure

11.13. Precautions & Safety

11.14. Quality Control procedures

11.15. Specimen preservation and storage before analysis and after analysis

11.16. Data management.

APPENDIX 2: HEALTH CARE WORKERS RECOMMENDED IMMUNIZATION

Vaccine	Recommendations in brief
Hepatitis B	Give 3-dose series (dose #1 now, #2 in 1 month, #3 approximately 5 months after #2). Give intramuscularly. Obtain anti-HBs serologic testing 1–2 months after dose #3.

APPENDIX 3: GUIDELINES ON QUALITY ASSURANCE

1. All laboratories must have a Quality Assurance Program (QAP) in place to provide Quality Assurance (QA), and to improve their standards when necessary to ensure continuous quality improvement.
2. QA is the total process whereby the quality of laboratory reports can be guaranteed. Incorrect Laboratory results may be due to :
    2.1. Pre-analytical stage: errors occurring during specimen collection
    2.2. Analytical stage: errors occurring during testing and/or while reporting
    2.3. Post-analytical stage: errors occurring during interpreting test results.
3. Quality Manager, designee or competent authorized person should review the quality control data and maintain record of evaluation. The two important tools toward maintaining laboratory quality are:
    3.1. Internal Quality Control (IQC)- for detection and minimization of immediate errors
    3.2. External Quality Assessment (EQA) - for monitoring long-term precision and accuracy of results.
    3.3. The laboratory should treat IQC/EQA samples and patients' specimens alike and use same procedures for analysis
4. Practice of IQC includes the following:
    4.1. Recognition of errors, which arise within the laboratory during analytical stage (testing).
    4.2. Taking steps to minimize errors.

4.3. Equipment & method calibration, method validation.

4.4. For quantitative tests, laboratories should perform IQC every day on tests run daily or every time the tests are run in case of infrequently run tests.

4.5. IQC checks should be employed for qualitative tests wherever applicable.

4.6. IQC for Quantitative Tests: using Levy Jennings's (LJ) chart or any similar chart may be used to plot daily QC values and Westgard rules or any similar may be used to interpret daily QC values.

5. The level of QC per day for Quantitative Tests:

5.1. The following protocol may be adopted by the laboratories according to the total number of specimens analysed per analyte:

5.1.1. Less than 40 per day: apply at least one level QC once a day.

5.1.2. Between 40-80 per day: apply two level QC at least once a day.

5.1.3. More than 80 per day: apply two level QC at least twice a day for such analytes.

5.2. For hematology: 2 level QC (using normal & high or normal & low controls) should be analysed at least once a day although it is preferable to run 3 level QC (using normal, high & low controls) once a day. In high volume testing laboratories at least two level QC per 8 hour maybe analysed.

5.3. The following guidelines will be useful to the laboratories in the practice of IQC using either one level or two level QC materials:

5.3.1. When one level QC is used: Reject test run if following errors occur:

a. Value is outside 3 SD (13s)

b. 2 consecutive values are outside 2 SD on the same side, but within 3 SD (2_{2s})

c. 4 consecutive value are outside 1SD on the same side, but within 2SD (41s)

d. 10 consecutive values are above or below the mean, but within 2 SD (10x)

5.3.2. When two level QC are used: Reject test run if following errors occur:

a. Either QC value is outside 3 SD (13s)

b. Both QC values are outside 2 SD on the same side, but within 3SD (22s)

c. Difference between the two level QC values is >4 SD i.e. one level QC is >2 SD and other level QC is < 2 SD (R4s)

d. 10 consecutive values of the same level QC are above or below the mean, but within 2 SD (10x)

e. 5 consecutive values of one level QC and 5 consecutive values of the other level QC are above or below the mean, but within 2 SD (10x).

5.4. Laboratories need to establish guidelines for responding to out of control situations Tests.

5.5. Tests for which control material is not available or when running of control is not viable due to low volume of tests, the laboratory should apply alternate quality control techniques such as :

5.5.1. Retesting of any randomly chosen specimen/s

5.5.2. Replicate test of specimen by different method, different machine and different person, wherever applicable

5.5.3. Correlation of test results with other parameters

5.6. IQC for Qualitative Tests

5.6.1. Wherever applicable, appropriate controls should be used when a new kit/lot number is used. Built-in test controls should be monitored as well.

5.6.2. For staining procedures, gram stains require both Gram positive and Gram negative control organisms to be used once per week.

5.6.3. IQC should also be run whenever a new lot of the stain procedure kit is used and/or any of the four components of the stain procedure kit is replaced with a new lot

APPENDIX 4: RETENTION OF DONOR RECORDS

Material/Record	**Period of Retention**
Donor acknowledgement that educational materials have been read	10
Consent of Donors	10
Donors placed on permanent deferral, indefinite and on surveillance for protection of recipient	Indefinite
Donor information, including address, medical history, physical examination, health history, or other conditions thought to compromise suitability of blood or blood component (Donor History Questionnaire)	10
A medical order from the patient's physician is required to collect blood for autologous use	10
Identification of individuals performing each significant step in collection, processing and transportation of blood & components	10
Review of donor records to ensure any units from an ineligible donor are quarantined	10
Adverse events related to donation	10
Look-Back investigation	10
Traceability of blood, blood components and critical materials	10
Notification of Abnormal Test Results	10
Other Documents and Records	
Exceptions to Policies, Processes and procedures	10
Emergency Operation Plan tested at defined intervals	2
Job Descriptions	5
Qualification of personnel performing Critical tasks	5
Training Records of Personnel	5
Evaluations of competence of personnel	5
Personnel Records of each employee	5

Record of names, signatures, initials or identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	10
Monitoring and maintenance of equipment/Equipment Qualification	10 after retirement of the equipment
Unique Identification of Equipment	5
Evaluation and participation in selection of suppliers	5
Inspection of incoming Critical Materials and containers	10
Validation of new or changed processes and procedures	5
Participation in Proficiency testing program	5
Quality Control records and review of quality control results for reagents, equipment and methods	10
Equipment Operating Manual	Until equipment is used
Container qualification and process validation records	10
Monitoring of biological, chemical and radiation safety	5
Appropriate Discard of blood and blood components	10
Biannual review of policies, processes and procedures	5
Review and approval of new and revised documents before use	5
Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5