



Ministry of Health

STANDARDS FOR SETTING UP BLOOD ESTABLISHMENTS IN KENYA



Kenya Tissue And
Transplant Authority



DamuKE
The Kenya Blood Banking Management System

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ACRONYMS AND ABBREVIATIONS

AABB	American Association for Blood Banking
AfSBT	Africa Society for Blood Transfusion
BE	Blood Establishment
BMIS	Blood Management Information System
BTU	Blood Transfusion Unit
COC	Clinical Officers Council
ELIZA	Enzyme Linked Immuno-Absorbent Assay
GLP	General Laboratory Practice
GMP	Good Manufacturing Practice
HTC	Hospital Transfusion Committee
ICT	Information Communication and Technology
ISO	International Standards Organization
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
KMPDC	Kenya Medical Practitioners and Dentists Council
KBTTS	Kenya Blood Transfusion and Transplant Service
M&E	Monitoring and Evaluation
MoH	Ministry of Health
NCK	Nursing Council of Kenya
TTI	Transfusion Transmitting Infection
PPB	Pharmacy and Poisons Board
WHA	World Health Assembly
WHO	World Health Organization
QMS	Quality Management System
SDS	Safety Data Sheet

DEFINITION OF TERMS

Blood: A body fluid in the (human) circulatory system that is composed of cellular components suspended in plasma.

Blood Collection: The procedure whereby a single donation of blood is collected in an anticoagulant and/or stabilizing solution, under conditions designed to minimize microbial contamination, cellular damage and/or coagulation activation of the resulting blood donation.

Blood Donor Services: The services related to the donor including mobilization, recruitment, education, blood collection, care retention and notification

Blood Establishment (BE): An entity that performs the functions of recruiting screening and selecting blood donors; collecting, processing receiving, storage of blood units and/or distributing blood products for transfusion purposes.

Blood Grouping: Determination of ABO group for collected blood by testing the red cells with anti-A and Anti-B reagents and by testing the serum for expected antibodies with carefully selected A, O, and B reagent cells.

Blood Product: Any therapeutic substance derived from human blood, including whole blood, blood components and plasma derived products.

Blood Service Entity: An institution or a provider offering blood transfusion services.

Blood Testing Laboratory: A laboratory certified by MoH to conduct transfusion transmissible infection, testing on donated blood and any other immune-haematological tests.

Blood Transfusion Processing Laboratory: A laboratory certified by MoH to transform whole blood into various blood products, including packed red blood cells, platelets, fresh frozen plasma, cryoprecipitate among others and to carry out quality checks on blood and blood components.

Blood Transfusion Service: Encompasses any function relating to blood donor recruitment and education; donor screening and selecting; collection, testing and processing, handling, storage, banking, distribution, transportation and transfusion of blood products.

Blood Transfusion Service Centre: A generic term that refers to all types of facilities dealing with all or either of the following functions: blood donor recruitment and education; donor screening and selecting; collection, testing and processing, handling, storage, banking, distribution, transportation and transfusion of blood products.

Blood Transfusion Units (BTU): A facility located within a hospital that receives and stores already screened blood and blood components, conducts pre-transfusion tests (compatibility testing) on patients' blood samples; issues blood or blood components for clinical transfusion; and monitors blood utilization (hemovigilance).

Distribution: The process of moving blood products within blood establishments within the national blood referral network and to the patients as the end-users.

Donor: A person who voluntarily gives whole blood or one of its components.

Good Distribution Practices: That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded medical products and health technologies.

Good Manufacturing Practice: A system for ensuring that products are consistently produced and controlled in accordance with quality standards.

Hospital Based Satellite: An entity operating within hospital settings and is linked and under the oversight management of a Regional Blood Transfusion Centre or Hospital Blood Transfusion centres. It also performs activities for collection of human blood for transfusion purposes also undertakes processing of blood products, storage and distribution to blood transfusion units for transfusion purposes.

Inventory: Refers to blood products, health products, items and materials sources, produced, used and held by an entity engaged in the activities of human blood donor mobilization and education, collection, processing, testing, storage, distribution, transportation and manufacturing blood transfusion business for selling in the market to earn a profit.

Inventory Management: The process of requesting, storing, issuing, utilizing a product and keeping up-to-date records of every transaction.

Non-Hospital Based Satellite: An entity operating outside hospital settings and is linked and under the oversight management of a Regional Blood Transfusion Centre or Hospital Blood Transfusion centres to perform activities for collection of human blood for transfusion purposes. It also undertakes processing of blood products, storage and distribution to blood transfusion units for transfusion purposes.

Mobile Collection Sites: An outreach to the various target groups for blood donations for transfusion services.

Kenya Blood Transfusion Service: The unit under the Ministry of Health responsible for overseeing blood transfusion services in the country from vein to vein.

Quality: Degree to which a set of inherent characteristics of blood, component, sample or service fulfils established requirements.

Quality System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality for their intended use.

Quarantine: To isolate nonconforming blood, component or materials.

Satellite: Is an entity that is linked and under the oversight management of a Regional Blood Transfusion Centre or Hospital Blood Transfusion centres to performs activities for collection of human blood for transfusion purposes also undertakes processing of blood products, storage and distribution to blood transfusion units for transfusion purposes.

Static Collection Site: A designated blood collection site located outside a blood transfusion centre but under the supervision of a registered blood establishment.

Supply chain: The links and interrelationships among the many organizations, people, resources, and procedures involved in getting health and blood products to intended persons or places.

Third Party Service Providers: Any unaffiliated person, company, or entity that performs blood products related services for an institution as part of a contract.

Transfer: Act of moving inventory from one point to another.

Transportation: Means by which inventory is moved from one point to another.

Voluntary Non-remunerated Donation: Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components on his / her own free will and receives no payment for it, either in cash or kind which could be considered a substitute for money. Small tokens, refreshments are compatible with voluntary, non-remunerated donation.

Whole Blood: Blood collected in an anticoagulant solution with or without additives.

There are terms specifically designed for the purpose of these standards. The term 'SHALL' is used to indicate a mandatory statement and describes the single acceptable activity or method.

The term 'SHOULD' is used to indicate a commonly accepted activity which may have an effective alternative that can be used also.

A glossary is included in the manual for the purpose of defining terms to reflect their usage in the context of these standards.

FOREWORD



Kenya is a signatory to international agreements and resolutions which outline how blood transfusion services are established and managed. These

include the World Health Assembly (WHA) resolution of 1975 which requires each member state to develop a comprehensive, coordinated national blood service based on voluntary non remunerated blood donations; WHA 58.13 of 2005 urges member states to establish or strengthen systems for the recruitment and retention of voluntary non-remunerated donors and implement stringent criteria for donor selection.

The Kenya health sector has re-aligned its policy and strategic direction in line with the Constitution of Kenya 2010 that requires that all citizens access the highest attainable standards of healthcare services including emergency and reproductive health care. Transfusion service is regarded as one of the emergency services and hence availability of safe blood remains one of the Ministry of Health key priorities. The Kenya Blood Transfusion and Transplant Service (KBTTS) under the direction of the Ministry of Health (MOH) is mandated to oversee the blood transfusion and transplant services in Kenya. KBTTS endeavours to ensure that the blood establishments in

the country have the required resources that support the provision of services in accordance with established standards. Despite the tremendous steps by KBTTS to meet the country's needs as per WHO guidance, this has not been fully achieved due to system deficiencies that have the potential risk of compromising the provision of quality and safe transfusion services. The Government of Kenya is committed to providing Universal Health Coverage so as to ensure that individuals and communities have access to quality essential health services without suffering financial hardship. To ensure equitable access to transfusion services there is need to increase the number of blood establishments across the country. The Standards for setting up Blood Establishments in Kenya stipulates the basic minimum requirements needed to set up a blood establishment in Kenya to ensure that quality and uniformity is maintained. We look forward to working collaboratively across the National and County Governments, faith-based organizations and private sector in implementation of the stipulated Standards for setting up Blood Establishments in Kenya.

A handwritten signature in black ink, appearing to read 'Patrick Amoth'. The signature is stylized and cursive.

Dr. Patrick Amoth, EBS

Ag. Director General for Health

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The Standards for setting up Blood Establishments in Kenya is a product of collaborative effort of various stakeholders.

The stakeholders who participated

in various stages of development of this document include the Council of Governors, County departments of health, regulatory bodies, academia, national and county health facilities, Ministry of Health representatives, development partners and implementation partners, faith-based organizations, and private sector.

The Ministry of Health appreciates the support provided in the development of the Standards by various stakeholders. Particularly, the financial and technical support given by the World Bank and Africa Resource Centre (ARC).

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A handwritten signature in black ink, appearing to read 'Julius Ogato', with a long horizontal line extending to the right.

Dr. Julius Ogato

Ag. Head, Directorate of Health Care Services

EXECUTIVE SUMMARY



The Ministry of Health is committed to improving quality and safety of blood services, improving accessibility, and enhancing sustainability. Well defined standards

for setting up blood establishments are intended to improve the blood transfusion services in the country. The standards described in this document provide the minimum requirements to be met by entities engaged in the processes of blood collection, processing, testing, and manufacturing.

This document will help the Kenya Blood Transfusion and Transplant Service (KBTTTS), the regulatory bodies and all entities that engage in the process of blood donor recruitment and education, donor screening and selecting, collection, testing and processing, handling, storage, banking, distribution, transportation and transfusion of blood products to understand the basic standards required to set up, operate and handle blood products in the most efficient way and thereby provide quality service delivery.

The target audience include the public, private, faith-based, community based and non-governmental organizations; regulatory authorities, government departments and third party service providers involved in blood donor recruitment and education, donor screening and selecting, collection, testing and processing, handling, storage, banking, distribution, transportation and transfusion of blood products and those engaged in regulation, oversight, funding and accreditation of national blood transfusion systems and programmes and policymakers in various government departments that are involved in reforming or improving blood services systems.

This document describes the:

- Blood supply key principles as guided by WHO.
- Overarching principles for management of blood products in Kenya.
- Operating environment for blood service entities.

- Factors to be considered when setting up blood establishments.
- Classification of and functions of blood establishments.
- Requirements for blood establishments.
 - a. Premises and space.
 - b. Staffing.
 - c. Equipment.
- Quality management systems, biosafety, biosecurity, and waste management considerations.
- Training and research.
- Registration and licensing requirements.

In addition to the standards provided in this document, all the target audience are urged to make use of other clinical guidelines, manuals and standard operating procedures while delivering services to the clients.

As a Ministry of Health, we expect that all registered entities and players within the blood ecosystem will adhere to set standards as per this Standards for setting up Blood Establishments in Kenya.



Dr. Nduku Kilonzo, PhD, EBS
Head, Kenya Blood Transfusion and Transplant Service

01.

INTRODUCTION

1.1 Background

According to the Constitution of Kenya (Section 43), it is the right of each person to access the highest attainable standard of health, which include the right to healthcare services that encompass blood products for transfusion services. Through the Ministry of Health (MoH), Kenya has adopted Universal Health Coverage as one of the priority agenda which envisages that all persons should have access to quality healthcare services they need. To achieve the UHC goal, the Government of Kenya is investing in a well-coordinated and regulated system that ensures affordable, quality, and safe blood products for transfusion services.

The World Health Organization (WHO) guidelines on blood need requirements estimate blood needs of a country to be 1 to 3% of the total population. Based on the 2019 Kenya Population and Housing Census Reports, the Kenya population was estimated at 47.5 million. This translates to 475,000 blood units annually. Since establishment of Kenya Blood Transfusion Unit in early 2000, the annual target has never been met and the collection drastically dropped in the year 2020 due to outbreak of COVID 19. However, by mid-2021, the Kenya Blood Transfusion and Transplant Service (KBTTTS) managed to collect about 40% of blood units, the highest ever collection over the last 20 years.

1.2 Rationale

Kenya Blood Transfusion and Transplant Service has endeavoured to meet the country's blood products needs as per WHO guidelines, however, this has not been achieved. To address the challenge of blood products shortages, many entities are engaging in activities of collection, processing, testing, and banking, which is likely to compromise the provision of quality and safe transfusion services. The guidance for setting up and operating the entities that engage in blood products has been lacking.

1.3 Mandate of KBTTTS

The Kenya Blood Transfusion and Transplant Service (KBTTTS) mandate include to:

- Formulate and oversee the implementation of policies for national blood transfusion and transplant services.
- Provide technical assistance and capacity building on blood transfusion services to both National and County Health services.
- Develop a comprehensive and coordinated national blood service based on voluntary non remunerated blood donations to guarantee availability of adequate and safe blood.

- Establish settings and mechanisms that will enable it to superintend, regulate and provide blood transfusion services in the Republic of Kenya as required by this Act or any other written law.
- Develop guidelines and standards for blood service in Kenya.

1.4 Purpose of the Standards

The purpose of this document is to provide standards for establishing Blood Transfusion Service (BTS) centres in Kenya. The standards provide the minimum requirements to be met by entities engaged in any functions related to blood products for transfusion purposes.

1.5 Objectives

The objectives of this Standards are to:

- 1.5.1 Provide guidance on minimum requirements for entities engaged in activities related to blood products for the purpose of transfusion.
- 1.5.2 Define the classification and functions of entities engaged in the activities of blood donor recruitment and education; donor screening and selecting; collection, testing and processing, handling, storage, banking, distribution, transportation, manufacturing

and transfusion of blood products.

1.6 Scope

This document covers the minimum requirements for setting up entities that engage in the blood donor recruitment and education; donor screening and selection; collection, testing and processing, handling, storage, banking, distribution, transportation, manufacturing, and transfusion of blood products.

1.7 Target Audience

The standards are intended for use by:

- 1.7.1 Public, private, faith-based, community-based, and non-governmental organizations engaged in activities relating to blood donor recruitment and education, donor screening and selection, collection, testing and processing, handling, storage, banking, distribution, transportation, manufacturing, and transfusion of blood products.
- 1.7.2 Regulatory authorities and mandated agencies involved in the regulation, oversight, funding and accreditation of blood transfusion services.
- 1.7.3 Policymakers involved in blood transfusion services.

1.8 Blood Supply Key Principles

A safe blood supply system depends on the following key principles including those that have been set out by the World Health Organization (WHO):

- 1.8.1 Establishment of a Kenya Blood Transfusion Service.
- 1.8.2 Collection of blood from only voluntary, non-remunerated, low-risk blood donors.
- 1.8.3 Screening of all donated blood for transfusion-transmissible infectious agents.
- 1.8.4 Reduction in unnecessary transfusions through the effective clinical use of blood.
- 1.8.5 Quality systems covering the entire transfusion process, from donor recruitment to follow-up of the recipients of transfusion.
- 1.8.6 Secure and efficient blood products supply chains.

02.

OVERARCHING PRINCIPLES FOR MANAGEMENT OF BLOOD PRODUCTS IN KENYA

The standards are based on the following tenets for essential healthcare according to the Kenya Health Policy 2014-2030.

- 2.1.1 Blood is a national resource that should benefit all recipients in need.
- 2.1.2 Blood transfusion services will be guided by the principles and practices of social accountability, that include reporting on performance, creation of public awareness and fostering transparency.
- 2.1.3 Ensuring provision of quality, safe and adequate blood products through supporting nationally coordinated blood transfusion services.
- 2.1.4 Ensuring equitable sharing of blood products as a national resource.
- 2.1.5 Promoting efficiency in the application of health technologies.
- 2.1.6 Blood is a special commodity that can only be obtained from human beings. Its availability depends entirely on the altruism of blood donors. Blood is a critical part of emergency care; hence needs to be readily available.
- 2.1.7 Ensuring efficiency, security and safety of blood products throughout supply chains.

03.

OPERATING ENVIRONMENT FOR BLOOD SERVICE ENTITIES

- 3.1.1 There shall be a national blood referral network established by the Kenya Blood Transfusion and Transplant Service (KBTTTS).
- 3.1.2 All blood entities shall comply with the national standards for blood transfusion services.
- 3.1.3 All blood establishments shall operate within the approved blood transfusion service network including mobile collection drives and activities.
- 3.1.4 All blood service entities shall be registered by the relevant authorities.
- 3.1.5 KBTTTS shall maintain and update a register of all entities engaged in blood services.
- 3.1.6 All blood service entities shall comply with the national standards and guidelines.
- 3.1.7 All importation and exportation of blood products shall be undertaken in line with regulations and guidelines from Pharmacy and Poisons Board (PPB).
- 3.1.8 A declaration shall be made to the Director General for all importation and exportation of blood products.
- 3.1.9 Inspection to oversee compliance shall be undertaken routinely.
- 3.1.10 KBTTTS shall provide routine feedback and update reports to blood establishments.

04.

ESTABLISHING BLOOD TRANSFUSION ENTITIES

4.1 The entities that engage in the activities of blood donor recruitment and education, donor screening and selecting, collection, testing and processing, handling, storage, banking, distribution, transportation, manufacturing and transfusion of blood products shall be referred as Blood Establishments (BE).

4.2 The blood establishment shall be classified based on scope of functions.

4.3 The following factors shall be considered for all blood establishments.

- Blood need and supply.
- Location.
- Access.
- Infrastructure.
- Financial resources to ensure quality services, adequate equipment, and staffing.

4.3.1 Blood Need and Supply

4.3.1.1 The blood need and supply across the country is not uniform and is based on population, number and capacity of health facilities and health status of the population. Prevalence of

malaria, anaemia, HIV and AIDS among other infections makes some areas less able to mobilize healthy blood donors to donate blood than others.

4.3.1.2 The setting up of a BE centre should be informed by demand and supply.

4.3.2 Location and Access

4.3.2.1 A BE should be set-up based on need.

4.3.2.2 Non-hospital BEs should make consideration for access to transport and populations.

4.3.3 Infrastructure

4.3.3.1 Infrastructure for BE relates to all the physical infrastructure, equipment, transport, power source, water, and technology (including ICT) required for effective delivery of blood services.

4.3.3.2 Every BE should meet the described infrastructure requirements in (4.3.3.1).

4.3.4 Financial Resources

4.3.4.1 Financial capacity to support quality services, adequate equipment and staffing are required to set up and sustain a BE.



4.3.5 Functions of Blood Services Entities

The following are functions of the Blood entities:

- Recruitment of donors.
- Education and mobilization of donors.
- Donor selection.
- Donor Counselling.
- Donor notification.
- Blood collection.
- Labelling of blood products.
- Blood testing.
- Blood products processing.
- Aliquoting and archiving.
- Storage and banking of blood products.

- Distribution of blood products.
- Transportation of blood products.
- Data collection and reporting through the national information system.
- Inventory management for blood products.
- Inventory management for health commodities.
- Quality control and Quality assurance.
- Hemovigilance.
- Manufacturing of blood products.

05.

BLOOD SERVICE ENTITIES

5.1 Blood Service Entities

- Blood Establishments.
- Third Party entities engaged in blood services.



06.

CLASSIFICATION AND FUNCTIONS OF BLOOD ESTABLISHMENTS



There following are seven (7) classes of blood establishments based on scope of functions that are interdependent:

- i. Blood Transfusion Unit (BTU).
- ii. Blood Collection Centre (BCC).
- iii. Hospital Blood Transfusion Centre (HBTC).
- iv. Blood Transfusion Satellite Centre (BTSC).
- v. Regional Blood Transfusion Centre (RBTC).
- vi. Blood Reference Laboratory- (BRL).
- vii. Blood Manufacturing Establishment (BME).

6.1 Blood Transfusion Unit

6.1.1 An establishment within a transfusing hospital where the storage and issuing of blood products is done for transfusion purposes.

6.1.2 Shall be licensed by Kenya Medical Practitioners and Dentists Council (KMPDC) as a Transfusing facility.

6.1.3 The laboratory shall be registered by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).

6.1.4 Service providers shall be duly registered and licensed.

6.1.5 Functions

- i. Receipt of blood products from registered blood entity.
- ii. Storage of screened, processed, and safe to transfuse blood products.
- iii. Inventory management for blood products.
- iv. Inventory management for health commodities.
- v. Maintain equipment for blood products storage and adhere to storage requirements.
- vi. Carry out compatibility testing.
- vii. Issue blood products to the wards.
- viii. Carry out hemovigilance activities and reporting as per national requirements.
- ix. A transfusing hospital shall establish and maintain functional Hospital Transfusion Committee (HTC).
- x. Maintain and report on data and information related to blood products as per national requirements.

- xi Quality control and quality assurance for all BTU related processes, procedures and activities.
- xii Comply with waste discard and management procedures.
- xiii Operate within the approved blood referral network.
- xiv Ensure every consignment is accompanied by relevant documentation clearly indicating the consignment details, the source and destination.
- xv Perform repair and preventive maintenance on all equipment.

6.2 Blood Collection Centre

- 6.2.1 An establishment that performs activities for collection of human blood for transfusion purposes.
- 6.2.2 A blood collection centre can be mobile or static.
- 6.2.3 Shall be under the oversight of, and linked to a registered hospital blood transfusion centre, a blood transfusion satellite or a regional blood transfusion centre.
- 6.2.4 Service providers shall be duly registered and licensed.

6.2.5 Functions

- i Donor recruitment.
- ii Donor education and mobilization.
- iii Donor selection.
- iv Donor Counselling.
- v Blood collection.
- vi Donor notification.
- vii Appropriate storage of blood.
- viii Appropriate Labelling of blood samples and products.
- ix Maintain and report on data and information related to blood products.
- x Inventory management for blood products.
- xii Inventory management for health commodities.
- xiii Carry out hemovigilance activities and reporting as per national requirements.
- xiv Maintain and report on data and information related to blood products as per national requirements.

- xv Quality control and quality assurance for all BTU related processes, procedures, and activities. storage and distribution to BTUs for transfusion purposes.
- xvi Comply with waste discard and management procedures. 6.3.2 Satellites refer their samples to their mapped testing centre.
- xvii Transfer all blood collected to a registered blood establishment. 6.3.3 A satellite can be hospital or non-hospital based.
- xviii All blood products shall be handled by registered blood service entities, including transportation and distribution. 6.3.4 The laboratory shall be registered by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).
- xix Shall be mapped to a registered blood establishment that undertakes testing. 6.3.5 Service providers shall be duly registered and licensed.
- xx Shall operate within the approved blood referral network. **6.3.6 Functions**
- xxi Ensure every consignment is accompanied by relevant documentation clearly indicating the consignment details, the source and destination. i Donor recruitment.
- ii Donor education and mobilization.
- iii Donor selection.
- iv Donor Counselling.
- v Blood collection.
- vi Donor notification.
- vii Appropriate storage of blood.
- viii Appropriate Labelling of blood samples and products.
- ix Maintain and report on data and information related to blood products.
- 6.3 Blood Transfusion Satellites Centres**
- 6.3.1 An entity that performs the functions of a blood collection centre and undertakes processing of blood products,

- x Inventory management for blood products. 6.3.7 Receipt of blood products can only be from or to a registered blood establishment.
- xi Inventory management for health commodities. 6.3.8 Sorting and distribution of blood products shall be for registered blood establishments.
- xii Perform repair and preventive maintenance on all equipment. 6.3.9 All blood products shall be handled by registered blood service entities, including transportation and distribution.
- xiii Quality control and quality assurance.
 - a Carry out hemovigilance activities and reporting as per national requirements. 6.3.10 Shall operate within the national blood referral network.
 - b Maintain and report on data and information related to blood products as per national requirements. 6.3.11 A hospital with a hospital-based satellite shall establish and maintain a functional hospital transfusion Committee.
 - c Ensure quality control and quality assurance for all BTU related processes, procedures and activities. 6.3.12 Every consignment shall be accompanied by relevant documentation clearly detailing the consignment details, the source and destination.

6.4 Hospital Blood Transfusion Centre

- xiv Processing of blood for blood products
 - a Component preparation. 6.4.1 Any hospital entity that performs activities of a BTU and a Blood Transfusion Satellite and additionally undertakes the function of testing and transfusion services.
 - b Aphaeretic collections. 6.4.2 Shall be licensed by Kenya Medical Practitioners and Dentists Council (KMPDC) as a Transfusing facility.

- 6.4.3 The laboratory shall be registered by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB). xi Inventory management for blood products.
- 6.4.4 Service providers shall be duly registered and licensed. a Inventory management for health commodities.
- b Quality control and quality assurance.
- 6.4.5 Functions.**
- i Donor recruitment. c Carry out hemovigilance activities and reporting as per national requirements.
- ii Donor education and mobilization. d Establish and maintain functional Hospital Transfusion Committee (HTC).
- iii Donor selection.
- iv Donor Counselling. e Maintain and report on data and information related to blood products as per national requirements.
- v Blood collection.
- vi Donor notification. f Ensure quality control and quality assurance for all processes, procedures and activities.
- vii Appropriate storage of blood.
- viii Appropriate labelling of blood samples and products. g Comply with waste discard and management procedures.
- ix Maintain and report on data and information related to blood products.
- x Perform repair and preventive maintenance on all equipment. xii Processing of blood for blood products.
- a Component preparation.
- b Aphaeretic collections.

- 6.4.6 Testing of blood shall in line with national standards.
- 6.4.7 Where a HBTC is receiving blood samples for testing from registered blood establishments, it shall be mapped in the national blood referral network.
- 6.4.8 Receipt or Transfer of blood products can only be from or to a registered blood establishment.
- 6.4.9 Where a HBTC is receiving, transferring blood products from registered blood establishments, it shall be mapped in the national blood referral network.
- 6.4.10 All blood products shall be handled by registered blood service entities, including transportation and distribution.
- 6.4.11 HBTC shall operate within the national blood referral network.
- 6.4.12 Every consignment shall be accompanied by relevant documentation clearly detailing the consignment details, the source and destination.

6.5 Regional Blood Transfusion Centre

- 6.5.1 An establishment that performs functions of a blood transfusion satellite, undertakes the function of testing, acting as a sample referral centre for hospital and periphery collection sites. In addition RBTCs include Hv and QA activities for BEs units remarks aggregated testing, hemovigilance and quality assurance for blood. Collection centres, blood transfusion units and satellites, and hospital-based transfusion centres in its network and liaises with other networks.
- 6.5.2 Regional Blood Transfusion Centre (RBTC) shall be affiliated and over sighted by the Kenya Blood Transfusion and Transplant Service.
- 6.5.3 The laboratory shall be registered by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).
- 6.5.4 Service providers shall be duly registered and licensed.
- 6.5.5 Regional blood transfusion head shall support quality management systems, ensure adherence and oversee compliance.

6.5.6 Functions		ix	Sorting and distribution to BTUs.
i	Donor recruitment.	x	Carry out hemovigilance activities and reporting as per national requirements.
ii	Donor education and mobilization.		
		xi	Maintain and report on data and information related to blood products as per national requirements.
iii	Donor selection.		
iv	Donor Counselling.		
v	Blood collection.	xii	Ensure quality control and quality assurance for all BTU related processes, procedures and activities.
vi	Donor notification.		
vii	Appropriate storage of blood.		
viii	Appropriate Labelling of blood samples and products.	xiii	Comply with waste discard and management procedures RBTCs shall carry out at the basic minimum following tests from referral sites as per the national guidelines and regulations.
ix	Maintain and report on data and information related to blood products.		
		a	TTI screening.
x	Inventory management for blood products.		
		b	Blood Grouping.
xi	Inventory management for health commodities.		
		c	Haematological tests.
xii	Quality control and quality assurance.	xix	Carry out aliquoting and archiving.
xiii	Processing of blood for blood products.	xx	Support supervision to the BEs within their network.
a.	Component preparation.	6.5.7	RBTC shall provide oversight to entities in their networks to include:
b.	Aphaeretic collections.		

- i Blood Transfusion Units.
- ii Blood Collection Centres.
- iii Blood Transfusion satellite Centres.
- iv Hospital Blood Transfusion centres.
- v Third part entities.

6.5.8 Where a RBTC is receiving blood samples for testing from registered blood establishments, it shall be mapped in the national blood referral network.

6.5.9 Where a RBTC is receiving, transferring blood products from registered blood establishments, it shall be mapped in the national blood referral network.

6.5.10 Receipt or Transfer of blood products can only be from or to a registered blood establishment.

6.5.11 All blood products shall be handled by registered blood service entities, including transportation and distribution.

6.5.12 A RBTC shall operate within the national blood referral network.

6.5.13 Every consignment shall be accompanied by relevant documentation clearly detailing the consignment details, the source and destination.

6.6 Blood Reference Laboratory

6.6.1 Is a laboratory that provides basic and specialized testing, references, internal and external quality assessment, standardization, validation of standards, verification and methodological guidance to other laboratories for blood and blood disorders.

6.6.2 Shall be licensed by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).

6.6.3 Functions

- i Basic and specialized tests.
- ii Provide a standard for references.
- iii Provide referral service for blood services.
- iv Provide confirmatory testing services for blood.
- v Carry out surveillance and research.
- vi Capacity building of the laboratory personnel.
- vii Maintain quality assurance programs for laboratory test.

- viii Provide proficiency testing.
- ix Provide inter-laboratory comparisons.
- x Carry out internal and external audits.
- xi Perform technical evaluation of reagents and diagnostic tests.
- xii Shall be part of the blood national referral network.
- xiii All blood samples and products to, from and within the laboratory shall be handled by registered blood service entities, including transportation and distribution.
- xiv Personnel shall be registered and licensed by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).
- xv Every consignment shall be accompanied by relevant documentation clearly indicating the consignment details, the source and destination.
- x Perform repair and preventive maintenance on all equipment.

6.7 Blood Manufacturing Establishment

- 6.7.1 Is an establishment that utilizes plasma that manufactures blood and plasma derived products.
- 6.7.2 Its function is manufacture of plasma derived products.
- 6.7.3 Shall be registered and licensed by the Pharmacy and Poisons Board.
- 6.7.4 Blood Manufacturing Establishment shall source plasma from registered blood establishments.
- 6.7.5 Every consignment shall be accompanied by relevant documentation clearly indicating the consignment details, the source and destination.

6.8 Third Party Service Entities

- 6.8.1 An entity engaged in the function of handling, distributing and transportation of blood samples and products.
- 6.8.2 A third party blood services entity shall be registered by KBTTS.

6.8.3 The entity shall adhere to the national standards for handling, distribution, and transportation of blood products prior to registration.

6.8.5 The entity shall handle, distribute, and transport blood samples and products within the defined blood service networks.

6.8.4 Every consignment shall be accompanied by relevant documentation clearly indicating the consignment details, the source and destination.

Name	Ref	Functions
Blood transfusion unit	BTU	Located in a hospital that receives blood products for grouping, cross-match and release to wards for transfusion.
Blood Collection Centre	BCC	Undertakes collection and storage of human blood products for transfusion purposes.
Blood Transfusion Satellites Centres	BTSC	Undertakes blood component separation, in addition to the functions of blood collection centre.
Hospital Blood Transfusion Centre	BTC	Located in a hospital and undertakes blood testing including screening and typing in addition to the functions of blood transfusion satellite centres and blood transfusion units.
Regional Blood Transfusion Centre	BBC	Undertakes the function of testing, including screening and typing, acting as a sample referral centre for hospitals and periphery collection sites. RBTCs undertake hemovigilance and quality assurance activities for blood establishment within its networks and liaises with other networks. RBTC are affiliated with the Kenya Blood Transfusion and Transplant Service.
Blood Reference Laboratory	BRL	A laboratory providing basic and specialized testing, reference services and coordination of inter-laboratory testing.
Blood manufacturing Establishments	BME	An entity that utilizes blood to manufacture blood and plasma derived products.
3rd Party Service Entities	BSE	Entities engaged in the function of handling, distributing and transportation of blood samples and products.

07.

REQUIREMENTS FOR SETTING UP BLOOD ESTABLISHMENTS

7.1 Premises

- 7.1.1 The specific establishment to be of recommended size, construction standards, and location to facilitate its proper operation, maintenance, and minimize the risk of occupational injury to the staff personnel and donors.
- 7.1.2 The premise design should allow proper work flow, space requirements, visual and acoustic privacy.
- 7.1.3 The construction materials used need to allow effective cleaning. Walls and floors should be non-absorbent, and should not have any holes, cracks and joints.
- 7.1.4 Work benches and other furniture should be made from material that is easy to clean. No curtains, window blinds, carpets or unsealed wood should be used in areas where donations and samples are handled, tested, processed or stored.
- 7.1.5 Physical separation of work areas should be ensured for example, processing, testing and labelling work areas should be separated.

- 7.1.6 An uninterrupted power supply should be available for critical equipment, especially component storage facilities.
- 7.1.7 Environmental control systems (for example, temperature controls and alarms) should be installed in all donations, component and sample handling, testing, processing and storage areas. Any temperature and/or humidity restrictions stipulated in the operating specifications for equipment used in these areas should be adhered to.
- 7.1.8 The following standards should be adhered to when constructing a blood establishment:
 - i The space shall be hygienic, safe, and away from open sewerage and public lavatories.
 - ii Adequate ventilation and lighting shall be provided for all technical activities that take place as per public health regulation.
 - iii The lay out of the service shall take into account the work flow and space demands. Required rooms/space include: waiting bay, donor reception and registration, record, donor pre- counselling and screening,

post-counselling, blood donation, post-donation care, sample preparation, blood quarantine, testing, processing, sorting and dispatch, blood storage, waste disposal, cleaning, sleuth, linen room, health commodities store, open plan offices, kitchen, staff toilets/bathrooms, donor toilets.

- iv Restricted access to all functional areas except the donor area. These areas shall be restricted to authorized personnel only.
- v A continuous water supply and uninterrupted power supply round the clock.
- vi The walls and floors of the rooms shall be smooth, easily washable and kept clean.

7.2 Space Requirements for Blood Establishments

- 7.2.1 The Blood Manufacturing establishment shall adhere to premises requirements provided in the WHO guidelines on good manufacturing practices for blood establishments.
- 7.2.2 Blood Transfusion Units, Blood Collection Centre, Sub-regional Blood Transfusion Satellite Centres, Hospital Blood Transfusion Centres, Regional Blood Transfusion Centres, and National Blood Reference Laboratory shall have the following minimum space requirements.

S/ No.	Space	Purpose	Blood Transfusion Units	Blood Collection Centre
Assumptions				4 couches/ 100 units per day
	Waiting area Reception	Size will depend on expected number of Donors	Allow for a minimum of 9 m ²	Allow 1.5 m ² for each person waiting. A minimum of 9m ² for the reception area
	Donor records	Should be accessible to the reception so that records can be retrieved on donor arrival		Allow for a minimum of 12 m ²
	Interview room(s) /	Rooms for collection of confidential and medical information as well as counselling		Allow for minimum 1 No. rooms each 7 m ²
	Haemoglobin screening	Room for Hb testing for potential donors		Allow for a minimum 1 No. room of 7m ²
	Examination room	Room for detailed medical procedure for first timers or returning		Allow for minimum 1 No. rooms each 9m ²
	Donation area	Space for couches and adjacent consumables storage. Additional space may be required if aphaeresis is carried out		Allow for 9m ² per donation couch
	Checking/ holding	Physical checking of collected units and donor samples prior to transportation to Holding facility or laboratory	Allow for a minimum of 12 m ²	Allow a minimum of 12m ²
	Donor care room	Space for donor treatment and recovery in case of an adverse reaction during or after donation		Allow for a minimum of 1No. room of 6 M ²
	Donor lounge	Post-donation lounge for donor recovery and refreshments		Allow for a minimum of 1No. room of 24 M ²
	Staff area	May include multi-purpose staff lounge and tearoom	Allow for 15 m ²	Provide for a minimum of 12 M ²

Hospital Transfusion Centre	Blood Transfusion Satellite Centre	Regional Blood Transfusion Centres	Blood Reference Laboratory
	10 couches/ 160 units per day	10 couches/ 160 units per day	
Allow a minimum of 15 m ² for waiting areas and a minimum of 9m ² for the reception area	Allow a minimum of 15 m ² for waiting areas and a minimum of 9m ² for the reception area	Allow a minimum of 30 m ² for waiting areas and a minimum of 9m ² for the reception area	
Allow for a minimum of 12m ²	Allow for a minimum of 12m ²	Allow for a minimum of 12 m ²	Allow for a minimum of 16 m ²
Allow for minimum 2 No. rooms each 7 m ²	Allow for minimum 2 No. rooms each 7 m ²	Allow for minimum 4 No. rooms each 7 m ²	
Allow for a minimum 1 No room of 7m ²	Allow for a minimum 1 No room of 7m ²	Allow for a minimum 2 No room of 7m ²	
Allow for minimum 1 No. rooms each 9m ²	Allow for minimum 1 No. rooms each 9m ²	Allow for minimum 2 No. rooms each 9m ²	
Allow for 9m ² per donation couch.	Allow for 9m ² per donation couch.	Allow a minimum of 10m ² per aphaeresis couch	
Allow a minimum 1no. rooms of 12m ²	Allow a minimum 1no. rooms of 12m ²		
Allow for a minimum of 1No. room of 6 M ²	Allow for a minimum of 1No. room of 6 M ²	Allow for a minimum of 1No. room of 12 M ²	
Allow for a minimum of 1 No. room of 30m ²	Allow for a minimum of 1 No. room of 30m ²	Allow for a minimum of 1 No. room of 60m ²	
Provide for a minimum of 16 M ²	Provide for a minimum of 16 M ²	Provide for a minimum of 16 M ²	Provide for a minimum of 36 M ²

S/ No.	Space	Purpose	Blood Transfusion Units	Blood Collection Centre
Assumptions				4 couches/ 100 units per day
	Offices	Facility management/ administrative staff	Provide for 12 m ²	Provide for a minimum of 2 No. offices of 9 M ²
	Boardroom	Meeting room for training and meetings	Provide for a minimum 18 m ²	-
	Store	Supplies for donor screening, blood Collection etc	Allow for 12 m ²	Provide for a minimum of 12 M ²
	Kitchenette	Storage and warming of food for staff	Provide for a minimum of 5m ²	Provide for a minimum of 3 M ²
	Pantry	Supplies and preparation of donor snacks and drinks post donation	Provide for a minimum of 8 m ²	Allow for a minimum of 8 M ² room
	Laundry/ linen	For linen and laboratory coats etc		Allow for a minimum of 2M ² linen bay for linen on trolley. Provide external laundry services where unavailable
	Sluice room			
	Cleaning room	Storage of cleaning equipment and waste And clean materials		Allow for a minimum of 4 M ²
	Toilets	Toilets for staff and donors, provide separate facilities for males and females	Allow for a Minimum of 3 no rooms of 3 m ²	Allow for a minimum of 3No. of 3M ² each

Hospital Transfusion Centre	Blood Transfusion Satellite Centre	Regional Blood Transfusion Centres	Blood Reference Laboratory
	10 couches/ 160 units per day	10 couches/ 160 units per day	
Provide for a minimum 3 No. offices of 9 M ² each	Provide for a minimum 3 No. offices of 9 M ² each	Provide for a minimum 4 No. offices of 9 M ² each	Provide for a minimum 4 No. offices of 9 M ² each
Provide for a minimum of 18 M ²	Provide for a minimum of 18 M ²	Provide for a minimum of 18 M ²	Provide for a minimum of 18 M ²
Provide for a minimum of 1 No. room of 16 M ²	Provide for a minimum of 1 No. room of 16 M ²	Provide for a minimum of 1 No. room of 20 M ²	Provide for a minimum of 1 No. room of 20 M ²
Provide for a minimum of 3 M ²	Provide for a minimum of 3 M ²	Provide for a minimum of 6 M ²	Provide for a minimum of 6 M ²
Allow for a minimum of 8 M ² room	Allow for a minimum of 8 M ² room	Allow for a minimum of 8 M ² room	Allow for a minimum of 2 M ² room
Allow for a minimum 1No. room of 5M ²	Allow for a minimum 1No. room of 5M ²	Allow for a minimum 1No. room of 10 M ²	Allow for a minimum 1No. room of 10 M ²
Allow for a minimum 1No. room of 4 M ²	Allow for a minimum 1No. room of 4 M ²	Allow for a minimum 1No. room of 4 M ²	
Allow for a minimum of 4 M ²	Allow for a minimum of 4 M ²	Allow for a minimum of 4 M ²	Allow for a minimum of 4 M ²
Allow for a minimum of 3No. of 3M ² each	Allow for a minimum of 3No. of 3M ² each	Allow for a minimum of 3No. of 6M ² each	Allow for a minimum of 2No. of 2M ² each for male and female

S/ No.	Space	Purpose	Blood Transfusion Units	Blood Collection Centre
Assumptions				4 couches/ 100 units per day
	Blood reception area	Physical checking of collected units and donor samples from different blood establishments		
	TTI testing labs			
	Blood Grouping and cross match		Provide for minimum 1 No room of 25m ²	
	Component preparation lab			
	Quarantine storage room		Provide for minimum 1 no room of 12m ²	
	Labelling/ sorting room			
	Cold Storage			
	Waste holding		Provide for a minimum of 4 m ²	
	Loading bay/ parking lots		Minimum of 2 no Parking lots	Minimum of 2No parking lots

Hospital Transfusion Centre	Blood Transfusion Satellite Centre	Regional Blood Transfusion Centres	Blood Reference Laboratory
	10 couches/ 160 units per day	10 couches/ 160 units per day	
Allow for a minimum of 1No. of 12M ²	Allow for a minimum of 1No. of 12M ²	Allow for a minimum of 1No. of 12M ²	Allow for a minimum of 1No. of 4M ²
Provide for minimum 1 No. labs of 20 m ²	Provide for minimum 1 No. labs of 20 m ²	Provide for minimum 1 No. labs of 25m ²	Provide for minimum 2 No. labs of 25m ²
Provide for minimum 1 No. labs of 25m ²	Provide for minimum 1 No. labs of 25m ²	Provide for minimum 1 No. labs of 25m ²	Provide for minimum 1 No. labs of 25m ²
Provide for minimum 1No. room 25m ²	Provide for minimum 1No. room 25m ²	Provide for minimum 1No. room 25m ²	Provide for minimum 1No. room 25m ²
Provide for minimum 1 No. room of 12m ²	Provide for minimum 1 No. room of 12m ²	Provide for minimum 1 No. room of 12m ²	Provide for minimum 1 No. room of 12m ²
Provide for minimum 1 No. room of 9m ²	Provide for minimum 1 No. room of 9m ²	Provide for minimum 1No. room of 9m ²	Provide for minimum 1No. room of 9m ²
Provide a minimum of 1No. room of 6m ²	Provide a minimum of 1No. room of 6m ²	Provide a minimum of 2 No. room of 6m ²	Provide a minimum of 2 No. room of 6m ²
Provide a minimum of 4 m ²	Provide a minimum of 4 m ²	Provide a minimum of 4 m ²	Provide a minimum of 4 m ²
Minimum of 2No parking lots	Minimum of 2No parking lots	Minimum of 4 No parking lots	Minimum of 4 No parking lots

08.

QUALITY MANAGEMENT SYSTEMS

- 8.1 To ensure that blood and blood components maintain consistent quality and safety standards, all BE centres shall adhere to the national quality management systems (QMS) standards.
- 8.2 All blood establishments should adhere to the ISO 15189 and African Society for Blood Transfusion Standards.
- 8.3 The blood Transfusion Centres shall develop a quality plan to document, and effectively implement policies, processes, and procedures for the quality system to ensure that requirements of these Standards are satisfied.
- 8.4 Each blood establishment shall provide sufficient evidence to demonstrate that it can conduct its activities in accordance with national quality management system and the requirements of these Standards and that its activities will not compromise human safety or the safety of blood.
- 8.5 The blood establishments shall define and document how the requirements of these Standards will be ensured for each new or changed product or service. The documentation shall be in a format that suits the nature of the change and the BE operation.

09.

BIOSAFETY, BIOSECURITY AND WASTE MANAGEMENT

- 9.1 The processes and procedures shall address biological, chemical, and, where applicable, radiation safety, and adhere to biosafety, biosecurity standards.
- 9.2 Entities shall adhere to biological, chemical, and, where applicable, radiation safety.
- 9.3 Biohazardous materials shall be managed in a manner that minimizes the potential for human exposure to infectious agents as per the Safety Data Sheet (SDS) and relevant regulations and guidelines.
- 9.4 Appropriate personal protective equipment should be used, and all blood and blood products should be considered infectious.
- 9.5 Accessible hand-washing facilities with hot and cold water should be provided in all areas where blood or blood products are handled.
- 9.6 Biosecurity should be ensured through the protection, control, and accountability for blood samples and products within blood establishment and transfusing facilities, and during transportation and distribution in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release to unauthorized persons.
- 9.7 Blood transfusion centres shall demonstrate capacity to manage waste on-site or off-site as per the waste management standard operating procedure on biosafety and waste management.

10.

BLOOD MANAGEMENT INFORMATION SYSTEMS (BMIS)

- 10.1 Blood establishments shall report data as per the requirements of the national electronic Kenya Blood Information System.
- 10.2 The KNBTS shall maintain an electronic register for all entities.
- 10.3 National and sample referral network shall be available electronically.
- 10.4 Blood service entities shall report into the Kenya Blood Banking Information System.
- 10.5 All donor data shall be managed in compliance with the Data Protection Act 2019.
- 10.6 Blood service entities with access to the Kenya Banking Information System shall ensure access is by authorized personnel and there is no attempt to interfere with the primary system and that data in the system is not shared with any unauthorized persons.
- 10.7 A contingency plan should be in place to manage any unplanned outages. The effectiveness of the plan should be checked periodically through simulation exercise.
- 10.8 Physical copies of donor data shall be maintained as back -up.
- 10.9 Data confidentiality shall be maintained in line with the national standards of blood transfusion services.
- 10.10 Records should be kept of all changes, performance monitoring, checks and backups.



11. Staffing

11.1 The number of staff and expertise mix shall be based on the functions and workload.

11.2 The following are the minimum staffing standards:

Name	Nurse	Laboratory technologists	Medical laboratory Officers	Pathologists
Blood Transfusion Units		6	2	1
Blood Collection Centre	2	3		
Hospital Blood Transfusion Centre	3	10	2	1
Blood Transfusion Satellite Centres	2	10	1	
Regional Blood Transfusion Centres	3	21	4	1
National Blood Reference Laboratory (NBRL)		15	3	2
Blood Manufacturing Establishment	As per WHO manufacturing guidelines			

Immuno-haematologists	Public health Officer	Recruiter	Support staff	Driver	HRIO	Medical engineer
1	1		1	1	1	1
		1	1	1	1	1
2		1	2	1	2	1
		1	2	1	1	1
1	1	1	3	2	2	1
1		3	2	2	1	10

12. Equipment

The following are the basic equipment required for different blood establishment:

#	Equipment	Blood Transfusion Units	Blood Collection Centre
1	Blood bank fridges	1 (at least 500 units capacity)	1 (at least 500 units capacity)
2	Blood bank freezers and ice packs	1 at least 500 units capacity)	1 at least 500 units capacity)
5	Refrigerated centrifuge	-	1
6	Sample centrifuge	2	-
7	Microscopes	2	-
8	Water bath	2	-
9	TTI testing analysers	-	-
10	Automated blood grouping equipment	1	-
11	Spring weighing balance	-	2
12	Weighing scale (bathroom scale)	-	3
13	Blood mixer	-	4
14	Automated Platelet agitator	2	-
15	Bio bank	-	-
16	Manual plasma extractor	-	-
17	Apheresis machine	-	-
18	BP machine	-	2
19	HB meter	-	2
20	Distiller/Deionizer	-	-
21	Blood donation couches	-	4
22	Room thermometer	To discuss	To discuss
23	Cold chain thermometer	4	2
24	Blood transport boxes (cool boxes)	3 (20 units capacity)	5 (20 units capacity)
25	Sample transport boxes (cool box)	5 (5 units capacity)	3 (100 samples capacity)

Blood Transfusion Satellite Centres	Hospital Blood Transfusion Centre	Regional Blood Transfusion Centres	National Blood Reference Laboratory	Blood Manufacturing Establishment
3 (at least 500 units capacity)	6 (at least 500 units capacity)	6 (at least 500 units capacity)	1 (at least 500 units capacity)-	As per WHO requirements
2 ((at least 500 units capacity)	4 ((at least 500 units capacity)	4 ((at least 500 units capacity)	1 ((at least 500 units capacity)	
2	4	4	-	
2	2	2	2	
2	2	2	2	
2	2	2	2	
-	2	2	1	
-	2	2	1	
6	12	12	-	
3	4	4	-	
4	10	10	-	
-	4	4	-	
1	1	1	1	
4	6	6	-	
-	4	4	-	
4	4	4	-	
2	4	4	1	
-	2	2	2	
10	20	20	-	
To discuss	To discuss	To discuss	To discuss	
10	20	20	4	
8 (20 units capacity)	10 (20 units capacity) 5 (4 units capacity)	10 (20 units capacity) 5 (4 units capacity)	-	
5 (100 samples capacity)	10 (100 samples capacity)	10 (100 samples capacity)	4 (20 units capacity)	

#	Equipment	Blood Transfusion Units	Blood Collection Centre
26	Power generator	1 (20 units capacity)	1
27	Cold room	1	-
28	Shakers	-	-
29	Automated pipettes and tips	-	2
30	Tacometer	3	1
31	Hydrometer	-	1
32	Haematological analysers	-	0
33	Hand tube stripper with roller and cutter	-	4
34	Dielectric tube sealer	-	2
35	NAT equipment kit	-	-
36	PCR machine	-	-
37	Irradiation Plant	-	-
38	Air conditioner		
39	Tents	To discuss	2 (50- and 100-seater)
40	Chairs	-	150

Blood Transfusion Satellite Centres	Hospital Blood Transfusion Centre	Regional Blood Transfusion Centres	National Blood Reference Laboratory	Blood Manufacturing Establishment
1	1	1	1	
-	1	1	-	
-	2	2	1	
6	8	8	8	
1	1	1	1	
2	2	2	1	
1	1	1	1	
8	16	16	-	
4	8	8	-	
-	1	1	1	
-	1	1	1	
-	-	-	-	
1 in sorting and labelling room	2 in sorting and labelling, and component rooms	2 in sorting and labelling, and component rooms	In all the laboratories	
3 (2, 50-seater and 1, 100-seater)	3 (1, 50-seater and 2, 100-seater)	3 (1, 50-seater and 2, 100-seater)	-	
200	250	250	-	

13. Location

- 13.1 It is appropriate to locate blood collection activities in purpose-built buildings.
- 13.2 A blood establishment can have several blood collection activities taking place in static or mobile sites which should be located in places with high pedestrian traffic including large shopping malls, city facilities, major industrial complexes, religious institutions, universities or hospitals.
- 13.3 Clear signage should be used to identify the collection sites and provide directions to the donors.
- 13.4 The sites shall be accessible to staff and donors with disabilities.
- 13.5 In the event blood collection is done outside a BE, provision should be made for the following areas/rooms.

Areas/room	Description
Waiting bay and Reception	Size will depend on expected number of donors and should allow 1.5 m ² for each person waiting
Donor records	Should be accessible to the reception so that records can be retrieved on donor arrival
Interview room(s)	Rooms for collection of confidential and medical information as well as counselling. Numbers will depend on expected daily workload
Haemoglobin screening	Room for Hb testing for potential donors
Donation	Space for couches and adjacent consumables storage. Additional space may be required if aphaeresis is carried out. Allow 9 m ² per coach Allow 10 m ² per aphaeresis couch
Checking/holding	Physical checking of collected units and donor samples prior to transportation to holding facility or laboratory
Donor care	Space for donor treatment and recovery in case of an adverse reaction during or after donation

Areas/room	Description
Applicable for only static sites	
Donor lounge	Post-donation lounge for donor recovery and refreshments
Staff	May include multi-purpose staff lounge and tearoom
Offices	Facility management/administrative staff
Meeting room	Meeting room for training and meetings
Store	Supplies for donor screening, blood collection etc
Laundry	For linen and laboratory coats etc
Cleaning room	Storage of cleaning equipment and waste and clean materials
Toilets	Toilets for staff and donors, provide separate facilities for males and females

14. Training and Research

- 14.1 A wide range of education and training activities may be carried out at the facilities.
- 14.2 Education and training programs may be planned and organized at the blood transfusion centre and be delivered at hospitals, clinics or in the wider community.
- 14.3 Education and training services may be provided to staff at hospitals and clinics and to donors or potential donors.
- 14.4 Any person or institution intending to carry out research activities at a blood establishment or/and involving use of blood products shall seek concurrence from by KNBTS.

15 Registration and Licensing of Blood Establishment

- 15.1 A licence is a certification awarded by a regulatory authority to an institution or a service provider offering blood transfusion services.
- 15.2 All health facilities that carry out blood transfusion to patients shall be registered and licensed by Kenya Medical Practitioners and Dentists Council (KMPDC).

- 15.3 All blood establishments engaged in laboratory services for samples for blood transfusion purposes shall be registered and licensed by Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).
- 15.4 All licensed blood entities shall have an authorization certification by the Pharmacy and Poisons Board (PPB) for collection, preparation, storage, release and distribution of blood products.
- 15.5 All medical and dental practitioners engaged in blood transfusion services shall be duly registered and licensed by the Kenya Medical Practitioners and Dentists Council (KMPDC).
- 15.6 All medical laboratory technician and technologist engaged in blood transfusion services shall be duly registered and licensed by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB).
- 15.7 All nursing practitioners engaged in blood transfusion services shall be duly registered and licensed by the Nursing Council of Kenya (NCK).

15.8 All clinical officers engaged in blood transfusion services shall be duly registered and licensed by the Clinical Officers Council (COC).

15.9 All pharmacist and pharmaceutical technologist engaged in blood transfusion services shall be duly registered and licensed by Pharmacy and Poisons Board (PPB).

15.10 The KBTTS will maintain a register of all blood service entities.

15.11 KBTTS will provide a registration certificate to all blood service entities that are not covered by the authorities in 16.1 to 16.10.

16 Review of the Standards

The standards described in this document shall be reviewed every three years.

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APPENDICES

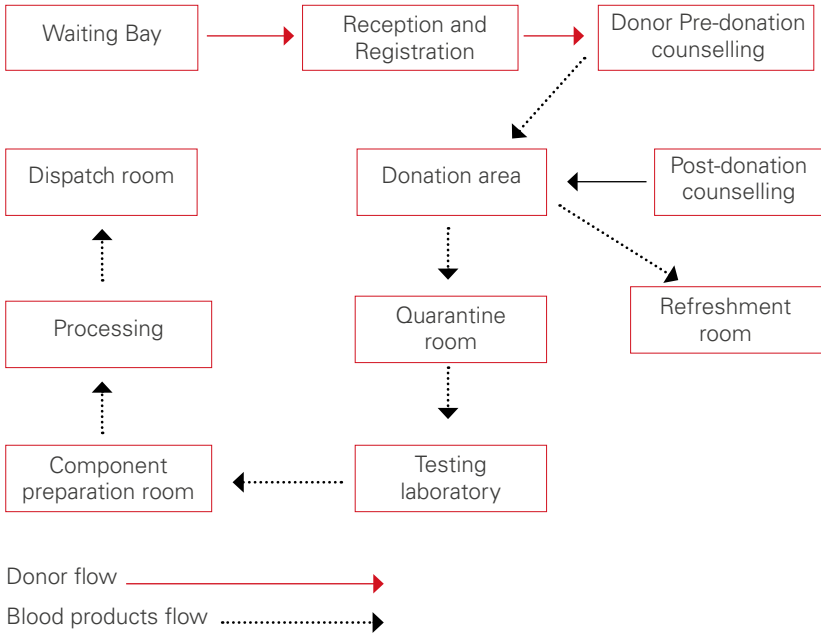
18.1 Summary of Blood Establishments Key Functions

Blood Establishments	Key Functions
Blood Transfusion Unit (BTU)	<ul style="list-style-type: none"> • Immunological procedures • Sorting • Storage • Dispatch
Blood Collection Centre (BCC)	<ul style="list-style-type: none"> • Blood collection • Transportation of blood units and blood samples to the Regional Blood Transfusion Centre
Hospital Blood Transfusion Centre (HBTC)	<ul style="list-style-type: none"> • Blood collection • Blood testing • Blood transfusion to patients
Blood Transfusion Satellite Centre (BTSC)	<ul style="list-style-type: none"> • Donor, recruitment and mobilisation. • Blood collection • Blood component preparation • Transportation of blood samples to the testing establishment • Sorting, labelling and distribution of blood and blood product
Regional Blood Transfusion Centre (RBTC)	<ul style="list-style-type: none"> • Donor recruitment and mobilization • Blood collection • Blood testing • Component preparation • Distribution of blood and blood products.
Blood Reference Laboratory- (BRL)	<ul style="list-style-type: none"> • Provide confirmatory testing for blood and blood products. • Proficiency testing • Quality assurance/control • Carry out internal and external audits. • Perform technical valuation of reagents.
Blood Manufacturing Establishment (BME)	Manufacture of plasma derived products.

18.2 Summary of Registration and Licenses Required in Blood Transfusion Services

Blood service entities	Premises	Blood products	Service providers
Blood Transfusion Unit (BTU)	KMLTTB KMPDC	PPB	KMPDC, KMLTTB, PPB, NCK, COC
Blood Collection Centre (BCC)	PPB KBTTs	PPB	KMPDC, KMLTTB, PPB, NCK, COC
Hospital Blood Transfusion Centre (HBTC)	KMPDC	PPB	KMPDC, KMLTTB, PPB, NCK, COC
Blood Transfusion Satellite Centre (BTSC)	KMLTTB	PPB	KMPDC, KMLTTB, PPB, NCK, COC
Regional Blood Transfusion Centre (RBTC)	KMLTTB	PPB	KMPDC, KMLTTB, PPB, NCK, COC
Blood Reference Laboratory- (BRL)	KMLTTB	PPB	KMPDC, KMLTTB, PPB, NCK, COC
Blood Manufacturing Establishment (BME)	PPB	PPB	KMPDC, KMLTTB, PPB, NCK, COC
Third Party Service Providers	-	-	KBTTs

18.3. Blood Establishments Generic Workflow Chart



18.4 Equipment Specifications

Name of the Equipment	Description of Function
Laboratory Incubator	For dry heat treatment of test samples at 37°C ±2°C during the immunohematology procedures (incubation of biological agents)
Blood Bank Centrifuge	For separation of blood samples and enhance serological reactions
Blood collection monitor with shaker	Accurate collection of blood volume and mixing during the blood donation process
Di-electric tube sealer	Hermetic sealing of the PVC tubing containing blood and blood components
Platelet agitator and incubator	Storage and agitation of platelets
Upright Plasma freezer	Rapid freezing process of the liquid plasma and subsequent storage of the plasma in the frozen state
Plasma thawing device [Warmer]	Thawing (liquefaction) of the frozen plasma at controlled temperature of +37°C ±2°C.
Standard upright blood bank refrigerator	-Storage of blood products
Automated Cell Washer	Washing red blood cells.
Electronic Blood measuring scale	To determine the weight /volume of various blood components during the process of blood component preparation
Blood collection spring scale	Special spring scale for measuring the blood volume (from 0 to 500ml) collected in the bag. Used during mobile blood donation camps
Haemoglobin estimation device	Haemoglobin levels determination
Hand tube stripper	For missing blood in the pilot tube.
Donor couch	A specially designed device where donor during blood donation.
Sterile connecting device	The system is used for automatically connecting in a sterile manner of the PVC tubing of the blood bags

Name of the Equipment	Description of Function
Refrigerated blood processing centrifuge	For separation of blood by centrifugation into various blood components under controlled temperature speed and time
Manual plasma expresser	The stand used to extract plasma manually
Semi-Automatic ELISA	For blood screening using ELISA assays
Cooler boxes	Transportation whole blood from one blood bank to another



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