

Federal Ministry of Health
National Blood Bank Services

Guideline on Blood Transfusion Service
Organization in Ethiopia

DRAFT

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1. Introduction

1.1 Background

Blood Transfusion Services were started and provided by the Ethiopian Red Cross Society from 1969 to 2010 through its 12 regional blood banks located in the capital cities of 8 of the 11 regions and covering the requirements of 52% of the hospitals in the country thus restricting access to comprehensive emergency obstetric care. The rest of the hospitals have been organizing their own blood sourcing mechanisms a system that compromised the quality of the blood supply. Since 2004 and with funding from PEPFAR through CDC, focus has been on expansion and consolidation of the service to ensure universal access. Renewed efforts to make the blood services an autonomous agency were also reinvigorated. The service was granted an autonomous status by the Council of Ministers under proclamation number 330/2014.(NBBS Annual Report)()

To cover the requirements of the whole country equitably, the ministry has established its own blood transfusion services with blood banks located to cover the blood transfusion requirements for hospitals and health units at 150km radius of each. Thus, a total of 25 blood banks have been functional since the end of 2013. Thus, increasing access to a safe blood supply to over 90% of hospitals by the year 2015. This blood distribution was initially 70% in Addis Ababa and 30% in the regions, where over 85% of the population lives. This was reversed to 32.7% in Addis Ababa, while the regions have access to 67.3% of the total blood supply in 2016. Testing which was not universal for all the WHO recommended disease markers (HIV, hepatitis B and C as well as Syphilis) had improved to cover 100% of all donations by 2008. Community involvement and ownership improved resulting not only in establishment of many community based blood donor clubs but also involvement of community leaders including parliamentarians and celebrities as blood donors as well as advocates for blood services with the resultant increase in voluntary blood donation.

The Collection Plan for 2010 E.C was 241,107 Units of which 186,853 (77.3 %) units were collected. And, 183,338(98.1%) were from voluntary non remunerated blood donors. The total units to be collected as a country as per WHO recommendation is approximately more than one million units per year (1-2% of total population) this shows there is still a major gap in the collection the needed amount of blood to serve the health institutions.

Cognizant of these risks to blood safety, the World Health Organization through the world health assembly, urged member states to enact effective legislative policies governing operations of blood transfusion services. The Federal Ministry of Health to this effect has set standards for the national blood transfusion services and also a strategic plan has been developed and implemented.

1.2 SITUATIONAL ANALYSIS

The blood transfusion service in the country is growing rapidly but still with some gaps in the systems and facing new challenges too. The key issues facing the BTS regarding organizational setup and national coordination are;

- ❖ There is a lack of clear document guideline on the setup of the BTS in country outlining the organization and Technical command and communication structure between stakeholders
- ❖ Currently all the 25 RBBs in the country collect , screen and distributed blood which is having considerable cost and efficiency implication in RBBs handling low volume of blood collections
- ❖ BTS in the country is financed by government budget ,whose availability is different between regions and blood banks making it sometimes difficult to carry out activities as planned and according to standards
- ❖ The BTS is facing a threat of defragmentation and weakening of the national coordination, with demand from communities and regional health bureaus for the expansion of the service specifically increasing the number of standalone blood banks.

In line with the national health policy (Blood Policy) and the mandate given to the National Blood Bank Service by the council of Ministers Regulation 330/2014 section 12 (Annex 1) and the national standards this guidance document has been developed to;

1. Provide clear guidance to establishments under the ministry of health and regional health bureaus who undertake activities related to the donor mobilization, collection, testing, processing, storage, and distribution of blood and blood products
2. provide a clear basis for the interaction between stakeholders in the blood transfusion service in the country
3. Be used as the governing document for the strategic and controlled expansion (upgrade) of the existing blood transfusion system setup in the country.
4. Serve as a reference for Future designing, construction and opening of new blood bank, Blood collection, processing and distribution sites

1.1 Scope

This guideline will be implemented to all governmental and Non Governmental organizations which are obliged and responsible to undertake task on BTS. This include FMOH,Regional Health Beuro, National and regional Blood Bank, Health facility as soon as this guideline is approved.

1.2 Objective

Ensure safe, adequate, timely and easily accessible supply of quality blood and blood product through establishment of well organized, coordinated and standardized blood transfusion service

2 Organization of Blood Transfusion Services

2.1 INSTITUTIONAL ARRANGEMENT

The Blood Transfusion Service in Ethiopia is organized in a decentralized (regional based) setup while at the same time being a nationally regulated and coordinated system. The different actors in the BTS and their role are;

2.1.1 Federal Ministry of Health

The FMOH is the responsible for access, and quality of blood transfusion services in the country.

- ❖ The FMOH identifies the NBBS and its regional blood banks as the sole provider of blood and blood products for the Ethiopian population and has delegated this responsibility of national Coordination to the National Blood Bank Service (NBBS).
- ❖ FMOH will ensure the availability of adequate financial resources and mechanisms for the NBBS through annual fiscal allocation of sufficient budgetary resources.FMOH will be responsible for securing Government commitment and support for the National Blood Service, to ensure a safe and adequate supply of blood nationwide
- ❖ FMOH shall be ultimately responsible for the National Blood and Blood Product supplies and shall ensure the provision of adequate resources for the procurement of blood from only voluntary non-remunerated blood donors from the low risk populations.
- ❖ FMOH will be ultimately responsible for the availability of safe, adequate and affordable blood and blood products to all patients in the country's hospitals requiring such therapy.

- 📌 FMOH will ensure that adequate human resources are available to maintain the highest possible standards of transfusion practice and quality management throughout the country
Create community mobilization and awareness strategy
- 📌 Incorporate Blood transfusion activity in FMOH Initiatives

2.1.2 National Blood Bank Service (NBBS)

The National Blood Service is dedicated to collect blood from safe, altruistic voluntary blood donors, process it into safe and effective blood components and to monitor the use of these in conformity with laid down standards and protocols.

- 📌 The NBBS develops national policy, strategies, guidelines, manuals and standard operating procedures for Blood transfusion activities in the country
- 📌 The NBS shall co-ordinate, integrate and supervise technically all the RBBs.
- 📌 The NBBS ensure BTS related activities in the country are carried out according to acceptable national and international standards.
- 📌 The NBBS will establish and support the implementation of a national Quality Management system across blood services in the country.
- 📌 The NBBS will develop a national blood stock management system and devise strategies to support the implementation of appropriate information communication technology tools across blood centres in the country
- 📌 The service shall ensure that its products are adequate, safe, accessible and affordable to all sections of the community. This function will be achieved by the co-ordinated activities of the national center and regional blood banks.
- 📌 NBBS will work with RHB ,RBBs and Health Facilities in promoting appropriate clinical use of blood and establishing a nationally coordinated hemovigilance system
- 📌 The NBBS will work with FMOH, RHB and RBB to ensure the centralized procurement of blood bank equipment, testing kits and reagents to ensure the standardization and sustainability of the service across the BBS.
- 📌 Conduct as necessary, researches related to the services, provide short term and on job trainings for staffs and update the service with the modern knowledge and technology in the field
enhance the number of blood donors by creating public awareness through mass media and other different means

2.1.3 Regional Health Bureaus

- 📌 RHBs are responsible to allocate adequate budget for RBBs and for the sustainability and monitoring of the quality of service given by blood banks in their respective regions in collaboration with the FMOH.

- 🩸 RHB will be responsible to ensure blood banks under their authority are discharging BTS service as per country set standards
- 🩸 The Regional health bureaus shall co-ordinate, integrate and supervise technically all regional blood banks collections and distribution centres.
- 🩸 The Regional health bureaus ensure BTS related activities in the region are carried out according to acceptable national and international standards.
- 🩸 The Regional health bureaus will establish and support the implementation of a national Quality Management system across blood services in the region.
- 🩸 The regional health bureaus will develop a regional blood stock management system inline with the national blood stock management system and devise strategies to support the implementation of appropriate information communication technology tools across blood centres in the region.
- 🩸 The service shall ensure that its products are adequate, safe, accessible and affordable to all sections of the community. This function will be achieved by the co-ordinated activities of the regional blood banks.
- 🩸 RHB will work with, RBBS and Health Facilities in promoting appropriate clinical use of blood and establishing a nationally coordinated hemovigilance system.
- 🩸 enhance the number of blood donors by creating public awareness through mass media and other different means
- 🩸 RHB shall Ensure the proper implementation of the national training policy and ensure staff are trained in competent to perform their duties

2.1.4 Regional Blood Banks, Collection and Distribution centers

- 🩸 RBB will be established to serve all blood transfusion requirements for health units in 150 km radius of its location and shall be established preferably as close to the major users as possible.
- 🩸 RBBs will plan its own catchment areas blood transfusion service activities as well as hospital based blood transfusion functions in their location.
- 🩸 RBBS will preposition Blood stocks at hospitals and health facilities depending on demand and utilization patterns.
- 🩸 RBBS will work with hospitals in their respective catchment area to scale up and strengthen the mini blood banks in high demand hospitals
- 🩸 RBBS will work for the establishment of Hospital Transfusion Committees (HTCs) to ensure the appropriate use of blood and blood products.
- 🩸 The RBBs shall carry out the sensitization/dissemination and recruitment of blood donors, collection, screening, testing, processing, storage and distribution of blood and

blood products, and auditing usage in all hospitals according to nationally set standards.

- enhance the number of blood donors by creating public awareness through mass media and other different means

2.1.5 HOSPITAL MINI BLOOD BANKS

- The HBB shall be responsible for patient grouping and cross-matching of screened blood from the BBs for transfusion and offer other immune-haematological services the hospital may require.
- The HBB shall receive processed blood and blood products from the RBB and issue out readily available blood and blood products of suitable quality in adequate amounts to patients in their respective hospitals.
- Medical Directors of the hospitals in consultation with RBBs in their catchment areas shall create functional Hospital Transfusion Committees (HTC) to encourage appropriate blood utilization in their hospitals, and auditing of same.
- HBB must submit blood need plan and blood usage reports and adverse event or reactions related to blood transfusion using the applicable tools and mechanisms provided by the national blood service into the national hemovigilance system
- Organization and coordination represented in the form of organogram
- enhance the number of blood donors by creating public awareness through mass media and other different means

Functional requirements

2.2 Establishing QA system in the NBBS and RBBs

The NBBS will support to establish a National Quality assurance system in the NBBS and RBBs.

- QA system will include all elements of quality according to WHO recommendations including organizational management, national standards for quality system, training, documentation and ongoing assessment.
- The quality system shall be subject to regular review with appropriate measures to be taken based on the findings of the quality review.
- It will ensure the quality of BTS through establishing QA systems (internal and external) at national and regional level.

- 📌 NBBS shall strengthen the national quality assurance scheme to ensure the quality of testing in all the blood banks in the country.
- 📌 Regular review of all the activities to assess the overall effectiveness of the quality system shall be done to ensure continuous improvement.

A national training and development policy and manual on blood safety based on WHO recommendations shall be developed and implemented for all staff members joining the BBS

2.3 HUMAN RESOURCE Requirement and Composition

- 📌 The service shall have a strategy in place to identify, recruit and retain all categories of staff.
- 📌 A training and staff development strategy shall be developed.
- 📌 All categories of staff working in the BTS across the country shall undergo regular approved in-service training and competency assessment at least once every year as well as other training as and when applicable.
- 📌 The NBBS shall make an input into the curriculum of the Pre-service training Institutions on Blood Transfusion Medicine.

All regional blood banks testing and collection sites should fulfil the minimum required human resources (annex 3)

2.4 FINANCING BLOOD TRANFUSION SERVICE

- 📌 The Government shall support the NBBS and its activities to ensure sustainability.
- 📌 The main sources of funding of the NBS shall be; budgetary allocation from the Government.
- 📌 The NBBS will explore and implement other means of cost recovery in consultation with the FMOH and resource mobilization to get Contributions by donors

2.5 Location and Design for New Sites

The FMOH, RHB and NBBS will be responsible for the coordinated assessment, mapping and establishment of blood center across the country in line with the national blood policy.

- 📌 The location and type of facility will be decided based on a joint assessment by the three parties(annex assessment check list)
- 📌 The following criteria will be taken into account when doing a joint assessment to decide the location and facility type of new BTS sites and location of new sites should fulfill the following preset requirements

- 📌 Population serving size (population density),
 - Potential donor population
- 📌 number of blood transfusing facilities,
 - total number of beds,
 - bed occupancy rate,
 - type of health care delivery which requiring blood transfusion,
- 📌 availability of nearby blood bank and road accessibility,
- 📌 International and national recommendation on the consolidation of blood transfusion services will be taken into account when proposing recommendations
- 📌 Sites which not functioning as the national or international recommendations and requirements shall be downgraded to the collection sites or satellite site

The design and spaces required shall be according to acceptable international recommendations which can be modified based on available standards (Annex)

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ADDIS ABABA 8th January, 2015

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፩. አጭር ርዕስ ይህ ደንብ “የብሔራዊ ደም ባንክ አገልግሎት ማቋቋሚያ የሚኒስትሮች ምክር ቤት ደንብ ቁጥር ፫፻፴/፪፻፮” ተብሎ ሊጠቀስ ይችላል።	1. Short Title This Regulation may be cited as the “National Blood Bank Service Establishment Council of Ministers Regulation No. 330/2014”.
፪. ትርጓሜ የቃሉ አገባብ ሌላ ትርጉም የሚያሰጠው ካልሆነ በስተቀር በዚህ ደንብ ውስጥ፦ ፩/ “ደም” ማለት በሰውነት ውስጥ የሚዘዋወር ፈሳሽ ሆኖ በውስጡ ነጭና ቀይ የደም ሴሎች፣ ፕላትሌቶችን እና ፕላዝማ የያዘ ነው፤ ፪/ “ደም ልገላ” ማለት በፍቃደኝነት ላይ የተመሠረተ ከሰብዓዊ አገልግሎቶች ውስጥ አንዱ የሆነ የሀይማኖት፣ የፆታ እና የዘር ልዩነት የማያደርግ የአብዛኛውን ኅብረተሰብ ክፍል ተሳትፎ የሚጠይቅ ደም የመስጠት ሃይት ነው፤	2. Definitions In this Regulation unless the context otherwise requires: 1/ “blood” means a fluid which circulates within the human body that contains red and white blood cells, platelets and plasma; 2/ “blood donation” means one of a voluntary humanitarian deed of provision of blood irrespective of gender, race and religious differences which requires participation of the public at large;

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- የአገልግሎቱ ዋና መሥሪያ ቤት በአዲስ አበባ ሆኖ እንደ አስፈላጊነቱ በማንኛውም ስፍራ ቅርንጫፎች ይኖሩታል።
- ፭. የአገልግሎቱ ዓላማ**
- የአገልግሎቱ ዓላማ በቂ፣ ደህንነቱ የተረጋገጠ እና በወቅቱ የተዘጋጀ ደምና የደም ተዋጽኦዎችን እንዲሁም ተያያዥነት ያላቸውን አገልግሎቶች በኢትዮጵያ ውስጥ ደም የሚያስፈልጋቸው ሁሉ እንዲያገኙ ማድረግ ይሆናል።

- 3/ “service” mean an autonomous entity which collects, processes and supplies safe and adequate blood;
 - 4/ “transfusion” means giving of blood or blood products to a patient when the patient’s need of blood is ascertained by a health professional;
 - 5/ “blood components” mean red and white blood cells, platelets and plasma;
 - 6/ “blood components preparation” means a process of separating red and white blood cells, platelets and plasma from the collected blood parts into their constituent;
 - 7/ “region” means any state referred to in Article 47 (1) of the Constitution of the Federal Democratic Republic of Ethiopia and includes the Addis Ababa and Dire Dawa City Administrations;
 - 8/ “Ministry” and “Minister” means the Ministry and Minister of Health, respectively.
 - 9/ any expression in the masculine gender includes the feminine.
- 3. Establishment**
- 1/ The National Blood Bank Service (hereafter referred to as the “Service”) is hereby established as an autonomous federal government organ having its own legal personality.
 - 2/ The Service shall be accountable to the Ministry.
- 4. Head Office**
- The Service shall have its head office in Addis Ababa and branch offices elsewhere, as may be necessary.
- 5. Objectives of the Service**
- The objective of the Service shall be to provide adequate, safe and timely prepared blood and blood products and other related services to all persons who need blood transfusion in Ethiopia.

፮. የአገልግሎት ሥልጣንና ተግባራት

የአገልግሎት የሚከተሉት ሥልጣንና ተግባራት ይኖሩታል፦

- ፩/ የተለያዩ ስልቶችን በመጠቀም በመገናኛ ብዙሃን እና በሌሎች ዘዴዎች ለህብረተሰቡ ግንዛቤ በመፍጠር የበጎ ፍቃድ የደም ለጋሾችን ቁጥር ማበራከት፤
- ፪/ በትምህርት፣ በጤና፣ መንግስታዊ እና መንግስታዊ ባልሆኑ፣ በሃይማኖት እና በሌሎች መሰል ተቋማት ጨምሮ በሕብረተሰቡ ውስጥ ለተቋቋሙት እና ወደፊት ለሚቋቋሙት የደም ለጋሾች ክበባት ቴክኒካዊ ድጋፍ ማድረግ፤
- ፫/ ደምና የደም ተዋጽኦዎች ክበጎ ፈቃድ ለጋሾች መገኘቱን ማረጋገጥ፤ ደምና የደም ተዋጽኦዎች መሰብሰብ፣ አስፈላጊውን የላቦራቶሪ ምርመራ ማድረግ፣ ማዘጋጀት፣ ተገቢ በሆነ መልኩ በማክማቸትና ደህንነቱ ተመርምሮ የተረጋገጠ ደም የደም ተዋጽኦዎች ህክምና ለሚሰጡ ጤና ተቋማት ማሰራጨት፤
- ፬/ የጤና ተቋማትን የደም አገልግሎት ወይም የደም አጠቃቀም ለማሻሻል ማጠናከር፣ በማንኛውም ጊዜ የደም ክምችት በየጤና ተቋማቱ መኖሩን ማረጋገጥ፣ የሆስፒታል ደም ህክምና ኮሚቴዎች መመስረታቸውንና በአግባቡ መስራታቸውን ማረጋገጥ፤
- ፭/ ለጤና ተቋማት በቁና ደህንነቱ የተጠበቀ ደምና የደም ተዋጽኦ ማቅረብ፤
- ፮/ በብሔራዊ ደረጃ የደም ክምችት መኖሩን ማረጋገጥ፣ የክልል የደም ባንኮችን ማስተባበር፣ ትሰስር መፍጠር እና የቴክኒክ ድጋፍ መስጠት፤
- ፯/ እንደ አስፈላጊነቱ ከሚሰጠው አገልግሎት ጋር የተገናኙ ምርምሮችን ማከናወን፣ የአጭር ጊዜና የሥራ ላይ ስልጠና ለሠራተኞች መስጠት እና የአገልግሎት አሰጣጡን በመስኩ ከሚገኘው ዘመናዊ እውቀትና ቴክኖሎጂ ጋር በማዛመድ ማሳደግ፤
- ፰/ ደም ለመሰብሰብ፣ ለመለየት፣ ለማዘጋጀት፣ ለማሠራጨት፣ ለማስወገድ እና የደም እና የደም ተዋጽኦን ለክሊኒክ አገልግሎት ለማዋል የሚያስችል የአሰራር መመሪያዎችን ማውጣት፤

6. Powers and Duties of the Service

The Service shall have the powers and duties to:

- 1/ enhance the number of blood donors by creating public awareness through mass media and other different means;
- 2/ provide technical support for blood donor clubs established and to be established in schools, health facilities, governmental and non-governmental organizations, religious institutions and other similar institutions of the community;
- 3/ ensure that blood and blood products are collected from voluntary donor, collect, conduct necessary laboratory testing, process and store blood and blood products properly and dispatch the screened safe blood and blood products to health facilities providing blood transfusion;
- 4/ strengthen health facilities to improve their blood service and utilization of blood; ensure the existence of an adequate stock of blood in health facilities and ensure the establishment and proper functioning of hospital blood transfusion committees;
- 5/ provide safe and adequate blood and blood products to health facilities;
- 6/ ensure the availability of sufficient stock of blood at national level and, coordinate, network and technically support regional blood banks;
- 7/ conduct, as may be necessary, researches related to the service, provide short term and on job trainings for staffs and update the service with the modern knowledge and technology in the field;
- 8/ issue guidelines for collection, screening, processing, providing, discarding and appropriate clinical usage of blood and blood products;

፱/ የንብረት ባለቤት መሆን፣ ውል መዋዋል፣ በራሱ ስም መክሰስና መከሰስ፤

9/ own property, enter into contract and sue and be sued in its own name;

፲/ ዓላማውን ከግብ ለማድረስ የሚረዱ ሌሎች ተዛማጅ ተግባራትን ማከናወን፡፡

10/perform other related activities as may be necessary for the attainment of its objectives.

፮. የአገልግሎት አጽም

አገልግሎቱ፡-

፩/ በሚኒስትሩ የሚመደብ ዋና ዳይሬክተርና እንደአስፈላጊነቱ ምክትል ዋና ዳይሬክተሮች፣ እና

7. Organization of the Service

The Service shall have:

1/ a Director General and, as may be necessary, Deputy Director Directors to be appointed by the Minister, and

፪/ አስፈላጊ ሠራተኞች፣ ይኖሩታል፡፡

2/ the necessary staff.

፯. የዋና ዳይሬክተሩ ሥልጣንና ተግባር

፩/ ዋና ዳይሬክተሩ የአገልግሎቱ ዋና ሥራ አስፈጻሚ በመሆን ከሚኒስትሩ በሚሰጠው አጠቃላይ መመሪያ መሠረት የአገልግሎቱን ሥራዎች ይመራል፣ ያስተዳድራል፡፡

8. Powers and Duties of the Director General

1/ The Director General shall be the chief executive officer of the Service and shall, subject to the general directions of the Ministry, direct and administer the activities of the Service.

፪/ በዚህ አንቀጽ ንዑስ አንቀጽ (፩) የተመለከተው አጠቃላይ አነጋገር እንደተጠበቀ ሆኖ ዋና ዳይሬክተሩ፡-

2/ Without limiting the generality of sub-article (1) of the Article the Director shall:

ሀ) በዚህ ደንብ አንቀጽ ፮ የተመለከተውን የአገልግሎቱን ሥልጣንና ተግባራትን ሥራ ላይ ያውላል፤

a/ exercise the powers and duties of the Service specified under Article 6 of this Regulation;

ለ) የአገልግሎቱን ሠራተኞች በፌዴራል ሲቪል ሰርቪስ ሕጎች መሠረት ይቀጥራል፣ ያስተዳድራል፤

b/ employ and administer employees of the Service in accordance with the federal civil service laws;

ሐ) የአገልግሎቱን ስትራቴጂክ ዕቅድ፣ ዓመታዊ ዕቅድ፣ የሥራ ፕሮግራምና በጀት አዘጋጅቶ ለሚኒስትሩ ያቀርባል፣ በመንግሥት ሲፈቀድም ተግባራዊ ያደርጋል፤

c/ prepare and submit to the Ministry the strategic plan, the annual work plan and budget of the Service, and implement same upon approval by the Government;

መ) ለአገልግሎቱ በተፈቀደው በጀትና የሥራ ፕሮግራም መሠረት ገንዘብ ወጪ ያደርጋል፤

d/ effect payments in accordance with the approved budget and work plan of the Service;

ሠ) ከሦስተኛ ወገኖች ጋር በሚደረጉ ግንኙነቶች አገልግሎቱን ይወክላል፤

e/ represent the Service in its dealings with third parties;

ረ) የአገልግሎቱን የሰራ አፈጻጸምና የሂሳብ ሪፖርቶች አዘጋጅቶ ለሚኒስትሩ ያቀርባል፡፡

f/ prepare and submit to the Ministry the performance and financial reports of the Service.

፫/ ዋና ዳይሬክቲሩ ለአገልግሎቱ ሥራ ቅልጥፍና በሚያስፈልግ መጠን ሥልጣንና ተግባርን በከፊል ለአገልግሎቱ ሌሎች ኃላፊዎችና ሠራተኞች በውክልና ሊሰጥ ይችላል።

፬. የምክትል ዋና ዳይሬክቲሮች ስልጣንና ተግባር

ምክትል ዋና ዳይሬክቲሮች የሚከተሉ ሥልጣንና ተግባራት ኖራቸዋል፡-

፩/ የአገልግሎቱን ተግባራት በማቀድ፣ በማደራጀት፣ በመምራት እና በማስተባበር ዋና ዳይሬክቲሩን ያግዛሉ።

፪/ በዋና ዳይሬክቲሩ ተለይተው የሚሰጡት ሌሎች ስራዎችን ያከናውናሉ።

፫/ ዋና ዳይሬክቲሩ በማይኖርበት ጊዜ በዋና ዳይሬክቲሩ ተለይተው በውክልና የሚሰጡ ቸውን ተግባራት ያከናውናሉ።

፭. በጀት

የአገልግሎቱ በጀት በመንግሥት ይመደባል።

፮. የሂሳብ መዛግብት

፩/ አገልግሎቱ የተሟሉና ትክክለኛ የሆኑ የሂሳብ መዛግብት ይይዛል።

፪/ የአገልግሎቱ የሂሳብ መዛግብትና ገንዘብ ነክ ሰነዶች በዋናው ኦዲተር ወይም ዋናው ኦዲተር በሚሰይመው ኦዲተር በየዓመቱ ይመረመራል።

፯. መመሪያ የማውጣት ሥልጣን

አገልግሎቱ ይህንን ደንብ ለማስፈጸም የሚያስፈልጉ መመሪያዎችን ከሚኒስቴሩ ጋር በመመካከር ሊያወጣ ይችላል።

፲፫. ደንቡ የሚጸናበት ጊዜ

ይህ ደንብ በነጋሪት ጋዜጣ ታትሞ ከወጣበት ቀን ጀምሮ የፀና ይሆናል።

አዲስ አበባ ታህሳስ ፴ ቀን ፪ሺ፮ ዓ.ም

ኃይለማርያም ደሳለኝ

የኢትዮጵያ ፌዴራላዊ ዲሞክራሲያዊ ሪፐብሊክ ጠቅላይ ሚኒስትር

3/ The Director General may delegate part of his powers and duties to other officers and employees of the Service to the extent necessary for the efficient performance of the activities of the Service.

9. Powers and Duties of the Deputy Director Generals

The Deputy Director Generals shall have the following powers and duties:

1/ support the Director General in planning, organizing, leading and coordinating the activities of the Service;

2/ perform other duties specifically assigned to them by the Director General;

3/ perform duties specifically assigned to them through delegation in the absence of the Director General.

10. Budget

The budget of the Service shall be allocated by the Government.

11. Books of Accounts

1/ The Service shall keep complete and accurate books of accounts.

2/ The books of accounts and other financial documents of the Service shall be audited annually by the auditor General or by an auditor designated by him.

12. Power to Issue Directive

The Service may issue directives necessary, in consultation with the Ministry, for the implementation of this Regulation.

13. Effective Date

This Regulation shall enter into force on the date of publications in the Federal Negarit Gazzette.

Done at Addis Ababa, this 8th day of January, 2015.

HAILEMARIAM DESSALEGN
PRIME MINISTER OF THE FEDERAL
DEMOCRATIC REPUBLIC OF ETHIOPIA

Ethics of Blood Transfusion Service by ISBT

Reference documents

WHO resolution on the national organization of Blood Safety

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Annex 1

Annex 2 –Basic Design Guidelines

Static collection centers

Static blood collection centers are facilities for blood donation in fixed or permanent locations. They are the first point of contact between the donor and the BTS. They may be stand-alone facilities or located within a blood center.

Scope of services

-  Screen potential donors.
-  Collect blood from eligible donors.
-  Supervise donor recovery.
-  Check and store donated blood prior to dispatch, to a testing and processing facility.
-  Manage donor results.

Workload

A 12 couch facility should be able to collect a minimum of 18,000 whole blood donations annually (or a minimum average of 72 donations daily). An 8 couch facility should be able to collect a minimum of 12,000 whole blood donations annually (or a minimum average of 50 donations daily).

Functional content

A static collection centre facility should provide the following areas:

Waiting area	Operators should assess numbers. Numbers will vary according to local practices, e.g. if donors are accompanied by a family member, if work or community groups attend together.
Reception	Staff base for the management and direction of donors on arrival.
Donor Records	Directly accessible from Reception so that records can be retrieved on donor arrival.
Interview	Rooms for collection of confidential and medical information as well as counselling. Numbers will depend on expected daily workload.
Haemoglobin Screening	Area for testing blood haemoglobin levels of potential donors.





Donation area	Space for couches and adjacent consumables storage. Additional space required if apheresis is carried out, but this can be carried out in an area shared with other couches.
Checking/holding	Physical checking of collected units and donor samples prior to transport to laboratory or holding facility respectively.
Donor treatment	Space for donor treatment and recovery in case of an adverse reaction during or after donation.
Donor lounge	Post-donation lounge for donor recovery and refreshment with accommodation for observation by staff.
Staff Area	Multi-purpose staff lounge and tea room.
Offices	Facility manager and other administrative staff.
Meeting room	BTS meetings and training activities.
Store	Supplies for donor screening, haemoglobin testing, blood collection, etc.
Laundry	For linen and staff lab coats if required. Alternatively, external laundry service may be used. Where the collection centre is located in a blood centre, a central laundry may be provided in the housekeeping area.
Cleaning room	Storage of cleaning equipment and waste and clean materials.
Toilets	Toilets for staff and donors.

Processing

The Processing Unit is responsible for the reception of all blood entering the blood centre, its processing and storage. The unit may be co-located with the Inventory and Distribution unit and the testing Laboratories or located on a separate site.

Scope of services

This Processing Unit is responsible for:

-  blood and blood sample reception and registration;
-  blood component preparation;
-  quarantine storage; and,
-  Labelling of verified blood prior to storage in the inventory and distribution unit.

The separation of processing activities from inventory and distribution activities is part of the organizational structure required to ensure the effective separation of untested from tested and verified blood.

Workflow

Blood reception

All blood units from collection facilities and referred blood samples from hospitals and clinics will be received at the central reception area. Blood reception and registration should follow the blood centre policy to permit the tracking of all blood and samples through the processing and testing system, with the capacity for “look back” and traceability.

Component preparation

Whole blood units are often separated into blood components for transfusion. In some situations, plasma may also be sent to a specialist facility for further fractionation. Blood is usually separated into plasma, red cells and platelets. Additional activities including leucocyte filtration, cryopreservation and washing of cellular components, and pathogen inactivation may also be carried out as part of component preparation.

Quarantine storage

After component preparation, blood components are held in temperature-controlled and quarantined storage prior to completion of testing and verification. The physical separation of quarantined and inventory blood for release is essential to the maintenance of a safe blood supply.

The capacity of processing cool rooms should be a minimum of 2.5 times the average daily service load plus 50% to allow for variations in daily work load.

The capacity of processing freezer rooms should be a minimum of 7 times the average daily service load plus 50% to allow for daily fluctuation.

Labelling

After testing verification, each blood component unit is labelled and issued to the Inventory and Distribution unit for inventory storage. Blood units not suitable for transfusion must be stored separately prior to disposal.

Functional content

Processing should include the following areas:

Loading dock	Delivery and dispatch truck parking and area to load and unload trucks. If space is available, delivery and dispatch functions should be separated.
Reception	Reception and registration of blood.
Storage	Storage of consumables used in the unit.
Component preparation	Processing blood in bags to be separated into components. Depending on the type of blood component prepared and complexity of the process, additional areas may be required (i.e. leucofiltration, blood irradiation, pathogen inactivation etc.)
Plasma Freezing	Bags of plasma frozen in freezing cabinets for storage in freezer rooms and/or refrigerated storage equipment.
Quarantine Blood Storage	Controlled temperature storage (refrigerator and freezer) of blood components prior to the verification of test results and transfer to Inventory and Distribution storage or disposal.
Verification	Labelling of verified blood components prior to transfer to Inventory and Distribution.
Offices	Process manager and process supervisors
Toilets	Separate male and female toilets

Schedule of Spaces

Processing—100 units/day centre

Space	Area	No.	Total	Comments
Loading dock	8	1	8	
Blood and sample reception	12	1	12	
Document store	7	1	7	Retention time of documents to be established
Store	9	1	9	
Handwash and gowning bay	6	1	6	At entry/exit to component preparation area
Component preparation	50	1	50	
Plasma freezing area	10	1	10	Rapid plasma freezing
Quarantine refrigerated cabinets for red cells (4°C)	5	1	5	
Quarantine freezer cabinets for plasma (-30°C)	9	1	9	
Quarantine store for platelets (20°C-24°C)	4	1	4	Walk-in store with platelets stored in cabinets
Quarantine freezers	8	1	8	Freezer cabinets
Contaminated blood store	4	1	4	Blood for disposal stored in refrigerated cabinets
Verification and labelling	9	1	9	

Schedule of spaces

Processing—200 units/day centre

Space	Area	No.	Total	Comments
Loading dock	8	1	8	Allow covered parking for two vehicles.
Blood and sample reception	12	1	12	
Document store	9	1	9	Check against local record storage regulations.
Store	12	1	12	
Hand wash and gowning bay	6	1	6	At entry/exit to component preparation area
Component preparation	80	1	80	-
Plasma freezing area	10	1	10	Rapid plasma freezing
Quarantine cool room for red cells (4°C)	7	1	7	Walk-in. Refer notes below



Quarantine freezer for plasma (-30°C)	14	1	14	Walk-in. Refer notes below
Quarantine store for platelets (20°C-24°C)	5	1	5	Walk-in store with platelets stored in cabinets
Quarantine freezers	8	1	8	Freezer cabinets
Contaminated blood store	4	1	4	Blood for disposal stored in refrigerated cabinets
Verification and labelling	12	1	12	
Waste holding	6	1	6	

Laboratories

Scope of services

The testing laboratories conduct testing of donor blood for blood group serology and infectious disease markers, and in-process quality control testing for blood and blood products.

Testing laboratories carry out automated and/or manual testing on donor samples for:

-  Blood group serology: determine ABO and Rh group; detection of unexpected antibodies to red cell antigens;
-  Infectious disease markers: according to BTS policy and national regulations, donor blood must be screened for transfusion transmitted infections such as Hepatitis B, Hepatitis C, Human Immunodeficiency Virus, and other agents as appropriate, e.g. syphilis, parasitic diseases, and bacterial screening. Testing laboratories may also carry out confirmatory testing on samples with positive or reactive responses during screening.

Schedule of spaces

Laboratories – 100 units/day

Space	Area	No.	Total	Comments
Shared Facilities				
Specimen reception and preparation	10	1	10	
Gowning and preparation	6	1	6	Entry to clean room.
Clean up and glass washing	12	1	12	
Cool room (4°C)	8	1	8	Storage of post-testing donor samples.
Freezer (-20°C)	8	1	8	
Freezer cabinets	8	2	16	For refrigerator and freezer cabinets.
Sample archive cool room		1		Retention period to be established
Reagent preparation	16	1	16	
Gowning	6	1	6	
Store	14	1	14	
Cleaner	5	1	5	
Hand washing	5	1	5	For hand washing and gowning at laboratory entry/exit.
Waste holding	6	1	6	
Solid Phase	12	1	12	Antibody screening.
	12	1	12	Antibody identification.

Schedule of spaces

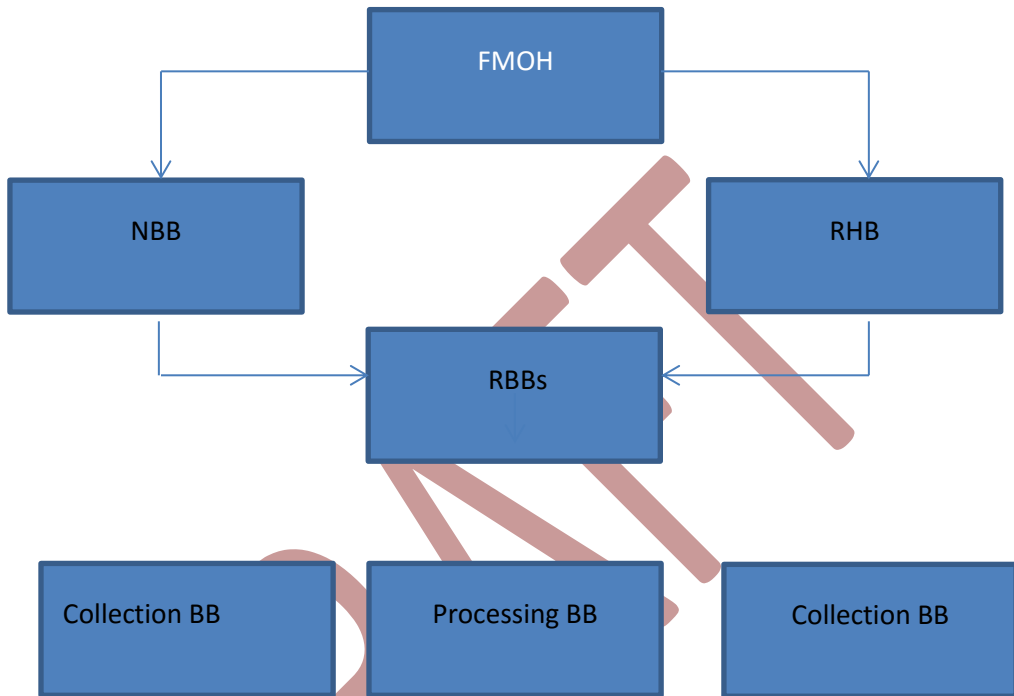
Laboratories – 200 units/day

Space	Area	No.	Total	Comments
Shared Facilities				
Specimen reception and preparation	12	1	12	
Clean up and glass washing	18	1	18	
Cool room (4°C)	10	1	10	Storage of post-testing donor samples.
Freezer (-20°C)	12	1	12	
Freezer cabinets	10	2	20	For refrigerator and freezer cabinets.
Sample archive cold room		1		
Reagent preparation/ Balance room	16	1	16	
Gowning	6	1	6	
Store	10	2	20	
Cleaner	5	1	5	
Hand washing	5	1	5	For hand washing and gowning at laboratory entry/exit.
Waste holding	6	1	6	

Criteria for establishing blood service

s.no	Criteria	
1	Minimum distance from nearby BB (150km radius) (irrespective of region location)	Based on geographical proximity
2	Transport Accessibility (> 12 hr travel from near by BBs)	Transport considerations
3	Number health facility who needs blood Govt and private Number of hospital beds >100	
4	Potential donor	
5	Vehicle	
6	Budget (HR, Medical equipment, supply, reagent...)	
7	Premises	
8		

Organization of Blood Transfusion Services



s.no	Professional composition	number	
1.	Admin staff		
2	HR		
3	ግዢ፣ፋይናንስ እና ንብረት አስተዳደር		
4	Cleaner		
5	Guards		
6	<u>Secretary</u>		
7	Clinical staff		
8	Nurse		
9	Lab		

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