NATIONAL BLOOD SERVICE COMMISSION (NBSC)

Safe Blood Saves Lives

NATIONAL BLOOD SAFETY STANDARDS FOR BLOOD ESTABLISHMENTS IN NIGERIA

AUGUST 2021

Approved by: **National Quality Manager**
Authorised by: **Director General**

QPM-QMD-011
REV (08/2021)
Effective Date: 01/01/2022

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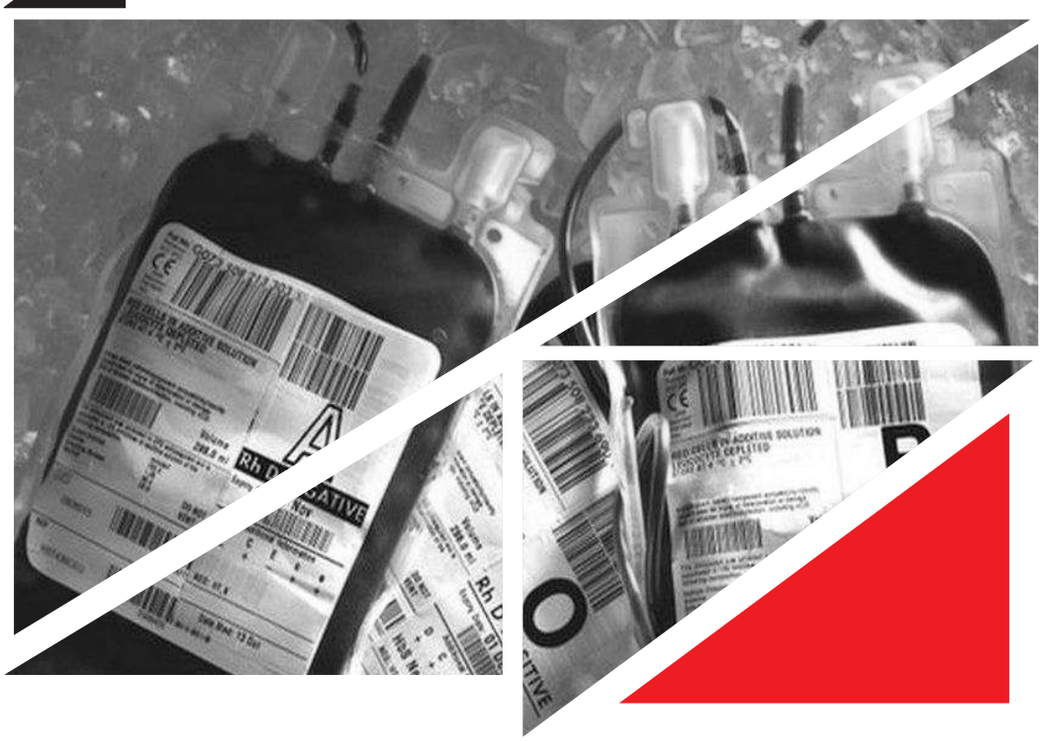

NATIONAL BLOOD SAFETY STANDARDS FOR BLOOD ESTABLISHMENTS IN NIGERIA

AUGUST 2021

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FOREWORD

Blood safety is key to quality healthcare service delivery. The transfusion of blood and its components plays a fundamental role in the management of various pathologies and is always a life-saving treatment, when implicated. Blood has remained an expensive as well as a limited resource, and needs for its use has risen over the years. Blood transfusion carries a potential risk of acute or delayed complications; and transmission of transfusion transmissible infections (TTIs), hence the need for its stringent regulations. All Member States of the World Health Organization (WHO), including Nigeria, endorsed World Health Assembly resolutions WHA28.72 (1) in 1975 and WHA58.13 (2) in 2005.

In order to achieve sufficiency and safety in blood transfusion to the grassroots' level in Nigeria, the National Blood Service Commission, in keeping with her mandates as provided for in the statutory laws of Federal Republic of Nigeria, has developed these standards for Blood Establishments. The document was developed with full participation of Experts Committee drawn from relevant stakeholder groups, professional associations, sister regulatory agencies in the Ministry of Health and academia.

Sustainability of safe blood transfusion practice depends on the use of appropriate technology and personnel; and adherence to processes that will be universally applied by Blood Establishments and rational use of blood and derived products. Standards regarding all the phases in transfusion practice are well highlighted in this document, for implementation by all blood Establishments in Nigeria.

Dr. E. Osagie Ehanire, MD, *FWACS*
*Honourable Minister of Heal*th

ACKNOWLEDGEMENT

I wish to acknowledgement the 2021 Expert Committee on National Blood Safety Standards for blood Establishments, who contributed in no small measure towards development and final review of this document.

Regulation, Coordination and assuring the provision of safe quality blood, blood products and services as well as other related matter in line with the National health plan is our ultimate goal, and that shall be achieved through universal application of the standards in this document.

We appreciate the visionary leadership of the Honourable Minister of Health, Dr. Osagie Ehinaire, for his unwavering interest and support for providing enabling environment and supports with which the strides being achieved have ensured that indeed, the entire re-invigorated National Blood Service Commission becomes a reality.

We sincerely appreciate, again, the 2021 Expert Committee on National Blood Safety Standards for blood Establishments, stakeholder agencies, professional associations and academic community representatives for their time, skills and patience expended during the process of preparation of this document. We thank the Regulatory Team and Staff of the NBSC.

Our appreciation goes to the Federal Government of Nigeria, for providing funding for all NBSC activities, including printing and circulation of this document.

OUR MANDATE

The Mandate of the National Blood Service Commission is to Regulate, Coordinate and Ensure the provision of quality blood, blood products and services in line with National Health plan and for related matters.

List of Stakeholders

1. World Health Organisation (WHO)
2. Safe Blood for Africa Foundation
3. National Agency for Food and Drugs Control (NAFDAC)
4. Haematology and Blood Transfusion Scientist Society of Nigeria (HBTSSN)
5. Association of Medical Laboratory Science of Nigeria (AMLSN)
6. Nigeria Medical Association (NMA)
7. Medical Laboratory Science Council of Nigeria (MLSCN)
8. Medical and Dental Council of Nigeria (MDCN)
9. Medical and Dental Consultant Association of Nigeria (MDCAN)
10. Nursing and Midwifery Council of Nigeria (NMCN)
11. Nigerian Society of Haematology and Blood Transfusion (NSHBT)
12. Pharmacist Council of Nigeria (PCN)
13. Ministry of Defense (MoD)
14. Voluntary Blood Donor Club of Nigeria (VOLBLODON)

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Acronyms

- BEs - Blood Establishments
- HIV - Human Immunodeficiency Virus
- SOPs - Standard Operating Procedures
- IQA - Internal Quality Assessment
- EQA - External Quality Assessment
- TTIs - Transfusion Transmissible Infections
- ABO - Blood Grouping
- RhD - Rhesus factor
- HCV - Hepatitis C Virus
- HBV - Hepatitis B Virus
- NBTS - National Blood Transfusion Service
- BCG - Bacille Calmette-Guerin
- HBsAg - Hepatitis B surface antigen)
- NAT - Nucleic Acid Testing
- FFP - Fresh Frozen Plasma
- WHO - World Health Organisation
- AfSBT - African Society for Blood Transfusion
- AABB - American Association of Blood Bank
- JPAC - Joint UK Blood Transfusion Service Professional Advisory Committee
- HRM - Human Resource Management
- NAAT - Nucleic Acid Amplification Test
- DNA - Deoxyribonucleic Acid
- ELISA - Enzyme-linked Immunoassay
- NAFDAC - National Agency for Food and Drugs Control
- MLSCN - Medical Laboratory Science Council of Nigeria
- CJD - Creutzfeldt-Jakob Disease
- vCJD - Variant Creutzfeldt-Jakob Disease
- TSE - Transmissible Spongiform Encephalopathy
- GMP - Good Manufacturing Practice
- SDP - Single Donor Platelet

Executive Summary

The NBSC is responsible for regulation, coordination, collection and distribution of blood products for Nigeria. A rigorous process is involved in providing safe and quality, in terms of donor-selection, technical aspect and client protection; without prejudice to existing laws.

The NBSC recognized the need to develop guidance on establishing acceptable systems for safety in blood transfusion. The expert committee was formed to develop the guidelines using international best practices.

The guidelines are presented in three (3) parts;

Section A: - Addresses the quality management system requirements which incorporates the mission and strategic plan. Organisation structure, quality management systems including quality team, financial resources, job descriptions, training records and documentations. It also considered equipment, the supplies and suppliers for the blood service.

Section B: - Considered technical requirements in terms of donor management, blood handling and transportation.

Section C: - Considered blood processing, blood ordering, selection, issuing, haemovigilance and clinical interface.

High level evidence using WHO, AfSBT, AABB, JPAC guidelines were used based on suitability and taking into account our cultural and environmental differences. International best practices, knowledge and expertise of the guideline development members were used.

It is anticipated that the recommendations in this document will remain valid until a period defined by the NBSC when a review of these guidelines will be undertaken to explore any new evidence especially where controversies arise or when changes may be appropriate.

GLOSSARY OF TERMS USED IN THESE STANDARDS

ABO compatible for plasma transfusions: This means that there is no ABO antibody in the plasma of the donation that is able to react with an antigen present on the red cells of the recipient (e.g., group B plasma transfused into a group A recipient would be ABO incompatible).

ABO compatible for red cell transfusions: This means that there is no ABO antigen present on the red cells of the donation that is able to react with an antibody present in the plasma of the recipient (e.g., group A red cells transfused into a group O recipient would be ABO incompatible).

ABO compatible for platelet transfusions: This means that there is no ABO antibody in the platelet concentrate of the donation that is able to react with an antigen present on the red cells of the recipient (e.g., group B platelets transfused into a group A recipient would be ABO incompatible).

Adverse Event: A complication in a donor or patient which may occur in relation to a blood donation or a transfusion.

Agreement: A contract, order, or understanding between two or more parties, such as between a facility and one of its customers, suppliers or sub-contractors, or a medical director and the qualified individual contracted to make medical decisions in the absence of the medical director.

Agreement Review: Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented and achievable.

Assessment: A systematic, independent examination that is performed at defined intervals and at sufficient frequency to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments may include comparison of actual results to expected results. Types of assessments include external assessments, internal assessments, quality assessments, peer-review assessments, and self-assessments.

Audit: An audit is an evaluation of an individual, organisation, system, process or product. In the context of these Standards, the term Audit is used interchangeably with Assessment.

Biohazardous Waste: Waste products such as body fluids and tissues, which have the risk of carrying human pathogens. It includes all consumables used in the collection, testing, dispatch and transfusion process that become contaminated with blood or any component.

Blood Components: Blood components are often also referred to as blood products. Blood components may be prepared from a whole blood collection or may be produced through an automated collection e.g., red blood cells, plasma and platelets.

Blood Service: An organization, generally with multiple facilities, that performs one or more of the following activities: donor mobilization, donor screening, blood collection, processing of

blood into components, compatibility testing, storage, selection, and distribution of blood and blood components.

By a Method Known to: Use of published data to demonstrate the acceptability of a process or procedure, particularly for blood and blood component preparation.

Calibration: A procedure that confirms under defined conditions, the relationship between values obtained from an instrument or system with those obtained using an appropriate certified standard. It may also include an adjustment activity. (See also "Qualification - equipment" and "Validation").

Change Control: A structured method of revising policies, processes or procedures including hardware or software design, transition planning, and revisions to all related documents.

Closed System: A system in which the contents are not exposed to air or outside elements during collection, preparation and separation of blood.

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

Competence: Ability of an individual to perform a specific task according to procedures.
Compliance: See Conformance.

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

Corrective Action: An activity performed to correct an existing non-conformance, or other undesirable situation. It may also be called a Remedial Action.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the safety and quality of the facility's products or services. Customer: The receiver of a product or service. A customer may be internal (i.e., another department within the same organization) or external (i.e., another organization). It is not implied that a financial transaction is, or will be, involved. Deviation: Any departure from policies, procedures, applicable regulations, standards, or specifications.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, policies, processes, procedures (including standard operating procedures), and forms.

Document (verb): To capture information for use in documents through writing or electronic media.

Donor: A person from whom a volume of blood is withdrawn for transfusion into a recipient.

Equipment: A durable item, instrument, or device used in a process or procedure.

Event: A generic term to encompass the terms "incident", "error", and "accident".

Expiry: The last day or time in which the blood or blood component is considered suitable for transfusion or infusion; or the last day on which reagents, test strips and other consumables are considered suitable for use.

External Quality Assessment (EQA): A method that allows for comparison of a laboratory's test results with a source outside and independent of the laboratory. A system for objectively checking the laboratory's performance using an external agency or facility. See also Internal Quality Assessment.

Facility: A location or operational area within an organization. The part of the organization that is assessed by an accrediting or certifying body and receives accreditation/certification for its specific activities.

Guidelines: Documented recommendations.

High Titre: Anti-A and/or anti-B in plasma or serum, which when diluted to 1 in 128 in normal saline, agglutinates red cells containing the corresponding antigens (i.e., A1, B or A1B cells).

Infant: A human child of 4 months of age or less.

Informed consent: Permission granted in writing in full knowledge and understanding of the possible consequences, such as that which is obtained from a prospective blood donor prior to donation, after he or she has been informed of the possible risks and benefits of the procedure.

Inspect: To measure, examine, or test one or more characteristics of a product or service and compare results with specific requirements or standards.
Internal Quality Assessment (IQA): The system used and managed within the organisation to monitor and evaluate products, tests or services. See also External Quality Assessment.

Issue: To release for clinical use (i.e., transfusion).
Label: An inscription affixed to a unit of blood, a blood component or a specimen for identification. May also be used as a verb e.g., to label tubes or samples.

Labelling: Information that is required or selected to accompany a unit of blood, blood component, or specimen, which may include content, identification, storage requirements, expiry date, cautionary statements, or indications for use. Unless specifically required in the standard, labelling requirements need not be affixed to the unit of blood or blood component, provided there is a means of tracing the information to that unit.
Lived with: Resided in the same dwelling (e.g., home, apartment, immediate family or relatives' residence).

Maintain: To keep in the current state.

Material(s): Goods or items used in the processing or testing of blood or blood components. Materials are a type of input product. Reagents are a type of material.

National Blood Service Commission (NBSC): The only organisation, with delegated responsibility from the government, that serves the blood transfusion needs of the country. The NBS is also known as the National Blood Transfusion Service (NBTS). An NBS coordinates all blood transfusion activities in the country and develops policies and procedures that are used nationally.

Non-conformance: Failure to meet requirements including standards.

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

Organization: An institution, or part thereof, which has its own functions and top management.

Paid Donor: A donor, who is compensated by a facility or a family for donating blood.

Policy: A documented general principle that guides present and future decisions. Preventive Action: An action taken to eliminate the cause of a possible non-conformance and to reduce the potential for non-conformances or other undesirable situations to recur.

Procedure: A written sequence of actions or instructions to be followed in accomplishing a task by one or many individuals.
Process: Set of interrelated or interacting activities that use inputs to deliver an intended result.

Process Control: Activities to standardize and control processes in order to produce predictable output.

Product: A tangible result of a procedure.

Proficiency Testing: The structured evaluation of procedures, equipment, materials and personnel to establish suitability.

Protocol: A system of rules that explain the correct conduct and procedures to be followed in formal situations.

Qualification - equipment: Verification that specified attributes required to accomplish the desired task, have been met. Equipment qualification may include the following elements:

Installation Qualification - providing objective evidence that equipment has been installed according to manufacturer's instructions and meets all specifications. Operational Qualification - providing objective evidence that a piece of equipment or a device performs as intended.

Performance Qualification - providing objective evidence that a piece of equipment or a device consistently performs as intended.

Qualification - staff: The aspects of an individual's education, training, competence and experience that are deemed necessary to successfully meet the requirements of a position.

Quality: Characteristics of a unit of blood, blood component or specimen, critical material, or service that bear on its ability to meet requirements.

Quality Control: Testing routinely performed on materials and equipment to check their proper function. When quality control testing does not provide the expected results, the tests done in parallel are to be deemed invalid.

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

Quality System: The organization's structure, responsibilities, policies, processes, procedures and resources established and approved by top management to achieve quality.

Quarantine: To isolate untested or non-conforming blood, blood components, or materials to prevent their distribution or use.

Reagent: A substance used to perform an analytical procedure.

Recipient: A person who receives any blood or blood component through transfusion.

Record (noun): Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved, such as test results or audit results. Records do not exist until the activity has been performed and documented. Record (verb): To capture information for use in records through writing or electronic media.

Regulations: Rules formulated by government authorities to implement laws enacted by legislative bodies.

Release: Removal of component from quarantine or in-process status for issue and distribution.

Repeat (Regular) Donor: For purposes of these Standards, a donor who has previously donated one or more times.

Replacement Donor (also Family Replacement Donor): A donor, who has been asked by the family of a patient in need of a transfusion to give blood for a specific recipient, or to replace the blood transfused to a specific recipient.

Sexual Contact: Any of the following activities (whether or not a condom or other protection was used): vaginal sex (contact between penis and vagina); oral sex (mouth or tongue on someone's vagina, penis, or anus); anal sex (contact between penis and anus).

Shall: A verb used to indicate a requirement.

Should: This indicates that an activity is recommended.

Specified Requirements: Any requirements in these Standards including, but not limited to, government requirements; requirements of a facility's internal policies, processes and procedures; manufacturers' instructions; customer agreements; and requirements of accrediting organizations.

Sub-contractor: A facility/person performing a task related to meeting the requirements of these Standards on behalf of the organization.

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

Top Management: The highest level of personnel within an organization, including employees and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or change the organization's quality policy. Top management may be an individual or a group of individuals.

Traceability: The ability to follow the history of a donor, blood component or process by means of recorded identification.

Transfusion Transmissible Infection: An infection that is capable of giving rise to a disease or condition caused by a virus, bacterium, fungus, parasite, agent of transmissible spongiform encephalopathy or other unidentified micro-organism that may be transmitted by transfusion of blood or blood components.

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

Validation: Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

Variance: A variance to standards is an alternative method or approach that deviates from, but meets the intent of, the Standards, and does not increase the safety risks to donors and/or transfusion recipients.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met. In the context of validation, verification means that a previously validated process has been effectively implemented in a different location.

Voluntary Non-Remunerated Blood Donor (VNRBD): A donor who has been motivated to donate blood without expectation of compensation or pursuant to third party pressure.

Background

Nigeria has made significant progress in medical treatments and blood needs are ever increasing to support many of such therapies. The need for blood transfusion in Nigeria includes management of maternal haemorrhage, sickle cell anaemia, chronic illnesses, under-5 malaria haemolysis, conflicts and insurgency complications and transplants.

While blood transfusion is generally safe, in most cases, some risk may be associated where standards are compromised. It is therefore important to set guidelines that would help in maintaining safety through the whole process in the transfusion chain.

The National Blood Service Commission (NBSC) is entrusted with the regulation of supply of safe and quality accessible blood for all Nigerians and it is paramount that such guiding principles come from this organisation which will be the baseline in which assessments of quality is made.

This guideline presents the minimum requirements for quality, donor recruitment, blood management and clinical interface such that when implemented, blood transfusion in Nigeria will likely become safer and more accessible.

SECTION A- QUALITY SYSTEM REQUIREMENTS

1. QUALITY SYSTEM REQUIREMENTS

1.1 Mission

1.1.1 The mission statement shall be further supported by a corporate code of ethics designed to guide management and staff in conducting their activities in accordance with the organisation's primary values and ethical standards.

1.1.2 The code of ethics shall be supported by processes to identify and resolve ethical dilemmas in a timely way

1.1.3 Cultural and spiritual preferences of donors and patients shall be recognised and appropriately addressed.

1.2 Strategic Plan

1.2.1 The BEs shall develop and maintain a strategic plan that clearly defines its scope and objectives. This Shall include strategy for the allocation of resources to pursue those objectives as well as addressing the major changes and improvements required to better realize its mission.

1.2.2 The strategic plan shall be supported by an organisational plan that identifies the expected milestones in the strategic plan, provides guidance and an action plan, and enables progress towards achieving the milestones to be measured.

1.3 Organisational Structure

1.3.1 The blood establishment shall have a structure that clearly defines the parties responsible for the activities covered by these regulations. This organizational structure shall be captured in writing, electronically or both, shall be authorized and shall form part of the Quality System documentation.

1.3.2 The following responsibilities within the organisation, together with any required delegation, shall be clearly defined:

1.3.2.1 Governance

1.3.2.2 Organizational management

1.3.2.3 Financial management

1.3.2.4 Quality performance

1.3.3 Responsibility for the activities detailed in these *Standards* shall be assigned to individuals and these individuals may be responsible for more than one activity. Some activities may be delegated to another entity provided the terms of delegated authority and responsibility are clearly defined in the organizational structure.

1.3.4 The organogram shall be reviewed at least every two years, as well at times of organisational change, and updated as required.

1.4 Top Management

1.4.1 The BEs shall be under the direction of a designated person(s) who shall be responsible and accountable for ensuring that all operations are carried out properly and competently as required by the relevant Nigerian extant Laws.

1.5 Medical Practitioner

1.5.1 The BEs shall have a medical practitioner qualified by education, training and/or experience, registered and licensed to practice in a medical field within the country.

1.5.2 The medical practitioner shall have responsibility and authority for all medical matters and for the consultative and support services that relate to the care and safety of donors and/or patients.

1.5.3 The medical practitioner may delegate these responsibilities to another qualified and licensed individual; however, the medical practitioner shall retain ultimate accountability for the delegated duties.

1.5.4 Exceptions to procedures warranted by clinical situations shall require justification and pre-approval by the medical practitioner or designated medical officer on a case-by-case basis.

1.6 Quality Manager (however named)

1.6.1 A designated individual, with training, competence and experience in quality management, shall be appointed with the authority and overall responsibility for quality within the BEs.

1.6.2 This individual shall be responsible for the implementation and maintenance of the quality system.

1.6.3 This individual shall report directly to the Head of the Blood Establishment.

2. QUALITY MANAGEMENT SYSTEM

2.1 Quality System Requirements

2.1.1 The BEs shall develop, implement and maintain a quality Management system, including a quality policy, to address the requirements of Section A of these *Regulation.*

2.1.2 The quality management system shall be communicated within the BEs so that all personnel understand their role in ensuring quality.

2.2 Management Review

2.2.1 Quality Team led by the Quality Manager shall conduct a management review meeting at the instance of Top Management to evaluate the quality system at planned intervals of no longer than 12 months and take action to ensure its continuing suitability, adequacy and effectiveness.

2.2.2 The quality review shall include at least the following:

2.2.2.1 Organisational management

2.2.2.2 Utilisation and efficiency of services

2.2.2.3 Outcomes of internal and external audits performed

2.2.2.4 Non-conformances/errors identified and the effectiveness of resulting corrective and preventive actions

2.2.2.5 Quality Control results on blood components produced.

2.2.2.6 Personnel training activities

2.2.2.7 Blood donor and customer feedback reports.
2.2.2.8 Outcomes and actions from previous quality review meetings

2.2.3 The BEs shall use reviews of the quality management system to assess opportunities for improvement, and the need for changes to the quality management system.

2.3 Quality Manual

2.3.1 The BEs shall maintain a quality manual that explains how elements of the quality system apply or have been implemented in the BEs. The elements that shall be included are:

2.3.1.1 Organization and Structure
2.3.1.2 The Quality management System
2.3.1.3 Resources
2.3.1.4 Documents and Records
2.3.1.5 Suppliers and Service Providers
2.3.1.6 Incoming Receipt, Inspection and Testing
2.3.1.7 Equipment
2.3.1.8 Work Environment and Safety
2.3.1.9 Internal and External Audits
2.3.1.10 Non-conformances
2.3.1.11 Continual Improvement
2.3.1.12 Process Control.

2.3.2 Quality management system regulations shall apply to all activities performed.

3. FINANCIAL RESOURCES

3.1 Financial Resources

3.1.1 The BEs shall develop a budget to ensure its ongoing operations.

4. HUMAN RESOURCE

4.1 Personnel

4.1.1 There shall be a system in place for determining the level of staffing and the skills required to meet the needs of the organisation.

4.2 Personnel records

4.2.1 Records of Personnel shall be maintained by HRM and should contain the following:

4.2.1.1 Education and professional qualifications
4.2.1.2 Copy of certification or licence when applicable
4.2.1.3 Job description
4.2.1.4 Training in current job tasks
4.2.1.5 Competency assessments
4.2.1.6 Records of continuing education
4.2.1.7 Reports of accidents and exposure to occupational hazards
4.2.1.8 Immunisation status when relevant to assigned duties

4.2.1.9 Driver's license when applicable

4.2.1.10 Record of signature and initials

5. DOCUMENTS AND RECORDS

5.1 Documentation Requirements

5.1.1 The BEs shall develop, implement and maintain a document control system that addresses document creation, identification, review, approval, revision, retention and final disposition. [*Refer to Table 1*]

5.1.2 The document control system shall define procedures for making changes to documents.

5.2 Documents

5.2.1 Documents shall be divided into internal and external:

5.2.1.1 All documents both internal and external should be reviewed and approved by authorized personnel and have a Unique standardized identifier.

5.2.1.2 All documents as in table 1 should be archived after the retention period.

5.2.1.3 The retention period of all documents should be defined by the BEs policy which should be verified.

5.2.2 Standard Operating Procedures

5.2.2.1 Shall be Legible written, authorized and approved.

5.2.2.2 Staff should be trained, certified competent and must sign to have understood how to use the SOP.

5.2.2.3 The SOP must be available and strictly adhere to.

5.3 Records

5.3.1 The BEs shall ensure identification, collection, indexing, access, filing, storage, and disposition of records in line with the BEs verifiable policy.

5.3.2 Records shall be legible; complete; maintained, stored and retrievable.

5.3.3 All records must be protected prevented from unauthorized access and strictly confidential with traceability.

5.3.4 Changes or corrections to records made shall be authorized and the correction effected shall be named, dated and signed Note: records shall not be defaced, deleted or erased.

5.3.5 Only recognized or defined abbreviations or acronyms shall be used in documents and records.

5.4 Electronic records

5.4.1 Electronic records shall be available, accessible, validated, maintained, and protected from unauthorized persons.

5.4.2 There shall be a system in place for routine backup of all critical data. Backup data shall be stored in an off-site location.

6. SUPPLIERS AND SERVICE PROVIDERS

6.1 Supplier Requirements

6.1.1 The BEs which performs procurement activities shall have vendors/ supplier selection criteria.

6.1.2 All critical goods or items shall meet acceptance criteria which shall be defined by the quality manual.

6.1.3 If the Bes is not the procurement authority, it shall define its own requirements to procurement

6.2 Inventory Management

6.2.1 The BEs shall develop, implement and maintain an inventory management system to ensure commodity security

7. INCOMING RECEIPT, INSPECTION AND TESTING

7.1 Requirements for Incoming Products

7.1.1 The BEs shall maintain a procedure for the qualification or acceptance of incoming products and critical materials prior to use. Incoming products and critical materials shall be received, inspected and tested, as necessary, before acceptance or use.

7.1.2 Critical materials shall meet specified requirements.

8. EQUIPMENT

8.1 Equipment Requirements

8.1.1 The BEs shall identify the equipment that is critical to the provision of blood, blood components and services.

8.1.2 The BEs shall have process for proper maintenance of the equipment.

8.2 Selection and qualification of Equipment

8.2.1 The BEs equipment shall be qualified and capable of achieving the accuracy required for intended use.

8.3 Use of Equipment

8.3.1 Equipment shall be adequate in number to carry out procedures in required time frames, placed in a location suitable for optimal operation and used in accordance with manufacturer's instructions.

8.3.2 Only trained staff shall handle specialized equipment.

8.4 Identification of Equipment

8.4.1 Equipment shall be uniquely identified.

8.4.2 The BEs shall maintain a list of critical equipment and its location.

8.5 Calibration

8.5.1 Calibrations and/or adjustments of critical items shall be performed using equipment and materials that have adequate accuracy and precision

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

8.5.3 At a minimum, calibrations and/or adjustments shall be performed:

8.5.3.1 Before use

8.5.3.2 After activities that may affect the calibration

8.5.3.3 At intervals prescribed by the manufacturer

8.6 Equipment Monitoring and Maintenance

8.6.1 The BEs shall have scheduled monitoring and preventive maintenance programmes in accordance with manufacturer's instructions, so that equipment remains fit for use. The programme shall include/define: frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.

8.7 Equipment Malfunction

8.7.1 Investigation and follow-up of equipment malfunctions or damage shall include:

8.7.1.1 Removal of the equipment from use and/or isolation, and identification as not suitable for use.

8.7.1.2 Assessment of blood and blood components affected by equipment that is found to be malfunctioning or out of calibration

8.7.1.3 Assessment of the effect on donor eligibility and donor and patient safety

8.7.1.4 Investigation of the malfunction or damage

8.7.1.5 Steps for requalification of the equipment

8.7.1.6 Reporting the nature of the malfunction or damage to the manufacturer, when indicated.

9. SAFETY AND RISK MANAGEMENT

9.1 Risk Management

9.1.1 Risk management framework should be in place and should address potential business and safety risks

9.1.2 The risk management framework shall be supported by:

9.1.2.1 A risk management plan and relevant policies on processes and procedures.

9.1.2.2 The maintenance of a risk register

9.1.2.3 Annual risk assessments to identify potential hazards in the workplace, to the environment, to staff and to clients

9.2 Work Environment

9.2.1 The work environment shall be suitable for the activities performed.

9.2.2 Premises shall allow for an orderly workflow with adequate separation between different functions and must be adequate in size, well ventilated, adequately lit and shall not invalidate or adversely affect operations.

9.2.3 Special conditions for mobile collections shall apply.

9.3 Safety Programme

9.3.1 A safety programme shall be designed to mitigate or prevent occupational hazards and should include:

9.3.1.1 A disaster preparedness plan

9.3.1.2 The provision of protective clothing and appropriate safety equipment
9.3.1.3 Regular workplace assessments
9.3.1.4 Workload monitoring and stress management
9.3.1.5 Staff vaccination as appropriate
9.3.1.6 Prevention of needle stick accidents
9.3.1.7 Prevention of exposure to radiation or dangerous chemicals
9.3.1.8 Management of violence or aggression in the workplace
9.3.1.9 Necessary hazards signs should be posted where appropriate to include wet floors

9.4 Working Conditions

9.4.1 The BEs shall have procedures to ensure the provision of safe working conditions that meet national laws and regulations (where applicable).

9.4.2 Accidents, incidents and near misses in the workplace Accidents/incidents recorded and investigated shall be reported, recorded and investigated

9.4.3 No unauthorised entry shall be permitted.

9.4.4 The BEs shall maintain procedures to ensure the safety of donors, patients and visitors on the premises

9.4.5 The BEs shall maintain a procedure for post exposure prophylaxis for workplace exposure to HIV and hepatitis.

9.4.6 The BEs shall maintain a systematic programme for the prevention and control of infections which includes an SOP for hand washing and cleaning requirements.

10. INTERNAL AND EXTERNAL AUDITS

10.1 Audit System Requirements

10.1.1 The Bes shall have procedures to ensure that audits of operations and quality systems are scheduled and conducted at least once in each calendar year

10.1.2 The BEs shall have procedures for reviewing the outcomes of all audits.

10.2 Internal Audits

10.2.1 Personnel performing audits shall be independent of the area being audited

10.2.2 The internal audit reports shall be reviewed by personnel having responsibility for the area audited and the quality/auditing manager.

10.2.3 When non-conformances are identified, corrective action shall be taken.

10.3 External Audits

10.3.1 The BEs shall participate in external audit programme(s) performed by a qualified independent body.

11. NON-CONFORMANCES

11.1 Non-conformance System

11.1.1 The BEs shall have procedures to detect and deal with non-conformances, including those reported by internal and external audits.

11.1.2 The BEs shall define the procedure for the disposition of non-conforming blood, blood components, critical materials, and services.

11.2 Corrective Action

11.2.1 The BEs shall have procedures for corrective action of non-conformances, complaints, work place accidents and incidents, to include the following elements:

11.2.1.1 Description of the event

11.2.1.2 Immediate remedial action

11.2.1.3 Investigation of the root cause

11.2.1.4 Determination of corrective action required

11.2.1.5 Evaluation to ensure that corrective action is taken in a defined time frame and that it is effective.

11.3 Preventive Action

11.3.1 The BEs shall have procedures for preventive action that include the following elements:

11.3.1.1 Review of information including audit results, proficiency testing results, quality control records, and complaints to detect and analyse potential causes of non-conformances.

11.3.1.2 Determination of steps needed to respond to potential problems requiring preventive action

11.3.1.3 Initiation of preventive action and application of controls to monitor effectiveness

11.4 Non-conformance Review

11.4.1 There shall be scheduled reviews of non-conformances to detect trends and address areas requiring specific action.

11.5 Non-conforming Components

11.5.1 Authorized Use:

11.5.1.1 In exceptional circumstances, at the discretion of the managing physician, blood and blood components may need to be issued when not conforming to all mandatory test requirements. Upon receipt of signed request, the BEs shall notify the managing physician that all requirements cannot be met.

11.5.1.2 The managing physician shall acknowledge in writing that the clinical situation is sufficiently urgent to require the release of the blood component before completion of the compatibility and/or infectious disease testing. The documentation of the authorisation given by the medical practitioner and the managing physician may be obtained after the event.

11.5.1.3 A label on the container shall indicate which of the required tests have not yet been performed or completed.

11.5.1.4 The required testing shall continue after the release of the units, and if any of the blood units are found to be unsuitable, it shall be reported immediately to the

attending doctor who shall be instructed to stop the transfusion immediately. The non-conforming unit(s) shall be recalled, if possible.

11.5.2 Recall:

11.5.2.1 The BEs shall have procedures for the recall of non-conforming blood or blood components that are determined, after release, not to meet specified requirements.

12. CONTINUAL IMPROVEMENT

12.1 Requirements for Continual Improvement

12.1.1 A quality improvement plan that includes all parts of the organisation shall be developed and implemented. This plan shall promote continual quality improvement, shall allocate responsibilities for effective implementation and shall be subject to regular evaluation.

12.1.2 The BEs shall have procedures for obtaining and acting on feedback, including compliments, suggestions and complaints, from donors and customers/ physicians.

12.1.3 The BEs shall have procedures to collect and evaluate quality indicator data annually.

12.1.4 Monitoring and evaluation data shall be used to improve operations of the Bes.

13. PROCESS CONTROL

The BEs shall ensure that activities that affect the quality of blood, blood components, and services are carried out under controlled conditions.

13.1 Validation Activities

13.1.1 The BEs shall develop and implement procedures for the validation of new or changed procedures, and test methods prior to implementation.

13.1.2 Validation plans shall be approved prior to the work being undertaken.

13.1.3 Results shall be reviewed and acceptance/rejection decisions made by authorized individuals.

13.1.4 Re-validation shall be performed where changes have occurred or results indicate the need.

13.2 Change Control

13.2.1 The BEs shall have procedures for the management of changes to the BEs operations and quality system so that the quality of the components and services is maintained.

13.3 Internal and External Quality Assessment (IQA/EQA)

13.3.1 The BEs shall have IQA/EQA schedule.

13.3.2 EQA is mandatory on all testing for TTIs.

13.3.3 All other test must have at least IQA,

13.3.4 Results of IQA and EQA shall be reviewed and corrective action taken, where appropriate, when expected results are not achieved.

13.3.5 If the BEs is not participating in an EQA system, then an inter-laboratory testing

programme to compare results of laboratory testing shall be defined and documented.

13.4 Quality Control

13.4.1 A programme of quality control shall be established that is sufficiently comprehensive to ensure that personnel, reagents, equipment and methods function as expected.

13.4.2 The BEs shall randomly sample and perform quality control testing on blood and blood components.

13.4.3 A minimum of 1% of the total number of each component routinely prepared or 4 units per month, whichever is higher, should be tested and at least 75% of components tested should comply with the specifications set.

13.4.4 A test for sterility should be done on 1% of the blood units collected or 10 per month whichever is higher. The microbiological test should not be done by a method that entails breaching the final container before the blood is transfused. The blood specimen from the tubing attached to the container should be used for sterility testing using appropriate techniques.

13.4.5 Results of quality control testing shall be reviewed to ensure that specifications are met and expected outcomes obtained.

13.4.6 Reagents shall not be used if quality control tests fail.

13.5 Use of Materials

13.5.1 All materials (including containers and consumables used in the BEs) shall be stored and used in accordance with the manufacturer's written instructions.

13.5.2 Reagents that are prepared by the BEs shall be standardized to meet or exceed performance specifications of commercial reagents.

13.6 Identification and Traceability

13.6.1 There shall be a documented procedure for tracing the staff responsible for activities in the entire transfusion chain (vein-to-vein)

13.6.2 The BEs shall ensure that blood, blood components and critical materials used in their processing, laboratory specimens, donor and patient records, are identified and traceable from source to final issue or disposition.

13.6.3 Where pooled products are prepared traceability to individual donations shall be maintained

SECTION B - TECHNICAL REQUIREMENTS

1. BLOOD DONOR MANAGEMENT

1.1. Mobilization and recruitment of blood donors

1.1.1. Blood Establishments (BE) shall mobilize blood donors through the use of social, print and electronic media and at the community level in strict adherence to the NBTS guidelines.

1.1.2. Prior to collection, the Blood Establishment shall educate potential blood donors through the medium of written materials in English and the relevant local languages, regarding the donation process, risks of transmitting infectious diseases through blood transfusion and the benefits of blood donation.

1.1.3. Blood shall be collected from healthy, voluntary non-remunerated donors identified by the Blood Establishment to be at low-risk for transfusion transmissible infections (TTIs).

1.1.4. At least 10% of blood collections should be from repeat (regular) blood donors. There should be a plan in place to encourage repeat (regular) blood donation.

1.1.5. The Blood Establishment shall liaise with the NBTS in their state or zone to monitor emerging infectious diseases that may be transmissible through blood transfusion.

1.1.6. The Blood Establishment shall not offer incentives that discourage candid responses to donor eligibility criteria. Blood donors shall be reimbursed reasonably for costs incurred in the process.

1.2. Donor selection criteria

1.2.1. The BE shall develop donor selection criteria that are based on NBTS standards and regulations.

1.2.2. The BE shall have procedures to ensure that Blood donors at risk are referred for medical consultation and follow-up and records of such referrals shall be kept by the BE.

1.2.3. Assistance shall be given by donor registration personnel to donors with special needs including illiterate donors according to the BE's defined criteria.

1.2.4. Directed blood donation shall not be resisted, provided such a donor passes the stringent selection and screening criteria.

1.3. Donor screening

1.3.1. A blood donor health history questionnaire that is designed to elicit information about risk factors to the donor or patient shall be used. The questionnaire shall be evaluated, periodically updated and used in a confidential manner and shall be completed prior to all collections.

1.3.2. A blood donor questionnaire shall be prepared in English language and shall be completed prior to each donation, to determine eligibility for donation.

1.3.3. Blood donors shall be interviewed to determine their suitability for donation. This interview shall be conducted in a manner that preserves the privacy of the donor. Any medical queries shall be referred to a suitably qualified health personnel.

1.4. Donor consent

1.4.1. Blood donors shall be informed about the blood donation procedure, potential adverse reactions and post-donation care, the tests to be carried out on the blood donor, the process for notification of abnormal results and information that may be released to a third party.

1.4.2. The written informed consent for blood donation, testing and notification of normal and abnormal test results shall be obtained from all blood donors prior to donation. The blood donor shall have the opportunity to ask questions and decline consent. In the event that a potential blood donor declines to provide consent, the blood donation shall not be drawn.

1.4.3. A mechanism shall be established to permit a blood donor to request in confidence and/or subsequent to donation, that their donated units be discarded.

1.5. Donor notification and counseling

1.5.1. Blood donors shall be notified in a confidential manner of any medically significant finding(s) identified during the pre-donation evaluation.

1.5.2. Blood donors found to be reactive during screening for one or more TTIs shall be notified, provided with counseling services and referred for medical intervention.

1.5.3. Every BE shall have trained and skilled counselors for pre- and post- donation counseling.

2. REQUIREMENTS FOR BLOOD DONOR QUALIFICATION

2.1. Age

2.1.1. Blood donors shall be considered suitable between the ages of 18 and 70 years except in cases of autologous blood donation where the medical team may consider other variables.

2.2. Blood anticoagulant ratio

2.2.1. Volume collected shall not exceed 10.5 ml/kg of donor weight, including specimens collected for screening.

2.2.2. Volume collected shall be proportional to the volume of the anticoagulant. Whole blood collected into an anticoagulant volume calculated for 450 ml should be between 405 ml and 495 ml.

2.2.3. When 300 to 404 ml of whole blood is collected into an anticoagulant volume calculated for 450 ± 45 ml, or when 333 to 449 ml of whole blood is collected into an anticoagulant volume calculated for 500 ± 50 ml, red blood cells prepared from such units shall be labelled as **'red blood cells, low-volume'** and may be made available for transfusion. No other components shall be made from a low volume collection.

2.3. Donor body mass

2.3.1. The lower limit of body weight shall be 50 kg for a blood pack holding 450 ml ±10%.

2.3.2. The lower limit of body weight shall be 45 kg for a blood pack holding 250 ml or less.

2.3.3. Unexplained recent weight loss of more than 10% of body weight shall be a reason for

deferral for a minimum of six (6) months.

2.4. Donation interval

2.4.1. A minimum of 90 days for males and 120 days for females shall be the interval between whole blood donations with exception of autologous donations.

2.4.2. The minimum interval between two apheresis collections shall be 72 hours and at most, 24 procedures shall be performed on any individual donor within a 12-month period.

2.5. Blood pressure

2.5.1. Blood donors with a BP within the range of 160/90 mmHg and 100/60 mmHg may be considered suitable.

2.6. Pulse

2.6.1. Blood donors with a regular pulse of 60 to 100 beats/minute may be considered suitable but a lower value not less than 50beats/minute may be considered for trained and active athletes.

2.7. Haemoglobin or Haematocrit

2.7.1. Haemoglobin must be greater than or equal to 12.5 g/dL for male donors and 11.5g/dL for female donors while Haematocrit must be greater than or equal to 38% for males and 34% for females.

2.8. Drug therapy

2.8.1. Blood donors who have taken Aspirin less than 72 hours prior to donation shall be deferred especially when platelet based products are anticipated.

2.8.2. Blood donors on other antiplatelet/antocaogulant therapies shall be deferred for a suitable time period or deferred as advised by their physician.

2.9. Medical history and general health

2.9.1. The prospective blood donor shall appear to be in good health, and not under the influence of alcohol or drugs.

2.9.2. The prospective donor shall be free from major organ diseases (e.g. heart, liver, lungs), cancer or abnormal bleeding tendency except for therapeutic reasons, as may be prescribed by a medical doctor.

2.9.3. The venepuncture site shall be evaluated for lesions on the skin. The venepuncture site shall be free from infectious skin diseases and any disease that might create a risk of contaminating the blood.

3. COLLECTION OF BLOOD FROM DONORS

3.1. Sterility

3.1.1. The blood collection equipment shall be sterile, pyrogen-free and for single-use, with a closed system of collection.

3.2. Protection against contamination

3.2.1. Prior to collection of blood, the container to be filled shall be inspected in a manner recommended by the manufacturer to ensure that the hermetic seal is intact, that there has been no leakage of the anticoagulant or preservative solution from the container and that the container is in all other respects suitable for use.

3.2.2. The venepuncture site shall be free from lesions and signs of infection that might create a risk of contaminating the blood during donation.

3.2.3. The venipuncture site shall be disinfected so as to minimize the risk of microbial contamination by following a validated method and using standard materials that will not adversely affect the blood collected.

3.2.4. Blood shall be collected by single venipuncture and the flow of blood shall be continuous.

3.2.4.1. Maximum collection time for whole blood intended for production of labile components shall not exceed 12 minutes for platelet based products and 15 minutes for cryoprecipitate and FFP.

3.3. Specimens

3.3.1. The blood specimens for laboratory tests shall be collected at the same time as the collection of blood, as part of the collection process. Donor identity shall be verified prior to venipuncture.

3.3.2. Specimens shall be labeled before the collection begins and shall be re-identified with the blood container immediately before the collection of the specimens.

3.3.3. Each specimen shall be identified by a numeric or alpha-numeric system at the time of collection of blood, so that donations can be traced back to the donor.

3.3.4. The pilot tubing of the plastic blood bag shall be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent testing.

3.4. Ratio of blood to anticoagulant

3.4.1. The volume of blood collected shall be proportionate to the volume of anticoagulant according to the manufacturer's instructions.

3.4.2. Blood shall be gently agitated using a method that has been shown to mix the blood and anticoagulant in a manner that prevents the formation of micro clots and thus the consumption of clotting factors, either by automatic or manual mixing.

3.5. Temperature during transportation

3.5.1. After collection, blood shall be stored under conditions appropriate for the components to be made from it.

3.6. Apheresis donation

3.6.1. Cytaphresis and plasmapheresis blood donors shall be subjected to stringent donor selection and screening criteria. Assessment of relevant components in the potential donor shall be done not more than 6 hours before donation.

3.7. Donor reactions

3.7.1. Resources shall be available and personnel shall be trained in the management of adverse reactions in donors, both for mobile and fixed sites.

4. HANDLING, TRANSPORTATION AND STORAGE

4.1. Transportation following collection

4.1.1. The BE shall have procedures to ensure that blood and blood components are handled, stored and transported in a manner that prevents damage and deterioration; and also meets specified requirements.

4.2. Transport Temperatures

4.2.1. Following collection, blood is placed in containers that allow for cooling towards +2°C to +10°C unless platelets are to be prepared, in which case blood donations are cooled towards +18°C to 22°C until arrival at the processing laboratory.

4.3. Storage devices for blood and blood components

4.3.1. Storage devices shall have the capacity and design to ensure that the correct temperature is maintained. There shall be provision of primary and standby power sources for every BE.

4.3.2. Cold rooms, refrigerators, freezers and platelet rotors shall have their temperature continuously monitored or shall be monitored at least 3 times at regular intervals over 24 hours.

4.3.3. The BE shall use designated storage areas to prevent deterioration and damage to materials, in-process and final products. The BE shall control access to such areas.

4.3.4. Cold rooms, refrigerators or freezers used for blood storage shall contain only donor blood, blood specimens, reagents or blood components and no other items, such as foodstuffs.

4.3.5. The BE shall have procedures to maintain blood and blood components at the required temperature, in the event of failure of the primary source of power or equipment. The procedure may include provision of back-ups or arrangement with a sister blood establishment with adequate facilities.

4.4. Alarm systems

4.4.1. Storage devices for blood and blood components shall have alarms that ring audibly in occasions of out-of-range temperature.

4.4.2. The alarm shall be set to activate under conditions that will allow timely actions to be taken before blood or blood components reach an unacceptable temperature.

4.4.3. The alarm system shall be tested at least every 3 months, or in accordance with the manufacturer's instructions if this is more frequent.

4.4.4. The alarm system in liquid nitrogen freezers shall be activated before the contained liquid nitrogen reaches a level that could result in the thawing of the contained blood component or other materials.

4.4.5. Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective actions.

4.5. Transportation of blood and blood components

4.5.1. Standardized containers used for the transportation of blood and blood components shall be validated to ensure they are suitable for maintaining required temperatures.

4.5.2. The BE shall verify that the establishment receiving the containers of blood and blood components maintains a system for checking that such containers arrive at their destination within the stipulated temperature ranges.

4.5.3. Corrective actions shall be taken by the receiving facility if the container did not arrive at the required temperature.

5. TESTING OF DONATED BLOOD

5.1. General Testing Requirements

5.1.1. Blood group serology and testing for infectious diseases shall be carried out on a specimen collected at the time of donation, on every unit of whole blood or apheresis unit collected.

5.1.2. The BE shall have procedures for the appropriate segregation and quarantine of untested units or those waiting for further testing.

5.1.3. The test method to be used shall be chosen from the list of technologies indicated below: For HIV- Fourth Generation ELISA screening, Chemiluminescence and Nucleic Acid Amplification Technique (NAAT).

5.1.3.1. For HBV- Third Generation ELISA screening for HBsAg, Third Generation ELISA screening for HBV markers (inclusive of HBsAg), Chemiluminescence and HBV-DNA

5.1.3.2. For HCV- ELISA for Anti-HCV, Chemiluminescence and Nucleic Acid Amplification Technique (NAAT)

5.1.3.3. For Syphilis- ELISA, Chemiluminescence and Nucleic Acid Amplification Technique (NAAT)

5.1.4. Any discrepancy in test results shall be resolved with the appropriate technology before the unit is released from quarantine and made available for transfusion.

5.2. Blood group serology

5.2.1. Records of testing for blood groups shall be maintained.

5.2.1.1. When ABO and/or RhD groups on record do not concur with current test results, an investigation to resolve the discrepancy shall be undertaken. Units for which a discrepancy remains unresolved shall not be transfused until the discrepancy is resolved.

5.2.1.2. The ABO group shall be determined for each collection by testing the red cells with anti-A, anti-B and anti-A plus B reagents and by testing the serum with A, B and O cells for the detection of expected antibodies. In case of automation, adhere to the manufacturer's instruction.

5.2.1.3. The RhD type shall be determined with anti-D reagent. If the blood of a donor is initially typed as RhD negative, it shall be further tested to detect weak D. When the test for weak D is positive, the unit shall be labelled as RhD positive.

When the tests for RhD and weak D are negative, the unit shall be labelled as RhD negative.

5.2.2. Group O, A and B donations shall be tested for relevant high titre allo-agglutinins and haemolysins

5.2.2.1. Whole blood and plasma containing high titre allo-agglutinins and haemolysins shall be labeled accordingly

5.2.2.2. Red cell concentrates need not be labeled 'high titre' or 'haemolysin containing', if the majority of the plasma is removed.

5.2.2.3. Whole blood or plasma labeled as 'High Titre' or 'haemolysin containing' shall be transfused into patients of the same ABO group only.

5.2.3. Serum or plasma from donors shall be tested for unexpected red cell antibodies using a validated method known to detect clinically significant antibodies. When these are detected, plasma from such units shall not be used for transfusion.

5.3. Testing for infectious diseases

5.3.1. The following tests shall be performed on blood specimens taken at the time of collection:

5.3.1.1. Human Immunodeficiency Virus (HIV). Minimum- P24 antigens and antibodies to HIV-1 and HIV-2.

5.3.1.2. Hepatitis B virus (HBV). Minimum - Hepatitis B surface antigen (HBsAg) with ELISA technique.

5.3.1.3. Hepatitis C virus (HCV). Minimum - antibodies to HCV with ELISA technique.

5.3.1.4. Syphilis (*Treponema pallidum*). Minimum - antibodies to *T. pallidum* with ELISA technique**.**

5.3.2. Only donations that are non-reactive for the markers listed above shall be transfused. **SPECIAL CLAUSE:** Malaria density shall be a basis for assessment of blood donors when preparation of platelet based products is intended because of the survival of the parasite at that temperature. Malaria parasite density will also be considered in case of expatriate transfusion or recipients coming from malaria free zones with compromised immunity against the parasite

5.3.3. Initially reactive donations should be re-tested in duplicates by the same assay. A repeatedly reactive donation should not be used for therapeutic use and should be destroyed unless used for non-therapeutic purposes.

5.3.4. Only tests kits approved by NAFDAC and MLSCN should be used and the test system in which such is used shall be validated by the BE.

5.3.5. Products that will not be refrigerated (e.g. platelet based products) should be screened for microfilaria and leishmaniasis.

5.3.6. The BE shall maintain algorithms for testing procedures and rejection in adherence to NBSC guidelines.

SECTION C:
PLASMA FRACTIONATION REQUIREMENTS

1. Blood Product Production

1.1 Separation Procedures

1.1.1 Methods that ensure the quality and safety of components, including aliquots and pooled components, shall be employed

1.1.2 Blood components shall be separated from whole blood no more than 24 hours after collection. If a facility plans to use the red cells only and to discard the plasma, the separation step can be performed at any point up to the expiry date unless an additive solution is being used, in which case the separation must occur within a maximum of 7 days of collection, in conformance with the manufacturer's instructions.

1.1.3 The expiry date of blood or blood components shall be calculated by considering the day of donation as day zero.

1.1.4 The sterility of components shall be maintained during processing by the use of closed systems, aseptic methods and sterile pyrogen-free disposable bags and solutions. If the closed system is compromised, the component should not be used. In the appropriate clinical situation (e.g in paediatric practice) where the he closed system is necessarily compromised, the expiry of the component shall be 6 hours or as determined by the responsible practitioner.

1.1.5 The facility shall implement procedures for using a sterile connecting device that does not compromise the closed system.

1.2 Visual Inspection and Release

1.2.1 The component shall be physically inspected for container integrity and normality of appearance prior to release. Action shall be taken if anomalies or errors are detected.

1.3 Labelling and Issue

1.3.1 All blood and blood components shall be accurately labelled using clear and legible labels that adhere firmly to pack surfaces at the range of temperatures experienced.

1.3.2 Label(s) shall not interfere with inspection of the contents or normal function of the container. Additional labels affixed shall not obscure/cover primary donor identification numbers and other information that will subsequently be relied upon to identify the unit and its important characteristics.

1.3.3 The facility shall use a numeric or alphanumeric system that will make it possible to:

1.3.3.1 Uniquely identify every unit and blood component and its status at any stage during process.

1.3.3.2 Trace any unit of blood or blood component from source to final disposition and to recheck records applying to the specific unit.

1.3.3.3 Identify the blood establishment that carried out any part of the preparation.

1.3.4 The numeric or alphanumeric identification on the label shall be applied by the collecting facility to each unit of blood and/or its components.

1.3.5 After processing the blood, a final label shall contain the following information, as a minimum:

1.3.5.1 Name of the component

1.3.5.2 The unique numeric or alphanumeric identification

1.3.5.3 The date of collection of the blood or component from the donor

1.3.5.4 The name and volume of anticoagulant solution and additive solution, where applicable, and the approximate volume of blood collected

1.3.5.5 For platelet concentrates, plasma and components obtained through apheresis donation, the approximate volume of the component is required, but not the volume of the anticoagulant

1.3.5.6 Storage and transportation temperatures

1.3.5.7 Expiry date, and time where appropriate

1.3.5.8 The ABO blood group and RhD type of the donor (except for fresh frozen plasma and cryoprecipitate where RhD type is not required

1.3.5.9 Titre (if applicable)

1.3.5.10 Name of the blood collection facility.

1.3.6 The blood collection facility shall provide the transfusing facility with information on the handling and administration of blood and blood components including:

1.3.6.1 Content shall not be used if there is any visible evidence of deterioration

1.3.6.2 Agitate gently before use

1.3.6.3 Do not add medications to the blood components

1.3.6.4 Match blood group on label and blood group of the recipient (if known) to check for suitability before administration

1.3.6.5 Use a sterile and pyrogen-free disposable transfusion set with filter to transfuse blood

1.3.6.6 Check identity of patient against the blood or blood component

1.3.6.7 What to do in the event of transfusion reaction (Should follow the blood as an insert)

1.3.6.8 Instructions to be followed if blood is to be warmed using special blood warmers.

2 Receipt, Ordering, Selection and Issuing of Blood and Blood Components

2.1 Receipt of Blood Components

2.1.1 The facility shall have procedures to check all incoming blood and blood components from another centre or other organisation against the delivery document for number and group of components. Also check for product integrity, expiry date, and temperature on receipt. Discrepancies shall be reported to the collecting facility and shall be resolved before use.

2.2 Orders for Blood Components for a Specific Patient

2.2.1 A request for blood shall be authorized by a medical practitioner or other authorized healthcare professional.

3 Haemovigilance and Clinical interface

3.1 Donor Adverse Events

3.1.1 Adverse events related to the blood donation process shall be assessed, investigated and monitored.

3.2 Transfusion Transmissible Infections:

3.2.1 Look-back: Patient initiated

3.2.1.1 When transmission of an infectious disease is suspected to be the result of transfusion, the facility that transfused the blood shall report that information to the BE and the NBTS should be notified.

3.2.1.2 The BE shall have procedures for investigating and deferring donors when such reports are received.

3.2.2 Look-Back: Donor initiated

3.2.2.1 The BE shall have procedures to notify the hospital or doctor of recipient(s) of units from a blood donor who is subsequently found to be infected with HIV, HBV or HCV

3.2.2.2 The BE shall provide guidance to the administering facility (hospital and doctor) which shall act on the information in the best interests of the patient.

3.3 Clinical Interface

3.3.1 A facility that transfuses blood shall develop or adopt clinical guidelines on the appropriate use of blood and blood components and to advocate for best transfusion practices, and promote continuing education in transfusion practice for clinical personnel. The guidelines shall include information on the products and services offered by the facility.

3.3.2 A facility that transfuses blood shall have procedures to communicate with clinical personnel to inform and educate on the availability of blood and blood components and their appropriate use.

3.4 Monitoring of Blood Usage

3.4.1 A facility that collects or issues blood for transfusion shall perform at least annual evaluations of blood need, blood supply and blood usage and shall use the information gained for continuous improvement and planning.

4 Blood Administration

4.1 Administration of Blood and Blood Components

4.1.1 The facility shall make guidelines available for the administration of blood and blood components including the use of infusion devices and ancillary equipment and the identification, evaluation and reporting of adverse events related to transfusion. The guidelines shall cover all the issues following hereafter in section four (4)

4.1.2 The medical practitioner shall advise the patient, in a language that he/she

understands, of the risks and benefits of transfusion and obtain written informed consent for the transfusion from the patient. (NBTS should develop a standard consent form for use by transfusing facilities and also policy on the retrieval of blood). At a minimum, elements of consent include:

4.1.2.1 A description of the risks, benefits and treatment alternatives (including non-treatment).

4.1.2.2 The opportunity to ask questions

4.1.2.3 The right to accept or refuse transfusion.

4.1.3 Before transfusion the blood or blood component shall be visually inspected and the expiry date on the label confirmed. The blood or blood component shall be used only if its appearance is normal and the expiry date has not been exceeded.

4.1.4 Immediately before transfusion, two individuals shall independently verify the identity of the patient at the bedside, the blood component, blood group and compatibility testing report and associated records. The recipient's vital signs shall be assessed and recorded prior to transfusion.

4.1.5 The transfusion shall be given with a sterile, pyrogen-free and disposable transfusion set with filter.

4.1.6 Transfusion of one unit of blood or a component shall not take longer than 4 hours. For patients requiring long-term transfusion the intravenous (IV) line shall be changed at least every 24 hours.

4.1.7 All identifications attached to the blood or blood component container shall remain attached during and after transfusion. The transfusion record shall be included in the patient's file.

4.1.8 The individual administering the blood or blood component shall regulate the speed of the transfusion and observe the patient for the first 15 minutes at the start of the transfusion, approximately every hour during the transfusion and periodically for 24 hours after the transfusion to observe any evidence of untoward reaction.

4.1.9 In the event of an adverse reaction the transfusion shall be stopped immediately and reported promptly to the attending doctor and the compatibility testing laboratory, and the Haemovigilance or Hospital Transfusion Committee.

4.2 Blood Warmers

4.2.1 Warming of blood (using blood warmers) to body temperature should be done in cases of rapid transfusion, massive transfusion, for patients with cold agglutinins and for exchange transfusion in infants. Blood **shall not** be warmed above +37ºC.

4.2.2 Where applicable warming of blood should be accomplished using a blood warming device attached to the transfusion set. The warming device shall be equipped with an alarm system. Blood that has been warmed shall be transfused within 4 hours and if not transfused, shall be clearly labelled as condemned, discarded and not be used for another patient. If blood warmer is under control of blood facility, Section A 7.3, Equipment Qualification and Section A 2, Process Control, apply.

4.3 Administration of Platelet Concentrate.

4.3.1 Platelets shall be administered through a standard platelet filter. Micro aggregate filters shall not be used for the administration of platelet components.

5 Requirements If Plasma Is Provided for Fractionation

5.1 Equipment

5.1.1 Equipment used for the collection and further separation of blood shall be maintained and calibrated regularly.

5.1.2 The collection and separation process shall be validated.

5.1.3 The quality of the recovered plasma shall be validated.

5.1.4 A set of quality control tests, including measurement of total proteins, residual blood cells, haemoglobin, and relevant coagulation factors, such as Factor VIII, shall be included in the validation process.

5.1.5 Validation studies of new apheresis procedures shall evaluate possible risks of activation of the coagulation, fibrinolysis, and complement systems potentially induced by the material in contact with blood, such studies are usually performed by the manufacturer of the apheresis machines but should be confirmed as part of the Quality Management System of the Blood Establishment.

5.2 Pre-Processing Storage

5.2.1 Whole Blood should be kept up to 20 hours at 20-24°C or not more than 8 hours at 4 °C prior to separation if the plasma is to be fractionated.

5.3 Communication with Fractionator

5.3.1 There shall be a system to ensure effective communication between the blood establishment and the fractionator so that information on significant post-donation events may be immediately transmitted to the fractionator and the national regulatory authority.

5.3.2 This procedure shall allow early and effective communication of any evidence for the presence of blood-transmissible infection in a donor whose plasma has been sent for fractionation.

5.4 Look-Back

5.4.1 A system shall be in place to perform a look-back procedure, preferably using a computer database.

5.4.2 A look-back procedure shall be performed if it is found retrospectively that a donation should have been excluded from processing, e.g. because that unit was collected from a donor who was subsequently rejected because of reactive viral marker, risk behaviour, exposure to CJD/vCJD or other risks related to infectious diseases.

5.4.3 The blood establishment shall transmit this information to the fractionator according to the agreements in place, and to the national regulatory authority.

5.4.4 Donor notification and counselling are recommended both for purposes of donor health and for the safety of the blood supply.

5.5 Transmissible Spongiform Encephalitis (TSEs)

5.5.1 Blood shall not be collected from persons who: -

5.5.1.1 Have a family history that places them at risk of developing a TSE.

5.5.1.2 Have received a corneal or dura mater graft.

5.5.1.3 Have been treated in the past with medicines made from human pituitary glands.

5.5.1.4 Have spent a cumulative period of 1 year or more in the United Kingdom between the beginning of 1980 and the end of 1996.

5.6 Containers used for the collection of blood

5.6.1 The containers used for the collection and storage of plasma for fractionation shall comply with the (appropriate regulatory authority) to be clarified by the house provisions and shall be under the control of the (regulatory authority) to be defined.

5.6.2 Containers shall comply with the regulatory and technical requirements of the plasma fractionator.

5.6.3 Containers shall be labelled with batch numbers traceable to individual donations. The quality of containers has a direct impact on the quality of the plasma produced and it is therefore part of GMP to control the suitability of this starting material before use.

5.6.4 Containers for whole blood collections shall be the same as for donations of whole blood from which plasma is used for fractionation.

5.6.5 Containers shall be plastic, and shall have been manufactured in such a way as to assure internal sterility; they shall be hermetically sealed to exclude contamination.

5.6.6 If the container is not manufactured as an integral part of a blood collection set, there shall be a mechanism for docking with the collection set that minimizes the risk of adventitious microbial contamination.

5.6.7 Validation studies shall be required to confirm the suitability of the container material (and the material of any tubing or harness through which plasma should pass) during storage in contact with the plasma.

5.7 Immunisation of donors

5.7.1 If immunisation of donors is practiced, procedures shall be available and followed that are in accordance with those formulated by the World Health Organisation (Requirements for the collection, processing and quality control of blood, blood components and plasma derivatives, WHO Technical Report Series, No. 840, 1994 or subsequent revision).

5.8 Records

5.8.1 The collection centre shall ensure that records of donors and donations made are kept in such a way that, while maintaining the required degree of confidentiality concerning the donor's identity, the origin of each donation in a plasma pool and the results of the corresponding acceptance procedures and laboratory tests can be traced.

5.9 Tests for Transfusion Transmissible Infections.

5.9.1 Only test kits approved by a nationally recognised institution (E.g. MLSCN (as the have the mandate to regulate invitro testing reagents) CE marked etc.) shall be used and the test system in which such a test kit is used shall also be validated by the collection centre.

5.9.2 Sensitivities of assay must always be representative of viral genotypes prevalent in the country.

5.10 Separation of Plasma from Red Cells

5.10.1 Plasma shall be prepared by a method that removes cells and cell debris as completely as possible.

5.10.2 Plasma shall be separated from the cells by a method designed to prevent the introduction of micro-organisms.

5.10.3 No antibacterial or antifungal agent shall be added to the plasma

5.10.4 The containers shall be closed so as to prevent contamination.

5.10.5 If two or more units are pooled prior to freezing, the operations shall be carried out using sterile connecting devices or under aseptic conditions and using containers that have not previously been used.

5.10.6 If the units of plasma are to be used for Fresh Frozen Plasma (FFP), the process must be completed under six hours of donation, failure which the product shall be labeled Single Donor Plasma-24 (SDP24), provided the preparation was completed under 24 hours. Any plasma produced after 24 hours shall not be used for clinical purposes.

5.11 Plasma NOT suitable for fractionation

5.11.1 Plasma obtained by therapeutic plasma exchange is not suitable for fractionation into plasma products.

5.11.2 Plasma from autologous blood donations is not suitable for fractionation and may have higher prevalence of viral markers.

5.12 Freezing of Plasma for Fractionation

5.12.1 When obtained by plasmapheresis, plasma intended for the recovery of labile proteins shall be frozen by cooling rapidly at - 30 °C or below as soon as possible and at the latest within 24 hours of collection.

5.12.2 When obtained from whole blood, plasma intended for the recovery of labile proteins shall be separated from cellular elements and frozen by cooling rapidly at - 30 °C or below as soon as possible and at the latest within 24 hours of collection.

5.12.3 When obtained from whole blood, plasma intended solely for the recovery of proteins that are NOT labile shall be separated from cellular elements and frozen at - 20 °C or below as soon as possible and at the latest within 72 hours of collection.

5.12.4 The method used for the freezing of plasma shall be validated prior to use and at defined intervals thereafter.

5.13 Storage and Transport

5.13.1 The optimal storage time and temperature for frozen plasma is 36 months at - 25 °C. In no event shall frozen plasma be stored or transported above - 20 °C.

5.14 Segregation Procedures for Plasma

5.14.1 Untested plasma and released plasma should be stored in separate freezers, or if both types of plasma are stored in a single freezer a secure segregation system shall be used.

5.14.2 Plasma donations initially reactive for TTIs shall be stored in a separate quarantine freezer or a secure system (e.g. validated computer hold system) shall be used to prevent issuing of reactive plasma.

5.14.3 Donations that are found to be unacceptable for fractionation shall be retrieved, disinfected and discarded using a secure system.

5.14.4 Plasma donations for shipment to the plasma fractionator shall be boxed in a secure manner and an effective procedure (such as a computerized system) should exist to make sure that only fully tested and released plasma donations are boxed.

5.14.5 Prior to shipment, plasma boxes shall be reconciled appropriately.

5.14.6 Prior to release of the plasma shipment to the fractionator, there shall be a formal review of the documentation to ensure that the plasma shipped complies fully with the specifications agreed upon with the plasma fractionator.

LIST OF TABLES

TABLE 1: Documents Required for Archiving After Retention Period

Reference	Record to be Maintained	Status
A 1.3.4	The BEs organogram	
A 1.5.4	Approved exceptions	
A 2.2	Top management review of quality system	
A 2.3	Quality manual, policies, processes & SOPs	
A 3.3	Job descriptions	
A 3.4.1	Training policy	
A 3.4.2	Evaluation of competence	
A 3.5	Personnel records	
A 5.1	Approved suppliers	
A 5.3.1	Agreement review	
A 5.3.2	Agreement concerning subcontractors	
A 6.1	Inspection of incoming materials and products	
A 7.7	Monitoring and maintenance of equipment	
A 7.2	Selection criteria for equipment	
A 8.3.2	Accident and incident reporting	
A 9.2.1	Internal audit review	
A 9.2.3	Corrective action	
A 9.3.1	Review of external audit performance results	
A 10.1	Detection, capture, assessment, investigation and monitoring of non-conformances	
A 10.5.1	Medical director approval of issue of blood and components that may not conform to all mandatory test requirements	
A 10.5.2	Discard of non-conforming units	
A 11.1.2	Review of feedback from donors and customers/ clinicians	
A 12.1	Validation of new or changed procedures, test methods or software implementation	
A 12.4.1	Quality control programme	
A 12.6	Traceability of blood, blood components and critical materials	
B 1.2	Donor selection criteria	
B 1.3	Donor deferral criteria	
B 1.3.1	Donor history questionnaire	
B 1.4.2	Donor consent	
B 2.7	Apheresis donor records	
B 3.4.6	Temperature monitoring of refrigerators, freezers and platelet incubators	
B 3.5.4	Monitoring of liquid nitrogen level or temperatures	
B 4.2	Blood group serology	

Reference	Record to be Maintained	Status
B 4.3	Infectious disease testing of blood specimens	
B 5.3.3	Unique identification of blood or blood components	
B 6.1	Receipt of blood or blood components	
B 6.2	Requests for blood or blood components	
B 7.1	Test results of ABO group and RhD type	
B 7.2.3	Blood transfusion record	
B 8.2	Management of adverse reactions in recipients	
B 8.2	Investigation of the transmission of transfusion transmitted infections	
B 8.3.1	Look back to identify recipient(s) of units from a blood donor who is subsequently found to have been infected with HIV, HBV or HCV	
B 9.1.3	Inspection of blood and blood components prior to release for transfusion	
B 9.1.4	Verification of patient identity at the bedside, prior to transfusion	
B 9.1.8	Transfusion record in hospital file	
B 9.1.9	Observation record during transfusion episode	

TABLE 2: Other deferral conditions

SN	Category	Criteria/Description	Deferral Period
1.	Dental Extraction/Surgery	Simple dental extraction	7 days
		Root canal work	14 days
		Dental surgery	4 weeks
2.	Pregnancy	Pregnancy	Deferred
		Lactation	24 weeks into lactation
		Termination of pregnancy	12 weeks
3	Receipt of blood /blood components	Deferral for receipt of blood, blood components, or plasma-derived medicinal products.	52 weeks
4	Immunizations and vaccinations	Receipt of live attenuated viral and bacterial vaccines for Measles, Mumps, Polio (Sabin/oral), Typhoid (oral) and Yellow fever.	2 weeks
		Receipt of live attenuated viral and bacterial vaccines for German measles (rubella), Chicken pox (varicella zoster) and BCG.	4 weeks
		Receipt of other vaccines, including emergency use approved vaccines.	52 weeks

5	Transfusion transmissible infections	Present or past clinical or laboratory evidence of infection with HIV, HBV and HCV.	Permanently deferred
		Malaria density shall be a basis for assessment of blood donors when preparation of platelet-based products is intended because of the survival of the parasite at that temperature. Malaria parasite density will also be considered in case of expatriate transfusion or recipients coming from malaria free zones with compromised immunity against the parasite.	
		Travel history: Evaluate the potential risks of travel to countries where transmissible infections are endemic and defer accordingly	Defer in line with the National Health Policy
		Following the diagnosis of a sexually transmitted infection such as syphilis	Permanently deferred
		Occupational exposure to blood and body fluids	52 weeks
		Non-sterile skin penetration with instruments, equipment, or weapons contaminated with blood or body fluids other than the donor's own, including tattoos, body piercing, and scarification.	52 weeks
		Had sexual contact or lived with an individual who: - Has acute or chronic hepatitis B (positive HBsAg test, HBV NAT) - Has hepatitis C	52 weeks
		Sexual contact with an individual with HIV infection or at high risk of HIV infection.	Permanently deferred

TABLE 3: Requirements for Separation, Preparation, Storage and Expiry (of Blood and Blood Products)

Component	Parameter	Specifications	Task	Status (Evidence of Compliance)	Remarks

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