NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT 1993 (AS AMENDED)

BLOOD AND BLOOD PRODUCT SAFETY REGULATIONS 2009.

Commencement

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by sections 5 and 29 of NAFDAC Act 1993 (as amended) and all the powers enabling it in that behalf, the Governing Council of NAFDAC with the approval of the Honourable Minister of Health makes the following Regulations:

Scope

1. These regulations prescribe the minimum requirements for donor examination, collection and testing of blood and blood components, whatever their intended purpose, and for their processing, labelling, storage, and distribution when they are intended to be used for transfusion or for further manufacturing.

Prohibition

2. a. No person shall collect, test, process, label, store and distribute blood and blood components except as provided in these regulations. Failure to comply with any provision set forth in these regulations in respect of donor examination, collection, testing, processing, labelling, storage and distribution shall render such blood and blood product unsafe and such blood and blood product, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

b. These Regulations apply without prejudice to the Medical Devices Regulations 2009.

c. These Regulations do not apply to the following:

i. Blood stem cells

ii. All investigational tests using blood and blood products for scientific and medical purposes. This prohibition does not include tests on blood and blood products intended for transfusion purposes.

Requirement for authorization

3. a. Except as authorized by the Agency, no person shall carry out the following:

i. The collection and testing of blood or blood components, whatever their intended purpose; and;

ii. The processing, storage and distribution of blood and blood components when they are intended to be used for transfusion or further manufacturing.

b. The blood establishment shall notify the Agency of any change or discontinuance of use of premises to which the authorization relates.

Organization and personnel

4. A blood establishment shall be an entity that is authorized by the Agency, to perform the intended function and which can be held accountable for its activities.

Personnel

5 a. The blood establishment shall designate a person responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components. The person shall have adequate educational background, training, and experience, including professional training as necessary, or combination thereof, to ensure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess.

Personnel

The blood establishment shall:

i. Notify the Agency of the name, address, qualification and experience of the person who will carry out the functions of responsible person

ii. Notify the Agency of any change to the responsible person

iii. Not permit any person to act as responsible person other than the person named in the authorization as the responsible person

b. The personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components shall be adequate in number, have adequate educational background, training, and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess.

c. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the procedures or control operations they perform, the necessary training or experience, and adequate information concerning the application of pertinent provisions of this section to their respective functions.

d. Persons whose presence can adversely affect the safety and purity of the products shall be excluded from areas where the collection, processing, compatibility testing, storage or distribution of blood or blood components is conducted.

Facilities

6. Facilities shall be maintained in a clean and orderly manner, and shall be of suitable size, construction and location to facilitate adequate cleaning, maintenance and proper operations. The facilities shall:

a. Provide adequate space for the following where applicable:
   i. Private and accurate examinations of individuals to determine their suitability as blood donors.
   ii. The withdrawal of blood from donors with minimal risk of contamination, or exposure to activities and equipment unrelated to blood collection.
   iii. The storage of blood or blood components pending completion of tests.
   iv. The quarantine storage of blood or blood components in a designated location pending repetition of those tests that initially gave questionable serological results.
   v. The storage of finished products prior to distribution.
   vi. The quarantine storage, handling and disposition of products and reagents not suitable for use.
   vii. The orderly collection, processing, compatibility testing, storage and distribution of blood and blood components to prevent contamination.
   viii. The adequate and proper performance of all steps in plasmapheresis, plateletpheresis and leukapheresis procedures.
   ix. The orderly conduction of all packaging, labeling, and other finishing operations.

b. Provide adequate lighting, ventilation, and screening of open windows and doors.

c. Provide adequate, clean, and convenient handwashing and toilet facilities for donors and personnel. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.

d. Provide for safe and sanitary disposal for the following:

   i. Refuse and items used during the collection, processing, and compatibility testing of blood and blood components.
   ii. Blood and blood components not suitable for use or distribution

e. Monitor and control access to blood and blood product facilities.

Equipment

7 a. Equipment used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be maintained in a clean and orderly manner and located so as to facilitate cleaning and maintenance.

b. Equipment shall be observed, standardized and calibrated on a regularly scheduled basis in accordance with the Standard Operating Procedures and with the minimum frequencies as

prescribed in Schedule "A" of these regulations to ensure compliance with the official specifications for blood and blood products.

c. Equipment employed in the sterilization of materials used in blood collection or for disposition of contaminated products shall be designed, maintained and utilized to ensure the destruction of contaminating microorganisms. The effectiveness of the sterilization procedure shall be no less than that achieved by an attained temperature of 121.5°□C maintained for 20 minutes by saturated steam or by an attained temperature of 170 °C maintained for 2 hours with dry heat.

Supplies and Reagents

8 a. All supplies and reagents used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be stored in a safe, sanitary and orderly manner.

b. All surfaces coming in contact with blood and blood components intended for transfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency or effectiveness of the product. All final containers and closures for blood and blood components not intended for transfusion shall be clean and free of surface solids and other contaminants.

c. Each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its use and immediately after filling. Such examinations shall include inspection for breakage of seals when indicated, and abnormal discoloration. Where any defect is observed, the container shall not be used, or, if detected after filling, shall be properly discarded.

d. Representative samples of each lot of the following reagents or solutions shall be tested on a regularly scheduled basis by methods described in the Standard Operating Procedures to determine their capacity to perform as required as prescribed in Schedule "B"

e. Supplies and reagents that do not bear an expiration date shall be stored in such a manner that the oldest is used first (first in first out).

f. Supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer.

g. Items that are required to be sterile and come into contact with blood shall be disposable whenever possible.

9 a. Written standard operating procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage and distribution of blood and blood components for transfusion and further manufacturing purposes. Such procedures shall be available to the personnel for use in the areas where the procedures are performed. The written standard operating procedures shall include, but are not limited to, descriptions of the following, when applicable:

i. Criteria used to determine donor suitability, including acceptable medical history criteria.
ii. Methods of performing donor qualifying tests and measurements, including minimum and maximum values for a test or procedure when a factor is used in determining acceptability.
iii. Solutions and methods used to prepare the site of phlebotomy to give maximum assurance of a sterile container of blood.
iv. Method of accurately relating the product(s) to the donor.
v. Blood collection procedure, including in-process precautions taken to measure accurately the quantity of blood removed from the donor.
vi. Methods of component preparation, including any time restrictions for specific steps in processing.
vii. All tests and repeat tests performed on blood and blood components during processing.
viii. Pre-transfusion testing, where applicable, including precautions to be taken to identify accurately the recipient blood samples and cross-matched donor units.
ix. Procedures for investigating adverse donor and recipient reactions.
x. Storage temperatures and methods of controlling storage temperatures for all blood products and reagents as prescribed in these regulations
xi. Determination of shelf life, if any, assigned for all final products as prescribed in these regulations.
xii. Criteria for determining whether returned blood is suitable for reissue.
xiii. Procedures used for relating a unit of blood or blood component from the donor to its final disposition.
xiv. Quality control procedures for supplies and reagents employed in blood collection, processing and pre-transfusion testing.
xv. Schedules and procedures for equipment maintenance and calibration.
xvi. Labeling procedures, including safeguards to avoid labeling mix-ups.
xvii. Procedures of plasmapheresis, plateletpheresis, and leukapheresis, if performed, including precautions to be taken to ensure reinfusion of a donor's own cells.
xviii. Procedure for preparing recovered plasma, if performed, including details of separation, pooling, labeling, storage, and distribution.
xix. Procedures to look at prior donations of whole blood, blood components, source plasma and Source Leukocytes from a donor who has donated blood and subsequently tests repeatedly reactive for antibody to human immunodeficiency virus or otherwise is determined to be unsuitable when tested.
    1. Procedures to quarantine in-house whole blood, blood components, source plasma and source leukocytes intended for further manufacture into injectable products that were obtained from such donors

2. Procedures to notify consignees regarding the need to quarantine such products
3. Procedures to determine the suitability for release of such products from quarantine
4. Procedures to notify consignees of whole blood, blood components, source plasma and source leukocytes from such donors of the results of the antibody testing of such donors and
5. Procedures to notify attending physicians so that transfusion recipients are informed that they may have received whole blood and blood components at increased risk for transmitting human immunodeficiency virus.

xx. Procedures for donor deferral and procedures for donor notification and autologous donor referring physician notification, including procedures for the appropriate follow-up if the initial attempt at notification fails.

b. All records pertinent to the lot or unit maintained pursuant to these regulations shall be reviewed before the release or distribution of a lot or unit of final product. The review or portions of the review may be performed at appropriate periods during or after blood collecting, processing, compatibility testing and storing. A thorough investigation, including the conclusions and follow-up, of any unexplained discrepancy or the failure of a lot or unit to meet any of its specifications shall be made and recorded.

c. In addition to the requirements of this sub-section, and in conformity with this section, any facility may utilize current standard operating procedures such as the manuals of the organizations, as long as such specific procedures are consistent with, and at least as stringent as, the requirements contained in this section.

Deviations

10 a. Any deviation from applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of the blood and blood product or represents an unexpected or unforeseeable event that may affect the safety, purity or potency of the blood and blood product shall be reported.

b. Any reported deviations from the standard operating procedures shall be properly investigated, justified and recorded.

c. There shall be a standard operating procedure for handling deviations such that a system is in place for approving changes that may affect safety, purity, or potency of the blood and blood product.

Plateletpheresis, Leukapheresis and Plasmapheresis

11. a. The use of plateletpheresis and leukapheresis procedures to obtain a product for a specif recipient may be at variance with the additional standards for specific produc prescribed in section 11 of these Regulations provided that:

i. A physician has determined that the recipient must be transfused with the leukocytes or platelets from a specific donor, and
ii. The procedure is performed under the supervision of a qualified licensed physician who is aware of the health status of the donor, and the physician has certified in writing that the donor's health permits plateletpheresis or leukapheresis.

b. Plasmapheresis of donors who do not meet the donor suitability requirements for the collection of plasma containing rare antibodies shall be permitted only with the prior approval of the Agency.

Finished Product Control

Labelling of blood and blood components and traceability

12a. A blood establishment shall ensure that the label on each unit of blood or blood component supplied by it, or imported by it, shall contain the following information –

i. The official name of the component;
ii. The volume or weight or number of cells in the component, as appropriate;
iii. A unique numeric or alphanumeric donation indication;
iv. The name of the producing blood establishment
v. The ABO group, except in the case of plasma intended only for fractionation;
vi. The Rhesus D group, either Rhesus D positive or Rhesus D negative, except in the case of plasma intended only for fractionation;
vii. The date or time of expiry, as appropriate;
viii. The temperature of storage;
ix. The name, composition and volume of any anticoagulant and any additive solution.

b. A blood establishment shall keep such records of the information referred to in section 12a and such additional records as are necessary –

1. For the identification of each single blood donation and each single blood unit and its components (including blood and blood components which are imported into the country; and
2. To ensure full traceability to the point of use, for a period of not less than 30 years.

Laboratory Controls

13. Laboratory control procedures shall include:

a. The establishment of scientifically sound and appropriate specifications, standards and test procedures to ensure that blood and blood components are safe, pure, potent, and effective.
b. Adequate provisions for monitoring the reliability, accuracy, precision and performance of laboratory test procedures and instruments.

c. Adequate identification and handling of all test samples so that they are accurately related to the specific unit of product being tested, or to its donor, or to the specific recipient, where applicable.

14. Standard operating procedures for compatibility testing shall include the following: ***Compatibility testing***

a. A method of collection and identification of blood samples of recipients to ensure positive identification.
b. The use of fresh recipient serum or plasma samples less than 3 days old for all pre-transfusion testing if the recipient has been pregnant or transfused within the previous 3 months.
c. Procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type.
d. A provision that, if the unit of donor's blood has not been screened by a method that will demonstrate agglutinating, coating and hemolytic antibodies, the recipient's cell shall be tested with the donor's serum (minor cross-match) by a method that will so demonstrate.
e. Procedures to expedite transfusion in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician.

15. a. An establishment that collects blood or blood components shall make reasonable attempts to notify any donor, including an autologous donor and his physician, who has been deferred based on the results of tests for evidence of infection with a communicable disease agent(s) or who has been determined not to be suitable as a donor based on suitability criteria.

b. The deferred donor, including an autologous donor and his physician, shall be provided the following information:

i. That the donor is deferred or determined not to be suitable for donation and the reason for that decision
ii. Where appropriate, the types of donation of blood or blood components that the donor shall not donate in the future
iii. Where applicable the results of tests for evidence of infection due to communicable disease agent(s) that were a basis for deferral including results of supplemental tests
iv. Where appropriate, information concerning medical follow-up and counseling

c. Reasonable attempt shall be made to notify the donor, including an autologous donor and his physician, within 8 weeks after determining that the donor is deferred or

determined not to be suitable for donation. The success or failure of notification shall be documented.

16 a. Records shall be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records shall be legible and indelible, and shall: ***Records***

i. Identify the person performing the work,
ii. Include dates of the various entries,
iii. Show test results as well as the interpretation of the results,
iv. Show the expiration date assigned to specific products, and
v. Be as detailed as necessary to provide a complete history of the work performed.

b. Appropriate records shall be available from which to determine lot numbers of supplies and reagents used for specific lots or units of the final product.

c. Records to be maintained shall include, but are not limited to, the following when applicable:

i. Donor records:
1. Donor selection, including medical interview and examination, and where applicable, informed consent.
2. Permanent and temporary deferrals for health reasons including reason(s) for deferral.
3. Donor adverse reaction complaints and reports, including results of all investigations and follow-up.
4. Therapeutic bleedings, including signed requests from attending physicians, the donor's disease and disposition of units.
5. Immunization, including informed consent, identification of the antigen, dosage and route of administration.
6. Blood collection, including identification of the phlebotomist.
7. Records to relate the donor with the unit number of each previous donation from that donor.
8. Records of quarantine, notification, testing, and disposition performed in relation to testing for communicable disease agents.
9. Records of notification of donor deferred or determined not to be suitable for donation, including appropriate follow-up if the initial attempt at notification fails as prescribed in section 15.
10. The donor's address provided at the time of donation where the donor may be contacted within 8 weeks after the donation.
11. Records of notification of the referring physician of a deferred autologous donor, including appropriate follow-up if the initial notification attempt fails as prescribed in section 15.

ii. Processing records:

1. Blood processing, including results and interpretation of all tests and retests.
2. Component preparation, including all relevant dates and times.
3. Separation and pooling of recovered plasma.
4. Centrifugation and pooling of source plasma.
5. Labeling, including initials of the person(s) performing the procedure.

iii. Storage and Distribution Records**:**

1. Distribution and disposition, as appropriate, of blood and blood products.
2. Visual inspection of whole blood and red blood cells during storage and immediately before distribution.
3. Storage temperature, including initialed temperature recorder charts.
4. Re-issue, including records of proper temperature maintenance.
5. Emergency release of blood, including signature of requesting physician obtained before or after release.

iv. Compatibility test records**:**

1. Results of all compatibility tests, including cross-matching, testing of patient samples, antibody screening and identification.
2. Results of confirmatory testing.

v. Quality control records**:**

1. Calibration and standardization of equipment.
2. Performance checks of equipment and reagents.
3. Periodic check on sterile technique.
4. Periodic tests of capacity of shipping containers to maintain proper temperature in transit.
5. Proficiency test results.

vi. Transfusion reaction reports and complaints, including records of investigations and follow-up.

vii. General records**:**

1. Sterilization of supplies and reagents prepared within the facility, including date, time interval, temperature, and mode.
2. Responsible personnel.
3. Biological product deviations.
4. Maintenance records for equipment and general physical plant.
5. Supplies and reagents, including name of manufacturer or supplier, lot numbers, expiration date and date of receipt.
6. Disposition of rejected supplies and reagents used in the collection, processing and compatibility testing of blood and blood components.

d. A donor number shall be assigned to each accepted donor, which relates the unit of blood collected to that donor, to his medical record, to any component or blood product from that donor's unit of blood, and to all records describing the history and ultimate disposition of these products.

e. Records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical

reactions. The retention period shall be no less than 5 years after the records of processing have been completed or 6 months after the latest expiration date for the individual product, whichever is a later date. When there is no expiration date, records shall be retained indefinitely.

f. A record shall be available from which unsuitable donors may be identified so that products from such individuals will not be distributed.

17a. Blood and blood products shall be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of such products or with requirements specified in an official compendium.

Storage and distribution

b. Appropriate temperature recording equipment, or logs shall be utilized to document proper storage of blood and blood products and the record shall be kept as prescribed in section 16. All monitoring equipment shall be qualified and/or calibrated as required.

c. Blood and blood products shall be visually inspected at the time of issue for any abnormality, such as hemoglobin in the plasma from red cell lysis, purple tinged red cells due to bacterial contamination, or blood clots.

18. Appropriate measures shall be put in place to check that shipments have been held under appropriate transit conditions.

Examination of shipments

19. Vehicles and equipment used in the distribution of blood and blood products shall be suitable for their intended use and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and integrity, and prevent contamination of any kind.

Vehicles and Equipment

20 .a All blood and blood products shall be stored and distributed in shipment containers which do not have any adverse effect on the quality and safety of the products, and which offer adequate protection from external influences, including contamination.

Shipment Containers and container labelling

b. Only internationally and/or nationally accepted abbreviations, names or codes shall be used in the labelling of shipment containers.

21 a. Distribution and receipt procedures shall include a system by which the distribution or receipt of each unit can be readily determined to facilitate its recall, if necessary.

Distribution and Receipt

b. Distribution records shall contain information to readily facilitate the identification of the name and address of the consignee, the date and quantity delivered, the lot number of the unit(s), the date of expiration or the date of collection, whichever is applicable, or for cross-matched blood and blood components, the name of the recipient.

c. Receipt records shall contain the name and address of the collecting facility, date received, donor or lot number assigned by the collecting facility and the date of expiration or the date of collection, whichever is applicable.

22. a. Records shall be maintained of any reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of blood collection or transfusion. A thorough investigation of each reported adverse reaction shall be made. A written report of the investigation of adverse reactions, including conclusions and follow-up, shall be prepared and maintained as part of the record for that lot or unit of final product by the collecting or transfusing facility. When it is determined that the product was at fault in causing a transfusion reaction, copies of all such written reports shall be forwarded to and maintained by the manufacturer or collecting facility.

Adverse reaction file

b. When a complication of blood collection or transfusion is confirmed to be fatal, the Agency, shall be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible; a written report of the investigation shall be submitted to the Agency, within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.

23 a. All product recall activities whether voluntarily or directed by the Agency shall be carried out expeditiously and the records kept.

Product recall

b. There shall be a standard operating procedure describing a product recall and shall define the circumstances under which a recall of a blood and blood product shall be considered.

c. The recall procedure shall designate:

i. Who should be involved in evaluating the information,

ii. How a recall should be initiated,

iii. Who should be informed about the recall, and
iv. How the recalled material shall be treated.

d. In the event of a voluntary recall or serious and/ or potentially life-threatening situation, local, national, and/or international authorities shall be informed and their advice sought.
e. Appropriate investigation for reason for the recall shall be conducted.
f. Where an investigation is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.

Penalty

24. A person who contravenes a provision of these regulations is guilty of an offence and liable on conviction:-

i. In the case of an individual, to imprisonment for a term not exceeding two years or to a fine not exceeding ~~₦~~50,000 or to both imprisonment and fine.
ii. In the case of body corporate, to a fine not exceeding N100,000.

b. Where an offence under these Regulations is committed by a body corporate or firm or other association of individuals:-

i. every director, manager, secretary or other similar officer of the body corporate; or
ii. every partner or officer of the firm; or
iii. every trustee of the body concerned; or
iv. every person concerned in the management of the affairs of the association; or
v. every person who was purporting to act in a capacity referred to in paragraphs (i) to (iv), is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Interpretations

25. In these regulations, unless the context otherwise requires, the following terms shall have the meanings specified:

Interpretation

Act	The NAFDAC Decree 1993 as amended
Adverse reaction	A response to a blood or blood product which is noxious and unintended associated with the collection or transfusion of blood or blood components.

Agency	National Agency for Food and Drug Administration and Control
Autologous donor	A donor who donates a unit of blood or blood component (pre-deposited) for his or her own use
Blood	Whole blood collected from a single donor and processed either for transfusion or further manufacturing.
Blood components	A therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods
Blood establishment	A place of business under one management at one general physical location. The term includes but is not limited to, human blood and plasma donor centers, blood banks, transfusion services, other blood product manufacturers and independent laboratories that engage in quality control and testing for blood products establishments.
Blood facilities	Any area used for the collection, processing, compatibility testing, storage or distribution of blood and blood components.
Blood product	Any therapeutic product derived from human blood or plasma
Blood product for further manufacturing	Blood component as raw material for the manufacture of another product. Further manufacturing of blood components shall be in accordance with current good manufacturing practice.
Communicable diseases	Diseases transmissible through blood and blood products. These include but are not limited to Human immunodeficiency virus, type 1; Human immunodeficiency virus, type 2; Hepatitis B virus; Hepatitis C virus; Human T-lymphotropic virus, type I; and Human T-lymphotropic virus, type II, cytomegalovirus, syphilis.
Compatibility testing	The procedures performed to establish the matching of a donor's blood or blood components with that of a potential recipient.
Component	That part of a single donor's blood separated by physical or mechanical means.
Control	Having responsibility for maintaining the continued safety, purity, and potency of the product and for compliance with applicable product and establishment standards.
Cross-match	A test for incompatibility between donor and recipient blood carried out prior to transfusion.
Deferral	Suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary;
Distributed blood or blood components	a. Blood or blood components that has left the control of the manufacturer, blood establishment, or transfusion service; or b. Source plasma or any other blood component from an establishment for use in the manufacture of a licensed

	biological product.
Leukapheresis	The procedure in which blood is removed from the donor, a leukocyte concentrate is separated, and the remaining formed elements and residual plasma are returned to the donor.
Person	An individual, partnership, corporation, association, government agency, or organizational unit thereof, and any other legal entity.
Phlebotomy	The practice of collecting or drawing blood samples
Plasma	The liquid portion of the blood in which the cells are suspended.
Plasma for further manufacturing	That liquid portion of blood separated and used as material to prepare another product.
Plasmapheresis	The procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor.
Plateletpheresis	The procedure in which blood is removed from a donor, a platelet concentrate is separated, and the remaining formed elements are returned to the donor along with a portion of the residual plasma.
Processing	Any procedure employed after collection and before compatibility testing of blood. This includes the identification of a unit of donor blood, the preparation of components from such unit of donor blood, serological testing, labeling and associated record keeping.
Regulatory action	Includes but are not limited to product hold, recall, forfeiture, or destruction, sealing of facility, withdrawal of authorization, prosecution.
Shipping	Moving, dispatching, transporting, conveying, sending, and distributing a product from one location to the other.
Standard operating procedures (SOP)	An authorized written procedure giving instructions for performing operations.
Unit	Volume of blood or one of its components in a suitable volume of anticoagulant obtained from a single collection of blood from one donor.
Unsuitable donor	Include but are not limited to those who test repeatedly reactive for anti-HIV or HGsAg and have not been properly reentered or have a medical history which would preclude donation.
Unsafe blood	Impure, not potent and ineffective blood or blood product
Whole blood	Blood collected from human donors for transfusion to human recipients

Citation

26. These Regulations may be cited as Blood and Blood Product Safety Regulations 2009 ***Citation***

Made at Abuja this ……Day of…… 2009

Chairman, Governing Council

Dr. Philip Emafor Phd. OFR

National Agency for Food and Drug

Administration and Control (NAFDAC)

Director General

Dr. Paul Orhii MD, Phd, Jd

National Agency for Food and Drug

Administration and Control (NAFDAC)

Schedule A

Equipment	*Performance check*	*Frequency*	*Frequency of calibration*
Temperature recorder	Compare against thermometer	Daily	As necessary
Refrigerated centrifuge	Observe speed and thermometer	Each day of use	As necessary
Haematocrit centrifuge	----------	----------	Standardize before initial use, after repairs or adjustments, and annually. Timer every 3 months
General lab centrifuge	----------	----------	Tachometer every 6 months
Automated blood-typing machine	Observe controls for correct results	Each day of use	
Haemoglobinometer	Standardize against cyanomethaemoglobin standard	Each day of use	
Refractometer	Standardize against distilled water	Each day of use	
Blood container scale	Standardize against container of known weight	Each day of use	As necessary
Water bath	Observe temperature	Each day of use	As necessary
Rh view box	Observe temperature	Each day of use	As necessary
Autoclave	Observe temperature	Each time of use	As necessary
Serologic rotators	Observe controls for correct results	Each day of use	Speed as necessary
Laboratory thermometers	----------	----------	Before initial use
Electronic thermometers	----------	----------	Monthly
Vacuum blood agitator	Observe weight of the first container of blood filled for correct results	Each day of use	Standardize with container of known mass or volume before initial use, and after repairs or adjustments

Schedule B

Reagent or Solution	*Frequency of Testing*
Anti-human globulin	Each day of use.
Blood grouping reagent	Each day of use.
Lechtins	Each day of use.
Antibody screening and reverse grouping cells	Each day of use.
Hepatitis test reagents	Each run.
Syphilis serology reagents	Each run.
Enzymes	Each day of use.