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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
(CAP 219)

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REGULATIONS

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(Made under section 122(1)(z)(dd)

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THE TANZANIA FOOD, DRUGS AND COSMETICS (CONTROL OF BLOOD AND BLOOD PRODUCTS) REGULATIONS, 2018

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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
(CAP 219)

REGULATIONS

(Made under section 122(1)(z)(dd)

THE TANZANIA FOOD, DRUGS AND COSMETICS (CONTROL OF BLOOD AND BLOOD PRODUCTS) REGULATIONS, 2018

PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations shall be cited as the Tanzania Food, Drugs and Cosmetics (Control of Blood and Blood Products) Regulations, 2018.

Scope of application

2. These Regulations shall apply in all regulatory controls related to blood and blood products including plasma-derived medicinal products in Mainland Tanzania.

Interpretation

3. In these Regulations, unless the context otherwise requires-

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"Act" means the Tanzania Food, Drugs and Cosmetics Act;

"additive solution" means a solution specifically formulated to maintain beneficial properties of cellular components during storage;

“allogeneic donation” means blood and blood components collected from an individual and intended for transfusion to another individual, for use in medical devices or as starting material or raw material for manufacturing into medicinal products;

“apheresis” means a method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process;

“applicant” means any legal or natural person, established within or outside Tanzania, seeking to obtain or having obtained the license to render blood transfusion service in terms of these regulations or a marketing authorisation holder of the blood product;

“Authority” means the Tanzania Food and Drugs Authority or its acronym ‘TFDA’ established under section 4(1) of the Act;

“autologous donation” means blood and blood components collected from an individual and intended solely for subsequent autologous transfusion or other human application to that same individual;

“autologous transfusion” means a transfusion in which the donor and the recipient are the same person and in which pre-deposited blood or blood components are used;

“blood” means whole human blood collected from a donor and processed either for transfusion or for further manufacturing, excluding blood specimens intended for pathology testing;

“blood component” means a constituent of blood (erythrocytes, leukocytes, platelets, cryoprecipitate and plasma) that can be prepared by various separation methods and under such condition can be used either directly for therapeutic purposes or for further processing or manufacturing;

“blood component release” means a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

“blood donor” means any living, voluntary, non-remunerated person from whom blood is withdrawn for the subsequent administering to another living person or to himself or for the processing into blood products;

“blood establishment” means any structure, facility or body that is responsible for any aspect of the collection, testing, processing, storage, release or distribution of human blood or blood component when intended for transfusion or industrial manufacturing;

“blood product” means any therapeutic product derived from human blood or plasma;

"buffy coat" means a blood component prepared by centrifugation of a unit of whole blood, and which contains a considerable proportion of the leucocytes and platelets;

"cryoprecipitate" means a plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and re-suspension of the precipitated proteins in a small volume of the plasma;

"cryopreservation" means prolongation of the storage life of blood components by freezing;

"deferral" means suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary;
"Director General" means the head of Authority;

"distribution" means the act of delivery of blood and blood components to other blood establishments, hospital blood banks, importers, wholesalers and manufacturers of blood products, other than the issuing of blood or blood components for transfusion;

"directed blood donor" means a blood donor who donate blood to be transfused to a specific patient which may promote discrimination based on colour, place or religion;

"doctor" means a registered medical practitioner;

"extended phenotyping" means red cell antigen typing other than ABOD but not limited to Kelly, Duffy, Lewis, kelano and MNS system;
"Family Replacement Donor" means who donate blood to replace the blood used by a patient who is family member or friend to him/her.

"good clinical practice" means a standard for the design, conduct, performance, monitoring, auditing, recording, analysing and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

"granulocytes apheresis" means a concentrated suspension of granulocytes obtained by apheresis;

"haemovigilance" means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

"hospital blood bank" means any unit within a hospital which stores and issues, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

"import" means entry into Mainland Tanzania products regulated by the Act;

"inspection" means formal and objective control to identify non-conformances in accordance with standards adopted to assess compliance with these Regulations;

"leucapheresis" means the process by which the blood drawn from a donor, after leucocyte concentrates have been separated, is re-transfused simultaneously into the said donor;

"licensing" means authorization by the Authority for the manufacturing, importation, exportation or distribution of blood and blood products;

"lookback haemovigilance system" means a form of haemovigilance system which involves efforts to identify recipients of a previously negative blood product from a particular donor usually after the donor is found to have a condition that may have put the recipient at risk of transmissible transfusion infections, followed by immediate quarantine, recall of product, counselling, testing and management of the recipient;

"manufacturer" means any natural or legal person with responsibility for any aspect of the following activities in relation to blood products: collection, testing, processing, storage, packaging, labelling, release or distribution;

"Minister" means the Minister for the time being responsible for health;
"NBTS Network" means organizations working in collaboration with NBTS to carry out blood safety activities including, donor education, donor recruitment of blood donors, collection, storage, production of blood products and blood components, transport and distribute blood.

"national blood transfusion service" or its acronym NBTS means *a designated department under regulation 4, which is under the Ministry for the time being responsible for health, to establish policy and standards, oversee and coordinate all blood safety activities including, recruitment of blood donors, collection, storage, and production of blood components and blood products, test for transfusion transmissible infections, transport and distribute blood, as well as guide appropriate use of blood and blood products through zonal blood centers and regional blood centers.*

"paid blood donor" means a person who donates blood in exchange for money or other form of payment;

"platelets apheresis" means a concentrated suspension of blood platelets obtained by apheresis;

"platelets apheresis, leucocyte-depleted" means a concentrated suspension of blood platelets, obtained by apheresis, and from which leucocytes are removed;

“platelets, recovered, pooled” means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation;

“platelets, recovered, pooled, leucocyte-depleted” means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation, and from which leucocytes are removed;

“platelets, recovered, single unit” means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood;

“platelets, recovered, single unit, leucocyte-depleted” means a concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leucocytes are removed;

“plasma” means the liquid portion of the blood in which the cells are suspended which are separated from the cellular portion of a whole blood for therapeutic use as fresh frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion;

“plasma-derived medicinal product” means any therapeutic product derived from human plasma and produced by an industrial-scale manufacturing process that pools multiple units;

“plasma, fresh-frozen” means the supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored;

“plasma, cryoprecipitate-depleted for transfusion” means a plasma component prepared from a unit of plasma, fresh-frozen and it comprises the residual portion after the cryoprecipitate has been removed;

“qualified health professional” means a doctor, nurse or a donor carer;

“recall” in relation to blood and blood products, means any action taken by manufacturer, importer, supplier or marketing authorization holder to remove blood or blood product from the market/blood bank or to retrieve blood or blood product from any person to whom it has been supplied, because the blood or blood product may-

(a) be hazardous to health;

(b) fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or efficacy; or

(c) not meet the requirements under these Regulations;

“recipient” means a person to whom blood or blood product is administered which has been donated by another person or by the person himself;

“red cells” means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed;

“red cells, buffy coat removed” means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation remove, whereby the buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed;

“red cells, leucocyte-depleted” means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed;

“red cells in additive solution” means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, whereby a nutrient or preservative solution is added;

“red cells, leucocyte-depleted, in additive solution” means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed whereby a nutrient or preservative solution is added;

“red cells, apheresis” means the red cells from an apheresis red cell donation;

“responsible person” means the person who has been designated to manage a blood establishment under these Regulations;

“serious adverse event” means any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood products that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

“serious adverse reaction” means an unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood products that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity;

“site”, means any premises at which the blood establishment carries out any of the activities listed in regulation 4(3), but shall not include any premises owned or managed by the blood establishment at which blood is collected, or any mobile blood collection unit;

“standards of practice” means the standards of practice for blood transfusion services as prescribed in these Regulations;

“transfusion reaction” means any adverse reaction as a result of the administration of blood or a blood product;

“transfusion transmissible infection” means an infection that can be transmitted by the transfusion of blood or blood product;

“validation” means the establishment of documented and objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

"washed" means a process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed and replaced following further centrifugation of the suspension.

PART II
CLASSIFICATION OF BLOOD ESTABLISHMENTS

Classification of blood establishments

4.-(1) There shall be blood establishments' classification.

(2) The blood establishments shall be classified in the following categories:

(a) manufacturing facilities;

(b) hospital blood banks;

(c) National Blood Transfusion Services;

(d) importers and wholesalers of plasma derived medicinal products, blood components, reagents and consumables;

(e) mobile blood collection units or vehicles; and

(f) any other establishment as the Authority may designate.

(3) Subject to sub-regulation (1),

(a) manufacturing facilities shall be responsible for manufacturing of plasma derived medicinal products;

(b) hospital blood banks shall be responsible for storage, compatibility testing, blood grouping and issuing of blood and blood products for transfusion;

(c) National Blood Transfusion Services shall be responsible for donor recruitment, collection, storage, component production, testing and distribution of blood and blood products intended to be used for transfusion;

(d) importers and wholesalers shall be responsible for importation, storage and distribution of blood products;

(e) mobile blood collection units shall be responsible for donation and conveyance of blood and blood products.

Prohibition to carry out activities without authorization

5. A person shall not carry out any of the activities listed in regulation 4(3) except for the establishments authorized in these Regulations.

Authorisation of a blood establishment

6.-(1) The blood establishment shall, before carrying out the activities referred to under regulation 4(3), make an application to the Authority for authorization by filling a form specified in the First Schedule.

(2) The Authority may, if satisfied with the application made under sub regulation (1), grant an authorisation to a blood establishment to carry out such activity.

(3) An application referred to under sub regulation (1) shall contain the following:

(a) the name and address of the blood establishment and general information about its activities which shall include;

(i) details of each site at which it wishes to carry out any of the activities;

(ii) a description of the activities which it wishes to carry out at each site;

(iii) where it has or intends to enter into a contractual arrangement with any person to carry out any of the services in respect or which it is seeking authorisation, the name and address of that person and of the services which he will carry out;

(iv) the name, qualifications and contact details of the responsible person for the establishment;

(v) the list of hospital blood banks which it supplies; and

(b) a description of the quality system in place at each site for each activity in respect of which the application for authorisation is made, which shall include the following information-

(i) documentation, such as an organization chart, setting out the responsibilities of responsible persons and reporting relationships;

(ii) documentation, such as a site master file or quality manual, describing the quality system and explaining how it meets requirements for quality and safety of blood and blood products as prescribed in these Regulations;

(iii) details of the number and qualifications of personnel;

(iv) details of hygiene provisions;

(v)details of premises and equipment; and

(vi)a list of standard operating procedures for-

(aa) recruitment, retention and assessment of donors;

(bb) processing, testing, distribution and recall of blood and blood products;

(cc) the reporting and recording of serious adverse reactions and events; and

(dd) any other procedures as designated by the Authority.

GN. 464 of 2015

(c) non-refundable application fee as may be prescribed in the Fees and Charges regulations in force.

Verification of application for authorisation

7.-(1) Authority shall, on receipt of the application for grant or renewal of authorisation,-

(a) verify the statements made in the application form;

(b) cause the blood establishment to be inspected in accordance with the provisions of these Regulations.

(2) Subject to sub regulation (1), the Authority may grant or refuse any application for authorization.

(3) Without prejudice to sub regulation (2), the application granted may be-

(a) in respect of particular sites or activities only, or

(b) subject to conditions.

(4) Where the Authority grants an application for authorisation, the Authority shall give a licence to the blood establishment specifying-

(a) the activities which the blood establishment may undertake under these Regulations at each site in respect of which authorisation is granted; and

(b) the conditions which apply to the undertaking of the activities.

Authority may vary the conditions

8.-(1) The Authority may at any time remove or vary any of the conditions or may impose additional conditions as provided for in these Regulations.

(2) Where the Authority removes or varies any condition or imposes any additional condition pursuant to sub-regulation (1), the Authority shall serve a notice on the blood establishment in question which shall-

(a) give details of the conditions which the Authority proposes to remove, or of the variation which the Authority proposes to make to any existing conditions, or of any additional condition which the Authority proposes to impose;

(b) give the reasons for the decision; and

(c) specify the date, which shall be not less than fourteen days from the date on which the notice is served, from which the removal or variation of any condition, or the imposition of any additional condition shall apply.

(2) A blood establishment shall not make any substantial change in the activities which it undertakes without making an application and obtained a prior written approval of the Authority.

(3)Any application for approval to make a substantial change in its activities shall be accompanied by a fee of the amount prescribed in the Fees and Charges Regulations in force.

(4) For the purpose of sub regulation (2), a substantial change in a blood establishment's activities is any change-

(a) to the sites from which the blood establishment operates or to the activities to be carried out at each site;

(b) which would result in breach of these Regulations or of any condition specified by the Authority pursuant to this regulation; or

(c) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the activities which the blood establishment has been authorized to undertake pursuant to this regulation.

Duration of Authorisation

9.-(1) The licence granted under these Regulations, unless sooner suspended, cancelled or revoked shall be valid for a period of one year starting from 1st of July of each year.

(2) The validity of authorisation may cease to exist upon-

(a) voluntary withdrawal

(b) suspension, revocation or cancellation by the Authority; or

(c) any other reason as the authority may deem just

Suspension or revocation of license

10-.(1) The Authority may suspend or revoke the license of a blood establishment on one or more of the following grounds -

(a) that the blood establishment has failed, in any material respect, to comply with the requirements of these Regulations;

(b) that the collection, testing, processing, storage or distribution of blood or blood product by the establishment cannot be carried out safely;

(c) that any blood or blood product cannot be supplied to hospital blood banks in such a state that they could be safely administered for transfusion;

(d) that the information given by the blood establishment pursuant to regulation 6(2) was false or incomplete in any material aspect;

(e) that the blood establishment has been found to collect blood from paid blood donors and engaged in selling of blood.

(2) Subject to sub - regulation (3), before suspending or revoking the authorisation of a blood establishment, the Authority shall serve a notice on the blood establishment stating the intention of the Authority to suspend or revoke its authorisation with effect from the date specified in the notice, which date shall be not less than thirty days from the date on which the notice is served.

(3) Where the Authority considers that it is necessary in the interests of safety, the Authority may, by a notice served on a blood establishment, suspend or revoke its authorisation with immediate effect.

(4) Where;

(a) the blood establishment has failed, in any material respect, to comply with the requirements of these regulations; or

(b) the information given by the blood establishment pursuant to regulation 6(4) was false or incomplete in any material respect, and the Authority considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the authorisation of the blood establishment in the first instance,

he may serve a notice on the responsible person of the blood establishment in accordance with sub-regulation (5).

(5) A notice served under this sub-regulation shall-

(a) identify the requirements of the regulations of which the blood establishment is in breach or, in the case of false and incomplete information, the further information which is required;

(b) identify the action which the blood establishment is required to take; and

(c) give the timescale within which the blood establishment shall take the action identified in paragraph (b).

(6) If the blood establishment fails to comply with the requirements set out in the notice within the specified timescale, the Authority may, by a notice served on the blood establishment, suspend or revoke the authorisation of the blood establishment.

(7) A suspension or revocation pursuant to sub - regulation (6) shall take effect-

(a) a case where the Authority considers that it is necessary in the interests of safety, immediately; or

(b) in all other cases, from a date specified in the notice.

(8) Any suspension pursuant to sub - regulations (1) or (6) shall be for such period as the Authority shall consider necessary having regard to the reasons for the suspension.

(9) The suspension or revocation of an authorisation under sub-regulation (1), may be total, or may be limited to a particular activity or to one or more activities carried out at a particular site or sites, or to a particular blood product.

PART III
REQUIREMENTS FOR BLOOD ESTABLISHMENTS

NBTS requirements

11.-(1) A National Blood Transfusion Services shall-

(a) ensure that the personnel directly involved in the collection, testing, processing, storage and distribution of human blood and blood products for the blood establishment are qualified *and certified competent* to perform those tasks and are provided with timely, relevant and regularly updated training;

(b) establish and maintain a quality system for blood establishments based on the principles of good practice as prescribed by the Authority;

(c) ensure that all testing methods and processes of the blood establishment which are referred to in these Regulations are validated;

(d) prepare and provide proficiency testing samples for blood grouping serology for all hospital blood bank

(e) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available;

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(f) notify the Authority of-

(i) any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood product by the blood establishment which may have an influence on their quality and safety, and

(ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood product collected, tested, processed, stored or distributed by the blood establishment as provided for under Part VIII of these Regulations; and

(iii) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood products associated with any notification referred under this paragraph.

(2) A blood establishment shall, in relation to the donation of blood-

(a) give all prospective donors of blood or blood products information in the manner prescribed in the Second Schedule of these Regulations;

(b) obtain from all persons who are willing to provide blood or blood products, information in the manner prescribed in the Third Schedule of these Regulations;

(c) put and keep in place procedures for the donor selection;

(d) apply eligibility criteria for all donors of blood and blood components in the manner prescribed in the Fourth Schedule of these Regulations;

(e) maintain records of the results of donor selection and report to donors any relevant abnormal findings from the donor selection;

(f) ensure that:-

(i) an examination of the donor, including an interview, is carried out before any donation of blood or blood components;

(ii)a qualified health professional is responsible for giving to and gathering from donors the information which is necessary to assess their eligibility to donate; and

(iii)on the basis of that information, a qualified health professional assesses the eligibility of all donors to donate.

(g) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood products are, in so far as possible, provided from such donations, in particular, by-

(i)disseminating information about blood donation; and

(ii)advertising for blood donors.

(3) The NBTS shall ensure that, in relation to the collection, processing, storage or distribution of blood and blood products-

(a) each donation of blood and blood products which are imported into Tanzania Mainland is tested in conformity with-

(i)the basic testing requirements for whole blood and apheresis donations, specified in sub - regulation (4), and

(ii)any additional tests which may be necessary for specific products, types of donors or epidemiological situations;

(b) the storage, transport and distribution conditions of blood and blood products comply with the requirements specified in the Fifth Schedule of these Regulations ; and

(c) quality and safety requirements for blood and blood products meet the standards specified in the Sixth Schedule of these Regulations including any amendments made thereof.

(4) Pursuant to sub-regulation (4)(a)(i), the sub-regulation 4(d) will be restricted to six (6) NBTS zonal centres and NBTS shall ensure basic testing requirements which includes-

(a) testing to establish ABO and Rh D group and extended phenotyping;

(b) testing for high alloaglutinin titres in all Group O donation;

(c) testing for red cell antibodies for first-time donors and donors with history of pregnancy or transfusion; and

(d) testing for the following infections of donors-

(i) Hepatitis B (HBs-Ag);

(ii) Hepatitis C (Anti-HCV);

(iii) HIV 1 and 2 (Anti-HIV 1 and 2); or

(iv) Syphilis.

(5) The Authority may issue guidance as to the additional tests referred to in sub-regulation (4) which are necessary in relation to specific products, types of donor or epidemiological situations and blood establishments shall have regard to such guidance.

(6) Subject to sub-regulation (5), the Authority shall, in issuing such guidance, collaborate with the NBTS.

(7) The NBTS shall, as soon as practicable, after the end of the reporting year, provide to the Authority a report specifying-

(a) the information referred to in sub - regulation (4) for that year; and

(b) details of the steps it has taken during that year to comply with sub-regulation (2)(g).

Hospital blood bank requirements

12.-(1) The Hospital blood bank shall shall-

(a) ensure that personnel directly involved in the testing, storage and distribution of human blood and blood products for the hospital blood bank are qualified *and certified competent* to perform those tasks and are provided with timely, relevant and regularly updated training;

(b) establish and maintain a quality system for the hospital blood bank which is based on the principles of good practice;

(c) ensure that all processes referred to in Fourth Schedule of these Regulations which are applicable to activities carried out by the hospital blood bank, are valid;

(d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available;

(e) maintain, for not less than 10 years, the data needed to ensure full traceability of blood and blood products, from the point of receipt of the blood or blood product by the hospital blood bank;

(f) any serious adverse events related to the testing, storage and distribution of blood and blood products by the hospital blood bank which may have an influence on their quality and safety, and

(g) notify the Authority and NBTS-

(i) any serious adverse events related to the testing, storage and distribution of blood and blood products by the hospital blood bank which may have an influence on their quality and safety, and

(ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood products issued for transfusion by the hospital blood bank as provided for in Part VIII of these Regulations;

(h) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood products associated with any notification referred to in paragraph (g); and

(i) ensure that the storage, transport and distribution conditions of blood and blood products by the hospital blood bank comply with the requirements in Fourth Schedule of these Regulations.

(j) ensure that the following testing requirements are conducted-

(i) testing to establish ABO and Rh D group and extended phenotyping;

(ii) testing for antibody screening and identification; and

(iii) testing for compatibility.

(2) Blood Component processing shall be carried out only at National and Zonal, and Regional referral hospitals

(3) All hospital blood banks stationed within National and zonal referral hospitals shall be supervised by a registered medical practitioner.

Manufacturing facility requirements

13. Manufacturing facilities engaged in manufacturing of blood products shall comply with the current good manufacturing practice requirements set-forth in the Good Manufacturing Practice Regulations in force.

Importers and wholesalers requirements

14. Importers and wholesalers of blood products shall be required to comply with the provisions set out in Part V of these Regulations.

Mobile blood collection units requirements

15. (1). – The mobile blood collection units or vehicles shall be required to meet the following minimum standards :-

(a) be designed to undertake blood donation especially in hard to reach areas;
(b) have adequate storage space or cabinets for keeping registers, blood bags, chemicals, reagents and other consumables;
(c) have donor bed of adequate size in case of the unit;
(d) have sufficient electrical equipment in case of the unit;
(e) be equipped with air conditioning facilities;
(f) have public address system;
(g) have refrigerator for storage of blood and blood products;
(h) have changing rooms with wash basin and chemical toilets conveniently placed;
(i) have evaporator for collection and transport of blood bags; and
(j) provide donor refreshments.

Person responsible for blood establishment

16.-(1) A blood establishment shall designate a person who is responsible for the following functions-

(a) ensuring that every unit of blood or blood products that has been collected or tested for any purpose has been collected and tested in accordance with the requirements of these Regulations;

(b) ensuring that every unit of blood or blood products intended for transfusion has been processed, stored and distributed in accordance with the requirements of these Regulations;

(c) providing information to the Authority relating to the authorisation of the blood establishment; and

(d) the implementation in the blood establishment of the requirements of these Regulations.

(2) A blood establishment shall not designate a person under sub-regulation (1) unless that person has-

(a) a degree in the field of medical or biological sciences recognized by relevant professional bodies;

(b) a diploma or other evidence of formal qualification in the field of medical or biological sciences recognized by relevant professional bodies; or

(c) a practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these Regulations for at least two years, in an establishment (or more than one establishment) authorized to undertake activities related to the collection or testing (or both) of blood and blood products, or to their preparation, storage and distribution.

(3) The responsible person may delegate any of the functions specified in sub - regulation (1) to other persons who are qualified and experienced to perform such functions.

(4) The blood establishments shall notify the Authority of the name of any persons to whom functions have been delegated by the responsible person under sub-regulation (3), and the specific functions which have been delegated to such persons.

(5) Where the responsible person or a person to whom functions have been delegated under sub-regulation (3) are permanently or temporarily replaced, the blood establishment shall without delay provide to the Authority, the name of the replacement, details of his qualifications and the date on which the replacement began his functions.

(6) If the Authority finds that the responsible person does not meet the requirements required under these Regulations, he may serve a notice to that effect on the blood establishment.

(7) If, within fourteen days of receiving a notice in accordance with sub-regulation (6), the blood establishment is not able to demonstrate to the reasonable satisfaction of the Authority that the responsible person does meet the requirements of sub - regulation (2), it shall, without delay-

(a) relieve such person of the duties of responsible person in respect of the establishment;

(b) appoint a new responsible person in his place; and

(c) notify the Authority that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

PART IV
MARKETING AUTHORISATION OF BLOOD AND BLOOD PRODUCTS

Marketing authorization of blood and blood products

17.-(1) Whole blood and its components shall not be subjected into procedures for marketing authorization under these Regulations.

GN. 314 & GN. 315 of 2015

(2) Blood products shall be subjected into procedures for marketing authorization in accordance with the requirements stipulated in the Regulations for Registration of Medicinal Products and Medical Devices including In-Vitro Diagnostics in force, as may be applicable.

PART V
IMPORTATION AND EXPORTATION OF BLOOD AND BLOOD PRODUCTS

Importation of blood and blood products GN. 312 of 2015

18. Any person intending to import into the Mainland Tanzania or export any blood or blood components (including blood or blood components intended for use as a starting material or raw material in the manufacture of medicinal products), shall be required to comply with the provisions of the Control of Import and Export Regulations in force.

PART VI
CLINICAL TRIALS FOR BLOOD AND BLOOD PRODUCTS

Authorization of clinical trials for blood and blood products GN. 53 of 2013

19. All applications for authorization of clinical trials involving blood and blood products as investigational products, shall be made in accordance with the provisions stipulated in Control of Clinical Trials Regulations in force.

Material Transfer Agreement

20. Subject to sub - regulation (1), transfer of investigational products in form of blood and blood products for clinical trial purpose, shall be done based on material transfer agreement and in accordance with the requirements provided for in the Ethical Regulations in force.

Good Clinical Practice Inspections GN. 53 of 2013

21. The Authority shall carry out regular good clinical practice inspections as provided for in the Control of Clinical Trials Regulations in force.

Ethical considerations

22. All ethical matters for clinical and non-clinical trials shall be made in accordance with the requirements provided for in the Ethical Regulations in force.

PART VII
INSPECTION OF BLOOD AND BLOOD PRODUCTS

Inspections

23.-(1) The Authority shall conduct regular inspection of each blood establishment for the purpose of ensuring that-

(a) blood establishments comply with the requirements of these Regulations; and

(b) non-conformances against these Regulations are identified.

(2) The Authority may also serve a notice on a blood establishment requiring that the blood establishment furnish it with such information concerning its compliance with these Regulations as shall be specified in the notice within such period as shall be specified in the notice.

(3) Any blood establishment which receives an order or information in accordance with sub-regulation (2) shall provide the information requested within the period specified in the notice.

(4) In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, the Authority shall request such information or conduct such inspections in accordance with this regulation as it shall consider appropriate.

(5) Any reference to an inspection of a site which the Authority is required or empowered to conduct by virtue of this regulation, shall be construed so as to include an inspection of premises within the Mainland Tanzania at which any of the activities listed in regulation 4(3) are carried out by any person on behalf of, and pursuant to a contractual arrangement with a blood establishment.

(6) The Authority may appoint such persons to be inspectors necessary for the proper discharge of its functions set out in these Regulations, and it may appoint such persons upon such terms and conditions as it shall deem appropriate.

(7) Any other Authority, Institution or Agency.

(8) *NBTS is mandated to discharge inspection for blood transfusion operation activities related to clinical part and blood banking*

Powers of Inspectors

24.-(1) For the purposes of enforcing compliance or conducting inspections, an inspector appointed in accordance with these Regulations shall, upon production of evidence that he is so authorized, have the right-

(a) at any reasonable time to enter any premises, other than premises used only as a private dwelling house, which he has reason to believe it is necessary for him to visit, including-

(i)any premises owned or managed by a blood establishment referred to in these Regulations;

(ii)any premises of any person who carries out any of the activities referred to in these Regulations on behalf of, and pursuant to a contractual arrangement with, a blood establishment; and

(iii)where any facilities for donor evaluation and testing are in the premises of any person other than a blood establishment, those facilities in that person's premises

(b) to carry out at those premises during that visit inspections, examinations, tests and analyses as he considers necessary;

(c) to require the production of, and inspect any article or substance at, the premises;

(d) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record (in whatever form it is held) at, or (in the case of computer data or records) accessible at the premises;

(e) to take possession of any samples for examination and analysis and any other article, substance, book, document, data, record (in whatever form they are held) at, or (in the case of computer data or records) accessible at, the premises;

(f) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;

(g) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities; and

(h) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him; but nothing in this sub - regulation shall be taken to compel the production by any person of a document of which he would on grounds of legal professional privilege be entitled to withhold production on an order for disclosure in an action in the court or, as the case may be, on an order for production of documents in an action in the court.

(2) If a justice of peace is satisfied by any written information on oath that there are reasonable grounds for entry into any premises, other than premises used only as a private dwelling house, for any purpose mentioned in sub - regulation (1), and-

(a) admission to the premises has been refused or is likely to be refused and notice of intention to apply for a warrant under this sub - regulation has been given to the occupier;

(b) an application for admission, or the giving of such notice, would defeat the object of the entry; or

(c) the premises are unoccupied or the occupier is temporarily absent and it might defeat the object of the entry to await his return, the justice may, by warrant signed by him, which shall continue in force for any reasonable time, authorise an inspector to enter the premises, if need be by force.

(3) An inspector entering premises by virtue of sub-regulation (1) or of a warrant under sub-regulation (2) may take with him when he enters those premises such equipment as may appear to him necessary and any person who is authorised by the Director General to accompany him on that visit.

(4) On leaving any premises which an inspector is authorised to enter by a warrant under sub-regulation (2), he shall, if the premises are unoccupied, or the occupier is temporarily absent, leave the premises as effectively secured against trespassers as he found them.

(5) Where, pursuant to sub-regulation (1) (e), an inspector takes possession of any article, substance, book, document, data or record, he shall leave at the premises with a responsible person, or if there is no such person present on the premises, leave in the premises in a prominent position, a statement giving particulars of the article, substance, book, document, data or record sufficient to identify it and stating that he has taken possession of it.

(6) Where, pursuant to sub-regulation (1) (e) an inspector takes a sample for analysis, the Director General may make such arrangements for analysis of that sample as he considers appropriate.

PART VIII

HAEMOVIGILANCE

Establishment of a haemovigilance system

25. All blood establishments shall set-up a haemovigilance system for receiving, handling, evaluating and reporting adverse events and reactions to the Authority.

Good Haemovigilance Practices

26. Blood establishments shall ensure that activities are conducted in accordance with but not limited to the following Good Haemovigilance Practice requirements-

(a) needs of patients, healthcare professionals and the public in relation to the safety of blood transfusion;

(b) assigning tasks and responsibilities to persons involved in implementation of the haemovigilance system;

(c) conducting and maintaining continuous quality improvement by all parties implementing the haemovigilance system;

(d) allocating resources and tasks to support proactive, risk-proportionate, continuous and integrated conduct of haemovigilance;

(e) seeking evidence on the risk-benefit balance of blood products and all relevant aspects, which could impact on the risk-benefit balance and the use of a blood product, to be considered for decision-making;

(f) fostering good cooperation between NBTS, hospital blood banks, manufacturers, marketing authorization holders, patients, healthcare professionals and other relevant bodies.

Requirements for the quality system

27. Every blood establishment shall maintain the quality system which consists of the following;

(a) a designated focal person responsible for haemovigilance;

(b) record management system to afford handling and storage of documentation for accurate reporting, interpretation and verification;

(c) document control in relation to their creation, revision, approval and implementation;

(d) continuous training relevant to the system;

(e) facilities and equipment to support haemovigilance processes which are located, designed, constructed, adapted and maintained to suit their intended purpose;

(f) procedures and processes in place to ensure continuous monitoring of haemovigilance data and scientific evaluation of all information on the risks of blood and blood products; and

(g) procedures and processes to ensure effective communication.

Role of the designated focal person

28. The designated focal person responsible for haemovigilance shall have the following roles-

(a) to establish and maintain haemovigilance and look-back systems;

(b) to provide oversight over the functioning of the system in all relevant aspects, including its quality system;

(c) to promote, maintain and improve compliance with the legal requirements;

(d) to ensure and verify that the information contained is accurate and up-to-date reflection of the haemovigilance system;

(e) to be aware of product safety profiles, emerging safety concerns, risk management plans and minimization measures;

(f) to ensure conduct of haemovigilance and submission of all haemovigilance-related documents in accordance with the legal requirements;

(g) to ensure the necessary quality, including the correctness and completeness, of haemovigilance data submitted to the Authority;

(h) to ensure validation of the adverse reaction database and implementation of corrective actions to address any failures and be informed of significant changes that are made to the database;

(i) to provide relevant information on benefit-risk evaluation to the Authority; and

(j) to provide responses to regulatory actions in emerging safety concerns including variations, urgent safety restrictions, and communication to patients and healthcare professionals.

(2) Notwithstanding the provisions of sub-regulation (1), the designated person may delegate specific roles, under supervision, to appropriately qualified and trained individuals and whereas, such delegation shall be writing.

Responsibilities of NBTS

29.-(1) The NBTS shall have responsibility of monitoring safety of blood and blood products distributed within their jurisdiction.

(2) With regards to haemovigilance system, the NBTS shall have the following responsibilities-

(a) identify focal persons to coordinate haemovigilance activities;

(b) plan and budget for haemovigilance activities;

(c) distribute reporting forms, collect and analyse safety data for blood products used;

(d) risk management and follow-up of patients;

(e) reporting of adverse events and reactions to the Authority for the blood products using forms in the Sixth Schedule of these Regulations;

(f) collaborate with the Authority in implementing haemovigilance activities including training of healthcare providers on haemovigilance;

(g) promote rational and safe use of blood and blood products by healthcare providers;

(h) educate and inform patients on importance of reporting adverse reactions; and

(i) assess and communicate risks and effectiveness of blood and blood products used.

Roles of hospital blood banks

30.-(1) The hospital blood banks shall establish a system for collecting, managing and reporting adverse reactions related to blood and blood products to the Authority.

(2) The hospital blood banks shall appoint a focal person for coordination of haemovigilance activities within their facilities;

(3) The hospital blood banks shall perform the following functions-

(a) receive and distribute adverse events reporting forms to health care providers;

(b) reporting of adverse events to the Authority for blood and blood products using forms prescribed in the Sixth Schedule these Regulations;

(c) detect, investigate, manage and report adverse events and take appropriate action(s) to prevent their occurrence;

(d) maintain a register of suspected adverse reactions, adverse events, therapeutic failures, near-miss, overload and quality defective blood products;

(e) communicate appropriate safety information to health management teams and the community including patients;

(f) implement look-back haemovigilance system;

(g) conduct preliminary identification of signals and other risk factors;

(h) organize and conduct staff training and sensitization on haemovigilance; and

(i) integrate haemovigilance concept into relevant committees including hospital transfusion committees and other health committees.

Reporting requirements for healthcare providers

31.-(1) The healthcare providers shall be obliged to report to the Authority all suspected adverse reactions, events or incidences related to blood and blood products reported by patients and any quality defect issues that may arise.

(2) The reports referred to under sub-regulation (1) shall be submitted in the forms prescribed in Sixth Schedule of these Regulation.

Responsibilities of manufacturers and marketing authorization holders

32.-(1) Without prejudice to the establishment of haemovigilance system as provided for under these Regulations, manufacturers and marketing authorization holders shall be required to report to the Authority any adverse reactions or events suspected to be associated with the use of blood and blood products notified to them by healthcare professionals, patients or consumers.

(2) The adverse event reports shall include reports that arise from post-marketing experience, unsolicited and solicited sources, clinical trials, non-interventional post–registration studies and other post-marketing studies.

(3) The manufacturers and marketing authorization holders shall systematically assess the reports to establish relationship to blood and blood products.

(4) The manufacturers and marketing authorization holders shall regularly monitor international and local literature and ongoing safety and efficacy studies for any identification of adverse reactions or relevant safety findings regarding their blood and blood products.

Expedited reporting and reporting timelines

33.-(1) All serious adverse reactions associated with the use of blood and blood products shall be reported on an expedited basis.

(2) All fatal and serious adverse reactions shall be reported to the Authority within 24 hours.

(3) The expedited reporting of non-serious reactions referred to in sub – regulation (1), shall be as soon as possible, but in no case later than 15 days of initial receipt of the minimum information.

(4) Any serious suspected adverse reactions occurring in all post-marketing studies of which the manufacturer is aware should be reported to the Authority on an expedited basis.

(5) A case initially classified as a non-expedited report, which qualify for expedited reporting upon receipt of follow-up information that indicates the case shall be re-classified;

(6) The reporting time shall be considered to begin again for submission of the follow-up report if any medically relevant information is received for a previously reported case; and

(7) The management of the adverse reaction shall follow good case management practice to ensure authenticity, accuracy, as complete as possible, and non-duplicative.

PART IX
RECALL AND DISPOSAL OF BLOOD AND BLOOD PRODUCTS

Recall and disposal

34.-(1) No person shall sell, offer or expose for sale any blood or blood product subjected for recall.

GN. 313 of 2015

(2) Recall of blood and blood products shall be in accordance with the provisions stipulated in the Regulations for Recall of Medicines in force.

GN. 313 of 2015

(3) In case of disposal of blood and blood products, the Regulations for Disposal of Medicines in force shall be applicable.

PART X

STANDARDS OF PRACTICE

Labelling of blood and blood products

35.-(1) A blood establishment shall ensure that the label on each unit of blood or blood product supplied by it, or received by it contain the following information-

(a) the official name of the product;

(b) the volume or weight or number of cells in the component, as appropriate;

(c) a unique numeric or alphanumeric donation indication;

(d) the name and address of the producing blood establishment;

(e) the ABO Group, except in the case of plasma intended only for fractionation;

(f) the Rh D Group, either Rh D positive or Rh D negative, except in the case of plasma intended only for fractionation;

(g) the date or time of expiry, as appropriate;

(h) the storage and transportation temperature;

(i) the name, composition and volume of any anticoagulant and any additive solution.

(2) A blood establishment shall keep such records of the information referred to in sub - regulation (1) and such additional records as are necessary-

(a) for the identification of each single blood donation and each single blood unit and blood and blood products which are imported into Mainland Tanzania; and

(b) to ensure full traceability to the point of delivery to a donation center for a period of not less than ten years.

Norms and standards for blood donation

36.-(1) No blood establishment shall provide or promise to provide any monetary compensation, benefits or any other interests to a blood donor.

(2) No blood establishment shall discriminate blood donor on the basis of race, gender, creed, nationality, religion or any other ethnicity.

(3) A blood establishment shall ensure that protection of blood donor identity is secured in all blood collection procedures.

(4) A blood establishment shall ensure that identification of blood donor and laboratory tests are carried out in accordance with professional and medical ethics except in court trials.

(5) A blood establishment shall ensure that-

(a) a blood donor at all times, is cared for, safeguarded, dignified and recognized;

(b) a blood donor honestly and conscientiously provides information on his medical history and physical conditions in order to ensure the collection and supply of safe blood;

(c) blood donation is done at a pleasant and safe environment;

(d) all matters related to donation procedures, anticipated adverse reactions, post-donation care, tests to be carried out and notification of results are communicated to donors for consent before blood donation;

(e) interview of blood donors for eligibility purpose is done and recorded in a private environment; and

(f) carefully observe whether a side effect from blood collection occurs, take necessary measures to prevent any side effects from blood collection and report any reactions to the Authority as provided for in Part VII of these Regulations.

Compensation for donated blood

37. A blood establishment shall ensure that-

(a) donation of blood at all times and in all circumstances shall be voluntary and not remunerated or made by coercion, force or undue influence;

(b) donors are not offered financial gains either in the form of cash, or in kind which could be considered a substitute for money; and

(c) incentives such as pins, plaques, badges, medals, commendation certificates, time-off from work, membership in blood transfusion programme, gifts, small tokens, snacks, meals, refreshments and reimbursements of direct travel costs are considered acceptable and can be offered.

Standards for blood transfusion

38. A blood establishment shall ensure that-

(a) prior to blood transfusion, patients are well informed of the known risks, benefits and alternatives of therapy and consent to be transfused blood;

(b) patients are afforded the right to accept or refuse transfusion, in the event that the patient has refused or unable to give informed consent, the basis of treatment for transfusion must be in the best interests of the patient;

(c) as far as practicable, patients should receive only those components, packed RBCs, plasma, platelets and cryoprecipitates that are clinically appropriate and afford optimal safety;

(d) patients are transfused blood based on transfusion triggers; and

(e) blood transfusion committees are created and operationalized based on guidelines promulgated by NBTS.

PART XI
DISCLOSURE OF INFORMATION AND RECORD KEEPING

Disclosure of information by blood establishments

39.-(1) A blood establishment shall ensure that the information collected for the purposes of these Regulations is held securely.

(2) The information held under sub-regulation (1) shall-

(a) be kept available for the purpose of tracing donations;

(b) not disclosed except-

(i) in accordance with one or more of the requirements of sub - regulation (3) or

(ii) where they have been rendered anonymous so that donors are no longer identifiable, subject to safeguards against unauthorized additions, deletions or modifications.

(3) The requirements of this sub - regulation are-

(a) the disclosure is made in accordance with an order of a court or is otherwise required by law;

(b) the disclosure is to an inspector appointed by the Director General in accordance to with these Regulations; or

(c) the disclosure is for the purpose of tracing a donation from donor to recipient or recipient to donor.

(4) Where a disclosure is made to an inspector pursuant to sub-regulation (2)(b), the inspector shall not further disclose the information received unless-

(a) the disclosure is made in accordance with an order of a court or is otherwise required by law;

(b) the disclosure is to another officer of the Authority where this is necessary for the proper performance of the inspector or officer's duties; or

(c) the information has been rendered anonymous so that that donors are no longer identifiable.

(5) Where a disclosure is made by an inspector to another officer of the Authority pursuant to sub-regulation (3), that person shall not further disclose the information he receives other than in accordance with the requirements of that sub - regulation.

Data discrepancies

40.-(1) The responsible person of the blood establishment shall ensure that they put in place a procedure to ensure that any discrepancies relating to data which are brought to their attention are resolved without delay.

Record keeping by blood establishments

41.-(1) The blood establishment shall, in relation to the activities specified in these Regulations keep and maintain records for not less than ten years.

(2) The information to be kept, shall include-

(a) the total number of donors who give blood and blood products;

(b) the total number of donations;

(c) the total number of recipients of blood transfusion and unit number;

(d) an updated list of the hospital blood banks which it supplies;

(e) the total number of whole donations not used;

(f) the number of each product produced and distributed;

(g) the incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood products;

(h) the number of product recalls; and

(i) the number of serious adverse events and serious reactions reported.

Records to be kept by the Authority

42. The Authority shall keep such records of information which it receives from, or relating to, blood establishments as it considers appropriate and shall, in particular, keep records relating to-

(a) all authorisations under these Regulations;

(b) notification of serious adverse events and serious adverse reactions by all establishments;

(c) inspections or requests for information; and

(d) any other records as the Authority may deem appropriate.

PART XII
GENERAL PROVISIONS

Objections to suspensions and revocations

43.-(1) A blood establishment that-

(a) objects to any suspension or revocation of authorisation, or to any notice served;

(b) objects to the refusal of authorisation or the imposition of any condition, may notify the Director General of its desire to make written representations to, or be or appear before and be heard by, a person appointed by the Director General for that purpose.

(2) Any notification of an objection pursuant to sub-regulation (1) shall be made within fourteen days of service on the blood establishment of the notice to which the notification pursuant to sub-regulation (1) relates.

(3) Where the Authority receives a notification pursuant to sub-regulation (1), he shall appoint a person to consider the matter.

(4) The person appointed pursuant to sub - regulation (3) shall determine the procedure to be followed with respect to the consideration of any objection.

(5) The person appointed pursuant to sub-regulation (3) shall consider any written or oral objections made by the blood establishment in support of its objection, and shall make a recommendation to the Authority.

(6) A recommendation made pursuant to sub - regulation (5) shall be made in writing to the Authority, and a copy of it shall be sent to the blood establishment concerned, or to its nominated representative.

(7) The Authority shall take into account any recommendation made pursuant to sub - regulation (5).

(8) Within fourteen days of receipt of any recommendation made pursuant to sub-regulation (5), the Director General shall inform the blood establishment whether he accepts the recommendation and, if he does not accept it, of the reasons for his decision.

(9) Where the Director General is notified of an objection pursuant to sub-regulation (1)(a) before the date upon which the suspension or revocation or the notice is due to take effect, the suspension or revocation of a notice in respect of which the objection is made shall not take effect until-

(a) the person appointed pursuant to sub - regulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and

(b) the Director General has informed the blood establishment concerned of his decision with regard to the recommendation pursuant to sub - regulation (8).

(10) Subject to sub-regulation (9), where the Director General is notified of an objection pursuant to sub-regulation (1)(a), within the period specified in sub-regulation (2), to a suspension, revocation or other notice which has already taken effect on the date the notification was made, the suspension, revocation or notice in respect of which the objection is made shall cease to have effect until-

(a) the person appointed pursuant to sub - regulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and

(b) the Director General has informed the blood establishment concerned of his decision with regard to the recommendation pursuant to sub - regulation (8).

(11) The provisions of sub-regulation (10) shall not apply-

a. in relation to a suspension or revocation, or a notice served, which takes immediate effect in accordance with these Regulations; or

b. in any other case, where the Director General determines that it is necessary in the interests of public safety for the suspension, revocation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the blood establishment concerned.

Appeals

44.-(1) Notwithstanding the provisions of regulation 38, any person aggrieved by a decision of the Authority may, within sixty days appeal in writing to the Minister.

(2) The appellant shall copy a notice of the appeal to the Authority who shall within fourteen days submit a written response to the Minister and copy the appellant.

(3) Where the Minister is of the opinion that a case has been made, he may summon parties for additional information or make a decision to allow or dismiss the appeal.

Offences and penalties

45. Any person who contravenes or fails to comply with these Regulations or directly or indirectly aids any other person to do what is prohibited under these Regulations shall be guilty of an offence and on conviction, shall be liable to the penalty prescribed by the Act.

Compounding of offences

46.-(1) The Director General, Inspector or any other authorized person may, subject to and in accordance with the provisions of these Regulations, if he is satisfied that a person has committed an offence against these Regulations, compound such offence by accepting from such person a sum of money in respect of which the offence has been committed.

(2) The sum of money payable under sub-regulation (1) shall not exceed five times the maximum amount of the fine prescribed as being payable in respect of such offence.

(3) The Power conferred by this section shall be exercised where a person admits that he has committed an offence and agrees in writing in the prescribed form to the offence being dealt with under this regulation.

(4) The Director General or officer exercising powers under this regulation shall give to the person from whom he receives any sum of money under sub regulation (2) a receipt which shall be in a prescribed form.

(5) Any sum of money received under this regulation shall be paid into the Authority.

(6) If any proceedings are brought against any person for an offence against these Regulations, it shall be a good defence if such person proves that the offence with which he is charged has been compounded under this regulation."

SCHEDULES

FIRST SCHEDULE

APPLICATION FOR A BLOOD ESTABLISHMENT AUTHORISATION

(Made under regulation 6)

(Please complete all relevant Sections in this form typed or in block capitals)

Section 1 – Applicant Details

Blood Establishment Name:	
Applicant Name:	
Address:	
Postcode:	
Telephone:	
Mobile	
E-mail address:	

Section 2 – Establishment/Site Information

Site Name:	
Site Address:	
Postcode:	
Site Contact Name	

Telephone:	
Mobile	
E-mail address:	
Add as many rows as possible (if more than one site)	

ESTABLISHMENT/SITE ACTIVITY – Please detail below site activity, for clarity please write 'Yes' or 'No' against each proposed activity type:		
	YES	**NO**
Collecting blood		
Testing blood		
Storing blood		
Distributing blood		
Processing blood into blood components		
Storage of blood products		
Distribution of blood products		

Section 3 – Establishment/Site Processes

Proposed processes to be conducted at this site - Please write Yes or No as required in the relevant column for each of the processes proposed to be conducted:

	YES	**NO**
Whole blood collection		
Autologous whole blood collection		
Testing donor samples		
Apheresis collection of components		
Please specify apheresis component type collected:		
Whole Blood Processing into:	**YES**	**NO**
Red cells		
Platelets		
Granulocytes		
Fresh frozen plasma		
Recovered plasma (for discard)		
Cryoprecipitate		
Cryoprecipitate depleted plasma		
Buffy coats		
Other (please specify):		

Components Processed into:	**YES**	**NO**
Methylene blue treated plasma		
Irradiated components		
Washed components		
Leucocyte depleted components		
Splitting into small volume packs		
Pooling cryoprecipitate		
Manipulation of haematocrit		
Other (please specify):		

Section 4 – Site Personnel

Please list below the names of Responsible Person (Blood) and other site personnel:

S/N	Name	Qualification	Responsible for

Section 5 – Declaration

I/we apply for the grant of a Blood Establishment Authorisation to the proposed holder named in this application form in respect of the activities to which the application refers.

Signed: _____ Date:_____

Name: _____

Position: _____

Stamp/Seal: _____

SECOND SCHEDULE

(Made under regulation 11 (2) (a))

INFORMATION TO BE PROVIDED TO PROSPECTIVE DONORS OF BLOOD OR BLOOD COMPONENTS

1. Accurate educational materials, which are written in terms which can be understood by members of the general public, about the essential nature of blood, the blood donation procedure, and the components derived from whole blood and apheresis donations and the important benefits to patients.

2. For both allogeneic and autologous donations, the reasons for requiring an examination and health and medical history, and the testing of donations, and the significance of "informed consent".

3. For allogeneic donations, the criteria for self-deferral, and temporary and permanent deferral, and the reasons why individuals are not to donate blood or blood components if there could be a risk for the recipient.

4. For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individual whether as donor or recipient of the autologous blood or blood components.

5. Information on the protection of personal data, including confirmation that there will be no disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed, other than in accordance with the requirements of these Regulations.

6. The reasons why individuals are not to make donations which may be detrimental to their health.

7. Specific information on the nature of the procedures involved either in the allogeneic or autologous donation process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements.

8. Information on the option for donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during the donation process, without any undue embarrassment or discomfort.

9. The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion.

10. Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show any abnormality of significance to the donor's health.

11. Information as to why unused autologous blood and blood components will be discarded and not transfused to other patients.

12. Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents, will result in donor deferral and destruction of the collected unit.

13. Information on the opportunity for donors to ask questions at any time.

THIRD SCHEDULE

(Made under regulation 11 (2) (b))

INFORMATION TO BE OBTAINED FROM DONORS BY BLOOD ESTABLISHMENTS AT EVERY DONATION

1. Personal data uniquely, and without any risk of mistaken identity, distinguishing the donor, as well as contact details.

2. Health and medical history, provided on a questionnaire and through a personal interview performed by a qualified health professional that includes relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves.

3. Signature of the donor, on the donor questionnaire, countersigned by the qualified health professional responsible for obtaining the health history confirming that the donor has:-

   (a) read and understood the educational materials provided;

   (b) had an opportunity to ask questions;

   (c) been provided with satisfactory responses to any questions asked;

   (d) given informed consent to proceed with the donation process; and

   (e) been informed, in the case of autologous donations, that the donated blood and blood components may not be sufficient for the intended transfusion requirements; and acknowledged that all the information provided by the donor is true to the best of his knowledge.

FOURTH SCHEDULE

(Made under regulation 11 (2) (d))

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD PRODUCTS

1. Acceptance criteria for donors of whole blood and blood products

Under exceptional circumstances, individual donations from donors who do not comply with following criteria may be authorised by a qualified healthcare professional in the blood establishment.

The criteria in this paragraph do not apply to autologous donations.

Age	18 to 65 years		
	16 to 17 years	For 16 or 17 aged individuals, a written consent from parents / guardians should be obtained before blood donation	
	First time donors over 60 years	At the discretion of the medical practitioner in the blood establishment.	
	Over 65 years	With permission of the medical practitioner in the blood establishment, given annually.	
Body weight	≥50 kg for donors either of whole blood or apheresis blood components.		
Haemoglobin	For females ≥12.5 g/dl	For males ≥ 13.5 g/dl	Applicable to allogeneic donors of whole blood and cellular components
Blood Pressure	Acceptable range of BP should be (90/60-140/90) that means Systolic BP90-140mmHg and Diastolic BP 60-90mmHg.		
Pulse rate	Acceptable pulse rate shall regular and not <60 or >100 beats/minute.		
Protein levels in donor's blood	≥60g/dl	The protein analysis for apheresis plasma donations must be performed at least annually.	
Platelet levels in donor's blood	Platelets Platelet number greater than or equal to 150 x 10^9/L		Level required for apheresis platelet donors
Blood Donation Interval	**Male:** The normal interval between whole blood donations is 12 weeks (three months)		**Female:** The normal interval between whole blood donations is 16 weeks (four months).

2. Deferral Criteria for Donors of Whole Blood and Blood Components

2.1 Permanent deferral criteria for donors of allogeneic donations

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure.
Central nervous system disease	A history of serious CNS disease.
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy.
Repeated episodes of syncope, or a history of convulsions	Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions.
Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases	Prospective donors with serious active, chronic, or relapsing disease.

Diabetes	All diabetics patients are permanently deferred from donating blood except for a female who had diabetes during pregnancy may donate provided the diabetes has resolved.
Infectious diseases	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune Hepatitis C HIV1&2, Babesiosis Visceral, Leishmaniasis, Chagas' disease and Lyme disease.
Malignant diseases	Defer permanently all Leukemia, Lymphoma, Kaposi Sarcoma and Malignant Melanoma, Except in situ cancer with complete recovery.
Transmissible spongiform encephalopathies (TSEs) (e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease)	All blood donors with a history of CJD diagnosis found at increased risk or if any relatives have been diagnosed with CJD are deferredindefinitely.
Intravenous (IV) or intramuscular (IM) drug use and oral drugs	Anti-epileptic drugs, anti-convulsant drugs such Tegratol, Pituitary Growth Hormone, body-building steroids or hormones Xenotransplant recipients.
Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood.

2.2. Temporary deferral criteria for donors of allogeneic donations

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery. However, the following deferral periods shall apply for the infections listed in the table:

Brucellosis	2 years following the date of full recovery
Osteomyelitis	2 years after confirmed cured
Q fever	2 years following the date of confirmed cure
Syphilis	1 years following the date of confirmed cure
Toxoplasmosis	6 years following the date of clinical recovery
Tuberculosis	2 years following the date of confirmed cure
Rheumatic fever	2 years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever >38°C	2 weeks following the date of cessation of symptoms
West Nile Virus (WNV)	28 days after leaving an area with ongoing transmission of WNV to humans

2.3 Exposure to risk of acquiring a transfusion-transmissible infection

- Endoscopic examination using flexible instruments - Mucosal splash with blood or needle stick injury - transfusion of blood components - tissue or cell transplant of human origin - major surgery - tattoo or body piercing - acupuncture unless performed by a qualified practitioner and with sterile single-use needles - persons at risk due to close household contact with persons with hepatitis B	Defer 6 months, or 4 months provided a NAT test for hepatitis C is negative
Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests

2.4 Vaccination

Killed and inactivated vaccines	
Inactivated/killed viruses, bacteria or rickettsiae vaccine Tetanus, Meningococcal Rabies Tetanus vaccine-accept individuals who Toxoids Hepatitis A or B vaccine Tick borne encephalitis vaccines	No deferral is required for the killed and inactivated vaccinations provided the donor feels well:
Live attenuated vaccines, examples	

BCG (Bacillus Chalmette-Guerin) Herpes Zoster, Varicella zoster Measles, Mumps, Rubella (MMR) Polio (Sabin, oral) Rubella that is German Measles (MMR) Typhoid (Oral) Yellow Fever Botulism Toxin Pertussis Immune Globulin Rabies - Treatment after with Immune Globulin Rh Immune Globulin (RhoGAM) Smallpox Tetanus Antitoxin Tetanus Immune Globulin Chickenpox (Varivax & immune globulin,) Hepatitis A and Hepatitis B (Twinrix) Hepatitis B (Engerix B, Recombivax–HB) Hepatitis B Immune Globulin (HBIG)	Defer for 4 weeks

2.5 Other temporary deferrals

Pregnancy	6 months after delivery or termination except in exceptional circumstances and at the discretion of a physician
Minor surgery	1 week
Dental treatment	Minor treatment by dentist or dental hygienist – defer until next day (NB: Tooth extraction, root-filling and similar treatment is considered as minor surgery)
Medication	Based on the nature of the prescribed medicine, its mode of action and the disease being treated. Refer to donor selection guideline

2.6 Deferral for particular epidemiological situations

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation

2.7 Deferral criteria for donors of autologous donations

Serious cardiac disease	Depending on the clinical setting of the blood collection
Active bacterial infection	
Additional requirements for autologous donations	Autologous blood and blood components must be clearly identified as such and stored, transported and distributed separately from allogeneic blood and blood components. The candidate for autologous blood donation must meet the all routine requirements for allogeneic donation and should donate one unit per week and no more than one unit every three days.

	Autologous blood and blood components must be labelled as required by these regulations, and, in addition, the label must include the identification of the donor and the warning "FOR AUTOLOGOUS TRANSFUSION ONLY".
	The unused blood for auto-transfusion cannot be used for other purposes, except by approval of the person who donated blood for autologous transfusion.

FIFTH SCHEDULE

(Made under regulation 11 (3) (b))

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

1. Storage

Component	Temperature of storage	Maximum storage time
Packed Red cell and whole blood (if used for transfusion as whole blood)	+2 to +6°C	28 to 49 days according to the processes used for collection, processing and storage.
Platelet	+20 to +24°C	3-5 days after blood collection, may be stored for 7 days in conjunction with detection or reduction of bacterial contamination.
Granulocytes	+20 to +24°C	24 hours

2. Cryopreservation

Component	Storage conditions and duration
Red blood cells	Up to 30 years according to processes used for collection, processing and storage.
Platelets	Up to 24 months according to processes used for collection, processing and storage.
Plasma and cryoprecipitate	Up to 36 months according to processes used for collection, processing and storage.
Cryopreserved red blood cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after thawing to depend on the method used.	

3. Transport and Distribution

Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product.

SIXTH SCHEDULE

(Made under regulation 11 (3) (c))

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD PRODUCTS

1. Blood and blood products must comply with the following technical quality measurements and meet the acceptable results.

2. Appropriate bacteriological control of the collection and manufacturing process must be performed.

Component	Quality measures required	Acceptable results for quality measures
Whole Blood	Volume	Volume of whole blood should be 405 – 495 ml (450mls ± 10%)
	Haemoglobin	Haemoglobin should be 45 g/dl per unit
	Haemolysis	Less than 0.8% of red cell mass at end of shelf life
	Haematocrit	35-45%
Packed Red Blood Cells	Preparation	Separate red cells and plasma within 6 to 18 hours after collection (if platelets are not being produced). Prepare components within 72 hours preferably but not more than 7 days after collection
	Volume	155 – 270 ml.
	Haemoglobin	Haemoglobin should be more than 45g/dL per unit
	Haematocrit	Haematocrit for PRC should be 60-80%
	Haemolysis	Less than 0.8% of red cell mass at end of shelf life
	Leucocyte	For leucocyte depleted PRBC-Leukocyte count should be $\leq 2.4 \times 10^9$/unit for red cells in additive solution and buffy-coat removed
Plasma (FFP)	Preparation	Separated from whole blood within 6 to 18 hours of collection and freeze solid at minus 18°C or, preferably, at minus 25°C or lower as early as possible
	Volume	225 – 250 ml
	Coagulation factor	FVIII: should be 80IU
Platelets	Preparation	Separate platelet concentrates from whole blood by centrifugation at +20°C to +24°C from either platelet rich plasma or buffy-coats using validated methods
	Volume	Suspend platelets in 50-70ml of plasma
	Leucocyte count	Platelet production methods adopted shall ensure that leucocyte is less than 5×10^6/L per pool

	Platelet count	Whole blood derived platelet unit should contain ≥5.5 x 10^9 platelets per unit in 50-70mls, pooled platelets (from random donors) should contain ≥2.4 x 10^{11} platelets per pool (200-300ml and apheresis platelet unit should contain ≥3 x 10^{11} platelets per unit,
	pH	The pH shall be 6.4 - 7.4 corrected for 22^0C at the end of shelf life
	Glucose	27 mmol/L
Cryoprecipitate	Volume	10 -15 ml
	Factor VIII	80-100U per unit
	Fibrinogen	200-300mg per unit
	Von Willebrand's factor	80U

SEVENTH SCHEDULE

(Made under regulation 29 (2) (e))

ADVERSE REACTION REPORTING FORMS

Form No. 1

BLOOD DONATION ADVERSE EVENT REPORTING FORM Scope: To be filled in by the donation team					
Donor Information:					
Donation site		Donor Number		Donation Number	
Donation Date		Type of Donation: Whole blood or Apheresis (Circle the appropriate)			
Donor Name				DOB	
Sex M/F		Donor status: First time/Repeat		Ethnic Group	
Donor weight		Donor Hb			
Phone No: Mobile		Phone no: Work		Phone No: Home	
Reaction/Injury Information					
Date of Incident/ Reaction began			Time of Incident/ Reaction began		
Time incident/ Reaction ended					
Type of Reaction/Injury (mark all signs and symptoms that apply)					
Donor Reaction with Generalized Symptoms – Vasovagal Reaction					**Tick √**
• Cold extremities/chills					
• Convulsions					
• Feeling of warmth					
• Hypotension					
• Light-headedness/dizziness					
• Loss of bladder and/or bowel control					
• LOC <60seconds					
• LOC >60seconds					
• Nausea/vomiting					
• Pallor(pale skin or lips)					
• Rapid pulse					
Hyperventilation Hyperventilation causes the **CO_2** level in the blood to decrease. This lower level of **CO_2** and reduction of blood flow to the brain, may result in the below nervous system and emotional symptoms. Over breathing can also cause the calcium levels to drop in your blood, which may result in the below nervous system symptoms:					
• Over breathing					**Tick √**
• Weakness					

• Fainting					
• Dizziness					
• Numbness and tingling both arm and mouth					
• Tetany (spasm or cramps of hand and feet)					
Then record vital signs after every 15mins in case of Vasovagal Reaction and Hyperventilation					
Pre-donation BP:			Pre donation Pulse rate		
Time recorded					
Respiratory rate R/ Min	Start	After 15min	After 15min	After 15min	After 15min
B/P mmHg					
Pulse (Beats/Minute)					
Rhythm: Regular/ Irregular					
Respiratory rate R/ Min					
Record Therapy Provided					
Type of Therapy		Route of Administration	Dose/Volume	Frequency/Times	Signature
Donor Reaction with localized Symptoms (mark all signs and symptoms that apply)					
Nerve Irritation					**Tick √**
• Immediate intense pain at site					
• Numbness or tingling of fingers, hand or arm					
• Shooting pain down arm					
• Weakness of arm					
Hematoma/Infiltration					
• Pain					
• Swelling					
Discharge/Release:					**Tick √**
Was Medical Practitioner notified					
Donor condition on leaving the premises					
Blood Centre instruction on the referral note					
Donor released to: Self others, if other, relationship to donor					
Donor released to Home Hospital specify					
Donor refused treatment/medical advice (please explain)					

Additional Information/Details: (i.e. parents phone calls, any information not on the check list)
Person Incharge of the blood collection team Name.....Signature.....Date.....

Form No. 2

ADVERSE TRANSFUSION EVENT NOTIFICATION FORM
(Scope: To be filled by blood establishment and sent to the Authority)

Confidentiality of this information is fundamental to the success of this program; we will contact you to obtain additional information if necessary, once the initial reaction has been reported. Report one adverse reaction per form. Thank you for taking the time to complete this form. Please feel free to contact TFDA should you require additional information.

To be reported from Wards by Nurse:

Report made by:
Name (Full name) …… Title:……
Facility name…….....Mobile number:……...

Patient Details
Surname:.....First name…….....Middle name……..
Hospital:..... Sex: F M
File number:..... Date of birth:...../...../.....
Diagnosis:.....
Reason for Transfusion…….....
Blood Component Details
Type of Blood Component implicated **(Whole Blood, Red Cells, Plasma, Platelets, Cryoprecipitate)**
Blood Unit Number……Blood Unit ABO & Rh Group……Expiry date……..
Patient ABO & Rh Group……
Date of implicated transfusion ……../…... /…... Time transfusion started……
Time reaction noticed…… hrs.
Findings of physical inspection of the blood unit……

Any Transfusion or Obstetrical History in the past (Circle the appropriate)

Transfusions:	Yes <3 month.	Yes >3 month.	No	Unknown
Pregnancy:	Yes <3 month.	Yes >3 month.	No	Unknown

Any history of Pre-medication during blood transfusion:
If yes, Specify Drug(s) or fluid used……

Please tick the Transfusion adverse reaction, Near miss or Error

	Suspected *Please Tick*	Certain & confirmed *Please Tick*
1. Adverse Reaction		
Acute Haemolytic Reaction (AHTR)		
Delayed Haemolytic Reaction (DHTR)		
Febrile non-Haemolytic TR (FNHTR)		
Allergic/Anaphylactic Transfusion Reaction (ATR)		
Transfusion-related acute lung injury (TRALI)		

Post-transfusion purpura (PTP)		
Transfusion-associated graft-versus-host disease (TA-GVHD)		
Transfusion associated circulatory overload (TACO)		
Transfusion-associated dyspnoea (TAD)		
Hypotensive (HT)		
Bacterial contamination (BC)		
Transfusion-transmitted infection (TTI)		

Clinical Signs and Symptoms in case of a reaction: *Please Circle*
Chills/Rigors: Haemoglobinuria: Tachycardia: Falling urinary output : Oliguria, Urticarial: Back pain: Nausea/Vomiting: Hypertension: Hypotension: Shock Fever: Jaundice: Dyspnoea: Dyspnoea Haemorrhage: Bradycardia: Pain along infusion site: Rising pCO_2: Hypoxemia (PaO_2 or SaO_2) Sub-Sternal discomfort: Stridor / Wheeze: GI symptoms, including cramps: Cyanosis: Falling O_2 saturation: Falling haemoglobin: Restlessness/anxiety: Chest x-ray changes: Other:

Measures Taken: *Please Circle*
None Required: Diuretics: Supplementary O_2: Antipyretics: Chest X-ray: Analgesics Antihistamines: Mechanical Ventilation :Transfusion Stopped: Steroids: ICU Required Transfusion Restarted: Vasopressors: Blood (Component Cultures Ordered): Patient Blood Culture Ordered: Other, Specify:

Patient outcome: *Please Circle*
Relationship of adverse reaction to transfusion
Definite Probable Doubtful Ruled Out Not determined
Severity of adverse reaction
Non-Severe Severe Life-threatening Death Not determined
Outcome of the patient
Death Major Long-term sequela Minor (no sequela) Not determined

To be reported by the Transfusing Nurse and Laboratory officer, where applicable

	Please Tick	
Near Miss and Errors		
Mix-up of donors or donated blood unit numbers		
Incorrect labelling		
Release of blood products that do not conform to specifications		
Incorrect testing		
Detection of a transfusion-transmissible infection in a blood donor		
Incorrect blood release to wrong patient(if no reaction)		
Incorrect ABO and Rh D group transfused (if no reaction)		
Transfusion of expired component		
Transfusion of incorrectly stored component		

Transfusion Reaction Sample Collected from Ward/Unit …….. Clerical error (unit labelling, check findings……. Please state the blood group of the patient: Pre transfusion ABO/Rh……Post transfusion ABO/ Rh……..... Please state the compatibility test results on Pre transfusion sample with Donor blood ……Post transfusion sample with Donor blood ……..... Please state if any post-transfusion antibody screen was positive…….……. What antibody (ies) were identified?..... Was DAT performed? Yes/No If yes, what was the result?..... State pre transfusion haemoglobin level ……..and post transfusion haemoglobin level…… State macroscopic and microscopic urinalysis results……. Blood Culture and other Bacteriological findings…….. State any other investigational results…….
Facility Lab Clerical Check Reported by: Name……...Date/Time……. Discrepancies…… Yes No If yes, Specify……

Dodoma,

……. ……., 2018

UMMY A. MWALIMU

Minister for Health, Community Development, Gender, Elderly and Children