No. R. 269 **1 April 2011**

NATIONAL HEALTH ACT. 2003

REGULATIONS RELATING TO BLOOD AND BLOOD PRODUCTS

The Minister of Health intends, in terms of section 90(1), read with section 68(1) of the National Health Act 2003 (Act No. 61 of 2003), and after consultation with the National Health Council, to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001, within three months of the date of publication of this notice.

SCHEDULE

CHAPTER 1

DEFINITIONS AND BLOOD TRANSFUSION SERVICE

1. In these Regulations any word or expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context otherwise indicates-

"Act" means the National Health Act, 2003, (Act no 61 of 2003);

"allogenéic transfusion" means the administering of blood or blood product to a person which has been donated by another person;

"applicant" means any person, organisation or institution that applies for a licence to render a national blood transfusion service in terms of regulation 2(6);

"autologous donation" means the donation of blood by a person for the later administering thereto to the same person;

"batch" in relation to –

(a) blood donations, means all the containers of blood filled at one bleeding session; and

(b) blood components or blood products, means the quantity of homogeneous material produced during a specific cycle of manufacture;

"blood" means blood intended for transfusion purposes, including the components thereof, but excludes blood specimens intended for pathology testing;

"blood component" means any constituent of blood derived from blood donations that is separated from blood by physical or chemical means;

"blood donor" means any living, voluntary, non-remunerated person from whom blood is withdrawn for the subsequent administering to another living person or to himself or for the processing into blood products;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 transfusion service" means the organisation licensed in terms of 53 of the Act to provide blood transfusion services;

"Companies'Act" means the Companies Act, 1973 (No. 61 of 1973);

"constituent part" means any regional unit, branch, office or any other unit or premises of the NBTS which performs any of the activities referred to in 2(1)(a), (b) or (c);

"designated donor" means a person nominated by a recipient to donate blood or a blood product for the recipient;

"homogeneous material" means material consisting of or composed of similar elements or ingredients;

"Inspector" means an inspector of blood transfusion services appointed in terms of regulation 5;

"medical practitioner" means a person registered as a medical practitioner in terms of the Health Professions Act,1974 (No. 56 of 1974);

"normal saline" means a 0,9% isotonic solution of sodium chloride in water;

"recipient" means a person to whom blood or a blood product is administered which has been donated by another person or by that person himself or herself;

"recognised identity number" means a personal identifier included in the official identification book issued by the Department of Home Affairs, a passport or driver's licence;

"standards of practice" means the standards of practice for blood transfusion services as determined by the Minister;

"stem cell" means any embryonic stem cell, circulating progenitor cell, bone marrow progenitor cell, umbilical cord progenitor cell, haemopoietic progenitor cell or any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell;

"transfusion reaction" means any adverse reaction as a result of the administration of blood or a blood product; and

"transfusion transmissible disease" means a disease that can be transmitted by the transfusion of blood or a blood product.

Licensing of national blood transfusion service

2. (1) No organisation, institution or person except a blood transfusion service contemplated in section 53 of the Act shall-

(a) be involved in the withdrawal of blood or a blood product from any living person, for the later administration thereof to that person or to any other person;

(b) store, preserve, test, process, separate or supply or in any other manner dispose of blood so withdrawn or imported, for use whether as whole blood, a blood component or in the form of any blood products; or

(c) produce, pack, seal and label any blood product or supply or in any manner dispose of any blood product.

(2) No other organisation, or authorised institution or person shall-

(a) be involved in the withdrawal of stem cells except embryonic stem cells from any living person for the later administration thereof to that person or to any other person;

(b) store, preserve, test, process, separate or supply or in any other manner dispose of progenitor cells so withdrawn or imported for use;

(3) A blood transfusion service must-

(a) conduct any activity referred to in sub-regulation (1)(a), (b) or (c), as the case may be, in accordance with the provisions of these regulations; and

(b) ensure that such activities comply with the minimum requirements as provided for in the standards of practice.

(4) The provisions of sub-regulation (1) shall not prohibit -

(a) a medical practitioner or dentist from performing any professional act within the scope of his or her profession;

(b) the production of a blood product which is not intended for therapeutic or prophylactic purposes in human beings.

(5) The professional act referred to in sub (4)(a) shall be limited to activities referred to in sub- regulation (1) in respect of an individual patient or patients of that medical practitioner or dentist and shall not be extended to include such activities in respect of a patient of another medical practitioner or dentist.

Oversight of Blood Transfusion Services

3. (1) If the Director-General is of the opinion on the strength of an inspection, report or recommendation contemplated in regulation 6(1) by an inspector that there are reasonable grounds to suspect that –

(a) any premises or equipment used by a blood transfusion service or authorised institution or any of its constituent parts, as the case may be, for the purposes of any of the activities is in a way hazardous to health, or that conditions constituting a hazard to health have been or are being created in or upon such premises; or

(b) the blood transfusion service or authorised institution is not complying with these regulations or the standards of practice;

the Director-General may serve a written notice, instructing the person in charge of such premises or equipment, to furnish reasons, at a place and time specified in such notice, why the matter should not be dealt with in terms of sub-regulation (3).

(2) A notice referred to in sub-regulation (1) shall set out such particulars as are reasonably adequate to inform the blood transfusion service or authorised institution why the suspension, revocation or withdrawal of the licence is contemplated, and shall be served by the Director-General not less than 21 days prior to the date specified in such notice.

(3) If it still appears to the Director-General after consideration of the reasons furnished in terms of sub-regulation (1) that-

(a) the premises or equipment referred to in sub-regulation (1) is hazardous to health or that conditions constituting a hazard to health have been or are being created in or upon such premises; or

(b) the licensee does not comply with the provisions of the Act, these regulations or the standards of practice;

the Director-General may recommend to the Minister that a licence be suspended or revoked.

Appointment of inspectors

4 The Director-General shall appoint persons in the employ of the Department as inspectors for blood transfusion services.

(2) (a) An inspector shall exercise the powers and perform the duties conferred or imposed upon or delegated or assigned to him or her under these regulations, subject to the control and directions of the Director-General or a person specifically designated by the Director-General.

(b) The Director-General, or any other officer in the full-time employment of the Department designated by her or him, may exercise any power conferred upon an inspector.

Powers of inspectors

5. (1) An inspectorate may -

(a) at any reasonable time for the proper performance of her or his functions and without prior notice enter any premises-

(i) in or upon which blood and blood products are used or are reasonably suspected to be used;

(ii) in or upon which the withdrawal of blood from any living person, and the preservation, testing, processing, supply or disposal of blood so withdrawn or imported, is carried out or is reasonably suspected to be carried out;

(iii) in or upon which the administering of blood or any blood product to any living person is carried out or reasonably suspected to be carried out; or

(iv) which are connected with or are reasonably suspected to be connected with any act or process referred to in subparagraphs (i), (ii) and (iii);

(b) examine any such premises or blood or blood product or other object found therein or thereon or any activity or process carried out in or upon those premises, and may open any package or container in or upon those premises which contains or is suspected to contain such blood and blood product, or other object, in order to ascertain whether the provisions of the Act and these regulations with regard to those premises or blood or blood products, other object, activity or process are being complied with;

(c) at any time demand from any person in or upon any such premises that she or he at a time and place determined by the inspector produce any register, record or other document which is in possession or custody or under the control of that person or any other person on her or his behalf;

(d) examine such a register, record or other document and require from any person referred to in paragraph (c) an explanation of anything appearing therein, and make copies thereof of extracts

there from, or seize such a register, record or other document, if in her or his opinion it may afford evidence of an offence in terms of the Act or these regulations;

(e) with regard to any matter which she or he is investigating, question, either alone or in the presence of another person, any person whom she or he finds in or upon the premises or whom she or he on reasonable grounds suspects to be or to have been employed in or upon such premises or to have possession or custody of or control over anything referred to in this regulation;

(f) order any person contemplated in paragraph (c) or (e) to appear before her or him at a time and place determined by her or him, and at that time and place question that person with regard to any matter which she or he is investigating;

(g) remove blood or blood products which is kept in or upon premises entered by her or him in terms of paragraph (a) if she or he deems it advisable, and recover the cost in connection with the removal and burial from the institution or person under whose care the body or tissue concerned was immediately before such removal.

(2) Any person who is in charge of any activity or process referred to in sub-regulation (1) in respect of which any premises contemplated in sub-regulation (1) are occupied or used, and any person employed by such person, shall at all reasonable times render such assistance as an inspector may require in the exercise of her or his powers under that regulation;

6. (1) An inspector may, in addition to exercising the powers referred to in subregulation (1) insofar as blood or any blood product or any matter relating thereto is concerned -

(a) take samples, or direct that such samples be forwarded or delivered to whomsoever he or she deems fit, in such quantities as he or she may consider necessary for testing; or

(b) weigh, count, measure, mark or seal any blood or blood product or any device, test reagent or substance.

(c) place under embargo or seize any blood, blood product or documentation if in her or his opinion it may produce evidence of an offence in terms of the Act.

(2) An inspector shall report immediately to the Director-General or a person specifically designated by him or her any non-compliance with these regulations or standards of practice which has come to his or attention during the exercise of his or her powers in terms of these regulations.

(3) An inspector shall exhibit the written authority by virtue of which she or he is authorised to any person affected by the exercise or performance of any power, duty or function when called upon to do so by that person.

Blood Transfusion Service

7. A blood transfusion service shall-

(a) must be a non-profit organization incorporated under section 21 of the Companies Act;

(b) must appoint a medical practitioner as medical director to be in charge of and take full responsibility for its medical and related activities and such medical director must at least have some experience in blood transfusion and related matters;

(c) must provide adequate clinical consultation facilities in respect of the practice of blood transfusion therapy and the management of complications arising there from; and

(d) may be reimbursed for the services rendered.

CHAPTER 2

ACQUISITION, TESTING, REQUISITION AND ADMINISTERING OF BLOOD AND BLOOD PRODUCTS

Recruitment of blood donors

8. The recruitment of blood donors must be in accordance with the criteria set out in the standards of practice.

Mandatory testing of donated blood and blood products

9. (1) The blood transfusion service must perform the following minimum tests on each donation:

(a) tests for the following infectious agents which may cause transfusion transmissible diseases:

(i) Syphilis;
(ii) Hepatitis B surface antigen (HBsAg);
(iii) Antibodies to the hepatitis C virus (anti-HCV);
(iv) Antibodies to the human immunodeficiency virus type 1 and 2 (anti-HIV 1 and 2); and
(v) p24 HIV1 antigen.

(b) red cell serology, including ABO grouping and Rh grouping; and

(c) Allo-agglutinin titre.

(2) (a) The blood transfusion service must from time to time evaluate the latest scientific information pertaining to mandatory tests referred to in subregulation (1) and based on scientific evidence, submit such information to the committee referred to in regulation 13 for a recommendation.

(b) The recommendation referred to in (a) must be submitted to the Minister for appropriate action where necessary.

(3) With the exception of an autologous blood transfusion, no blood must be released for transfusion purposes if there is any reason to suspect from the donor's laboratory test results, medical history, past donation record or physical condition that his or her blood may transmit disease.

Requisition and administering of blood and blood products

10. (1) No blood or blood product may be ordered unless –

(a) it is prescribed by a medical practitioner in writing on a form created by the blood transfusion service;

(b) the form referred to in paragraph (a) must be signed by the person -

(i) taking a blood sample from the recipient for compatibility testing; and

(ii) identifying the patient for the purpose of taking a blood sample for compatibility testing.

(2) Any institution or facility where blood and blood components are administered to any living person must ensure that –

(a) policies and procedures are in place to ensure the correct identification of the recipient at the time of the taking of a blood sample for compatibility testing as well as at the time of administering the blood or blood product; and

(b) records are kept in permanent patient records of all such products administered in paragraph (a) and any adverse reactions there from.

(3) A person responsible for administering blood or a blood product to a living person shall positively ascertain the identity of the intended recipient and that the identification of the blood sample on the label is correct for the recipient.

(4) The blood transfusion service must inform the Director-General or a person specifically designated by him or her, verbally immediately of any report received in terms of subregulation (3), of any serious or life threatening reaction or death and confirm such report in writing as soon as possible.

Autologous and designated donations

11. The provisions set out in these regulations as well as the standards of practice shall apply to a designated donation and an autologous donation.

Record of blood donors, blood donations, blood containers, statistics and untoward reactions

12. (1) Subject to subregulation (2), a blood transfusion service shall keep or cause to be kept -

(a) a register of blood donors;

(b) a record of blood donations and the processing thereof;

(c) a record of every container of blood received for processing;

(d) a record of statistics in respect of all donations of blood and the disposal of all containers of such blood; and

(e) a register of transfusion reactions.

(2) Particulars of records to be kept in subregulation (1) must be in accordance with the standards of practice.

(3) (a) The blood transfusion service shall submit a monthly report of all incidents referred to in subregulation (1)(e) to any inspector appointed in terms of regulation 5.

(c) The inspector shall submit an annual report on the reports received in terms of paragraph (a) to the Director-General, no later than the last day of March of the year following the calendar year in respect of which the report is made;

(d) any other report required by the Minister from time to time in respect of the activities of inspectors.

(e) If it comes to the inspector's notice that a transfusion reaction, including transfusion transmitted disease or death, has resulted from the administering of the blood or blood product, immediately report such transfusion reaction, including transfusion transmitted disease or death to the medical practitioner responsible for the treatment of such patient, and-

(i) the said medical practitioner must report the incident verbally and subsequently in writing to the blood transfusion service which supplied the blood or blood product;

(ii) the blood transfusion service shall immediately inform an inspector for the area in which the blood was supplied verbally of any serious or life threatening reaction or death resulting from the administering of such blood or blood product and confirm such report in writing as soon as possible; and

(iii) the blood transfusion service shall inform the Director General accordingly.

CHAPTER 3

GENERAL PROVISIONS

Standards of practice for blood transfusion in South Africa

13. A blood transfusion service shall comply with the provisions in the standards of practice for blood transfusion as determined by the Minister.

Offences and penalties

14. Any person who contravenes or fails to comply with any provision of these regulations shall be guilty of an offence and liable on conviction to a fine or imprisonment not exceeding 10 years or to both fine and such imprisonment.

Repeal of regulations

15 (1) The regulations published under Government Notice No- R *1935 of* 17 *August* 1990, Government Notice No. R 298 of 26 February 1993 are hereby repealed.

DR A MOTSOALEDI

MINISTER OF HEALTH