No. R. 267 1 April 2011

NATIONAL HEALTH ACT, 2003 (Act 61 of 2003)

REGULATIONS RELATING TO TISSUE BANKS

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

Interested persons are invited to submit written comments on the proposed regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 within three months from the date of publication of this notice.

SCHEDULE

CHAPTER 1

DEFINITIONS

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

"altered form" means human tissue that has been adapted, changed or transformed from its original form as donated by a person, to a form that is more suitable for transplantation into another person;

"competent person" means a medical practitioner or any other person who by qualification or experience is competent to remove the specific tissue from a living or deceased person;

"donor" means a person who has donated tissue in terms of the Act;

"inspector" means an inspector contemplated in the Regulations Relating to Blood and Blood Products;

"**standards of practice**" means the standards of practice for tissue banks as determined by the Minister:

"**tissue *bank***" means an organization, institution or person registered in terms of regulations 3 of these regulations as a tissue bank;

"***tissue* typing**" means any steps, procedures, investigations or tests which are required to establish compatibility between the tissue of the donor and that of the recipient;

"***transplantation transmittable disease***" means a disease that can be transmitted by the transplantation of tissue or a tissue product donated by a person, into the body of another person; and

"***vascularised organ***" means any organ which is dependent on the establishment of a direct blood supply with the blood supply of a human recipient during the transplantation thereof into that recipient.

REGISTRATION

2. (1) An organization, institution or person, must not –

(a) acquire or import human tissue or tissue product from an living or deceased person;

(b) preserve, screen, test, process, store, separate, label, pack or supply or in any other manner dispose of human tissue so acquired or imported for use, whether in its original form or in any altered form; or

(c) produce, pack, seal and label any tissue product or supply or in any manner dispose of any tissue product;
for the purpose of transplanting such tissue or tissue product in
the body of a person unless —

(i) it or he or she is registered with the Department in terms of regulation 3(3)(a); and

(ii) it or he or she conducts any activity referred to in paragraphs (a), (b) or (c) above in accordance with the provisions of these regulations.

(2) The provisions of sub-regulation (1) are not applicable to an organisation, institution or person that -

(a) uses the tissue or tissue product for non-clinical scientific or educational purposes only;

(b) transport the tissue or tissue product in the usual course of business as a carrier; or

(c) does not carry out the activities referred to in sub- regulation (1)(a), (b) or (c) above but only receives or stores tissue solely for transplantation within the facility of such organisation, institution or person.

APPLICATION FOR REGISTRATION

3 (1) An organisation. institution or person requiring registration as a tissue bank must apply for such registration to the Director- General, indicating the nature of tissue or tissues for which registration is required.

(2) The Director-General may-

(a) direct the applicant concerned to furnish such further information in respect of his or her application as deemed necessary or expedient;

(b) may cause the applicant to be investigated; or

(c) may obtain such further information as he or she deems necessary for the consideration of the application.

(3) (a) The Director-General may, on application in terms of sub-regulation (1), register the applicant concerned as a tissue bank subject to such conditions as she or he may determine

(b) Where such applicant is not approved, the Director-General shall notify the applicant in writing accordingly, stating the reason for such non-registration.

SUSPENSION OR REVOCATION OF REGISTRATION

4. (1) If the Director-General on the strength of an inspection, report and recommendation by an Inspector is of the opinion that there are reasonable grounds to suspect that —

(a) any premises or equipment used by the tissue bank are hazardous to health; or
(b) the tissue bank is not complying with the Act, these regulations or standards of practice, she or he may, subject to the provisions of sub-regulation (2), serve a written notice on the tissue bank instructing it to furnish reasons, at a place and time specified in such notice, why the registration concerned must not be suspended or revoked.

(2) The Director-General may, notwithstanding the provisions of sub-regulation (1) immediately suspend the registration.

(3) A notice referred to in sub-regulation (1) shall set out such particulars as are reasonably adequate to inform the tissue bank why the suspension or revocation of the registration is contemplated, and shall be served by the Director-General not less than twenty-one (21) days prior to the date specified in such notice.

(4) If it still appears to the Director-General after considering the reasons furnished in terms of regulation 4(1) or where no reasons were furnished, that –

(a) the premises or equipment 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 tissue bank does not comply with the provisions of the Act, these regulations or standards of practice, she or he may revoke the registration of a tissue bank

(5) The suspension or revocation of a registration shall have the effect that, from the date of such suspension or revocation –

(a) tissue must not be acquired and supplied in its original or altered form or as any tissue product for the transplantation thereof in a living person;
(b) tissue must not be processed by the tissue hank into any tissue component or tissue product;
in or upon the premises of the tissue bank in terms of which such order has been issued.

ADDITIONAL POWERS AND DUTIES OFAN INSPECTOR OF ANATOMY OR INVESTIGATING OFFICER

5. (1) An Inspector may, in addition to exercising the powers referred to in the Regulations Regarding Blood and Blood Products, as far as tissue or any tissue product or any matter relating *thereto* is concerned —

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

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

(c) request information or registers from the management of the tissue bank and interview any employee of the tissue bank or related persons in connection with —

(i) any premises, equipment or methods used or being used by the tissue bank; or
(ii) any tissue or tissue product or any test reagent or substance referred to in these regulations or the standards of practice;

(d) place under embargo or seize any tissue or tissue product or documentation if in her or his opinion it may produce evidence of an offence in terms of the Act, these regulations or standards of practice

(2) An Inspector must report to the Director-General any untoward reaction, including transplantation transmittable disease, or death brought to her or his notice in terms of these regulations.

(3) An Inspector must exhibit the written authority by virtue of which she or he was authorised to any person affected by the exercise or performance of any power, duty or function under the Act when called upon to do so by that person

CHAPTER 2

DUTIES OF TISSUE BANK

6. (1) The tissue bank must keep or cause to be kept —

(a) a register of tissue donors in which must be entered at least the following particulars pertaining to each tissue donor :

(i) the surname, first name and initials of the other names;
(ii) the gender;
(iii) the date of birth or approximate age if the former is not available;
(iv) an identity number, where available;
(v) the residential address;
(vi) the nature and quantity of the tissue concerned;

(b) a record of tissue donations in which the following information in respect of each donation must be entered:

(i) a unique identifiable code which will be traceable to the tissue donor while protecting the donor's anonymity;
(ii) the date and place where the tissue was retrieved from the body of the relevant donor;
(iii) the name of the competent person who removed the tissue from the relevant donor;
(iv) the name and address of the organisation, institution or person from whom the tissue concerned was received;
(v) the date on which the tissue concerned was received; or person referred to in sub-paragraph (iv);
(vi) the results of tests for transplantation transmittable diseases;
(vii) the results of tissue typing if available;
(viii) whether any untoward reaction or death was reported following upon the transplantation of the tissue, the code referred to in sub-paragraph (I) and the serial number of the entry in respect of this reaction or death as recorded in the register of untoward reactions, including transplantation transmittable diseases, and deaths referred to in paragraph(d)
(ix) if the tissue was condemned or discarded —

(aa) the date on which it was condemned or discarded; and

(bb) the reason for which it was condemned or discarded;

(c) a record of statistics in respect of all donations of tissue, in which at least the following information in respect of all the tissue donations and the supply of such tissue by the tissue bank over each month must be entered:

(i) the number of tissue donors;
(ii) the nature and total number of tissues supplied;
(iii) the names and addresses of the organisations, institutions or persons to whom the tissue was supplied;
(iv) the nature and number of tissues which were condemned or discarded and the reason for which they were condemned or discarded;

(v) the nature and number of tissues which gave results indicative of microbial contamination;
(vi) the number of untoward reactions, including transplantation transmittable diseases, or deaths entered in the register referred to in paragraph (d);

(d) a register of untoward reactions, including cases of transplantation transmitted diseases, and deaths in which shall be entered every reported incident of an untoward reaction, including transplantation transmitted disease, or death apparently caused by the transplantation of tissue supplied by the tissue bank, and the serial number of the entry as well as the code referred to in sub-paragraph (b)(i).

(2) The tissue bank must -

(a) inform the Director-General of any change in its name, address, medical director or owner; and

(b) request the Director-General in writing to remove it's name from the register if it no longer intends to carry out the activities in terms of these regulations.

(3) (a) The tissue bank must submit a monthly report of all incidents referred to in paragraph (1)(d) to the Inspector for the area in which the tissue was supplied.

(b) The Inspector must submit annual reports on the reports received in terms of paragraph (1)(d) 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.

(4) Strict confidentiality must be observed by all employees of the tissue bank with regard to all information pertaining to tissue donors and recipients in whose treatment the tissue bank is involved.

CHAPTER 3

QUALITY MANAGEMENT

7. (1) (a) The tissue bank must have a policy on quality management of activities referred to in regulation 2(1)(a), (b) and (c).

(b) The policy referred to in paragraph (a) above must be communicated in writing to all ernployees of the tissue bank.

(2) The tissue bank must appoint a person who will be responsible for quality management.

RECRUITMENT OF DONORS

8. The tissue bank must establish criteria on standards of practice for acceptance or deferral of tissue donors.

MANDATORY TESTING AND DISPOSITION OF TISSUE AND TISSUE PRODUCTS

9. (1) The tissue bank must ensure that tissue and tissue products cannot be released for transplantation until the laboratory tests referred to in sub-regulation (2) have been completed, documented and approved.

(2) The tissue bank must ensure that the results of the following tests on each tissue donation are available:

(a) Tests according to latest scientific information for infectious agents which may cause transfusion transmitted diseases:

(i) Syphilis;
(ii) Hepatitis B;

(iii) Hepatitis C;
(iv) Human Immunodeficiency Virus type 1 and 2;

(b) Tests for tissue typing.

(3) No tissue or tissue product giving a positive or reactive result for any of the tests in paragraph (2)(a) must be made available for transplantation.

(4) Tissue and tissue products must only be released *for* recipient use when all required tests have been satisfactorily completed and all records of the tissue or tissue products reviewed for conformance to specified requirements according to the standards of practice.

(5) (a) The tissue bank must implement procedures to identify receipts of tissue and tissue products from donors who at subsequent donations are found to have infection with the Human Immunodeficiency Virus. Hepatitis B virus or Hepatitis C virus.

(b) Recipients of tissue and tissue products referred to in paragraph (a) above must be informed of the risk of infection as early as reasonably possible.

CHAPTER 4

APPEALS

10. (1) A tissue bank or an organisation, institution or person who applied for registration may appeal in writing to the Minister against any decision made by the Director- General in terms of any provision of these regulations in respect of such tissue bank or organisation, institution or person, as the case may be.

(2) An appeal in terms of sub-regulation (1) must be lodged within fourteen (14) days of the receipt of a notice of such decision by the tissue bank or organisation, institution or person, as the case may be, and must clearly state -

(a) against which decision such appeal is lodged; and

(b) the grounds on which such appeal is lodged.

(3) Any appeal in terms of these regulations shall be lodged with the

Director-General, who shall submit it to the Minister together with his or her reasons for the decision against which the appeal is being lodged.

(4) The Minister may confirm, amend or revoke a decision taken by the Director-General in terms of the provisions of these regulations and inform the tissue bank or organisation, institution or person, as the case may be, in writing of his or her decision.

DELEGATIONS

11. (a) The Director-General may subject to such conditions she or he may determine, in writing delegate, whether general, in a particular case or in cases of a particular nature, to any officer in the Department any power conferred upon her or him by or under these regulations.

(b) The Director-General shall not be divested of a power delegated by her or him under paragraph (a) above, and may alter or set aside any decision by an officer taken in the exercise of a power so delegated.

GENERAL PROVISIONS

12. (1) A tissue bank must appoint a medical practitioner as medical director to be in charge of and take full responsibility for the medical and related activities of the tissue bank.

(2) The medical practitioner referred to in subregulation (1) shall have experience in the science of human tissue transplantation and related matters.

13. Any person who contravenes or fails to comply with the provisions of these regulations and standards of practice, commits an offence and shall on conviction be guilty of the offence and liable to a fine not exceeding R40 000.00 and/or imprisonment for a period not exceeding two years.

DR A MOTSOALEDI

MINISTER OF HEALTH