NATIONAL HEALTH ACT

Act 61 of 2003.

REGULATIONS RELATING TO TISSUE BANKS

[Updated to 2 March 2012]

GoN R182, G. 35099 (c.i.o 2 March 2012).

The Minister of Health has, in terms of section 68 of the Health Act, 2003 (Act 61 of 2003), made regulations in the Schedule.

SCHEDULE

ARRANGEMENT OF REGULATIONS

1. Definitions

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—

“Act” means the National Health Act, 2003 (Act 61 of 2003);

“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;

“audit” means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and / or vendors to evaluate adherence to the written SOPM, Regulations, or laws as well as Department of Health’s regulations;

“competent person” means a medical practitioner and registered as such in terms of the Health Professions Act, 1974 (Act 56 of 1974);

“dispensing service” means a facility responsible for the receipt, maintenance and delivery to the ultimate user (e.g. transplanting surgeon, surgical center or research facility) of cells and / or tissue for transplantation or research;

“distribution” means a process that includes receipt of a request for cells and / or tissue, selection and inspection of appropriate cells and / or tissue, and inspection, and subsequent shipment and delivery of cells and / or tissue to another tissue bank, tissue distribution intermediary, or tissue dispensing service;

“disposition” means the final destination of cells and / or tissue, including use for transplantation, research or discard;

“donor” means a person from who tissue, blood, blood products or stem cells is donated in terms of this regulation;

“donor suitability assessment” means the evaluation of all available information about a potential donor to determine whether the donor meets qualifications specified in the SOPM and Regulations. This includes, but is not limited to: medical, social histories; laboratory test results; physical assessment or physical examination, and autopsy findings (if performed);

“end-user” means a health care practitioner who performs transplantation procedures;

“next of kin” means the person(s) most closely related to a deceased individual as designated by the applicable laws;

“package insert” means the written material accompanying cells and / or tissue allograft or autograft bearing further information about the cells and / or tissue, directions for use, and any applicable warnings;

“procedure” means a series of steps, which when followed, is designed to result in a specific outcome;

“preservation” means the use of chemical agents, alterations in environment conditions or other means during processing to prevent or retard biological or physical deterioration of tissue or blood products or stem cells;

“processing” means all procedures involved in the preparation, manipulation, preservation and packaging of tissues, blood products or stem cells intended for human applications;

“quality” means the conformance of cells and / or tissue or a process with pre-established specifications or Regulations;

“quality assurance (QA) program” means a program that defines the policies and environment that are required to meet standards of quality and safety and that provides confidence that the processes and cells and / or tissue consistently conform to requirements for quality. Dimensions of QA may include quality control, auditing and process control, standards for personnel, facilities, procedures, equipment, testing, and record keeping activities;

“quality control (QC)” means specific tests defined by the QA Program to be performed to monitor retrieval, processing, preservation and storage, cells and / or tissue quality, and test accuracy. These may include but are not limited to, performance evaluations, inspection, testing, and controls used to determine the accuracy and reliability of the tissue bank’s equipment and operational procedures, as well as the monitoring of supplies, reagents, equipment, and facilities;

“quarantine” means to isolate retrieved tissue, or blood products or stem cells physically or by other means whilst awaiting a decision on their acceptance or rejection;

“recall” means an action taken by a tissue bank to locate and retrieve cells and / or tissue from distribution and dispensary inventories;

“recipient” means an individual into whom cells and / or tissue is transplanted;

“relevant medical records” means a collection of documents including a current donor risk assessment interview, a physical assessment / physical examination of the donor, laboratory test results, relevant donor records, existing autopsy reports, as well as information obtained from any source or records which may pertain to donor suitability regarding high risk behaviours, and clinical signs and symptoms for any relevant communicable disease agent or disease, and / or treatments related to medical conditions suggestive of such risk;

“responsible person” means a person who is authorised to be a medical director of a tissue bank;

“retrieval” means the removal, acquisition, recovery, harvesting, or collection of donor cells and / or tissue;

“serious adverse event” means any adverse experience occurring at any dose or procedure that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalisation or prolongation of existing hospitalisation, a persistent or significant disability or incapacity, or congenital anomaly / birth defect or required intervention to one of the outcomes listed in the definition;

“standard operating procedure manual (SOPM)” means a group of standard operating procedures (SOPs) detailing the specific policies of a tissue bank and the procedures used by the staff / personnel. This includes, but is not limited to, procedures to: assess donor suitability, retrieval, processing, quarantine, release to inventory, labeling, storage, distribution, and recalling cells and / or tissue;

“sterility” means the absence of detectable, viable micro-organism;

“storage” means maintaining the product, e.g. stem cells under appropriate controlled conditions for future use or until distributed;

“tissue” means a functional group of cells. The term is used collectively in Regulations to indicate both cells and tissue;

“tissue bank” means an organisation, institution or person that provides or engages in one or more services involving cells and / or tissue from living or deceased individuals for transplantation purposes and is registered in terms of regulation 3 of these Regulations;

“tissue dispensing service” means any entity that receives, stores, and provides cells and / or tissue directly to an end-user for immediate transplantation. Tissue dispensing services may or may not be tissue banks, depending on what other functions they perform;

“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;

“traceability” means the ability to locate cells and / or tissue during any step of its donation, collection, processing, testing, storage, distribution or disposition. It implies the capacity to identify the medical facility receiving the cells and / or tissue and, at the medical facility, the ability to identify the recipient;

“transplantation” means the transfer of allograft cells and / or tissue to a recipient. This includes musculoskeletal, skin, cardiovascular, and foetal cells and / or tissue;

“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, including a genetic disease;

“validation” means the process of establishing documented evidence that provides a high degree of assurance that specific process will consistently produce the predetermined outcome;

“verification” means the conformation by examination and provision of objective evidence that specified requirements have been fulfilled.

1. Use of human tissue

(1) No person, shall—

(a) remove, acquire or import human tissues from any living or deceased person;

(b) preserve, screen, test, process, store, separate, produce, label, pack, supply or distribute or export or in any other manner dispose of human tissues whether in its original form or in any altered form;

(c) release any human tissue products for transplantation in the body of a person; or

(d) use human tissues or its products for therapeutic, research or educational purpose unless he or she—

(i) is authorised with the Department in terms of regulation 3(3)(c);

(ii) conduct any activity referred to in paragraph (a), (b), (c) or (d), as the case may be, in accordance with the provisions of these Regulations;

(iii) laboratory tests for infectious agents which may cause transplantation transmitted diseases, have, been completed and the results of each donation are available;

(2) The provisions of subregulation (1) are not applicable to a tissue bank that—

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

(b) transport human tissue, blood or blood products in the usual course of business as a carrier; or

(c) does not carry out the activities to in subregulation (1)(a), (b), (c) or (d) above but only receive or store tissue solely for transplantation within the facility of such tissue bank.

[**Editor Note:** Numbering as per original *Gazette*.]

3. Application for authorisation

(1) An application for authorisation of a tissue bank shall be made to the Director General, indicating the nature of tissue for which authorisation is required;

(2) The application referred to in subregulation (1) shall contain the following information—

(a) the name and nature of the applicant;

(b) location of the premises where business is to be conducted;

(c) an indication of how records and data shall be kept;

(d) the quality management system to be used;

(e) details of the responsible person;

(f) any other information the Director-General may consider necessary for the consideration of the application;

(3) The Director-General may, on application in terms of subregulation (1)—

(a) cause the applicant to be investigated; or

(b) obtain such further information as he or she deems necessary for the consideration of the application;

(c) authorise, the applicant concerned as a human tissue bank or organisation, subject to such conditions as he or she may determine; and

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

4. Suspension or withdrawal of authorisation

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

(a) any premises or equipment used by an authorised tissue bank, organisation or person are in any way hazardous to health;

(b) the authorised tissue bank, organisation or person is not complying with the Act or these Regulations; or

(c) the rights of the donor or recipient are violated; and

(d) The authorised tissue bank, organisation or person, after being afforded an opportunity by the health officer to rectify the situation referred to in paragraphs (a), (b) or (c), failed to rectify such situation,

the Director-General may, suspend or withdraw the authorisation.

(2) The Director General, before suspending or withdrawing an authorisation as contemplated in subregulation (1), shall afford the authorised tissue bank, organisation or person an opportunity to show cause why the authorisation should not be suspended or withdrawn.

(3) The suspension or withdrawal of authorisation in terms of this regulation shall have the effect that, from the date of such suspension or revocation, the authorised tissue bank or organisation shall cease to carry out any activities referred to in subregulation 2(a), (b), (c) and (d).

5. Organisational structure of tissue banks

(1) The purpose of the tissue bank shall be clearly formulated and documented. The tissue bank shall state whether it is a freestanding entity or part of an institution;

(2) All activities of an authorisation tissue bank relating to cell and / or tissue procurement, processing and distribution shall comply with the Guiding Principles of the W.H.O. as contained in the Declaration of Istanbul on Organ trafficking and Transplant Tourism of 2009;

(3) The tissue bank shall have designated person(s) responsible in whom policy-making authority resides, unless otherwise provided by the institution of which it is a part;

(4) The tissue bank shall have an appointed registered medical practitioner who has experience in the science of human tissue transplantation to fulfill the duties of a Medical Director to advise and oversee the authorisation's medical activities;

(5) A tissue bank shall establish and maintain a mechanism to access medical, technical, and scientific advice as needed;

(6) The responsible person shall—

(a) implement policies of the governing body;

(b) shall be responsible for all operations, including compliance with the Act and requirements of these Regulations;

(c) provide information to the Director-General as required in terms of these Regulations;

(7) Only a competent person will be directly involved in activities referred to in regulation 2(1)(a), (b) and (c) in the tissue bank or institution;

(8) An authorised tissue bank, organisation or person may only receive payment for activities as indicated in section 60 of the Act.

6. Duties and reporting obligations

(1) Each tissue bank shall develop a donor record management system that will keep—

(a) register of tissue donors, in which shall be entered at least the following particulars pertaining to each tissue donor from whose body the authorised tissue bank, organisation or person has obtained the tissue—

(i) the name, surname and gender of the donor;

(ii) the ID number, where available;

(iii) the identity and relationship of the consenting person, including name address and telephone number;

(iv) a description and number of the types of cells and / or tissue retrieved;

(v) to have access to the donor's medical records;

(vi) a statement that tissue samples from the donor will be tested for certain transmissible diseases;

(vii) a description of the general purposes for which retrieved cells and / or tissue may be used, including a statement that such uses may include transplantation, research and medical education;

(viii) the date and place where the tissue was retrieved from the body of the relevant donor; and

(ix) the name of the competent person who removed the tissue from the relevant donor;

(b) document the tissue banking process(es) for which the bank is responsible and must be made concurrent with each significant step and must include, but not limited to—

(i) informed written consent;

(ii) donor suitability assessment and donor identification;

(iii) detailed cell and / or tissue retrieval, transport, and processing records;

(iv) quarantine and infectious disease testing;

(v) tissue typing, where applicable;

(vi) in-process testing;

(vii) record review;

(viii) cell and / or tissue labeling, storage, release, and distribution;

(x) quality control;

[**Editor Note:** Numbering as per original *Gazette*.]

(c) a record of statistics in respect of tissue donations, in which shall be entered at least the following information in respect of all the tissue donations and the supply of tissues by the authorised tissue bank or organisation over each month—

(i) the number of tissue donors;

(ii) the type 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 number of tissue donations which were condemned or discarded and the reason for which they were condemned or discarded;

(iv) the nature and number of tissue donation which gave results;

(v) indicative of microbial contamination and / or infectious disease; and

(vi) the number of serious adverse events referred to in subregulation (d);

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(d) a system in place to receive, investigate, register and transmit information on a monthly basis, to the Director-General about serious adverse events which may have been influenced by the quality and safety of tissues and which may be attributed to the procurement, testing, processing, storage and distribution of tissues;

(e) an accurate, rapid and verifiable procedure is in place which will enable recall from distribution any product(s) which may be related to a serious adverse event;

(f) Distribution records shall be maintained by the tissue bank that distributes cells and / or tissue (including unfinished or as yet unreleased cells and / or tissue) to other entities;

(g) records shall be readily accessible for inspection by the health officer.

(2) The authorised tissue bank must—

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

(b) and inform Director-General in writing within 30 days if it no longer intends to carry out the activities referred to in regulation (2)(1)(a) and (b).

(3) The health officer shall submit a monthly report on the reports received in terms of subregulations (2)(b) to the Director-General.

(4) Any payment made according to section 60(1)(a) and (b) of the Act must be recorded-the amount paid, to whom payment was made, reason for payments and who made payment, according to Section 60(4)(a) of the Act.

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

(6) The Director-General shall establish and maintain an accessible database of authorised tissue banks, specifying the activities for which they have been authorised.

7. Additional duties of the health officer

(1) A health officer may, as far as tissues or any matter relating thereto is concerned—

(a) take samples, or direct that such samples be forwarded or delivered to whom so ever or 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 or seal any container with tissue or any device, test reagent or substance;

(c) request information or registers from the management of the authorised tissue bank and interview any member of the staff of the authorised tissue bank, organisation or related persons in connection with—

(i) any premises, equipment or methods used or being used by the authorised tissue bank, organisation or person;

(ii) any tissue or tissue product or any test reagent or substance referred to in these Regulations; or

(iii) any applicable standards operating procedures;

(d) place under embargo or seize any tissue or tissue product; or

(e) document, if in her or his opinion it may produce evidence of an offence in terms of the Act and regulations.

(2) A health officer shall 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.

8. Inspection and Control Measures

A tissue Bank shall be inspected at least every year to ensure that it complies with these Regulations and any other relevant requirements.

9. Quality Management

(1) An authorised tissue bank shall take necessary measures to ensure that—

(a) a policy on quality management and safety system of activities referred to in regulation 2(1)(a), (b), (c) and (d), based on the principle of best laboratory and manufacturing practice is put in place;

(b) the policy referred to in (a) must be communicated in writing to all employees of the tissue bank;

(c) a person is appointed who will be responsible for quality management;

(d) the quality assurance and safety system referred to in paragraph (a) includes at least the following documentation—

(i) standard operating procedures (SOP) and forms;

(ii) reports of process validation and equipment qualification;

(iii) training and reference manuals;

(iv) donor records;

(v) information on the final destination of tissues; and

(vi) audit records;

(e) the documentation referred to in paragraph (d) is available for inspection by the health officer.

10. Quarantine

All tissue shall be kept in quarantine until such times as the requirements relating to donor information, selection criteria and test results as stipulated in the standard operating procedure have been met.

11. Processing

An authorised tissue bank or organisation shall include in their standard operating procedures—

(1)

(a) all processes that affect quality, safety and controlled conditions;

(b) special provision for the handling of tissue to be discarded, in order to prevent the contamination of other tissue, processing environment or personnel;

(2) Any modification to the process used in the preparation of tissue shall also meet the criteria laid down in its standard operating procedure; and

(3) The authorised tissue bank or organisation shall ensure that the equipment used, the working environment process design, validation and control conditions are in accordance with its standard operating procedures.

12. Storage conditions

An authorised tissue bank shall—

(1) ensure that all procedures associated with the storage of tissue are documented in standard operating procedures;

(2) have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored tissue shall be transferred to other authorised tissue banks accredited and authorised; and

(3) ensure that all tissue samples which are not utilised in its facility for transplantation, therapeutic or research purposes shall be destroyed in accordance with the relevant standard operating procedures.

13. Labeling, documentation and packaging

An authorised tissue bank shall ensure that—

(1) labeling, documentation and packaging conform to the standard operating procedures;

(2) all labeling claims shall be clear, accurate, substantiated, and not misleading;

(3) the following information shall be included on container label unless space limitations require use of a corresponding insert—

(i) descriptive name of the cells and / or tissue;

(ii) unique identification code for traceability purposes;

(iii) name(s) and address(es) of tissue bank(s) responsible for determining donor suitability, processing and distribution;

(iv) expiration date (if applicable);

(v) acceptable storage conditions;

(vi) disinfection or sterilisation procedure utilised (if applicable);

(vii) preservative and / or method of Preservation (if applicable);

(viii) quantity of cells and / or tissue expressed as volume, weight, dimensions, if applicable;

(ix) potential residues of processing agents / solutions (e.g., antibiotics, ethanol, ethylene oxide, dimethyl sulfoxide); and

(x) status of sterility.

14. Traceability

Tissue banks must ensure that—

(a) all its activities referred to in regulations 2(1)(a), (b) and (c) can be traced from donor to recipient and vice versa;

(b) it has a unique donor identification system which assigns a code to each donation and to each product associated with it; and

(d) data necessary to ensure traceability at all stages is kept for a minimum of 30 years after donation or clinical use and such data may be in electronic form.

[**Editor Note:** Numbering as per original *Gazette*.]

15. Data protection and confidentiality

(a) An authorised tissue bank or organisations shall ensure that all data, including genetic information, collated within the scope of this regulation remain confidential at all times;

(b) For the purpose of subregulation (a), an authorised tissue bank, or organisation shall ensure that—

(i) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records and transfer of information;

(iii) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations; and

(iv) anonymity and privacy of donors are protected.

[**Editor Note:** Numbering as per original *Gazette*.]

16. Distribution and dispensing

(1) An authorised tissue bank or organisation shall ensure the quality of cells / or tissues during distribution is not compromised. This includes cold chain maintenance.

(2) Provision of cells and / or tissue for transplantation shall be restricted to hospitals, free-standing medical facilities, tissue banks, Tissue Dispensing Services, and End-Users (e.g., physicians, dentists, or other medical professionals).

(4) The import and export of tissue samples shall be according to the Act.

(5) A tissue bank shall establish a policy authorising or prohibiting the return of cells and / or tissue in its original, unopened container.

17. Research

(1) All activities at tissue banks which involve the research and development of tissue samples shall be in accordance with—

(a) chapter 9 of the Act;

(b) be approved by the relevant ethics committee that guides the activities of the tissue bank; and

(c) take place under the supervision of a scientist registered as such in terms of the Health Professions Act, 1974 (Act 56 of 1974).

(2) All research results shall be recorded and documented in accordance with the Act.

18. Third parties

An authorised tissue bank shall—

(1) evaluate and select third parties on the basis of their ability to meet the required standards laid down in these Regulations.

(2) shall establish a written agreement with the third party when an external activity takes place which influences the quality and safety of tissue, and in particular in the following circumstances—

(a) where an authorised tissue bank, organisation or person entrusts one of the activities in 2(1)(a) and (b) to a third party;

(b) where a third party provides goods and services that affect tissue quality and safety assurance, including their distribution;

(c) where an authorised tissue bank or organisation distributes tissues retrieved by third party.

(3) not provide services to a third party which is not accredited.

(4) provide copies of agreements with the third party on request to the health officer.

19. Appeals

(1) A tissue bank or an organisation, institution or person who applied for authorisation 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 subregulation (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 decisions such decisions such an appeal is lodged; and

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

(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; and

(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.

20. Delegations

(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; and

(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.

21. Offences and penalties

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 not exceeding R40 000 and / or imprisonment for a period not exceeding two years.

(Signed)

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 1/3/2012