IMPORTANT NOTICE

The Government Printing Works will not be held responsible for faxed documents not received due to errors on the fax machine or faxes received which are unclear or incomplete. Please be advised that an “OK” slip, received from a fax machine, will not be accepted as proof that documents were received by the GPW for printing. If documents are faxed to the GPW it will be the sender’s responsibility to phone and confirm that the documents were received in good order.
Furthermore the Government Printing Works will also not be held responsible for cancellations and amendments which have not been done on original documents received from clients.

CONTENTS • INHOUD

<table>
<thead>
<tr>
<th>No.</th>
<th>Page</th>
<th>Gazette No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GOVERNMENT NOTICES

Health, Department of

Government Notices

R. 175 National Health Act (61/2003): Regulations: Artificial fertilisation of persons ........................................... 3 35099
R. 176 do.: do.: Rendering of clinical forensic medicine services ............................................................... 22 35099
R. 177 do.: do.: Use of human biological material ........................................................................... 31 35099
R. 178 do.: do.: Registration of microbiological laboratories and the acquisition, importation, handling, maintenance and supply of human pathogens ........................................................... 39 35099
R. 179 do.: do.: Blood and blood products ............................................................................................... 62 35099
R. 180 do.: do.: General control of human bodies, tissue, blood, blood products and gametes ........................................ 75 35099
R. 181 do.: do.: Import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes and gametes .................................................................................. 97 35099
R. 182 do.: do.: Tissue banks .................................................................................................................... 125 35099
R. 183 do.: do.: Stem cell banks .................................................................................................................. 142 35099
REGULATIONS RELATING TO ARTIFICIAL FERTILISATION OF PERSONS

The Minister of Health has, in terms of section 68 of the National Health Act 2003 (Act No. 61 of 2003), made the regulations in the Schedule.

SCHEDULE

Definitions

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).

"artificial fertilisation" means the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction and includes artificial insemination, in vitro fertilisation, gamete intrafallopian tube transfer, embryo intrafallopian transfer or intracytoplasmic sperm injection;

"artificial insemination" means the placing of male gametes (sperm) into the female reproductive tract by means other than copulation;
"blastocyst" means a pre-implantation embryo consisting of an outer layer, which forms the placenta and a 30 to 200-cell inner cell mass, which develops into the foetus;

"cell" means the basic structural and functional unit in people and all living things and is a small container of chemical and water wrapped in a membrane;

"central data bank" means an electronic bank into which all information regarding artificial fertilisation treatment outcome is stored and managed;

"competent person" in relation to artificial fertilisation means a person registered as such in terms of the Health Professions Act, 1974 (Act No. 56 of 1974); who is -
(a) a medical practitioner specialising in gynaecology with training in reproductive medicine;
(b) a medical scientist, medical technologist, clinical technologist, with training in reproductive biology and related laboratory procedures;

"deceased" means somatic death where there is cessation of circulation and respiration, including loss of corneal reflexes, the eyeballs become flaccid, and the pupils are fixed and dilated;

"embryo transfer" means the placing of the embryo into the uterus or fallopian tube of the recipient;

"freezing or cryopreservation" means freezing or cryopreserving genetic material including ova, sperm, embryos, ovarian tissue or stem cells by an authorised institution;

"gamete donor" means a living person from whose body a gamete or gametes are removed or withdrawn, for the purpose of artificial fertilisation;
"genetic carrier" means an individual who has a disease-causing mutation but will not develop the condition and the individual would have one normally functioning and one faulty gene (i.e. a heterozygote);

"intracytoplasmic sperm injection" is the process of microscopic technology to bring about fertilisation of an ovum with a male sperm outside the body in an authorised institution;

"in vitro fertilisation" is the process of spontaneous fertilisation of an ovum with a male sperm outside the body in an authorised institution;

"oocyte" means the female gamete;

"recipient" means a female person in whose reproductive organs a male gamete or gametes are to be introduced by other than natural means; or in whose uterus/womb or fallopian tubes a zygote or embryo is to be placed for the purpose of human reproduction;

"register" means a register contemplated in regulation 14(1);

"sperm" means the male gamete;

"surrogate" is a voluntary recipient of an embryo who will carry such embryo to birth for contractual parents;

"serious genetic condition" means a genetic condition, which compromises functional physical or mental ability and may sometimes be lethal;

"stimulation" means any process, method or procedure used to facilitate the withdrawal or removal of a gamete or gametes;
Application of the Regulations

2. These regulations only apply to the withdrawal of gametes from and for use in living persons.

Removal or withdrawal and storage of gametes

3. (1) No person, except a competent person, may remove or withdraw a gamete or cause a gamete to be removed or withdrawn, from the body of a gamete donor for the purpose of artificial fertilisation.

(2) Once gametes are removed in terms of sub-regulation (1), they shall be stored in a frozen state or cryopreserved.

Compensation in respect of the withdrawal or removal of gametes

4. A person from whose body a gamete has been removed or withdrawn may be reimbursed for any reasonable expenses incurred by him or her in order to donate a gamete as contemplated in section 60(4)(a) of the Act.

Establishment of a Central Data Bank

5. The Director-General shall establish an electronic central data bank into which all information regarding gamete and embryo donations is stored.

Restriction on donation of gametes

6. A competent person –

(a) shall not remove or withdraw a gamete, or cause a gamete to be removed or withdrawn, from the body of a gamete donor if the
competent person has information or suspects that a maximum of six children have been conceived through the artificial fertilisation using the gametes of that gamete donor;

(b) shall, where the gamete donor has conceived six children as contemplated in paragraph (a), inform that gamete donor that she may not make any further donation of gametes; and

(c) must immediately relay all the information relating to such gamete donor, the removal or withdrawal of a gamete and the artificial fertilisation, to the central data bank contemplated in regulation 5.

**Prerequisites for removal or withdrawal of gametes**

7. A competent person who intends to remove or withdraw a gamete, or cause a gamete to be removed or withdrawn from the body of a gamete donor, shall, before such removal or withdrawal –

(a) ensure that if a gamete donor file has not previously been opened in respect of that gamete donor, open such a file, to which a unique identification number shall be allocated in respect of the gamete donor;

(b) ensure that the information obtained in paragraph (a) is submitted to the central data bank;

(c) in the case of a known donor, ascertain from the central data bank that not more than six children have been conceived through the artificial fertilisation of a person with the gametes of that gamete donor;

(d) obtain a signed statement from the gamete donor stating whether the gamete donor has previously made a donation of gametes and, if so, where and when that donation of gametes took place;

(e) obtain informed consent from the gamete donor relating to –
   (i) physical examination and questioning by a competent person;
   (ii) the removal or withdrawal a gamete for testing, analysing or other processing as the competent person may deem necessary;
(iii) particulars contemplated in regulation 8(1)(a)(ii), (iii) and (iv), (b), (c) and (f) being made available to the recipient and the competent person who is to perform the artificial fertilisation;

(iv) to particulars contemplated in regulation 8(2)(c) being made available to the Director-General; and

(v) to particulars contemplated in regulation 8(2)(c) being submitted to the central data bank;

(f) ascertain the age of the gamete donor;

(g) ascertain that the gamete donor has on two occasions, not more than three months apart and one month prior to that donation of gametes, undergone —
   (i) medical tests for sexually transmissible diseases; and
   (ii) a semen analysis, in the case of a male gamete donor;

(h) ascertain that in the case of a female gamete donor, the donor has undergone a gynaecological examination prior to stimulation for the withdrawal of gametes;

(i) question such gamete donor concerning her or his family history, especially with regard to any possible genetic condition or carrier status and mental illness in respect of any child, brother, sister, parent or grandparent of such gamete donor; and

(j) shall, in the event of a request in respect of which the donor and recipient are known to each other, ensure that there is—
   (i) written confirmation by both parties that they known each other;
   (ii) psychological evaluation of both parties.

Gamete donor files, availability of information and destroying of gametes

8. (1) The competent person must immediately record the following information and documents in the gamete donor’s file before a gamete is removed or withdrawn—

(a) the gamete donor’s —
   (i) full name, surname, date of birth and identity number;
(ii) age, height, mass, eye colour, hair colour, complexion, population group, nationality, sex, religion, occupation, highest educational qualification and fields of interest;

(iii) family history referred to in regulation 7(i); and

(iv) subject to regulation 6(a), wishes in respect of the number of artificial fertilisations for which her or his gametes may be used;

(b) the particulars of medical tests for genetically transmissible disorders or for infectious diseases, or genetic evaluation of the gamete donor;

(c) particulars of any evaluation of the psychological suitability of the gamete donor to donate a gamete;

(d) particulars of each donation of gametes made by the gamete donor, including the date on which the donation of gametes was made;

(e) the informed consent and documents contemplated in regulation 7(e);

(f) results of the tests and the analysis or examination contemplated in regulation 7(e) to (g); and

(g) any other relevant document or information that the competent person may request.

(2) The competent person—

(a) shall retain the gamete donor file in safe-keeping and shall not destroy the file, except with the written permission of the Director-General;

(b) shall make the particulars set out in sub-regulation (1)(a)(ii), (iii) and (iv), (b), (c) and (f), together with the identification number referred to in regulation 7(a), available to the recipient and the competent person who is to effect the artificial fertilisation of the recipient;

(c) shall furnish the central data bank before 31 January of each year with the following particulars regarding the preceding year in respect of the gamete donor:

(i) the identification number of the gamete donor file;
(ii) the number of donations of gametes, with the dates on which the donations were made; and

(iii) the number of children conceived through the artificial fertilisation of a person that have been born alive from the gametes of the gamete donor;

(d) shall not make the gamete donor file, or information there from, available to any person other than a person acting under her or his supervision, except in terms of legislation or a court order;

(e) shall immediately, after, if it has come to her or his attention that a maximum of six children conceived through the artificial fertilisation have been born alive from the gametes of a specific gamete donor –

(i) make a conspicuous note to that effect in the gamete donor file;

(ii) make available this information to the Central Data Bank;

(iii) destroy all gametes donated by such gamete donor and any gametes that the competent person has in storage, unless the Minister consents to the competent person keeping those gametes; and

(iv) inform the donor of the actions taken as in terms of subparagraph (iii).

(f) who wants to keep the gametes referred to in paragraph (e)(iii) –

(i) shall forthwith address a substantiated request including the informed consent document from the gamete donor to the Minister for her or his consent to keep the gametes; and

(ii) may refrain from destroying the gametes until the Minister notifies the competent person of her or his decision.
Place where and person who effects artificial fertilisation and embryo transfer

9. (1) Artificial fertilisation or embryo transfer must only be effected at an authorised institution; and

(2) Only a competent person may effect artificial fertilisation.

Control over artificial fertilisation, embryo transfer, storage and destroying of zygotes and embryos

10. (1) No gamete –

(a) that has not been imported, removed or withdrawn in terms of the provisions of the Act or these regulations;

(b) from a gamete donor of whom the results of the tests, analysis or examination referred to in regulation 7(e) to (g), as the case may be, are not available yet; or

(c) from the gamete donor younger than 18 years of age except in the case of a medical indication, may be used for artificial fertilisation.

(2) (a) A competent person shall not effect in vitro fertilisation except for embryo transfer, to a specific recipient and then only by the union of gametes removed or withdrawn from the bodies of –

(i) such recipient and an individual male gamete donor; or

(ii) an individual male and an individual female gamete donor;

(b) an embryo, referred to in paragraph (a) shall be stored in a frozen/cryopreserved state in a prescribed institution;

(c) a competent person shall destroy an embryo, which she or he has in storage as soon as the recipient for whom that embryo has been effected conceives or as soon as it is
decided not to go ahead with the embryo transfer into that recipient, unless –

(i) the competent person decides, and with the informed consent of the recipient, to store such embryo for a further period for the purpose of a subsequent embryo transfer to that recipient; or

(ii) the recipient consents in writing that the competent person –
     (aa) may, with the informed consent of such recipient, use such embryo for transfer to another specific recipient; or
     (bb) may, with the informed consent of such recipient; use the embryo for a purpose, other than embryo transfer, which purpose shall be stated in that consent,

(d) a competent person shall destroy an embryo that has been unclaimed by the recipient for a period of 10 years.

Requirements for artificial fertilisation and embryo transfer

11. A competent person intending to effect the artificial fertilisation or embryo transfer to a recipient shall, before effecting the artificial fertilisation or embryo transfer –

(a) ensure that if a recipient file has not previously been opened in respect of that recipient, open such a recipient file, to which a unique identification number shall be allocated in respect of the recipient;

(b) obtain informed consent from the recipient relating to –
     (i) physical examination and questioning by a competent person;
     (ii) the removal or withdrawal of a gamete from the body of the donor for the purpose of such testing, analysing or other
processing of that gamete, as the competent person may
deem necessary;

(iii) artificial fertilisation of, or embryo transfer to herself;

(iv) particulars contemplated in regulation 13(2)(c) being made
available to the central data bank;

(c) ensure that –

(i) the gamete donor's particulars and wishes referred to in
regulation 8(1)(a)(i) to (iv) are conformed with;

(ii) the recipient's particulars and wishes referred to in regulation
13(1)(a)(i) to (iii) are conformed with;

(iii) if the recipient or the gamete donor should be a carrier of a
serious genetic condition –

(aa) the recipient and the gamete donor are tested to
determine whether they are such genetic carriers; and

(bb) if it is determined that both the recipient and the gamete
donor are such carriers or the gamete donor is such a
carrier, a gamete from that gamete donor is not used
for the artificial fertilisation of or the embryo transfer to
the recipient;

(iv) if, on account of the family history of the recipient or the
gamete donor, the possibility exists that one of them is a
carrier, or both of them are carriers of a genetically
transmissible disorder, the recipient or gamete donor, as the
case may be, is examined or tested to determine whether
she or he is such a carrier, and –

(aa) if it is determined that the recipient is such a carrier, the
recipient is informed about the implications thereof; or

(bb) if it is determined that the gamete donor is, or may
probably be, such a carrier –

(aaa) a gamete from that gamete donor is not used for
artificial fertilisation of; or

(bbb) the competent person who has removed or
withdrawn a gamete, or caused a gamete to be
removed or withdrawn, from the body of that
gamete donor is informed that the gamete donor is, or probably may be, such a carrier.

12. No more than three zygotes or embryos may be transferred to the recipient during an embryo transfer procedure, unless there is a specific medical indication to the contrary.

*Pre-implantation and prenatal testing for sex selection*

13. Pre-implantation and prenatal testing for selecting the sex of a child is prohibited except in the case of a serious sex linked or sex limited genetic conditions.

*Recipient files and availability of information*

14. (1) A competent person who effects the artificial fertilisation of or embryo transfer to a recipient shall immediately record or file the following particulars and documents in a recipient file referred to in regulation 11(a):

(a) the recipient's –

(i) full name, surname, date of birth and identity number;

(ii) family history, especially with regard to possible carrier status for genetic and or mental disorders;

(iii) wishes in respect of the population group of which the gamete donor, whose gametes are to be used for the artificial fertilisation, should be a member and the religion, which the gamete donor should profess, as well as any other wish of the recipient concerning the gamete donor;

(b) particulars of medical tests done for sexually transmissible infections, or communicable diseases in respect of the recipient;

(c) particulars of genetic evaluation made in respect of the recipient;
(d) particulars of an evaluation if indicated, made of the psychological or social suitability of the recipient with a view to her artificial fertilisation;

(e) the informed consent contemplated in regulation 11(b);

(f) any other relevant document or information that the competent person may obtain, including a document or information regarding a previous artificial fertilisation of or embryo transfer to the recipient;

(g) in the case of in vitro fertilisation of or embryo transfer –

(i) the number of embryos effected for the embryo transfer to the recipient;

(ii) the number of embryos used for each embryo transfer procedure;

(iii) the number of embryos in storage;

(iv) the number of embryos used for purposes other than embryo transfer; and

(v) the number of embryos destroyed.

(2) The competent person referred to in sub-regulation (1) shall –

(a) retain the recipient file in safe-keeping and shall not destroy the file, except with the written permission of the Director-General;

(b) not make the recipient file, or information there from, available to any person other than a person acting under her or his supervision, except where a law provides otherwise or a court so orders;

(c) make available to the central data bank before 31 January of each year the following particulars regarding the preceding year in respect of the recipient;

(i) the identification number of the recipient file;

(ii) the date on which an artificial fertilization of the recipient, was effected;

(iii) the number of in vitro fertilisations of the recipient effected;
(iv) the particulars contemplated in sub-regulation (1)(g);
and
(v) the results of each procedure referred to in subparagraph (ii).

Recording of names of authorised institutions and competent persons in register

15. (1) The Director-General shall keep a register with particulars of—
(a) authorised institutions in terms of section 54 of the Act, where artificial fertilisation or embryo transfer may be effected;
(b) a prescribed institution in terms of section 63 of the Act; and
(c) a competent person who effects such artificial fertilisation or embryo transfer.

(2) The Director-General shall delete from the register the name of—
(a) a competent person who has died;
(b) a competent person who requests the Director-General in writing to remove her or his name from the register;
(c) a competent person who was found to have contravened or failed to comply with the provisions of these regulations; or
(d) an authorised or prescribed institution in the case where the owner, manager or person in charge of such institution requests the Director-General to remove the name of such a place from the register.

(3) A competent person who has changed her or his name or address of practice or a person in charge of an authorised or prescribed institution, the name or address of which has been changed, shall within 30 days of such change inform the Director-General in writing of such change.
(4) The Director-General may—

(a) after an inspection of an authorised or prescribed institution or any activity or process connected with artificial fertilisation of or embryo transfer to a recipient in or on such an institution;

(b) on the grounds of a report by any—

(i) health officer contemplated section 80 of the Act; and

(ii) any other officer of the Department specifically so designated in terms of sections 77 and 78 of the Act;

(c) on the grounds of a complaint, charge or allegation of which she or he has knowledge or which may come to her or his notice in connection with such authorised or prescribed institution, activity or process and after any inspection or collection of information in connection with such complaint, charge or allegation that she or he may deem necessary or expedient; or

(d) in the case where she or he is of the opinion that on or in such place conditions exist which are dangerous or harmful or likely to be dangerous or harmful to health, provisionally delete the name of such place from the register, and must in writing notify the person in charge of such authorised or prescribed institution accordingly.

(5) Any notice referred to in sub-regulation (4) shall provide sufficient details of grounds for the deletion.

(6) The deletion made in terms of this regulation shall—

(a) be entered in the central data bank; and

(b) be valid until the danger or situation which gave rise to such suspension has, to the satisfaction of the Director-General been removed: provided that if such danger or situation is not removed or rectified within a period of three months from the date of notice contemplated in sub
regulation (1), such authorised institution must be deleted from the register and may not perform artificial fertilisation or embryo transfer.

**Reporting of births**

16. (1) (a) All births delivered as a result of artificial fertilisation shall be recorded by the person in charge of the facility where such delivery has taken place, into the central data bank within 3 months of such birth.

(b) The mother who gives birth shall ensure that the competent person who effected the artificial fertilisation of or embryo transfer is informed of such birth and recording of the information referred to in sub-regulation (2), within 30 days of such birth.

(2) The information recorded in terms of sub-regulation (1) shall include, but not limited to:

(a) confirmation of birth;

(b) The unique identification number referred to in regulation 11(a); and

(c) any genetic disorder or birth defect in the child.

**Reporting of disorders and mental illnesses**

17. (1) An authorised institution that effected the artificial fertilisation or embryo transfer shall, should it come to their notice that a child born as a result of the artificial fertilisation displays any genetic disorder or suffers from any mental illness –

(a) determine if the cause of the disorder or mental illness can be traced back to the gamete donor or the recipient; and

(b) should the disorder or mental illness be traced back to the gamete donor, in writing, notify the authorised institution that effected the donation of gametes, of the disorder or mental
illness, any tests carried out with regard to the disorder or mental illness, the results of the tests and their view on the disorder or mental illness.

(2) A parent of a child referred to in sub-regulation (1) shall, where it comes to her or his attention that the child displays any disorder or suffers from any mental illness, report the disorder or mental illness to the authorised institution that effected the artificial fertilisation.

Ownership of gametes, zygotes and embryos

18. (1) Before artificial fertilisation, the ownership of a gamete donated for the purpose of artificial fertilisation is vested –

   (a) in the case of a male gamete donor but –

      (i) before receipt of such gamete by the authorised institution to effect artificial fertilisation by the authorised institution which removed or withdrew the gamete; and

      (ii) after receipt of such gamete by the authorised institution that intends to effect artificial fertilisation, in that institution;

   (b) in the case of a male gamete donor for the artificial fertilisation of his spouse, in that male gamete donor; and

   (c) in the case of a female gamete donor, for the artificial fertilisation of a recipient, in that female gamete donor.

(2) After artificial fertilisation, the ownership of a zygote or embryo effected by donation of male and female gametes is vested –

   (a) in the case of a male gamete donor, in the recipient; and

   (b) in the case of a female donor, in the recipient.
Prohibition of Disclosure of certain facts

19. No person shall disclose the identity of any person who donated a gamete or received a gamete, or any matter related to the artificial fertilisation of such gametes, or reproduction resulting from such artificial fertilisation except where a law provides otherwise or a court so orders.

Appeals

20. (1) (a) A person aggrieved by the decision of the Director-General in terms of these regulations may within 14 days of receiving such decision, appeal in writing to the Minister against such decision.

(b) A copy of the appeal shall be sent to the Director-General for his or her information and response if necessary.

(2) An appeal in terms of sub-regulation (1) shall clearly state the grounds on which such appeal is lodged.

(3) The Minister may confirm, amend or revoke a decision taken by the Director-General in terms of the provisions of these regulations and thereafter inform the appellant of her or his decision.

Offences and penalties

21. Any person who contravenes or fails to comply with any provision of these regulations commits an offence and is liable on conviction to a fine or imprisonment for a period not exceeding 10 years, or to both such fine and imprisonment.

Savings and withdrawal

22. (1) Subject to the provisions of sub-regulation (2) and (3), the regulations promulgated under Government Notice No. R. 1182
of 20 June 1986, No. R. 1354 of 17 October 1997 are hereby repealed.

(2) The register kept by the Director-General in terms of regulation 14(2) of the regulations referred to in sub-regulation (1) is incorporated into and constitutes part of the register kept by the Director-General in terms of these regulations.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 3 April 2012
NATIONAL HEALTH ACT, 2003

REGULATIONS REGARDING THE RENDERING OF CLINICAL FORENSIC MEDICINE SERVICES

The Minister of Health has, in terms of section 68 of the National Health Act, 2003 (Act No. 61 of 2003), made the regulations in the Schedule.

SCHEDULE

1. Definitions

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

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

"application" means an application in terms of section 30 or 32 of Criminal Act

"body fluid" means anybody substance which may contain HIV or any other sexually transmissible infection, but does not include saliva, tears or perspiration;

"body specimen" means anybody sample which can be tested to determine the presence or absence of HIV infection;

"Clinical Forensic Medicine Service" means a clinical investigative process applied in the determination of cause and manner of injuries to living victims of sexual assault and related matters
“Criminal Law Amendment Act” means Criminal Law (Sexual Offences and Related Matters) Amendment Act, 2007

“Designated health facility” is a public health facility where investigative process are applied in the determination of cause and manner of injuries to living victims of sexual assault is conducted;

“HIV” means the Human Immuno-deficiency Virus;

“HIV test” means any validated and medically recognised test for determining the presence or absence of HIV infection in a person;

“interested person” means any person who has a material interest in the well-being of a victim, including a spouse, same sex or heterosexual permanent life partner, parent, guardian, family member, care giver, curator, counselor, medical practitioner, health service provider, social worker or teacher of such victim;

“investigating officer” means a member of the South African Police Service responsible for the investigation of an alleged sexual offence or any other offence or any member acting under his or her command;

“medical practitioner” means a person registered as a medical practitioner in terms of the Health Professions Act, 1974 (Act No. 56 of 1974), and who is authorised to take body specimens as contemplated in the of the Criminal Amendment

“nurse” means a professional registered with the South African Nursing Council trained in forensic clinical medicine who, is authorised to examine, take forensic evidence for investigation and provide counseling and testing to the victim of sexual assault.

“offence” means any offence, other than a sexual offence, in which the HIV status of the alleged offender may be relevant for purposes of investigation or prosecution;
"Patient" means an individual who are receiving a service from, or are being cared for by, health worker

"PEP" means Post Exposure Prophylaxis;

"sexual offence" means a sexual offence in terms of this Criminal Act in which the victim may have been exposed to body fluids of the alleged offender; and

"victim" means any person alleging that a sexual offence has been perpetrated against him or her.

"Informed consent" means obtaining informed consent means explaining all aspects of the consultation to the patient;

**Health Services provided for victims of sexual assault**

1. (1) (a) If a victim has been sexual assaulted and accesses the designated health facilities he or she may—

   (i) receive PEP for HIV infection, at a designated public health facility designated from time to time by the Minister of Health by notice in the Government Gazette

   (ii) be given free medical advice surrounding the administering of PEP prior to the administering thereof;

   (iii) receive voluntary counseling and testing and any other relevant treatment appropriate

   (iv) be supplied with a prescribed list, containing the names, addresses and contact particulars of accessible public health establishments

(b) Subject to section 30 of the Criminal Law amendment Act, the victim may apply to a magistrate for an order that the alleged offender be tested for HIV, at State expense.

(2) A victim who-
(a) lays a charge with the South African Police Service in respect of an alleged sexual offence; or

(b) reports an incident in respect of an alleged sexual offence at a designated health facility within 72 hours after the alleged sexual offence took place, will receive the services contemplated in (1)(a).

(3) A victim contemplated in (1) or an interested person must—

(a) when or immediately after laying a charge with the South African Police Service or making a report in respect of the alleged sexual offence be informed by the police official to whom the charge is made or by a medical practitioner or a nurse to whom the incident is reported, as the case may be, of the—

(i) Importance of obtaining PEP for HIV infection within 72 hours after the alleged sexual offence took place;

(ii) need to obtain medical advice and assistance regarding the possibility of other sexually transmitted infections; and

(iii) Services referred to in subsection (1); and

(b) in the case of an application contemplated in section 30 of the Criminal Law amendment Act, be handed a notice containing the prescribed information regarding the compulsory HIV testing of the alleged offender and have the contents thereof explained to him or her.

Designated health facilities for treatment of victims of sexual assault- Fundamental requirements

2. (1) (a) 24 hours forensic clinical medical services will be provided for all victims of sexual assault

(b) At both an individual and community level there adequate measures to protect the patients, staff, health records and the facility itself shall be taken.

(c) Unauthorised people should not be able to view or hear any aspects of the consultation. Alleged perpetrators must be kept separate from their victims.
Application

3.  (a) These regulations are to be used by health professionals, communities and are applicable to both victims and perpetrators of crime or violence.

(b) For purposes of these regulations, the term “injury due to crime and/or violence” includes-
   i. sexual assault
   ii. physical assault
   iii. psychological trauma
   iv. domestic violence
   v. substance, drugs and alcohol related injuries or violence.
   vi. drunken driving
   vii. child abuse
   viii. elderly abuse

Clinical Forensic Medicine Service

4.  (a) The relevant member of the Executive Council of a province must, within national policy and in terms of these regulations, ensure that there is a Clinical Forensic Medicine Service within the respective provincial Department of Health, with a dedicated manager at provincial level.

(b) Wherever a clinical forensic examination is performed, informed, legally acceptable, consent must be obtained where relevant.

5.  Clinical forensic medical examinations should entail the following minimum details:
   a) examination of complainants of sexual and physical assault.
   b) examination of alleged perpetrators.
   c) examination of victim for signs of alleged abuse.
   d) Visit to crime scenes, evidence collection and documentation.
h) age assessments for medico-legal purposes. Appearing in court to give objective, impartial expert evidence. (Expert witness are there to provide support to the court and do not "belong" to either of the parties)

i) general wound identification, documentation and interpretation as to causation factors.

6. The purpose of a clinical forensic medicine service is to meet the medical, forensic, advocacy / counseling and educational needs of the individuals, families, groups and communities that it serves.

7. All victims of violence should be given access to CFM services, irrespective of age, gender, developmental level, health status (physical and mental), ethnicity or socioeconomic background.

8. Facilities for Clinical Forensic Medicine services should be provided at designated health facilities

**Health officials authorised to conduct clinical forensic examinations.**

9. Medical practitioners and nurses trained in clinical forensic medicine are authorised to conduct Clinical Forensic Medicine examinations.

10. A person still in clinical forensic medicine training (in-service or formal training for nurses) may participate in a clinical forensic examination only under the direct guidance and supervision of an authorised person.

**Additional evidence from a clinical forensic medicine examination**

11. Subject to any other law, an authorised person may submit for examination, or cause to be submitted, to an authorised institution, any tissue, fluid, or object, for furthering the administration of justice.

12. An authorised person is the only person who has the authority to decide what samples to collect for special investigation.
Protection of Records

13. (1) The person in charge of a designated facility in which clinical forensic medicine examinations are conducted must set up control measures in order to prevent unauthorized access to records relating to such examinations; and to the storage facility in which records are kept.

(2) Any person who-
   a) falsifies any record by adding or changing any information contained in that record; 
   b) creates, changes or destroys a record without authority to do so; 
   c) fails to create or change a record when properly required to do so;  
   d) provides false information with the intention that it be included in a record;  
   e) without authority, copies any part of the record;  
   f) without authority, connects the personal identification elements of a patient’s record with any element of that record that concerns the patient’s history and/or examination;  
   g) gains unauthorized access to a record or record-keeping system, including intercepting information in transit from one person, or one part of a record-keeping system, to another;  
   h) without authority, connects any part of a computer or other electronic system on which records are kept to-
      (i) any other computer or electronic system; or 
      (ii) any terminal or other installation connected to or forming part of any other computer or electronic system; or 
   j) without authority, modifies or impairs the operation of-
      (i) any part of the operating system of a computer or other electronic system on which a patient’s records are kept; or
      (ii) any part of the programme used to record, store, retrieve or display information on a computer or other electronic system on which a patient’s records are;

commits an offence.
14. The person in charge of a designated facility must ensure that a register is kept in which any file, or any part of a file, that is removed from the storage facility, is recorded, and in which he or she must enter all particulars of the person authorized to remove such file or any of its part, the purpose, date and time when removed and returned and the information extracted.

**Establishment and Composition of NCFMC**

15. (1) The Minister hereby establishes the National Clinical Forensic Medicine Service Committee (NCFMC).

(2) The NCFMC consists of –

- two officials from the National Department of health;
- one official from each provincial department of health who has experience in clinical forensic medicine service;
- one representative from each academic institution involved in teaching clinical forensic medicine or providing such a service

all of whom will be appointed to the NCFMC by the Minister.

**Duties and powers of NCFMC**

16. The committee shall advise the Minister on-

- policy concerning any matter that will ensure, promote, improve or maintain clinical forensic medicine services;
- norms, standards and guidelines for the rendering of clinical forensic medicine services, including health and safety standards and the minimum standards for accreditation of designated facilities; and
- any technical matter related to clinical forensic medicine services that may have an impact on health policies and strategies.
Accounting and Reporting Requirements

17. The Head of Department must submit annual returns of statistics covering all clinical forensic medical cases to the Director General in a format to be determined by the Director General from time to time.

Offences

18. Any person who fails to comply with any of the provisions of these regulations is guilty of an offence and is liable on conviction to a fine, or to imprisonment for a period not exceeding five years, or to both a fine and such imprisonment.

Delegation

19. (1) The Head of Department or the provincial head of the Service may, in writing, and on such conditions as he or she may determine, delegate or assign any power or duty to an official of the provincial department or staff of the designated facility, as the case may be, unless there is a specific prohibition of such delegation or assignment.

(2) A delegation or assignment made under sub-regulation (1) does not-

(a) divest the Head of Department or the provincial head of the Service of the responsibility or accountability concerning the performance of the function involved; or

(b) prohibit the performance of the function involved by the Head of Department or the provincial head of the Service.

(3) The Head of Department or the provincial head of the Service may amend or set aside any decision taken by a person in the exercise of any such power delegated to that person.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 13.01.12
NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO THE USE OF HUMAN BIOLOGICAL MATERIAL

The Minister of Health has, in terms of section 68 of the National Health Act 2003 (Act No. 61 of 2003), made the regulations in the Schedule.

SCHEDULE

Definitions

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);

"autosomal" means one of the 22 pairs of chromosomes that are not sex chromosomes;

"biological material" means material from a human being including DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, small tissue biopsies and growth factors from the same;

"cell" means the smallest structural and functional unit of an organism, consisting of cytoplasm and a nucleus enclosed in a membrane in living things;

"chromosome" means a thread-like structure made up of DNA found in the nucleus of all cells;

"competent person" means trained and -
(a) in the case of the intravenous withdrawal of blood, a person registered as such in terms of the Health Professions Act, 1974 (Act No.56 of 1974) as a medical practitioner or the Nursing Act, 2005 (Act No. 33 of 2005) as a nurse, or a health professional trained as a phlebotomist and registered as such in terms of the Health Professions Act, 1974 (Act No.56 of 1974);

(b) in the case of intra-arterial withdrawal of blood, a medical practitioner registered as a specialist in the procedure and registered as such in terms of the Health Professions Act, 1974 (Act No.56 of 1974);

(c) in the case of a finger prick for the withdrawal of a drop of blood for testing purposes and registered as such in terms of the Health Professions Act, 1974 (Act No.56 of 1974);

(d) in the case of a developing blastocyst, a person trained in basic or clinical embryology as well as tissue culture techniques and registered as such in terms of the Health Professions Act, 1974 (Act No.56 of 1974);

(e) in the case of a female gamete or ovum removal or withdrawal, a gynaecologist with training in reproductive endocrinology, and in the use of ovulation-inducing agents and the hormonal control of the menstrual cycle and registered as such in terms of the Health Professions Act, 1974 (Act No.56 of 1974);

(f) in the case of sperm withdrawal, an expert in male reproductive health or an urologist and registered as such in terms of the Health Professions Act, 1974 (Act No.56 of 1974);

(g) in the case of a foetal tissue, including amniocyte, chorionic villi and an utero cord blood, a medical practitioner and registered as such in terms of the Health Professions Act, 1974 (Act No. 56 of 1974); and

(h) in the case of research, a medical technologist or scientist registered as such in terms of the Health Professions Act 1974, (Act No. 56 of 1974);

"cultured cells" means cells that have been grown outside the body;

"DNA" means deoxyribonucleic acid, which is a nucleic acid, composed of building blocks called nucleotides;

"donation" means donation of human biological material for genetic testing, genetic training, and genetic health research for therapeutic purposes;
"donor" means a person from whose body human biological material has been removed or withdrawn for the purpose of genetic testing, genetic training, genetic health research and therapeutics;

"embryonic stem cell" means any cell from the 30-200 inner cell mass of the blastocyst;

"foetus" means a human offspring from eight weeks after conception until birth;

"in vitro fertilisation" means the process whereby a female gamete is fertilised with a male gamete outside the body of a female person;

"genetic carrier" means an individual who has a disease-causing mutation but will not develop the condition and the individual would have one normal and one faulty;

"mutation" means a permanent change and structural alteration in the DNA;

"polar body" means a product that is formed during the development of the female gamete (during meiosis), which contains little cytoplasm and a haploid number of chromosomes;

"primordial germ cells" are stem cells found in the gonad of a foetus capable of becoming ova or sperm;

"progenitor cells" means stem cells which give rise to a distinct stem cell line;

"serious genetic condition" means a condition which compromises the functional, physical or mental ability of a person and which can sometimes be lethal;

"stem cell" means a cell that has both the capacity to self-renew as well as to differentiate into mature, specialised cells;

"stem cell therapy" means the use of stem cells for therapeutic purposes;

"transgenic cells’ means cells derived from a species other than human;

"umbilical cord blood stem cells” means stem cells found in umbilical cord blood;
“validation” means the process of establishing documented evidence that provides a high degree of assurance that specific process will consistently produce the predetermined outcome.

Removal of human biological material

2. (a) No person, except a competent person, may remove biological material for genetic testing, genetic health research or therapeutic purposes.

(b) Biological material for genetic testing, genetic training, genetic health research or therapeutic purposes may only be removed in -

(i) an authorised institution;

(ii) prescribed institution; and

(iii) a research institution prescribed in terms of the National Heritage Resources Act, 1999 (Act No. 25 of 1999), for ancestry analysis.

Removal or withdrawal of biological samples from living persons

3. (1) A competent person may not remove any biological material from the body of another living person for the purpose of genetic testing, genetic training, genetic health research or therapeutics, unless it is done –

(a) with written informed consent of the person from whom such biological material is removed; or

(b) where the person is younger than 18 years for the medical treatment of such person as defined in section 129 of the Children’s Act, 2005 (Act No. 38 of 2005) -

(i) written informed consent by a child over the age of 12 years, provided the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and implications of the procedure;

(ii) written informed consent of a parent, guardian or care giver where the child is younger than 12 years or the child is over 12 years but has no sufficient maturity and the mental capacity to understand the benefits, risks, social and implications of the procedure;

(iii) consent by head of the health establishment in the case of an emergency;
(iv) consent by the Minister if the parent, guardian or caregiver of the child-

(aa) unreasonably refuses to give consent or assist the child in giving consent;

(bb) is incapable of giving consent or cannot assist the child in giving consent;

(cc) cannot be readily traceable; or

(dd) is deceased.

(c) where the removal or withdrawal is for the treatment of a person with mental illness, written informed consent of-

(i) the mentally ill person, if he or she is capable of giving consent;

(ii) a curator appointed by the court, a spouse, next of kin, a parent or guardian, major child, brother or sister, partner or associate if such mentally ill person is incapable of giving consent; and;

(iii) the head of the health establishment in the case of an emergency.

(2) No person shall carry out genetic health research unless such research has been approved by a registered health research ethics committee referred to in section 73(1) of the Act.

**Removal of biological material from deceased persons**

4. (1) Any organisation or institution or person that intends to use tissue from a deceased person for purposes of genetic testing, health research and therapeutics, where no consent has been given by the deceased person before her or his death and where there is no evidence that the removal of the tissue or cells would be contrary to a direction given by the deceased before his or her death, must take steps contemplated in sub-regulation (2) to locate the spouse, partner, major child, parent, guardian, major brother or major sister of a deceased person, in the specific order mentioned, in order to obtain consent.

(2) The steps contemplated in sub-regulation (1) must include, but not limited to, obtaining the name, address, the telephone number of the spouse, partner, major child, parent, legal guardian, major brother or major sister of the deceased person from:

(i) any person working in the relevant hospital, institution or facility where the deceased died; or
(ii) any person who visited the deceased before his or her death.

(3) In cases where none of the persons referred to in sub-regulation (2) can be located, an application, including evidence that the above steps have been taken must be submitted with the request to remove such tissue, to the Director-General in terms of section 62(3) of the Act.

**Use of human biological material**

5. Human biological material, may be removed or withdrawn from living persons for the following medical and dental purposes -

   (a) DNA, RNA and chromosome-based genetic testing;
   (b) Health research referred to in section 69(3) of the Act;
   (c) Training referred to in section 64(1)(a) of the Act; or
   (c) Studies of archeological, medical or heritage value on DNA obtained from human genetic material, conducted in terms of the of the National Heritage Resources Act, 1999 (Act No.25 of 1999).

**Pre-implantation and prenatal testing for sex selection**

6. Pre-implantation and prenatal testing for selecting the sex of a child is prohibited except in the case of serious sex linked or sex limited genetic conditions.

**Research utilising embryonic stem cells and umbilical cord blood stem cells**

7. Excess embryos obtained from *in vitro* fertilisation may be used to produce embryonic stem cell lines for the purpose of research, provided that the competent person obtains written informed consent from embryo donor or cord blood donor.

**Research utilising primordial germ cells**

8. Research on primordial germ cells obtained from aborted foetuses may be carried out provided that the competent person obtains prior written informed consent from the donor of the aborted foetus.
Stem cell therapy utilising adult, embryonic and umbilical cord cells

9. Any competent person who wishes to utilise embryonic, adult, foetal or umbilical cord stem cells for stem cell therapy must obtain written informed consent from the donor of such stem cells.

Use of transgenic cells for stem cell therapy

10. Transgenic cells shall only be used for stem cell therapy in humans provided –
(a) clinical validity and utility of the cells have been demonstrated
(b) prior permission is obtained from the Council.

Compensation in respect of withdrawal of human biological material

11. A person from whose body human biological material is withdrawn may only be reimbursed for reasonable expenses incurred by him or her in order to effect the donation concerned as defined in section 60(4) of the Act.

Human Biological Material Registers

12. (1) An authorised institution that performs genetic research or generates embryonic stem cells, must have separate registers to record such genetic research or generation of embryonic stem cell lines.
(2) The authorised institution must submit details of the registers referred to in sub-regulations (1) to the Minister by the end of March of each year.

Storage and control of flow of genetic information

13. An authorised institution that keeps or discloses genetic material records and other individually identifiable or related health information in any form, whether electronically, orally or on paper must ensure that-
(a) the information is treated confidentially;
(b) health care providers or planners give users a clear explanation of how the user can use, keep and disclose their information;
(c) users have access to their records;
(d) user's written informed consent is obtained before information is released to health insurers, other health care providers or any other relevant person;
(e) the information is used for the purpose for which it was originally intended;
(f) the written informed consent of the user or donor is obtained for long term storage of genetic material, stem cells or research findings;
(g) the records are destroyed after the purpose for which they were created has been served; and
(h) the information is treated as anonymous if used for research purposes.

Offences

14. Any person who contravenes these regulations or fails to comply with any provision of these regulations, is guilty of an offence, and liable upon conviction to a fine or imprisonment of not more than 10 years, or both such fine and such imprisonment.
NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO THE REGISTRATION OF MICROBIOLOGICAL LABORATORIES AND THE ACQUISITION, IMPORTATION, HANDLING, MAINTENANCE AND SUPPLY OF HUMAN PATHOGENS

The Minister of Health has, in terms of section 68 of the National Health Act, 2003, (Act No 61 of 2003), made the regulations in the Schedule.

SCHEDULE

DEFINITIONS

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 —

"biosafety code" means a code for classifying human pathogens into five categories in accordance with the relative risk or risks that a particular human pathogen or any manipulation thereof, may pose in causing human disease and the relative seriousness of such disease, as set out in Table 2, 3, 4 and 5 of the standards;

"BSL code" means laboratory biosafety level code;

"diagnostic specimen" means any human or animal material, including excreta, secreta, blood and its components, tissue or tissue fluids, that is to be used for the purpose of diagnosis, but does not include live infected animals;

"human pathogen" means —
(a) an infectious substance (b) the toxin of an infectious substance, or (c) any diagnostic specimen, vector or other material that contains, or that is reasonably suspected to contain an infectious substance or a toxin of an infectious substance;

"infectious substance" means — (a) a micro-organism, virus or parasite that is capable of causing human disease, or (b) an artificially produced hybrid or mutant micro-organism that contains genetic components of any micro-organism capable of causing human disease;

"laboratory biosafety level code or BSL Code" means a code for the classification of microbiological laboratories into four levels of containment of human pathogens to conduct the activities referred to in regulation 3(a) or (b) in respect of human pathogens with a specific biosafety code;

"microbiological laboratory" means a laboratory which handles human pathogens capable of colonising in humans, irrespective of whether or not the laboratory undertakes specific culture of such human pathogens or merely receives and handles tissue and other specimens potentially infected or infested which such human pathogens, and including laboratories which handle infected or infested, or potentially infected or infested, indigenous vectors of human pathogens, or exotic vector species irrespective of whether the are infected or infested;

"routine diagnostic specimen" means any biological specimen obtained routinely from patients for determination of the presence or not of human pathogens in order to identify, confirm or exclude infectious diseases in such patients, but excludes human pathogens with biosafety codes 3, 4 or 5;

"standards" means the Biosafety Standards for Microbiological Laboratories as determined by the Minister;

"toxin of an infectious substance" means a toxin capable of causing human disease;

Application of the regulations.

2. (1) These regulations apply to all microbiological laboratories which acquire, receive, import, handle, manipulate, maintain, store, culture or in any way process, issue or dispose of human pathogens so acquired, received or imported.
(2) These regulations do not apply to veterinary, agricultural or industrial laboratories which conduct the, activities referred to in regulation 3(a) or (b) in respect of animal pathogens, or toxins thereof, incapable of causing human disease.

Registration of laboratories and the issuing of permits

3. No person shall-

(a) acquire, receive or import human pathogens; or (b) handle, manipulate, maintain, store, culture or in any way process, issue or in any way dispose of human pathogens so acquired, received or imported, unless the person-

(i) is registered with the Department as a microbiological laboratory in terms of regulation 6(1)(a); (ii) is assigned a BSL code in terms of regulation 6(1)(a); (iii) is in possession of a permit issued in terms of regulation 6(1)(b) to conduct the activities referred to in paragraph (a) or (b) in respect of human pathogens in accordance with the BSL code of the laboratory indicated on the permit; and (iv) conducts any activity referred to in (a) or (b), as the case may be, in accordance with the provisions of these regulations and the standards.

4 (1) An application for registration of a microbiological laboratory must be submitted to the Director-General in Form 2 and 3, 4 or 6, as the case may be, as provided for in the annexure.

(2) An application for a permit contemplated in regulation 3(b) (iii) must be submitted to the Director-General in Form 1 as provided for in the annexure.

(3) The applications referred to in sub-regulations (1) and (2) must be accompanied by an application fee as may be determined by the Director-General.

5 (1) When considering an application made in terms of regulation 4 the Director-General may require the applicant to furnish such further information and materials in respect of the application as the Director-General may deem necessary.

(2) The Director-General may direct a health officer to-
(i) inspect, at any reasonable time, the physical facilities, equipment, operational protocols, systems or manuals or any other documents related to the functioning of the laboratory; (ii) take samples of any of the human pathogens found in the laboratory for testing or analyses; or (iii) investigate any other aspect of the laboratory that may assist the Director-General in making a decision on the application.

(3) The health officer referred to in sub regulation (2) must submit a report to the Director-General of the findings of the inspection.

6 (1) After considering an application, the Director-General may with regard to an application for-

(a) registration, issue a registration certificate to the applicant concerned, indicating a specific BSL code which is applicable to that laboratory, and any conditions that he or she may determine; or

(b) permit, determine the biosafety code of the human pathogens in a particular instance for which the application is being made and issue a permit to the applicant concerned, indicating in respect of which human pathogens activities may be conducted.

(2) In the case an application or applications received for registration of more than one laboratory from a single applicant, the Director-General shall determine what constitutes a separate laboratory in each case for the purpose of registration.

(3) The Director-General may by notice in writing sent by registered mail to the applicant, refuse to issue a registration certificate or permit and stating the reasons for such a decision.

(4) A permit issued in terms of this regulation is valid for a period of 90 days from the date of issue and for a single acquisition, receipt or importation of human pathogens.

7. Notwithstanding regulation 6, a laboratory issued with a permit for human pathogens with biosafety codes 1 or 2, need not apply for a permit for each acquisition from within the Republic of the same type of human pathogen for which such laboratory has been issued with a permit.

8. A laboratory which imports human pathogens or to which a permit has been issued for human pathogens with biosafety codes 3, 4 or 5, must apply for a permit for each import or acquisition of human pathogens.
9. (1) A person who acquired or imported a human pathogen that belongs to biosafety code 3, 4 or 5 shall keep the pathogen in the laboratory located at the address indicated in the application for a permit and shall ensure that the human pathogen is used only for work carried out or directed by such person in that laboratory.

(2) A person who intends to transfer a human pathogen to another person shall submit an application in writing to the Director-General for such a transfer.

(3) The Director-General may grant or reject an application for the transfer of a human pathogen.

10. A permit is not required for activities in respect of routine diagnostic specimens which are to be examined for human pathogens for which the laboratory concerned has been registered and assigned with the appropriate BSL code.

11. The original certificate of registration must be displayed in a conspicuous place in the laboratory.

**Transfer of human pathogens**

12. (1) The acquisition of human pathogens resulting from a transfer shall only take place with the written consent of the person in charge of the supplying registered laboratory and that of the receiving registered laboratory.

(2) The supplying laboratory is responsible for ensuring that the receiving laboratory is registered and assigned the appropriate BSL code to receive the human pathogens transferred.

(3) Records in respect of transfers shall be preserved and produced by the person in charge of the laboratory on demand to the Director-General.

(4) The transfer of human pathogens must be accompanied by the relevant permit.
Importation of human pathogens

13. (1) No person shall receive or import a human pathogen that belongs to biosafety code 3, 4 or 5, unless-

(a) prior to shipment of the human pathogen, that person notifies the supplier that the outer container in which the human pathogen is transported must display clearly, on the outside surface of the container, the number of the permit issued and the following statement preceding that number:

"Human Pathogen — Permit Number"; and

(b) the original permit issued in respect of the human pathogens accompanies the consignment of such human pathogen and is attached to the outer container of such human pathogen.

(2) A person who arranges to transfer or import a human pathogen that belongs to biosafety code 3, 4 or 5 and does not receive it within 3 days after such date as may be reasonably expected in the circumstances, shall-

(a) notify Director-General that the person has not received the human pathogen; and

(b) forthwith take all reasonable measures to locate the human pathogen

Suspension or cancellation of registration or permit

14. (1) If the Director-General is of the opinion on the strength of an inspection report or recommendation by a health officer, or any other person designated by the Director-General, that there are reasonable grounds to suspect that-

(a) the premises or equipment used by the laboratory to which a permit was issued or registered are hazardous to health;
(b) the laboratory is not complying with these regulations or the standards,

the Director-General may serve a written notice on the laboratory instructing the laboratory to furnish reasons, at a place and time specified in such notice, why the registration or permit concerned must not be suspended or cancelled.

(2) The Director-General may, notwithstanding sub-regulation (1), suspend the registration or permit immediately if she or he is of the opinion that the hazard referred to in sub-regulation (1) constitutes an immediate danger to health or a contravention of these regulations.

(3) A notice referred to in sub-regulation (1) shall set out such particulars as are reasonably adequate to inform the laboratory why the revocation of registration or permit is necessary.

15. The suspension or revocation of a registration or permit or both the registration and permit in terms of this regulation shall have the effect that, from the date when it is served on the laboratory, no activities referred to in regulation 3 may be conducted in or upon the premises of the laboratory.

16. Where the Director-General is of the opinion that a condition that gave rise to the revocation of a registration or permit was rectified after such revocation, she or he may, upon written application, reinstate such registration or permit.

**Appeals**

17. A registered laboratory or a laboratory which has applied for registration or the issuing of a permit, may appeal in writing to the Minister against any decision of the Director-General made in terms of these regulations.

18. An appeal in terms of regulation 17 shall be lodged within 14 days of the receipt of a notice of such decision by the laboratory, and shall clearly state -

(a) against which decision such appeal is lodged; and (b) the grounds of such appeal.

19. 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 appealed against.
20. The Minister may confirm, amend or set aside a decision of the Director-General in terms of the provisions of these regulations and inform the laboratory in writing of his decision.

Offences and penalties

21. Any person who contravenes the provisions of these regulations shall be guilty of an offence and shall on conviction be liable to a fine or imprisonment for a period not exceeding 10 years or to both fine or imprisonment.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 29 3 02
FORM 1

DEPARTMENT OF HEALTH

APPLICATION FOR PERMIT TO ACQUIRE, IMPORT OR HANDLE HUMAN PATHOGENS

in terms of regulation 3 of the Regulations Regarding the Registration of Microbiological Laboratories and the Acquisition, Importation, Handling, Maintenance and Supply of Human Pathogens,

No. R.... of ...................... 2012

TO BE COMPLETED IN BLOCK LETTERS BY LABORATORY SUPERVISOR.

Item 1: Registration number of laboratory

| B | S | L |  |  |  |  |

(Leave the number blank if the laboratory is not registered and complete the necessary sections in Form 2)

Item 2: Name of laboratory or institution

|  |

Item 3: Postal address of laboratory or institution

|  |  |

City/Town  Code

Item 4: Street address of laboratory where human pathogens will be maintained

|  |  |

City/Town  Code

Item 5: Laboratory Supervisor

| Name |
| Qualifications |
| Health Professions Council of |
| SA Registration number

| Relevant experience |
|  |
| Telephone number (work) |
| Telephone number (after hours) |

Item 6: Institution from which human pathogens are to be acquired or imported (supplier)

| Name |
| Postal address |

1 Attach copy of registration certificate
Item 7: Has the necessary clearance been obtained from the [Yes] [No] (Provide evidence, e.g. photocopy of letter, etc.)

Item 8: Consignment of human pathogens

<table>
<thead>
<tr>
<th>Expected date of arrival</th>
<th>Port of entry²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Means of transport</td>
<td></td>
</tr>
</tbody>
</table>

Item 9: List of human pathogens to be imported or otherwise acquired³

<table>
<thead>
<tr>
<th>Human pathogen</th>
<th>Purpose for which required</th>
<th>OFFICIAL USE (Dios of the code)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Item 10: Additional information furnished by applicant³

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

I certify that the information given in this application is correct and complete in every respect. Signed at ........................................ on this ....... day of ........................................ 20 ......

Signature of applicant ..................................................

(Laboratory Supervisor)

² If human pathogens are imported
³ Attach separate page if not sufficient space
FORM 2  
DEPARTMENT OF HEALTH  

APPLICATION FOR REGISTRATION OF A MICROBIOLOGICAL LABORATORY  
in terms of regulation 3 of the Regulations Regarding the Registration of Microbiological Laboratories and the Acquisition, Importation, Handling, Maintenance and Supply of Human Pathogens, No. R.... of .....................  

TO BE COMPLETED IN BLOCKLETTERS BY LABORATORY SUPERVISOR. THE RELEVANT FORM 3, 4, 5 OR 6 MUST ALSO BE COMPLETED.  

| Item 1: Name of laboratory or institution |  
| Item 2: Postal address of laboratory or institution |  
| City/Town | Code |  
| Item 3: Street address of laboratory to be registered |  
| City/Town | Code |  
| Item 4: Laboratory Supervisor |  
| Name |  
| Date of birth |  
| Qualifications |  
| Health Professions Council of |  
| SA registration number |  
| Relevant experience |  
| Telephone number (work) |  
| Telephone number (after hours) |  
| Item 5: Owner(s) of laboratory |  
| Name |  
| Postal address |  
| City/Town | Code |  

1 Attach copy of registration certificate
Item 6: Contact person for owner (if different person from owner)

<table>
<thead>
<tr>
<th>Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Postal address</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City/Town Code</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Item 7: Intended function(s) of the laboratory

Item 8: Brief description of premises to be registered (Type of construction; numbers of rooms stating floor dimensions and intended function of each; type of equipment and number of each; insert sketch of floor plan with room dimensions)

Item 9: Has the laboratory been registered with the Department of Trade and Industry?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>If yes, please attach a copy of the registration certificate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I certify that the information given in this application is correct and complete in every respect.

Signed at ........................................ on this ........ day of .................................. 20 ....

Signature of applicant ...........................................(Laboratory Supervisor)

---

2 Attach separate page if not sufficient space
BIOSAFETY STANDARDS FOR MICROBIOLOGICAL LABORATORIES

1. PRINCIPLES OF BIOSAFETY

1.1 The term "containment" is used in describing methods for managing parasites, infectious agents and infected or potentially infected animals, tissues or other materials in the laboratory environment where they are handled or maintained. The purpose of containment is to reduce exposure of laboratory workers, other persons and the outside environment to potentially hazardous agents.

1.2 Primary containment, the protection of personnel and the immediate laboratory environment from exposure to parasitic or infectious agents is provided by good microbiological technique and the use of appropriate safety equipment.

1.3 Secondary containment, the protection of the external laboratory environment from exposure to parasites or infectious materials, is provided by a combination of facility design and operational practices. In some instances primary containment is of less importance than secondary containment e.g where work is done with agents which are not hazardous to humans, but which are of significance should they escape to the environment.

1.4 This document specifies four biosafety levels (BSL, 2, 3 and 4) which consist of combinations of laboratory practices and techniques, safety equipment and laboratory facilities which are commensurate with the intended function of the laboratory and the nature of the infectious agents to be handled or maintained therein. Specific metazoan parasites and infectious agents are assigned to one or more of five biosafety levels on the basis of the potential hazard which they constitute and of the intended laboratory procedure to which they will be subjected. A fifth category (BSL5) of parasite or infectious agent refers to certain exotic or eradicated parasites or infectious agents whose acquisition and maintenance is entirely proscribed or authorized in exceptional circumstances only. Work on recombinant DNA molecules or with radio-active isotopes is subject to separate control and is not dealt with in this document beyond insisting that laboratories conform
with the relevant requirements. Likewise, this document is concerned with biosafety in animal experiments and does not deal with quality of animal care or experimental design beyond insisting that these conform with all statutory, scientific and ethical requirements which are subject to separate control.

2. TYPICAL APPLICATIONS FOR WHICH THE FOUR RIO-SAFETY LEVELS ARE APPROPRIATE

2.1 Biosafety level I (BSL1)

BSL1 practices, safety equipment and facilities are those appropriate for secondary educational and undergraduate training and teaching laboratories and for other facilities working with defined and characterized strains of viable infectious agents not known to cause disease in healthy adult humans or not known to colonize in humans. *Bacillus cereus*, *Naegleria gruberi* and canine distemper virus (Snyder-Hill strain) are representative of those microorganisms assigned to BSL1. However, it should be remembered that many agents not ordinarily associated with disease processes or colonization in humans are opportunistic pathogens and may cause infection in the young, the aged and in immunodeficient or immunosuppressed individuals. Vaccine strains which have undergone multiple *in viva* passages should not *a priori* be considered avirulent.

2.2 Biosafety level 2 (BSL2)

BSL2 practices, safety equipment and facilities are those which are applicable to clinical, diagnostic, teaching and other facilities working with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. Activities with low aerosol potential with these agents can be conducted on the open bench using good microbiological techniques. The hepatitis agents (hepatitis A, hepatitis B, hepatitis C), and the salmonellae are representative of microorganisms assigned to BSL2. Primary hazards to personnel working with these agents relate to accidental auto-inoculation or ingestion of infectious materials. Procedures with high aerosol potential may predictably and significantly increase the risk of exposure of personnel to infectious aerosols and must be conducted in primary containment equipment or devices.

2.3 Biosafety level 3 (BSL3)

BSL3 practices, safety equipment and facilities are those which are applicable to clinical, diagnostic, teaching, research or production facilities working with indigenous or exotic agents
which may readily cause serious and potentially lethal infections, *Mycobacterium tuberculosis* when
grown to bulk or inoculated into animals (see Section 6). Rift Valley fever virus and *Coxiella
burnett*i are representative of microorganisms assigned to BSL3. Primary hazards to personnel
working with these agents relate to auto-inoculation, ingestion and exposure to infectious aerosols.

2.4 Biosafety level 4 (BSL4)

BSL4 practices, safety equipment and facilities are those which are applicable to working with
dangerous and exotic agents which pose a high individual risk of life-threatening disease, or which
are potentially of great veterinary or agricultural significance. All manipulations of potentially
infectious diagnostic materials isolates and naturally or experimentally infected animals pose a high
risk of exposure and infection to laboratory personnel, or of escape of the infectious agent to the
environment. Crimean-Congo haemorrhagic fever and foot and mouth disease of cattle are viruses
representative of the microorganisms assigned to BSL4.

3. SUMMARY OF LABORATORY FACILITY DESIGN AND FUNCTIONS•

3.1 The basic laboratory

This Laboratory provides general space appropriate for work with defined viable agents which are
not associated with disease processes in healthy adults or which do not colonize in humans. All
activities are regularly conducted on the open bench using standard laboratory practices.

3.2 The containment laboratory

This laboratory provides general space appropriate for work with infectious agents or potentially
infectious materials when the hazard levels are low and laboratory personnel can be adequately
protected by standard laboratory practice. Work is commonly conducted on the open bench with
certain operations confined to biological safety cabinets. Conventional laboratory designs are
adequate. Areas known to be sources of general contamination such as animal rooms and waste
staging areas should not be adjacent to media processing areas, tissue culture laboratories, or
patient care activities. Public areas and general offices to which non-laboratory staff requires
frequent access should be separated from spaces which primarily support laboratory functions.

3.3 The high containment laboratory

This laboratory has special engineering features which make it possible for laboratory workers to
handle hazardous materials without endangering themselves, the community, or the environment.
The unique features which distinguish this laboratory from the basic and containment laboratories
are the provisions for access control and a specialized ventilation system. This high containment laboratory may be an entire building or a single module or complex of modules within a building. In such cases, the laboratory is separated by a controlled access zone from areas open to the public and laboratory personnel from other areas.

3.4 The maximum containment laboratory

This laboratory has special engineering and containment features that will allow the safe conduct of activities involving infectious agents that are extremely hazardous to the laboratory worker or that may cause serious epidemic disease. Although the maximum containment laboratory is generally a separate building, it can be constructed as an isolated area within a building. The distinguishing characteristic of the laboratory is the provision of secondary barriers to prevent hazardous materials from escaping into the environment. Such barriers include sealing of all openings into the laboratory and installing airlocks or liquid disinfectant barriers, a contiguous clothing change and a shower room, a double door autoclave, a biowaste treatment system, a separate ventilation system, and a treatment system to decontaminate exhaust air.

4. BIOLOGICAL SAFETY CABINETS

4.1 The Class I biological safety cabinet is an open-fronted, negative-pressure, ventilated cabinet with a minimum inward face velocity of the working opening of at least 23 metres per minute. The exhaust air from the cabinet is filtered by a high efficiency particulate air (HEPA)1 filter- This cabinet may be used in three operational modes: with a full-width open front, with an installed front closure panel not equipped with gloves and with an installed front closure panel equipped with arm-length rubber gloves.

4.2 The Class II vertical laminar-flow biological cabinet is an open-fronted, ventilated cabinet with an average inward face velocity at the work opening of at least 23 metres per minute. This cabinet provides a high efficiency particulate air-filtered (HEPA), recirculated mass airflow within the work space. The exhaust air from the cabinet is also filtered by high efficiency particulate air(HEPA) filters.

Personnel protection provided by Class I and Class II cabinets is dependent on the inward airflow, since the face velocities are similar; they generally provide an equivalent level of personnel protection. The use of these cabinets alone, however, is not appropriate for containment of highest-risk infectious agents because aerosols may accidentally escape through the open front.

The use of a Class II cabinet in the microbiological laboratory offers the additional capability and advantage of protecting materials contained within it from extraneous airborne contaminants; this
capability is provided by the high efficiency particulate air filtered (HEPA) recirculated mass airflow within the work space.

4.3 The Class III cabinet is a totally enclosed ventilated cabinet of gas-tight construction. Operations within the Class III cabinet are conducted through attached rubber gloves. When in use, the Class III cabinet is maintained under negative air pressure of at least 12.5mm water gauge. Supply air is drawn into the cabinet through high efficiency particulate air (HEPA) filters installed in series. The exhaust fan of the Class III cabinet is separate from the exhaust fan in the facility's ventilation system and exhaust air is also high efficiency particulate air-filtered (HEPA).

The Class III cabinet provides the highest level of personnel and product protection. This protection is provided by the physical isolation of the space in which the infectious agent is maintained. When these cabinets are required, all procedures involving infectious agents are contained within them. Several Class III cabinets are therefore typically set up as an interconnected system. All equipment required by the laboratory activity, such as incubators, refrigerators, and centrifuges, must be an integral part of the cabinet system. Double-doored autoclaves, chemical dunk tanks, fumigation chambers or ultraviolet-irradiated airlocks are also attached to the cabinet system to allow safe introduction and removal of supplies and equipment.

4.4 Personnel protection equivalent to that provided by Class III cabinets can also be obtained with a personnel suit area and Class I or Class II cabinets. This area is one in which the laboratory worker is protected from a potentially contaminated environment by a one-piece positive pressure suit ventilated by a life-support system. This area is entered through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surfaces of the suit as the worker leaves the areas. The exhaust air from the suit area is filtered by two high efficiency particulate air (HEPA) filter units installed in series.
BIOSAFETY STANDARDS FOR MICROBIOLOGICAL LABORATORIES

5. SUMMARY OF BIOSAFETY LEVELS FOR MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES

*Table 1*

<table>
<thead>
<tr>
<th>BITY</th>
<th>SAFETY Equipment</th>
<th>FACILITITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSL1</td>
<td>Standard micro-biological practices</td>
<td>Basic laboratory</td>
</tr>
<tr>
<td></td>
<td>None: primary containment provided by adherence to standard laboratory practices during open bench operations</td>
<td></td>
</tr>
<tr>
<td>BSL2</td>
<td>BSL1 practices plus: protective gloves and coats when conducting procedures with infectious agents; decontamination of all infectious waste; limited access</td>
<td>Containment laboratory</td>
</tr>
<tr>
<td></td>
<td>Partial containment equipment (i.e. Class I or II biological safety cabinets) used to isolate mechanical and manipulative procedures that produce readily detectable aerosols</td>
<td></td>
</tr>
<tr>
<td>BSL3</td>
<td>BSL2 practices plus: special laboratory clothing; controlled access</td>
<td>High containment laboratory</td>
</tr>
<tr>
<td></td>
<td>Partial or total containment equipment (class I, II or III biological safety cabinets) isolate all procedures that may produce aerosols</td>
<td></td>
</tr>
<tr>
<td>BSL4</td>
<td>BSLS practices plus: entrance through change room where street clothing removed and laboratory clothing donned; shower on exit; all waste decontaminated on exit from facility</td>
<td>Maximum containment laboratory</td>
</tr>
<tr>
<td></td>
<td>Total containment equipment (i.e. Class III biological safety cabinets) used to isolate all the procedures and operations involving infectious materials of partial containment equipment in combination with full body air-supplied, positive pressure personnel suit used for all procedures and activities</td>
<td></td>
</tr>
</tbody>
</table>
6. BIOSAFETY CODES ASSIGNED TO PARASITIC AND INFECTIOUS AGENTS AND VECTORS OF HUMAN DISEASE

6.1 Explanation of Tables 2 to 5

6.1.1 In Tables 2 to 5 and Section 6.2 biosafety codes are assigned to parasitic and infectious agents and vectors of human disease. Codes 1 to 4 correspond to BSL1 to 4 as set out in Forms 3, 4, 5 and 6 in this document as being appropriate combinations of laboratory practices, safety equipment and facility design for handling and maintaining the agents or vectors concerned. Code 5 does not correspond to a particular biosafety level, but pertains to agents which may only be acquired in exceptional circumstances outlined in Section 6.1.8 below.

6.1.2 In many instances different biosafety codes are assigned to the same agent. This is because greater risk may be associated with handling larger volumes, greater concentrations or animals infected with the same agent.

6.1.3 The lists are not intended to be exhaustive. In general, it can be accepted that free-living microorganisms not known to cause disease in or to colonize in humans are assigned to biosafety code I BSLI laboratories may be given special permission to handle agents assigned to codes higher than I for teaching purposes.

6.1.4 With regard to parasitic or infectious agents assigned to codes higher than BSLI, the intention is to specify particularly agents which are known or are likely to occur in South Africa. Where possible, broad categories are specified, e.g. the category human enterovirus serotypes 1-72 includes the polio-viruses. Coxsackie A and B viruses, echoviruses and the most recent members of this group such as the agents of haemorrhagic conjunctivitis and hepatitis A.

6.1.5 In many instances it is necessary to stipulate individual members of the group since they may differ with regard to biosafety requirements or known prevalence in South Africa. Many individual agents from the “International Catalogue for Arboviruses” are stipulated since they occur in South Africa or elsewhere in Africa, or are likely to be required here for identification of agents isolated in this country.

6.1.6 Important or particularly hazardous pathogens not known to occur in this country are also specified since identification would be needed urgently if an outbreak of these viruses were to occur here.
6.1.7 Zoonotic agents and selected important veterinary pathogens appear on the lists, but there has been no attempt to include the broad spectrum of non-zoonotic veterinary pathogens prevalent in this country.

6.1.8 Agents which have been assigned to biosafety code 5 may be imported or otherwise acquired in exceptional circumstances only. Some are important human pathogens which have been eradicated or do not occur here, such as smallpox virus. Others, such as 8V40 virus, could contaminate vaccines. Most are extremely important animal pathogens which may only be acquired with the permission of the Director of Veterinary Services of the Department of Agricultural Economics and Marketing. Plant pathogens or parasites are not specified in this document and may only be acquired with the permission of the Director of Plant and Seed Control of the Department of Agricultural Economics and Marketing.

Medical laboratories which intend to work with any veterinary or agricultural pathogens or parasites should ascertain from the above authorities whether or not there are current restrictions on work with the agents concerned, irrespective of whether or not the agents are assigned to code 5.

Once a laboratory has obtained permission to acquire a code 5 agent, the Director-General will assign a new biosafety code, ranging from 1 to 4, to that agent. The new code has relevance only to the handling of the agent in the particular laboratory concerned and the agent remains code 5 for all other laboratories unless a ruling to the contrary is made.

6.1.9 In instances where laboratories wish to acquire agents which are not included in Tables 2 to 5 and Section 6.2, the Director General shall make individual rulings on the biodiversity code assigned to the agents concerned.

It should be noted that the lists and the codes assigned to agents are subject to modification as dictated by changing circumstances and by the experience gained in applying the system.

6.1.10 Symbols used in Tables 2 to 5

Laboratory function to be performed:

A Activities involve the use or manipulation of small quantities or low concentrations of cultures or other materials known or suspected of containing the agent, i.e. up to 2 litres of non-concentrated culture fluid or 10 per cent infected tissue suspension, or up to 10ml of culture which has been concentrated.
B Activities involve the use or manipulation of large quantities or high concentrations of cultures or other materials known or suspected of containing the agent, i.e. more than 2 litres of nonconcentrated culture fluid or 10 per cent infected tissue suspension, or more than 10 ml of culture which has been concentrated.

C Activities involve the use or manipulation or vertebrate animals with natural or induced infection with the agent.

**Biosafety codes:**

1 Agent to be used or manipulated in compliance with BSL1 requirements.

2 Agent to be used or manipulated in compliance with BSL2 requirements.

3 Agent to be used or manipulated in compliance with BSL3 requirements.

4 Agent to be used or manipulated in compliance with BSL4 requirements.

5 Importation or other acquisition of the agent prescribed or authorized in exceptional circumstances only.

6.2 Prescribed biosafety codes for invertebrate vectors of parasitic or infectious agents of human disease

Indigenous invertebrate vectors of human disease which are infected or potentially infected with the parasitic or infectious agents which they transmit, are assigned to the biosafety codes which pertain to the relevant parasites or infectious agents in Tables 2 to 5.

Exotic vector species fall under BSL5 and are assigned to a new code, ranging from SSL1 to 4, with respect only to laboratories which have been granted special permission to acquire and to perform studies with a particular species.

Work with non-infected indigenous invertebrate vectors of human disease is not subject to specific control, but such vectors must be housed and handled under secure conditions as described in Section 4 of Forms 3 to 6 if they are moved to areas where they do not already occur in nature,
7. IMMUNOPROPHYLAXIS

Additional protection of personnel at risk can be achieved through prophylactic vaccination. Each institution should devise its own written policy with regard to immunization and maintain records of all vaccinations performed.

It is recommended that personnel who handled human blood or blood products should be tested for immunity to hepatitis B and immunized if susceptible. Other vaccines for which the known effectiveness clearly outweighs possible adverse reactions, including for example vaccines against yellow fever, plague, rabies and poliomyelitis, may be considered for use in situations where there is deemed to be particular risk. All normal precautions should apply in carrying out such immunizations and the use of non-registered vaccines, such as that for Rift Valley fever, must be cleared with the Medicines Control Council.

The Director-General of the Department of Health may rule that the use of a particular vaccine makes it permissible to work with an infectious agent in a laboratory of lower biosafety rating than would normally be permitted. However, the potential exposure of non-immunized persons to infection, and the possible contamination of the environment, remain prime consideration in such instances.

8. SHIPMENT OF HUMAN PATHOGENS AND RELATED MATERIALS

Routine medical specimens or cultures assigned to BSL1 and 2 and being transported to laboratories or between laboratories within South Africa by clinicians, pathologists or their delegates. e.g. messengers, are not subject to special restrictions but should be packed safely. Materials sent by mail or public transport should be packed in accordance with postal and transport requirements.

All materials containing, or potentially containing, agents assigned to BSL3, 4 and 5, as well as all infectious agents consigned within South Africa to external destinations, must be packaged and consigned in compliance with international requirements (see also Figures):

8.1 Briefly, the primary container (usually a sealed glass ampoule, tube or bottle) is wrapped in sufficient absorbent material (paper towels or tissues) to absorb the entire contents in the event of leakage.

8.2 The wrapped primary container is placed in a durable, leak-proof secondary container. This is preferably a leak-proof, rigid, screw-cap, metal or plastic container. The secondary container is placed in a similar tertiary container. If the material to be shipped is stable or has been freeze dried,
this tertiary container serves as the shipping container and is labeled with the address of the shipper and consignee. It also receives an etiologic or infectious agent label as per examples in Figures........... and........ available at airports. Parcels sent abroad must also have a customs declaration label- The import permit obtained from the consignee is placed in an envelope taped to the outside of the parcel where it is available to transport, customs and health officials.

The import permit issued in some countries, notably the USA, takes the form of a label which is attached to the outside of the parcel.

8.4 If unstable materials are being consigned in the wet or frozen state, the tertiary container must be placed in a suitable cold box (e.g. expanded polystyrene container) which contains sufficient cold packs or dry ice to maintain the agent at the desired temperature during the estimated duration of the journey.

The outer wrapping of the parcel is labeled as in Section 8.3 and, if necessary extra labels are added indicating which end of the parcel is to face upwards and that the parcel is to be kept refrigerated or frozen, and that the contents are fragile.

8.5 If specimens are sent by air, it may be necessary to complete a shipper's declaration of dangerous goods in addition to the air waybill.

8.6 Always inform the consignee of the means of transport and expected arrival times of the consignment.
NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO BLOOD AND BLOOD PRODUCTS

The Minister of Health has, in terms of section 68 of the National Health Act 2003 (Act No. 61 of 2003), to made the regulations in the Schedule.

SCHEDULE

Definitions

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);

"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 product, 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 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);

“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;

“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 a cell that has both the capacity to self renew as well as to differentiate into mature, specialized cells;

“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 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 a health officer 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 health officers

4. (1) The Minister shall appoint persons in the employ of the National Department as health officers for blood transfusion services.

(2) (a) A health officer shall exercise 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 a health officer.
Duties of the health officer

5. (1) A health officer 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 health officer 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 a blood product 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 a health officer may require in the exercise of her or his duties under that regulation;

(1) A health officer may, in addition to exercising the duties 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) A health officer 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 duties in terms of these regulations.

(3) A health officer 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.
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 donation, 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 s 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 health officer appointed in terms of regulation 5.
(b) The health officer 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;

(c) any other report required by the Minister from time to time in respect of the activities of health officers.

(d) If it comes to the health officer'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 health officer 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.

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**


[Signature]

DR. A MOTEEOLEDI
MINISTER OF HEALTH
DATE: 13/03/12
NATIONAL HEALTH ACT, 2003

REGULATIONS REGARDING THE GENERAL CONTROL OF HUMAN BODIES, TISSUE, BLOOD, BLOOD PRODUCTS AND GAMETES

The Minister of Health has, in terms of section 90(1), read with section 68(1) of the National Health Act 2003 (Act No. 61 of 2003), made the regulations in the Schedule.

SCHEDULE

Definitions

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)

“artificial fertilisation” means the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction and includes

“artificial insemination” means in vitro fertilisation, gamete intrafallopian tube transfer, embryo intrafallopian transfer or intracytoplasmic sperm injection;
“bury” means inter or cremate or dispose of a dead person in any other lawful manner;

“competent person” means –
(a) in the case of the intravenous or intra-arterial withdrawal of blood, a person registered in terms of the Health Professions Act, 1974 or the Nursing Act, 2005 or
(b) in the case of a finger prick for the withdrawal of a drop of blood for testing purposes, a person authorised in terms of the Regulations Relating to the Withdrawal of Blood From a Living Person for Testing.

“dentist” means a person registered as a dentist in terms of the Health Professions Act, 1974 (Act No 56 of 1974);

“donation” means the donation of a human body, blood or any specific tissue in accordance with the Act;

“donee” means an institution or person to which or to whom a human body, blood, gamete or tissue has been donated;

“health officer of blood transfusion services” means a health officer of blood transfusion services appointed by the Minister in terms of section 80;

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

“national blood transfusion service” means the organisation established in terms of section 53;

“section” means a section of the Act; and

“tissue bank” means an institution authorised to store tissue.
Consent for the removal of tissue, blood and gametes from living persons

2. A person may not remove tissue, blood or gametes from the body of another living person for a purpose referred to in section 54 and regulation 3 unless written consent thereto has been granted as follows -

(a) where such person is older than 18 years, by that person;
(b) where such person is younger than 18 years, by the parents or guardians of that person;
(c) paragraph (b) is not applicable to gametes donors who shall never be younger than 18 years; and

Purposes for which tissue, blood or gametes of living persons may be used and the withdrawal of blood

3. (1) Tissue, blood and gametes removed or withdrawn from living persons may only be used for medical and dental purposes, including –

(a) in case of such tissue, the transplanting thereof in the body of another living person or for the production of a therapeutic, diagnostic or prophylactic substance;
(b) in the case of such blood, for testing, the administering thereof to another living person or the production of a blood product; and
(c) in the case of such gamete, the artificial fertilisation of another person.

(2) No person, except a competent person, may for the purposes of this regulation, withdraw any blood or blood product from the body of a living person.
Institutions to which and persons to whom human tissue, blood, blood product and gametes may be donated

4. Specific tissue, blood, blood product or gametes from a living person may be donated to any of the following institutions or persons –

(a) in the case of tissue -
   (i) a hospital;
   (ii) a university or University of Technology;
   (iii) an authorised institution;
   (iv) a medical practitioner;
   (v) a dentist;
   (vi) a tissue bank or any person who requires therapy in which the tissue concerned can be used;

(b) in the case of blood or blood product, to the national blood transfusion service or an authorised institution;

(c) in the case of gametes, to a competent person or authorised institution;

Donations

5. (1) A donation that does not have a specific institution as donee, the institution in the appropriate category which is nearest to the place where the body is kept of the person whose body or tissue has been so donated, shall be deemed to be the donee.

(2) If a donation has been made to a specific donee who is not within easy reach at the time and place of the death of the person whose body or any specific tissue thereof was so donated the institution in the appropriate category which is nearest to that place shall be deemed to be the donee.
6 If a person has made conflicting donations, effect shall be given to the donation which was last made: provided that if such a person had first donated her or his entire body to one donee and thereafter donated any specific tissue thereof to another donee, the donation of her or his entire body shall be deemed to be a donation of the remainder of her or his body.

**Purposes of donation**

7. (1) The purposes of a donation need not be expressly stated, but a donation shall be of no force and effect if made for any purpose other than a purpose referred to in section 64(1).

(2) An institution, medical practitioner, dentist or person to whom specific tissue has been supplied may use the tissue only for the purposes referred to in section 64).

**Removal of donated tissue**

8. (1) Except in the case of a donation of the entire body, a donee shall have a period of 24 hours after the death of the person of whom any specific tissue was donated within which she or he may remove or cause to be removed the tissue so donated.

(2) After expiry of the period referred to in subregulation (1) and irrespective of whether or not the donee has so removed that tissue or caused to be removed, the body may be claimed for burial or otherwise by spouse, partner, major child, parent, guardian, major brother or major sister in the specific order mentioned.

(3) Authority under section 67) for the removal of eye tissue in terms of subregulation (1) and (2) shall not be required if the medical practitioner
effecting the removal or under whose supervision the removal is effected, is satisfied that –

(i) the tissue concerned has been donated in accordance with section 62;
(ii) the body concerned is no longer required for the purpose of an examination and
(iii) the removal of the tissue concerned is necessary for any of the purposes referred to in section 64.

Establishment of death

9. The death of a person concerned shall be established by at least two medical practitioners, one of whom shall have been practising as a medical practitioner for at least five years after the date on which she or he was registered as a medical practitioner, and none of those medical practitioners shall transplant tissue removed from that person into a living person or take part in such transplantation: Provided that where the tissue concerned is eye tissue, the death of the person from whom the tissue is removed shall be deemed to have been established by the issuing of a certificate of death in terms of the relevant law by a medical practitioner in respect of that person.

Disposal of unclaimed bodies of deceased persons

10. (1) The body of a deceased person that is not buried, or claimed for burial within 30 days after the death of that person by the by spouse, partner, major child, parent, guardian, major brother or major sister in the specific order mentioned or bona fide friend of the deceased, shall be at the disposal of the health officer in whose area the body is.

(2) Subject to any order by a health officer, the person in charge of an institution or any other person in whose care the body referred to in subregulation (1) is, shall not hand it over to any person other than a by
spouse, partner, major child, parent, guardian, major brother or major sister in the specific order mentioned referred to in subregulation (1), who is known to her or him, unless the person requesting it produces to her or him an order of a magistrate authorising the handing over of the body to that person.

(3) A health officer shall not issue an order referred to in subregulation (2) unless the person applying for the order undertakes to pay the cost of the burial of the body concerned, and the magistrate is satisfied that that person is the by spouse, partner, major child, parent, guardian, major brother or major sister in the specific order mentioned or a relative or bona fide friend of the deceased.

Notice to the health officer

11. (1) If a body has not within 30 days after the death of the deceased been buried, or claimed for burial by a spouse, partner, relative or friend, the person in charge of the institution concerned, or any other person in whose care the body is, shall forthwith direct a notice to that effect, stating the particulars in respect of the body, to the health officer concerned.

(2) If the notice referred to in subregulation (1) has not been directed to the health officer in writing, it shall be repeated in writing within 30 days after the death of the deceased.

Handing over of bodies to certain institutions

12. (1) An health officer may on receipt of a notice contemplated in regulation 11(1) by written order direct that the body concerned be handed over to a specific institution situated within the area of the health officer concerned, or such an institution nearest to where the body is.
(2) (a) A health officer shall not issue an order contemplated in subregulation (1) if she or he suspects on reasonable grounds that the deceased at the time of her or his death was suffering from a disease specified by the Director-General in a notice given by her or him for the purpose of this regulation to every health officer.

(b) The Director-General may at any time amend or withdraw such a notice.

(3) If no order under subregulation (1) is issued within 2 days after the receipt of a notice contemplated in regulation 11(1), the body concerned shall no longer be at the disposal of the health officer concerned.

Bodies to be preserved for certain period before use

13. (1) The person in charge of an institution to which a body has been handed over shall keep and preserve that body for a period of not less than 14 days before it may be used: Provided that, if the said person deems it advisable, any tissue of such a body may be removed and preserved separately.

(2) The provisions of regulation 10(2) and (3) shall also apply if any person within the period referred to in subregulation (1) requests the person in charge of the institution concerned to hand over to her or him the body which is being kept and preserved in terms of subregulation (1).

Granting of authority

14. (1) No authority shall be granted for conducting a post-mortem examination or the removal of tissue unless the medical practitioner concerned is satisfied, except in a case where application is made for conducting a post-mortem examination for a purpose referred to in section 66 that-
(a) the body or tissue concerned was donated;
(b) the body concerned is no longer required for the purpose of an examination.
(c) the removal of the tissue concerned or the post-mortem examination concerned is necessary for any of the purposes referred to in section 64(1) or 66(c).

(2) Notwithstanding the provisions of subregulation (1)(b)(i), authority may be granted for the removal, of any specific tissue from a body which is required for the purpose of an examination, if the medical practitioner who is to conduct the examination concerned, certifies that she or he is satisfied that the removal of that tissue will in no way affect the outcome of that examination and that she or he has no objection to the removal of that tissue.

(3) If a person who has died has in her or his will or in a document donated tissue of her or his body, a medical practitioner may act upon that will or document if on the face of it appears to be legally valid.

Disposal of bodies and tissue

15. An institution which or a person who has obtained a human body or tissue, and no longer requires such body or tissue or any part thereof shall -

(a) bury or cause to bury such body or tissue or such part thereof; and
(b) enter in the register referred to in regulation 16, the date, place and manner of such burial.

Registers

16. (1) A register shall be kept by -
(a) a medical practitioner —
   (i) who has removed eye tissue or under whose supervision such removal was effected;
   (ii) who has removed or caused to be removed tissue and who has handed over such tissue to the holder of an authority; or
   (iii) who has granted an authority in terms of section 66 and 67; or

(b) an institution which or person who receives a body or specific tissue donated in terms of section 62; and

(c) an institution —
   (i) which supplied tissue; or
   (ii) to which a body has been handed over.

(2) The following particulars shall be recorded in a register —
   (i) The name, population group, sex and age at the time of death of the deceased concerned;
   (ii) the nature and quantity of the tissue concerned;
   (iii) the name and address of the institution or person to which or to whom the tissue concerned was donated; and
   (iv) the date of removal of the tissue concerned from the body of the deceased; and
   (v) the nature of the donation and, if the body as a whole was not donated, particulars of the specific tissue donated;
   (vi) the date of receipt of the body concerned; and
   (vii) the date of the order referred to in regulation 12(1).
(3) A register referred to in subregulation (1) –

(a) shall, when not in use, be stored in a strong-room or, where a strong-room is not readily available, in a place where it is reasonable protected against fire, theft or destruction; and

(b) shall, except where a health officer otherwise determines in writing, be retained for a minimum period of at least five years after the last entry in such register.

Handling, conveyance and burial of bodies

17. (1) The body of a person who suffered from anthraxcholera, a haemorrhagic fever of Africa, hepatitis B, rabies, meningococcemia, plague, poliomyelitis or typhoid fever at the time of his or her death may not be conveyed in public in any way unless -

(a) such a body is sealed in an airtight container and placed in a sturdy non-transparent sealed coffin and the total surface of the body is covered with a 5 cm layer of wood sawdust or other absorbent material which is treated with an disinfectant and an authorised medical officer or an environmental health practitioner in the employ of the state or local authority concerned, or any medical practitioner specifically so authorised by the local authority concerned declares in writing that in his or her opinion the conveyance of the body will not constitute a health hazard; and

(b) such declaration accompanies the body at all times during the conveyance and up to the burial.

(2) The declaration referred to in subregulation (1) shall be shown to a health officer on demand, by the person responsible for the conveyance of the body.
(3) No person shall damage a container referred to in subregulation (1) (a), or open such container or remove the body from the container or come into direct contact with the body after it has been sealed without prior approval from an officer or practitioner referred to in subregulation (1) (a).

(4) No person shall convey a body –

(a) on public transport unless the body has been sealed in an airtight container and placed in a non-transparent, sturdy, sealed coffin; or

(b) in any other way in public unless the body has been placed at least in a container.

(5) No coffin or container in which a body has been placed may be conveyed unless -

(a) the outer surface of such coffin or container is free from any liquid or any other unhygienic matter originating from such body; and

(b) offensive odours are absent.

(6) The person responsible for the conveyance of a body shall, at the expense of the person on whose behalf the body is conveyed, ensure that if the body conveyed by him or her gives off an offensive odour, or if any liquid or other unhygienic matter originating from a body is present on the outer surface of a coffin or container, such coffin or container is taken forthwith to the nearest mortuary or undertaker's premises, where the necessary measures shall be taken to eliminate the offensive odour or to free the outer surface of such coffin or container from the said liquid or unhygienic matter.
Measures regarding the import and export of bodies

18. (1) (a) No person may import a body unless he or she has a written authorisation by the Director-General or a person specifically designated by him or her and which is valid for a period of 30 days after the date of issue.

(b) If a body is imported without authorisation the Director-General or a person specifically designated by him or her may order that such body be kept in a mortuary or at an undertaker's premises at the expense of the person who imported the body until the necessary authorisation has been issued: Provided that if the prescribed authorisation is not issued within 30 days after the date of the order, the Director-General or a person specifically designated by him or her may order in writing that such body be buried or dealt with in the way referred to in the order at the expense of the person who imported the body.

(2) Any person requiring a written authorisation referred to in subregulation
(a) shall apply to the Director-General or a person specifically designated by him or her and shall furnish the following particulars and documents;

(a) A death certificate with at least the deceased's name, the date and place of death and the cause of death, in one of the official languages of the country;

(b) the name and export permit of the country from which the body is to be imported;

(c) the name of the border post where the body is to be imported, the type of transport to be used to import the body and convey it to the place of burial;

(d) the name of the place in the Republic where burial of the body is to take place or if the body will not be buried the reason why the body is being brought in; and
(e) an embalming certificate, where necessary unless where embalming is prohibited for religious reasons.

(3) The provisions of this regulation shall also apply to the body of a person that has died in transition on a boat or aircraft the moment that the body is being brought into the Republic, irrespective of whether such body is to be buried in the Republic.

(4) The authorisation referred to in subregulation (1) (a) shall be in the possession of the person responsible for the conveyance or burial of the body and shall be produced on demand to a health officer.

**Measures regarding the disinterment of bodies**

19. No person may disinter a body or remove a body from any grave unless the following measures are taken:

1) the disinterment or removal of a body shall be carried out under the supervision of an environmental health practitioner of the local authority in whose area of jurisdiction the body is buried provided that if the local authority concerned does not have the services of an environmental health practitioner;

2) the local authority may use the services of an environmental health practitioner of another local authority or an environmental health practitioner in private practice to perform the duties as referred to in this regulation;

3) only persons with direct involvement may be present at the disinterment or removal of a body and no dogs or other animals may be allowed at the grave;
5) persons handling a body shall be supplied with and wear protective
overwear, gloves and face masks which cover at least the nose and
mouth;

6) if demanded by an environmental health practitioner, the grave and
the body shall be treated with a disinfectant or other protective
measures demanded by an environmental health practitioner;

7) washing facilities shall be available at the grave for the cleansing of
persons handling the body;

8) a body shall be placed in a non-transparent and closely sealed
airtight container immediately after it has been disinterred and be
handled in such a way that no nuisance or health hazard is
caused; and

9) during the disinterment or removal of a body the grave shall not be
left unguarded and immediately after the remains have been
removed such grave shall be covered or sealed.

Appointment of Health officers

20. (1) The Member of the Executive Council in each province may appoint a
person in the provincial department as a health officer.

(2) (a) A health officer shall exercise the duties conferred or imposed upon
or delegated or assigned to her or him by or under these
regulations, subject to the control and Member of Executive
Council of health or the directions of the Minister.

(b) The Member of the Executive Council, or any other officer in the
full-time employment of the provincial department designated by
her or him, may exercise any power conferred upon a health officer.

(3) A health officer shall exercise her or his powers and perform her or his duties in an area defined by the Member of the Executive Council.

(4) The appointment of a health officer and the definition of the area within which she or he may perform his duties and shall perform her or his duties shall be made known in the Government Gazette.

21. (1) If the Director-General or Member of Executive Council can appoint any person who is not in the full-time employment of the State as a health officer in any particular case to investigate any matter falling under these regulations or may so appoint such person to assist a health officer of blood transfusion services with any matter which falls within the duties of such relevant health officer.

(2) (a) a health officer, may, subject to the control and directions of the Member of Executive Council or the Minister, for the purpose of the investigation for which she or he has been appointed, perform duties conferred on a health officer of blood transfusion services;

(b) the Minister or Member of Executive Council shall furnish an investigating officer with a letter of appointment, signed by the Minister or Member of Executive Council;

(c) a health officer shall on request produce for inspection the letter of appointment furnished to her or to him in terms of paragraph (b).
Duties of health officers

22. (1) A health officer 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 a human body or tissue is used or stored is reasonably suspected to be used for any purpose in terms of the Act or these regulations;

(ii) in or upon which the production from tissue of any therapeutic, diagnostic or prophylactic substance or the supply of such substance so produced is carried on or is reasonably suspected to be carried on;

(i) in or upon which the artificial fertilisation of any person is effected or is reasonably suspected to be effected;

(ii) in or upon which any prescribed activity or process is carried on or reasonably suspected to be carried on; or

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

provided that if a health officer (appointed by the Minister) of blood transfusion services has been appointed and his or her duties not applicable to a health officer (appointed by the Member of Executive Council);

(b) examine any such premises or any body, tissue, product or substance or other object found therein or thereon or any activity or process carried out on 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 body, tissue, product, substance or other object, in order to ascertain whether the
provisions of the Act and these regulations are being complied with;

(c) at any time demand from any person in or upon any such premises that she or he forthwith or at a time and place determined by the health officer produce to her or to him any register, record or other document which is in the 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 therefrom, 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, as she or he may deem fit, any person whom she or he finds in or upon premises entered by her or him in terms of paragraph (a) 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 and bury the remains of a human body or tissue which is kept in or upon premises entered by her or him 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 and burial.

(2) Any person who is in charge of any activity or process referred to in subregulation (1) in respect of which any premises contemplated in subregulation (1) are occupied or used, and any person employed by such person, shall at all reasonable times render such assistance -

(a) as a health officer may require in the exercise of her or his duties under these regulations;
(b) as the Member of the Executive Council of health or any officer referred to in regulation 17(2) (b) may require; or
(c) as a health officer may require in the exercise of his or her powers.

Reports

23. A health officer shall furnish the provincial head of department of health as well as to the Director-General –

(a) as soon as possible after the thirty-first day of December of each year a report in respect of her or his work during the year which ended on that day and in respect of the operation of the provisions of the Act and these regulations in so far as they apply to her or to him;
(b) any other report required by the member of the executive council or the Minister from time to time in respect of the activities of the health officer.

GENERAL AND SUPPLEMENTARY PROVISIONS

Prohibition of publication of certain facts

24. (1) No person shall publish or make known any fact whereby the identity of –
(a) a deceased person whose body or any specific tissue thereof has been donated;

(b) the donor of the body of a deceased person or any specific tissue thereof;

(c) a living person from whose body any tissue, blood or gamete has been removed or withdrawn for any purpose; or

(d) the person who has given her or his consent to the removal of any tissue, blood or gametes from a living person for such purpose;

may possibly be established, unless consent thereto was granted.

(2) No person shall publish to another person any fact whereby the identity of the recipient of any tissue removed from another person before or after the death of the said person may possibly established, unless –

(a) in the case of a recipient who is still alive at the time of such publication, that recipient before such publication granted her or his consent thereto in writing; or

(b) in the case of a recipient who at the time of such publication has died –

(i) that recipient before her or his death granted consent to such publication in writing; or

(ii) that recipient did not before her or his death indicate in any manner that she or he would not be prepared to grant such consent and the spouse, partner, major child, parent, guardian, major brother or major sister of the recipient before such publication granted consent in writing.
Offences and penalties

25. Any person who –

(a) except in so far as it may be permitted by or under any other law, acquires, uses or supplies a body of a deceased person or any tissue, blood or gamete of a living or deceased person in any other manner or for any other purpose than that permitted in the Act and these regulations;
(b) refuses or fails to comply to the best of her or his ability with any demand, requirement or order of a health officer or a health officer of blood transfusion services or any other person made or given in terms of any provision of the Act and these regulations; or
(c) hinders any person in the performance of her or his duties in terms of the Act and these regulations;

shall be guilty of an offence and liable on conviction to a fine or imprisonment for a period of 10 years or to both fine and imprisonment.

Exclusive rights in respect of bodies of deceased persons, tissue, blood and gametes

26. Any person who acquires the body of a deceased person or any tissue, blood or gamete by virtue of any provision of the Act and these regulations, shall, subject to any restrictions in terms of the Act or any other law and provided she or he uses the body, tissue, blood or gamete for the purposes for which it has been donated, handed over or supplied to her or to him, on receipt of that body, tissue, blood or gamete acquire exclusive rights in respect thereof.
Repeal

27. The regulations published under Government Notice No. R 2876 of 29 December 1989 are hereby repealed.

[Signature]

DR R MOYOLOLEDI, MP
MINISTER OF HEALTH
DATE: 2 March 2012
NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO THE IMPORT AND EXPORT OF HUMAN TISSUE, BLOOD, BLOOD PRODUCTS, CULTURED CELLS, STEM CELLS, EMBRYOS, FOETAL TISSUE, ZYGOTES AND GAMETES

The Minister of Health has, in terms of section 68 of the National Health Act, 2003 (Act No. 61 of 2003), made the regulations in the Schedule.

SCHEDULE

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:

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

   "annexure" means an annexure to these regulations;

   "applicant" means any organisation, institution or person applying for an export or import permit;
"authorised organisation, institution or person" means any organisation, institution or person referred to in regulation 3(1), 4, 5(1), 6(1) or 7(1);

"biological standards" mean norms or guidelines used to ensure the preservation of biological substances of human origin for the purpose which these substances are intended to be used;

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

"blood donor" means any living person who voluntarily and not for remuneration has blood withdrawn from him or her for the subsequent administering thereof to themselves or another person or for processing into blood products;

"category" means the classification of human substances in categories as set out in Annexure 1, 2 and 3;

"cultured cells" means any human cells grown in vitro supported by suitable growth media;

"DNA" means Deoxyribose Nucleic Acid which is a nucleic acid composed of building blocks called nucleotides;

"diagnostic substance" means any product or device produced from a substance that may be used in the diagnosis of any disease or condition that may be transmitted by blood or a blood product;

"embryo" means a human offspring in the first eight weeks of conception;

"embryonic tissue" means tissue from an embryo;
“foetus” means a human offspring from eight weeks after conception until birth;

“foetal tissue” means tissue from a foetus;

“import” means import into the Republic in any manner;
“Medicines Control Council” means the organisation established in terms of section 2 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) or its successor in title;

“plasma” means –
(a) the fluid portion of blood obtained as a by-product of whole blood donation; or
(b) plasma collected directly from a person by a process of plasmapheresis;

“primary container” means the container into which plasma is directly placed;

“primary organisation or person” means an organisation or person which or who is, within the relevant laws of the particular country, an organisation or person similar to an authorised organisation, institution or person;

“Republic” means the Republic of South Africa;

“Standards of Practice” means the standards of practice for blood transfusion in South Africa, determined by the Minister;

“stem cell” means any embryonic stem cell or circulating, bone marrow, umbilical cord or haemopoietic progenitor cell, or any cell that is capable of replicating or proliferating and giving rise to a differentiated cell;
"substance" means tissue, blood, blood product or gamete;

Import and Export Permits

2 (1) No person may import or export any tissue or any blood, blood product, cultured cells, gametes, stem cells or embryos without a permit issued in terms of these regulations.

(2) Any person who wishes to import or export any tissue or any blood, blood product, cultured cells, stem cells, embryo, zygote or gamete, must apply in writing to the Director-General in the form set out in Annexure 4 or 5 of these regulations.

(3) The Director-General may on receipt of the application issue a permit to a person authorising such a person to import or export, subject to such conditions as the Director-General may determine and record on the permit, including an expiry date, any tissue or any blood, blood product, and cultured cells.

(4) The Director-General may issue a permit authorising the applicant to export or import any tissue, blood, blood product, and cultured cells. If he or she is satisfied that the information submitted in support of an application for a permit meets the requirements of these regulations.

3 (1) An applicant for an export permit must have proof in writing that the tissue or gametes for which an export permit is being applied for, was or were donated in terms of the Act, and that the tissue or gametes to be exported are to be used in terms of the Act, and such proof must accompany the application.
(2) In the case of gametes, zygotes and embryos a permit will only be issued if-

(a) An application for an export permit is accompanied by the donor information required in terms of Regulations Relating to Artificial Fertilisation of Persons and Related Matters but excluding the identification of the donor or

(b) An application for an import permit is accompanied by the information required in terms of regulation 3(3) (a) above, and the gametes are to be used in an identified and confirmed recipient.

Whole blood, red cell concentrate, fresh or frozen plasma and platelet concentrate

4 (1) The Director-General may at her or his discretion issue an export permit which is contrary to the provisions of regulation 4(10)(a) and 4(12)(a) and subject to the provisions of regulation 4(12)(b) –

(a) for rare blood or whole blood, red cell concentrate, fresh frozen plasma and platelet concentrate, on humanitarian grounds;

(b) in a case of emergency; or

(c) for the blood or whole blood, red cell concentrate, fresh frozen plasma and platelet concentrate to be administered to a citizen or permanent resident of the Republic who is in a country other than the Republic.

(2) No import or export permit shall be issued for placenta tissue, embryonic or foetal tissue, or embryonic, foetal and umbilical stem cells, except with
the written consent of the Minister and subject to any condition as the
Minister may determine.

(3) In the case of tissue for therapeutic use, an import permit shall only be
issued if the application is accompanied by information in respect of the
health status of the donor, particularly regarding transmissible diseases
and the results of tests performed in that regard.

(4) Tissue with a mass less than 50g and which is intended for diagnostic and
research purposes, is excluded from the provisions of regulation 4(3).

(5) (a) The Director-General may refuse to issue an import or export
permit under regulation 4(1) if the information required in terms of
these regulations has not been provided.
(b) In the event of the Director-General not issuing a permit in terms of
regulation 4(5) (a), the reasons for not issuing a permit must be
provided in writing to the applicant.

(6) A permit issued in terms of regulation 4(1) must not be used for any
commercial or advertising purposes.

(7) An applicant to whom a permit has been issued, must ensure that the
transportation of the substance for which a permit has been issued, is in
accordance with biological standards applicable to such substance...

(8) (a) An applicant to whom a permit has been issued in terms of
regulation 4(1), must keep a record of such export or import in
accordance with the form in Annexure 6 or 7;
(b) The record in paragraph (a) must be submitted to the Director-
General before the end of February each year, for the preceding
calendar year; and
(c) The provisions of paragraphs (a) and (b) are not applicable to the exportation or importation of blood, plasma and serum in category 3 of Annexure 3, and tissue in regulation 7(6).

(9)  (a) Prior to the issuing of an export permit for biological substances of human origin the Director-General must be satisfied that the supply requirements of the Republic for the substance for which an export permit is being applied for, have been met;
(b) The supply requirements under paragraph (a) shall be determined by a minimum level of national stock, for a period determined by the Director-General based on the average, supply or availability, as the case may be; and
(c) In compliance with paragraph (b), the applicant must provide the Director-General with written information of stock levels, with the export permit request.

(10) (a) The issuing of an export permit for biological substances may only be to a Southern African Development Community (SADC) member state, provided that the requirements of the Republic's market have been met;
(b) Each consignment of biological substances of human origin imported into the Republic shall be accompanied by a certificate from the supplier, stating that the substance has been exported in terms of the applicable laws and regulations of the country from which such substance originates;
(c) Each consignment of biological substances of human origin exported from the Republic shall be imported in terms of the applicable laws and regulations of the country for which such substance is procured.
(11) Each consignment of blood or blood products to be exported or imported shall be accompanied by –

(a) a certificate from the national blood transfusion service stating that the blood or blood product has been tested in accordance with the Act;
(b) the results of such tests; and
(c) substantive motivation addressed to the Director-General in writing in a case of any deviation from the provisions of paragraphs (a) or (b).

(12) (a) notwithstanding the provisions of this paragraph, each consignment of blood or substance to be used for the supply of a blood product which is imported and which is intended for therapeutic purposes, must be tested by the national transfusion service in accordance with the requirements of the Act; and
(b) the Director-General may, after consultation with the national blood transfusion service, determine the tests that must be carried out on imported substances.

(13) The Minister may, subject to the provisions of section 58 of the Act, based on substantive motivation, exempt any organisation, institution or person from any provision of these regulations subject to conditions the Minister may determine.

Blood, plasma and serum, cultured cells, stem cells, embryo, zygote or gamete for reagent, research or diagnostic purposes

5 (1) An applicant for a category 1 blood product in Annexure 3 must be an organisation
or person conducting *bona fide* research in the human health field, or be involved in the
testing of human substances for diagnostic purposes.

(2) (a) Plasma may only be exported for the manufacture of reagents, controls or diagnostic substances for blood transfusion services.

(b) Plasma referred to in paragraph (a) may only be exported to a primary organisation or person, or an organisation which or person that is a manufacturer or supplier of diagnostic substances for blood transfusion services.

(3) The organisation or person referred to in subregulation (2)(a), must state in writing the purpose for which the plasma exported from the Republic will be used, and such statement must accompany the application for an export permit.

(4) Each primary container with plasma must be conspicuously marked with the following words: "HUMAN PLASMA FOR DIAGNOSTIC OR RESEARCH PURPOSES: NOT FOR THERAPEUTIC USE", with each character of such wording being at least 5mm in size.

(5) The total volume of plasma exported per shipment for purposes referred to in subregulation (2)(a), shall not exceed 5000 ml.

(6) Every application for an export permit for plasma referred to subregulation (2)(a), is restricted to a single organisation or person mentioned in that application and for a single shipment from a single authorised organisation, institution or person.
Disposal of tissue, blood, blood products, cultured cells, stem cells, embryos or gametes imported without permit or contrary to permit conditions

6  (1) Where any tissue or blood, blood product, cultured cells, stem cells, embryo or gamete has been imported in contravention of these regulations or conditions of a permit, the Director-General may—

(a) Order the importer concerned in writing to destroy or to remove from the Republic the tissue, blood, blood product, cultured cells, stem cells, embryo or gamete so imported within the period determined by the Director-General and at the expense of that importer; and

(b) Order that, if the importer concerned does not so destroy or remove the tissue, blood, blood product, cultured cells, stem cells, embryo or gamete concerned, it shall be forfeited to the State.

(2) If the importer contemplated in sub-regulation (1), after receipt of a written order under that regulation, fails to comply with such order, the Director-General may seize the tissue, blood, blood product or gamete and so dispose thereof in such manner as she or he may deem fit, at the expense of the importer.

(3) Any person who considers herself or himself aggrieved by a decision of the Director-General in connection with her or his application for the issue of a permit in terms of regulation 2(2) or with an order under regulation 6(1), may within 60 days after the date of such decision or order appeal in writing to the Minister, who may confirm, alter or set aside that decision or order.
Register

7 (1) A register must be kept by an authorised institution that has imported or exported any biological substance in terms of these regulations.

(2) The following particulars must be recorded in the register contemplated in sub-regulation (1), in respect of -

(a) import of a biological substance, in which case the form in Annexure 6 must be completed:

(i) the name, address, telephone number, facsimile number and e-mail address of the authorised institution that has imported the substance;

(ii) the name, address, telephone number, fax number and e-mail address of the organisation or person who has imported the substance on behalf of an authorised institution;

(iii) the period for which the record of imports are applicable;

(iv) the name of the substance, date of import, quantity of the substance and the name of the primary organisation or person which or who has exported or supplied the substance to the Republic for each import of each substance within the period referred to in sub-paragraph (iii) above;

(v) the name of the substance, date of import, quantity of the substance and the name of the organisation or person which or who has exported or supplied the substance to the Republic, on behalf of a primary organisation or person, for each import of each substance within the period referred to in subparagraph (iii);

(vi) in respect of the person entering information in the register of imports –
(aa) the name of the person;
(b) position or rank of the person within the authorised institution; and
(c) the signature of that person; and
(vii) the date on which the information has been entered in the import register by the person referred to in subparagraph (vi) above;

(b) export of a human substance, in which case the form in Annexure 7 must be completed:
(i) the name, address, telephone number, fax number and e-mail address of the authorised institution that has exported the substance;
(ii) the name, address, telephone number, fax number and e-mail address of the organisation or person who has exported the substance on behalf of an authorised organisation, institution or person;
(iii) the period for which the record of exports are applicable;
(iv) the name of the substance, date of export, quantity of the substance and the name of the primary organisation or person which or who has procured the substance from the Republic, for each export of each substance within the period referred to in sub-paragraph (iii) above;
(v) the name of the substance, date of export, quantity of the substance and the name of the organisation or person which or who has procured the substance from Republic on behalf of the primary organisation or person, for each export of each substance within the time period referred to in sub-paragraph (iii) above;
(vi) in respect of the person entering information in the register of exports —
(aa) the name of the person;
(bb) position or rank of the person within the authorised organisation or institution, or organisation or institution; and
(cc) the signature of that person; and
(vii) the date on which the information has been entered in the export register by the person referred to in sub-paragraph (vi) above.

(3) (a) a copy of the register referred to in sub-regulation (1) must be provided to the Director-General at intervals not exceeding six months by the authorised institution.;
(b) the register referred to in paragraph (a) must be retained for a minimum period of five years after the last entry in such register.

**Delegation of powers**

8 (a) The Director-General may, subject to such conditions she or he may determine, in writing delegate 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), and may alter or set aside any decision by an officer taken in the exercise of a power so delegated.
Offences and penalties

9. 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 to imprisonment for a period not exceeding 10 years or to both fine and such imprisonment.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: [Signature]
Annexure 1

BLOOD, PLASMA, CULTURED CELLS, STEM CELLS, EMBRYO, ZYGOTE, GAMETES AND SERUM FOR REAGENT, DIAGNOSTIC, THERAPEUTIC, REPRODUCTIVE OR RESEARCH PURPOSES

<table>
<thead>
<tr>
<th>Diagnostic, Therapeutic, Reproductive or Research Material (&lt; 50 ml)</th>
<th>Bulk Unprocessed Laboratory Plasma (50 ml - 5000 ml) Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td>Bulk diseased-state plasma</td>
</tr>
<tr>
<td>Plasma</td>
<td>Plasma</td>
</tr>
<tr>
<td>Serum</td>
<td></td>
</tr>
<tr>
<td>Cultured cells</td>
<td></td>
</tr>
<tr>
<td>Chorionvillus sample</td>
<td></td>
</tr>
<tr>
<td>Stem cells</td>
<td></td>
</tr>
<tr>
<td>Embryos</td>
<td></td>
</tr>
<tr>
<td>Zygotes</td>
<td></td>
</tr>
<tr>
<td>Gametes</td>
<td></td>
</tr>
<tr>
<td>Foetal tissue</td>
<td></td>
</tr>
</tbody>
</table>
### Annexure 2

**DEPARTMENT OF HEALTH**  
**APPLICATION FOR AN IMPORT LICENCE FOR BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN**

**PART A**

<table>
<thead>
<tr>
<th>APPLICANT</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>Rank/Position</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>MAIN BUSINESS1[1]</td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SUBSTANCE(S) FOR WHICH AN IMPORT PERMIT IS REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Period during which import(s) will take place

---

1[1] The main business of the organisation or person must be provided, e.g. fractionation unit, exporting agent or broker, researcher, etc.

3[3] The quantity must be expressed in mass, volume or units, whichever is most appropriate.
<table>
<thead>
<tr>
<th>ORGANISATION OR PERSON EXPORTING THE SUBSTANCE (S) TO SOUTH AFRICA</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>Rank/Position</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>COUNTRY</td>
</tr>
<tr>
<td>MAIN BUSINESS²</td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
</tr>
<tr>
<td>PURPOSE (S) FOR WHICH SUBSTANCE (S) IS (ARE) TO BE USED²</td>
</tr>
</tbody>
</table>

---

4[4] If the exporting organisation or person is not a primary organisation or person in terms of the Regulations and intends to export the substance(s) on behalf of such primary organisation or person, the applicant must obtain the information required in Section 2 of Part B in respect of such primary organisation or person.

5[5] The synopsis and not the substance of the detail must be furnished.
Annexure 2

DEPARTMENT OF HEALTH

APPLICATION FOR AN IMPORT LICENCE FOR BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

PART B

Section 1

<table>
<thead>
<tr>
<th>AUTHORISED ORGANISATION, INSTITUTION OR PERSON IMPORTING THE SUBSTANCE (S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>Rank/Position</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
</tr>
</tbody>
</table>


Section 2

<table>
<thead>
<tr>
<th>PRIMARY ORGANISATION OR PERSON EXPORTING THE SUBSTANCE(S) TO SOUTH AFRICA</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>Rank/Position</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>COUNTRY</td>
</tr>
<tr>
<td>MAIN BUSINESS^2</td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
</tr>
<tr>
<td>NAME OF ENQUIRIES CONTACT PERSON</td>
</tr>
<tr>
<td>NAME OF PERSON SUBMITTING APPLICATION</td>
</tr>
</tbody>
</table>
Annexure 3

DEPARTMENT OF HEALTH

APPLICATION FOR AN EXPORT LICENCE FOR BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

PART A

<table>
<thead>
<tr>
<th>APPLICANT1</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>Rank/Position</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NAME OF ORGANISATION</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address of organisation or person</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>MAIN BUSINESS2</th>
</tr>
</thead>
<tbody>
<tr>
<td>TELEPHONE NO.</td>
</tr>
<tr>
<td>FAX NO.</td>
</tr>
<tr>
<td>E-MAIL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SUBSTANCE(S) FOR WHICH AN EXPORT PERMIT IS REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUBSTANCE3</td>
</tr>
<tr>
<td>QUANTITY4</td>
</tr>
</tbody>
</table>

Period during which import(s) will take place

---

1 If the applicant is not an authorised institution in terms of the s 54 Notice and intends to export the substance(s) on behalf of such authorised institution, then the applicant must obtain the information required in Section 1 of Part B in respect of such authorised institution.

2 The main business of the organisation or person must be provided, e.g. fractionation unit, exporting agent or broker, researcher, etc.

4 The quantity must be expressed in mass, volume or units, whichever is most appropriate.
<table>
<thead>
<tr>
<th>ORGANISATION OR PERSON IMPORTING THE SUBSTANCE (S) FROM SOUTH AFRICA</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>Rank/Position</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>COUNTRY</td>
</tr>
<tr>
<td>MAIN BUSINESS</td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
</tr>
<tr>
<td>PURPOSE(S) FOR WHICH SUBSTANCE(S) IS(ARE) TO BE USED</td>
</tr>
</tbody>
</table>

5 If the importing organisation or person is not a primary organisation or person in terms of the Regulations and intends to import the substance(s) on behalf of such primary organisation or person, the applicant must obtain the information required in Section 2 of Part B in respect of such primary organisation or person.

6 Although detail is not required, the specific purpose(s) for which the substance(s) is(are) to be used must be clearly stated.
Annexure 3

DEPARTMENT OF HEALTH

APPLICATION FOR AN EXPORT LICENCE FOR SUBSTANCES OF HUMAN ORIGIN

PART B

Section 1

<table>
<thead>
<tr>
<th>AUTHORISED ORGANISATION, INSTITUTION OR PERSON EXPORTING THE SUBSTANCE (S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
</tr>
</tbody>
</table>

Section 2

<table>
<thead>
<tr>
<th>PRIMARY ORGANISATION OR PERSON IMPORTING THE SUBSTANCE (S) FROM SOUTH AFRICA</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>COUNTRY</td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NAME OF ENQUIRIES CONTACT PERSON</th>
<th>TELEPHONE NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>( )</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NAME OF PERSON SUBMITTING APPLICATION</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
</table>
Annexure 4

REGISTER OF Imported BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

Section 1

<table>
<thead>
<tr>
<th>AUTHORISED ORGANISATION, INSTITUTION OR PERSON IMPORTING THE SUBSTANCE(S)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rank/Position</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address of organisation or person</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FAX NO.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-MAIL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 2

<table>
<thead>
<tr>
<th>ORGANISATION OR PERSON IMPORTING THE SUBSTANCE(S)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rank/Position</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address of organisation or person</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TELEPHONE NO.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FAX NO.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-MAIL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 If the imports have been done on behalf of the authorised institution by another organisation or person, section 2 must also be completed.
Section 3

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUBSTANCE</th>
<th>QUANTITY</th>
<th>NAME OF PRIMARY ORGANISATION OR PERSON EXPORTING/SUPPLYING THE SUBSTANCE TO SOUTH AFRICA2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. If the exports to South Africa have been done on behalf of a primary organisation or person, section 4 must also be completed.
Annexure 5

REGISTER OF IMPORTED BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

Section 4

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUBSTANCE</th>
<th>QUANTITY</th>
<th>NAME OF ORGANISATION OR PERSON EXPORTING/SUPPLYING THE SUBSTANCE TO SOUTH AFRICA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 53

<table>
<thead>
<tr>
<th>NAME OF PERSON PROVIDING INFORMATION</th>
<th>POSITION IN ORGANISATION</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3 Section 5 must be completed in all instances.
Annexure 6

REGISTER OF EXPORTED BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

Section 1

<table>
<thead>
<tr>
<th>AUTHORISED ORGANISATION, INSTITUTION OR PERSON EXPORTING THE SUBSTANCE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>Rank/Position</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>TELEPHONE NO. FAX NO. E-MAIL</td>
</tr>
</tbody>
</table>

Section 2

<table>
<thead>
<tr>
<th>ORGANISATION OR PERSON EXPORTING THE SUBSTANCE(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF PERSON</td>
</tr>
<tr>
<td>Rank/Position</td>
</tr>
<tr>
<td>NAME OF ORGANISATION</td>
</tr>
<tr>
<td>Address of organisation or person</td>
</tr>
<tr>
<td>TELEPHONE NO. FAX NO. E-MAIL</td>
</tr>
</tbody>
</table>

1 If the exports have been done on behalf of the authorised institution by another organisation or person, section 2 must also be completed.
Section 3

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUBSTANCE</th>
<th>QUANTITY</th>
<th>NAME OF PRIMARY ORGANISATION OR PERSON IMPORTING/PROCURING THE SUBSTANCE FROM SOUTH AFRICA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2 If the imports from South Africa have been done on behalf of a primary organisation or person, section 4 must also be completed.
Section 4

<table>
<thead>
<tr>
<th>DATE</th>
<th>SUBSTANCE</th>
<th>QUANTITY</th>
<th>NAME OF ORGANISATION OR PERSON IMPORTING/PROCURING THE SUBSTANCE FROM SOUTH AFRICA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 5

<table>
<thead>
<tr>
<th>NAME OF PERSON PROVIDING INFORMATION</th>
<th>POSITION IN ORGANISATION</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO TISSUE BANKS

The Minister of Health has, in terms of section 68 of the Health Act, 2003 (Act No 61 of 2003), made regulations in the Schedule.

SCHEDULE

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:

   “Act” means the National Health Act, 2003 (Act No 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 No. 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 hospitalization or prolongation of existing hospitalization, 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 microorganism;

“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.

Use of human tissue

1. (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 sub-regulation (1) (a) (b) (c) or (d) above but only receive or store tissue solely for transplantation within the facility of such tissue bank.

Application for authorisation

3. (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 sub regulation (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 sub regulation (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.
Suspension or withdrawal of authorisation

4.  (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 sub regulation (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 sub-regulation 2 (a), (b), (c) and (d).
Organisational structure of tissue banks

5. (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.

Duties and reporting obligations

6. (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;

(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 indicative of microbial contamination and/or infectious disease; and
(vi) the number of serious adverse events referred to in subregulation (d);

(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 sub regulations (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.

Additional duties of the health officer

7. (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.

Inspection and Control Measures

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

Quality Management

9. 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.

Quarantine

10. 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.
Processing

11. 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.

Storage conditions

12. 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 authorized; and

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

Labeling, documentation and packaging

13. 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 utilized (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.

Traceability

14. 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.

Data protection and confidentiality

15. (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 sub regulation (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;

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

(iv) anonymity and privacy of donors are protected.
Distribution and dispensing

16. (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.

Research

17. (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 No. 56 of 1974).
   (2) All research results shall be recorded and documented in accordance with the Act.

Third parties

18. 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.

Appeals

19. (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 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 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.

Delegations

20. (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.
Offences and penalties

21. 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.

[Signature]

DRA Motsoaledi, MP
Minister of Health
Date: [Signature]
NATIONAL HEALTH ACT, 2003

REGULATIONS RELATING TO STEM CELL BANKS

The Minister of Health has, in terms of section 68 of the Health Act, 2003 (Act No 61 of 2003), made regulations in the Schedule.

SCHEDULE

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-

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

"Council" means the National Health Research Ethics Council referred to in section 72 of the Act;

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

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

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

“stem cells” means cells that have both the capacity to self-regenerate as well as to differentiate into mature specialised cells;

“third party” means an organisation or institution commissioned by a stem cell bank to provide services that the stem cell bank cannot perform;

“transplantation transmittable disease” means a disease that can be transmitted by the transplantation of tissue product donated by a person, into the body of another person, including a genetic disease.
Use of stem cells

2. (1) No person, shall —

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

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

(c) release any stem cell products for therapeutic use, unless-

i) these activities are authorised in terms of section 54 of the Act; and

ii) laboratory tests for the following infectious agents which may cause transplantation transmitted diseases have been completed and the results of each are available:

- Syphilis
- Hepatitis B
- Hepatitis C
- Human Immunodeficiency Virus type 1 and 2.

(2) Where stem cells are for autologous use, the tests referred to subregulation (1) (c) (ii) may not be required;

(3) No person shall use stem cells 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)(a);
ii. conducts any activity referred to in sub-regulation (1) (a) or (b), as the case may be, in accordance with the provisions of these regulations;

iii. has obtained informed written consent of the donor even in the case of residual tissue, blood or blood products; and

iv. is sure that the donor has donated voluntarily and it documented as such;

(4) The provisions of subregulation (1) are not applicable to a person transporting human tissue, blood or blood products in the usual course of business as a carrier, if special transport requirement are adhered to.

Application for authorisation

3. (1) An application for authorisation shall be made to the Director-General;

(2) The application referred to in sub-regulation (1) shall contain the following information;

(a) the name of the bank;
(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 sub-regulation

(a) request that the stem bank be investigated;
(b) Obtain such information as she or he deems necessary for the consideration of the application.
(c) authorise the applicant concerned as a stem cell bank subject to such conditions as the Director-General may determine.

Suspension or withdrawal of authorisation

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

(a) any premises or equipment used by the stem cell bank are in any way hazardous to health;

(b) the authorised stem cell bank is not complying with any requirements, standards of practice, standard operating procedures or policies;

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

(d) the authorised stem cell bank after been afforded an opportunity by the health officer to show cause why the authorisation should not be suspended or withdrawn and the stem cell bank has failed to show such cause;

(e) the Director-General may, suspend or withdraw the authorisation.

(2) the Director-General before suspending or withdrawing an authorisation as contemplated in sub-regulation (1), shall afford the authorised stem cell bank an opportunity to show cause why the authorisation should not be suspended or withdrawn; and

(3) the suspension or withdrawal of authorisation in terms of this regulation shall have the effect that, the authorised stem cell bank shall cease to carry out any activities.
Keeping of records and reporting obligations

5. (1) The authorised stem cell bank shall keep-

(a) a register of stem cell donors in which shall be entered at least the following particulars pertaining to each stem cell donor from whose body the authorised stem cell bank has obtained the stem cell:

(i) the surname, first name and initials or the other names;

(ii) gender;

(iii) unique identification number or other recognised identification number;

(iv) the date of birth or approximate age if the former is not available;

(v) the address;

(vi) the nature and quality of the stem cells donation concerned;

(vii) reason for acquiring the stem cells; and

(viii) a record of the written informed consent;

(b) a record of stem cell donations in which shall be entered the following information:

(i) a unique identifiable code which will be traceable to the stem cell donor while protecting the donor’s identity;

(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 stem cell donation from the relevant donor;
(iv) the name and address of the stem cell bank/organisation or institution from whom the stem cell donation concerned was received;

(v) the date on which the stem cell donation concerned was received from the stem cell bank/organisation or institution referred to in (iv)

(vi) the results of tests for transplantation transmittable diseases and/or genetic traits if any is known;

(vii) the results of tissue typing if available;

(viii) whether any serious adverse events or reaction or death was reported following upon the treatment and the serial number of the entry in respect of the reaction or death as recorded in the register of adverse events, including transplantation communicable diseases;

(ix) any stem cells rejected, reasons for rejection;

(x) if the stem cells were condemned or discarded —
   (aa) the date on which it was condemned or discarded;
   and
   (bb) the reason for which it was condemned or discarded;
   (cc) the method used for discarding

(xi) long term outcomes of stem cell donation and transplants of the living donor and recipient;

(c) a record of statistics in respect of cell donations, in which shall be entered at least the following information in respect of all the stem cell donations and the supply of such stem cell donation by the authorised stem cell bank over each month;
i) the number of stem cell donors and recipients;

ii) the type and total number of stem cells donations supplied;

iii) the names and addresses of the organisations, institutions or persons to whom the cell were supplied;

iv) the number of stem cell donations which were condemned or discarded and the reason for which they were condemned or discarded;

v) the nature and number of stem cells donation which gave results indicative of microbial contamination.

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

vii) the number of stem cells in storage and the period for such storage;

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

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

(2) The authorised stem cell bank must –

(a) inform the Director-General of any change in its name, address or a responsible person;
(b) provide the health officer for the area in which the stem cell donation were supplied immediately with the information referred to in subregulation (1)(c); and

(c) inform Director General in writing 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 stem cell bank with regard to all information pertaining to stem cells donors and recipients; and

6. The Director-General shall establish and maintain an accessible database of authorised stem cell institutions or organizations, specifying the activities for which they have been authorised.

Additional duties of the health officer

7. (1) A health officer may, as far as stem cells or any matter relating thereto is considered –

(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, of tissue or any tissue product or of any device or test reagent or other material used in the testing or preparation of such tissue or tissue product;

(b) mark or seal any container with stem cell or any device, test reagent or substance;

(c) request information or registers from the management of the authorised stem cell bank and interrogate any member of the staff of the authorised stem cell bank in connection with —
   i) any premises, equipment or methods used or being used by the authorised stem cell bank;
   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 stem cells; or

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

**Inspection and control measures**

8. A stem cell bank shall be inspected at least once every year to ensure that it complies with these regulations and any other relevant requirements.
Traceability

9. Stem cells 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 products associated with it;

(c) all stem cells be identified with a label that contains the information or references allowing a link to the information referred to in regulation 5(1) (b);

(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.

Data protection and confidentiality

10. An authorised stem cell bank shall -

a) ensure that all data, including genetic information, collated within the scope of this regulation remain confidential at all times.

b) for that purpose of subregulation (1), an authorised stem cell bank 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.

   (ii) procedures are in place to resolve data discrepancies;

   (iii) no unauthorised disclosure of information occurs, whilst
guaranteeing the traceability of donations; and
(iv) anonymity and privacy of donors are protected

Quality and safety of stem cells

11. (1) An authorised stem cell bank shall take necessary measures to ensure that-

a) an updated quality control and safety system based on the principle of best laboratory and, manufacturing practice is put in place;
b) the quality control and safety system referred to in paragraph (a) includes at least the following documentation;

(i) standard operating procedures (SOP);
(ii) guidelines;
(iii) training and reference manuals;
(iv) reporting forms;
(v) donor records; and
(vi) information on the final destination of the stem cells

c) the documentation referred to in paragraph (a) and (b) is available for inspection by the health officer.

Responsible person

12. (1) Responsible persons shall be responsible for:

(a) ensuring that stem cells in the authorised stem cell bank be handled according to these regulations.

(b) providing information to the Director-General as required in terms of this regulation; and
(c) compliance with the requirements of these regulations.

(2) where there is a change of the responsible person, an authorised stem cell bank shall immediately inform the Director-General of that fact.

Stem cell quarantine

13. Stem cells shall be kept in quarantine until such times as the requirements relating to donor information and test results have been met.

Stem cell processing

14. (1) An authorised stem cell bank shall include in their standard operating procedures and guidelines:

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

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

(2) any modification to the process used in the preparation of stem cells shall also meet the criteria laid down in its standard operating procedure.

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

Stem cell storage condition

15. An authorised stem cell bank shall -
(1) ensure that all procedures associated with the storage of cells are documented in standard operating procedures and that the storage conditions comply with the requirements referred to in standards of practice.

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

Labeling, documentation and packaging

16. An authorised stem cell 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 the 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 stem cell bank(s) responsible for determining donor suitability, processing and distribution;
   iv) expiration date (if applicable);
   v) acceptable storage conditions;
   vi) disinfection or sterilisation procedure utilized (if applicable);
   vii) preservative and/or method of preservation (if applicable)
   viii) quality of cells and/or stem cells expressed as volume, weight, dimensions, if applicable;
   ix) potential residues of processing agent(s) solutions
   x) preservative and/or method of preservation (if applicable); and
   x) sterility status.
Distribution

17. (1) An authorised stem cell bank shall ensure the quality of stem cells during distribution is not compromised; and

(2) the Minister will determine allocation of stem cells.

Relationship between authorised stem cell banks and third parties

18. An authorised stem cell 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) establish written agreements with the third party each time an external activity takes place which influence the quality and safety of stem cells processed cooperation with a third party, and in particular in the following circumstances:

(a) where an authorised stem cell bank entrusts one of the activities in 2(l)(a) and (b) to a third party;

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

(c) where an authorised stem cell bank distributes stem cells harvested by third party;

(d) an authorised stem cell bank shall not provide services to a third party which is not accredited by the South African Accreditation System;
(3) keep a complete list of the agreements they have established with third parties;

(4) ensure that agreements between authorised stem cell bank and third parties shall specify the responsibilities of the third parties and detailed procedures;

(5) provide copies of agreements with the third party on request to the Director-General;

Appeals

19. (1) A stem cell bank who applied for authorization 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 stem cell bank as the case may be;

(2) an appeal in terms of sub-regulations (1) must be lodged within fourteen (14) days of the receipt of a notice of such decision by the stem cell bank, and must clearly state:

(a) against which decisions such 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 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 the Director General in terms of the provisions of these regulations and inform the stem cell bank, as the case may be, in writing of his or her decision.
Delegations

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

(2) the Director General shall not be divested of a power delegated by her or him under sub-regulation (1) above, and may alter or set aside any decision by an officer taken in the exercise of a power so delegated.

Offences and penalties

21. 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 for a period not exceeding 10 years or to both fine or such imprisonment.

DR A MOTSOALEDI

MINISTER OF HEALTH

DATE: 3/20/12