2005 No 528

New South Wales

Human Tissue Regulation 2005

under the

Human Tissue Act 1983

Her Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Human Tissue Act 1983*.

JOHN HATZISTERGOS, M.L.C.,
Minister for Health

Explanatory note

The object of this Regulation is to remake, with some changes as a consequence of the amendments made by the *Health Legislation Amendment Act 2004*, the provisions of the *Human Tissue Regulation 2000*. The new Regulation makes provision for or with respect to the following matters:

(a) the certificates required to be completed before making a donation of blood or semen and the persons who are able to witness such a certificate,

(b) the particulars required in relation to an application for authorisation to carry on a business of supplying semen, the conditions to which authorisations are subject, the qualifications of certain employees of such a business and the requirements in relation to the premises at which such business is to be carried on,

(c) the amount of blood or semen that will give rise to a presumption that a person is carrying on a business of supplying blood or semen,

(d) the means by which consent may be given to the removal of certain tissue,

(e) the period for which certain tissue may be retained after being lawfully removed,

(f) organisms and substances that are prescribed contaminants for the purposes of the Act,

(g) the classes of medical practitioners who are eligible for appointment as "designated specialists" under the Act.

This Regulation is made under the *Human Tissue Act 1983*, including sections 5 (2) (b), 20D, 20F (6), 21A (b), 21H (2), 21I (1) and (3), 21M (b), 23 (3) (b), 24 (3), 34 (1) (b2) and 39 (the general regulation-making power).

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This Regulation comprises matters of a machinery nature and matters that are not likely to impose an appreciable burden, cost or disadvantage on any sector of the public.

This Regulation is made in connection with the staged repeal of subordinate legislation under the *Subordinate Legislation Act 1989*.

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Human Tissue Regulation 2005

under the

Human Tissue Act 1983

Part 1 Preliminary

1 Name of Regulation

This Regulation is the *Human Tissue Regulation 2005*.

2 Commencement

This Regulation commences on 1 September 2005.

Note. This Regulation replaces the *Human Tissue Regulation 2000* which is repealed on 1 September 2005 under section 10 (2) of the *Subordinate Legislation Act 1989*.

3 Definitions

(1) In this Regulation:

AS 3864—1997 means AS 3864—1997, *Medical refrigeration equipment—For the storage of blood and blood products*, published by Standards Australia, as in force on 1 September 2005.

Director-General means the Director-General of the Department of Health.

the Act means the *Human Tissue Act 1983*.

(2) Notes in this Regulation do not form part of this Regulation.

Part 2 Certificates

4 Certificates relating to donors

For the purposes of the definition of ***certificate*** in section 20D (1) of the Act, the prescribed form in relation to a donation of blood or semen is Form 1 of Schedule 1.

5 Prescribed witnesses

For the purposes of section 20D (2) of the Act, the following persons are prescribed witnesses:

(a) medical practitioners or nurses employed where the blood is to be removed or where the semen is to be obtained or received,

(b) persons who:

(i) are employed where the blood is to be removed or where the semen is to be obtained or received, and

(ii) have been nominated by their employer as appropriate persons to witness signatures, and

(iii) have been approved by the Director-General in writing as appropriate persons to witness signatures.

6 Keeping of certificates

(1) A certificate signed for the purposes of section 20D of the Act must be retained, for a period of not less than 10 years from the date on which it was signed, by the person by whom the blood was removed or by whom the semen was obtained or received.

(2) If the person who removed the blood, or obtained or received the semen, did so in the person's capacity as an employee or agent of some other person or body, that other person or body must retain the relevant certificate.

Maximum penalty: 2 penalty units.

Part 3 Regulation of business supplying semen

7 Applications for authorisations

(1) For the purposes of section 21H (2) of the Act, the prescribed particulars to be contained in or to accompany an application for an authorisation to carry on the business of supplying semen are the following:

(a) the full name and address of the applicant,

(b) the type of business to be carried on,

(c) the proposed name of the business,

(d) the proposed location of the business (details of which are to include two copies of sketch plans of the premises at which it is proposed to carry on the business, drawn to a scale of at least 1:100 and showing the dimensions of each part of the premises and the use to which each part is to be put, with any proposed alterations or extensions to the premises shown by distinctive colouring or cross-hatching),

(e) details of the management structure of the business (including the full names of key personnel involved in its administration),

(f) the full name and qualifications of the person (or each person, if more than one is to be appointed) who will superintend the collection, testing, storage and supply of semen and the keeping of records relating to that collection, testing, storage and supply,

(g) in the case of a business to be conducted by a corporation:

(i) the registered number (being the Australian Company Number or Australian Registered Body Number) of the corporation, and

(ii) the full name and residential address of each director of the corporation, and

(iii) the full name and residential address of the principal executive officer of the corporation, and

(iv) the full name and residential address of the secretary of the corporation,

(h) in the case of a business to be conducted by a corporation limited by shares:

(i) the types of shares and the number of shares of each type issued, and

(ii) in the case of a private corporation, the full name of, and the number of shares held by, each shareholder, and

(iii) in the case of a public corporation, a list of the 20 largest shareholdings and of the full names of the holders of each of those shareholdings, and

(iv) if shares in the corporation are held by another corporation, the name of the ultimate holding company of those shares.

(2) In this clause:

ultimate holding company, in relation to a corporation, means a body corporate that is a holding company of the corporation and is not itself a subsidiary of any body corporate.

8 Qualifications for persons performing particular functions

For the purposes of section 21I (1) (c) of the Act, a person employed to superintend the collection, testing, storage or supply of semen, or the keeping of records relating to that collection, testing, storage or supply, must be a medical practitioner.

9 Requirements for premises

For the purposes of section 21I (1) (d) of the Act, premises used for carrying on the business of supplying semen must include the following:

(a) a reception area,

(b) an area set aside for the processing of semen for storage,

(c) an area set aside for the storage of semen that is equipped with one or more cryo-storage vessels for the storage of semen in liquid nitrogen,

(d) an area set aside for the secure storage of records relating to the collection, identification, testing, storage and supply of semen,

(e) if semen is to be provided by donors at the premises, semen collection rooms,

(f) if testing of semen for prescribed contaminants is to be carried out on the premises, a laboratory set aside for that purpose.

10 Conditions to which authorisations are subject

For the purposes of section 21I (3) of the Act, the conditions set out in Schedule 2 are prescribed in respect of an authorisation to carry on the business of supplying semen.

11 Prescribed quantity of semen

For the purposes of section 21M (b) of the Act, the prescribed quantity of semen is 1 millilitre.

Part 4 Removal of tissue after death

12 Consent to removal of tissue

For the purposes of sections 23 (3) (b) and 24 (3) of the Act, the consent of a senior available next of kin of a deceased person may be given verbally if:

(a) an audio or audio visual recording is made of the consent, and

(b) the senior available next of kin has consented to the making of that audio or audio visual recording.

Note. This clause allows a senior available next of kin of a deceased person to consent verbally to the removal of tissue from the deceased person for transplant purposes or other purposes. Under the Act, consent may also be given in writing (for example, by facsimile or other means).

13 Retention of tissue lawfully removed

For the purposes of section 34 (1) (b2) of the Act, tissue may be retained for a period not exceeding 72 hours if the tissue was removed from the body of a person during medical, dental or surgical treatment performed as a matter of urgency in order to save the life of the person or to prevent serious damage to the health of the person.

Part 5 Miscellaneous

14 Prescribed contaminants

The following organisms and substances are declared to be prescribed contaminants for the purposes of the Act, including for the purposes of section 20F (6):

Hepatitis B virus

Hepatitis B surface antigen

Hepatitis C virus

Hepatitis C antibody

Human T-lymphotropic virus Type-I (HTLV-I)

Human T-lymphotropic virus Type-I (HTLV-I) antibody

Human immunodeficiency virus

Human immunodeficiency virus antibody

Treponema pallidum

Treponema pallidum related antibody

15 Designated specialists

For the purposes of section 5 (2) (b) of the Act, the following classes of medical practitioners are prescribed:

(a) Fellows of the Australasian College of Emergency Medicine,

(b) Fellows of the Australian and New Zealand College of Anaesthetists,

(c) Fellows of the Joint Faculty of Intensive Care Medicine of the Australian and New Zealand College of Anaesthetists and the Royal Australasian College of Physicians,

(d) Fellows of the Royal Australasian College of Physicians,

(e) Fellows of the Royal Australasian College of Surgeons,

(f) Fellows of the Royal Australian College of Obstetricians and Gynaecologists.

16 Prescribed quantities of blood and blood products

For the purposes of section 21A (b) of the Act:

(a) the prescribed quantity of blood is 1 litre, and

(b) the prescribed quantity of blood products is, in relation to any particular kind of blood product, the quantity of blood products of that kind that is equivalent to the quantity of blood products of that kind that can be derived or extracted from 1 litre of blood.

17 Savings provision

Any act, matter or thing that, immediately before the repeal of the *Human Tissue Regulation 2000*, had effect under that Regulation is taken to have effect under this Regulation.

Schedule 1 Form

Form 1 Donor certificate

(Clause 4)

(Human Tissue Act 1983, section 20D)

Questions

(Please circle your answers)

	To the best of your knowledge have you:	
1	in the last 6 months had an illness with swollen glands and a rash, with or without a fever?	Yes/No
2	ever thought you could be infected with HIV or have AIDS?	Yes/No
3	ever "used drugs" by injection or been injected, even once, with drugs not prescribed by a doctor or dentist?	Yes/No
4	ever had treatment with clotting factors such as Factor VIII or Factor IX?	Yes/No
5	ever had a test which showed you had Hepatitis B, Hepatitis C, HIV or HTLV?	Yes/No
6	in the last 12 months engaged in sexual activity with someone you might think would answer "Yes" to any of questions 1–5?	Yes/No
7	since your last donation or in the last 12 months engaged in sexual activity with a new partner who currently lives or has previously lived overseas?	Yes/No
	Within the last 12 months have you:	
8	had male to male sex?	Yes/No
9	engaged in sexual activity with a male who you think might be bisexual?	Yes/No
10	been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?	Yes/No
11	engaged in sexual activity with a male or female sex worker?	Yes/No
12	been injured with a used needle (needlestick)?	Yes/No
13	had a blood or body fluid splash to eyes, mouth, nose or to broken skin?	Yes/No
14	had a tattoo (including cosmetic tattooing), skin piercing, electrolysis or acupuncture?	Yes/No
15	been imprisoned in a prison or lock-up?	Yes/No

16	had a blood transfusion?	Yes/No
17	had (yellow) jaundice or hepatitis or been in contact with someone who has?	Yes/No

I declare that I have understood the information on this form and answered the questions in the declaration to the best of my knowledge.

Signature of donor
Name *(please print)*

Signature of witness
Name *(please print)*

Schedule 2 Prescribed conditions—authorisations to carry on business of supply of semen

(Clause 10)

1 General

Semen may be stored only at:

(a) the premises specified in the authorisation, or

(b) a pathology laboratory accredited under section 23DN of the *Health Insurance Act 1973* of the Commonwealth, or

(c) a laboratory accredited for the storage of semen by an accrediting body of the Fertility Society of Australia, or

(d) the premises of an exempt supplier.

2 Testing of semen and blood

(1) All donated semen (other than semen donated solely for the purpose of its use for the artificial insemination of the donor's spouse) must be tested by culture of specimens in aerobic, anaerobic and carbon dioxide enriched environments.

(2) If any semen is found by the tests referred to in subclause (1) to be positive for any pathogenic micro-organism, the semen must not be supplied for use for any therapeutic purpose unless that therapeutic purpose is approved by the Director-General.

(3) Blood samples must be taken from all donors at the time of donation (or at an earlier time that is as close as practicable to that time) and at the expiry of the quarantine period referred to in clause 5, and must be tested for the prescribed contaminants using the tests approved by the Director-General.

(4) If any blood is found by the tests referred to in subclause (3) to be positive for a prescribed contaminant:

(a) the donor and the referring medical practitioner must be notified of the result, and

(b) any stored semen, or semen subsequently obtained, from that donor must not be supplied for use for any therapeutic purpose unless that therapeutic purpose is approved by the Director-General, and

(c) the cryo-storage vessel containing the semen must be prominently labelled to indicate the presence of a contaminant.

3 Labelling of straws of semen

Each straw containing donated semen must be labelled with a code that corresponds to an entry in the records showing the donor and the date of the donation.

4 Storage and transportation of semen

All semen must be stored and transported in cryo-storage vessels containing liquid nitrogen.

5 Quarantine period

Semen must not be released for use until after the expiry of such quarantine period (if any) as may be recommended by the Fertility Society of Australia.

6 Quality assurance

A quality assurance program, approved by the Fertility Society of Australia, must be established and maintained by the authorised supplier.

7 Facilities must comply with certain requirements

The facilities provided by the authorised supplier must meet the requirements of an accrediting body of the Fertility Society of Australia.

8 Records

(1) The following records must be maintained by the authorised supplier in respect of each donation:

(a) the full name and date of birth of the donor,

(b) the donor's written consent to the use of his semen for the artificial insemination of women,

(c) the results of all tests performed in accordance with clause 2 (1) and (3),

(d) the identification details referred to in clause 3,

(e) the name of the medical practitioner to whom the semen is supplied,

(f) any quality assurance records made for the purposes of clause 6.

(2) The records required by subclause (1) must be retained at the premises specified in the authorisation:

(a) in the case of records that relate to donors aged 20 years or over at the date of donation—for a period of not less than 10 years after the date of donation, or

(b) in the case of records that relate to donors aged under 20 years at the date of donation—until the donor to whom the record relates attains, or would have attained, the age of 30 years.