1995—No. 487

HUMAN TISSUE ACT 1983—REGULATION

(Human Tissue Regulation 1995)

NEW SOUTH WALES

[Published in Gazette No. 105 of 1 September 1995]

HIS Excellency the Governor, with the advice of the Executive Council, and in pursuance of the Human Tissue Act 1983, has been pleased to make the Regulation set forth hereunder.

ANDREW REFSHAUGE,
Deputy Premier and Minister for Health.

Citation

1. This Regulation may be cited as the Human Tissue Regulation 1995.

Commencement

2. This Regulation commences on 1 September 1995.

Definitions

3. (1) In this Regulation:

"AS 3864" means the Australian Standard Specification entitled "Medical Refrigeration Equipment for the Storage of Blood and Blood Products and Containers for the Transport of Blood and Blood Products" and numbered AS 3864 of the Standards Association of Australia, as in force on 1 September 1995;

"Director–General" means the Director-General of the Department of Health;

"the Act" means the Human Tissue Act 1983.

(2) In this Regulation, a reference to a form is a reference to a form set out in Schedule 1.

Prescribed contaminants: sec. 4

4. The following organisms and substances are declared to be prescribed contaminants for the purposes of the Act:

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

Designated specialists: sec. 5

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

(a) Fellows of the Australian and New Zealand College of Anaesthetists;

(b) Fellows of the Royal Australasian College of Physicians;

(c) Fellows of the Royal Australasian College of Surgeons;

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

Certificates relating to blood and semen donors: sec. 21C

6. For the purposes of section 21C (1) and (2) of the Act, the prescribed form is:

(a) Form 1, except in the case of a form to be completed by a donor referred to in paragraph (b); and

(b) Form 2, in the case of a form to be completed by a donor who donates blood solely for the purpose of clinical trials approved by the Director-General.

Prescribed witnesses in relation to certificates by donors: sec. 21C

7. (1) For the purposes of section 21C (1) of the Act, a prescribed person is:

(a) a medical practitioner; or

(b) a nurse; or

(c) a person whose nomination by the person's employer as an appropriate person for the purpose of being a prescribed person is approved by the Director-General,

who is employed where the blood is to be removed or where the semen is to be obtained or received.

(2) For the purposes of section 21C (2) of the Act, a prescribed person is:

(a) a medical practitioner; or

(b) a nurse; or

(c) a person whose nomination by the person's employer as an appropriate person for the purpose of being a prescribed person is approved by the Director-General,

who is employed where the blood is to be removed or used or where the semen is to be obtained, received or used.

(3) For the purposes of section 21C (3) (a) and (b) of the Act, a prescribed person is:

(a) a medical practitioner; or

(b) a nurse; or

(c) a person whose nomination by the person's employer as an appropriate person for the purpose of being a prescribed person is approved by the Director-General,

who is employed where the certificate is signed.

Keeping of certificates: sec. 29C

8. (1) A certificate signed for the purposes of section 21C (1) of the Act is to 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) A certificate signed for the purposes of section 21C (2) of the Act is to 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 or semen was used.

(3) If the person who removed or used the blood, or obtained, received or used 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 is to retain the relevant certificate.

Maximum penalty: 2 penalty units.

Applications for authorisations: secs. 21H and 21I

9. For the purposes of sections 21H and 21I of the Act, the prescribed particulars to be contained in or to accompany an application for an authorisation to carry on a business of supplying blood, blood products or semen are those specified in Schedule 2.

Qualifications for persons performing particular functions: sec. 21I

10. (1) The qualifications specified in this clause are prescribed for the purposes of section 21I (1) (c) of the Act.

(2) A person employed to superintend the collection, testing, storage or supply of blood or blood products, or the keeping of records relating to that collection, testing, storage or supply, must be a Fellow of the Royal College of Pathologists of Australasia or a medical practitioner recognised by that College as a specialist pathologist.

(3) 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.

(4) A person employed to collect blood from donors must be:

(a) a medical practitioner; or

(b) a registered nurse; or

(c) an enrolled nurse working under the direct supervision of a registered nurse.

Requirements for premises: sec. 21I

11. (1) The requirements specified in this clause are prescribed for the purposes of section 21I (1) (d) of the Act.

(2) Premises used for carrying on the business of supplying blood or blood products must include the following:

(a) a reception area;

(b) an area set aside for the processing of blood for storage;

(c) an area set aside for the storage of blood and blood products;

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

(e) if blood is to be collected from donors at the premises:

(i) a blood collection room; and

(ii) a recovery and refreshment area;

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

(3) An area set aside for the storage of blood and blood products must be equipped with one or more refrigerators that comply with the relevant provisions of AS 3864.

(4) Premises used for carrying on the business of supplying semen must include the following:

(a) a reception area;

(b) an area set aside €or the processing of semen for storage;

(c) an area set aside for the storage of semen;

(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.

(5) An area set aside for the storage of semen must be equipped with one or more cryo-storage vessels for the storage of semen in liquid nitrogen.

Conditions to which authorisations are subject: sec. 21I

12. For the purposes of section 21I (3) of the Act:

(a) the conditions set out in Schedule 3 are prescribed in respect of an authorisation to carry on the business of supplying blood or blood products; and

(b) the conditions set out in Schedule 4 are prescribed in respect of an authorisation to carry on the business of supplying semen.

Prescribed quantities of blood: sec. 21M

13. For the purposes of section 21M (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; and

(c) the prescribed quantity of semen is 1 millilitre.

Repeal

14. (1) The Human Tissue Regulation 1984 is repealed.

(2) Any act, matter or thing that, immediately before the repeal of the Human Tissue Regulation 1984, had effect under that Regulation is taken to have effect under this Regulation.

SCHEDULE l—FORMS

Form 1

(Cl. 6 (a))

HUMAN TISSUE ACT 1983

(Section 21C)

***PART A—CERTIFICATE BY PERSON DONATING BLOOD**

BEFORE YOU GIVE BLOOD

There are some people in the community who MUST NOT donate blood because it may transmit infections to patients who receive it.

You must complete this form if you want to donate blood. If you do not know how to answer any of the questions, please check with the interviewing sister. It is against the law to knowingly make a false or misleading statement. If you do, you may receive a $5,000 fine or 1 year in prison, or both.

TO THE BEST OF MY KNOWLEDGE MY ANSWERS TO THE FOLLOWING QUESTIONS ARE TRUE

1. Have you any reason to believe that:

—you have AIDS (Acquired Immune Deficiency Syndrome)? Yes No

—you have been infected with the virus that causes AIDS (HIV)? Yes No

2. In the last 6 months have you had:		
—night sweats?	Yes	No
—unexplained weight loss?	Yes	No
—persistent fever?	Yes	No
—diarrhoea?	Yes	No
—swollen glands?	Yes	No
3. Have you had male to male sexual activity since 1997?	Yes	No
4. Have you had sexual activity with a bisexual male since 1977?	Yes	No
5. Have you had sexual activity with any person who may have been exposed to the virus that causes AIDS (HIV)?	Yes	No
6. Have you EVER injected yourself, or been injected with, any drug not prescribed by a doctor?	Yes	No
7. Have you EVER shared drug needles?	Yes	No
8. Have you been accidentally stuck with a used needle in the last 12 months?	Yes	No
9. Have you EVER been a male or female prostitute?	Yes	No
10. Have you had sexual activity with a male or female prostitute in the last 12 months?	Yes	No
11. Have you been tattooed within the last 12 months?	Yes	No
12. Have you received a blood transfusion or treatment with human blood products in the last 12 months?	Yes	No
13. In the last 2 years have you had jaundice or hepatitis, or been in close contact with any person with either of these illnesses?	Yes	No
14. Are the answers to questions 1–13 also correct for your present and past spouse(s) and present and past sexual partner(s)?	Yes	No

Please do not sign the form yet.

Take it with you to the interviewer.

Signature of Donor .....

Name (PRINT) .....

Signature of Witness .....

Name (PRINT) .....

DATE .....

***PART B—CERTIFICATE BY PERSON DONATING SEMEN**

BEFORE YOU DONATE SEMEN

There are some people in the community who MUST NOT donate semen because it may transmit infections to patients who receive it.

You must complete this form if you want to donate semen. If you do not know how to answer any of the questions. please check with a nurse or medical practitioner. It is against the law to knowingly make a false or misleading statement. If you do, you may receive a $5,000 fine or 1 year in prison, or both.

TO THE BEST OF MY KNOWLEDGE MY ANSWERS TO THE FOLLOWING QUESTIONS ARE TRUE

1. Have you any reason to believe that:		
—you have AIDS (Acquired Immune Deficiency Syndrome)?	Yes	No
—you have been infected with the virus that causes AIDS (HIV)?	Yes	No
2. In the last 6 months have you had:		
—night sweats?	Yes	No
—unexplained weight loss?	Yes	No
—persistent fever?	Yes	No
—diarrhoea?	Yes	No
—swollen glands?	Yes	No
3. Have you had male to male sexual activity since 1977?	Yes	No
4. Have you had sexual activity with a bisexual male since 1977?	Yes	No
5. Have you had sexual activity with any person who may have been exposed to the virus that causes AIDS (HIV)?	Yes	No
6. Have you EVER injected yourself, or been injected with, any drug not prescribed by a doctor?	Yes	No
7. Have you EVER shared drug needles?	Yes	No
8. Have you been accidentally stuck with a used needle in the last 12 months?	Yes	No
9. Have you EVER been a male or female prostitute?	Yes	No
10. Have you had sexual activity with a male or female prostitute in the last 12 months?	Yes	No
11. Have you been tattooed within the last 12 months?	Yes	No
12. Have you received a blood transfusion or treatment with human blood products in the last 12 months?	Yes	No
13. In the last 2 years have you had jaundice or hepatitis, or been in close contact with any person with either of these illnesses?	Yes	No
14. Are the answers to questions 1–13 also correct for your present and past spouse(s) and present and past sexual partner(s)?	Yes	No

Please do not sign the form yet.

Take it with you to a nurse or medical practitioner.

Signature of Donor .....

Name (PRINT) .....

Signature of Witness .....

Name .....

DATE .....

* Delete whichever Part is inapplicable.

Form 2

(Cl. 6 (b))

HUMAN TISSUE ACT 1983

(Section 21C)

CERTIFICATE BY PERSON DONATING BLOOD FOR USE IN A CLINICAL TRIAL

The following certificate must be completed and signed by any person who wishes to donate blood for the purposes of a clinical trial conducted by ..... at ..... Please read it carefully. It is against the law to knowingly make a statement which is false or misleading. If you do, you may receive a $5,000 fine or 1 year in prison, or both. If in doubt please consult a medical practitioner or nurse.

CERTIFICATE

I hereby certify that to the best of my knowledge all of the following statements are true:

1. I have reason to believe that I am carrying the virus that causes Acquired Immune Deficiency Syndrome (AIDS).
2. I am donating blood solely for the purposes of its use in a clinical trial which is being conducted by ..... at .....

I am signing this certificate in the presence of a *medical practitioner/nurse/other person nominated for that purpose who is employed at the place I am attending.

Name: .....
(Please print)

.....
Signature of donor

.....
Signature of witness

Date: .....

* Delete whichever is inapplicable.

SCHEDULE 2—PARTICULARS TO ACCOMPANY APPLICATION FOR AUTHORISATION TO CARRY ON BUSINESS OF SUPPLYING BLOOD, BLOOD PRODUCTS OR SEMEN

(Cl. 9)

1. Full name and address of applicant.
2. Type of business to be carried on.
3. Proposed name of business.
4. Proposed location of 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).
5. Details of the management structure of the business (including the full names of key personnel involved in its administration).
6. In the case of a business to be conducted by a corporation:
   (a) the registered number of the corporation; and
   (b) the address of the registered office of the corporation; and
   (c) the full name, residential address and position of
      (i) each current director of the corporation; and
      (ii) the principal executive officer of the corporation; and
      (iii) the secretary or, if there is more than one, each secretary of the corporation;
   (d) in the case of 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;

(e) if the shares are held by another corporation, the name of the ultimate holding corporation.

7. 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 blood, blood products or semen and the keeping of records relating to that collection, testing, storage and supply.

SCHEDULE 3—PRESCRIBED CONDITIONS FOR AUTHORISATIONS FOR THE SUPPLY OF BLOOD OR BLOOD PRODUCTS

(Cl. 12 (a))

General

1. (1) The collection, storage and supply of blood and blood products must be for the following purposes only:

(a) the transfusion of blood back to the person from whom the blood was removed; or

(b) the use of blood or blood products for other therapeutic purposes, or for medical purposes or scientific purposes, involving the treatment of the person from whom the blood was removed; or

(c) the use of blood or blood products for the purpose of cross-matching with other blood or blood products.

(2) Blood for storage or supply may be collected only at the premises specified in the authorisation or at the premises of an exempt supplier.

(3) Blood and blood products 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) the premises of an exempt supplier.

Attendance by medial practitioner

2. A medical practitioner must be in attendance whenever blood is being collected from a donor unless the donor:

(a) falls within the criteria for acceptability of blood donors prepared by the Australian Red Cross National Blood Transfusion Committee; and

(b) is not pregnant or, if pregnant, is not expected to give birth within the following 4 weeks.

Statement to be signed

3. (1) An intending blood donor must be required to complete and sign a statement in or to the effect of Part A of Form 1.

(2) If the intending donor is unable to complete and sign a statement in accordance with subclause (l), blood must not be collected from the intending donor unless:

(a) the matter is referred to a medical practitioner; and

(b) the medical practitioner to whom the matter is referred gives written authority for the collection of the blood; and

(c) any conditions specified by the medical practitioner to whom the matter is referred are complied with.

Testing of blood

4. (1) All donated blood must be tested for ABO and Rh (D) blood groups.

(2) All donated blood must be tested for the prescribed contaminants using the tests approved pursuant to section 21DA (3) (b) (ii) or 21DA (4) (a) (ii) of the Act.

(3) If any blood is found by the tests referred to in subclause (2) to be positive for a prescribed contaminant:

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

(b) the blood must not be used for any therapeutic purpose without the approval of the Director-General; and

(c) the container of the blood must be prominently labelled with the biohazard symbol.

Labelling of containers of blood and blood products

5. (1) The container of any donated blood, or of any blood product derived or extracted from donated blood, must be labelled with:

(a) the name of the business conducted by the authorised supplier; and

(b) a unique identification number; and

(c) the product type; and

(d) the blood group; and

(e) the date of collection; and

(f) the expiry date; and

(g) the full name and date of birth of the donor; and

(h) the signature of the donor.

(2) Before any donated blood, or any blood product derived or extracted from donated blood, is released for use, its container must be labelled with the name of the medical practitioner requesting the blood or blood product.

(3) The particulars referred to in subclause (1) (b), (c) and (d) must be printed in both of the following forms:

(a) machine-readable barcode printed in accordance with specifications prepared by the Committee for Commonality in Blood Banking Automation, as published by the America Blood Commission; and

(b) readable alpha-numeric form corresponding with the machine-readable code referred to in paragraph (a).

(4) The identification number referred to in subclause (1) (b) must be integrated with the numbering system used throughout Australia by the Australian Red Cross Society.

Storage and transportation of blood and blood products

6. All blood and blood products must be stored and transported in refrigeration equipment that complies with the relevant provisions of AS 3864.

Service and maintenance of equipment

7. All equipment must be properly serviced and maintained in good working order, and a record made of all servicing and maintenance of the equipment for the life of the equipment.

Certain blood and blood products to be discarded

8. Any blood or blood products must be discarded if the temperature during storage in the liquid state rises above 10°C for more than 30 minutes at any one time.

Emergency resuscitation equipment

9. Emergency resuscitation equipment must be immediately available at all times while blood is being collected from donors, and staff trained to use the equipment must be in attendance throughout the blood collection and recovery period.

Quality assurance

10. A quality assurance program, approved by the Director-General, must be established and maintained by the authorised supplier.

Records

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

(a) the donor's written consent and the statement completed by the donor in accordance with clause 3 (1);

(b) if a written authority has been given by a medical practitioner in accordance with clause 3 (2), that authority;

(c) the results of all tests performed in accordance with clause 4 (1) and (2);

(d) the identification details referred to in clause 5 (1);

(e) the name of the questing practitioner referred to in clause 5 (2);

(f) any temperature monitoring records made for the purposes of clause 6;

(g) any equipment maintenance records made for the purposes of clause 7;

(h) any quality assurance records made for the purposes of clause 10.

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

(a) where they relate to donors aged 20 years or over at the date of donation—for a period of not less than 10 years from the date of donation; or

(b) where they 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.

(3) If the authorisation is revoked or suspended, or the authorised supplier ceases to carry on the business of supplying blood or blood products, the authorised supplier must deal with the records in accordance with the instructions of the Director-General.

SCHEDULE 4—PRESCRIBED CONDITIONS FOR AUTHORISATIONS FOR THE SUPPLY OF SEMEN

(Cl. 12 (b))

General

1. 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 that purpose by an accrediting body of the Fertility Society of Australia; or

(d) the premises of an exempt supplier.

Testing of semen and blood

2. (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 used for any therapeutic purpose without the approval of 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 pursuant to section 21DA (3) (b) (ii) or 21DA (4) (a) (ii) of the Act.

(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 used for any therapeutic purpose without the approval of the Director-General; and

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

Labelling of straws of semen

3. Each straw containing donated semen must be labelled with a code identified in the records with the donor and the date of the donation.

Storage and transportation of semen

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

Quarantine period

5. 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.

Quality assurance

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

Facilities must comply with certain requirements

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

Records

8. (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;

(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 authority:

(a) where they 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) where they 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.

(3) If the authorisation is revoked or suspended, or the authorised supplier ceases to carry on the business of supplying semen, the authorised supplier must deal with the records in accordance with the instructions of the Director-General.

NOTES

TABLE OF PROVISIONS

EXPLANATORY NOTE

The object of this Regulation is to repeal the Human Tissue Regulation 1984 and to remake the provisions of that Regulation, other than the provisions relating to exempt suppliers and certain consents given by coroners. The provision concerning exempt suppliers related to a period that ended on 31 August 1990, and the provisions concerning coroners, consents have now been incorporated in the Human Tissue Act 1983.

The new Regulation makes provision with respect to the following matters:

(a) organisms and substances that are prescribed contaminants for the purposes of the Act (clause 4);

(b) the classes of medical practitioners that are eligible for appointment as "designated specialists" under the Act (clause 5);

(c) the certificates to be signed by intending donors of blood or semen (clauses 6–8 of the Regulation and Forms 1 and 2 of Schedule 1);

(d) applications for authorisations to carry on the business of supplying blood, blood products or semen, the qualifications of the persons who are to be employed in the business, the premises at which the business is to be carried on and the conditions to which authorisations are subject (clauses 9–12 of the Regulation and Schedules 2–4);

(e) the quantities of blood, blood products or semen that give rise to a presumption that a person (other than the donor) who supplies them to another person on at least 2 occasions, or keeps them on premises he or she occupies, is carrying on the business of supplying blood, blood products or semen (clause 13); and

(f) other provisions of a technical nature (clauses 1–3 and 14).

The Regulation is made under the Human Tissue Act 1983, including section 39 (the general regulation-making power) and sections 4, 5, 21C, 21H, 21I and 21M.

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