1990 - No. 307

HUMAN TISSUE ACT 1983 - REGULATION

(Relating to the supply of blood, blood products and semen)

NEW SOUTH WALES

[Published in Gazette No. 71 of 1 June 1990]

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.

PETER COLLINS
Minister for Health.

Commencement

1. This Regulation takes effect on 1 June 1990.

Amendment

2. The Human Tissue Regulation 1984 is amended:

(a) by inserting after clause 9 the following clauses:

Exempt suppliers (sec. 4)

10. (1) Any person who was lawfully carrying on the business of supplying blood or blood products immediately before 1 June 1990 is, for the period beginning on that date and ending on 31 August 1990, an exempt supplier for the purposes of the Act in relation to the supply of blood and blood products.

(2) Any person who was lawfully carrying on the business of supplying semen immediately before 1 June 1990 is, for the period beginning on that date and ending on 31 August 1990,

an exempt supplier for the purposes of the Act in relation to the supply of semen.

Prescribed contaminants (sec. 4)

11. 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 immunodeficiency virus.
Human immunodeficiency virus antibody.
Treponema pallidum.
Treponema pallidum related antibody.

Applications for authorisations

12. (1) An application under section 21H of the Act for an authorisation to carry on a business of supplying blood, blood products or semen must be in or to the effect of Form 4.

(2) For the purposes of sections 21H and 21I of the Act, the prescribed particulars to be contained in or to accompany such an application are those specified in Form 4.

Qualifications for persons performing particular functions

13. For the purposes of section 21I (1) (c) of the Act:

(a) a person employed to superintend the collection, testing, storage or supply of blood, blood products or semen, or the keeping of records relating thereto:

(i) must be a medical practitioner having such qualifications (if any) in pathology as may be approved by the National Australian Specialist Qualifications Advisory Committee and having such further qualifications (if any) as may be required by the Pathology Laboratories Accreditation Board; or

(ii) must be a person (whether or not a medical practitioner) having such qualifications (if any) as may be approved by the Director-General; and

(b) a person employed to collect blood from donors:

(i) must be a medical practitioner; or

(ii) must be a registered nurse having such qualifications (if any) in the collection of blood donations as may be approved by the Director-General; and

(c) a person employed to process semen for cryo-storage must be a person having such qualifications (if any) as may be recognised by the Fertility Society of Australia.

Requirements for premises

14. (1) For the purposes of section 211 (1) (d) of the Act, premises used for carrying on the business of supplying blood or blood products must include:

(a) a reception area; and

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

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

(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; and

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

(i) a blood collection room; and

(ii) a recovery and refreshment area; and

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

(2) 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 Australian Standard AS 3770 "Medical Refrigeration Equipment - For the Storage of Blood and Blood Products and Containers for the Transport of Blood and Blood Products".

(3) For the purposes of section 211 (1) (d) of the Act, premises used for carrying on the business of supplying semen must include:

(a) a reception area; and

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

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

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

(e) if semen is to be provided by donors at the premises, a semen collection room; and

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

(4) 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

15. (1) 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 blood or blood products.

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

Prescribed quantities of blood etc. (sec. 21M)

16. 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.

(b) by inserting in Schedule 1 after Form 3A the following Form:

Form 4

(Cl. 12)

HUMAN TISSUE ACT 1983

(Section 21H)

APPLICATION FOR AUTHORISATION TO CARRY ON A BUSINESS OF SUPPLYING BLOOD, BLOOD PRODUCTS OR SEMEN

I,.....
(full name of applicant)

of.....
(address of applicant)

apply for authorisation to carry on the business of supplying:

* blood;
* blood products;
* semen.

The business will be known as:

.....
(propsed name of business)

and will be situated at:

.....
(proposed location of business)

I attach the following information:

(1) The management structure of the business, including the full names of key personnel involved in its administration.

(2) In the case of a business to be conducted by a corporation:

(a) a copy of the certificate of incorporation;

(b) the address of the registered office of the corporation;

(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.

(3) 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 thereto.

(4) Two copies of sketch plans of the premises at which it is proposed to carry on the business, drawn to a scale of 1:100 and showing the dimensions of each part of the premises and the use to which each part is to be put (any proposed alterations or extensions to the premises to be shown by distinctive colouring or cross-hatching).

....
(Print name) *(Signature)*

....
(Position) *(Date)*

* Delete whichever is not applicable

(c) by inserting after Schedule 1 the following Schedules:

SCHEDULE 2 - PRESCRIBED CONDITIONS FOR AUTHORISATIONS FOR THE SUPPLY OF BLOOD OR BLOOD PRODUCTS

(Cl. 15 (1))

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 the Pathology Laboratories Accreditation Act 1981; or

(c) the premises of an exempt supplier.

Attendance by medical 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 requested to complete and sign a statement in or to the effect of Part A of Form 3.

(2) If the intending donor is unable to complete and sign a statement in accordance with subclause (1), 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 following prescribed contaminants, using the tests approved pursuant to section 21DA (3) (b) (ii) or 21DA (4) (a) (ii) of the Act:

Hepatitis B surface antigen.
Hepatitis C antibody.
Human immunodeficiency virus antibody.
Treponema pallidum related antibody.

(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 Australian Standard AS 3770 "Medical Refrigeration Equipment - For the Storage of Blood and Blood Products and for the Transport of Blood and Blood Products".

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:

(a) if the temperature during storage in the liquid state rises above 10°C for more than 30 minutes at any one time; or

(b) if the temperature during storage in the frozen state rises above -18°C for more than 1 minute 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.

Facilities must comply with certain requirements of the Pathology Laboratories Accreditation Act 1981

11. The facilities provided by the authorised supplier must meet the requirements for accreditation of that type of establishment under the Pathology Laboratories Accreditation Act 1981.

Records

12. (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 requesting 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 3 - PRESCRIBED CONDITIONS FOR AUTHORISATIONS FOR THE SUPPLY OF SEMEN

(Cl. 15 (2))

General

1. Semen may be stored only at:

(a) the premises specified in the authorisation; or

(b) a pathology laboratory accredited under the Pathology Laboratories Accreditation Act 1981; 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.

Statement to be signed

2. (1) An intending semen donor must be requested to complete and sign a statement in or to the effect of Part B of Form 3.

(2) If the intending donor is unable to complete and sign a statement in accordance with subclause (1), semen 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 semen; and

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

Testing of semen and blood

3. (1) All donated semen 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 and at intervals of 3 months and 6 months after that time, and must be tested for the following prescribed contaminants, using the tests approved pursuant to section 21DA (3) (b) (ii) or 21DA (4) (a) (ii) of the Act:

Hepatitis B surface antigen.
Hepatitis C antibody.
Human immunodeficiency virus antibody.
Treponema pallidum related antibody.

(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) the semen 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

4. 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

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

Quarantine period

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

Quality assurance

7. 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 of the Pathology Laboratories Accreditation Act 1981

8. The facilities provided by the authorised supplier must meet the requirements for accreditation of that type of establishment under the Pathology Laboratories Accreditation Act 1981 or, in the absence of such requirements, the requirements of an accrediting body of the Fertility Society of Australia.

Records

9. (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 and the statement completed by the donor in accordance with clause 2 (1);

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

(d) the results of all tests performed in accordance with clause 3 (1) and (3);

(e) the identification details referred to in clause 4;

(f) the name of the medical practitioner to whom the semen is supplied;

(g) any quality assurance records made for the purposes of clause 7.

(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 semen, the authorised supplier must deal with the records in accordance with the instructions of the Director-General.

EXPLANATORY NOTE

The object of this Regulation is to amend the Human Tissue Regulation 1984 so as to make provision, consequent on the commencement of the Human Tissue (Amendment) Act 1987, for:

(a) the collection, testing, storage and supply of blood, blood products and semen; and

(b) the regulation of the premises at which the collection, testing, storage and supply of blood, blood products and semen takes place; and

(c) the records to be kept by suppliers of blood, blood products and semen; and

(d) the form to be used in applications to become an authorised supplier of blood, blood products or semen.
