



New South Wales

# Human Tissue Regulation 2010

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*.

CARMEL TEBBUTT, MP  
Minister for Health

## Explanatory note

The object of this Regulation is to remake, with minor amendments, the provisions of the *Human Tissue Regulation 2005*, which is repealed by this Regulation.

This Regulation makes provision with respect to the following:

- (a) the organisms and substances that are prescribed contaminants,
- (b) the classes of medical practitioners who are eligible for appointment as designated specialists,
- (c) the certificate required to be completed before making a donation of blood,
- (d) the amount of blood that will give rise to a presumption that a person is carrying on a business of supplying blood,
- (e) the means by which consent may be given to the removal of certain tissue,
- (f) savings and formal matters.

This Regulation is made under the *Human Tissue Act 1983*, including sections 4 (1) (definition of *prescribed contaminant*), 5 (2) (b), 20D (1) (definition of *certificate*) and (2), 20F (6) (definition of *prescribed contaminant*), 20H, 21A (b), 23 (3) (b), 24 (3), 34 (1) (b2) and 39 (the general regulation-making power).

This Regulation comprises or relates to matters set out in Schedule 3 to the *Subordinate Legislation Act 1989*, namely 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.

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## Human Tissue Regulation 2010

under the

Human Tissue Act 1983

### 1 Name of Regulation

This Regulation is the *Human Tissue Regulation 2010*.

### 2 Commencement

This Regulation commences on 4 July 2010 and is required to be published on the NSW legislation website.

**Note.** This Regulation replaces the *Human Tissue Regulation 2005* which is repealed by this Regulation.

### 3 Definition

(1) In this Regulation:

*the Act* means the *Human Tissue Act 1983*.

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

### 4 Prescribed contaminants

For the purposes of the definitions of *prescribed contaminant* in sections 4 (1) and 20F (6) of the Act, the following organisms and substances are declared and prescribed to be prescribed contaminants:

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

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### 5 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 College of Intensive Care Medicine of Australia and New Zealand,
- (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.

### 6 Certificates

- (1) For the purposes of the definition of *certificate* in section 20D (1) of the Act, the prescribed form of the certificate is set out in Schedule 1.
- (2) For the purposes of section 20D (2) of the Act, the following persons, if employed where the blood is to be removed, are prescribed witnesses:
  - (a) medical practitioners,
  - (b) nurses,
  - (c) persons who have been nominated by their employer, and approved by the Director-General in writing, as appropriate persons to witness signatures.
- (3) 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:
  - (a) the person by whom the blood was removed, or
  - (b) if the person who removed the blood did so in the person's capacity as an employee or agent of some other person or body— that other person or body.

Maximum penalty: 2 penalty units.

### 7 Presumption that person is carrying on blood supply business

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 can be derived or extracted from 1 litre of blood.

**8 Removal of tissue after death**

- (1) 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).

- (2) 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.

**9 Repeal and savings**

- (1) The *Human Tissue Regulation 2005* is repealed.
- (2) Any act, matter or thing that, immediately before the repeal of the *Human Tissue Regulation 2005*, had effect under that Regulation continues to have effect under this Regulation.

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Schedule 1 Blood donor certificate

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### Schedule 1 Blood donor certificate

(Clause 6 (1))

(Human Tissue Act 1983, section 20D)

#### Questions

(Please circle your answers)

To the best of your knowledge have you:

- |   |  |        |
|---|--|--------|
| 1 | in the last 12 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 had sexual activity with a new partner who currently lives or has previously lived overseas? | Yes/No |

Within the last 6 months have you:

- |   |   |        |
|---|---|--------|
| 8 | had a tattoo (including cosmetic tattooing), body and/or ear piercing, electrolysis or acupuncture? | Yes/No |
|---|---|--------|

Within the last 12 months have you:

- |    |   |        |
|----|---|--------|
| 9  | had male to male sex (that is oral or anal sex) with or without a condom?                                   | Yes/No |
| 10 | had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man? | Yes/No |
| 11 | been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?                  | Yes/No |
| 12 | engaged in sexual activity with a male or female sex worker?  | Yes/No |
| 13 | been injured with a used needle (needlestick)?  | Yes/No |
| 14 | had a blood/body fluid splash to eyes, mouth, nose or to broken skin?                                       | 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 |

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I agree to have blood taken from me under these conditions. I declare that I have understood the information on this form and have answered the questions in the declaration honestly and to the best of my knowledge. I understand that there are penalties, including fines and imprisonment, for providing false or misleading information. I have been advised that there are some possible risks associated with donating blood and that I must follow the instructions of the Blood Service staff to minimise these risks.

**Donor (please print)**

Surname/family name

Given name

Date of birth

**Please ONLY sign in the presence of the interviewer**

Signature

Date