



New South Wales

Human Tissue Regulation 2015

under the

Human Tissue Act 1983

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

JILLIAN SKINNER, MP
Minister for Health

Explanatory note

The object of this Regulation is to repeal and remake, without substantive changes, the provisions of the *Human Tissue Regulation 2010*, which would otherwise be repealed on 1 September 2015 by section 10 (2) of the *Subordinate Legislation Act 1989*.

This Regulation provides for the following:

- (a) the organisms and substances that are prescribed contaminants,
- (b) the classes of medical practitioners who are eligible to be appointed as designated specialists,
- (c) the certificate required to be completed by a person donating 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 a senior available next of kin of a deceased person may give consent to the removal of tissue from the person,
- (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 (definitions of *certificate* and *prescribed witness*), 20F (6) (definition of *prescribed contaminant*), 21A, 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.

Contents

	Page
1 Name of Regulation	3
2 Commencement	3
3 Definition	3
4 Prescribed contaminants	3
5 Designated specialists	3
6 Certificates	4
7 Presumption that person is carrying on blood supply business	4
8 Removal of tissue after death	4
9 Repeal and savings	5
Schedule 1 Blood donor certificate	6

Human Tissue Regulation 2015

under the

Human Tissue Act 1983

1 Name of Regulation

This Regulation is the *Human Tissue Regulation 2015*.

2 Commencement

This Regulation commences on the day on which it is published on the NSW legislation website.

Note. This Regulation repeals and replaces the *Human Tissue Regulation 2010*, which would otherwise be repealed on 1 September 2015 by section 10 (2) of the *Subordinate Legislation Act 1989*.

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 prescribed or declared:

- (a) Hepatitis B virus,
- (b) Hepatitis B surface antigen,
- (c) Hepatitis C virus,
- (d) Hepatitis C antibody,
- (e) Human T-lymphotropic virus Type-I (HTLV-I),
- (f) Human T-lymphotropic virus Type-I (HTLV-I) antibody,
- (g) Human immunodeficiency virus,
- (h) Human immunodeficiency virus antibody,
- (i) *Treponema pallidum*,
- (j) *Treponema pallidum* related antibody.

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 and New Zealand 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 employed to work as donor services nursing assistants at the Australian Red Cross Blood Service,
 - (d) persons who have been nominated by their employer, and approved by the Secretary 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.
- (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 2010* is repealed.
- (2) Any act, matter or thing that, immediately before the repeal of the *Human Tissue Regulation 2010*, had effect under that Regulation continues to have effect under this Regulation.

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 EVER:

- | | | |
|---|--|--------|
| 1 | thought you could be infected with HIV or have AIDS? | Yes/No |
| 2 | “used drugs” by injection or been injected, even once , with drugs not prescribed by a doctor or dentist? | Yes/No |
| 3 | had treatment with clotting factors such as Factor VIII or Factor IX? | Yes/No |
| 4 | had a test which showed you had Hepatitis B, Hepatitis C, HIV or HTLV? | Yes/No |

In the last 12 months have you:

- | | | |
|----|---|---------------------------|
| 5 | had an illness with both a rash and swollen glands, with or without a fever? | Yes/No |
| 6 | engaged in sexual activity with someone you might think would answer “Yes” to any of questions 1–5? | Yes/No |
| 7 | had sexual activity with a new partner who currently lives or has previously lived overseas? | Yes/No |
| 8 | 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 |
| 9 | had male to male sex (that is oral or anal sex) with or without a condom? | Yes/No/
I am
female |
| 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 imprisoned in a prison or been held in a lock-up or detention centre? | Yes/No |
| 13 | had a blood transfusion? | Yes/No |
| 14 | had (yellow) jaundice or hepatitis or been in contact with someone who has? | Yes/No |

In the last 6 months have you:

- | | | |
|----|--|--------|
| 15 | been injured with a used needle (needlestick)? | Yes/No |
| 16 | had a blood/body fluid splash to eyes, mouth, nose or to broken skin? | Yes/No |
| 17 | had a tattoo (including cosmetic tattooing), body and/or ear piercing, electrolysis or acupuncture (including dry-needling)? | Yes/No |

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.

Donor (please print)

Surname/family name

Given name

Date of birth

Please ONLY sign in the presence of the interviewer

Signature

Date