

# **Human Tissue Regulation 2015**

[2015-185]



# **Status Information**

# **Currency of version**

Historical version for 1 May 2015 to 10 September 2016 (accessed 24 December 2024 at 3:49)

Legislation on this site is usually updated within 3 working days after a change to the legislation.

#### **Provisions in force**

The provisions displayed in this version of the legislation have all commenced.

#### Notes-

 Does not include amendments by Human Tissue Amendment (Blood Donor Certificate) Regulation 2016 (512) (LW 12.8.2016) (not commenced — to commence on 11.9.2016)

## **Authorisation**

This version of the legislation is compiled and maintained in a database of legislation by the Parliamentary Counsel's Office and published on the NSW legislation website, and is certified as the form of that legislation that is correct under section 45C of the Interpretation Act 1987.

File last modified 12 August 2016

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# **Human Tissue Regulation 2015**



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This Regulation repeals and replaces the *Human Tissue Regulation 2010*, which would otherwise be repealed on 1 September 2015 by section 10 (2) of the *Subordinate Legislation Act 1989*.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

thought you could be infected with HIV or have AIDS?

Yes/No

2	"used drugs" by injection or been injected, <b>even once</b> , 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