

**Submission for changes to:
THERAPEUTIC GOODS ORDER NO.XX – Standards for banked human cardiovascular tissue**

**New Zealand Heart valve Bank
11February 2010**

7 General Requirements (6) points (b) and (c)

Reword:

(b) a deceased donor as soon as possible after death and take place within 44 hours of death

Delete:

(c)

7 General Requirements (8) points (b) and (c) (ii)

Reword:

(b) transported on wet ice to the laboratory where processing and antimicrobial treatment must commence within 48 hours of death or collection from a living donor,.....

(c) (ii) 1°C to 10°C for up to 48 hours

New Zealand standard practice is to accept donations that can begin a 48 hour disinfection process in cold antibiotic solution within 48 hours of death. Four hours is allowed for dissection.

The suitability of the condition of the body is assessed on a case by case basis rather than refrigeration time frame. For example a body remaining in a cold house in winter may be in suitable condition after more than 20 hours whereas a body in a heated house may be decomposing after only 10hours

It is generally accepted that refrigerated temperature limits are 1°C to 10°C

7 General Requirements (12)

No change to:

Cryopreserved cardiovascular tissue must be transported at or below minus 100°C in a validated container system

This wording is in line with international guideline:

AATB – STANDARDS FOR TISSUE BANKING 12th Edition Printing Date February 2008

7 General Requirements - Footnote 2

Please explain the requirement for antibiotic neutralisation and how this would be achieved.

New Zealand protocol is for microbiology/bioburden testing at each of five processing stages - before antibiotic treatment, during antibiotic treatment and after antibiotic treatment

Samples for testing are representative of the tissue itself, samples are not altered or pretreated

Antibiotics breakdown naturally and we are unsure of the purpose of this requirement