DRAFT THERAPEUTIC GOODS ORDER - *Standards for banked human cardiovascular tissue*

Donor Tissue Bank of Victoria submission Feb 2010

Clause Ref.	Page Ref.	Comment	Rationale
4(2)	2	**Allogeneic** – does not include provisions for identical twin, hence description should state "from an individual other than the recipient"	Donation between identical twins is allogeneic
4(2)	3	**Banked –** Propose changing text to 'means tissue stored within a bank for the purpose of human therapeutic use'.	The standard does not appear to include tissues that are held in a tissue bank yet to be released (the majority of tissue held) under this definition.
4(2)	3	**Clean collection environment** – Humidity and particulates are rarely monitored in hospitals, mortuaries and hospices, and cannot be controlled by the tissue bank. The tissue bank cannot control access to areas that they are 'visitors' in. Access to pest control records as visitors is also likely to be problematic.	Not possible or practicable for offsite donation sites.
4(2)	3	**Competent valve** – Change to 'means a dissected valve that is capable of functioning in a defined effective manner'	Where competency is measured is not part of the definition.
4(2)	3	**Container** – definition indicates this is the inner packaging in contact with the tissue which is very confusing as the container is commonly used to indicate the outer packaging in other standards. See comment on 'Primary Pack'.	Terminology should be consistent with other standards.
4(2)	4	**Donor** – should state "every *human* source" not "every source"	Could inadvertently include animal derived products.
4(2)	4	**Grade B & C** – Definition is what should be what is in the pharmacopoeia and PIC/S. Add Grade A	This description only refers to particulate limits and not viable counts and is incomplete. Tissues that do not undergo a terminal sterilisation step should be processed in a grade A environment – see below (7 (8) b).
4(2)	4	**Primary Pack** – definition indicates this is the outer packaging which is very confusing as the primary pack is commonly used to indicate the packaging that is in contact with the product in other standards. Terminology should be consistent with other standards, why change this. See comment on 'Container'.	Terminology should be consistent with other international standards.
7(8) b)	7	The critical processing zone should be equivalent to Grade A	Accepted international best practice for non-terminally sterilised tissues. Note that in European Directive requires an A with a D background.
Footnote 2	7	Antimicrobial neutralisation must be demonstrated prior to sampling the tissue for bioburden testing. The statement should be "where applicable, the sampling methodology should include neutralisation of the disinfectant agents in the sample".	Need to neutralise the sample, not the tissue.
7(14)	8	Change to 'A heart valve must be determined to be a competent valve prior to freezing'.	It is not practicable for the manufacturer to determine the valve to be competent after thawing or ensure that it happens, as the thawing is usually performed by the

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			theatre team during implantation surgery. Competency can only be assured by the manufacturer prior to freezing. The freezing/thawing protocols should be designed to ensure that the competency of the valve is not affected by the freezing/thawing process.
Schedule 1			
1a) or b)	9	**General comments:** TGA Orders for Musculoskeletal tissue request for identification of retrieval site and for human skin the order requests for identification of collection site. Here the site is not required at all. Need to also define collection and retrieval site, does it refer to the location on the body or the place (which could be anything from a 'country' to a room) it was retrieved in.	The terminology used and requirement is not consistent.
2	9	Labelling should not be on the sterile pack. Label should be on the secondary pack surrounding the sterile pack. If the packs are labelled, why is it necessary to label the outer (transport) box with all these details. There should be an option for what HAS to be on the label and what MAY be on the accompanying paperwork.	It is hard to obtain sterile labels which can be printed with the additional data determined during processing (e.g. dimensions) whilst retaining sterility. Tissue products are not shipped in outer containers with all the tissue labels on it. Many tissues are packaged such that it would be impossible to include all of this information on the label.
2b)(v)	9	Remove manufacturers date	Manufacturers date is not relevant for tissue banking. Donation date may be more relevant (where processing does not happen immediately after donation e.g. for bone tissue). The standards are also not consistent (skin also requires manufacture date, but bone and ocular does not).
2b)(vii)	9	Remove 'sterile (if applicable)' or define 'sterile' as determined free of bioburden.	Most processes do not have a terminal sterilisation step for cardiovascular tissue.
3c)	10	"Biohazard" label is not appropriate (although the statement is)	Such a label would indicate something that should not be transplanted (provides a confused message to the user).