DRAFT THERAPEUTIC GOODS ORDER - *Standards for banked human musculoskeletal 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 twins, hence description should state "from an individual other than the recipient"	Donation between identical twins is allogeneic
4(2)	2	**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	**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)	3	**Donor** – should state "every *human* source" not "every source"	Could inadvertently include animal derived products.
4(2)	3 & 4	**Grade B, C & D** – 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.
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(3) b)(iv)	6	Squamous cell carcinomas are not acceptable for <u>any</u> tissue donors. Remove this exception for living donors.	Follows same concept as to any metastatic cancer and also its potential transmissible agent.
7(4) b)	6	Change the age criteria to allow the bank to establish their own suitable age criteria.	It is unclear how the age criteria was established. International practice generally allows the bank to establish it's own age criteria for all grafts. 15 years may be too young if the bone attached is relevant (as bony plates are not fused) and evidence suggests to DTBV tendon strength is

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			not significantly reduced until after the age of 65.
7(5) b)	6	Note that for cardiac tissue the limit is refrigerated within 15 hours. We believe the MSK standard to be correct (within 12 hours) but needs to be consistent between standards.	Translocation of gut bacteria will affect cardiac tissue before MSK tissue (due to proximity of death).
7(9) c)	7	Should be grade A if terminal sterilisation (of bacteria) is not performed.	Common international practice (other international standards e.g. European Directive allows A with a D background) have allowed varying background grade environments to allow the variation from defined GMP grade A (which requires a grade B background) to allow for the difficulties presented in maintaining this grade B room environment when processing tissues).
Footnote 1	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(10) d)	8	Remove '…of musculoskeletal tissue….'	A suitable sample may be spore strips included in the load which are a worst case scenario negating the need to test the tissue itself.
Schedule 1			
1a) or b)	9	**General comments:** TGA Orders for Musculoskeletal tissue request for identification of retrieval site, for human skin, the order requests for identification of collection site. The terminology used is not consistent. 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.	Clarity and consistency.
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.

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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).