

DRAFT THERAPEUTIC GOODS ORDER - Standards for banked human ocular 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)	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 <i>human</i> source” not “every source”	Could inadvertently include animal derived products.
4(2)	3	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.
5(3) b)	4	Where does amniotic membrane fall if it does not apply in this order?	Does not seem to be covered in the standards yet should be as it is a human product with similar risks to other tissues covered in standards.
7(8)	5	Use of Class II Biosafety cabinet – The other standards state environment according to PIC/S cleanroom grade (i.e. grade A). This standard refers to the equipment to achieve the air classification. Propose change to ‘Grade A’.	Consistency. A Laminar Flow Cabinet can achieve grade A (al-be-it without operator protection) which would also presumably be acceptable.