Comments on TGO for Banked Human Ocular Tissue dated December 2009

clean retrieval environment means an area or facility, r with the following conditions:

(a) control measures to limit access to authorized staff
(b) sufficient space to perform the tissue retrieval and avoid cross contamination; and
(c) a work surface able to be adequately cleaned prior to commencing retrieval;

7. General requirements

(1) Each manufacturer releasing banked tissue for supply in Australia must have a formally established quality system that meets the requirements of the *Australian Code of Good Manufacturing Practice Human Blood and Bllod Components, Human Tissues and Human Cellular Therapies.*

(4)
Each tissue establishment must have a documented policy regarding the age limit for donation.

(5) Retrieval of eye tissue from a deceased donor should take place n a clean retrieval environment using sterile equipment. For a living donor the ocular tissue must be retrieved in an operating theatre.

(6)
Time intervals between death and enucleation and preservation and/or corneal excision must be recorded.

(7) Critical materials, media, containers and closures employed in the manufacture of banked ocular tissue must be of a design, composition, quality and safety to protect the quality and safety of the biological at the various stages during manufacture and transport.

Comment [p1]: Removal of eye tissue has historically taken place in many different environments ranging from an operating theatre, through mortuaries in hospitals or funeral directors and ultimately to private residencies. It is not possible to control and have environmental records for all these areas. Furthermore, the eyes are normally exposed to such environments before death and so having environmental limits after death seems unnecessary. Sourcing cur ... [1]

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Comment [p2]: A quali ... [6]

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Peter Madden

(8) The critical processing zone for processing of ocular tissue in the tissue facility is a Class II Biosafety cabinet although examination of the eye may take place in other areas.

(9) Ocular tissue

(a) is preserved as:

(i) a globe (whole eye) in a moist chamber system at 0°C to 10°C for no more than 48 hours;

(ii) excised cornea in a corneal storage medium under refrigeration at 0°C to 10 C for no more than 14 days;

(iii) excised cornea maintained in culture medium at 28°C to 37°C for no more than 30 days;

(iv) excised cornea maintained in a cryopreservation medium between minus 75°C to minus 196°C for up to 2 years;

(v) sclera in accordance with conditions and duration specified for the chosen preservation medium;

(b) described in subsection 7(9)(a)(i),(ii), or (iii) may be banked for an extended period of time under the specified conditions, but that period must be less than the expiry date of the medium used and only if authorised by the Medical Director of the facility and with the agreement of the transplanting surgeon.

(c) that is excised corneas, preserved according to subsections 7(9)(a)(iii), then a subsequent exposure to transport medium must not exceed 5 days.

(10) Eye tissue must be sealed within a container and packaged and sealed so as to…

8. Evaluation and testing of ocular tissue

(1) Corneas must be evaluated by one or more of the following methods. Observations and results obtained from the following examinations and evaluations must be recorded.

(3) For eye tissue that is preserved according to subsection 7(9)(a)(iii) its storage medium must be tested for microbial growth using a validated method. prior to release of the tissue.

(a) Visual evidence of growth or positive microbial culture results in discard of the biological; and

(b) results of growth from any microbial tests must be reported to the transplanting surgeon.

Comment [p7]: The whole eye is examined before it is processed and this stage does not need to be in a biosafety cabinet.

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Comment [p8]: The time frame is appropriate for penetrating keratoplasty where the endothelial layer must be maintained. For lamellar tissue though a viable endothelium is not necessary and the time frame of suitable storage could be much longer than this. 30 days is a common time frame.

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Comment [p9]: Storage media can be at any temperature between 0 and 37C.

Deleted: at 28 C to 37 C

Comment [p10]: Eye tissue is not sterile.

Deleted: Ocular

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Comment [p11]: This section appears to have come from an only part of the EBAANZ standards. I think that it should be replaced with the current section of the standards.

Deleted: Bioburden on ocular

Deleted: and/or

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Comment [p12]: If there appears to be growth an… [17]

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Peter Madden

Schedule 1 Labelling

(1) The container and primary pack in which each final biological product that is ocular tissue is packaged and banked, and for release to the transplant unit must be labelled with at least the following:

(a) name of the supplying tissue establishment;

(2) The exterior of the transport container must clearly display:

…(f) a statement that despite appropriate review infectious disease transmission cannot be excluded. t

(3) Documentation to accompany tissue to Transplant Unit must include, at minimum, tissue specific details and product information relating to tissue processing and handling as follows:

(b) tissue establishment, donor and tissue information

(i) name of Eye Bank;
(ii) address and telephone number of Eye Bank; and may include email address/web address;
(iii) unique tissue identification number;
(iv) type of preservation medium;
(v) age of donor;
(vi) death and preservation dates and times, and/or death-to-preservation interval and storage interval;
(vii) results confirming mandatory serological test were non-reactive;

(c)

(i) the recommended temperature for maintaining specific type of tissue (cornea, sclera, whole globe) and the preservation method, with emphasis being given to prohibited conditions after arrival at the transplant unit.

Comment [p14]: The address may not be on the container but it would be on a product insert.

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Comment [p15]: It would seem alarmist to use the wording that was in the draft.

Deleted: biohazard label and

Deleted: including that the biological could transmi

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Comment [p16]: The results of no growth does not seem useful. I could understand if a statement had to be made saying microbial testing had been performed.

Deleted: (viii) results of microbiological tests performed in accordance with

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Peter Madden

Page 1: [1] Comment [p1] **peterm** **10/02/2010 9:35:00 PM**

Removal of eye tissue has historically taken place in many different environments ranging from an operating theatre, through mortuaries in hospitals or funeral directors and ultimately to private residencies. It is not possible to control and have environmental records for all these areas. Furthermore, the eyes are normally exposed to such environments before death and so having environmental limits after death seems unnecessary. Sourcing current pest control measures would be restrictive if not impossible. The suggested change to authorised staff is added because mortuary, nursing or funeral directors may also necessarily be present for the retrieval to occur. The facility may require their presence for the retrieval to occur and so requiring qualified staff would prevent some retrievals.

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(a) air-conditioning to regulate temperature, humidity and particulates required for

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maintenance of tissue quality; and

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qualified and operational persons; and

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(e) records confirming current pest control measures.;

Page 1: [6] Comment [p2] **peterm** **10/02/2010 9:37:00 PM**

A quality system is comprehensive and documented. Also the ocular tissue should meet the Code not only the Act. The Act is coved by the Code.

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is fully documented and

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Therapeutic Goods Act 1989

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The minimum donor age to donate ocular tissue for a banked biological for
allogeneic use is two (2) years old.

Page 1: [10] Comment [p3] **peterm** **10/02/2010 9:39:00 PM**

Upper and lower age limits depend upon the storage method and type off tissue storage. Also new methods are being introduced where the age limit may differ from previous methods.

Page 1: [11] Comment [p4] **peterm** **10/02/2010 9:49:00 PM**

As above. Also retrieval may need to take place in a room that is not surgically clean, yet the tissue is not compromised.

Page 1: [12] Comment [p5] **peterm** **10/02/2010 9:39:00 PM**

I would prefer for eye to be used throughout to aid clarity.

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such as a mortuary or equivalent facility

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The collection of tissue from a deceased person must occur as soon as possible and

Page 1: [15] Comment [p6] **peterm** **10/02/2010 9:31:00 PM**

Time intervals vary depending upon body storage and use of the tissue.

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no more than 24 hours after death

Page 2: [17] Comment [p12] **peterm** **10/02/2010 9:46:00 PM**

If there appears to be growth and the tissue is discarded there appears to be no purpose in classifying to genus level.

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report of positive microbial culture must include an estimate of the total viable count and the organism(s) identified to at least the genus level

Page 2: [19] Comment [p13] **peterm** **12/02/2010 4:03:00 PM**

Bioburden testing of the cornea is not required. The cornea is not sterile and bioburden testing is not appropriate.

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on ocular tissue that is preserved in accordance with subsection

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7(9)(a)(iv) and (v) must be determined and meet specification documented for the

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clinical application of the tissue prior to its release by the manufacturer