



11 February 2010

Blood and Tissues Unit  
Standards and Code of GMP  
Office of Devices Blood and Tissues  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606  
[biologicals\\_consultation@tga.gov.au](mailto:biologicals_consultation@tga.gov.au)

Dear Sir/Madam:

On behalf of the 85 U.S. and 14 international eye bank members, the Eye Bank Association of America (EBAA) appreciates the opportunity to comment on the Australian Therapeutic Goods Administration's (TGA) Draft *Standards for banked human ocular tissue*.

**EBAA Background**

The 85 U.S. and 14 international eye bank members of the EBAA are proud of their history. The first corneal transplant was performed in 1905 and the first eye bank opened in New York in 1944, marking the first organized attempt to facilitate the transfer of tissue from donor to patient. This eye banking model was successfully replicated in other communities across the United States. Following the development of the eye banking system, the EBAA was founded in 1961 by the American Academy of Ophthalmology.

All eye bank members of the EBAA are not for profit organizations whose mission is to recover and provide donated human eye tissue for sight restoring transplantation procedures, education, and research. Significant gains in ophthalmology are, in part, due to donated ocular tissue provided by these eye banks. The EBAA strives to ensure the superior quality of banked human eyes through the adoption and implementation of stringent medical standards.



U.S. eye banks lead the transplantation field with an accreditation program and medical standards that provide a model of success in the transplant community. The present system works extremely well, as demonstrated by our ability to provide sufficient amounts of tissue to those in need of sight restoring transplants and by the history of providing tissue safe for transplantation.

All EBAA member eye banks are not for profit organizations, operating on limited and carefully planned budgets that are supplemented in many communities by philanthropic organizations like the Lions Club and other charity organizations. Securing these precious human gifts of donation is a labor intensive process.

Balance must be achieved in drafting regulations with significant differences between the processing of eye tissue and the processing of other types of cellular and tissue-based products. In addition, about 20% of corneal tissue is distributed outside the U.S. which makes harmonization of international standards crucial to the global distribution of these tissues. To this end, EBAA believes the comments on the following pages complement and achieve TGA's safety objectives as well as harmonize with international standards.

**7. General Requirements, page 5**

(8) The critical processing zone for processing and handling of ocular tissue in the tissue establishment's laboratory is a Class II Biosafety cabinet

Comment: The words "and handling" is nonspecific. Not all handling of tissue needs to be in a Class II cabinet. Some processing, such as laser processing, may not be possible in a Class II cabinet. Not all processing equipment will fit in a cabinet.



Recommendation: Require an environment for open container processing at least at the level of air cleanliness, as in the operating room environment, but not necessarily more stringent than that. Harmonize with EBAA standards by using similar verbiage as below:

*(EBAA Medical Standard) E1.200 Open-Container Processing and Preservation*

*Open-container processing must be performed in a) a laminar air flow hood or cabinet which meets ISO Class 5 standards, b) in an accredited operating room, or c) in another environment documented annually to have less than 25 colony forming units per 90 mm settle plate per one hour exposure.*

## **7. General Requirements, page 5**

(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 maximum documented storage period respective to the medium used and only if authorised by the Medical Director of the facility and with the agreement of the transplanting surgeon.



Comment: It seems the above standard is missing corneas preserved in glycerine.

Recommendation: Add "non-viable corneas or sclera in accordance...." in (v).

### **8. Evaluation and testing of ocular tissue, pages 6-7**

In 8 (3) and 8 (4), culturing is required for corneas and sclera other than whole globes < 48 hours and corneas < 14 days.

Comment: Culturing is not done by U.S. eye banks because the results are not received back in time to release the tissue.

Recommendation: Remove culturing requirements to harmonize with EBAA standards.

*(EBAA Medical Standard) G1.210 Microbiologic Culturing*

*Culturing of eye bank donor eyes may be performed despite the recognition by many that bacteriologic contamination of donor eyes does not necessarily lead to infection and that presurgical or surgical cultures may not correlate with postoperative infection if it should occur. Cultures may be performed either before and/or at the time of surgery.*

#### *a. Presurgical Cultures*

*Eye banks may elect to perform corneal-scleral rim cultures at the time of corneal preservation in tissue culture medium. Positive culture reports shall be reported to the receiving surgeon or recipient eye bank.*

#### *b. Surgical Culturing*

*Each eye bank shall indicate on the information sheet accompanying the tissue for transplantation whether corneo-scleral cultures were performed prior to distribution. Positive results in cases of postoperative infection shall be reported to the eye bank that recovered the tissue as well as to the eye bank that distributed the tissue.*



The Eye Bank Association of America appreciates this opportunity to provide public comments on the Australian Therapeutic Goods Administration's draft regulations.

Sincerely,

A handwritten signature in cursive script that reads "Patricia Aiken-O'Neill".

Patricia Aiken-O'Neill, Esq.  
President & CEO  
Eye Bank Association of America (EBAA)