22 December 2022

MEDICAL STANDARDS
ASSOCIATION OF EYE BANKS OF ASIA

1.Introduction

The AEBA Medical Standards are developed to assure consistently acceptable levels of quality, proficiency, and ethics in dealing with eye tissue for transplantation and define the minimum standards of practice in the recovery, preservation, storage, and distribution of eye tissue for transplantation and research, as determined by the AEBA Council and the ophthalmological medical community in Asia. The AEBA recognizes that every country has its own laws on eye banking and organ/ tissue donation, and that eye banks may have different organizational structures. These standards are not meant to replace such laws or organizational structures but are meant to help ensure ethics, safety and quality in their operations.

These standards are intended to apply to any and all aspects of eye banking, to include:

- Recovery of eye and corneal tissue
- Processing of tissue
- Storage of tissue
- Evaluation of tissue
- Determination of donor eligibility
- Distribution of tissue for transplant, research and teaching

These standards shall be reviewed periodically and revised as necessary to incorporate current research findings and improve clinical practice.

2. Personnel and Governance

Each eye bank is responsible for determining its organizational structure as well as the appropriate type and number of staff it wishes to employ in accordance with each country's legal requirements.

The following are the recommended positions in an eye bank:

Medical Director

The Medical Director and Deputy Medical Director(s) (if applicable) must be an ophthalmologist who has completed a corneal fellowship or who has demonstrated expertise in external eye disease, corneal surgery, research or teaching in cornea and/or external disease. If the Medical Director has not fulfilled any of the above requirements then the eye bank must have and document a consulting relationship with an ophthalmologist who has.

Director or Equivalent (i.e. Eye Bank Manager, Clinical Laboratory Director, etc)

All policies and procedures of each eye bank shall be under the supervision of aDirector appointed by the eye bank's Board of Directors or other governing body. The Director shall be responsible for all administrative operations including compliance with these standards.

The Director or equivalent shall be the individual responsible for the day-to-day operation of the eye bank. It is this individual's responsibility to carry out policies of the eye bank's Board, to determine what tissues are to be collected, and to prescribe clinically acceptable means for their processing, quality control, storage and distribution.

The Director or equivalent shall consult with the Medical Director and/or other working directors if applicable, as well as other medical and legal authorities, in carrying out prescribed responsibilities as necessary. These consultations shall be documented and made available for review during a site inspection. The Director or equivalent shall provide all staff members with adequate information to perform their duties safely and competently. Delegation of responsibility for the clinical work of the eye bank shall be as follows:

Staff (Technical and Supportive) Performing Eye Banking Functions

The Director or equivalent, in consultation with other working directors when applicable, shall appoint technical and supportive staff and ensure that this staff has the appropriate qualifications and training for the performance of their job responsibilities.

The Director orequivalent shall ensure that there are a sufficient number of qualified eye bank technicians and support staff to perform all eye bank laboratory tests and

procedures at a level of proficiency established by the bank. The eye bank Medical Director or Medical Director's designee must document in writing those eye bank tasks in which each staff member is qualified and released to perform independently.

3. Training, Certification and Competency Reviews of Personnel Performing Eye Banking Tasks

An eye bank must provide a formal orientation program for each new employee and the employee's participation must be documented. An eye bank must also establish a comprehensive and well-defined training program outlining specific job-related tasks that each employee is being trained to perform. This training program shall contain documentation indicating when each employee is released to perform their job-related tasks independently. This comprehensive training program shall include the implementation and documentation of annual competency reviews of the skills and job-related knowledge of all eye bank employees performing eye banking functions and conform to the basic principles outlined in these Medical Standards.

4. Facilities

Each establishment performing any eye bank function must have sufficient space, equipment and supplies to accommodate the volume of services performed with optimal accuracy, efficiency, sterility, timeliness and safety.

4.1 Eye Bank Laboratory

The laboratory must be a separate area with limited access in which activities directly related to eye banking are carried out. The laboratory shall have a sink with a drain and running water. There must be adequate counter space for preparation of donor material. The room including walls, floor and sink must be kept clean at all times. Appropriate documentation of regular laboratory cleaning schedules must be maintained and kept on file for a minimum of three years.

Each eye bank laboratory must have an adequate stable electrical source and a sufficient number of grounded outlets for operating laboratory equipment.

4.2 Equipment, Maintenance and Cleaning

Each eye bank laboratory shall have a refrigerator with a device, visible without opening the refrigerator, for recording temperature variations. The temperature recording device should reflect the temperature of the stored tissue under normal storage conditions. Temperature variations must be recorded daily and remain within the range of 2 to 8 degrees Celsius. The refrigerator's continuous temperature recorder must be calibrated against a standard thermometer at least once a year. The refrigerator shall be maintained for the use of tissue and tissue storage media and must contain clearly defined and labelled areas for all tissue stored, i.e., quarantined tissue, surgical tissue awaiting distribution, and research tissue. Eye banks must detail required refrigerator cleaning intervals and documentation in their Policies and Procedures manual.

In the event of a temperature deviation outside the acceptable range, there must be provision for immediate notification and action to be taken. Testing of the alarm system must be performed and documented on a regular basis. The eye bank laminar airflow cabinet or flow hood must be cleaned before and after each use and at regularly scheduled intervals to prevent cross contamination. Appropriate maintenance and accreditation records must be maintained on each piece of equipment. These records must show dates of inspection, performance evaluations and any maintenance procedures or repairs performed.

The eye bank must include in its procedures manual, the monitoring, inspection and cleaning procedures and schedules for each piece of equipment. Documented cleaning schedules for laboratory equipment must be kept on file for a minimum of three years.

4.3 Instruments and Reagents

Adequate instrumentation must be available to provide for sterile removal of whole eyes and/orretrieval of corneas. Instruments must be inspected frequently enough to assure that they function properly. An eye bank that uses an autoclave to sterilize its instruments shall adhere to the maintenance procedures for autoclaves as recommended by their country's regulatory agency. The eye bank must outline these steps in its procedure manual. Annual certification to validate temperature, pressure and time shall be performed and documented. If instruments are sterilized outside of the eye bank, the eye bank shall provide documentation of appropriate sterilization.

All sterilized instruments, supplies and reagents, such as corneal preservation medium, must contain sterilization dates, method or appropriate expiration dates that are current at all times if applicable.

4.4 Procedures Manual

Each eye bank shall maintain its own policies and procedures manual that details all aspects of its specific recovery, processing, preservation, testing, storage, distribution, and quality assurance practices. Each procedure must be initially approved, signed, and dated by the Medical Director or equivalent. An annual review of each eye bank's procedure with signing and dating by the Medical Director or equivalent is required. Each eye bank must maintain copies of each procedure it uses and the length of time the procedure was in use.

4.5 Infection Control and Personnel Safety

Written safety procedures for the eye bank operation shall be established in compliance with each country's occupational safety regulations. All eye bank personnel must operate under the current Universal Precautions for health care workers. These written procedures must be included in the eye bank's procedure manual.

4.6 Biohazardous Waste Disposal

Human tissue and waste items shall be disposed of in such a manner as to minimize any hazard to eye bank personnel and the environment and to comply with each country's regulations. Dignified and proper disposal procedures shall be used to remove recognizable human remains and must be documented.

5. Donor Eligibility

Before tissue is made available for distribution, the Donor Eligibility Determination must be made by a responsible person. Prior to making an eligibility determination, the donor must be screened and evaluated for suitability using AEBA guidelines.

All donors must be identified by name. The only exception shall be those unidentified decedents at the time of death where cornea or eye retrieval is permitted in accordance with the laws of the country concerned; provided further that these decedents do not exhibit any characteristics that may render them unsuitable as cornea or eye donors.

All prospective donors shall undergo a physical examination as close as possible to the donation with special attention to physical signs of HIV disease, infectious hepatitis, and injecting drug use. Each eye bank shall have a consistent policy for conducting and documenting this examination. Each eye bank shall also have a consistent policy for examination and documentation of the prospective donor's available medical record and death investigation. Review of all available records on each donor shall be performed by an individual who is qualified by profession, education, or training to do so, and who is familiar with the intended use of the tissue.

Medical and social histories are important aspects of donor evaluation. Adequate donor evaluation includes:

1. Infectious disease testing
2. Physical assessment of the donor
   - A thorough physical inspection of the body is recommended as close as possible to the donation with special attention to physical signs of HIV disease, infectious hepatitis, and injecting drug use. However, because of cultural and social sensitivities in certain Asian nations, each eye bank must stipulate in writing the extent to which physical examination of the donor is to be conducted and to document these findings.
3. Tissue evaluation
4. Donor history evaluation: this must include the donor's name, social history and donor information obtained from at least one of the following:
   a. Medical record or hospital chart
   b. Treating physician interview
   c. Donor risk assessment interview
   d. Pathologist or medical examiner physical assessment of death report
   e. Medical examiner's investigative report
   f. Medical director oversight to review any donor information where questions arise in the above areas. This shall be documented.

5.1 Donor Screening

The eye donor's relevant medical records must be reviewed for:

- AEBA specific contraindications; and
- Other diseases as required by the country of import

5.2 Screening for Relevant Communicable Disease Agents and Diseases

Tissue from persons exhibiting risk factors for, clinical evidence of, or physical evidence of relevant communicable disease and high risk behaviour associated with relevant communicable disease must not be used for transplant purposes.

5.3 Donor Testing

The eye donor must be tested according to:

- AEBA testing requirements (see 5.4);
- Health Ministry/Department requirements of the respective countries;
- Other testing requirements of the country of import, if applicable

The infectious disease testing laboratory and test kits used must meet the country's regulatory requirements.

If plasma dilution sufficient to affect the results of communicable disease testing is suspected, the donor should be considered ineligible, unless a pre- transfusion or infusion sample drawn up to 7 days before recovery is tested; or an algorithm designed to evaluate volumes administered in the 48 hours before specimen collection is used, showing that plasma dilution sufficient to affect the results has not occurred.

5.4 AEBA Testing Requirements *

Donors must be screened and tested negative for the following in order for the tissue to be deemed suitable for transplant:

- HIV
- Hepatitis B(HBsAg,anti-HBc)
- Hepatitis C. (anti-HCV)
- Syphilis
- Any other relevant communicable disease agent as mandated by each country's health authority or regulatory agency.

*Countries may differ in terms of required tests. Each eye bank must comply with the required testing method/s stipulated by their respective health authority or regulatory agency.

5.5 Non-Required Testing Results

All non-required positive infectious disease tests must be reported to the eye bank's Medical Director, who must review and act on them, or the eye bank must have a standard policy regarding the action to be taken in response to the individual test.

All discordant infectious disease test results must be reported to the eye bank's medical director, who must review and act on them within a reasonable period of time and in accordance with the eye bank's procedures manual.

5.6 Documentation of Donor Information

Donor screening forms and/or copies of relevant medical records reviewed must be completed and retained on all donated eye tissue as part of the donor record.

A unique donor identifying number, i.e, medical examiner or coroner case number, hospital medical record number, social security or driver's license number, shall be obtained and recorded in the donor record.

5.7 Method and Authorization for Donation

Documentation of legal authorization for recovery is essential for medical-legal reasons. Authorization procedures and forms must conform with the country's law and documentation for authorization must be retained. In medical examiner's/coroner's cases, the eye bank shall adhere to the regulations specified by the medical examiner's or coroner's legislation for each country. In each case the authorization designation and restrictions, if any, must be adhered to and cannot be altered without the witnessed resigning or redesignation of the legally appropriate person.

5.8 Donor Age

Since in general, no definite relationship has been established between the quality of donor tissue and age, the upper and lower age limit is left to the discretion of the Medical Director.

References: Sugar J, Montoya M et al .Donor Risk Factors for Graft Failure in the Cornea Donor Study . Cornea. 2009 October; 28 (9): 981-985

5.9 Interval Between Death, Enucleation, Excision, Preservation, and Processing

Acceptable time intervals from death, enucleation or excision to preservation may vary according to the circumstances of death and interim means of storage of the body. It is

generally recommended that corneal preservation occur as soon as possible after death. All time intervals for each donor, i.e., the time of death to the time of enucleation and preservation, and/or the time to corneal excision, and/or the time to additional tissue processing, shall be recorded. The time that cooling of ocular tissues and/or refrigeration of the body began shall be recorded, if applicable.

5.10 Eye Maintenance Prior to Recovery

The prospective donor's corneal integrity should be maintained. Recommended procedures for eye maintenance shall be found in the procedures manual. Each individual eye bank's procedure is left to the discretion of the Medical Director and shall be clearly documented.

5.11 Living Donors

Eye tissue (with the exception of limbal transplants) that is removed and processed for surgical use from a living donor must comply with all legal and ethical regulations relevant to the respective country and shall have the same standards applied as for all cadaveric tissue, e.g., the same donor medical history shall be obtained, the same records, infectious disease tests, etc. No extended quarantine period, outside the usual 24-48 hours for infectious disease test results, shall be required for corneal tissue used for transplantation that is stored in short or intermediate term storage medium.

6. Recovery,Processing, and Preservation

Recovery, processing, and preservation must be done using aseptic technique. All procedures must be documented.

The Medical Director is responsible for establishing the eye bank's procedures for recovery, processing, and preservation of tissue. The Medical Director or equivalent is responsible for assuring that eye bank personnel comply with all applicable procedures for the recovery, processing, and preservation of tissue.

6.1 Recovery

Recovery may be performed via enucleation or in-situ method. 5 % Povidone-iodine solution shall contact the surface of any ocular tissue intended for transplantation at least twice between the time of the donor's death and tissue preservation (e.g. cornea in Optisol-GS or whole globe in moist chamber). The concentration (i.e. 2.5 to 5%) , volume of solution to be instilled, maximum duration of ocular surface exposure (whether to go beyond the minimum 5 minutes),and whether any residual PI is to remain on the ocular surface during excision,shall be specified in the eye bank's operating procedure and determined by the Medical Director.

The eye shall be examined with a penlight prior to enucleation or in- situ corneoscleral rim excision.

Tissue from donors with the following is hazardous to eye bank staff. Furthermore they are among the contraindications for donation:

- Active Viral Hepatitis
- Acquired Immunodeficiency Syndrome (AIDS)or HIV seropositivity
- Active viral encephalitis or encephalitis of unknown origin
- Creutzfeldt-Jakob Disease
- Rabies

6.2 Processing and Preservation

Processing must be performed either: 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.

a. Whole Globe

Eye banks that preserve and store whole eyes for lamellar or refractive keratoplasty may use preservation methods such as moist chamber at 2-8 degrees Celsius, freezing below zero degrees Celsius, or some other validated method.

b. Cornea

Eye banks that preserve corneas intended for transplant may use one of the following methods. The Medical Director must develop appropriate tissue selection criteria and approve the procedure for each method utilized. All processes must be validated.

1. Preservation via Excision of the Corneoscleral Rim from Enucleated Whole Globes
2. Lamellar Tissue Processing
   Preparation of lamellar tissue may be performed using manual or automated methods (e.g. microkeratome).
3. Laser Assisted Processing
   Lasers may be used to prepare lamellar tissue or custom wound architecture (e.g. femtosecond laser).

c. Sclera

There are various methods of preserving sclera, including the use of 70%or greater ethyl alcohol, sterile glycerin, cryopreservation, and gamma radiation.

6.3 Use of Short or Intermediate Term Preservation Medium

AEBA member eye banks shall use an appropriate corneal storage medium that has been manufactured in accordance with Good Manufacturing Practices if this is required in the respective countries. The medium shall be used and stored according to the manufacturer's recommendations for temperature, date and other factors. The manufactured medium purchased and shipped to the eye bank shall be inspected for damage upon arrival. The lot number of medium used for each cornea shall be recorded on the tissue report containing the unique identification number of the tissue to allow tracking and recall.

6.4 Long Term Preservation

Some eye banks employ long-term preservation of corneal tissue, such as organ culturing. While these methods are not in widespread use, an eye bank that uses long-term preservation shall carefully document the procedure in their procedures manual, and adhere to rigid aseptic technique.

7. Tissue Evaluation

The ultimate responsibility for determining the suitability of the tissue for transplantation rests with the transplanting surgeon.

7.1 Gross Examination

The corneal-scleral segment shall be initially examined with a penlight or portable slit-lamp for clarity, epithelial defects, foreign objects, contamination and scleral color, e.g., jaundice.

7.2Slit-lamp Examination

The cornea shall be examined for epithelial and stromal pathology and in particular endothelial disease. Whole globes to be distributed for lamellar processing must have the same examination. After corneal excision and after lamellar preparation of the corneal tissue, the tissue shall be evaluated by slit lamp biomicroscopy. Biomicroscopy shall be performed even if the eye donor has been examined with the slit lamp prior to the corneal-scleral rim or anterior or endothelial lamellar tissue preparation. This examination is to ensure that there was no damage to the relevant transplantable tissue.

Document the observations of the slit lamp examination with particular attention to the epithelium, stroma, and endotheliumsuch as, but not limited to scars, edema, significant arcus,pterygia, neovascularization, striae, epithelial defects, guttata, polymegathism, pleomorphism, infiltrates, or foreign bodies.

7.3 Endothelial Cell Density and Pachymetry

Determination of endothelial cell density via specular microscopy (or quantitative light microscopy for organ cultured corneas)shall be the recommended method of corneal tissue evaluationforall member eye banks of AEBA.

Minimal endothelial cell count limits are left to the discretion of the Medical Director. When it is impossible to obtain an endothelial cell count, this requirement may be waived on a case-by-case basis by the Medical Director.

For lamellar grafts, pachymetry and cell density measurement shall be performed following lamellar tissue preparation. Calibration of endothelial cell counting equipment shall be done according to manufacturer guidelines, when applicable, and on at least an annual basis. Calibration procedures shall include specific directions and limits for accuracy.

7.4 Suitability for Surgical Use

The eye bank responsible for evaluation of ocular tissue shall specify whether the tissue meets the criteria for penetrating keratoplasty, anterior lamellar keratoplasty, endothelial keratoplasty, keratolimbal allograft, andother surgical use (e.g. keratoprosthesis, tectonic use, etc.)

8. Quality Assurance

Each eye bank shall have a formally established quality assurance program. This program shall include:

- Establishing and maintaining procedures for all activities performed by the eye bank (including review, approval, and revision);
- Ongoing monitoring and evaluation of activities through periodic audits of all eye bank functions by an individual(s) not regularly involved in the processes being monitored;
- Identification of problems and complaints relating to activities (receiving, investigating, evaluating, and documenting information relating to eye banking requirements);
- Development of plans for corrective actions, including monitoring for effectiveness.

The quality assurance program shall address applicable requirements relating to the following areas:

1. Facilities
2. Environmental control
3. Equipment
4. Supplies and reagents
5. Recovery
6. Processing and processing controls
7. Labelling controls
8. Storage
9. Receipt, pre-distribution shipment, and distribution
10. Donor eligibility determinations, donor screening, and donor testing
11. Tissue evaluation

Each eye bank shall document all aspects of its quality assurance program. Records relating to the quality assurance program shall be maintained for a minimum of 10 years. These records shall be made available at the time of site inspection.

The eye bank's quality assurance program shall include a method for the receiving surgeon to report adverse reactions from the transplantation of corneal, scleral, or other ocular tissue to the distributing eye bank. If applicable, the distributing eye bank must forward the adverse reaction information to the source eye bank which made the donor eligibility determination.

The source bank must notify all entities involved in the recovery, processing, storage, final distribution, tissue evaluation, and donor eligibility determination of the results of the investigation. Each of the involved entities must maintain documentation of the adverse event and results of the investigation forwarded to it by the source bank. Infection that the medical director's investigation determines to be reasonably likely to be of a systemic nature must be communicated to all entities that recovered organs or received or recovered tissues from that donor.

An adverse reaction is any communicable or other disease reasonably likely or proven to be due to donor eye tissue, including infection (as manifested by endophthalmitis, keratitis or systemic disease) and biologic dysfunction (such as immediate endothelial failure, donor corneal dystrophy, or evidence suggestive of prior refractive surgery). If systemic infectious disease such as HIV, hepatitis or syphilis or CJD develops in a recipient, whether or not it is suspected to be due to donor tissue, this must be reported to each eye bank's Medical Director. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines are indicated.

8.1 Quality Control

The Medical Director shall prescribe tests and procedures for measuring, assaying or monitoring properties of tissues essential to the evaluation of their safety for transplantation, e.g., hepatitis B surface antigen and human immunodeficiency virus (HIV) antibody, and conform with each country's requirements and laws. Results of all such tests or procedures, together with evaluations based on these findings, shall become part of permanent record of all tissues processed.

8.2 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.

   It is recommended that corneal surgeons perform donor rim fungal cultures for all corneas prepared in the eye bank for Endothelial Keratoplasty.

   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, if applicable.

8.3 Tissue Recall or Tissue Withdrawal

Eye banks must have a policy and procedure for potential recall of tissue.

Positive test results or information about behavioral risks or medical history, received after release of tissue, that indicate a risk for transmission of a relevant communicable disease must be reported to the:

- Eye bank's medical director
- Consignee (i.e. the transplanting surgeon or distributing eye bank)as soon as the information is available.
- Other appropriate government agency such as the Health Ministry/Department within45 days

9. Non-Surgical Donor Tissue

The use of ocular tissue from a donor determined to be ineligible is not prohibited for non-clinical uses, so as long as they bear the Bio- hazard legend and are labelled "For Non-clinical Use Only".

Tissue distributed for non-clinical purposes (e.g., teaching and/or research) from a donor who has been determined to be ineligible for transplantation due to results of required testing and/or screening or from donors who have not been tested for required infectious diseases, must have a label affixed to the individual tissue container which contains the information below.

1. "For Non-clinical Use Only"
2. "Bio-hazardous" or bio-hazard legend

10. Storage

All tissue shall be transported and stored in quarantine from the time of recovery until the donor eligibility determination has been completed. Quarantined tissue must have a label designating the tissue as "quarantine" affixed to the individual tissue container.

All surgical tissue shall be stored in quarantine in a physically separate area clearly identified for such use, or through use of other procedures such as automatic designation, until a determination of eligibility has been made.

If a donor is determined ineligible, you must store or identify the tissue in a physically separate area labelled for such use, or follow other procedures that are adequate to prevent improper release.

All tissue shall be stored aseptically at a temperature appropriate to the method of preservation used. Eye banks must precisely document their procedures for storage of corneal tissue, whether it is in the form of the whole eye or the cornea only in an appropriate medium.

10.1 Expiration Dating

Where appropriate, an expiration date must be assigned based upon methods of processing, preservation, storage, and packaging.

11. Labelling

All ocular tissue distributed for surgical use shall be in a container which is clearly and indelibly labelled to include at least the information below. Eye Banks are encouraged to use ICCBBA Eye Bank Technical Advisory Group (EBTAG) nomenclature to describe ocular tissue classes and attributes. They are also encouraged to work towards using ISBT tissue identifiers in all eye bank records.

1. Name of source eye bank.
2. Tissue identification number. There must be a unique identification number for each ocular tissue or fraction thereof. Moving forward, member eye banks are encouraged to make provisions for adopting the ISBT 128 tissueidentifier which includes the Domain Identification Number (DIN), Product Code, and Processing Facility Information Code (if applicable)
3. Type of tissue (e.g. cornea, whole globe, sclera).
4. If cornea has been pre-cut, clearly indicate this on the label
5. Date and time of donor's death
6. Date and time of corneal/scleral preservation
7. Expiration date of tissue, preferably in the international format (YYYY_MM_DD)
8. A statement that the tissue is not considered sterile unless tissue has been subjected to a validated process to ensure sterility.
9. Type of preservation medium.
10. If a single cornea or sclera is intended for multiple uses, it is the surgeon's responsibility to inform the eye bank. In addition, a standardized system of notification and tracking must be in place so that the surgeon knows how to fill up the relevant reporting forms. For example, Tissue 001 can be labelled as :

    Tissue 001-A: full thickness cornea
    Tissue 001-B: anterior lamellae
    Tissue 001-C: posterior lamellae (EK)
    Tissue 001-D: stroma

12. Distribution of Tissue

12.1 Review of Donor Medical Information

Prior to distribution of tissue for transplantation, the Medical Director or his/her designee shall review and document that the medical and laboratory information is in accordance with medical standards.

12.2 Receivers of Tissue

Tissue shall be distributed to surgeons, institutions and other eye banks. All tissue sent from AEBA member eye banks to eye banks in other countries must comply with the standards defined by AEBA .

12.3 Fair and Equitable System

Eye banks shall establish and document a system of distribution that is just, equitable and fair to all patients served by the eye bank or as applicable to documented local laws. Documentation of distribution (time and date of requests for, offers of, and delivery of eye tissue) is strongly recommended.

12.4 Returned Tissue

For tissue returned and redistributed, tissue transportation and storage information must be documented and made available to the eye bank and transplanting surgeon.

12.5 Fraudulent Activity

If the eye bank discovers fraudulent activity that has occurred in the distribution, shipping, labelling of any tissue imported or exported by the eye bank, an investigation shall be performed to identify the root cause of the occurrence. The results of the investigation are to be relayed to the eye bank Medical Director who shall notify the appropriate regulatory agencies of the fraudulent activity if deemed necessary.

13. Documentation to Accompany Donor Tissue

13.1 Tissue Report Form

A copy of the tissue report form shall accompany the tissue. The tissue report shall contain the following:

1. Name of (Source) eye bank
2. Location of eye bank
3. Telephone number of eye bank
4. Eye bank identification number unique to each ocular tissue or fraction thereof
5. Type of preservation medium
6. If cornea is processed, clearly indicate the type of pre-cut method performed or the indicated use (e.g. endothelial keratoplasty, posterior lamellar keratoplasty, anterior lamellar keratoplasty, laser assisted keratoplasty, etc).
7. Tissue evaluation reporting requirements according to Table 1.
8. A summary of records reviewed regarding the eligibility of tissue for transplant

Table 1. Reporting Requirements

Content Required on Tissue Report Form	**Unprocessed Tissue in Short or Intermediate-Term Storage**	**Processed Tissue in Intermediate –Term Storage** ***(manual, microkeratome, laser processed for PK, EK, ALK)***	**Processed Tissue in Long – Term Storage** ***(frozen whole globe or cornea, cornea in glycerin, irradiated cornea, sclera)***
Donor Age	Required	Required	Not required
Donor Cause of Death	Required	Required	Not required *(except for sclera)*
Donor Death and Time	Required	Required	Not required
Preservation date and time	Required	Required	Not required
Additional processing date and time	Not applicable	Required	Not required
Date and time that cooling of ocular tissue or body refrigeration began	Required	Required	Not required
Name/identifier of recovery	Required	Required	Not required

technician			
Name/identifier of technician who initially preserved the tissue	Required	Required	Not required
Name/identifier of technician who evaluated the tissue	Required	Required	Not required
Morphology and dimensions of processed tissue	Not applicable	Required	Required
Diameter of processed graft	Not applicable	Required	Not required
Pachymetry (graft thickness)	Not applicable	Required	Not required
Slit lamp observations	Required	Required	Required *(other visual exam acceptable)*
Specular microscope findings and endothelial cell density	Required *(unless whole eye, anterior lamellar or tectonic use only)*	Required *(unless whole eye, anterior lamellar or tectonic use only)*	Not required
Suitability for indicated surgical uses	Required	Required	Required

13.2 Package Insert Form

A "Package Insert" form that meets the AEBA requirements defined below shall accompany the tissue for transplantation. This form shall include the following:

1. Recommended storage temperature for specific type of tissue (cornea; sclera; whole globe). Specific emphasis on DO NOT FREEZE for corneas.
2. That the surgeon should check for integrity of the seal and immediately report to the eye bank of any evidence of possible tampering.
3. For corneas in Optisol-GS, that color change per the manufacturer's guidelines may indicate a change in pH, in which case the tissue should not be used and a report made immediately to the eye bank.
4. Whether pre-surgical microbiologic cultures were performed by the eye bank.
5. The form shall also advise the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.

6. The form shall advise the transplanting surgeon that the distributing eye bank must be notified in writing of, the tissue recipient's name, unique identification number, age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery, and the name of the transplanting surgeon when the tissue is transplanted. This information is needed to track the tissue from the donor to the recipient.
7. Infectious disease tests were performed by a government accredited or certified laboratory.
8. That serology tests consistent with international standards were used to screen donors for transmissible infectious diseases.
9. A list of infectious disease test results for that specific donor.

This information may be included on the eye bank's donor screening form as long as it is easily noticed; otherwise a separate package insert form is advised.

13.3 Packaging, Sealing and Packing for Transport

Each tissue shall be individually packaged and sealed with a tamper- evident seal. Each eye bank shall use a packaging method for transplantable corneal tissue designed to maintain cool conditions where the package content demonstrates remaining coolant effect at the time of use or removal to mechanical storage or replacement of the coolant, and to prevent freezing. For other tissue (e.g., sclera) the packaging method shall be appropriate to the method of preservation used. Packing shall be done so that the tissue label and documentation to accompany the tissue do not become wet. Special instructions shall be included on a Package Insert.

14. Eye Bank Records

Eye Banks are encouraged to use ICCBBA Eye Bank Technical Advisory Group (EBTAG) nomenclature to describe ocular tissue classes and attributes. They are also encouraged to work towards using ISBT tissue identifiers in all eye bank records.

14.1 Length of Storage

All records shall be kept for a minimum of ten years from the date of transplantation/implantation, distribution or whichever is longer; or based upon the records storage laws of the country concerned.

14.2 Confidentiality

All eye bank records and communications between the eye bank and its donors and recipients shall be regarded as confidential and privileged.

14.3 Donor Screening Forms

Donor screening forms shall contain information regarding the circumstances surrounding the death of a donor and adequate medical history so that the suitability of the tissue for transplantation may be judged.

14.4 Minimum Information to Be Retained

Forms for retaining donor and recipient information shall be established for permanent record and shall be readily accessible. Eye bank records shall include the following minimum information:

1. Eye bank identification number unique to each tissue graft
2. Name of eye bank
3. Type of preservation medium
4. Preservation media lot numbers
5. Unique donor identification number
6. Name of donor (or if import tissue, name of importing eye bank and their unique ID number)
7. Age of donor
8. Cause of death
9. Death date and time
10. Enucleation or in-situ excision date and time
11. Preservation date and time
12. The time that cooling of ocular tissues and/or refrigeration of the body was begun, if applicable
13. Additional tissue processing date and time
14. Slit lamp report(s)
15. Specular microscopy report(s) (if done)
16. Name of enucleator/processor/evaluator/technician
17. Name of surgeon receiving tissue/consignee
18. Recipient identification readily traceable to each unique graft number
19. Date, time, method of transportation
20. Utilization of tissue: i.e., surgical, research, training

21. Printed results of all AEBA required and non-required infectious disease screening tests
22. Microbiologic screening results if performed
23. Microbiologic reports of positive donor rim cultures from the receiving surgeon if reported
24. Adverse reactions if reported
25. Documentation that postoperative outcome information from the transplanting surgeon has been requested

14.5 Recipient Follow-Up Information

1. Each distributing eye bank shall obtain recipient information from the transplanting surgeon on each eye tissue used for human transplantation distributed to the surgeon by the bank.
2. This information shall include the following:
   - Patient's name
   - Unique identification number depending on each country. Any of the following:
     a. Passport number
     b. Driver's license number
     c. Hospital information number
   - Age and/or Date of Birth
   - Patient's contact details (phone, address, e-mail)
   - Diagnosis
   - Name of surgeon receiving transplanting tissue
   - Date of surgery
   - Location of surgery
   - Post-operative complications (tissue related)
   - Type of surgery performed, e.g. penetrating keratoplasty, anterior lamellar keratoplasty, endothelial keratoplasty, keratolimbal allograft, and/or tectonic.

3. Corneas and scleral tissue that can be used beyond 14 days post-mortem may be stocked by the receiving institution only if it is for single patient use; the distributing eye bank must be notified of the recipient information when tissue is used and must be able to track the tissue.

4. Each distributing eye bank should request postoperative outcome information between three andsixmonths after transplant from the transplanting surgeon concerning possible adverse reactions on all eye tissue used for human transplantation that was distributed to the surgeon by that bank. This request should be addressed to the transplanting surgeon.

15. Amendments

These standards may be amended as required. The AEBA Council shall be charged with proposing amendments to these standards as medical technology, techniques and information require. A comment period may be provided prior to the intended effective date.