



Medical Standards

**These Standards have the approval of the Eye Banking Committee
of the American Academy of Ophthalmology**

October 2011

Published by:

EBAA

1015 18th Street, NW, Suite 1010, Washington, DC 20036, USA

www.restoresight.org

TABLE OF CONTENTS

A1.000	Introduction and Purpose	5
	A1.100 Scope.....	5
B1.000	Active Membership	5
	B1.100 Eye Bank Inspection.....	6
	B1.200 Inspections by Official Agencies.....	6
C1.000	Personnel and Governance	6
	C1.100 Director.....	6
	C1.200 Medical Director.....	7
	C1.300 Staff (Technical and Supportive) Performing Tasks Overseen and/or Regulated by the EBAA, FDA, and Other State and Federal Agencies.....	8
	C1.400 Change in Governance.....	9
C2.000	Training, Certification and Competency Reviews of Personnel Performing Tasks Overseen and/or Regulated by the EBAA, FDA, and and Other State Federal Agencies	9
C3.000	Facilities	10
	C3.100 Eye Bank Laboratory.....	10
	C3.200 Equipment, Maintenance and Cleaning.....	10
	C3.300 Instruments and Reagents.....	11
	C3.400 Procedures Manual.....	11
	C3.500 Other Establishments Performing Eye Banking Functions	12
	C3.510 Utilization of Services Provided by Establishments Performing Limited Eye Banking Functions.....	12
	C3.600 Infection Control and Personnel Safety.....	12
	C3.700 Biohazardous Waste Disposal.....	13
D1.000	Donor Eligibility	13
	D1.100 Donor Screening.....	14
	D1.110 EBAA Specific Contraindications to Transplant.....	14
	D1.120 Screening for FDA Defined Relevant Communicable Disease Agents and Diseases.....	16
	D1.200 Donor Testing.....	16
	D1.210 EBAA Testing Requirements.....	17
	D1.220 FDA Testing Requirements.....	17
	D1.230 Non-Required Testing Results.....	17
	D1.300 Documentation of Donor Information.....	17

D1.400	Method and Authorization for Donation.....	17
D1.500	Donor Age.....	18
D1.600	Interval Between Death, Enucleation, Excision, Preservation and Processing.....	18
D1.700	Eye Maintenance Prior to Enucleation.....	18
D1.800	Living Donors.....	18
E1.000	Recovery, Open-container Processing, and Preservation.....	18
E1.100	Recovery.....	19
E1.200	Open-container Processing and Preservation.....	19
E1.210	Whole Globe.....	20
E1.220	Cornea.....	20
E1.221	Preservation via Excision of the Corneoscleral Rim from Enucleated Whole Globes.....	20
E1.222	Lamellar Tissue Processing.....	20
E1.223	Laser Assisted Processing.....	20
E1.230	Sclera.....	20
E1.300	Use of Short or Intermediate Term Preservation Medium.....	20
E1.400	Long Term Preservation.....	21
F1.000	Tissue Evaluation.....	21
F1.100	Gross Examination.....	21
F1.200	Slit-lamp Examination.....	21
F1.300	Endothelial Cell Density and Pachymetry.....	21
F1.400	Suitability for Surgical Use.....	22
G1.000	Quality Assurance.....	22
G1.100	Quality Control.....	23
G1.200	Microbiologic Culturing.....	23
G1.300	Tissue Recall or Tissue Withdrawal.....	24
H1.000	Non-Surgical Donor Tissue.....	24
I1.000	Storage.....	25
I1.100	Expiration Dating.....	25
J1.000	Labeling.....	25
K1.000	Distribution of Tissue.....	26
K1.100	Review of Donor Medical Information.....	26

K1.200	Receivers of Tissue.....	26
K1.300	Fair and Equitable System.....	26
K1.400	Returned Tissue.....	26
L1.000	Documentation to Accompany Donor Tissue.....	26
L1.100	Tissue Report Form.....	26
L1.200	Package Insert Form.....	27
L2.000	Packaging, Sealing and Packing for Transport.....	28
M1.000	Eye Bank Records.....	28
M1.100	Length of Storage.....	28
M1.200	Confidentiality.....	29
M1.300	Donor Screening Forms.....	29
M1.400	Minimum Information to Be Retained.....	29
M1.500	Recipient Follow-up Information.....	30
M1.600	Statistical Reporting.....	31
N1.000	Amendments.....	31
	Glossary (Definitions of Terms).....	32
	Index	42

EBAA MEDICAL STANDARDS

A1.000 Introduction and Purpose

These standards have been 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 ophthalmological medical community.

A1.100 Scope

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 at least annually and revised as necessary to incorporate current research findings and improved clinical practice.

B1.000 Active Membership

In order for an eye bank to become an active member of the Eye Bank Association of America (EBAA), it must comply with the EBAA Bylaws and the following:

1. Demonstrate compliance with EBAA Medical Standards.
2. Maintain accreditation status by passing the site inspection as administered by the EBAA Accreditation Board.
3. Demonstrate proficiency in any aspect of eye banking including recovery, processing, tissue storage, evaluation, donor eligibility determination and final distribution.
4. Proficiency shall be demonstrated by providing documentation, at the time of completing the application, of the handling of at least 25 surgical corneas for each eye bank function for which it is seeking accreditation.
5. Certify compliance with applicable Federal and State regulations.

Once accredited, an eye bank must be inspected and reaccredited at least every three years to maintain active membership in the EBAA.

B1.100 Eye Bank Inspection

The Accreditation Board of the EBAA shall be responsible for inspecting member eye banks as outlined in the written procedures of the Board.

Accreditation and reaccreditation site inspections shall be scheduled following written notification of the impending inspection. Unannounced inspections may be conducted should an allegation of violation of Medical Standards be made to the Accreditation Board, or should the results of inspections by official agencies indicate violation of Medical Standards. Failure to permit an inspection will result in suspension or revocation of an eye bank's accreditation.

Demonstration of proficiency in any and all aspects of eye banking may be required during the site inspection and of any or all technical personnel. The Accreditation Board may review and make a determination to accept findings from outside agencies.

B1.200 Inspections by Official Agencies

Any written documentation of observations, findings, or results (including but not limited to Food and Drug Administration (FDA) Form 483) received by an eye bank which are related to any inspection by an official agency shall be sent to the EBAA office and the Chair of the Accreditation Board within ten (10) business days of receipt. The EBAA office and the Chair of the Accreditation Board shall be copied on all future related correspondence.

C1.000 Personnel and Governance

C1.100 Director

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

The Director 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 shall consult with the Medical Director, 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 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:

C1.200 Medical Director

The eye bank must have a Medical Director. When the Medical Director is not available, a back-up Medical Director shall be designated who is capable of fulfilling the responsibilities of the Medical Director on an interim basis.

The Medical Director and a back-up Medical Director 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 served a corneal fellowship, then the eye bank must have and document a consulting relationship with an ophthalmologist who has.

Any physician who provides verification of competency for tissue recovery and preservations shall attend the Medical Directors' Symposium at the annual meeting of the EBAA at least once every three years and a Medical Advisory Board meeting once every three years. A newly appointed Medical Director shall attend a Medical Directors' Symposium and a Medical Advisory Board Meeting within one year of appointment, unless a Co-Medical Director has fulfilled the requirement. The eye bank shall provide written documentation of such attendance at the time of the eye bank site inspection.

The Medical Director shall oversee and provide advice on all medical aspects of the eye bank operations. These include but are not limited to:

1. Formulation, approval, and implementation of medical policies and procedures.
2. Participation in training and oversight of technical staff with regard to tissue recovery, tissue preservation, tissue processing, and tissue evaluation.
3. Participation in establishment and operation of a quality assurance program.
4. Responsibility for verification of competency for tissue recovery and preservation by personnel applying for CEBT certification

An eye bank's Medical Director must observe the designated staff trainer or trainers performing the following procedures as applicable on an annual basis:

1. In-situ corneal excision or laboratory corneoscleral rim removal from whole globe

2. Posterior lamellar processing procedure that utilizes a microkeratome
3. A laser-assisted processing procedure
4. Each manual dissection processing procedure(s) for EK and ALK (i.e. DSEK or DMEK)

If an eye bank Medical Director has not designated any individuals as staff trainers, he/she must observe each technician they have qualified to perform any of the above procedures on an annual basis.

The Medical Director may delegate responsibility for tissue recovery, preservation, processing, evaluation and release for transplant to qualified eye bank personnel; however, the Medical Director shall ensure that the eye bank operates in compliance with the EBAA Medical Standards. Ultimate responsibility for the suitability of each tissue for the transplantation in patients rests with the transplanting eye surgeon.

An eye bank has three months to replace a Medical Director who has resigned.

C1.300 Staff (Technical and Supportive) Performing Tasks Overseen and/or Regulated by the EBAA, FDA, and Other State and Federal Agencies.

The Director 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 shall ensure that there are a sufficient number of qualified eye bank technicians and supportive 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.

Each eye bank must employ at least one EBAA CEBT in a supervisory and training role(s).

If the only function the establishment performs is recovery and/or storage, a documented contractual, consultative relationship with a CEBT and the accredited organization in which the CEBT is employed may be an acceptable alternative to having a CEBT on staff.

An eye bank or other establishment which performs eye banking functions has six months in which to replace their required EBAA CEBT(s) provided that:

- a. The establishment notifies the EBAA CEO and the Chair of the Accreditation Board in writing that it does not meet this standard.
- b. The establishment submits appropriate evidence of its intent to comply with the "required CEBT" standard.

- c. A documented interim consultative relationship is established with a CEBT and the accredited organization in which the CEBT is employed.
- d. The non-CEBT technician in charge in the interim has demonstrated competency to the Medical Director of the involved establishment.

If a six month deadline cannot be met, the establishment may request an extension by writing to the EBAA CEO and the Chair of the Accreditation Board. An extension may be granted on a case-by-case basis after review by the Chair of the Accreditation Board, in consultation with the EBAA CEO or designee.

C1.400 Change in Governance

An eye bank that undergoes a change in governance must notify the EBAA office and the Chair of the Accreditation Board (in writing) within 30 days. Changes in governance include merger of eye banks, affiliation of two or more eye banks, affiliation of an eye bank with another non-eye bank organization (E.G. tissue banks, organ procurement organizations, hospitals, blood banks, etc.), a change in the name of the eye bank, or a change in required personnel, i.e. Director, Medical Director.

C2.000 **Training, Certification and Competency Reviews of Personnel Performing Tasks Overseen and/or Regulated by the EBAA, FDA, and Other State and Federal Agencies.**

An eye bank or other establishment performing eye banking functions, must provide a formal orientation program for each new employee and the employee's participation must be documented.

An eye bank or other establishment performing eye banking functions, 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. The person responsible for these competency reviews must be a CEBT or an individual who has been qualified by a CEBT who is part of the organization's comprehensive quality program.

Eye bank technicians seeking to receive EBAA certification or become re-certified must meet the criteria set forth in the EBAA document Criteria for Certification and Recertification of Eye Bank Technicians.

All EBAA accredited eye banks must have one CEBT attend an EBAA sponsored skills workshop once every three years.

C3.000 Facilities

Each establishment performing any eye bank function listed in Medical Standard A1.100 (Scope), must have sufficient space, equipment and supplies to accommodate the volume of services performed with optimal accuracy, efficiency, sterility, timeliness and safety. The EBAA office and the Chair of the Accreditation Board shall be notified (in writing) within 30 days of the relocation, laboratory expansion or addition of a satellite to an eye bank.

C3.100 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.

C3.200 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° Celsius. The refrigerator's continuous temperature recorder must be calibrated against an NIST standard thermometer (or for eye banks outside the U.S.A., a standard thermometer as defined by their countries' regulatory agencies) 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 labeled 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.

C3.300 Instruments and Reagents

Adequate instrumentation must be available to provide for sterile removal of whole eyes and 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 in the current Association for the Advancement of Medical Instrumentation (ANSI/AAMI) Standard 79 – “Comprehensive guide to steam sterilization and sterility assurance in health care facilities”. 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.

C3.400 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 Director and Medical Director. An annual review of each eye bank’s procedure with signing and dating by the Director and Medical Director is required. Each eye bank must maintain copies of each procedure it uses and the length of time the procedure was in use.

C3.500 Other Establishments Performing Eye Banking Functions

Any establishment performing any of the following functions: recovery, processing, evaluation, storage, donor eligibility determination, and final distribution, must employ a CEBT. A recovery and/or a storage-only establishment may meet this requirement by having a documented consultative relationship with a CEBT and the EBAA accredited organization in which the CEBT is employed.

All establishments performing specialized or specific eye banking services must have a Medical Director or access to a Medical Director through a documented consultative relationship with an EBAA accredited organization. This Medical Director must meet the requirements of Medical Director as outlined in section C1.200 of these standards. Establishments performing specific eye banking services may be inspected as part of the EBAA accreditation process of an organization in which they provide services.

C3.510 Utilization of Services Provided by Establishments Performing Specialized or Specific Eye Banking Services

Any EBAA accredited organization using eye banking services provided by another establishment must either:

- 1.) obtain and document the establishment's current EBAA accreditation certificate and status; or
- 2.) document that the establishment is in compliance with EBAA medical standards, state and federal regulations appropriate to their function(s). This option requires a written agreement and the EBAA accredited organization is responsible for performing compliance audits. Policies and procedures shall describe the audit plan, scope, and frequency.

C3.600 Infection Control and Personnel Safety

Written safety procedures for the eye bank operation shall be established in compliance with the Occupational Safety and Health Act (OSHA Act) of 1970 and the 1991 amendments to Part 1910 of title 29 of the Code of Federal Regulations), Subpart Z and/or applicable state statutes, which may supersede. For eye banks where OSHA regulations do not apply, written safety procedures in compliance with the relevant regulatory agencies are an acceptable substitute. All eye bank personnel must operate under the current Universal Precautions for health care workers issued by the CDC of HHS.¹

¹ On December 6, 1991, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor (DOL) published its final rules regulating worker occupational exposure to bloodborne pathogens, including but not limited to hepatitis B virus (HBV) and human immunodeficiency virus (HIV). These regulations went into effect March 6, 1992, and make employers responsible for providing and ensuring safe working conditions in all work settings. See the December 6, 1991, *Federal Register*, Vol. 56, no. 235.

These written procedures must be included in the eye bank's procedure manual.

C3.700 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 state and federal regulations. Dignified and proper disposal procedures shall be used to obviate recognizable human remains and must be documented.

D1.000 Donor Eligibility

Before tissue is made available for distribution, the Donor Eligibility Determination must be made by a responsible person. Reference Appendix II for requirements related to the donor eligibility process.

Prior to making an eligibility determination, the donor must be screened according to D1.200. In addition to donor eligibility determination, tissue must be evaluated for suitability per F1.000.

All donors must be identified by name. 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 (see G1.200)
2. Physical assessment of the donor (see above paragraph)
3. Tissue evaluation (see F1.000)
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) Pathologist or medical examiner physical assessment of death report
 - b) Police investigation report accompanied by (a) and/or (c)
 - c) Medical examiner's investigative report
 - d) Donor risk assessment interview
 - e) Medical record or hospital chart
 - f) Treating physician interview

- g) Medical director oversight to review any donor information where questions arise in the above areas (see C1.200). This shall be documented.

D1.100 Donor Screening

The eye donor's relevant medical records must be reviewed for (Reference Appendix III for FDA requirements related to review of relevant medical records):

- EBAA specific contraindications (Ref. D1.110); and
- FDA defined relevant communicable disease agents and diseases (Ref. D1.120); and
- Other diseases as required by the country of import, if exported outside of the United States

D1.110 EBAA Contraindications to Transplant

Tissue from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes:

1. All Ocular Donors

1. death of unknown cause and there is likelihood of other exclusionary criteria;
2. congenital rubella;
3. Reyes Syndrome within the past three months;
4. Active viral encephalitis of unknown origin or progressive encephalopathy (e.g., subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, etc.);
5. active bacterial or viral meningitis;
6. active bacterial or fungal endocarditis;
7. suspected rabies and persons who, within the past six months, were bitten by an animal suspected to be infected with rabies;
8. Down Syndrome-exclusive for penetrating keratoplasty or anterior lamellar keratoplasty;
9. intrinsic eye disease;
 - a. retinoblastoma;
 - b. malignant tumors of the anterior ocular segment or known adenocarcinoma in the eye of primary or metastatic origin;
 - c. active ocular or intraocular inflammation: conjunctivitis, keratitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis; or

- d. congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use, e.g., a central donor corneal scar for an intended penetrating keratoplasty, keratoconus, and keratoglobus;
- 10. leukemias; or
- 11. active disseminated lymphomas

B. Donors for Penetrating Keratoplasty Procedures

- 1. Prior intraocular or anterior segment surgery
 - a. Refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc.
 - b. Laser photoablation surgery (these corneas may be used for tectonic grafting and posterior lamellar procedures).
 - c. Corneas from patients with anterior segment (e.g., cataract, intraocular lens, glaucoma filtration surgery) may be used if screened by specular microscopy and meet the eye bank's endothelial standards.
- 2. Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button.

C. Donors for Anterior Lamellar Keratoplasty Procedures or Tectonic Grafts

Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma, (e.g., donors with a history of endothelial dystrophy or iritis are acceptable).

D. Donors for Epikeratoplasty Procedures

Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the corneal endothelium, (e.g., donors with a history of endothelial dystrophy or iritis are acceptable). Death to preservation time may be extended.

E. Donors for Endothelial Keratoplasty Procedures

Criteria are the same as listed for penetrating keratoplasty, except that tissue with non-infectious anterior pathology that does not affect the posterior stroma and endothelium is acceptable. Surgeons must be notified of any prior pathology prior to placing tissue for transplant.

F. Scleral Tissue Donors

Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the cornea is acceptable for use. Death to preservation time may be extended.

D1.120 Screening for FDA Defined Relevant Communicable Disease Agents and Diseases

The FDA defines communicable disease agents and diseases considered relevant (Ref. Appendix I). Tissue from persons exhibiting risk factors for, clinical evidence of, or physical evidence of relevant communicable disease and high risk behavior associated with relevant communicable disease must not be used for transplant purposes (Ref. Appendix II).

D1.200 Donor Testing

The eye donor must be tested according to:

- EBAA testing requirements (D1.210)
- FDA testing requirements (D1.220)
- State requirements
- Other testing requirements of the country of import, if exported outside of the United States

A review of written results of infectious disease testing shall be received by the eye bank prior to releasing tissue designated for surgical use.

The infectious disease testing laboratory and test kits used must meet FDA regulatory requirements (Ref. Appendix IV). Eye banks outside the U.S. must use a laboratory that is accredited by, and whose tests are approved by their own countries' regulatory agencies.

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 (Ref. Appendix IV).

Eye banks outside of the U.S.A. shall use a plasma dilution algorithm which meets the requirements of their own countries' regulatory agencies. If no such requirements exist, they shall use an algorithm which meets FDA requirements.

D1.210 EBAA Testing Requirements

The results of the following EBAA required testing must be negative or non-reactive for the tissue to be acceptable for transplant:

- anti-HIV-1, anti-HIV-2 (or combination test)
- Hepatitis B surface antigen (HBsAg)
- anti-HCV

D1.220 FDA Testing Requirements

Refer to Appendix IV for FDA donor testing requirements and recommendations. Results must be negative or non-reactive for the tissue to be acceptable for transplant except as indicated for syphilis.

D1.230 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 conflicting infectious disease test results must be reported to the:

- eye bank's medical director, who must review and act on them; and
- EBAA, within 45 days

D1.300 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. See Section L1.000.

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.

D1.400 Method and Authorization for Donation

Documentation of legal authorization for recovery is essential for medical-legal reasons. Authorization procedures and forms must conform with state

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 in its state. 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.

D1.500 Donor Age

Since 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.

D1.600 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 was begun shall be recorded, if applicable.

D1.700 Eye Maintenance Prior to Enucleation

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.

D1.800 Living Donors

Eye tissue that is removed and processed for surgical use from a living donor 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 immediate term culture medium.

E1.000 Recovery, Open-container Processing, and Preservation

Recovery, open-container processing, and preservation must be done using aseptic technique. AORN's *Recommended Practices for Surgical Hand Antisepsis/Hand*

Scrubs” and “*Recommended Practices for Maintaining a Sterile Field*” shall be used as guidance for aseptic technique during ocular tissue procurement and processing.

All procedures must be documented.

Specific recovery, open-container processing, and preservation procedures can be found in the EBAA Procedures Manual. EBAA Procedures Manual is available for use as a Guidance Document. This manual is periodically reviewed and modified as necessary by the Technician Education Committee. Revisions and modifications are approved by the Medical Advisory Board.

The Medical Director is responsible for establishing the eye bank’s procedures for recovery, open-container processing, and preservation of tissue. The Medical Director and Director are responsible for assuring that eye bank personnel comply with all applicable procedures for the recovery, processing, and preservation of tissue.

E1.100 Recovery

Recovery may be performed via enucleation or in situ method.

Povidone-iodine solution shall contact the surface of any ocular tissue intended for transplantation at least once between the time of the donor’s death and tissue preservation (e.g. cornea in Optisol-GS or whole globe in moist chamber). Excess povidone-iodine solution should be irrigated from the ocular surface prior to preservation. The concentration, volume of solution, and the duration of ocular surface exposure to the solution shall be specified in the eye bank’s operating procedures.

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

Note: Tissue from donors with the following is hazardous to eye bank personnel and requires special handling:

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

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.

E1.210 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.

E1.220 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.

E1.221 Preservation via Excision of the Corneoscleral Rim from Eucleated Whole Globes

E1.222 Lamellar Tissue Processing

Preparation of lamellar tissue may be performed using manual or automated methods (e.g. microkeratome).

E1.223 Laser Assisted Processing

Lasers may be used to prepare lamellar tissue or custom wound architecture (e.g. femtosecond laser).

E1.230 Sclera

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

E1.300 Use of Short or Intermediate Term Preservation Medium

Eye banks shall use an appropriate corneal storage medium that has been manufactured in accordance with FDA Good Manufacturing Practices. 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.

E1.400 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

F1.000 **Tissue Evaluation**

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

F1.100 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.

F1.200 Slit-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 insure that there was no damage to the relevant transplantable tissue.

Document that a slit lamp examination has been performed with particular attention to the epithelium, stroma, and endothelium such as but not limited to scars, edema, significant arcus, striae, epithelial defects, guttata, polymegathism, pleomorphism, infiltrates, or foreign bodies.

F1.300 Endothelial Cell Density and Pachymetry

Determination of endothelial cell density via specular microscopy (or quantitative light microscopy for organ cultured corneas) shall be a standard method of corneal tissue evaluation at all member eye banks of the EBAA, effective December 2001. 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 posterior lamellar grafts, pachymetry and cell density measurement shall be performed following processing. Cell density measurements are not required for tissues where corneal endothelium is not utilized. 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.

F1.400 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, and/or tectonic use.

G1.000 **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. Labeling controls
8. Storage
9. Receipt, pre-distribution shipment, and distribution
10. Donor eligibility determinations, donor screening, and donor testing

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 ten 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. 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 perform an investigation and must report the adverse reaction information within 30 days to the EBAA office for review by the Medical Advisory Board. In accordance with FDA 1271.350, adverse reactions involving a relevant communicable disease must be reported to the FDA within 15 calendar days of receipt of the information if the adverse reaction is fatal, life-threatening, results in permanent impairment or damage or requires medical or surgical intervention.

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 reportable to the EBAA 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 the EBAA office. The Medical Director shall receive and review all adverse reaction reports, documenting any corrective actions he/she determines are indicated.

G1.100 Quality Control

The 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 federal requirements as well as individual state 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.

G1.200 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.

G1.300 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), within 45 days
- EBAA office, within 45 days
- FDA or other appropriate government agency, within 45 days

Consignee notification of positive test results or information that do not indicate a risk of transmission of a relevant communicable disease does not require EBAA notification.

H1.000 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 labeled “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

I1.000 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 labeled 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.

I1.100 Expiration Dating

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

J1.000 Labeling

All ocular tissue distributed for surgical use shall be in a container which is clearly and indelibly labeled to include at least the information below.

1. Name of source eye bank.
2. Tissue identification number. There must be a unique identification number for each ocular tissue or fraction thereof.
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.
8. A statement that the tissue is intended for single patient application only and that it is not to be considered sterile.
9. Type of preservation medium.

K1.000 Distribution of Tissue

K1.100 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.

K1.200 Receivers of Tissue

Tissue shall be distributed to physicians, dentists, institutions and other eye banks.

All tissue sent from EBAA accredited eye banks to eye banks in this or other countries must comply with the standards defined by the EBAA Medical Advisory Board.

K1.300 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. Documentation of distribution (time and date of requests for, offers of, and delivery of eye tissue) shall be available for inspection by the Accreditation Board. Access to tissue shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin.

K1.400 Returned Tissue

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

L1.000 Documentation to Accompany Donor Tissue

L1.100 Tissue Report Form

For special research studies, by recommendation of the Medical Advisory Board and approved by the EBAA Board of Directors, certain specific data may be masked on the tissue report form and label. 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 tissue graft
5. Type of preservation medium
6. If cornea is pre-cut, 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. If prepared for laser assisted penetrating keratoplasty:
 - a. Morphology and dimensions of cut
 - b. Pre and post-cut slit lamp reports
 - c. Pre and post-cut specular microscopy reports
8. If prepared for lamellar anterior or endothelial keratoplasty:
 - a. Estimate thickness of transplant portion
 - b. Diameter of cut
 - c. Pre and post-cut slit lamp reports
 - d. Pre and post-cut specular microscopy reports for tissue intended for endothelial keratoplasty use
9. Age of donor
10. Cause of death
11. Death date and time
12. Preservation date and time
13. Additional tissue processing date and time
14. The time that cooling of ocular tissues and/or refrigeration of the body was begun
15. Name of technician who enucleated, excised, processed, and evaluated the tissue
16. Slit lamp report/date of each evaluation
17. Specular microscopy report/date of each evaluation
18. Name and EBAA Accreditation Status of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, tissue storage, evaluation, donor eligibility determination and final distribution
19. A summary of records reviewed regarding the eligibility of tissue for transplant

L1.200 Package Insert Form

A “Package Insert” form that meets the EBAA 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 any evidence of possible tampering.
3. For corneas in Optisol. 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 CLIA certified and FDA registered laboratory.
8. That FDA approved tests were used for infectious disease testing as required by the FDA and EBAA, some of which are approved for pre-mortem blood and that FDA approved tests for cadaveric blood were used where available.
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.

L2.000 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. See *Section LI.200*.

M1.000 Eye Bank Records

M1.100 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.

M1.200 Confidentiality

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

M1.300 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.

M1.400 Minimum Information to Be Retained

Forms for retaining donor and recipient information shall be established and shall be readily accessible for inspection by the EBAA Accreditation Board. Eye bank records shall include the following minimum information:

See Section L1.000 for information to be included on the Tissue Report Form.

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
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 (See Section M1.500)
19. Date, time, method of transportation

20. Utilization of tissue: i.e., surgical, research, training
21. Printed results of all EBAA 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 post operative outcome information from the transplanting surgeon has been requested

M1.500 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 (if allowed by law)
 - Unique identification according to the following order of preference:
 - a. Social security number
 - b. Driver's license number
 - c. Hospital information number
 - d. Alien identification
 - e. Passport number
 - f. Other unique identifier appropriate to the health care delivery system where surgery is performed
 - Age and/or Date of Birth
 - 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 at an institution only if it is for single patient use; the distributing eye bank must be able to track the tissue to the consignee.
4. Each distributing eye bank must request postoperative outcome information between three and twelve months after transplant from the transplanting surgeon concerning possible adverse reactions on all cornea tissue used for human transplantation that was distributed to the surgeon by that bank. This request must be addressed to the transplanting surgeon

and delivered separately from the documentation that accompanies the eye tissue. For special research studies where postoperative outcomes are monitored by other means, by recommendation of the Medical Advisory Board and approval by the EBAA Board of Directors, eye bank solicitation of postoperative outcome information and documentation of such solicitation (under M1.400 item 25) will not be required.

M1.600 Statistical Reporting

Each eye bank shall report annual statistics to the EBAA as established by the Medical Advisory Board within the first 30 days of each new calendar year. Each source eye bank shall report information on surgical technique and indications for surgery.

N1.000 Amendments

These standards may be amended as required.

The Medical Advisory Board 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.

Glossary Definition of Terms

***Note:** The Eye Bank Association of America (EBAA) Glossary pertains to association members, which are required to meet EBAA Medical Standards and follow applicable federal and state regulations.*

Adverse Reaction (EBAA reportable). Any communicable or other disease that is reasonably likely or proven to have been transmitted by transplantation of donor eye tissue including infection and biologic dysfunction. See also **Eye Bank Association of America (EBAA) Medical Standard G1.100.** (Reference: Guidance Document for Adverse Reaction Reporting to the EBAA)

Anterior Lamellar Keratoplasty. Transplantation of the anterior stroma of the cornea.

Aseptic Technique. Method by which contamination with microorganisms is prevented.

Audit. A documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors to evaluate adherence to the written SOP, standards, or federal, state and/or local laws and regulations.

Autologous use. The implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.

CDC. An abbreviation for the *Centers for Disease Control and Prevention*, Atlanta, Georgia.

CFR. An abbreviation for the *Code of Federal Regulations*. Published by the Office of the Federal Register, National Archives and Records Administration, Washington, DC.

CJD. An abbreviation for *Creutzfeldt-Jakob Disease*.

Colloid. A protein or polysaccharide solution such as albumin, dextran, or hetastarch that can be used to increase or maintain osmotic (oncotic) pressure in the intravascular compartment, or certain blood components, such as plasma and platelets.

Complaint. Any written or oral communication concerning dissatisfaction with the identity, quality, packaging, durability, reliability, safety, effectiveness, or performance of tissue.

Competency. The ability of an employee to acceptably perform tasks concomitant with his/her educational level for which he/she has been trained.

Competency Assessment. The evaluation of the ability of an employee to acceptably perform tasks that are expected of the employee for the duties/responsibilities assigned to him/her.

Consent. A process where approval for donation is obtained from the donor (called “First Person consent” or “FP”) or the donor’s next of kin or other legally recognized representative.

Consignee. Any eye bank, eye banking intermediary (whether individual, agency, institution, or organization) that receives tissue and assumes responsibility for any step in the processing, storage, distribution and/or use of such tissue.

Container. A receptacle that is used to contain tissues and is in direct contact with the tissue.

Contract Services. Those functions pertaining to the recovery, screening, testing, processing, storage, and/or distribution of tissue that another establishment agrees to perform for an eye bank.

Cross-Contamination. The transfer of infectious agents from one tissue to another tissue, or from one donor's tissue to another donor's tissue.

Crystalloid. A balanced salt and/or glucose solution, such as saline, TPN (total parenteral nutrition), Ringer's lactate solution, or 5 percent dextrose in water, used to replace electrolytes or to increase intravascular volume.

Decontamination. The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Dehydration. The removal of water from cells and/or tissue.

Designee. A person authorized by responsible party to perform assigned duties.

Disinfectant. An agent that reduces the number of viable cellular microorganisms.

Disinfection. A process that reduces the number of viable cellular microorganisms, but does not necessarily destroy all microbial forms, such as spores and viruses.

Disposition. The final destination of tissue, including use for transplantation, education, research, or discard.

Distributing Establishment. An entity that is reimbursed for or invoices for providing tissue to the end user. Responsible for obtaining recipient information, post op follow up and reporting any adverse reaction to the source establishment.

Donor. A living or deceased individual who provides the source of tissue for transplantation, education, or research.

Donor Eligibility Determination. The evaluation of all available information about a potential donor to assess whether the donor meets qualifications specified in the SOP and standards. This includes, but is not limited to: medical, social, and sexual histories; laboratory test results; physical assessment or physical examination; and autopsy findings (if performed).

Donor Referral Sources. Entities such as hospitals, medical examiners, coroners and individual allied health care professionals or others who identify potential eye tissue donors and refer them to eye banks.

Donor Screening. See **EBAA Medical Standard D1.000.**

End User. A hospital, surgeon, surgicenter, research center or any entity that utilizes tissue provided by an eye bank.

Endothelial Keratoplasty. Transplantation of the corneal endothelium attached to a carrier.

Enucleation. Recovery of the whole globe.

Equipment Qualification. Protocols designed to adequately evaluate, prior to use, whether or not pieces of equipment will perform to expectation, and normally function within the required tolerance limits.

Evaluation. The assessment of an entity, tissue, equipment, personnel, performance in relation to predetermined expectations or standards.

Expiration Date. The date after which instruments, supplies or tissues are deemed no longer suitable for use.

Eye Bank. An entity that provides or engages in one or more services involving ocular tissue from living or deceased individuals for transplantation, research, and/or educational purposes. These services include but are not limited to assessing donor suitability (including screening), recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, tracking, disposition, and recall of ocular tissue.

FDA. An abbreviation for the United States *Food and Drug Administration*.

Final Distribution. Shipment of tissue that has been released for transplantation.

Freezing. The cooling of tissues to a set temperature below 0°C without the addition of a cryoprotectant.

Graft. Tissues prepared for use in transplantation.

HBC. An abbreviation for *hepatitis B core*.

HBsAg. An abbreviation for *hepatitis B virus surface antigen*.

HCV. An abbreviation for *hepatitis C virus*.

HIV. An abbreviation for *human immunodeficiency virus*.

HTLV. An abbreviation for *human T-cell lymphotropic virus*.

Identification Number. An unique numeric or alphanumeric designation assigned to, and thus associated with, a donor or recipient, a specific establishment (or facility) and tissues for the purpose of tracking and confidentiality. If donated ocular tissue is divided, an unique donor identification number is distinctly assigned to each part.

IVF. An abbreviation for *in vitro fertilization*.

Laser Assisted Keratoplasty. Corneal surgeries in which wound architecture is shaped by laser.

- a. **Laser Assisted Anterior Keratoplasty.** Anterior keratoplasty in which the lamellar and/or side dissection of the donor tissue is prepared using a laser.
- b. **Laser Assisted Endothelial Keratoplasty.** Endothelial keratoplasty (surgery) in which the lamellar and/or side dissection of the donor tissue is prepared using a laser.
- c. **Laser Assisted Penetrating Keratoplasty.** Penetrating keratoplasty in which the donor and recipient wound architecture are shaped by laser.

Medical Director. See **EBAA Medical Standard C1.200**.

Donor Risk Assessment Interview. A documented dialogue in person or by telephone with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior. For example this may be: the donor, if living; the next of kin; the nearest available relative; a member of the donor's household; other individual with an affinity relationship (e.g., caretaker, friend, significant life partner); and/or the primary treating physician. Alternatively, a living donor may complete a written questionnaire. Relevant social history is elicited by questions regarding certain activities or behaviors that are considered to place such a potential donor at increased risk for a relevant communicable disease agent or disease.

Microorganism. A microscopic organism; viruses, while sometimes included in this classification, are not included here.

Next Of Kin. The person(s) most closely related to a deceased individual as designated by applicable law such as the Uniform Anatomical Gift Act.

NIST. An abbreviation for the *National Institute of Standards and Technology*.

ODO. An abbreviation for *organ donation organization*.

Open-Container Processing. Any manipulation of the ocular tissue, intended for transplant, that involves opening a previously sealed container after recovery.

OPO. An abbreviation for *organ procurement organization*.

Package. A labeled carton, receptacle, or wrapper containing one or more containers and accompanying labeling and package insert materials.

Package Insert. The written material accompanying tissue bearing further information about the tissue, directions for use, and any applicable warnings.

Physical Assessment. A limited autopsy or recent ante-mortem or post-mortem physical examination of the donor to assess for signs of a relevant communicable disease and for signs suggestive of any risk factor for a relevant communicable disease.

Physical Examination. See Physical Assessment.

Plasma Dilution. A decrease in the concentration of the donor's plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids, i.e., colloid(s) and/or crystalloid(s).

Policies and Procedures Manual. A group of standard operating procedures (SOPs) that detail the specific policies of an eye bank and the procedures used by the staff/personnel. This includes but is not limited to, procedures to assess donor eligibility; this includes operations such as; screening, recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, tracking, disposition, and recalling tissue.

Pre-Cut Tissue. Corneal tissue in which lamellar or vertical dissection has been prepared for surgical use, by eye bank or other organization, prior to distribution for surgical use.

Pre-Distribution Shipment. Shipment of tissue in quarantine within an establishment or between establishments (recovering eye bank to processing eye bank) of tissue that has not been released for final distribution. Tissue must be shipped in quarantine.

Preservation. The use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of ocular tissues.

Preservation Medium. See **Storage Medium**.

Primary Graft Failure. Corneal edema present from the time of keratoplasty that does not clear after eight weeks and in which there is no known operative or postoperative complication or underlying recipient condition that would explain the biologic dysfunction

Procedure. A series of steps, which when followed, are designed to result in a specific outcome.

Process Controls. A system of checks and balances incorporated into standard operating procedures involving critical operations to prevent errors.

Process Validation Studies. The process of demonstrating a specific process or procedure will consistently produce expected results within predetermined specifications.

Processing. Activities that may include, but are not limited to, the assessment, preparation, manipulation/sizing, testing, decontamination, and/or sterilization of ocular tissues. See also Open-container Processing.

Processing Establishment. The entity that performs post-recovery tissue processing.

Procurement. See **Recover(y)**.

Product Deviation. An event that represents a deviation from a current good practice, applicable standard, or established specification; or an unexpected or unforeseen event that may relate to the transmission or potential transmission of a notifiable disease agent or disease from a tissue, or organ to the recipient, or may lead to product contamination, or may adversely affect the function or integrity of the product.

Proficiency. An evaluation of laboratory methods and test results that assesses the quality of standard operating procedures, equipment, supplies, and reagents, as well as the skill of the personnel performing the testing.

QA. An abbreviation for *quality assurance*.

QC. An abbreviation for *quality control*.

Qualification. The process of establishing confidence that equipment, reagents, and ancillary systems are capable of consistently operating within established limits and tolerances. Process performance qualification is intended to establish confidence that the process is effective and reproducible.

Qualified. Deemed competent by a recognized authority.

Quality. The conformance of ocular tissue or a process with pre-established specifications or standards.

Quality Assurance (QA) Program. A program that: 1) defines the policies and environment required to meet standards of quality and safety and, 2) provides confidence that the processes and tissue consistently conform to requirements for quality. Dimensions of QA may include quality control, auditing and process control, standards for personnel, facilities, procedures, equipment, testing, and record keeping activities.

Quality Control (QC). Specific tests defined by the eye bank's QA Program to be performed to monitor retrieval, processing, preservation and storage, tissue quality, and test accuracy. These may include, but are not limited to: performance evaluations, inspection, testing, and controls used to determine the accuracy and reliability of the eye bank's equipment and operational procedures, as well as the monitoring of supplies, reagents, equipment, and facilities.

Quarantine. The identification of ocular tissue as not currently suitable for transplantation, including ocular tissue that has not yet been characterized as being suitable for transplantation. Quarantine includes the storage of such tissue in an area clearly identified for such use, or other procedures, such as automated designation, to prevent the premature release of such ocular tissue for transplantation.

Recall. An action taken to locate and retrieve tissue from distribution and dispensary inventories. Removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. (Reference: EBAA Tissue Recall Guidance Document)

Receiver. An establishment (facility or entity) or individual that accepts shipment of distributed tissues for transplantation (e.g. physicians, dentist, institutions, other eye banks).

Recipient. An individual who receives an ocular tissue transplant.

Recover(y). The removal, acquisition, recovery, or collection of donor tissue.

Recovery Establishment. Entity that recovers tissue from a donor.

Relevant Communicable Disease. Any communicable disease relevant to transplantation of tissue in humans as defined by FDA regulations, FDA guidance documents or US law.

Relevant Medical Records. A collection of documents including a current donor risk assessment interview, a physical assessment/physical examination of the donor, laboratory test results (in addition to results of testing for required relevant communicable disease agents), relevant donor records, existing coroner and autopsy reports, as well as information obtained from any source or records that may pertain to donor suitability regarding high risk behaviors, and clinical signs and symptoms for any relevant communicable disease agent or disease (RCDAD), and/or treatments related to medical conditions suggestive of such risk.

Repeat Reactive. A blood sample that is reactive on initial testing and is still reactive in at least one of two duplicate samples when the same test is repeated using the same blood sample.

Resolution. Adjustment, clarification, and/or correction of practices and/or procedures that results in compliance with the SOPM and/or standards.

Responsible Party. A person who is authorized to perform designated functions for which he or she is trained and qualified.

Retrieval. See Recover(y).

Safety. A level of quality of tissue that indicates handling according to acceptable standards and assures substantial freedom from the potential for harmful effects to recipients.; the condition of being protected from risk or injury associated with occupational exposure.

Satellite Facility. An establishment in a location physically separate from its main facility where any activities occur that contribute to screening, recovery, transport, processing, evaluation, testing, quarantine, labeling, storage, distribution, tracking, disposition, or recall of ocular tissue under the management or direct supervision of the same corporate entity or it's employee(s).

Services to Donor Families. A defined policy or program that implements an eye bank's recognition of the value of donation by the consenting party. These may include written communications regarding: potential uses of tissue; recovery outcome information; bereavement support; provision of a copy of the Document of Consent; and/or guidance describing how to contact the eye bank if any questions arise regarding the donation. Frequency of follow-up and program maintenance is at the discretion of the Executive Director.

Shall. A figure of speech used interchangeably with "must."

Should. A figure of speech used to indicate a recommendation; advisory, indicating a commonly accepted activity for which there may be effective alternatives.

SOP. An abbreviation for *standard operating procedures*.

Source Establishment (or Facility). The entity that releases tissue following donor eligibility determination, and is responsible for maintaining donor records and evaluating adverse reaction reports

Standards. The Medical Standards of the EBAA.

Sterile. The absence of detectable, viable, microorganisms (refer to ANSI/AAMI ST79:2006).

Sterilization. A validated process used to render ocular tissue free from viable microorganisms (refer to ANSI/AAMI ST79:2006) including spores.

Store or Storage. The maintenance of ocular tissue for future use.

Storage Establishment. The entity that stores tissue at any time prior to distribution to the end user.

Storage Medium. The reagent utilized in the preservation of a tissue for its intended use.

Summary of Records. A condensed version of the required testing and screening records that contains the identity of the testing laboratory, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical

records, and the name of the person or establishment determining the suitability of the ocular tissue for transplantation.

Time of Death. For purposes of eye donation, the time of death is the cessation of heartbeat, cardiac death, asystole, cross-clamp, last known alive (LKA), or it can be the time of death established by core temperature, when applicable and with appropriate documentation from a medical professional.

Tissue. A functional group of ocular cells, such as cornea, sclera. Tissues may be transplanted as viable cells or otherwise preserved or fixed. Tissue does not include perfusable organs for transplantation.

Tissue Bank. An entity that provides or engages in one or more services involving tissue from living or deceased individuals for transplantation, research, and/or educational purposes. These services include but are not limited to assessing donor suitability (including screening), recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, tracking, disposition, and recall of tissue.

Tissue Identification Number. Any unique combination of letters, numbers, and/or symbols assigned to ocular tissue and linked to a donor, from which the complete history of the collection, processing, packaging, quarantine, labeling, storage, and distribution of ocular tissue can be traced.

Tissue Type. Refers to whole globe or a specific portion of the eye, such as cornea or sclera.

Tolerance Limits. The limits that define a range of acceptable values established for each testing procedure that, when exceeded, require the implementation of corrective actions designed to produce results within the acceptable range in future tests.

Traceability. The act or ability to locate ocular tissue during any step of its recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, disposition, or recall. It includes the capacity to identify the medical facility receiving the tissue and, at the medical facility, the ability to identify the storage, recipient or final disposition of the tissue.

Tracking. The act or ability to locate individual tissue during any step of its recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, disposition, and recalling. It includes the capacity to identify the consignee and recipient.

Transplantation. The transfer of tissue to a recipient.

Transplant Program. An organization of medical personnel and allied health care professionals, operating in one or more transplant centers, with the responsibility for the transplantation of one or more types of tissues, and/or organs.

Transport Medium. Any microbiological medium capable of maintaining cellular viability during the transport of ocular tissue.

Validation. The process of establishing documented evidence that provides a high degree of assurance that specific process will consistently produce the predetermined outcome.

Variance. A departure from *Standards* that is pre-approved by the EBAA, Medical Director, Executive Director, or governing authority prior to implementation.

Verification. The confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

Wet Ice Temperatures. Temperatures ranging from 1-10°C.

Withdrawal (or Market Withdrawal). Removal or correction of a distributed product by an eye bank that involves a minor violation that would not be subject to legal action by the FDA, or that involves no violation. Does not involve a relevant communicable disease. No notification to FDA or EBAA is required. (Reference: EBAA Tissue Recall Guidance Document)

Index

A

Accreditation.....5, 6, 8, 12, 26, 27
 specific eye banking services 12
 suspension or revocation of6
 Active disseminated lymphomas 15
 Adenocarcinoma..... 14
 Adverse event 23
 Adverse reaction..... 22, 23, 29, 30, 32
 Aseptic technique..... 18, 21, 32
 Associate for the Advancement of Medical
 Instrumentation (AAMI) 11, 39
 Autoclave 11
 Autopsy 13, 33, 36, 38

B

Banks outside U.S. 16, 26
 Blood banks 9
 Blood loss / volume..... 16
 Blood sample..... 16, 28
 Bloodborne pathogens.....*See* Universal precautions
 Bylaws EBAA 5

C

Cause of death..... 13, 27, 29
 CDC (Centers for Disease Control and Prevention)
 12, 32
 CEBT (Certified Eye Bank Technician) 7, 8, 9,10,12
 certification..... 7, 9
 certification renewal..... 9
 consultative relationship with..... 8, 9
 exam 9
 meeting attendance requirements EBAA 10
 replacement..... 8
 Cleaning 10, 11, *See also* Facility
 CLIA (Clinical Laboratory Improvement
 Amendments)..... 28
 Complaints 32. *See* Quality program
 Congenital rubella..... 14
 Conjunctivitis 14
 Consent 17, 32, 39
 Consignee..... 24, 29, 33, 40
 Cornea 5, 7, 11, 14, 15, 18, 19, 20, 21, 22, 23, 24,
 25, 26, 27, 28, 32, 40. *See also* Preservation
 organ cultured 21
 Coroner *See* Medical examiner
 Creutzfeldt-Jakob disease 14, 19, 23, 32
 Cross contamination prevention..... 11, 33
 Culture..... 21, 23, 24, 27, 29. *See also* Medium
 corneoscleral rim..... 24, 29
 microbiologic..... 23, 27, 29

organ..... 20, 21
 pre-surgical..... 23, 24, 27
 surgical 23, 24, 27

D

Director

co-medical..... 7
 executive 6, 7, 8, 9, 11, 19, 23, 39, 41
 medical 6, 7, 8, 9, 11, 12, 13, 17, 18, 19, 21, 23,
 24, 26, 35, 41
 adverse reaction review..... 22, 23, 32, 39
 back up..... 7
 corneal fellowship requirement..... 7
 donor record review..... 13, 17, 33, 38, 39
 infectious disease testing 16, 23
 newly appointed..... 7
 plasma dilution 16, 36
 replacement of 8
 requirements 7
 tissue recall or withdrawal. 20, 24, 36, 38, 39,
 40, 41

Distributing bank..... 22, 24, 28, 30, 33
 Distribution 5, 6, 10, 11, 12, 13, 22, 23, 24, 26,
 27, 28, 33, 36, 38, 39, 40. *See also* Waste disposal
 distributing eye bank 22, 24, 28, 30, 33
 fair and equitable system 26
 labeling 25
 non-surgical tissue 24
 packaging tissue 28
 receivers of tissue (end users) 26
 returned tissue..... 26
 sclera 8, 16, 19, 20, 21, 22, 24, 25, 27, 28, 30, 40
 single use, not sterile statement..... 25
 test results prior to 17, 26, 38
 tissue report form..... 26, 29
 tracking 20, 34, 35, 36, 39, 40
 Documentation . 5, 6, 7, 9, 10, 11, 13, 17, 23, 26, 28,
 29, 30, 40
 accompanying tissue 24, 26, 36
 adverse reaction 22, 23, 29, 30, 32, 33, 39
 complaints..... 22
 consent legal 17, 32, 39
 disposition of human remains 13
 distribution..... 13, 23, 24, 25, 26, 28, 36, 38, 40
 equipment 10, 11, 21, 22, 32, 34, 37
 HIV testing 23
 inspections 6
 laser assisted penetrating keratoplasty... 15, 26,
 30, 35
 limited membership consultation with CEBT .. 8
 long term perservation..... 20, 21

medical director. 6, 7, 8, 9, 11, 12, 13, 17, 18, 19, 20, 21, 23, 24, 26
 package insert form..... 27, 28, 36
 physical assessment of donor 13, 33, 36, 38
 plasma dilution.....16, 36
 post operative outcome information.....29, 30
 quality program 7, 9, 11, 22, 23, 37
 returned tissue 26
See also Records 11, 13, 14, 17, 18, 22, 27, 28, 29, 32, 38, 39
 slit lamp exam 21, 27, 29
 tissue lamellar anterior or endothelial
 keratoplasty 15, 27, 30, 34, 35
 training.....9, 13, 29
 Donor age..... 18, 27, 29
 Donor eligibility 5, 12, 13, 22, 23, 25, 27, 32, 33, 36, 39
 contraindications..... 14
 death to preservation 15, 16, 18
 exclusionary criteria 14, 15
 eye maintenance 18
 forms 17, 27, 29
 HIV 13, 17, 19, 23, 34
 living donors.....18, 35
 physical assessment..... 13, 33, 36, 38
 plasma dilution.....16, 36
 plasma dilution algorithm 16
 potentially hazardous tissue 13, 19
 record review..... 13, 17, 33, 38, 39
 review of donor history 13, 27
 risk assessment interview..... 13, 35, 38
 testing... 10, 11, 13, 16, 17, 22, 24, 28, 33, 34, 36, 37, 38, 39, 40
 Donor identification by name 13, 29, 30
 Donor rim culture *See* Culture
 Donor risk assessment interview 13, 35, 38
 Donor screening or suitability. *See* Donor eligibility

E

ECD (endothelial cell density) *See* Evaluation
 Eligibility of tissue *See* Evaluation, tissue
 Encephalitis 14, 19
 End users..... *See* Distribution
 Endocarditis..... 14
 Environmental control.....19, 22
 Epikeratoplasty 15
 Equipment 10, 11, 21, 22, 32, 34, 37
 autoclave 11
 laminar flow hood 11, 19
 records 11, 22, 28, 32
 refrigerator..... 10
 emergency power requirements 10
 specular microscopy calibration 21
 temperature recording device.....10, 11

Ethics 5
 Evaluation .. 5, 7, 8, 11, 12, 13, 21, 22, 23, 27, 32, 33, 34, 36, 37, 39, 40
 ECD (endothelial cell density).....21
 gross eye exam 21
 pachymetry.....21
 penlight exam 19, 21
 penlight or portable slit lamp exam 21
 slit lamp exam 21, 27, 29
 specular microscopy..... 15, 21, 27, 29
 tissue 5, 7, 8, 12, 13, 14, 15, 19, 21, 22, 23, 27, 34, 40

Excusatory criteria *See* Potentially hazardous tissue
 Expiration dating 11, 20, 25, 34
 Eye maintenance..... 18, 39

F

Facilities 10, 11, 22, 32, 37
 Facility
 cleaning 10, 11
 laboratory..... 8, 10, 16, 28, 39
 relocation.....10
 requirements 10
 FDA (U.S. Food and Drug Administration) 6, 8, 9, 14, 16, 17, 20, 23, 24, 28, 34, 38, 41
 CFR 1271.350 23
 CFR 29 subpart Z..... 12

G

Good Manufacturing Practices (GMP) 20, 37
 Governance..... 6, 9
 executive director appointment..... 6
 Gross eye exam *See* Evaluation

H

Hazardous tissue.. *See* Potentially hazardous tissue
 HCV..... 17, 34
 Hepatitis..... 13, 17, 19, 23, 34
 Hepatitis B..... 17, 23, 34
 Hepatitis B surface antigen 17, 23, 34
 Hepatitis C..... 17, 34
 HIV..... 13, 17, 19, 23, 34
 Hood *See* Laminar flow hood
 Hospitals..... 9, 34
 HTLV 35
 Human tissue remains..... 13

I

Identification number (donor or tissue). 17, 20, 25, 26, 28, 29, 30, 35, 40
 Indications for surgery 30
 Infection 14, 23, 24, 32
 Infection control..... 12
 Infectious disease testing..... *See* Testing

Inspections 5, 6, 7, 22, 26, 29, 37
 distribution system 25, 26
 donor and recipient record retention .. 22, 28, 29
 FDA form 483 6
 medical director meeting attendance EBAA 7
 official agencies 6, 12
 quality program 7, 9, 11, 22, 23, 37
 unannounced..... 6
 Instruments 11, 34
 Intraocular or anterior segment surgery..... 14, 15
 Intrinsic eye disease..... 14
 IV drug abuse or use 13

K

Keratoplasty ... 14, 15, 16, 19, 22, 26, 27, 30, 32, 34, 35, 36.

L

Labeling 10, 22, 24, 25, 26, 28, 34, 36, 39, 40
 non-surgical tissue..... 24
 See also Distribution..... 25, 26
 tissue storage 10, 38
 Laboratory 10, 11, 16, 18, 28, 39, *See* Facility
 Laminar flow hood..... 11, 19
 Laser surgical procedures 15, 20, 26, 27, 35
 Legal 6, 17, 32, 38, 41
 Legislation
 medical examiner or coroner..... 17
 Leukemias..... 15
 Limited function/specific services 12
 Living donors 18, 33, 34, 35, 40

M

Malignant tumors..... 14
 Medical examiner 13, 17, 34
 Medical examiner or coroner legislation..... 17
 Medical social history interview of donor..... 13, 33, 35
 Medium 11, 18, 20, 24, 25, 26, 29, 36, 39, 40
 inspection..... 20, 22
 labeling..... 25
 Membership
 active 5
 limited 8, 12
 Meningitis 14

N

Neurological disease unknown diagnosis 14, 19
 NIST (National Institute of Standards and Technology) thermometer calibration 10
 Non-required laboratory tests 17, 29

O

Operating room 19
 Organ procurement organization..... *See* Transplant organization
 OSHA..... 12
 Other establishments performing eye bank
 functions 8, 12, 36

P

Pachymetry..... 21, *See* Evaluation
 Package insert form 27, 28, 36. *See also* Documentation
 Packaging 25, 28, 32, 40
 Pathologist..... 13
 Penlight 19, 21
 Penlight exam *See* Evaluation
 Physical assessment of donor 13, 33, 36, 38
 Plasma dilution *See* Donor eligibility
 Police report..... 13
 Policy 6, 7, 10, 11, 13, 17, 24, 36, 37, 39
 Post-mortem examination..... *See* Autopsy
 Post-op outcome information 29, 30
 Potentially hazardous tissue..... 13, 19
 Povidone-iodine 19
 Pre-cut *See* Processing
 Preservation..... 5, 7, 8, 11, 15, 16, 18, 19, 20, 21, 24, 25, 26, 27, 28, 29, 36, 37, 39
 aseptic technique requirements ... 18, 21, 25, 32
 cornea..... 20, 21
 excision of corneoscleral rim..... 8, 19, 20
 lamellar tissue 20
 long-term 20, 21
 medium 20, 21
 penlight exam 19, 21
 sclera 20
 whole globe 19, 20, 27
 Procedures 6, 7, 8, 10, 11, 12, 13, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 32, 36, 37, 38, 39, 40
 Procedures manual 10, 11, 12, 18, 21, 22, 36
 EBAA guidance document..... 18, 19, 32, 38, 41
 Processing..... 5, 6, 7, 8, 11, 12, 18, 19, 20, 21, 22, 23, 25, 27, 29, 33, 34, 35, 36, 37, 39, 40
 laser assisted..... 8, 20, 26, 27, 35
 open-container..... 18, 19, 35, 37
 pre-cut..... 25, 26, 27, 36
 Procurement *See* Recovery
 Progressive multifocal leukoencephalopathy..... 14

Q

Quality program 6, 7, 9, 11, 22, 23, 32, 37
 adverse reactions..... 22, 23, 29, 30, 32, 33, 39
 complaints..... 22, 32
 corrective actions 22, 23, 40

executive director responsibility .. 6, 7, 8, 11, 19, 23, 41
 scope5, 10, 12, 22, 23
 testing... 10, 11, 13, 16, 17, 22, 23, 24, 28, 36, 37, 38, 40
 Quarantine.....*See Storage*

R

Rabies 14, 19
 Reagents 11, 22, 37
 Recipient ... 14, 23, 24, 26, 28, 29, 30, 33, 35, 36, 37, 38, 39, 40
 Records*See Donor eligibility:record review*
 accompanying tissue..... 26, 27, 28
 cause of death 13, 27, 29
 cleaning and maintenance.....10, 11
 confidentiality29, 35
 culture 21, 23, 24, 27, 29
 donor identification.....17, 29
 donor identification (ID) number . 17, 29, 35, 40
 donor information. 13, 14, 17, 18, 28, 29, 38, 39, 40
 donor source..... 22, 23, 25, 26, 30, 34, 39
 equipment..... 10, 11, 21, 22, 34, 37
 eye maintenance18, 39
 minimum information to retain.....17, 29
 post-op outcome information requirements .. 29
 processing 7, 8, 11, 18, 19, 20, 21, 22, 23, 25, 27, 29, 36, 37, 40
 quality program6, 7, 9, 11, 22, 23, 32, 37
 recipient identification..... 28, 29, 30, 35, 40
 recipient information 23, 28, 29, 30, 33, 40
 recovery 11, 17, 18, 19, 22, 23, 27, 39, 40
 refrigeration of body or cooling of ocular tissue 18, 27, 29
 retention..... 10, 11, 22, 23, 28, 39
 testing... 16, 17, 22, 23, 24, 28, 29, 33, 36, 37, 38, 39
 tissue report form 20, 26, 27, 29
 Recovery.....5, 7, 8, 11, 12, 16, 17, 18, 19, 22, 23, 25, 27, 33, 34, 36, 38, 39, 40
 aseptic technique requirements18, 32
 body storage related to..... 18
 eye maintenance prior18, 39
 Refractive cornea procedures..... 15, 19, 23
 Refrigeration
 donor’s body or ocular tissue 18, 27, 29
 Refrigerator *See Equipment*
 Refrigerator temperature *See Storage:temperature*
 Regulations 5, 9, 12, 13, 16, 17, 20, 23, 32, 38
 Relevant communicable disease.. 14, 16, 23, 24, 35, 36, 38, 41
 Retinoblastoma 14
 Reyes syndrome..... 14

S

Safety 7, 10, 12, 23, 32, 37, 39 *See also Infection Control*
 Sclera 16, 20, 21, 22, 24, 25, 27, 28, 30, 40
 Screening *See Donor eligibility*
 Slit lamp 21, 27, 29, *See Evaluation*
 Social history of donor. *See Donor risk assessment interview*
 Source bank..... 22, 23, 26, 30
 Specific Services.....12
 Specular microscopy 15, 21, 27, 29, *See also Evaluation.*
 Staff 7, 8, 12, 36
 competency verification 7, 9, 32
 non-CEBT..... 9
 qualified 8, 9, 13, 37, 38
 supportive 8
 technical 6, 7, 8
 training and qualifications..... 7, 8, 9, 13
 Standards.... 5, 6, 8, 10, 12, 15, 18, 19, 26, 32, 33, 34, 35, 37, 38, 39, 41. *See also FDA*
 amendments.....31
 compliance5, 6, 8, 37, 38
 EBAA medical 5, 6, 8, 12, 26, 31, 32, 39
 minimum 5
 review of 5
 scope 5
 violation allegation..... 6
 Statistical Reporting 31
 Sterilization 11, 37, 38
 Storage. 5, 6, 8, 10, 11, 12, 18, 20, 22, 23, 25, 26, 27, 28, 33, 34, 36, 37, 38, 39, 40
 medium 10, 20, 36, 39
 non-surgical tissue 24
 quarantine.....10, 18, 25, 36, 38
 sclera at surgical site 30
 tamper evident seal 27, 28
 temperature 10, 20, 25, 27, 34, 41
 package insert language 27, 36
 temperature requirements..... 10, 20, 27, 34, 41
 Subacute sclerosing panencephalitis 14
 Supplies 10, 11, 22, 34, 37
 Syphilis 17, 23

T

Testing ... 8, 11, 13, 16, 17, 18, 22, 23, 24, 28, 29, 33, 34, 36, 37, 38, 39, 40
 hepatitis B surface antigen 17, 23, 34
 HIV 17, 23, 34
 HIV antibody 17, 23
 outside United States 10, 16
 package insert language..... 27, 28, 36
 reporting positive results..... 17, 24
 required results transplant tissue..... 16, 17, 24

Tissue banks9, *See also* Transplant organization
Tissue recall or tissue withdrawal.....20, 24, 34, 36,
38, 40, 41
Tissue report form20, 26, 29, *See also* Records
Tracking..... 20, 26, 27, 28, 30, 34, 35, 36, 39, 40
Training7, 8, 9, 13, 29, 32
 CEBT role8
 documentation.....9
 orientation.....9
 program7, 9
Transplant organization..... 9, 33, 36, 40
Transplanting surgeon 8, 16, 21, 22, 24, 26, 27, 28,
29, 30, 34

 recipient information responsibility 30, 33
U
Universal precautions.....12
V
Validation11, 20, 37, 39, 41
W
Warranty tissue
 package insert language.....27, 28
Waste disposal13