The proposed AHCA changes include various definitional changes. For instance, the underlying definitions (under 59A.1003) define "Agency" as "means an organ procurement organization (OPO), tissue bank, or eye bank." Rather than use that definition, the latest AHCA draft instead inserts "OPO, tissue bank, or eye bank" each time the term "Agency" occurs. In addition, the revised terminology tends to use "Agency" to refer to AHCA. Given these changes, we understand that AHCA intending to make corresponding changes to 59A.1003 at a later time.

59A Definitions related to Informed Consent/Authorization. As noted below, the biggest issue is that the regulatory definition of "informed consent[1]" per 59A relates to a deceased donor (not authorization), which complicates the discussion regarding informed consent/authorization. Therefore, when AHCA opts to revisit the definitions, we urge AHCA to consider ensuring that the definitions are appropriately aligned.

59A – AHCA Proposed Changes (March 2017)	Proposed changes	Rationale
59A-1.005 Standards for OPOs, Tissue Banks and Eye Banks. (1) Organizational requirements. (a) Institutional identity. ~~The purpose of the OPO, Eye Bank, or Tissue Bankagency shall be clearly established and documented. Documentation of institutional identity shall include whether the OPO, Eye Bank, or Tissue Bankagency is an independent agency or part of another institution. The OPO, Eye Bank, or Tissue Bankagency shall have a functional identity with a professional staff and a commitment to maintain and preserve records and operating procedures for future reference and historical continuity. Policies and procedures shall be maintained for personnel and other agency activities.~~ 1. The purpose of the OPO, Eye Bank, or Tissue Bank shall be clearly established and documented. 2. Documentation of institutional identity shall include whether the OPO, Eye Bank, or Tissue Bank is independent or part of another institution. 3. The OPO, Eye Bank, or Tissue Bank shall have a functional identity with a professional staff and a commitment to maintain and preserve records and operating procedures for future reference and historical continuity. 4. Policies and procedures shall be maintained for personnel and other activities.	Agree with changes.	AHCA requirements are duplicative of 21 CFR 1271. Duplicative of AATB B1.100 and AATB B2.100
(b)~~1.~~ Board of directors or advisory board.~~ Each agency shall have a board of directors or an advisory board which provides consultation and direction on all policy-making decisions as well as issues of liability, fiduciary responsibility, and selection of the agency director. Where the agency operates within the jurisdiction of a state educational institution, or is a hospital-based facility, the responsibilities of this board shall not conflict with the responsibilities or span of control of the duly authorized administrator of the agency.~~ 1. Each OPO, Eye Bank, or Tissue Bank shall have a board of directors or an advisory board which provides consultation and direction on all policy-making decisions as well as issues of liability, fiduciary responsibility, and selection of the director. 2. Where the OPO, Eye Bank or Tissue Bank operates within the jurisdiction of a state educational institution, or is a hospital-based facility, the responsibilities of this board shall not conflict with the responsibilities or span of control of the duly authorized administrator of the OPO, Eye Bank, or Tissue Bank.	(b)~~1.~~ Board of directors or advisory board. Each OPO, Eye Bank, or Tissue Bank shall have a board of directors~~, or~~ an advisory board **or a designated responsible individual to aid in policy-making decisions, unless otherwise provided by the institution of which it is part.**~~which provides consultation and direction on all policy-making decisions as well as issues of liability, fiduciary responsibility, and selection of the director.~~ ~~2. Where the agency operates within the jurisdiction of a state educational institution, or is a hospital-based facility, the responsibilities of this board shall not conflict with the responsibilities or span of control of the duly authorized administrator of the OPO, Eye Bank, or Tissue Bank.~~	Duplicative of AATB B1.200. AOPO and CMS also have advisory board standards for OPOs Note: The AATB *Standards* states the following: "The tissue bank shall have a Governing Body that may consist of a Board of Trustees, Board of Governors, Board of Directors or a designated responsible individual in whom policy-making authority resides, unless

[1](24) "Informed consent" means permission to procure an organ(s) and tissue(s) from a non-living donor which is obtained only under circumstances that provide the prospective donor or donor's next of kin sufficient opportunity to consider whether or not to agree to such donation and that minimize the possibility of coercion or undue influence.

		otherwise provided by the institution of which it is a part. A Board shall consist of individuals from various professions. This Board or designated individual shall determine the scope of activities to be pursued by the tissue bank." Thus, we respectfully request that you ensure that a "designated responsible individual" be added to the overall language.
(c)~~2.~~ OPO, Eye Bank, or Tissue Bank~~agency~~ director. All procedures and policies shall be developed and maintained under the supervision of an OPO, Eye Bank, or Tissue Bank~~agency~~ director appointed by the board of directors or advisory board or, in the case of a state educational institution, the duly authorized administrator of the OPO, Eye Bank, or Tissue Bank~~agency~~. This person shall be qualified by training and experience for the scope of activities being pursued.	(c). OPO, Eye Bank, or Tissue Bank director. All procedures and policies, **including those pertaining to personnel, retrieval, processing, testing, storage, and distribution practices,** shall be developed and maintained under the supervision of the OPO, Eye Bank, or Tissue Bank director**.** ~~appointed by the board of directors or advisory board or, in the case of a state educational institution, the duly authorized administrator of the agency. This person shall be qualified by training and experience for the scope of activities being pursued.~~	Duplicative of 1271.47, 1271.170, and 1271.80 and AATB B1.200 and B1.300 Duplicative of AATB B1.200, B1.300, B2.100, B2.122, B2.200, J2.000 and J3.00 Language is deleted, given that not all licensees appoint directors in this manner.
a. The ~~agency~~ director shall be responsible for all administrative operations including, but not limited to, compliance with these standards. If the ~~agency~~ director appointed does not have medical licensure, the OPO, Eye Bank, or Tissue Bank~~agency~~ shall have a licensed physician (or physicians) under contract to ensure compliance with all medical-legal aspects and with all requirements for specialist knowledge of the particular organs and tissues processed.	a. ~~The director shall be responsible for all administrative operations including, but not limited to, compliance with these standards.~~ **Each Director of a licensee involved with retrieval shall have a working relationship with medical examiner offices in the licensee's service area.** If the director appointed does not have medical licensure, the OPO, Eye Bank, or Tissue Bank shall have a licensed physician (or physicians) under contract to ensure compliance with all medical-legal aspects and with all requirements for specialist knowledge of the particular organs and tissues processed.	Duplicative of AATB B2.200. Not all licenses opt to have the Director participate in all of these requirements.
b. The ~~agency~~ director shall be the individual responsible for the daily operation of the OPO, Eye Bank, or Tissue Bank~~agency~~. It is this person's responsibility to carry out policies of the board of directors or advisory board, and to prescribe technically acceptable means for retrieving, processing, quality control, storage, and distribution.	~~b. The director shall be the individual responsible for the daily operation of the OPO, Eye Bank, or Tissue Bank. It is this person's responsibility to carry out policies of the board of directors or advisory board, and to prescribe technically acceptable means for retrieving, processing, quality control, storage, and distribution.~~	Duplicative of 1271.180 and AATB B2.100; Some language added to description above. Note: Not all licensees have such an arrangement with the Board of Directors or Advisory Board.
c. The ~~agency~~ director shall provide all staff members with adequate information to perform their duties safely and competently.	Agree with changes.	Duplicative of 1271.170, 1271.180 and AATB J2.0000 and J3.00.

d. The ~~agency~~ director shall be responsible for ensuring that technical staff maintain competency by participation in training courses and technical meetings or other educational programs. Such training shall be recorded in the employees personnel file. Delegation of responsibility for technical work, record-keeping, and administration shall be made.	Agree with changes.	
e. To ensure quality control the ~~agency~~ director shall be responsible for ensuring that the medical director prescribes tests and procedures for measuring, assaying, or monitoring properties of organs and tissues essential to the evaluation of their safety and usefulness~~, e.g., hepatitis B surface antigen (HBsAg), human immunodeficiency virus-1 antibody (anti-HIV-1) and human immunodeficiency virus-2 antibody (anti-HIV-2), and hepatitis C virus antibody (anti-HCV)~~. Any clinical laboratory tests performed within a certified OPO, tissue bank or eye bank must comply with ~~Chapter 483, F.S., and~~ the Clinical Laboratories Improvement Act of 1988 (CLIA-88), as applicable.	Agree with changes.	
f. The ~~agency~~ director shall establish a quality assurance program. This program shall include ongoing monitoring and evaluation of activities, identification of problems, and development of plans for corrective action. These procedures and records shall be reviewed at least annually and shall provide the basis for the development of the quality assurance program. Each OPO, Eye Bank, or Tissue Bank~~agency~~ shall document all aspects of its quality assurance program and maintain records of all quality assurance activities for a minimum of seven years for OPOs and ten years for tissue banks and eye banks.	Agree with changes.	Duplicative of 1271.160 and AATB B2.150 CMS and AOPO also have QA standards
g. The ~~agency~~ director shall appoint technical staff and be responsible for ensuring that staff have capabilities and training appropriate to their function.	Agree with changes.	AOPO also has standards
~~3. Medical director. Each OPO, tissue bank, and eye bank shall employ or have under contract a physician medical director, licensed to practice medicine and surgery in the state in which the agency is incorporated. In the case of Florida-based agencies, the physician must be licensed to practice medicine and surgery in Florida. The medical director shall provide direction and supervision to coordinators and all other staff who assist in the procurement of organs, tissues, or eyes for transplantation. With the exception of organ procurement surgery, this~~	Agee with changes.	AOPO and CMS also have standards

~~may be by indirect physician supervision. The medical director or his physician designee shall be available at all times, in person or by telephone, to provide medical direction, consultation, and advice in cases of tissue donation and retrieval. Responsibility for technical performance must rest with the licensed physician medical director.~~		
3.~~4.~~ Each ~~agency~~ director shall have a working relationship with medical examiner offices in the OPO's, Eye Bank's or Tissue Bank's~~agency's~~ service area.	Agree with changes.	
4.~~5.~~ Personnel policies and procedures. Job descriptions, including scope of activities, specific responsibilities, and reporting relationships, for all personnel shall be established by written personnel policies and procedures approved by the ~~agency~~ director.	Agree with changes.	Remove text. Duplicative of AATB B2.300. Redundant, as the director already approves policies and procedures.
5.~~6.~~ Policies and procedures. Each OPO, Eye Bank or Tissue Bank~~agency~~ shall maintain policies and procedures which detail all aspects of retrieval, processing, testing, storage, and distribution practices. a. Each of these procedures shall be reviewed and affirmed in writing annually by the ~~agency~~ director or designee. Modifications of standard procedures and development of new procedures shall be approved by the ~~agency~~ director or designee. b. Obsolete revised procedures shall be retained separately to maintain a historical sequence. c. Copies of ~~the agency's~~ policies and procedures shall be available to the staff at all times. Technical staff shall be required to state in writing that they have read and understand the manual. ~~d. Copies of procedures from published literature cited by reference shall be attached in an appendix to the procedures manual.~~ d.~~e.~~ Copies of ~~the agency's~~ policies and procedures shall be available to surveyors ~~for the AHCA~~ for inspection upon request. e.~~f.~~ Procedures shall be detailed and unambiguous.	Agree with changes.	Minor changes to conform with overall structure.
(b) Records. 1. Donor and recipient records shall be accurate, complete, and confidential~~.~~	(b) Records. 1. Donor and recipient records shall be accurate, complete and confidential, as required by Section 456.057, F.S. Donor record confidentiality shall not	Deleted provisions are duplicative of 1271.20, 1271.50, AATB C2.000, and AATB

as required by ~~pursuant to~~ Section 456.057, F.S. Donor record confidentiality shall not preclude access by surveyors for the AHCA when conducting an inspection or investigation pursuant to paragraphs 59A-1.009(1)(a), (b), (c), F.A.C., and the medical examiner for cases which fall within the medical examiner's jurisdiction, as established under Section 406.05, F.S. Donor medical records and ~~a~~ final ~~hard copy of the~~ results of all laboratory tests shall be reviewed and affirmed in writing by the medical director, designees, or medical contractee to ensure suitability of the donated organ(s) or tissue(s) for the intended application.	preclude access by surveyors for the AHCA when conducting an inspection or investigation pursuant to paragraphs 59A-1.009(1)(a), (b), (c), F.A.C., and the medical examiner for cases which fall within the medical examiner's jurisdiction, as established under Section 406.05, F.S. Donor medical records and final results of all **available** laboratory tests shall be reviewed and **documented.** ~~affirmed in writing by the medical director, designees, or medical contractee to ensure suitability of the donated organ(s) or tissue(s) for the intended application.~~	B2.220. Made changes to conform with current practice. In the electronic era, "affirmed in writing" can be problematic.
2. Documentation shall be concurrent with the performance of each activity in the retrieval, preparation, testing, storage, and distribution of organs and tissues in such a manner that all activities can be clearly traced. All records shall be legible and indelible and shall identify the person performing the procedures/tasks. The record shall include dates of entries and test results. The expiration period assigned to specific categories of processed tissues is to be recorded in the ~~agency's~~ policies and procedures. 3. Records shall be as detailed as necessary for a clear understanding of each activity and shall be available for inspection by AHCA surveyors ~~for the AHCA~~ when conducting an inspection or investigation pursuant to paragraphs 59A-1.009(1)(a), (b), (c), F.A.C., upon request and within the bounds of medical-legal confidentiality, pursuant to Section 456.057, F.S. 4. Each organ donor, ~~and~~ tissue and any components derived from tissue ~~therefrom~~ shall be assigned, in addition to generic designation, one unique identification number which shall serve as a lot number to identify the material from retrieval through distribution and utilization. 5. Records shall identify the donor, document the pathological and microbiological evaluation of the donor, verify the conditions under which the organ or tissue is retrieved, processed and stored, if applicable, and indicate disposition of the transplanted organ or tissue. Maintenance of these records shall be the responsibility of the ~~agency~~ director or designee. All records concerning donor history and processing information shall be made available to	2. Documentation shall be concurrent with the performance of each activity in the retrieval, preparation, testing, storage, and distribution of organs and tissues in such a manner that all activities can be clearly traced. All records shall be legible and indelible and shall identify the person performing the procedures/tasks. The record shall include dates of entries and test results. The expiration period assigned to specific categories of processed tissues is to be recorded in the policies and procedures. 3. Records shall be as detailed as necessary for a clear understanding of each activity and shall be available for inspection by AHCA surveyors when conducting an inspection or investigation pursuant to paragraphs 59A-1.009(1)(a), (b), (c), F.A.C., upon request and within the bounds of medical-legal confidentiality, pursuant to Section 456.057, F.S. 4. Each organ donor, and tissue and any components derived from tissue shall be assigned, in addition to generic designation, ~~one~~ **a** unique identification number ~~which shall serve as a lot number~~ to identify the material from retrieval through distribution and utilization. 5. Records shall identify the donor, document the pathological and microbiological evaluation of the donor, verify the conditions under which the organ or tissue is retrieved, processed and stored, if applicable, and indicate disposition of the transplanted organ or tissue. Maintenance of these records shall be the responsibility of the director or designee. ~~All records~~ **Information** concerning donor history and processing ~~information~~ shall be made available to the transplant surgeon upon request, except those infringing upon donor confidentiality. 6. All records and communication between the OPO, Eye Bank, or Tissue Bank and its donors**, donor families,** and patient recipients shall be regarded as confidential and privileged. Surveyors for the AHCA shall have access to records and communication at the time of the inspection as specified in Rule 59A-1.009, F.A.C.	Deleted provisions duplicative of 1271.270, 1271.290(c), and 1271.200. All well covered in CMS and AOPO and OPTN standards and requirements Duplicative of 21 CFR Part 1271.200, 1271.270(d) and 1271.320(c), effective May 2005, and AATB C1.300, J5.000 and K4.300, effective July 2016. Current UDI practices may have the distinct identification code (DIC) as part of either the lot number, serial number, or the DIN. Made some changes to update the language to reflect current practice. Clarified that the confidentiality and privilege extends to the donor families.

the transplant surgeon upon request, except those infringing upon donor confidentiality. 6. All records and communication between the OPO, Eye Bank or Tissue Bank~~agency~~ and its donors and patient recipients shall be regarded as confidential and privileged. Surveyors for the AHCA shall have access to records and communication at the time of the inspection as specified in Rule 59A-1.009, F.A.C.		
7. Maintenance and certification records, if applicable, on facilities, instruments, and equipment, including their monitors, shall be maintained. These records shall indicate dates of inspection, name of facility, and performance evaluations. Each OPO, Eye Bank or Tissue Bank~~agency~~ shall include in its procedures manual, the monitoring, inspection and cleaning procedures and schedules for each piece of equipment. Documented cleaning schedules for laboratory equipment shall be maintained. Records of function checks requiring interpretation of findings must include the interpretation. Records must include: a. Temperature of incubators when in use; b. Spore lot number and expiration date used for autoclave function check; and c. Control and test results. 8. An adverse reactions file shall be maintained pursuant to Rule 59A-1.011, F.A.C. 9. All of these records shall be retained for seven years for OPOs and ten years for tissue banks and eye banks after distribution of organs or tissues and be available for AHCA inspection.	Agree with changes.	
(2) Safety and environmental control. Written procedures for the operation ~~of the agency~~ shall be established and approved by the ~~agency~~ director. Instructions for action in case of emergency or exposure to communicable disease, chemical and biological hazard precautions shall be included.	Agree with changes.	Duplicative of 1.0005(1)(e) and AATB J3.100
(a) Human waste items shall be disposed so as to minimize any hazard to personnel or the environment as required by Section 381.0098, F.S., Chapter	(a) Human waste items shall be disposed so as to minimize any hazard to personnel or the environment as required by Section 381.0098, F.S., Chapter 403, Part IV, F.S., and Chapter 64E-16, F.A.C.	Duplicative of AATB J3.600 Clarified that certain entities will

403, Part IV, F.S., and Chapter 64E-16, F.A.C.. ~~Dignified and proper disposal procedures shall be used to obviate recognizable human remains. Any organs or tissues from a donor whose blood test for HIV or hepatitis pursuant to Section 381.0041, F.S., that are confirmed as positive by confirmatory testing shall be destroyed, treated, or disposed, in accordance with Section 381.0098, F.S., Chapter 403, Part IV, F.S. and Chapter 64E-16, F.A.C.~~ (b) Dignified and proper disposal procedures shall be used to obviate recognizable human remains. (c) All organs or tissue found positive for human immunodeficiency virus shall be rendered noncommunicable or shall be destroyed, unless specifically labeled to identify the human immunodeficiency virus and: 1. Is used for research purposes; or 2. Is used to save the life of another and is transferred with the recipient's informed consent.	(b) Dignified and proper disposal procedures shall be used to obviate recognizable human remains. (c) All organs or tissue found positive for human immunodeficiency virus shall be rendered noncommunicable or shall be destroyed, unless specifically labeled to identify the human immunodeficiency virus and: 1. Is used for research purposes; or 2. Is used to save the life of another and is transferred with the recipient's informed consent **or an acknowledgement from the transplanting center**.	not have the recipient's informed consent.
(d)~~(b)~~ Each OPO, Eye Bank or Tissue Bank~~agency~~ shall comply with Occupational Safety and Health Administration (OSHA) rules 29 Code of Federal Regulations (CFR) Part 1910.1030, effective April 3, 2012 which are incorporated herein by reference.~~1991.~~ These rules establish requirements for minimizing exposure to hepatitis, HIV, and other blood-borne pathogens.	Agree with changes.	
(3) Facilities and equipment. (a) Facilities shall be designated for the specialized purposes for which they are to be used and shall be maintained in a clean and orderly manner. All instruments and equipment shall be subject to regularly scheduled maintenance and calibration. All temperature measuring devices must be calibrated against U.S. Bureau of Standards certified thermometers. Refrigerators and freezers used for the storage of tissues shall have monitors. Each OPO, Eye Bank or Tissue Bank~~agency~~ shall have established procedures to follow in the event of electrical failure. (b) ~~There shall be policies and procedures to define limited access available for review by surveyors for the AHCA as specified in Rule 59A-1.009, F.A.C.~~ Facility a~~A~~ccess shall be limited to ~~agency~~ employees of the OPO, Eye Bank or	(3) Facilities and equipment. (a) Facilities shall be designated for the specialized purposes for which they are to be used and shall be maintained in a clean and orderly manner. All instruments and equipment shall be subject to regularly scheduled maintenance and calibration. All temperature measuring devices must be calibrated against ~~U.S. Bureau of Standards~~ **[update]** certified thermometers. Refrigerators and freezers used for the storage of tissues shall have monitors. Each OPO, Eye Bank, or Tissue Bank shall have established procedures to follow in the event of electrical failure. **Each OPO, Eye Bank, or Tissue Bank shall have written procedures regarding facility maintenance and guidelines.** (b) Facility access shall be limited to employees of the OPO, Eye Bank, or Tissue Bank, contractual employees of the OPO, Eye Bank, or Tissue Bank, and surveyors for an approved accreditation organization, and governmental surveyors as permitted by applicable laws. A security system or physical configuration shall be established to prevent entry of unauthorized persons. There shall be policies and procedures to define limited facility access. Such	Duplicative of (21 CFR Part 1271.190 and 1271.200, effective May 2005, and AATB E1.100, J4.100, J4.400, J5.300 and J5.600, effective July 2016). Temperature monitoring – Duplicative of 1271.200 and AATB E1.450, J5.300 and J5.500. Facility access – Duplicative of AATB J4.400 U.S. Bureau of Standards no longer exists. Need to update that language.

Tissue Bank, contractual employees of the OPO, Eye Bank or Tissue Bank~~agency~~, surveyors for an approved accreditation organization, and governmental surveyors as permitted by applicable laws~~for the AHCA~~. A security system or physical configuration shall be established~~provided~~ to prevent entry of unauthorized persons. There shall be policies and procedures to define limited facility access. Such policies and procedures shall be made available for review by AHCA surveyors as specified in Rule 59A-1.009, F.A.C.	policies and procedures shall be made available for review by AHCA surveyors as specified in Rule 59A-1.009, F.A.C.	Added specific language related to procedures for facility maintenance and guidelines.
(4) Ethical standards. (a) Each OPO, tissue bank, and eye bank shall have policies to avoid conflicts of interest. The policy shall ensure that no employee of the OPO, tissue bank and eye bank shall: 1. Have any interest, financial or otherwise, direct or indirect; 2. Engage in any business transaction or professional activity; or 3. Incur any obligation of any nature which is in substantial conflict with the full and competent performance of duties ~~in the agency in which he or she is employed~~. (b) In the event that services other than obtaining referral or consent are provided to the procuring OPO, Eye Bank or Tissue Bank~~agency~~, ~~that procuring agency may make~~ arrangements may be made to pay expenses incurred for services rendered. Reimbursement to the individual shall not be in conflict with the personnel policies of the primary employer.	(4) Ethical standards. (a) Each OPO, tissue bank, and eye bank shall have policies to avoid conflicts of interest. The policy shall ensure that no employee of the OPO, tissue bank and eye bank shall: 1. Have any interest, financial or otherwise, direct or indirect, **unless disclosed**; 2. Engage in any business transaction or professional activity; or 3. Incur any obligation of any nature which is in substantial conflict with the full and competent performance of duties. (b) In the event that services other than obtaining referral **or authorization** or **informed** consent are provided to the procuring OPO, Eye Bank, or Tissue Bank, arrangements may be made to pay expenses incurred for services rendered. Reimbursement to the individual shall not be in conflict with the personnel policies of the primary employer.	Being an employee of the agency is, in and of itself, a potential conflict. Therefore, the point is to disclose the conflict. Expanded the language to include authorization and informed consent.
~~(5) Community involvement and educational standards.~~ ~~(a) Each OPO, tissue bank and eye bank shall assist hospitals in establishing and implementing protocols for making routine inquiries regarding organ and tissue donations by potential donors.~~ ~~(b) Each agency shall maintain documentation, that shall be available for review by surveyors for the AHCA, of educational services provided to the community, health care professionals and hospitals in the agency's service area.~~ ~~(c) Documentation of education of professionals shall be maintained. Documentation of donor hospital policies, procedures, characteristics and donor~~	Agree with changes.	

~~related activities shall be kept. Written agreements between the hospital and the agency shall document these activities.~~ ~~(d) Each agency shall produce or have available literature and media items that will provide education for donation of organs, tissues, or eyes. Each agency shall be responsible for establishing and assisting in the dissemination of these materials.~~		
(5)~~(6) Agency investigations.~~ Each OPO, Eye Bank or Tissue Bank~~agency~~ shall provide to the AHCA, upon request, a copy of any audit, review, or study performed by any federal or accreditation organization ~~that has or is reviewing that agency~~.	Agree with changes.	
(6)~~(7)~~ Acquisition of organs and tissues. (a) General. 1. OPO, Eye Bank, or Tissue Bank personnel ~~Agency personnel~~ shall ensure that consent for donation is obtained in compliance with Chapter 765, F.S. 2. OPO, Eye Bank, or Tissue Bank personnel ~~Agency personnel~~ shall be trained regarding obtaining and documenting consent for donation. 3. Consent shall be obtained from the donor, next of kin, or other designated legal entity in order of priority and availability according to Section 765.512, F.S. 4. A copy of the~~The~~ original signed consent form shall remain a part of the patient's hospital medical record if signed at the hospital. 5. The~~A copy of the~~ original signed consent form or record of telephone consent shall be retained in the OPO's, Eye Bank's, or Tissue Bank's~~agency's~~ donor record.	(6) Acquisition of organs and tissues. (a) General. 1. OPO, Eye Bank, or Tissue Bank personnel shall **have written procedures to** ensure that **authorization or informed** consent for donation is obtained in compliance with Chapter 765, F.S. 2. OPO, Eye Bank, or Tissue Bank personnel shall be trained regarding obtaining and documenting **authorization or informed** consent for donation. 3. **Authorization or informed c**~~C~~onsent shall be obtained from the donor, next of kin, or other designated legal entity in order of priority and availability according to Section 765.512, F.S. 4. A copy of the ~~original~~ signed **informed** consent **or authorization** form shall remain a part of the patient's hospital medical record if signed at the hospital. 5. The original signed consent form or record of telephone consent shall be retained in the OPO's, Eye Banks, or Tissue Bank's donor record.	Duplicative of uniform anatomical gift act, AATB J2.100, AATB D2.000 Clarified the need for written procedures. Ensured that it covered both informed consent and authorization.
(b) Informed consent. 1. Permission to obtain organs and tissues from donors by informed consent shall be as defined in Rule 59A-1.003, F.A.C., and shall be documented in writing. The consent form shall include the organs and tissues for which permission is granted (e.g., bone from the upper or lower extremities or bone from below the waist). Information provided shall be written or spoken in language understandable to the donor or the donor's next of kin. 2. Permission to retrieve organs and tissues from non-living donors shall be sought from next of kin in order of legal precedence as required by Section 765.512, F.S. In any cases falling under the provisions of Chapters 406 and 765, F.S., the permission of the medical examiner or appropriate designee shall be obtained prior to the procurement of any organ(s) and tissue(s). The donor	(b) Informed consent **or Authorization.** 1. **In any cases falling under the provisions of Chapters 406 and 765, F.S., P**~~p~~ermission **of the medical examiner or appropriate designee shall be obtained prior to the procurement of any** ~~to obtain~~ organ**(s)** and tissue**(s)** from donors by informed consent **or authorization** shall be as defined in Rule 59A-1.003, F.A.C., and shall be documented ~~in writing~~. The consent form shall include the organs and tissues for which permission is granted (e.g., bone from the upper or lower extremities or bone from below the waist). Information provided shall be written or spoken in language understandable to the donor or the donor's next of kin. 2. Permission to retrieve organs and tissues from non-living donors shall be sought from next of kin in order of legal precedence as required by Section	Duplicative of D2.000, uniform anatomical gift act, AATB J2.100, AATB D2.000 Ensured that it covered both informed consent and authorization. Clarified the application.

records shall indicate the name of the contact person in the medical examiner's office, date and time of contact, and limitations, if any, imposed by those giving permission (e.g., DO NOT TOUCH CHEST).	765.512, F.S. In any cases falling under the provisions of Chapters 406 and 765, F.S., the permission of the medical examiner or appropriate designee shall be obtained prior to the procurement of any organ(s) and tissue(s). The donor records shall indicate the name of the contact person in the medical examiner's office, date and time of contact, and limitations, if any, imposed by those giving permission (e.g., DO NOT TOUCH CHEST).	
(7)~~(8)~~ Premortem donations under the Anatomical Gift Statute. Written consent expressed by a living person to donate organs and tissues under provisions of the Anatomical Gift Statute, Chapter 765, Part X, F.S., are legally valid and permits organ procurement organizations, tissue banks, and eye banks to procure organs and tissues without further authorization from next of kin.	~~(~~7) Premortem donations under the Anatomical Gift Statute. Written **informed** consent expressed by a living person to donate organs and tissues under provisions of the Anatomical Gift Statute, Chapter 765, Part X, F.S., are legally valid and permits organ procurement organizations, tissue banks, and eye banks to procure organs and tissues without further authorization from next of kin.	Duplicative of AATB D2.000, uniform anatomical gift act. Clarified that it was informed consent.
(8)~~(9)~~ Compensation for donors. Monetary compensation other than reimbursement of donation-related expenses is prohibited.	Agree with changes.	Duplicative of AATB D1.100
~~(10) Sale of anatomical matter. Sale of one of a pair of organs (such as an eye or kidney) by a living donor for financial compensation is illegal under Public Law 98-507, s. 301; 42 United States Code s. 274e; and Chapter 873, F.S.~~	Agree with Changes.	Duplicative of AATB D1.100
No similar language.	**(8) Autopsy. A gross external and internal examination of any area of the donor altered by the excision shall be performed and dictated or otherwise recorded by the procuring person(s) at the time of the surgical removal of tissues from the deceased donor. A written report of these findings shall be immediately prepared and delivered to the person(s) responsible for the autopsy of the donor. The report shall contain itemization notation of normal conditions as well as an itemization of all abnormal findings found during the gross examination of the donor. Whenever a full medical autopsy of the donor will not subsequently be performed by a medical examiner, the medical director or designees may elect to obtain a full medical autopsy by other means when deemed necessary. If performed, the medical director or designees shall justify and document the need for full autopsy in the donor's medical record and the tissue bank shall affix a copy of the autopsy report to the donor record.**	Moved from OPO and tissue bank section below so that it applies to all agencies.
(9)~~(11)~~ Donor selection. Suitability of a specific individual for organ and tissue donation shall be based upon the medical history and clinical status of the donor and the need for particular organs and tissues. Consent must be obtained from the medical examiner, if appropriate. (a) Criteria for evaluating a potential donor include presence of infectious disease, malignant disease (with specific exceptions), neurological degenerative disease, and diseases of unknown etiology or any other diseases or conditions	(9) Donor selection. Suitability of a specific individual for organ and tissue donation shall be based upon the medical history and clinical status of the donor and the need for particular organs and tissues. ~~Consent must be obtained from the medical examiner, if appropriate.~~ **Each agency shall have written procedures regarding donor selection.** (a) Criteria for evaluating a potential donor include presence of infectious disease, malignant disease (with specific exceptions), neurological degenerative disease, and diseases of unknown etiology or any other diseases or conditions which may be transferred to the recipient. ~~Administration of human pituitary gland extracts (growth hormone) precludes~~	Duplicative of 21 CFR Part 1271.50 and 1271.75, effective May 2005 and AATB D2.000 and D4.000, effective July 2016 Duplicative of 21 CFR Part 1271.50, effective May 2005, and AATB D4.000, effective July 2016

which may be transferred to the recipient. Administration of human pituitary gland extracts (growth hormone) precludes tissue donation. In equivocal situations, a specialist in the particular area of medicine shall be consulted. Criteria as published according to the Administrative Procedures Act (APA), U.S. Code, Title 5, Chapter 5, ss. 500-706, incorporated herein by reference, shall be followed for OPOs, tissue banks and eye banks. (b) Evaluation of the donor record shall be performed by a licensed physician or a professional familiar with the conditions for which the procured organs or tissues will be used so that organs or tissues procured shall not be the source of any toxic or harmful effects per se when transplanted to another individual. (c) Age of the donor shall be a significant consideration in the effective transplantation of certain organs or tissues but does not preclude an individual from donation. The medical director or designee shall be responsible for donor selection. (d) The medical director, designee, or medical contractee shall have the responsibility to document in writing that the donor is acceptable according to the criteria established in this rule.	~~tissue donation. In equivocal situations, a specialist in the particular area of medicine shall be consulted.~~ Criteria as published according to the Administrative Procedures Act (APA), U.S. Code, Title 5, Chapter 5, ss. 500-706, incorporated herein by reference, shall be followed for OPOs, tissue banks and eye banks. (b) Evaluation of the donor record shall be performed by a licensed physician or a professional familiar with the conditions for which the procured organs or tissues will be used so that organs or tissues procured shall not be the source of any toxic or harmful effects per se when transplanted to another individual. (c) Age of the donor ~~shall be a significant consideration in the effective transplantation of certain organs or tissues but~~ does not preclude an individual from donation. The medical director or designee shall be responsible for donor selection. (d) The medical director, designee, or medical contractee**,** shall have the responsibility to document ~~in writing~~ that the donor is acceptable according to the criteria established in this rule.	Medical examiner language is included above (as permission). Language is a little too specific regarding the donor criteria. Therefore, it should be deleted. Updated the language to reflect current practice (regarding the age of the donor).
(10)~~(12)~~ Reconstruction. Each OPO, Eye Bank or Tissue Bank~~agency~~ shall have a policy for the reconstruction of the body which is integral to maintaining the dignity of the donor.	Agree with changes.	Duplicative of AATB D5.900
(11)~~(13)~~ Quality assurance. The ~~agency's~~ quality assurance program shall include a method for the transplanting surgeon to report adverse reactions from the transplantation of organ(s) and tissue(s) to the source OPO, tissue bank or eye bank, which in turn shall forward the adverse reaction information to the AHCA as described in Rule 59A-1.011, F.A.C.	Agree with changes.	Duplicative of 21 CFR Part 1271.320, effective May 2005, and AATB K4.000, effective July 2016. CMS, OPTN and AOPO also have standards
(12)~~(14)~~ Recall procedures. A written procedure shall exist for recall of organs or tissues or notification of recipient agencies of the possibility of contamination, defects in processing, preparation or distribution, or other factors affecting suitability of the organs or tissues for their intended application. Procedures for documenting the steps in recall shall be included in the ~~agency's~~	Agree with changes.	Duplicative of 21 CFR Part 1271.160, effective May 2005, and AATB H5.000, effective July 2016. May want to add a definition of recall that is consistent with the

policies and procedures.		FDA equivalent ("field correction or removal").
(13)~~(15)~~ Look back procedures. Each OPO, tissue bank, and eye bank shall have procedures for notifying the transplanting facility~~agency~~ or physician that they may have received infected organs or tissues. Documentation of look back procedures shall be included in the ~~agency's~~ policies and procedures.	Agree with changes.	Duplicative of 21 CFR Part 1271.160, effective May 2005, and AATB H5.000, effective July 2016.
(14)~~(16)~~ HIV notification requirements. Notification of HIV test results to donors and recipients of organs, tissues, and eyes in this state shall be given as required by ~~in accordance with~~ Section 381.0041, F.S. and Rule 64D-2.005, F.A.C.	(~~14~~**14**) HIV notification requirements. Notification of HIV test results ~~to donors and recipients of organs, tissues, and eyes in this state~~ shall be given as required by Section 381.0041, F.S. and Rule 64D-2.005, F.A.C.	Updated to reflect current statutory requirements.
(15)~~(17)~~ Data collection. Each organ procurement organization, tissue bank, and eye bank shall collect, maintain, and report the following data annually to the AHCA: (a) Number of donors by age and race; (b) Type of donation; (c) Cause of death for all donors; (d) Donor source (hospital, medical examiner, or funeral home); (e) Number of organs retrieved and number of tissue allografts and eyes processed; (f) Disposition of processed organs, tissues, and eyes with respect to in-state, national, or international distribution; and (g) Revenues derived from retrieving, processing, or distributing organs and eye tissue, and revenues derived from retrieving, processing, storing or distributing tissues; (h) Expenses associated with retrieving, processing, or distributing organs and eye tissue, and expenses associated with retrieving, processing, storing or distributing tissues.	Agree with changes.	
~~(18) Revision of standards. All proposed revisions, additions, and deletions shall be reviewed for acceptance or rejection at least annually by the Florida Statewide Organ and Tissue Procurement and Transplantation Advisory Board's Standards Subcommittee. Recommendations from the Standards Subcommittee~~	Agree with changes.	

~~shall be reviewed by the Florida Statewide Organ and Tissue Procurement and Transplantation Advisory Board and subsequently submitted to the AHCA for consideration and appropriate action.~~		
(16)~~(19)~~ Fair and equitable system. Each OPO, Eye Bank, or Tissue Bank~~agency~~ shall establish and document a system of distribution that is just, equitable, and fair to all patients served ~~by the agency~~. Documentation of distribution (date of requests for, offer of, and delivery of organs and tissues) shall be available for examination by authorized individuals, including surveyors for the AHCA. Access to organs and tissues shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin.	Agree with changes.	
(17)~~(20)~~ Each OPO shall comply with 42 CFR Part 485, 1994, and make the records relating to the federal standards available upon request to surveyors for the AHCA. (18) Each OPO shall employ or have under contract a physician medical director who: (a) is licensed to practice medicine in the state of Florida; (b) is board certified in a specialty recognized by the American Board of Medical Specialties (ABMS); and (c) has a minimum of two (2) years affiliation with an OPO, transplant program or tertiary care hospital associated with a transplant program. (19) The Medical Director shall provide direction and supervision to coordinators and all other staff who assist in the procurement of organs for transplantation.	~~(17)~~ **59A-1.___ Standards for Organ Procurement Organizations** Each OPO shall comply with 42 CFR Part 48~~65~~, 1994, and make the records relating to the federal standards available upon request to surveyors for the AHCA. **(1)** Each OPO shall employ or have under contract a physician medical director**.** ~~who~~ ~~(a) Is licensed to practice medicine in the state of Florida;~~ ~~(b) Is board certified in a specialty recognized by the American Board of Medical Specialties (ABMS); and~~ ~~(c) Has a minimum of two (2) years affiliation with an OPO, transplant program or tertiary care hospital associated with a transplant program.~~ (2)The Medical Director shall provide direction and supervision to coordinators and all other staff who assist in the **recovery of** ~~procurement of~~ organs for transplant~~ation~~ **and research**. **With the exception of organ procurement surgery, this may be by indirect physician supervision.**	AATB and AHCA are in agreement related to the overall language. However, AATB further suggests that it would be beneficial to have separate sections specifically dedicated to OPOs, Eye Banks, and Tissue Banks.
(20)~~(21)~~ Financial policies and procedures. Each OPO shall comply with existing federal laws and guidelines in its fiscal and accounting procedures. (a) The OPO shall have accounting and other fiscal procedures necessary to ensure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant centers. 1. There shall be an annual budget approved by the board of directors or advisory board. 2. Unless otherwise provided by law, there shall be an annual audit conducted by an independent public accountant. In the case of hospital ~~H~~OPOs, the hospital must undergo an annual financial audit. 3. There shall be adequately trained staff or qualified contractors to ensure the	(~~20~~3) Financial policies and procedures **shall be in writing.** ~~Each OPO shall comply with existing federal laws and guidelines in its fiscal and accounting procedures.~~ (a) The OPO shall have accounting and other fiscal procedures necessary to ensure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant centers. ~~1. There shall be an annual budget approved by the board of directors or advisory board.~~ ~~2. Unless otherwise provided by law, there shall be an annual audit conducted by an independent public accountant. In the case of hospital~~	

establishment and maintenance of internal controls and general accounting functions. The general accounting functions shall include management of accounts receivable, management of accounts payable and other disbursements, and the handling of cash. An OPO shall maintain the ability to generate periodic statements of the status of the ~~agency's~~ assets, liabilities and fund balance, and statements of its periodic revenues and expenses. Hospital ~~H~~ shall be exempt from this requirement to the extent that these functions are performed by hospital staff. (b) The OPO shall have policies and procedures established for the documentation of all direct and indirect costs. These costs shall be used as the basis for the establishment of organ and tissue procurement charges. (c) An OPO shall establish accounting policies and procedures to permit allocation of all its direct and indirect costs to the organ and tissue cost centers maintained ~~by the agency~~. Hospital ~~H~~shall adhere to an appropriate hospital authority for established accounting policies and procedures. (d) The accounting records of the OPO shall include documentation of allocations made to organ and tissue cost centers, as applicable, for each direct expense incurred by the OPO. Allocations shall be made insofar as they are related to the procurement of the particular organ. For example, records documenting the payment of a donor hospital bill shall identify the procured organs of the particular case and shall document the equal allocation of the costs to each organ type. The same procedure shall apply to other direct expenses related to the procurement, such as tissue typing or transportation. When these expenses are for the purpose of procurement of a particular organ(s), the cost shall be allocated only to that organ(s). (e) The accounting records of the OPO shall permit the expensing of indirect costs, (e.g., office rent, utilities, administrative salaries and salary related costs) so that they may be allocated in compliance with Medicare rules and guidelines. 1. The OPO's costs shall be charged as expenses and allocated in accordance with the appropriate guidance provided by the Medicare program or by the appropriate hospital authority for hospital ~~H~~OPOs and by established agreements with other agencies, companies, providers or vendors. 2. The costs paid by the OPO for services used in the procurement of organs (for example, surgeon's fees, donor evaluation fees, laboratory, transportation, etc.) shall be based on reasonable and customary fees within the service area as determined by the OPO. The OPO may refer to limitations on the reimbursement of such costs as specified by the Medicare program. (f) The OPO shall maintain the ability to develop and utilize average procurement costs as a basis for establishment of its organ and tissue acquisition charges. The acquisition charges are to be established in accordance with the OPO's board of directors or advisory board and with reference to prevailing Medicare program rules and regulations. These charges shall be reviewed at least semi-annually and appropriate adjustments made unless otherwise proscribed.	~~OPOs, the hospital must undergo an annual financial audit.~~ ~~3. There shall be adequately trained staff or qualified contractors to ensure the establishment and maintenance of internal controls and general accounting functions. The general accounting functions shall include management of accounts receivable, management of accounts payable and other disbursements, and the handling of cash. An OPO shall maintain the ability to generate periodic statements of the status of the assets, liabilities and fund balance, and statements of its periodic revenues and expenses. Hospitals shall be exempt from this requirement to the extent that these functions are performed by hospital staff.~~ (b) The OPO shall have policies and procedures established for the documentation of all direct and indirect costs. These costs shall be used as the basis for the establishment of organ and tissue procurement charges. ~~(c) An OPO shall establish accounting policies and procedures to permit allocation of all its direct and indirect costs to the organ and tissue cost centers maintained. Hospital shall adhere to an appropriate hospital authority for established accounting policies and procedures.~~ (~~d~~**c**) The accounting records of the OPO shall include documentation of allocations made to organ and tissue cost centers, as applicable, for each direct expense incurred by the OPO. ~~Allocations shall be made insofar as they are related to the procurement of the particular organ. For example, records documenting the payment of a donor hospital bill shall identify the procured organs of the particular case and shall document the equal allocation of the costs to each organ type. The same procedure shall apply to other direct expenses related to the procurement, such as tissue typing or transportation. When these expenses are for the purpose of procurement of a particular organ(s), the cost shall be allocated only to that organ(s).~~ ~~(e) The accounting records of the OPO shall permit the expensing of indirect costs, (e.g., office rent, utilities, administrative salaries and salary related costs) so that they may be allocated in compliance with Medicare rules and guidelines.~~ ~~1. The OPO's costs shall be charged as expenses and allocated in accordance with the appropriate guidance provided by the Medicare program or by the appropriate hospital authority for hospital OPOs and by established agreements with other agencies, companies, providers or vendors.~~ (~~2~~**d**) The costs paid by the OPO for services used in the procurement of organs (for example, surgeon's fees, donor evaluation fees, laboratory, transportation, etc.) shall be based on reasonable and customary fees within the service area as determined by the OPO. The OPO may refer to limitations on the reimbursement of such costs as specified by the Medicare program. (~~f~~**e**) The OPO shall maintain the ability to develop and utilize average procurement costs as a basis for establishment of its organ and tissue	

	acquisition charges. The acquisition charges are to be established in accordance with the OPO's board of directors or advisory board and with reference to prevailing Medicare program rules and regulations. These charges shall be reviewed at least semi-annually and appropriate adjustments made unless otherwise proscribed.	
(21)~~(22)~~ Verification of death. The OPO shall ensure that death has been determined in accordance with traditional cardiopulmonary criteria or as required by Section 382.009, F.S., and documented in the organ donor's medical record.	(~~21~~**4**) Verification of death. The OPO shall ensure that death has been determined in accordance with traditional cardiopulmonary criteria or as required by Section 382.009, F.S., and documented in the organ donor's medical record.	Agree with changes. Suggest alternative structure for language.
~~(23) Autopsy. A gross external and internal examination of any area of the donor altered by the excision shall be performed and dictated or otherwise recorded by the excising surgeon(s) at the time of the surgical removal of organs from the cadaveric donor. A written report of these findings shall be immediately prepared and delivered to the person(s) responsible for the autopsy of the donor. The report shall contain an itemization of all normal conditions noted as well as all abnormal pathological findings found during the gross internal examination of the donor. Whenever a full medical autopsy of the donor will not subsequently be performed by a medical examiner, the OPO shall attempt to obtain a full medical autopsy by other means. Upon request, the OPO shall make a copy of the autopsy report available to all recipient transplant programs that were in receipt of the donor's organs, tissues and eyes and will affix a copy of the report to the donor record.~~		Agree with changes.
(22)~~(24)~~ Guidelines for the evaluation and management of a potential cadaveric organ donor. Evaluation and management of donors is mandatory for organs which may be allocated to and received by the Organ Procurement and Transplantation Network (OPTN)-approved transplant programs to ensure that all organ donors meet the minimum standards and the requirements established by the OPTN. The OPTN guidelines are part of UNOS requirements incorporated herein by reference, effective March 22, 1996. (a) The OPO's organ donor evaluation and management procedures shall be approved by the OPO's medical director. These procedures are to be undertaken with medical supervision and support. (b) Once the patient has been declared dead or death is imminent and	(~~22~~**5**) Guidelines for the evaluation and management of a potential ~~cadaveric~~ **deceased** organ donor **shall be in writing.** ~~Evaluation and management of donors is mandatory for organs which may be allocated to and received by the Organ Procurement and Transplantation Network (OPTN) approved transplant programs to ensure that all organ donors meet the minimum standards and the requirements established by the OPTN. The OPTN guidelines are part of UNOS requirements incorporated herein by reference, effective March 22, 1996~~. (a) The OPO's organ donor evaluation and management procedures shall be approved by the OPO's medical director. These procedures are to be undertaken with **direct or indirect** medical supervision and support. (b) Once the patient has been declared dead or death is imminent and ~~consent~~ **authorization** for donation has been obtained ~~from the next of kin~~ and from the medical examiner, if the death meets the requirements for	The term "deceased" is preferred to "cadaveric." Made changes to clarify that it is authorization, not consent. Important to remove the UNOS reference. Delete all specifics, all covered by OPTN, AOPO and CMS.

consent for donation has been obtained from the next of kin and from the medical examiner, if the death meets the requirements for referral to the medical examiner as specified in Chapter 406, F.S., the OPO shall implement the guidelines for the evaluation and management of the potential organ donor. (c) The evaluation of the donor shall include: 1. An attempt to acquire a social history which may be obtained from individuals not limited to the person giving consent; 2. A physical examination of the donor; 3. Documentation of the donor's ABO group, donor's weight and height; 4. A review of the donor's current inpatient medical record; and 5. Documentation of significant events in the donor's clinical course. (d) In the brain dead donor, the OPO shall ensure that adequate respiratory, hemodynamic and electrolyte management of the donor is provided. (e) The OPO shall ensure that the donor receives appropriate antibiotic coverage, if a need is indicated. (f) The OPO shall evaluate the infectious disease status of the potential donor. All serological testing shall be noted to be either pre- or post-transfusion. Such evaluation shall include: 1. Hepatitis testing according to OPTN policies and procedures; ~~2. FDA-licensed HTLV test;~~ 2.~~3.~~ Appropriate FDA-licensed HIV-1/ ~~and~~ HIV-2 screens; 3.~~4.~~ Serologic test for syphilis (STS); 4.~~5.~~ Blood and urine cultures; ~~6. Cultures of preservation solutions;~~ 5.~~7.~~ Cytomegalovirus (CMV); and 6.~~8.~~ Complete blood count (CBC).	referral to the medical examiner as specified in Chapter 406, F.S., the OPO shall implement the guidelines for the evaluation and management of the potential organ donor. **(c) Potential donor evaluation policies and procedures shall be in writing.** ~~(c) The evaluation of the donor shall include:~~ ~~1. An attempt to acquire a social history which may be obtained from individuals not limited to the person giving~~ **authorization**~~consent;~~ ~~2. A physical examination of the donor;~~ ~~3. Documentation of the donor's ABO group, donor's weight and height;~~ ~~4. A review of the donor's current inpatient medical record; and~~ ~~5. Documentation of significant events in the donor's clinical course.~~ ~~(d) In the brain dead donor, the OPO shall ensure that adequate respiratory, hemodynamic and electrolyte management of the donor is provided.~~ ~~(e) The OPO shall ensure that the donor receives appropriate antibiotic coverage, if a need is indicated.~~ ~~(f) The OPO shall evaluate the infectious disease status of the potential donor. All serological testing shall be noted to be either pre- or post-transfusion. Such evaluation shall include:~~ ~~1. Hepatitis testing according to OPTN policies and procedures;~~ ~~2. Appropriate FDA-licensed HIV-1/HIV-2 screens;~~ ~~3. Serologic test for syphilis (STS);~~ ~~4. Blood and urine cultures;~~ ~~5. Cytomegalovirus (CMV); and~~ ~~6. Complete blood count (CBC).~~	
(21)~~(25)~~ Allocation of donated organs. (a) Each OPO shall have a policy to ensure that donated organs are allocated according to the standards of the OPTN and in keeping with OPTN-approved local variances. Organs that are allocated outside of the sequence of patients, as determined by the OPTN, shall have documentation explaining the	(~~21~~**6**) Allocation of donated organs. Each OPO shall have a policy to ensure that donated organs are allocated according to the standards of the OPTN ~~and in keeping with OPTN-approved local variances. Organs that are allocated outside of the sequence of patients, as determined by the OPTN, shall have documentation explaining the reason for the variance.~~ b) The OPO shall document that the OPTN computer was accessed and	All covered by OPTN. Variances no longer exist.

reason for the variance. (b) The OPO shall document that the OPTN computer was accessed and reason for selection of a donor/recipient match and the placement allocation of the donor organ. (c) Organs shall be allocated by the OPO utilizing the sequence of patients as determined by OPTN computer or by an approved OPTN variance. (d) Any variation from the OPTN donor/recipient match routine shall be documented and made a permanent part of the donor record. (e) Documentation of actual allocation of each organ procured shall be filed in accordance with OPTN guidelines as specified in subsection 59A-1.005(24), F.A.C.	reason for selection of a donor/recipient match and the placement allocation of the donor organ. (c) Organs shall be allocated by the OPO utilizing the sequence of patients as determined by OPTN computer ~~or by an approved OPTN variance~~. ~~(d) Any variation from the OPTN donor/recipient match routine shall be documented and made a permanent part of the donor record.~~ (~~e~~**d**) Documentation of actual allocation of each organ procured shall be filed in accordance with OPTN guidelines as specified in subsection 59A-1.005(24), F.A.C.	
(23)~~(26)~~ Procurement procedures. The OPO shall have policies and procedures to facilitate and coordinate the procurement of donated organs by trained and qualified personnel. (a) A certified HHS OPO shall ensure that any surgeons (i.e., surgeons whose fees are paid by the OPO) working as consultants to the OPO for the surgical recovery of donated organs meet qualifications and standards as set by the OPO's medical director. (b) The medical director of the OPO shall be responsible for the surgical standards and technical quality of services provided by their consulting surgeons. (c) In the brain dead donor, the OPO is responsible for coordinating anesthesia support for the organ procurement process. The OPO shall provide protocols to the anesthesia support service for the intra-operative procedure. The goal of this intra-operative support includes: 1. Maintaining an adequate blood pressure, fluid volume, organ perfusion and function; 2. Adequate oxygenation and oxygen transport to the organs being procured; 3. Replacement of excessive volume loss; and 4. Administration of required and desirable medications to facilitate organ procurement and function.	(~~23~~**7**) Procurement procedures. The OPO shall have policies and procedures to facilitate and coordinate the ~~procurement procurement~~ **recovery** of donated organs by trained and qualified personnel. ~~(a) A certified HHS OPO shall ensure that any surgeons (i.e., surgeons whose fees are paid by the OPO) working as consultants to the OPO for the surgical recovery of donated organs meet qualifications and standards as set by the OPO's medical director.~~ (~~b~~**a**) The medical director of the OPO shall be responsible for the surgical standards. ~~and technical quality of services provided by their consulting surgeons.~~ (~~c~~**b**) In the brain dead donor, the OPO is responsible for coordinating anesthesia support for the organ procurement process. The OPO shall provide protocols to the anesthesia support service for the intra-operative procedure. ~~The goal of this intra-operative support includes:~~ ~~1. Maintaining an adequate blood pressure, fluid volume, organ perfusion and function;~~ ~~2. Adequate oxygenation and oxygen transport to the organs being procured;~~ ~~3. Replacement of excessive volume loss; and~~ ~~4. Administration of required and desirable medications to facilitate organ procurement and function.~~ ~~(d) If the anesthesia records are not included in the donor's chart, records reflecting documentation of anesthesia protocol used by the OPO shall be available for inspection.~~ ~~(e) In all organ donors, the OPO is responsible for packaging and labeling organs, tissue typing material and blood, according to OPTN policy 5.0, incorporated herein by reference.~~ ~~(f) In all organ donors, the OPO is responsible for distributing the following documentation to each transplant center receiving an organ from an individual donor:~~ ~~1. Verification of donor ABO type;~~	Recovery is the more appropriate term. Paragraph (a) does not appropriately describe how this currently occurs. Language in paragraph (b) is not indicative of current practice. Language in paragraph (c) is to proscriptive. For the new paragraph (d), please use the term "information" rather than "documentation," given that much is now shared via electronic medical record so there is no actual hard copy of information. Further, OPOs strongly prefer that this is not so specific so that we may change as federal regulations change. If it is retained, it will need to be updated regarding the terms "authorization" and "informed consent."

(d) If the anesthesia records are not included in the donor's chart, records reflecting documentation of anesthesia protocol used by the OPO shall be available for inspection. (e) In all organ donors, the OPO is responsible for packaging and labeling organs, tissue typing material and blood, according to OPTN policy 5.0, incorporated herein by reference. (f) In all organ donors, the OPO is responsible for distributing the following documentation to each transplant center receiving an organ from an individual donor: 1. Verification of donor ABO type; 2. Copy of death determination from the donor's medical record; 3. Copy of consent for organ procurement from the donor's medical record; and 4. Copy of the following OPO donor information: a. The OPO shall be responsible for documentation of demographic information relative to the donor so that pertinent information is available for centers considering organs for transplant. The OPO shall document information that will enable follow-up with the next of kin and donor hospital personnel. b. The OPO shall have a standardized method of recording the following information on each donor: (I) Name; (II) Age, sex, race; (III) Cause of death; (IV) Time and date of hospital admission; (V) Time and date of pronouncement of death; (VI) United Network for Organ Sharing (UNOS) identification number; and (VII) OPO identification number. c. The OPO shall document the following information for purposes of follow-up: (I) Name and address of the legal next of kin; (II) Record of the organs donated;	~~2. Copy of death determination from the donor's medical record;~~ ~~3. Copy of consent for organ procurement from the donor's medical record; and~~ ~~4. Copy of the following OPO donor information:~~ ~~a. The OPO shall be responsible for documentation of demographic information relative to the donor so that pertinent information is available for centers considering organs for transplant. The OPO shall document information that will enable follow-up with the next of kin and donor hospital personnel.~~ ~~b. The OPO shall have a standardized method of recording the following information on each donor:~~ ~~(I) Name;~~ ~~(II) Age, sex, race;~~ ~~(III) Cause of death;~~ ~~(IV) Time and date of hospital admission;~~ ~~(V) Time and date of pronouncement of death;~~ ~~(VI) United Network for Organ Sharing (UNOS) identification number; and~~ ~~(VII) OPO identification number.~~ ~~c. The OPO shall document the following information for purposes of follow-up:~~ ~~(I) Name and address of the legal next of kin;~~ ~~(II) Record of the organs donated;~~ ~~(III) Name of attending and consulting doctor;~~ ~~(IV) Medical examiner or coroner, as applicable;~~ ~~(V) Copy of signed **authorization**consent form; and~~ ~~(VI) Copy of declaration of death note.~~ ~~d. Documentation of donor history. The OPO shall obtain a medical and social history of each potential donor in an attempt to determine whether the potential donor is in a "high-risk" group as described in paragraph 59A-1.005(11)(a), F.A.C. That history shall be communicated in writing to the physician responsible for the care of the recipient.~~ ~~e. The documented past medical history shall, when available, include significant episodes of the following:~~ ~~(I) Any previous hospitalization;~~ ~~(II) Any prior surgery;~~ ~~(III) History of a chronic illness, e.g., diabetes, hypertension, cardiovascular disease, etc.;~~ ~~(IV) History of communicable disease, e.g., hepatitis; and~~ ~~(V) History of disease specific to transplantable organs and treatment of same.~~ ~~f. The current hospital history is the most vital and shall include:~~ ~~(I) Description of injuries and treatments (e.g., surgeries);~~ ~~(II) Account of significant febrile episodes – duration, treatment, and response;~~ ~~(III) Account of cardiac and pulmonary arrests – type, duration, and all treatment required to restore function (particularly closed chest massage);~~	

(III) Name of attending and consulting doctor; (IV) Medical examiner or coroner, as applicable; (V) Copy of signed completed consent authorization form; and (VI) Copy of declaration of death note. d. Documentation of donor history. The OPO shall obtain a medical and social history of each potential donor in an attempt to determine whether the potential donor is in a "high-risk" group as described in paragraph 59A-1.005(11)(a), F.A.C. That history shall be communicated ~~in writing~~ to the physician responsible for the care of the recipient. e. The documented past medical history shall, when available, include significant episodes of the following: (I) Any previous hospitalization; (II) Any prior surgery; (III) History of a chronic illness, e.g., diabetes, hypertension, cardiovascular disease, etc.; (IV) History of communicable disease, e.g., hepatitis; and (V) History of disease specific to transplantable organs and treatment of same. f. The current hospital history is the most vital and shall include: (I) Description of injuries and treatments (e.g., surgeries); (II) Account of significant febrile episodes – duration, treatment, and response; (III) Account of cardiac and pulmonary arrests – type, duration, and all treatment required to restore function (particularly closed chest massage); and (IV) Record of blood transfusions – type and amount. g. Documentation of donor hemodynamics. It is essential that the OPO document a detailed picture of the donor's hemodynamic status from admission through organ procurement in a standardized, easy to interpret manner. h. Documentation of blood pressures shall include: (I) Average pressure; (II) Any hypotensive periods – noting lowest pressure and duration;	~~and~~ ~~(IV) Record of blood transfusions – type and amount.~~ ~~g. Documentation of donor hemodynamics. It is essential that the OPO document a detailed picture of the donor's hemodynamic status from admission through organ procurement in a standardized, easy to interpret manner.~~ ~~h. Documentation of blood pressures shall include:~~ ~~(I) Average pressure;~~ ~~(II) Any hypotensive periods – noting lowest pressure and duration~~; ~~(III) Use of vasopressors – type, amount, duration, and response;~~ ~~(IV) Any periods of prolonged hypertension – highest pressure, duration, and treatment instituted;~~ ~~(V) Any abnormal heart rhythm and treatment; and~~ ~~(VI) Swan-Ganz and central venous pressure readings and which shall be correlated with blood pressure, when available.~~ **(c) OPO procurement procedures shall be in writing and shall demonstrate adherence to all federal regulations to ensure required donor information is obtained and shared with transplant centers as required.** **(d) In all organ donors, the OPO is responsible for packaging and labeling organs, tissue typing material and blood, and labeling with organ type and ABO.**	

(III) Use of vasopressors – type, amount, duration, and response; (IV) Any periods of prolonged hypertension – highest pressure, duration, and treatment instituted; (V) Any abnormal heart rhythm and treatment; and (VI) Swan Ganz and central venous pressure readings and which shall be correlated with blood pressure, when available.		
i. Transfused donor. (I) All potential donors are to be tested for HIV-1/ ~~and~~ HIV-2 antibodies, pursuant to Rule 64D-2.005, F.A.C~~., and for HTLV antibodies for which FDA licensed test systems are available~~. If the donor's pre-transfusion test is antibody negative and subsequent transfusions are pre-tested, retesting for HIV-1/~~and~~ HIV-2 antibodies ~~and HTLV antibodies~~ is not necessary. If no pre-transfusion blood sample is available, the donor institution must provide, along with the screening test results, a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organs. Organs from donors with repeatedly reactive screening tests for HIV-1/ ~~and~~ HIV-2 antibodies ~~and HTLV antibodies~~ are not suitable for transplantation unless subsequent confirmation testing unequivocally indicates that the original test result was unconfirmed. If additional tests related to HIV-1/ ~~and~~ HIV-2 antibodies ~~and HTLV antibodies are performed~~, the results of all tests must be	i. Transfused donor. **Requirements for transfused donors shall be in writing.** ~~(I) All potential donors are to be tested for HIV-1/HIV-2 antibodies, pursuant to Rule 64D-2.005, F.A.C. If the donor's pre-transfusion test is antibody negative and subsequent transfusions are pre-tested, retesting for HIV-1/HIV-2 antibodies is not necessary. If no pre-transfusion blood sample is available, the donor institution must provide, along with the screening test results, a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organs. Organs from donors with repeatedly reactive screening tests for HIV-1/HIV-2 antibodies are not suitable for transplantation unless subsequent confirmation testing unequivocally indicates that the original test result was unconfirmed. If additional tests related to HIV-1/ HIV-2 antibodies are performed, the results of all tests must be communicated immediately to the recipient's institution. Exception to cases in which the testing cannot be completed prior to transplant are as follows:~~ ~~(II) Exceptions to the guidelines set forth above shall be made in cases involving non-renal organs, when, in the medical judgment of the staff of the donor and recipient institutions, an extreme medical emergency warrants the transplantation of an organ, the results of which are not immediately available for HIV-1/HIV-2 antibodies. The transplant surgeon is obligated to notify the~~	To keep the language from being overly proscriptive, it should just require appropriate documentation. If any of the language is retained, the exception in (II) should not be limited to non-renal organs. That is not consistent with today's science. If the state does not approve the language we suggested, this section needs to change to be permissive for donation under the Hope Act. In addition, the "non-renal" concept is outdated, any organ including kidneys can be considered if no test results are available prior to recovery.

communicated immediately to the recipient's institution. Exception to cases in which the testing cannot be completed prior to transplant are as follows: (II) Exceptions to the guidelines set forth above shall be made in cases involving non-renal organs, when, in the medical judgment of the staff of the donor and recipient institutions, an extreme medical emergency warrants the transplantation of an organ, the results of which are not immediately available for HIV-1/ ~~and~~ HIV-2 antibodies ~~and HTLV antibodies~~. The transplant surgeon is obligated to notify the recipient or next of kin in such cases.	~~recipient or next of kin in such cases.~~	
(24)~~(27)~~ Documentation of organ-specific laboratory results. The OPO shall provide the transplanting physician with certain test results for the evaluation of organ function. These results shall be documented in a standardized manner. (a) The OPO shall document the following available lab results for ALL donors: 1. CBC; 2. Electrolytes; 3. ABO typing; 4. Blood and urine cultures; 5. Serological testing in accordance with OPTN guidelines; 6. Appropriate FDA-licensed HIV-1/ ~~and~~ HIV-2 screens~~, FDA-licensed HTLV test~~. If blood products have been given, a pre-transfused sample shall be obtained. If unavailable, explanation shall be documented in the donor's medical record; 7. Cultures, including blood, and urine ~~urinary, and perfusion fluid, when appropriate~~, which allow for interpretation of laboratory results. Each OPO must define procedures for the type, source and indication for obtaining these cultures; 8. CMV antibody. (b) Kidney evaluation: 1. Urinalysis; 2. Creatinine; and 3. Blood urea nitrogen (BUN). (c) Liver evaluation:	(~~27~~**8**) Documentation of organ-specific laboratory results. **Requirements for organ specific testing shall be in writing.and shall be consistent with the requirements of the OPTN.** ~~The OPO shall provide the transplanting physician with certain test results for the evaluation of organ function. These results shall be documented in a standardized manner.~~ ~~(a) The OPO shall document the following available lab results for ALL donors:~~ ~~1. CBC;~~ ~~2. Electrolytes;~~ ~~3. ABO typing;~~ ~~4. Blood and urine cultures;~~ ~~5. Serological testing in accordance with OPTN guidelines;~~ ~~6. Appropriate FDA-licensed HIV-1/ and HIV-2 screens, FDA-licensed HTLV test. If blood products have been given, a pre-transfused sample shall be obtained. If unavailable, explanation shall be documented in the donor's medical record;~~ ~~7. Cultures, including blood, and urine urinary, and perfusion fluid, when appropriate, which allow for interpretation of laboratory results. Each OPO must define procedures for the type, source and indication for obtaining these cultures;~~ ~~8. CMV antibody.~~ ~~(b) Kidney evaluation:~~ ~~1. Urinalysis;~~	Delete all specific requirements, transplant centers define what is needed for each organ and it may differ over time. The OPTN is the more appropriate entity to reference.

1. Liver enzymes; 2. Total bilirubin; 3. Direct bilirubin; and 4. Prothrombin time/partial thromboplastin time (PT/PTT). (d) Heart evaluation: 1. 12 lead EKG; 2. Cardiology consult; 3. Chest X-ray; 4. Blood gases; 5. Echocardiogram or cardiac cath (optional); and 6. Creatine phosphokinase including MB fraction. (e) Pancreas evaluation: 1. Serum amylase; 2. Serum lipase; and 3. Glucose. (f) Lung evaluation: 1. Blood gases; 2. Chest X-ray; and 3. Sputum gram stain and culture. (g) The OPO shall utilize an internal standard format or form (i.e., UNOS Cadaver Donor Registration/Referral Form) to document all of the above-mentioned information according to UNOS requirements in subsection 59A-1.005(24), F.A.C.	~~2. Creatinine; and~~ ~~3. Blood urea nitrogen (BUN).~~ ~~(c) Liver evaluation:~~ ~~1. Liver enzymes;~~ ~~2. Total bilirubin;~~ ~~3. Direct bilirubin; and~~ ~~4. Prothrombin time/partial thromboplastin time (PT/PTT).~~ ~~(d) Heart evaluation:~~ ~~1. 12 lead EKG;~~ ~~2. Cardiology consult;~~ ~~3. Chest X-ray;~~ ~~4. Blood gases;~~ ~~5. Echocardiogram or cardiac cath (optional); and~~ ~~6. Creatine phosphokinase including MB fraction.~~ ~~(e) Pancreas evaluation:~~ ~~1. Serum amylase;~~ ~~2. Serum lipase; and~~ ~~3. Glucose.~~ ~~(f) Lung evaluation:~~ ~~1. Blood gases;~~ ~~2. Chest X-ray; and~~ ~~3. Sputum gram stain and culture.~~ ~~(g) The OPO shall utilize an internal standard format or form (i.e., UNOS Cadaver Donor Registration/Referral Form) to document all of the above-mentioned information according to UNOS requirements in subsection 59A-1.005(24), F.A.C.~~	
(25)~~(28)~~ In brain dead donors, the OPO shall document detailed information on volume intake and urine output in order to assess and maintain donor stability. (a) The OPO shall document volume intake type (crystalloid vs. colloid) and amount for a minimum of 8 hours prior to organ procurement and for the duration of the operative procedure. The use of any blood or blood products shall be noted.	(~~25~~9) **The OPO shall document detailed information on intake volume and urine and other body fluid output.** ~~In brain dead donors, the OPO shall document detailed information on volume intake and urine output in order to assess and maintain donor stability.~~ ~~(a) The OPO shall document volume intake type (crystalloid vs. colloid) and amount for a minimum of 8 hours prior to organ procurement and for the~~	Better to look more generally at bodily fluid output.

(b) The OPO shall document urine output for a minimum of 8 hours prior, if possible, to organ retrieval and for the duration of the operative procedure. Any periods of oliguria, anuria, or the occurrence of diabetes insipidus and its treatment shall be documented.	~~duration of the operative procedure. The use of any blood or blood products shall be noted.~~ ~~(b) The OPO shall document urine output for a minimum of 8 hours prior, if possible, to organ retrieval and for the duration of the operative procedure. Any periods of oliguria, anuria, or the occurrence of diabetes insipidus and its treatment shall be documented.~~ .	
((26)~~(29)~~ Documentation of retrieval procedure. (a) The OPO is responsible for proper documentation of the events surrounding the surgical removal of all organs for transplantation. (b) On ALL donors, the OPO shall document the following intra-operative information: 1. Blood pressures, urine output, and fluids administered; 2. Medications administered; 3. Blood products administered; 4. Type and amount of perfusion solution and flush characteristics; 5. Type of storage solution; 6. Type of procurement procedure (i.e., enbloc, in-situ perfusion); 7. Aortic cross-clamp time and date; 8. Description of typing material available; 9. Warm ischemia time; 10. Anatomical description: a. Kidneys – include number of vessels and approximate length and diameter of each; b. Extra renal – include description and any injuries or abnormalities; and	(~~26~~**10**) Documentation of retrieval procedure. The OPO is responsible for proper documentation of ~~the events~~ **intra operative information and all information related to** surgical ~~removal~~ **recovery** of organs for transplant~~ation~~ **or research**. ~~(b) On ALL donors, the OPO shall document the following intra-operative information:~~ ~~1. Blood pressures, urine output, and fluids administered;~~ ~~2. Medications administered;~~ ~~3. Blood products administered;~~ ~~4. Type and amount of perfusion solution and flush characteristics;~~ ~~5. Type of storage solution;~~ ~~6. Type of procurement procedure (i.e., enbloc, in-situ perfusion);~~ ~~7. Aortic cross-clamp time and date;~~ ~~8. Description of typing material available;~~ ~~9. Warm ischemia time;~~ ~~10. Anatomical description:~~ ~~a. Kidneys – include number of vessels and approximate length and diameter of each;~~ ~~b. Extra renal – include description and any injuries or abnormalities; and~~	
11. Organs procured and not disposed. If the organs are not used for transplantation or research, a written note regarding discard shall be documented in the OPO's donor records.	Organs ~~procured~~ **recovered** and not **utilized**~~disposed~~. If the organs are not used for transplantation or research, a written note regarding discard shall be documented in the OPO's donor records.	More appropriate terminology.
(27)~~(30)~~ Documentation of recipient information. (a) The OPO shall document specific information on the recipients of	(~~27~~**11**) Documentation of recipient information. ~~(a)~~ The OPO shall document specific information on the recipients of ~~procured~~ organs **recovered for transplant as required by OPTN policy.** ~~(b) The following information shall be documented on each recipient:~~	

procured organs. (b) The following information shall be documented on each recipient: 1. Name; 2. A UNOS recipient identification number; 3. Recipient center; and 4. Age, sex, and race.	~~1. Name;~~ ~~2. A UNOS recipient identification number;~~ ~~3. Recipient center; and~~ ~~4. Age, sex, and race.~~	
(28)~~(31)~~ Completion of OPTN required forms. Each OPO shall routinely submit documentation describing donor activity to the OPTN, as required by 42 CFR Part 485, 1994. The OPO shall comply with OPTN reporting requirements.	(~~28~~**12**) Completion of OPTN required forms. [No additional changes other than number/structure.]	
(29)~~(32)~~ Each tissue bank shall comply with 21 CFR Parts 16 and 1270 and 1271, ~~1993~~ and make the records relating to the federal standards available to surveyors for the Agency~~AHCA~~.	**59A-1.__ Standards for Tissue Banks** (~~29~~**1**) Each tissue bank shall comply with 21 CFR Parts 16 and 1270 and 1271, and make the records relating to the federal standards available to surveyors for the Agency**.**	Duplicative of 21 CFR Parts 16 and 1270, 1271 FDA Guidance for Industry "Eligibility Determination for Donors of Human Cells, Tissues and Cellular and Tissue-based Products (HCT/Ps)," FDA Guidance for Industry "Current Good Tissue Practice (cGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues and Cellular and Tissue Based Products (HCT/Ps)" and American Association of Tissue Banks standards 14th edition, in effect on July 18, 2016. The tissue bank must make the records demonstrating compliance to the federal regulations and AATB standards available to surveyors for the Agency.
(30)~~(33)~~ Organizational staff requirements. (a) Each Tissue Bank shall employ or have under contract a physician medical director who maintains a valid state license from any state within the United States. (b) Medical Directors for Tissue Banks are limited to performing their responsibilities for multiple banks under the following criteria: 1. Medical Directors for Tissue Banks where at least one of the Tissue	(~~30~~**2**) ~~Organizational staff requirements.~~ ~~(a) Each Tissue Bank shall employ or have under contract a physician medical director who maintains a valid state license from any state within the United States.~~ ~~(b) Medical Directors for Tissue Banks are limited to performing their responsibilities for multiple banks under the following criteria:~~ ~~1. Medical Directors for Tissue Banks where at least one of the Tissue Banks is performing Recovery, Processing and Distribution are not permitted to act as Medical Director for more than three (3) Tissue Banks at one time;~~ ~~2. Medical Director for Tissue Banks which perform any one of the following (but no single Tissue Bank performing all three activities): Recovery,~~	See above for discussion re: Medical Directors. AATB does not believe that the proposed language related to Medical Directors is appropriate.

Banks is performing Recovery, Processing and Distribution are not permitted to act as Medical Director for more than three (3) Tissue Banks at one time; 2. Medical Director for Tissue Banks which perform any one of the following (but no single Tissue Bank performing all three activities): Recovery, Processing or Distribution are not permitted to act as Medical Director for more than five (5) Tissue Banks at one time; (c) Medical Directors are required to assure that no actual or potential conflict of interest occurs when acting as Medical Director for multiple tissue banks. (d)~~(a)~~ Qualifications of technical personnel vary by nature of responsibility. Qualifications may be demonstrated by certification or by examination administered by the American Association of Tissue Banks for a certified tissue banking specialist. (e)~~(b)~~ All supervisory or senior technical personnel shall be certified in tissue banking ~~by a recognized organization (e.g., t~~he American Association of Tissue Banks~~)~~ within one year of employment with a licensed tissue bank.	~~Processing or Distribution are not permitted to act as Medical Director for more than five (5) Tissue Banks at one time;~~ ~~(c) Medical Directors are required to assure that no actual or potential conflict of interest occurs when acting as Medical Director for multiple tissue banks.~~ **(2) Training, certification, and continuing education.** (~~d~~**a**) Qualifications of technical personnel vary by nature of responsibility. Qualifications may be demonstrated by certification ~~or~~ by examination administered by the American Association of Tissue Banks ~~for a certified tissue banking specialist~~. (~~e~~**b**) All supervisory or senior technical personnel **responsible for performing retrieval or processing activities** shall be certified in tissue banking by the American Association of Tissue Banks~~)~~ within **18 months** ~~one year~~ of employment with a licensed tissue bank.	Eliminated some unnecessary specificity (CTBS). Clarified who the supervisory or technical personnel are. AATB suggests that 18 months is a more appropriate timeframe for this activity.
(31)~~(34)~~ Donor selection. (a) A medical history shall be examined, if available. If scant medical history is available, as in the case of a sudden death, a documented attempt shall be made to acquire information beyond what is available before these tissues can be released. In the event that additional information or records cannot be found, the medical director shall determine if these tissues are suitable for release for transplantation and document the release in the donor's medical record. (b) HIV infections. HIV testing is required under Rule 64D-2.005, F.A.C. Potential donors falling into a high-risk group shall be eliminated from the donor pool. INSERT LANGUAGE HERE RE: CDC RECOMMENDATIONS ~~This includes high-risk behavior groups and high-risk ethnic or geographic groups, pursuant to paragraph 59A-1.005(11)(a), F.A.C., and the partners of the above groups, as well as intravenous recreational drug users~~. (c) Tissues with evidence of infectious diseases are conditions which shall preclude distribution for transplantation. The following is a list of examples of	(34) Donor selection. **Each donor must be screened and tested for relevant communicable disease agents or diseases (RCDADs). The eligibility of each donor must be determined by a licensed Medical Director. Donors exhibiting evidence of RCDADs, as outlined under 21 CFR 1271.3(r) and 21 CFR 1271.45(b), shall be determined ineligible for transplantation. Eligibility of each donor as determined by the Medical Director using all available relevant information shall be documented.** ~~(a) A medical history shall be examined, if available. If scant medical history is available, as in the case of a sudden death, a documented attempt shall be made to acquire information beyond what is available before these tissues can be released. In the event that additional information or records cannot be found, the medical director shall determine if these tissues are suitable for release for transplantation and document the release in the donor's medical record.~~ ~~(b) HIV infections. HIV testing is required under Rule 64D-2.005, F.A.C. Potential donors falling into a high-risk group shall be eliminated from the donor pool.~~ ~~(c) Tissues with evidence of infectious diseases are conditions which shall preclude distribution for transplantation. The following is a list of examples of commonly encountered conditions which preclude donation of tissues:~~ ~~1. Infectious diseases such as:~~ ~~a. Septicemia (demonstrable) at time of death;~~	Duplicative of FDA and AATB Standards. 21CFR1271.3(r) reads as follows: (r) Relevant communicable disease agent or disease means: (1)(i) For all human cells and tissues, a communicable disease or disease agent listed as follows: (A) Human immunodeficiency virus, types 1 and 2; (B) Hepatitis B virus; (C) Hepatitis C virus; (D) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease; and (E) Treponema pallidum. (ii) For viable, leukocyte-rich cells and tissues, a cell-

commonly encountered conditions which preclude donation of tissues: 1. Infectious diseases such as: a. Septicemia (demonstrable) at time of death; b. Systemic mycoses; c. Meningitis or encephalitis; d. Active systemic viral disease or past history of chronic viral disease; e. Active tuberculosis or history of tuberculosis; f. Active hepatitis; and g. Active syphilis or anatomically demonstrable syphilitic lesions. 2. Bacterial infections such as: a. Pyelonephritis; b. Peritonitis; c. Pneumonia (other than non-confluent bronchopneumonia); d. Bacterial endocarditis; e. Osteomyelitis; and f. Other potential transmittable bacterial diseases. 3. Malignancies. Individuals with malignancies arising anywhere in the body shall be excluded from the donor pool. Any exceptions shall be approved by the medical director. 4. Collagen and immune complex diseases such as: a. Rheumatoid arthritis; b. Systemic lupus erythematosus; c. Polyarteritis nodsa; d. Sarcoidosis; e. Myasthenia gravis; and f. Acute rheumatic fever. 5. Severe trauma. Patients who have a tracheotomy or have been on a respirator for over 96 hours and have evidence of infection, multiple open wounds, or wounds to the abdomen are excluded from the donor pool. 6. Transfused donor. a. Tissues from a donor who has been transfused shall comply with the FDA	~~b. Systemic mycoses;~~ ~~c. Meningitis or encephalitis;~~ ~~d. Active systemic viral disease or past history of chronic viral disease;~~ ~~e. Active tuberculosis or history of tuberculosis;~~ ~~f. Active hepatitis; and~~ ~~g. Active syphilis or anatomically demonstrable syphilitic lesions.~~ ~~2. Bacterial infections such as:~~ ~~a. Pyelonephritis;~~ ~~b. Peritonitis;~~ ~~c. Pneumonia (other than non-confluent bronchopneumonia);~~ ~~d. Bacterial endocarditis;~~ ~~e. Osteomyelitis; and~~ ~~f. Other potential transmittable bacterial diseases.~~ ~~3. Malignancies. Individuals with malignancies arising anywhere in the body shall be excluded from the donor pool. Any exceptions shall be approved by the medical director.~~ ~~4. Collagen and immune complex diseases such as:~~ ~~a. Rheumatoid arthritis;~~ ~~b. Systemic lupus erythematosus;~~ ~~c. Polyarteritis nodsa;~~ ~~d. Sarcoidosis;~~ ~~e. Myasthenia gravis; and~~ ~~f. Acute rheumatic fever.~~ ~~5. Severe trauma. Patients who have a tracheotomy or have been on a respirator for over 96 hours and have evidence of infection, multiple open wounds, or wounds to the abdomen are excluded from the donor pool.~~ ~~6. Transfused donor.~~ ~~a. Tissues from a donor who has been transfused shall comply with the FDA Guidance Concerning the Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by reference.~~ ~~b. The decision as to whether or not an individual who received a blood transfusion(s) six months or less before death should serve as a tissue donor is a medical judgment. Therefore, the responsibility of accepting tissue from transfused donors rests with the medical director or physician designee. In making such a decision, factors such as information obtained on retesting of blood donors, testing of organ donor recipients, etc., shall be taken into account.~~ ~~7. Recipients of organ transplants. Recipients or organ transplants shall not be eliminted because of the transplant per se, but must be carefully evaluated because of the drug therapy they receive and the disease processes they might have.~~ ~~8. Other. Toxic exposure sufficient to affect tissue procured and an unknown but suspicious medical history shall constitute a reason for rejecting a donor.~~ ~~(35) Required studies of the tissue donor in addition to FDA requirements specified in Rule 59A-1.005, F.A.C.~~	associated disease agent or disease listed as follows: (A) Human T-lymphotropic virus, type I; and (B) Human T-lymphotropic virus, type II. 21 CFR 1271.45(b) reads as follows: (b) Donor-eligibility determination required. A donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, is required for all donors of cells or tissue used in HCT/Ps, except as provided under 1271.90. In the case of an embryo or of cells derived from an embryo, a donor-eligibility determination is required for both the oocyte donor and the semen donor. Not clear if the current language (if retained) would require tissue banks to check in with blood banks regarding donor suitability.

Guidance Concerning the Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by reference. b. The decision as to whether or not an individual who received a blood transfusion(s) six months or less before death should serve as a tissue donor is a medical judgment. Therefore, the responsibility of accepting tissue from transfused donors rests with the medical director or physician designee. In making such a decision, factors such as information obtained on retesting of blood donors, testing of organ donor recipients, etc., shall be taken into account. ~~7. A potential donor who has chronic blood transfusions shall be eliminated from the donor pool.~~ 7.~~8.~~ Recipients of organ transplants. Recipients or organ transplants shall not be eliminted because of the transplant per se, but must be carefully evaluated because of the drug therapy they receive and the disease processes they might have. ~~9. Therapeutic drugs. Donors receiving chronic corticosteroid drugs shall be eliminated as bone donors because of the effect on bone. Other drugs in therapeutic doses, which might reside in the tissues, may eliminate the donor from the donor pool. Discoloration of bone with tetracycline does not constitute a reason for eliminating a donor.~~ 8.~~10.~~ Other. Toxic exposure sufficient to affect tissue procured and an unknown but suspicious medical history shall constitute a reason for rejecting a donor. (32)~~(35)~~ Required studies of the tissue donor in addition to FDA requirements specified in Rule 59A-1.005, F.A.C. (a) Serologies: 1. HBcAb; 2. FDA-licensed HTLV test for viable, leukocyte rich cells or tissues only; 3. Serologic test for syphilis (STS) – confirmed. Tissues from donors with positive (confirmed) tests shall not be used for transplantation; and 4. Rh determination shall be provided cautioning about the possibility of sensitization.	~~(a) Serologies:~~ ~~1. HBcAb;~~ ~~2. FDA-licensed HTLV test for viable, leukocyte rich cells or tissues only;~~ ~~3. Serologic test for syphilis (STS) – confirmed. Tissues from donors with positive (confirmed) tests shall not be used for transplantation; and~~ ~~4. Rh determination shall be provided cautioning about the possibility of sensitization.~~ ~~(b) Evaluation of the donor. Prior to transplantation, the medical director, designees, or medical contractee shall state in writing that the current medical history, postmortem examination and laboratory test results, together with the available previous medical history, are sufficient to indicate that the donor is acceptable for tissue donation.~~	

(b) Evaluation of the donor. Prior to transplantation, the medical director, designees, or medical contractee shall state in writing that the current medical history, postmortem examination and laboratory test results, together with the available previous medical history, are sufficient to indicate that the donor is acceptable for tissue donation.		
(33)~~(36)~~ Microbiological examination. Each tissue bank shall have microbiological laboratory policies and procedures which ensure allograft safety. Documentation of adherence to these policies and procedures is required.	(~~33~~**5**) Microbiological examination. Each tissue bank shall have **written** microbiological laboratory policies and procedures ~~which ensure allograft safety~~**.** Documentation of adherence to these policies and procedures is required.	Duplicative of AATB K2.300 and K2.400, effective July 2016. The procedures do more than just ensure allograft safety and should be in writing.
(34)~~(37)~~ Autopsy. A gross external and, if applicable, internal examination of any area of the donor altered by the retrieval shall be performed and dictated or otherwise recorded by the procuring person(s) at the time of the removal of tissues from the cadaveric donor. A written report of these findings shall be immediately prepared and delivered to the person(s) responsible for the autopsy of the donor. The report shall contain a notation of normal conditions as well as all itemization of all abnormal pathological findings found during the gross examination of the donor. Whenever a full medical autopsy of the donor will not subsequently be performed by a medical examiner, the medical director or designees may elect to ~~the tissue bank shall~~ obtain a full medical autopsy by other when deemed necessary. If performed, the medical director or designees shall justify and document the need for full autopsy in the donor's medical record and the ~~The~~ tissue bank shall affix a copy of the autopsy report to the donor record. ~~The medical director or designees may exercise a waiver of an autopsy on a case-by-case basis and shall justify and document that waiver in the donor's medical record.~~	~~(34) Autopsy. A gross external and, if applicable, internal examination of any area of the donor altered by the retrieval shall be performed and dictated or otherwise recorded by the procuring person(s) at the time of the removal of tissues from the cadaveric donor. A written report of these findings shall be immediately prepared and delivered to the person(s) responsible for the autopsy of the donor. The report shall contain a notation of normal conditions as well as all itemization of all abnormal pathological findings found during the gross examination of the donor. Whenever a full medical autopsy of the donor will not subsequently be performed by a medical examiner, the medical director or designees may elect to obtain a full medical autopsy by other when deemed necessary. If performed, the medical director or designees shall justify and document the need for full autopsy in the donor's medical record and the tissue bank shall affix a copy of the autopsy report to the donor record.~~	Moved to general section above.
(35)~~(38)~~ Records. (a) Responses from transplant centers which identify adverse reactions attributable to allografts shall be maintained. The records of the tissue banks shall be open to inspection by the AHCA at a mutually convenient time. (b) Records shall show the expiration date assigned to specific processed tissues as defined in the ~~agency's~~ policies and procedures.	(~~35~~**6**) Records. (a) Responses from transplant centers which identify adverse reactions attributable to allografts shall be maintained. The records of the tissue banks shall be open to inspection by the AHCA at a mutually convenient time. (b) Records shall show the expiration date assigned to specific processed tissues as defined in the policies and procedures. (c) To ensure suitability of donated tissues for transplantation, records shall be made concurrently with the performance of each step of processing of tissue allografts. Distribution records shall be available but these may be	Duplicative of – 21 CFR Part 1271.260, 1271.270 and 1271.290, effective May 2005, 1270.33, effective April 1998 and AATB C1.100, C1.300, D5.400, E1.100, G3.200 and H1.400, effective July 2016

(c) To ensure suitability of donated tissues for transplantation, records shall be made concurrently with the performance of each step of processing of tissue allografts. Distribution records shall be available but these may be collected and stored separately. All records shall be legible and indelible, shall identify the person or persons performing the procedures, and shall include the dates of written entry. All records shall be made available to that surgeon on request. The only exception is information infringing upon donor confidentiality. All records shall be maintained for a minimum of ten years. (d) A tissue bank, when sending tissue to a hospital or surgeon, must request in writing that the transplanting surgeon report allograft-related complications to the tissue bank's medical director. Records of adverse reactions and all related follow-up documentation shall be maintained for a period of ten years. (e) Inventory. A record of all unprocessed, processed, and distributed tissues shall be maintained.	collected and stored separately. All records shall be legible and indelible, shall identify the person or persons performing the procedures, and shall include the dates of written entry. All records shall be made available to that surgeon on request. The only exception is information infringing upon donor confidentiality. All records shall be maintained for a minimum of ten years. (d) A tissue bank, when sending tissue to a hospital or surgeon, must request in writing that the transplanting surgeon report allograft-related complications to the tissue bank's medical director. Records of adverse reactions and all related follow-up documentation shall be maintained for a period of ten years. (e) Inventory. A record of all unprocessed, processed, and distributed tissues shall be maintained.	
(36)~~(39)~~ Documentation of donor information. The records shall include all information on the donor including laboratory reports, autopsy reports, a clinical history, a tissue procurement record, and related material. The records of the permission to procure the tissue are kept permanently. A final summary statement is written by the physician responsible for the quality assurance of the allografts which he or she has made available to the transplant surgeon.	(36) Documentation of donor information. The records shall include all information on the donor including laboratory reports, autopsy reports, a clinical history, a tissue procurement record, **donor eligibility determination,** and related material. The records of the **informed consent or authorization** ~~permission to procure the tissue~~ are kept ~~permanently~~ **as required by 1271.55(d)(4).** ~~A final summary statement is written by the physician responsible for the quality assurance of the allografts which he or she has made available to the transplant surgeon.~~	Updated language to better reflect current practice. 21CFR 1271.55(d)(4) reads as follows: You must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest.
(37)~~(40)~~ Timely procurement. The time limitation for tissue retrieval shall be 24 hours if the cadaver is refrigerated and 15 hours if the cadaver is unrefrigerated.	(37)~~ Timely procurement. The time limitation for tissue retrieval shall be 24 hours if the cadaver is refrigerated and 15 hours if the cadaver is unrefrigerated.~~**The tissue bank shall have written procedures that specify the time limits for the recovery of tissue consistent with tissue-specific standards, where applicable.**	Updated language to better reflect current practice. Proposed language is from AATB Standard D5.400.
(38)~~(41)~~ Facilities and equipment. (a) If the tissue bank has an operating room it shall be reserved for the retrieval of cadaveric tissue on a 24-hour basis. Such an operating room shall conform to standard operating room requirements under Chapter 59A-3, F.A.C. It	(~~38~~**37**) Facilities and equipment. **Environmental monitoring procedures shall be established, where appropriate, as part of the quality assurance program. Monitoring procedures may include, but are not limited to, static and dynamic particulate air samplings (e.g., air bacterial content assays) equipment and personnel monitoring where tissue contact occurs, and work-surface cultures.**	Duplicative of 21 CFR Part 1271.195, effective May 2005, and AATB J4.300, effective July 2016. Current language is not reflective

shall have air filtration, stainless steel furniture, washable walls, etc. Ultraviolet lights and bacterial filters may be utilized to reduce the ambient bacterial flora. (b) Environmental monitoring procedures shall be established and periodic sampling of air, drains, surfaces, and water faucets shall be documented.	~~(a) If the tissue bank has an operating room it shall be reserved for the retrieval of cadaveric tissue on a 24-hour basis. Such an operating room shall conform to standard operating room requirements under Chapter 59A-3, F.A.C. It shall have air filtration, stainless steel furniture, washable walls, etc. Ultraviolet lights and bacterial filters may be utilized to reduce the ambient bacterial flora.~~ ~~(b) Environmental monitoring procedures shall be established and periodic sampling of air, drains, surfaces, and water faucets shall be documented.~~	of current practice. Not all tissue recovery occurs in an operating room. And, even those which do occur there, the operating room is not available on a 24-hour basis. Proposed language is from AATB Standard J4.300.
(39)~~(42)~~ Retrieval and processing procedures. (a) Tissues shall be retrieved using either aseptic or clean, nonsterile techniques. If tissues are retrieved using aseptic techniques, methods shall be consistent with standard operating room practice. Aseptic technique does not necessarily preclude the need for subsequent tissue sterilization. Allografts procured using aseptic or clean, nonsterile techniques are suitable for transplantation if adequate precautions are taken to identify and eliminate microorganisms.	(4~~2~~**3**) Retrieval and processing procedures. (a) Tissues shall be retrieved using either aseptic or clean, nonsterile techniques. If tissues are retrieved using aseptic techniques, methods shall be consistent with standard operating room practice. Aseptic technique does not necessarily preclude the need for subsequent tissue sterilization. Allografts procured using aseptic or clean, nonsterile techniques are suitable for transplantation if adequate precautions are taken to identify and eliminate microorganisms.	Duplicative of 21 CFR Part 1271.195 and 1271.215, effective May 2005, and AATB D5.530, E1.000, J4.300 and K2.300, effective July 2016. No proposed changes.
(b) Tissue banks employing ethylene oxide (ETO) for sterilization of tissues, chambers of freeze-dryers, instruments or equipment must monitor occupational exposure to ethylene oxide. Semi-annual reports of ETO monitoring must be kept for 30 years. Specifically the following requirements must be met and documented: 1. Air change rate – minimum rate for rooms where ethylene oxide is used is 10 air changes per hour. 2. Review of gas circuits. The following must be checked for leaks: a. Gas tank valves; b. Gas tank manifolds including filter cartridges; c. Sterilizer and other equipment door seals; d. Pressure relief valves; e. Gas-steam mixing chambers; f. All elbows, compression fittings, gauges, valves, etc. along the gas circuit; g. Gas inlet into chamber; and h. Chamber air intake filter. 3. ETO alarm must be installed near equipment where ETO spill may be	(b) Tissue banks employing ethylene oxide (ETO) for sterilization of tissues, chambers of freeze-dryers, instruments or equipment must monitor occupational exposure to ethylene oxide. Semi-annual reports of ETO monitoring must be kept for 30 years. Specifically the following requirements must be met and documented: 1. Air change rate – minimum rate for rooms where ethylene oxide is used is 10 air changes per hour. 2. Review of gas circuits. The following must be checked for leaks: a. Gas tank valves; b. Gas tank manifolds including filter cartridges; c. Sterilizer and other equipment door seals; d. Pressure relief valves; e. Gas-steam mixing chambers; f. All elbows, compression fittings, gauges, valves, etc. along the gas circuit; g. Gas inlet into chamber; and h. Chamber air intake filter. 3. ETO alarm must be installed near equipment where ETO spill may be possible. 4. Automatic aeration after sterilization without having to open sterilizer door must be provided. 5. Periodic personnel exposure monitoring must be conducted. 6. A canister type respirator (NIOSH approved and rated for 5,000 ppm ETO) and gloves must be kept in the gas sterilization area in case of an emergency. 7. ~~Material~~ **S**~~s~~afety data sheets must be kept in the tissue bank and the	Duplicative of 29 CFR Part 1910.1047, effective March 2012, and 21 CFR Part 1271.200, effective May 2005. Note: ETO sterilization is not very common. Updated to reflect current language.

possible. 4. Automatic aeration after sterilization without having to open sterilizer door must be provided. 5. Periodic personnel exposure monitoring must be conducted. 6. A canister type respirator (NIOSH approved and rated for 5,000 ppm ETO) and gloves must be kept in the gas sterilization area in case of an emergency. 7. Material safety data sheets must be kept in the tissue bank and the location of these sheets and content must be known to the employee. 8. An emergency evacuation plan must be posted for all employees to see. 9. Personnel must be trained regarding the safe use of ETO and records retained in the file. 10. All exhaust systems must be non-circulating.	location of these sheets and content must be known to the employee. 8. An emergency evacuation plan must be posted for all employees to see. 9. Personnel must be trained regarding the safe use of ETO and records retained in the file. 10. All exhaust systems must be non-circulating.	Duplicative of 21 CFR Part 1271.220, effective May 2005, and AATB E1.000, effective July 2016
(c) Tissues shall be processed into specimens appropriate for clinical use. The specific methods employed may vary with each type of tissue and with the manner in which it has been procured, but each type of tissue shall be prepared according to written tissue bank procedures.	(c) Tissues shall be processed into specimens appropriate for clinical use. The specific methods employed may vary with each type of tissue and with the manner in which it has been procured~~., but e~~**E**ach type of tissue shall be ~~prepared~~ **processed** according to written tissue bank procedures.	Duplicative of 21 CFR Part 1271.190, effective May 2005, and AATB E2.200 and J5.500, effective July 2016.
(d) Sterile bone and tissue allografts shall be packaged in minimum room class 1000 environments. Certification of conformance, issued by outside agencies, must attest that the room meets cleanliness requirements for class 1000 or less of FED-STD-209D. Such certification must be obtained every 12 months. If processing is performed in laminar flow hoods, and not in clean rooms, the latter must be similarly certified every 12 months. Adequate supplies must be available, and there must be adequate space for equipment.	(d) ~~Sterile~~ **B**one and tissue allografts shall be packaged in~~. minimum room class 1000 environments. Certification of conformance, issued by outside agencies, must attest that the room meets cleanliness requirements for class 1000 or less of FED-STD-209D. Such certification must be obtained every 12 months. If processing is performed in laminar flow hoods, and not in clean rooms, the latter must be similarly certified every 12 months. Adequate supplies must be available, and there must be adequate space for equipment~~ **an environment specified in written procedures**.	Updated to reflect current practice. ISO standards are utilized at this point.
(40)~~(43)~~ Labeling. (a) Visual inspection. A sufficient area of the container shall remain unobstructed when the label has been affixed to the container to permit inspection of the contents of freeze dried tissue allografts. Tissues that are vacuum sealed shall be spark tested prior to disposition. (b) Container label. Containers shall be labeled so as to identify the	(40) Labeling. ~~(a) Visual inspection. A sufficient area of the container shall remain unobstructed when the label has been affixed to the container to permit inspection of the contents of freeze dried tissue allografts. Tissues that are vacuum sealed shall be spark tested prior to disposition.~~ (b) Container label. Containers shall be labeled so as to identify the following: 1. Name of the product; 2. Name and address of the tissue bank; 3. Tissue identification number; and	Duplicative of 1271.370, AATB G2.340, AATB G3.120, and AATB G3.310 Note: Visual inspection language is no longer indicative of current practice and is confusing.

following: 1. Name of the product; 2. Name and address of the tissue bank; 3. Tissue identification number; and 4. Expiration date, if applicable. (c) Shipping label. Packages shall be labeled so as to identify the following: 1. Identification of human tissue; 2. Name and address of tissue bank; 3. Name of facility to which tissue is being shipped; 4. Recommended storage temperature; and 5. Special instructions indicated by the particular product, e.g., DO NOT FREEZE.	4. Expiration date, if applicable. (c) Shipping label. Packages shall be labeled so as to identify the following: 1. Identification of human tissue; 2. Name and address of tissue bank; 3. Name of facility to which tissue is being shipped; 4. Recommended storage temperature; and 5. Special instructions indicated by the particular product, e.g., DO NOT FREEZE.	
(40)~~(44)~~ Shipping. (a) Shipping shall maintain sterility of the contents and maintain integrity of the appropriate container. (b) Package insert. All tissues shall be accompanied by a package insert which contains instructions for proper storage and reconstituting when appropriate. Specific instructions shall be enclosed with tissues requiring special handling. Such instructions shall include: 1. Presence of known sensitizing substances; 2. Type and estimated amount of antibiotics added during processing; 3. Source of the tissue (when it is a factor in safe administration); 4. All donor test results and laboratory procedures (including an autopsy, if performed); 5. Secondary sterilization procedure, if utilized; 6. Any chemical agent that may cause a change; and 7. All preservation and the concentration of the preservation used in the processing of tissue allografts, if utilized.	(~~40~~**9**) Shipping. **Each tissue bank shall have written procedures for shipping.** **Packaging shall be designed to ensure tissue quality and prevent contamination of the contents of the final container(s).** ~~(a) Shipping shall maintain sterility of the contents and maintain integrity of the appropriate container.~~ ~~(b) Package insert.~~ All tissues shall be accompanied by a package insert which contains instructions for proper storage and reconstituting when appropriate. Specific instructions shall be enclosed with tissues requiring special handling. Such instructions shall include: 1. Presence of known sensitizing substances; 2.~~ Type and estimated amount of antibiotics added during processing;~~ **Type of antibiotics present (if applicable);** ~~3. Source of the tissue (when it is a factor in safe administration);~~ **3.**~~ 4. All donor test results and laboratory procedures (including an autopsy, if performed);~~ **Statement that it has undergone infectious disease testing;** **4.**~~ 5. Secondary s~~ **S**terilization procedure, if utilized; **and** ~~6. Any chemical agent that may cause a change; and~~ **5.** ~~7. All preservation and the concentration of the preservation used in the processing of tissue allografts, if utilized.~~ **Concentration of preservative(s) and/or cryoprotectant(s) in final package solution (if applicable).**	Duplicative of 21 CFR Part 1271.265(d), effective May 2005, and AATB G3.220 and H3.200, effective July 2016 Updated language to reflect current practice and AATB Standards.
(41)~~(45)~~ Tissue tracking. (a) Each tissue and any components derived therefrom shall be assigned, in addition to generic designation, one unique tissue identification number which	(~~41~~**10**) Tissue tracking. (a) **Each tissue bank shall have written procedures for tissue tracking.** Each tissue and any components derived therefrom shall be assigned, in addition to generic designation, one unique tissue identification number ~~which~~	Duplicative of 21 CFR Part 1271.290(c), effective May 2005. Note: The tissue identification

shall serve as a lot number to identify the material during all steps from retrieval through distribution and utilization. Donor number and lot number shall be the same.	~~shall serve as a lot number~~ to identify the material during all steps from retrieval through distribution and utilization. ~~Donor number and lot number shall be the same.~~	number (TIN), known as the distinct identification code (DIC) per FDA, is not always included in the lot number as part of the FDA's Unique Device Identifier (UDI) final rule.
(43)~~(46)~~ Each eye bank shall comply with 21 C.F.R. Parts 16 and 1270 and 1271, ~~1993~~ and make these records relating to the federal standards available to surveyors for the AHCA.	**59A-1.___Standards for Eye Banks** (~~43~~**1**) Each eye bank shall comply with 21 C.F.R. Parts 16 and 1270 and 1271 and make these records relating to the federal standards available to surveyors for the AHCA.	
(44)~~(47)~~ Organization staff requirements. (a) The medical director shall have ~~demonstrated an expertise in external eye disease, corneal surgery, research or teaching in cornea and external disease. If the medical director has not~~ served a corneal fellowship, and shall be certified by the American Board of Ophthalmology ~~the eye bank shall have and document a consulting relationship with an ophthalmologist who has~~. (b) Technical personnel. 1. A supervisory eye bank technician shall be the individual responsible for the daily operation of the eye bank laboratory. The supervisory eye bank technician shall ensure compliance with these standards for the eye bank laboratory. Each eye bank processing laboratory must have at least one certified technician in a supervisory role. 2. An eye bank technician shall be trained in acquisition, evaluation, processing, storage and distribution of eye tissue for transplantation. 3. A procurement technician shall be proficient in screening and retrieval of the eye tissue.	(~~47~~**2**) Organization staff requirements. [No additional changes other than number/structure.]	
(45)~~(48)~~ Training, certification, and continuing education. (a) An eye bank shall provide an orientation program for each new technician and the employee's participation shall be documented. (b) An eye bank shall provide educational opportunities such as in-service training programs, attendance at meetings, seminars, and workshops for all technical personnel, including laboratory supervisors, at a frequency that is defined and reasonable for the size and needs of the technical staff. (c) To function as the supervisory technician in the eye bank processing	(~~48~~**3**) Training, certification, and continuing education. [No additional changes other than number/structure.]	

laboratory, the technician must pass the Eye Bank Association of America's (EBAA) Technician Certification examination or an approved examination administered by a medical school's Department of Ophthalmology approved for residency training in ophthalmology.		
(46)~~(49)~~ Performance standards. (a) Each eye bank shall demonstrate proficiency in all aspects of eye banking by annually retrieving, processing, or~~and~~ distributing at least 100 corneas for penetrating keratoplasty and provide the Agency~~AHCA~~ with documentation of its performance upon request. (b) Each eye bank shall have a consistent policy for the physical inspection of the donor and examination and documentation of the prospective donor's available medical record or death investigation. (c) Review of all available records on each donor shall be performed by an individual who is qualified by profession, education and training to do so, and who is familiar with the intended use of the tissue.	(~~494~~) Performance standards. [No additional changes other than number/structure.]	
(47)~~(50)~~ Donor selection. (a) Eye tissue from donors with the following shall not be used for penetrating keratoplasty, lamellar keratoplasty, patch grafts, epikeratoplasty or any other type of surgery: 1. Death of unknown cause; 2. Death from central nervous system diseases of unknown etiology; 3. Creutzfeldt-Jakob disease; 4. Subacute sclerosing panencephalitis; 5. Progressive multifocal leukoencephalopathy; 6. Congenital rubella; 7. Reye's syndrome; 8. Active viral encephalitis of unknown origin; 9. Active septicemia (bacteremia, fungemia, viremia); 10. Active bacterial or fungal endocarditis; 11. Active viral hepatitis; 12. Rabies;	(~~475~~) Donor selection. (a) Eye tissue from donors with the following shall not be used for penetrating keratoplasty, lamellar keratoplasty, patch grafts, epikeratoplasty or any other type of surgery: 1. Death of unknown cause; 2. Death from central nervous system diseases of unknown etiology; 3. Creutzfeldt-Jakob disease; 4. Subacute sclerosing panencephalitis; 5. Progressive multifocal leukoencephalopathy; 6. Congenital rubella; 7. Reye's syndrome; 8. Active viral encephalitis of unknown origin; 9. Active septicemia (bacteremia, fungemia, viremia); 10. Active bacterial or fungal endocarditis; 11. Active viral hepatitis; 12. Rabies; 13. Intrinsic eye disease: a. Retinoblastoma; b. Malignant tumors of the anterior ocular segment; c. Active ocular or intraocular inflammation: conjunctivitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis; d. Congenital or acquired disorders of the eye which would preclude a successful outcome for the intended use, e.g., a central donor corneal scar for an intended penetrating keratoplasty, keratoconus, and keratoglobus; and	Additional changes may be warranted. Removed the requirement regarding HTLV.

13. Intrinsic eye disease: a. Retinoblastoma; b. Malignant tumors of the anterior ocular segment; c. Active ocular or intraocular inflammation: conjunctivitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis; d. Congenital or acquired disorders of the eye which would preclude a successful outcome for the intended use, e.g., a central donor corneal scar for an intended penetrating keratoplasty, keratoconus, and keratoglobus; and e. Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button. f. Exceptions are that tissue with local eye disease affecting the corneal endothelium may be used for epikeratoplasty, patch grafts, and scleral transplant surgery, and tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma may be used for lamellar keratoplasty or patch grafts. 14. Prior intraocular or anterior segment surgery: a. Refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc.; b. Laser photoablation surgery; c. If corneas are used from donors who have had prior anterior segment surgery (e.g., cataract, intraocular lens, glaucoma filtration), the corneas shall be screened by specular microscopy and meet the eye bank's endothelial standards as determined by the medical director; and d. Laser surgical procedures such as argon laser trabeculoplasty, retinal and panretinal photocoagulation do not necessarily preclude use for penetrating keratoplasty but shall be cleared by the medical director. 15. Active leukemia; 16. Active disseminated lymphomas; 17. Hepatitis B surface antigen positive donors; 18. Recipients of human pituitary-derived growth hormone (pit-hGH) during the years from 1963-1985;	e. Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button. f. Exceptions are that tissue with local eye disease affecting the corneal endothelium may be used for epikeratoplasty, patch grafts, and scleral transplant surgery, and tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma may be used for lamellar keratoplasty or patch grafts. 14. Prior intraocular or anterior segment surgery: a. Refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc.; b. Laser photoablation surgery; c. If corneas are used from donors who have had prior anterior segment surgery (e.g., cataract, intraocular lens, glaucoma filtration), the corneas shall be screened by specular microscopy and meet the eye bank's endothelial standards as determined by the medical director; and d. Laser surgical procedures such as argon laser trabeculoplasty, retinal and panretinal photocoagulation do not necessarily preclude use for penetrating keratoplasty but shall be cleared by the medical director. 15. Active leukemia; 16. Active disseminated lymphomas; 17. Hepatitis B surface antigen positive donors; 18. Recipients of human pituitary-derived growth hormone (pit-hGH) during the years from 1963-1985; 19. HIV seropositive donors; 20. Acquired immunodeficiency syndrome (AIDS); 21. Children (under 13 years old) and infants of mothers with AIDS or at high risk of HIV infection; 22. High risk for HIV infection based on the FDA Guidance Concerning Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by reference. ~~23. HTLV infection except in the case of viable, leukocyte cell or tissue donors;;~~ **23**~~24~~. Active syphilis; and **24**~~25~~. Hepatitis C seropositive donors. (b) Tissue from donors meeting the criteria in paragraph 59A-1.005(50)(a), F.A.C., above shall not be used for epikeratoplasty or other surgery with the exception that tissue with local eye disease affecting the corneal endothelium (e.g., aphakia, iritis) is acceptable for use. Interval of time from donor's death to preservation of eye tissue may be extended.	

19. HIV seropositive donors; 20. Acquired immunodeficiency syndrome (AIDS); 21. Children (under 13 years old) and infants of mothers with AIDS or at high risk of HIV infection; 22. High risk for HIV infection based on the FDA Guidance Concerning Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by reference. 23. HTLV infection except in the case of viable, leukocyte cell or tissue donors; 24. Active syphilis; and 25. Hepatitis C seropositive donors. (b) Tissue from donors meeting the criteria in paragraph 59A-1.005(50)(a), F.A.C., above shall not be used for epikeratoplasty or other surgery with the exception that tissue with local eye disease affecting the corneal endothelium (e.g., aphakia, iritis) is acceptable for use. Interval of time from donor's death to preservation of eye tissue may be extended.		
((48)~~(51)~~ Testing. (a) Microbiologic culturing. Culturing of eye bank donor eyes is recommended. However, the responsibility for determining the need for culturing shall reside with the transplanting surgeon. 1. 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. 2. Surgical culturing. Each eye bank shall recommend culturing of the corneal-scleral rim for corneal transplantation, or a piece of sclera for scleral implantation at the time of surgery. Positive culture results in cases of postoperative infection shall be reported to the eye bank that processed the tissue. (b) HIV screening. 1. Each eye bank shall have an HIV screening program using FDA-approved	(~~486~~) Testing. (a) Microbiologic culturing. Culturing of eye bank donor eyes is recommended. However, the responsibility for determining the need for culturing shall reside with the transplanting surgeon. 1. 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. 2. Surgical culturing. Each eye bank shall recommend culturing of the corneal-scleral rim for corneal transplantation, or a piece of sclera for scleral implantation at the time of surgery. Positive culture results in cases of postoperative infection shall be reported to the eye bank that processed the tissue. (b) HIV screening. 1. Each eye bank shall have an HIV screening program using FDA-approved tests, pursuant to Rule 64D-2.005, F.A.C., for all donors of surgically designated tissue. A negative screening test shall be documented prior to release of tissue for transplantation. 2. Eye tissue from a donor who has been transfused shall comply with the FDA Guidance Concerning the Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by	Removed the requirement regarding HTLV screening.

tests, pursuant to Rule 64D-2.005, F.A.C., for all donors of surgically designated tissue. A negative screening test shall be documented prior to release of tissue for transplantation. 2. Eye tissue from a donor who has been transfused shall comply with the FDA Guidance Concerning the Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by reference. (c) Hepatitis B screening. Each eye bank shall have a hepatitis B screening program using an FDA-approved test, pursuant to Rule 64D-2.005, F.A.C., for hepatitis B surface antigen for all donors of surgically designated tissue. A negative screening test or neutralization or confirmatory test must be documented prior to release of tissue for transplantation. (d) Hepatitis C screening. Each eye bank shall have a hepatitis C screening program using an FDA-approved test, pursuant to Rule 64D-2.005, F.A.C., for hepatitis C surface antigen for all donors of surgically designated tissue. A negative screening test or neutralization or confirmatory test must be documented prior to release of tissue for transplantation. (e) HTLV screening. If donor screening for HTLV has been performed, a negative screening test shall be obtained and documented prior to release of tissue for transplantation. (f) Syphilis screening. If the screening test is performed and is positive, a negative confirmatory test shall be obtained and documented prior to release of tissue for transplantation.	reference. (c) Hepatitis B screening. Each eye bank shall have a hepatitis B screening program using an FDA-approved test, pursuant to Rule 64D-2.005, F.A.C., for hepatitis B surface antigen for all donors of surgically designated tissue. A negative screening test or neutralization or confirmatory test must be documented prior to release of tissue for transplantation. (d) Hepatitis C screening. Each eye bank shall have a hepatitis C screening program using an FDA-approved test, pursuant to Rule 64D-2.005, F.A.C., for hepatitis C surface antigen for all donors of surgically designated tissue. A negative screening test or neutralization or confirmatory test must be documented prior to release of tissue for transplantation. ~~(e) HTLV screening. If donor screening for HTLV has been performed, a negative screening test shall be obtained and documented prior to release of tissue for transplantation.~~ (~~e~~f) Syphilis screening. If the screening test is performed and is positive, a negative confirmatory test shall be obtained and documented prior to release of tissue for transplantation.	
(49)~~(52)~~ Documentation of donor information. (a) Donor screening forms and copies of medical charts, medical examiner, or coroner review forms and gross autopsy results, if performed, shall be completed and retained on all donated eye tissue as part of the donor record. Until the final written autopsy report becomes available, documentation of verbal reports of autopsy findings are acceptable. (b) Donor information forms shall contain information regarding the circumstances surrounding the death of the donor and medical history so that the	(~~49~~7) Documentation of donor information. [No additional changes other than number/structure.]	

suitability of the tissue for transplantation may be evaluated. (c) Minimum information to be retained. A report form for retaining donor and recipient information shall be established for permanent record and shall be readily accessible for inspection by authorized individuals, including surveyors for the AHCA. The record shall include the following minimum information: 1. Eye bank identification number unique to each tissue graft; 2. Name of eye bank; 3. Location of eye bank; 4. Phone number; 5. Type of preservation; 6. Age of donor; 7. Cause of death; 8. Death date and time; 9. Enucleation or in-situ retrieval date and time; 10. Preservation date and time; 11. Slit lamp report; 12. Specular microscopy, if performed; 13. Name of enucleator/evaluator/technician; 14. Name of surgeon receiving tissue; 15. Recipient identification; 16. Utilization of non-transplantable tissue; 17. All serological or microbiological tests performed; and, 18. Adverse reactions, when reported. (d) Length of storage. All records shall be maintained for a minimum of ten years from the date of transplantation/ implantation.		
(50)~~(53)~~ Facilities and equipment. (a) Each eye bank shall have sufficient space, equipment and supplies to perform the volume of laboratory services with optimal accuracy, efficiency, sterility, timeliness and safety. (b) Each eye bank shall have an adequate stable electrical source and a sufficient number of grounded electrical outlets for operating laboratory	(~~50~~**8**) Facilities and equipment. [No additional changes other than number/structure.]	

equipment. Laminar flow hoods or similar piece of equipment shall be available for sterile processing. (c) Each eye bank shall have a refrigerator with a device for recording temperature variations. Temperature variations shall be recorded daily and remain within the range of 2 degrees to 6 degrees C. These records shall be kept for a minimum of ten years. The refrigerator shall be maintained for the exclusive use of donor related material and shall contain clearly defined and labeled areas for all tissue stored, i.e., quarantined tissue, surgical tissue awaiting distribution, and research tissue. (d) In the event of a power failure, there shall be established policies and procedures for action to be taken, which may include an emergency power supply to maintain essential refrigeration. (e) No sterilized instruments, supplies, and reagents, such as corneal preservation medium for surgical tissues, shall be used beyond the expiration date for surgical tissues.		
(51)~~(54)~~ Satellite eye banks. Satellite eye banks that retrieve, process, and distribute tissue shall have a technician and be supervised by and have access to a qualified medical director or designee. Such satellite eye bank shall be inspected by surveyors for the AHCA as part of the certification process for the parent eye bank.	(~~5~~**19**) Satellite eye banks. [No additional changes other than number/structure.]	
(52)~~(55)~~ Retrieval and processing procedures. (a) Enucleation procedure. Ultimate responsibility for personnel who perform enucleation rests with the ~~agency~~ director and the medical director. (b) In-situ and facility-based removal of the corneal-scleral rim. Removal of the corneal-scleral rim shall be performed using sterile technique by individuals specifically trained in in-situ retrieval and facility-based removal of the corneal-scleral segment. (c) Use of preservation medium. Eye banks shall use a corneal storage medium which has been used and stored according to the manufacturer's recommendations. The manufacturer's recommendations must be retained and made available for inspection by surveyors for the AHCA.	(~~5~~2**10**) Retrieval and processing procedures. [No additional changes other than number/structure.]	

(d) Long-term preservation. Eye banks employing long-term preservation of corneal tissue, such as organ culturing, shall carefully document the procedure in their procedures manual, and adhere to strict aseptic technique. (e) Whole globe preservation. Eye banks that store whole eyes for lamellar or refractive keratoplasty shall employ aseptic practices using one of the preservation methods given in the eye bank's procedures manual. The selected preservation method shall be documented in the eye bank's own procedure manual. (f) Scleral preservation. 1. If the eye bank preserves scleral tissue, the selected preservation method shall be documented in the eye bank's own procedures manual. 2. An expiration date for use of tissue shall be indicated based on the container capability and factors documented or recommended by the eye bank. (g) Interval between death, enucleation, procurement, and preservation. Acceptable time intervals from death, enucleation, or procurement to preservation of eye tissue may vary according to the circumstances of death and interim means of storage of the body. Corneal preservation shall occur as soon as possible after death and within the time frame determined by the medical director as defined by the ~~agency's~~ policies and procedures. All time intervals (i.e., time of death to the time of enucleation and preservation) shall be recorded for each donor. (h) Eye maintenance prior to enucleation. The prospective donor's corneal integrity shall be maintained. Procedures for eye maintenance shall be described in the eye bank's policies and procedures. Each individual eye bank's procedure is left to the discretion of the medical director and shall be clearly documented and adhered to. (i) Review of donor medical history. Prior to distribution of tissue for transplantation, the medical director or designee shall review and document the medical and laboratory information in accordance with criteria established in this rule. (j) Non-surgical donor tissue. If donor tissue is provided for purposes other		

than surgery, e.g., research, practice surgery, etc., and if that donor tissue is not screened for HIV, hepatitis, or syphilis, a label stating that screening for HIV-antibody, hepatitis B, hepatitis C, or syphilis has not been carried out or stating "Potentially Hazardous Biological Material" shall be attached to the container used for the donor tissue storage and transport.		
((53)~~(56)~~ Tissue evaluation. The transplanting surgeon has ultimate responsibility for determining the suitability of the tissue for transplantation. (a) Gross examination. The corneal-scleral segment shall be initially examined grossly for clarity, epithelial defects, foreign objects, contamination, and scleral color (e.g., jaundice). (b) Slit lamp examination. The cornea shall be examined for epithelial and stromal pathology and in particular endothelial disease. Enucleated whole globes shall be examined in the laboratory prior to distribution and corneal retrieval. After corneal retrieval, the corneal-scleral rim shall be evaluated by slit lamp biomicroscopy, even if the donor eye has been examined with the slit lamp prior to retrieval of the corneal-scleral rim, to ensure that damage to the corneal endothelium or surgical detachment of Descemet's membrane did not occur.	(~~53~~**11**) Tissue evaluation. [No additional changes other than number/structure.]	
(54)~~(57)~~ Storage. (a) All surgical tissue shall be stored in quarantine until negative serology results have been documented, pursuant to Rule 64D-2.005, F.A.C. (b) All tissue shall be stored at a temperature appropriate to the method of preservation used. (c) Each eye bank shall precisely document its procedures for storage.	(~~54~~**12**) Storage. [No additional changes other than number/structure.]	
(55)~~(58)~~ Labeling. (a) Visual inspection. A sufficient area of the container shall remain unobstructed to permit inspection of the contents. (b) Each corneal or scleral tissue shall be clearly and indelibly labeled to include, at least, the following: 1. Name of source eye bank; 2. Tissue identification number; 3. Type of tissue;	(~~55~~**13**) Labeling. [No additional changes other than number/structure.]	

4. Date and time of donor's death; 5. Date and time of corneal-scleral preservation; 6. Expiration date for scleral tissue; and 7. A statement shall accompany the tissue stating that: a. The tissue is intended for single patient application only and that it is not to be considered sterile and that the FDA therefore recommends culturing or reculturing; and, b. The tissue was procured from a donor who was non-reactive when tested for HIV-1 and HIV-2 antibodies, hepatitis B surface antigen (HBsAg), and hepatitis C antibody (HCV) using a test approved by the FDA and follows provision of Rule 64D-2.005, F.A.C.		
(56)~~(59)~~ Packaging. (a) Each tissue shall be individually packaged and sealed with a shrink wrap. (b) The tissue shall be packed in a water proof container with wet ice, so as to maintain the temperature of the tissue at an acceptable level. Packing shall be done so that the package insert and tissue label do not become wet. Special instructions shall be included on the package insert. (c) Package insert. A package insert form shall accompany the tissue for transplantation. This form shall include the following: 1. Recommended storage temperature with specific emphasis on Do Not Freeze; 2. That the surgeon shall check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering; 3. That color change per the manufacturer's guidelines may indicate a change in pH, in which case the tissue shall not be used and a report made immediately to the eye bank; 4. Whether pre-surgical microbiological cultures were performed by the eye bank, including the advisement that culture of the donor rim and sclera shall be performed at the time of surgery; and, 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	(~~59~~**14**) Packaging. [No additional changes other than number/structure.]	

purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.		