

## Overview and Updates - 13<sup>th</sup> Edition of AATB *Standards for Tissue Banking*

This report contains an overview and updates announced for the first time. Previously published updates to the 12<sup>th</sup> edition of AATB's *Standards for Tissue Banking (Standards)* are not included in this report but they will appear in the 13<sup>th</sup> edition and can be found on the AATB website at:

<http://www.aatb.org/Standards-Updates-for-the-12th-Edition>

The following standards were affected in the list of fifteen previous announcements: A2.000, B1.521, D3.000, D4.354, D4.355, D4.357, D5.400, D5.521, G3.210, G3.310, J1.900, K1.100, K2.210, K2.220, and numerous consent-related standards.

For the first time in the *Standards for Tissue Banking*:

- it not only contains all current AATB Guidance Documents, but also the AATB Accreditation Policies for Transplant Tissue Banks;
- the cover selection is an image of human tissue;
- Preface appears before the Introduction that describes history of the development of the *Standards*; and
- where a few standards are being discussed and will be revised, a “Note” was inserted as an alert.

When applicable, each AATB Guidance Document now includes the names of contributors to each document, and they were also converted to Times New Roman font (from Arial) to match the font used in *Standards*. These were not substantive updates so the version numbers did not change. References to new Guidance Documents also appear within specific standards and some guidance documents require updating during 2012.

The Introduction has been revised to include references to new councils, utilization of task forces, as well as new consent-related terminology (authorization), and wording was adjusted to clarify when a request for variance is required.

To assist all accredited tissue banks with benefits associated with instituting certain Quality Program initiatives, various standards were revised, and some were created, to harmonize with concepts found in FDA's Quality Systems Regulations (QSR) for medical device manufacturers (Current Good Manufacturing Practice requirements at 21 CFR part 820). These include but are not limited to: investigations (corrective and preventive action, complaints), internal audits, management responsibility, reagents/supplies, suppliers, purchasing controls, staff training, in-process controls, and process validation studies. As part of this update, use of the term “Director” for the tissue bank's Director position has been removed throughout the *Standards* and replaced, where appropriate, with a reference to a responsible representative of management or simply the “tissue bank.” A tissue bank can continue to use the term “Director” for this specific position but must be sure to designate this individual as “Management with Executive Responsibility” and define those responsibilities to be compliant with applicable standards in these updates. The term “Medical Director” remains in use as is (unchanged).

The AATB-accredited tissue banks that process (V) and/or (C) tissue convened to review and update the standards specific to these tissue types. This resulted in changes and some reorganization of these standards.

In affected standards, references to “computer,” “computer operations” and “computer systems” were changed to “electronic” or “electronic systems,” and a definition was created for “electronic systems.”

Although not individually reproduced here due to affecting numerous standards, previous references to “applicable federal, state and/or local laws and regulations,” or similar wording, were generally shortened to “applicable laws and regulations” to make sentence structure less cumbersome throughout and enhance comprehension. Some examples are included later in this report.

Standard D5.900 Transportation of Tissue Following Recovery includes an additional example to assist accredited tissue banks with compliance to FDA's CGTP Final Rule at § 1271.60(c) *Shipping of HCT/Ps*

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*in quarantine*. This change is made because tissue banks have been cited during FDA inspections for not including specific wording in the records accompanying a shipment in quarantine, specifically when tissue is sent from recovery to a processor (FDA term equates to a “pre-distribution shipment”). See the update where a description that “Donor Eligibility Has Not Been Completed” should be added to such records accompanying this type of shipment. Standards Committee discussion included that, to meet this expectation, this information could appear on the shipping container label or inside the shipping box.

To accommodate variations in local laws, regulations, and tissue bank practices, as well as concerns regarding liability issues and differences in the relevance of positive test results, Standard D4.356 Notification of Positive Infectious Disease Test Results was amended and renamed D4.356 Disclosure and Availability of Positive Infectious Disease Test Results. These changes were proposed and discussed during a panel presentation at the AATB Annual meeting last September. The use of “should” is used at parts that may be controversial. Membership is encouraged to send your concerns, as well as ideas for other approaches that could be used, to the AATB Chief Policy Officer.

Where applicable for standards that address skin (S) tissue, revisions were made to accommodate the handling of decellularized dermis allografts. Previously, the intent of the (S) standards only included fresh or cryopreserved skin allografts.

When applicable, AATB-accredited tissue banks and their recovery partners screen the birth mother of certain child donors for vertical transmission disease risks that are not required by current FDA regulations or AATB *Standards*. A need was identified to update *Standards* to be in line with professional standard of practice of our accredited tissue banks and to harmonize with related sections of regulation from Health Canada (referenced to the Canadian Standards Association’s “*CSA/Z900.1 (2nd edition); Cells, Tissues and Organs for Transplantation – General Requirements*,” see part 13.1.3 and Annex E, listings e) and f) at E.2) and the applicable European Commission Directive that addresses exclusion criteria for deceased child donors of tissues and/or cells (see “*COMMISSION DIRECTIVE 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells*” at ANNEX I, listing 1.2.1.). For these reasons, screening of the birth mother has been updated to not only include risk associated with HIV but also risk associated with HBV, HCV, and other infectious agents when indicated. Refer to F1.100 Donor Suitability Review and the appropriate listing in the Behavior/History Exclusionary Criteria in Appendix II of the 13<sup>th</sup> edition of *Standards*.

Another update to the Behavior/History Exclusionary Criteria in Appendix II is that a reference to “juvenile detention” has been clarified to be any juvenile correctional facility. The reference to “detention” has been removed.

Standard E4.141 Storage Conditions for Commonly Transplanted Human Tissue was improved to include a more detailed description of tissue that meets the designation as musculoskeletal (MS) tissue.

At the request and direction of AATB’s Reproductive Council, a new standard, H1.130 Donor Conceived Offspring Limitations, was created to address this concern.

Standard K3.000 MICROBIOLOGIC TESTING was improved to offer better direction for accredited tissue banks.

Many standards updates follow but not all revisions are recreated here (i.e., some updates are editorial), and for many updates only the relevant part of the standard is included here. Text added to a standard is underlined, italicized and appears in blue font (e.g., *Example*), and text that has been deleted utilizes the strikethrough (e.g., ~~Example~~).

## INTRODUCTION

*(relevant parts only)*

The AATB's "*Standards for Tissue Banking*" (*Standards*) reflect the collective expertise and conscientious efforts of tissue bank professionals to provide a comprehensive foundation for the guidance of tissue banking activities. The *Standards* are reviewed periodically and revised by the AATB Standards Committee to incorporate scientific and technological advancements. The Standards Committee receives input from tissue-specific *the Association's* Councils (*Accredited Tissue Bank*, Physicians', *Musculoskeletal Processing and Distribution*, *Quality, Recovery and Donor Screening*, and *Reproductive, Skin, and Tissue Bank*) and appropriate standing *committees* and/or ad hoc *committees* *task forces*, as needed. All revisions are subject to approval by the AATB Board of Governors.

These *Standards* establish performance requirements for *Informed Consent/Authorization*, *Donor selection Suitability Assessment through Donor screening and testing*, as well as for the *Recovery*, *Processing*, *Storage*, packaging, labeling, and *Distribution* of transplantable human *cells*, musculoskeletal, skin, reproductive, cardiac, and vascular tissue. The *Standards* are intended to be applied to tissue bank functions that relate to *quality*, staff, donor, *and* tissue, ~~and record management~~, but do not encompass the clinical use of cells and tissue.

Use of the words "*Shall*" or "*Must*" in these publications *Standards* indicates mandatory compliance, whereas use of the words "*Should*" *and* "*May*" indicates recommended compliance. If accredited tissue banks, or banks *one* seeking accreditation, ~~are found~~ *does* not to comply with these *any mandatory standard Standards*, they must provide the Association with a sufficient *a* written rationale for noncompliance with those standards, which are recommended ("should") *that sufficiently demonstrates equivalency is required*. The *Details regarding the* process to request a variance from *Standards* is *are* specified in Appendix I. Accreditation by the AATB is based on verified compliance with these *Standards* and is strongly recommended *encouraged*.

## SECTION A GENERAL INFORMATION

### A2.000 DEFINITIONS OF TERMS

***ALLOGENEIC***— *used as an adjective to modify donation, tissue, donor or recipient when transplantation is intended for a genetically different person.*

***AORTOILIAC GRAFT (C)*** - *The distal segment of the abdominal aorta including the bifurcation and proximal segments of both the left and right common iliac arteries.*

***ARTERIAL GRAFT (V)***—A segment of *peripheral* artery that is recovered, processed and preserved.

***ASYSTOLE***—The reference time for cardiac death. A documented pronounced time of death is used as 'asystole' when life-saving procedures have been attempted and there were signs of, or documentation of, recent life (e.g., *witnessed event*, agonal respirations, pulseless electrical activity). If a death was not witnessed, 'asystole' must be determined by the last time known alive. Asystole will be 'cross clamp time' if the tissue donor was also a solid organ donor.

***AUDIT***—A documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or ~~vendors~~ *suppliers* to evaluate adherence to the written SOPM, standards, ~~or federal, state and/or local~~ *applicable* laws and regulations.

***AUTOLOGOUS***—*Used as an adjective to modify donation, tissue, donor or recipient when transplantation to only one's self is involved.*

**CBER** — *Center for Biologics Evaluation and Research*

**DISINFECTION**—A process that reduces the number of viable cellular microorganisms, but does not necessarily destroy all microbial forms, such as spores and viruses. *Use of antibiotics, while not normally described as disinfection, is included here.*

**ELECTRONIC SYSTEMS**— *Computerized systems that create source documents (electronic records).*

**ERROR**—A departure from the SOPM, *Standards*, or applicable laws or regulations.

**ESTABLISH(ED)** – *define, document and implement.*

**ISO** – *International Organization for Standardization*

**MANAGEMENT WITH EXECUTIVE RESPONSIBILITY** – *Those senior employees of a tissue bank who have the authority to establish or make changes to the tissue bank’s quality policy and quality system.*

**MAY**—Used to reflect *indicate* an acceptable method that is recognized but not essential.

**MUST**—Used to indicate a mandatory requirement. *The same as SHALL.*

**PATCH GRAFT (C)**—A segment of cardiac allograft conduit to be used in cardiovascular repair, *replacement*, construction, or reconstruction.

**PROCESSING**—Any activity performed on tissue, other than *donor screening, donor testing*, tissue recovery or *and* collection *functions, storage or distribution*. ~~including preparation, preservation for storage, and/or removal from storage, to assure the quality and/or sterility of human tissue. Processing includes steps to inactivate and/or remove adventitious agents.~~

**QUALITY POLICY** – *The overall intentions and direction of an organization with respect to quality, as established by Management with Executive Responsibility.*

**QUALITY SYSTEM** – *The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.*

**SHALL**— *Used to indicate a mandatory standard*, same as MUST.

**WET ICE TEMPERATURES**—Temperatures ranging from ~~+~~ *above freezing (0°C) to* 10°C.

## SECTION B GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

### B1.000 GENERAL INSTITUTIONAL REQUIREMENTS

#### B1.200 Governing Body

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 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*.

*The Governing Body shall designate one or more senior employees as Management with Executive Responsibility.* Issues of liability, ethical considerations, fiduciary responsibility, and compliance with applicable governmental laws and regulations, these *Standards*, and the tissue bank's *SOPM* shall be the responsibility of the Governing Body *and Management with Executive Responsibility.*

### **B1.500 Multi-Facility Tissue Banking**

When two or more *Tissue Banks* participate jointly in *Recovery*, *Processing*, *Storage*, and/or *Distribution*, the relationship and responsibilities of each shall be delineated in writing and that documentation shall be maintained at each participating bank or facility. Any records necessary to demonstrate compliance shall be readily accessible to the distributing tissue bank. Compliance with *Standards* by all parties shall be required and documented. ~~However, if~~

*If* an AATB-accredited bank *obtains from and* processes tissue for a tissue bank *not accredited by the AATB that is* located outside of the United States (U.S.), the requirement for compliance with *Standards* does not apply to the foreign *tissue* bank if the processed tissues will not be distributed within, or to, the U.S. All cells and tissues imported from entities that do not follow AATB *Standards* shall be appropriately *Quarantined* throughout import, *Storage*, *Processing*, and export. The U.S. *AATB-accredited* tissue bank must verify that the foreign tissue bank *not accredited by the AATB* complies with regulations of the governmental authority having jurisdiction in their country for the functions they perform (e.g., consent/*authorization*, *Donor* screening, *Recovery*, donor testing). Additionally the *tissue* bank *not accredited by the AATB* should be verified to be in compliance with existing standards or guidelines, as appropriate. Examples of established standards include the current editions of: Health Canada's "Safety of Human Cells, Tissues and Organs for Transplantation Regulations;" the Directive (and Commission Directives) 2004/23/EC of the European Parliament and the Council; or, expectations as described in the World Health Organization's "Aide Mémoires for Human Cells and Tissues for Transplantation."

### **B1.520 On-site Inspections**

#### **B1.521 Inspections/Audits of Other Facilities**

(Refers to inspections/*Audits* that an accredited tissue bank must perform for activities/services rendered by another entity.)

Before an entity performs any activity/*service* under contract, agreement or other arrangement, the accredited tissue bank must ensure that the entity will comply with applicable AATB *Standards*, federal regulations, and applicable state or local laws. Thereafter, the accredited tissue bank is responsible for ~~certifying~~ *verifying*, at least biennially, that the activities or service(s) has/have been performed in conformance with ~~these~~ *applicable* *Standards*, ~~federal regulations, and applicable state or local laws~~ *and regulations.* *This requirement does not apply to any other AATB-accredited entity. When applicable, this* ~~This~~ must be documented on a form provided by, or pre-approved by, the AATB *Director of Accreditation Program Manager* (refer to the AATB Accreditation Policies). The *Verification* of activities or services performed by others shall be documented (e.g., a paper *Audit*, on-site *Audit*, on-site inspections, etc.). Regardless of whether the facility performing activities or services for others is accredited, it is the responsibility of the tissue bank receiving those activities/services to periodically verify that *Procedures* related to the activities/services performed are in compliance with these *Standards*, federal regulations, applicable state or local laws, and the written agreement/contract. The inspection/*Audit* plan, policies, and procedures shall be specified in the *SOPM*.

Documentation that an *Audit*/inspection specific for activities or services ~~performed~~ shall be maintained by the tissue bank. Such documentation shall itemize all operational systems that were verified to determine compliance with these *Standards*, ~~federal regulations, applicable state or local laws, and the~~ agreement/contract, *and applicable laws and regulations.* This itemization of the systems reviewed shall be

provided to AATB on-site inspectors upon request. [For an audit tool and guidelines to be used for a partner performing recovery services, refer to Guidance Document No. 6.](#)

If, during the course of this contract, agreement, or other arrangement, information suggests that the entity may no longer be in compliance with such requirements, the accredited bank must take steps to ensure compliance. If it is determined that the entity will not comply, the contract, agreement, or other arrangement must be terminated.

### **B1.600 Contracted and Non-contracted Laboratory Services**

*Tissue Banks* that contract for laboratory services shall retain in their records the name and address of the contracted facility and documentation of the inclusive dates of the contract period. Proof of current laboratory licensure and accreditation must be maintained. *Tissue Banks* that obtain testing results from non-contracted laboratory services (e.g., other tissue banks, organ procurement organizations) shall maintain the name, address, licensing and accreditation information for each laboratory from which test results are obtained for the purpose of donor suitability or tissue qualification assessments. ~~The Director or Medical Director of the tissue bank~~ [Appropriate Management with Executive Responsibility](#) shall be responsible for understanding the principles of bacteriological and/or infectious disease test procedures employed by a laboratory as well as the interpretation of results. Records of laboratory results used to determine final release shall become part of the donor or *Processing* record.

NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority [having jurisdiction](#) apply regarding establishment registration, laboratory certification, test kit licensing/approval, and test run record retention.

## **B2.000 FUNCTIONAL COMPONENTS OF A TISSUE BANK**

### **B2.100 ~~Director~~ [Management Responsibility](#)**

#### **B2.110 ~~Qualifications~~ [Quality Policy](#)**

~~The Director~~ [Management with Executive Responsibility](#) shall be qualified by training and experience for the scope of activities conducted by the tissue bank.

#### **B2.120 ~~Responsibilities~~ [Organization](#)**

[Each tissue bank shall establish and maintain an adequate organizational structure to ensure that donors are consented/authorized, screened and tested, and tissue is recovered or collected, processed, stored, packaged, labeled, and distributed in accordance with the requirements of these Standards.](#)

#### **B2.121 ~~General~~ [Responsibilities and Authority](#)**

~~The Director shall implement policies of the Governing Body and shall be responsible for all operations, including compliance with all current federal, state, and/or local laws and/or regulations, including those of the Food and Drug Administration (FDA), state and local regulations, standards, and the tissue bank's own SOPM.~~

[Each tissue bank shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks in accordance with these Standards. The tissue bank shall ensure that responsibilities and authorities are defined, documented and communicated within the tissue bank.](#)

### **B2.122 Personnel Resources**

The *Tissue Bank* shall have sufficient technical staff and a written policy to maintain and preserve records and operating procedures for future reference and historical continuity resources, including the assignment of trained personnel, for management, performance of work, and assessment activities to meet the requirements of these Standards.

The Director or designee shall prepare and maintain a current organizational chart that delineates the function of each staff member of the tissue bank. Members of the supervisory and technical staff shall be appointed, directed, disciplined, and supervised by the Director and/or Medical Director, although members of an independent Quality Assurance unit may report to the Governing Body independent of the Director. The Director or designee shall approve and maintain job descriptions and shall document staff responsibilities. The Director or designee shall ensure that personnel responsible for performing tissue banking activities are adequate in number, qualified for the functions to be performed, and shall be assigned responsibilities commensurate with their skills and qualifications.

The Director or designee shall also be responsible for developing, reviewing, and approving employee training programs.

### **B2.123 Management Representative**

Management with Executive Responsibility shall appoint a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for ensuring that quality system requirements are effectively established and effectively maintained. The management representative shall periodically report on the performance of the quality system to management with executive responsibility for review.

### **B2.130 Management Review**

Management with Executive Responsibility shall review the suitability and effectiveness of the Quality System at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of these Standards and the tissue bank's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

### **~~B2.140~~23 Implementation and Evaluation of all Technical Policies and Procedures**

The Director or designee shall be responsible for the implementation and evaluation of all technical Technical policies and procedures utilized in the operation of the tissue bank must be established and maintained. The tissue bank may adopt current standard procedures, such as those in a technical manual prepared by another organization, provided that the tissue bank has verified that the procedures are consistent with, and at least as stringent as, the requirements of these *Standards* and appropriate for operations.

### **~~B2.150~~24 Quality Assurance Program**

The Director shall be responsible for establishing and maintaining a A Quality Assurance (QA) Program shall be established and maintained to ensure that the entire operation is in conformity with the tissue bank's SOPM, government regulations, and these *Standards*, and applicable laws and regulations. The Director shall require a A documented annual internal review or Audit to ensure compliance with the SOPM, federal, state, and/or local laws and/or regulations, and these Standards must be performed. The Self-assessment Tool/Audit Report (STAR) must be completed annually and documented on a form provided by, or pre-approved by, the AATB Director of Accreditation (refer to the AATB Accreditation Policies).

## **B2.200 Medical Director**

### **B2.210 Qualifications**

The *Tissue Bank* shall have a Medical Director who maintains a valid state license from any state (or for international members, the physician must maintain an equivalent medical license). ~~The Medical Director may also be the Director.~~ He/she should have training and experience in evaluating and determining donor suitability particularly with regard to infectious diseases, or use a Medical Advisory Committee or consultants to assist in those areas.

### **B2.223 ~~Notification of Confirmed Positive Test Results~~**

The Medical Director shall be responsible for notifying appropriate parties of confirmed positive infectious disease test results, in accordance with ~~Section~~ [Standard](#) D4.356 ~~of these Standards.~~

## **B2.300 Technical Staff**

### **B2.310 Qualifications**

Staff must possess the educational background, experience, and training sufficient to assure assigned tasks are performed in accordance with the tissue bank's established procedures. [Donor Authorization, informed consent for living donors, donor screening and testing, Tissue Recovery or Collection, Processing, packaging, labeling, storage, and Distribution, and Cryopreservation](#) shall be performed by trained personnel. Staff training shall be documented in individual employee training files.

### **B2.320 Responsibilities**

~~Technical staff~~ [Staff](#) shall be responsible for implementation of policies and procedures as established by the ~~Director~~ [tissue bank](#). Duties of each staff member shall be described in written job descriptions. Staff must demonstrate *Competency* in the operations to which they are assigned.

## **B2.400 Quality Assurance Program**

### **B2.410 Staff Qualifications**

A designated individual, generally familiar with, but not having performed, the specific work being reviewed, shall be responsible for each *Quality Assurance* review. ~~This individual shall report, for this function, specifically to the Director, his/her designee, or other designated responsible party.~~

## **SECTION D ACQUISITION OF TISSUE: [AUTHORIZATION, INFORMED](#) CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION**

### **D4.100 General**

Donor suitability criteria shall be established by the Medical Director and shall not conflict with these *Standards*. Each donor shall be evaluated according to established criteria. The suitability of each donor shall be determined by the Medical Director or licensed physician designee upon review of all records as specified in Section F1.100 and in accordance with the *SOPM*.

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- (A) Donor suitability criteria shall be established and documented by a licensed physician caring for the patient-donor. It is not necessary to document a *Physical Examination*, a *Donor Risk Assessment Interview*, or medical history and medical record review for autologous tissue in the tissue bank records.
- (S) *Potential donors shall be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and skin condition.*
- (C) Heart donors shall also meet the following criteria:
- ~~1) There shall be no history of coronary artery bypass grafting (CABG), bacterial endocarditis, rheumatic fever, semilunar valvular disease, or a cardiomyopathy of viral or idiopathic etiology;~~
  - ~~2) Any history of previous cardiac surgery (other than CABG), closed chest massage (CPR), cardiac defibrillations, penetrating cardiac injury, or other potentially deleterious cardiac intervention shall be evaluated on a case-by-case basis;~~
  - ~~3) Recovery of a heart valves from an anencephalic infants shall begin only after *Asystole*;~~
  - ~~4) In the case of suspected Sudden Infant Death Syndrome (SIDS), an autopsy should be performed and results reviewed to confirm the cause of death;~~
  - ~~5) Mitral valve donors shall not have a history of mitral valve disease, including mitral valve prolapse; and~~
  - ~~6) Heart valve donors shall be evaluated for the risk of Chagas' disease.~~
- ~~(V) Vascular donors shall also meet the following criteria:~~
- ~~1) Veins—There shall be no history of vein stripping, varicose veins, or leg ulcers;~~
  - ~~2) Arteries—There shall be no known (reported) history of arteriosclerosis; and~~
  - ~~3) Trauma shall be evaluated on a case-by-case basis for any vascular tissue *Recovery*.~~
- (R) Criteria for accepting *Client Depositors* and potential reproductive cell and tissue donors shall be established by the ~~Director and Medical Director~~ *or licensed physician designee.*

### **D4.200 Assessment**

#### **D4.211 Physical Examination**

- (LD) Except for autologous and embryo donations, prior to the donation of tissue from a potential *Living Donor*, a *Physical Examination* shall be performed by the Medical Director or physician designee, or by a physician involved with the individual's medical care, or designee *as permitted by law.* If an examination of a *Living Donor* was performed for other reasons, review of the findings of such an examination shall be performed and documented in the donor's record, as well as all other examination findings. After a *Donor Risk Assessment Interview* is completed, if any history is suspect, a directed *Physical Examination* shall be performed. The directed examination shall include any of the above applicable items (see D4.210) that would assist with information to determine whether there is evidence of high risk behavior. The *Physical Examination* should be used to determine overall general health of the donor.

#### **D4.220 Donor Risk Assessment**

#### **D4.230 Relevant Medical Records Review**

Prior to cell and/or tissue donation, a preliminary review of readily available medical information *Relevant Medical Records* shall be conducted by a trained individual; ~~this information may include medical records and test results, information derived from pertinent donor medical records, and/or conversations with attendant medical staff, and/or family members.~~

#### **D4.300 Disease Screening**

#### **D4.320 Miscellaneous Adverse Conditions**

Tissue from donors with any of the following conditions shall be evaluated by the Medical Director for suitability for transplantation in accordance with the tissue bank's *SOPM*:

- 1) History of autoimmune diseases; or
- 2) Ingestion of, or exposure to, toxic substances.

(MS) In addition to the general exclusion criteria, the following medical conditions shall also preclude musculoskeletal tissue donation:

- 1) Rheumatoid arthritis;
- 2) Systemic lupus erythematosus;
- 3) Polyarteritis nodosa;
- 4) Sarcoidosis; and
- 5) Clinically significant metabolic bone disease.

(C) Heart donors shall also meet the following criteria:

- 1) There shall be no history of bacterial endocarditis, rheumatic fever, or a cardiomyopathy of viral or idiopathic etiology;
- 2) Any history of previous cardiac surgery (i.e., CABG), semilunar valvular disease, closed chest massage (CPR), cardiac defibrillations, penetrating cardiac injury, or other potentially deleterious cardiac intervention shall be evaluated on a case-by-case basis; and
- 3) Mitral valve donors shall not have a history of mitral valve disease, including mitral valve prolapse.

(V) Vascular donors shall also meet the following criteria:

- 1) Veins—There shall be no history of vein stripping, varicose veins, or evidence of venous insufficiency;
- 2) Arteries—There shall be no known (reported) history of peripheral vascular disease or systemic vasculitis; and
- 3) Trauma shall be evaluated on a case-by-case basis for any vascular tissue Recovery.

#### D4.352 Plasma Dilution

(A sentence was added to the general standard.)

*Alternative algorithms to evaluate plasma dilution can be used if justified.*

#### D4.356 Notification *Disclosure and Availability* of Positive Infectious Disease Test Results

The donor, if living, shall be notified of *provided* test results as required by applicable federal, state and/or local laws and/or regulations. For deceased donors, unless otherwise directed by federal, state and/or local laws and/or regulations, the donor's *Next of Kin* or a physician who will counsel the *Next of Kin* shall be notified of confirmed positive test results that may be medically relevant as determined by the Medical Director or licensed physician designee. *the Authorizing Person should be contacted regarding the availability of infectious disease test results that may be of medical significance as determined by the Medical Director or licensed physician designee. Contact should include the means by which available test results should be requested. If a Document of Gift was used (i.e., there is no Authorizing Person), contact regarding the availability of infectious disease test results should be made to the person who would have been the Authorizing Person had no gift been made during the life of the Donor, or to the person authorized to make arrangements for final disposition of the body. These records should be provided upon written request as permitted by law or regulation. The Positive test results shall be reported to state and/or local health department(s) as required by law or regulation.* ~~shall be notified of positive test results as required by state and/or local laws and/or regulations.~~

All organizations involved in the *Recovery, Collection and/or Processing* of tissue from a donor with a repeatedly reactive (positive) infectious disease test result shall be notified of the donor's status within one working day of receipt of the test results. Policies regarding notification of confirmatory testing results shall be established by the Medical Director.

*Contact regarding availability and/or disclosure of Test test results notification* shall be documented.

#### D4.370 Semen Analysis

- (R) **Semen Donors:** Prior to enrollment of a donor in the sperm donor program, his *Semen* shall be tested for sperm quality and found acceptable for such parameters as sperm motility, concentration, and post-thaw motility. Donors shall be excluded unless the specimen meets criteria set by the ~~Director in consultation with the~~ Medical Director and, when appropriate, the Medical Advisory Committee. Criteria for *Directed Donors* may differ from those for *Anonymous Donors*. Sperm quality tests shall be repeated at a frequency determined by the ~~Director~~ *tissue bank.*

#### D4.400 Age Criteria

The Medical Director and/or tissue bank Medical Advisory Committee shall determine age criteria for donor suitability ~~in accordance with the following tissue-specific standards.~~

- (A) There are no age limits for autologous tissue donation.
- (C) ~~Acceptable donors shall be within the range of newborn (minimum weight generally 6 pounds/2.7 Kg) to 60 years of age.~~

- (V) — ~~The Medical Director shall determine the age limits for vascular tissue donors.~~
- (MS) — ~~The Medical Director shall determine age limits for bone and soft tissue donors.~~
- (OA) — ~~The Medical Director shall determine age limits for *Osteoarticular* donors.~~
- (R) *Semen* donors shall be younger than 40 years of age to minimize the risk of genetic anomalies except with the written agreement of the user physician. For *Donated* embryos, the female (*Oocyte Donor*) shall be younger than 35 years, unless an exception has been made by the Medical Director with documented agreement of the user physician.
- (S) — ~~Potential donors shall be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and skin condition.~~

## D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

### D5.100 Verification Procedures

#### D5.110 ~~Informed Consent~~ Confirmation

Prior to *Recovery* or *Collection*, staff shall confirm that *in the case of a deceased donor, Authorization for donation has been obtained and documented in a Document of Gift/Authorization, and in the case of a Living Donor, Informed Consent* for donation has been obtained and documented. *If Informed Consent was not obtained prior to Recovery, confirmation must occur as soon as practical after Recovery and before use of the tissue.*

(The last sentence above was added since the previous update was announced.)

#### D5.700 ~~Post-Recovery and Post-Collection~~ Packaging

- (S) ~~All~~ *Recovered* skin tissue shall be packaged in a *Sterile* solution immediately following *Recovery* *or packaged by another method that maintains the integrity of the tissue for its intended use (e.g. decellularized dermis).* *If in solution,* ~~the~~ volume of transport solution must be adequate to cover the entire skin. The type, *Lot* number, manufacturer, and expiration date(s) shall be documented. *If in solution,* ~~the~~ transport container must be fluid tight and designed to prevent contamination of the contents.
- (R) — ~~Reproductive tissue shall be deposited individually into a pre-labeled aseptic receptacle labeled with the donor identification, date, and type of tissue enclosed as appropriate (abbreviations may be used if defined in the SOPM). The tissue shall be maintained at defined environmental temperatures until and during transport to the *Processing* laboratory. Maintenance of such temperatures shall be documented. The tissue shall be transported to the *Processing* laboratory within a reasonable time period as defined by the SOPM, so as to maintain the functional integrity of the tissue.~~

#### D5.800 Post Collection Packaging

- (R) *Semen shall be collected into a pre-labeled sterile collection container. The collection container shall be labeled with the donor or client depositor identification, date, and time of collection. Oocytes shall be collected into a primary collection receptacle pre-labeled with the donor or client*

depositor identification. If the tissue requires transportation to the Processing laboratory, it should be transported within a reasonable time period as defined by the SOPM, so as to maintain the functional integrity of the tissue.

#### **D5.8100 Transportation of Tissue to Processing Center Following Recovery**

Following tissue *Recovery*, tissue shall be packaged in a manner that permits required environmental conditions to be maintained for the duration of transportation. Transportation temperatures do not require monitoring if the packaging and transport conditions have been validated to maintain the required environmental conditions, including temperatures. The transportation receptacle must indicate that “DONATED HUMAN TISSUE” is enclosed as well as include the name and address of the *Recovery* agency and *Processing* center (if different) in accordance with applicable federal, state and/or local laws and/or regulations. All human tissue processed or shipped prior to determination of donor suitability must be under *Quarantine*, accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation (e.g., “*Quarantine*”; “Donor Eligibility Has Not Been Completed”; and “Not Suitable for Transplant in its Current Form”).

- (A) Autologous tissue shall be transported to the *Processing*/storage center on wet ice in the time limits appropriate for the particular tissue.
- (C, V) The transport container shall be transported ~~on wet ice~~ at Wet Ice Temperatures. Time of acceptance of the tissue into the *Processing* center shall be documented. Cardiac and vascular tissues shall be received at the Processing location within sufficient time following Recovery to allow for the start of Disinfection within the established Cold Ischemic Time limit.
- (MS) The recovered tissue shall be wrapped in an aseptic fashion with at least one moisture barrier and shall be transported at *Wet Ice Temperatures* or colder. The maximum time that recovered tissue shall remain at *Wet Ice Temperatures*, prior to either *Processing* or freezing, shall be no longer than 72 hours.
- (OA) The recovered tissue shall be transported at *Wet Ice Temperatures*. The maximum time that recovered tissue shall remain at *Wet Ice Temperatures* prior to *Processing* shall be no longer than five days.
- (S) If the tissue is to be cryopreserved, the skin transportation container shall be transported at *Wet Ice Temperatures* or packaged by another method that maintains the integrity of the tissue for its intended use.

#### **~~D5.810 Time Limit for Receipt by Processing Center~~**

~~(C, V) Cardiac and vascular tissues shall be received at the Processing location within sufficient time following Recovery to allow for the start of Disinfection within the established Cold Ischemic Time limit.~~

#### **D6.0100 Reagents and General Supplies**

All instruments, solutions, and supplies used to recover human tissue used for transplantation shall be *Sterile*, unless otherwise indicated. All non-disposable surgical instruments and parts of mechanical/ electrical equipment which come in contact with tissues during tissue *Recovery* shall be properly cleaned,

disinfected, and *Sterilized* between donor recoveries according to written procedures prepared to control the prevention of infectious disease contamination or *Cross-Contamination* by tissues. All reagents shall be used and stored in accordance with manufacturers' instructions.

#### **D6.110 Stock Rotation**

Reagents and supplies with expiration dates or production dates shall be stored in a manner to facilitate inventory rotation. Supply and reagent inventories not bearing expiration or production dates shall be labeled with the date of acquisition and stored in a manner to facilitate inventory rotation. Older reagents and supplies should be used first. Expired reagents and supplies shall not be used.

### **SECTION E PROCESSING, PRESERVATION, QUARANTINE, AND STORAGE**

#### **E1.000 PROCESSING, PRESERVATION, QUARANTINE, AND STORAGE—GENERAL**

~~The Director shall establish~~ *Processing* and *Preservation* methods *shall be established* in accordance with *Standards* and applicable federal, state, and/or local laws and/or regulations. All tissue shall be processed, preserved, *Quarantined*, and/or stored pursuant to such methods so as to render them suitable for clinical use.

- (C, V) *Processing* shall include a *Disinfection* period followed by rinsing, packaging, and *Preservation*. *Processing* of cardiac and vascular tissue shall be conducted so as to alter the tissue minimally.

#### **E1.010 Receipt of Tissue at Processing Center**

- ~~(C, V) The presence of wet ice or a transport solution temperature range of 1 to 10°C shall be documented prior to acceptance of cardiac or vascular tissue into the facility for further *Processing*. The movement into storage facilities at the receiving center shall be documented, including condition of transport device (e.g., presence/absence of ice), date and time of movement into storage at the *Processing* facility, and personnel involved.~~

(C, V, MS, OA, S)

Approval or rejection of the receipt of tissue into the processing or storage facility must be documented. The movement into storage, to immediate processing or to removal, shall be documented, including condition of the transport Package, evidence that proper environmental conditions were maintained (e.g., presence/absence of ice/coolant), the date and time of movement into storage, and personnel involved.

#### **E1.020 Processing Environment**

- (A) If *Processing* of autologous tissue is required, it shall occur in a bacteriologically and climate-controlled environment utilizing aseptic technique.
- (C, V) *Processing*, which includes dissection, *Disinfection* and packaging, of cardiac and vascular tissues, shall be performed in a certified and qualified ISO 5 (Grade A, Class 100) (or cleaner) laminar flow

environment. Tissue shall be processed in an aseptic fashion using *Sterile* drapes, packs, solutions, instruments, and packaging material.

### **E1.033~~2~~ Temperature Limits**

- (C) To prevent additional warm ischemia and potential cellular or matrix damage caused by temperature cycling, methods shall be employed that maintain the tissue and solutions during heart dissection ~~within 1°C~~ above freezing (0°C) to 10°C. Methods/equipment shall be qualified to maintain the appropriate temperatures.
- (V) Methods shall be employed that maintain the tissue at desired *Processing* temperatures as required by reagents used and as described in written procedures.
- (S) ~~To prevent~~ If additional warm ischemia and potential cellular or matrix damage caused by temperature cycling impact integrity for intended use (e.g. cryopreserved), methods shall be employed that maintain the tissue or solutions above 10°C for no longer than 2 hours. The methods/equipment shall be qualified to maintain the appropriate temperatures.

### **E1.033 Time Limits for Processing and Preservation Phases**

Time limits and/or other valid process-control end points or limits for the completion of each phase of Processing and Preservation shall be established.

(C, V) Disinfection of cardiac and vascular tissue shall be accomplished via a time-specific, validated incubation and regimen (Disinfection Time). The Total Ischemic Time shall not exceed 48 hours.

(OA) Processing of Osteoarticular tissue shall be completed within five days of Recovery.

(R) After Collection, examination and/or Processing of donor Semen specimens shall be initiated within a time period appropriate for retention of functional integrity, as specified in the SOPM.

(S) Processing of skin that is to be frozen/Cryopreserved shall be initiated within 10 days of Recovery, provided the skin is placed in tissue storage media which is replaced at least every 72 hours. If the media is not changed, Processing shall be initiated within 96 hours of Recovery.

(The above standard is a combination of previous standards numbered as E1.041, E1.036, and E1.500.)

### **E1.034 Prevention of Matrix Deterioration**

(C, V, S)

To prevent drying and possible cellular, tissue, and matrix deterioration, the tissue shall be kept moist at all times during *Processing* using a *Sterile*, isotonic solution/medium. If drying does not impact integrity for intended use (e.g. decellularized dermis), the requirement to prevent drying is not applicable.

#### **E1.036 Time Limit for Dissection**

~~(C, V) The *Total Ischemic Time* shall not exceed 48 hours.~~

#### **E1.040 Sterilization/Disinfection of Tissue**

Individual *Processing* facilities shall establish, validate, and document ~~antibiotic~~ *disinfection or sterilization* regimens and microbial surveillance methods. The *SOPM* shall establish a list of organisms which necessitate discard, *Sterilization* and/or *Disinfection* of tissue. The list shall be based upon not only the category type of tissue but also the method by which the tissue was processed (e.g., *Cryopreserved MS* tissues that cannot be “sterilized” and can only be “disinfected”).

(S) The following are considered to be pathogenic, highly virulent *Microorganisms* that result in tissue discard *unless treated with a disinfection or sterilization process validated to eliminate the infectivity of such organisms*:

- 1) *Staphylococcus aureus*;
- 2) *Streptococcus pyogenes* (group A strep.);
- 3) *Enterococcus* sp.;
- 4) gram negative bacilli;
- 5) *Clostridium*; and
- 6) fungi (yeasts, molds).

#### **~~E1.041 Disinfection of Tissue~~**

~~(C, V) *Disinfection* of cardiac and vascular tissue shall be accomplished via a time-specific, validated incubation and regimen (*Disinfection Time*).~~

#### **E1.050 Tissue Evaluation**

(C, V, OA)

Standardized evaluation and classification system is required (e.g., valve with no visible abnormalities or aberrations, implantable *Allograft* with some imperfection(s), and discard/non-implantable *Allograft*). ~~The transplanting surgeon should be notified before the final dispensing of *Allografts* with imperfections; notification shall be documented.~~ The *Allograft* evaluation system shall be made available to the implanting surgeon ~~upon request~~.

#### **E1.060 Tissue Preservation/Cryopreservation**

##### **E1.061 Techniques**

(C, V) The *Allograft* shall be removed from the *Disinfectant* solution then rinsed in a disinfectant-free solution. If tissue is to be *Cryopreserved* it will be packaged with a *Cryoprotectant* medium then frozen at a steady, controlled, predetermined rate with compensation for heat of crystallization/*latent heat of fusion*. The tissue shall be frozen at a specific rate to a predetermined

specific end-point (a temperature of -40°C or colder). If tissue is to be preserved using other methods, appropriate protocols shall be determined and described in written procedures validated with respect to tissue integrity.

- (S) When the tissue is to be cryopreserved, Freezing of skin shall be done in a manner that ensures a slow cooling rate to maintain the structural integrity of the skin. Variable-rate cooling using insulated heat sink boxes or programmed control-rate freezing techniques are acceptable methods of skin *Cryopreservation*. When programmed control-rate techniques are utilized, they must allow the tissue to freeze at a steady, predetermined rate with heat of crystallization compensation. The tissue shall be frozen at a specific rate to a predetermined specific end-point, not warmer than -40°C.

### **E1.300 Reagents and Supplies—General**

The reagents used in *Processing* and *Preservation* shall be of appropriate grade for the intended use and *Sterile*, if indicated. Selection criteria used to qualify reagents and supplies must be documented. A record shall be made of all reagents and supplies following receipt including the type, manufacturer, *Lot* number, date of receipt, and expiration date. The inspection of reagents and supplies shall be documented, including identification of the staff performing the inspection.

### **E1.6510 Specimen Sizing**

- (C) *Allograft* heart valve grafts shall be inspected, evaluated, and sized by internal valve annulus diameter, and recorded in millimeters (mm).

The length of the aortic conduit, main pulmonary artery, and right and left pulmonary artery remnants shall be recorded in millimeters (mm) or centimeters (cm), as measured along the anterior midline of each conduit.

### **E1.7600 In-Process Controls**

*In-Process Controls* shall be applied as necessary and according to the *SOPM* during *Processing* and packaging to ensure that each process meets requirements specified in the *SOPM*. The Director of tissue bank, in collaboration with technical staff and QA staff, shall determine when, which, and how controls are to be performed (e.g., residual moisture testing, microbial cultures of tissue, solutions, packaging, or equipment, pH measurements, or post-thaw sperm quality). Sampling for *In-Process Controls* shall be designed to be representative of the materials to be evaluated.

*Process Control* procedures shall be designed to assure that tissue has the identity, characteristics, and quality intended. ~~The Director or Medical Director or designee shall review these p~~ Procedures and any changes in these procedures shall be reviewed to ensure that such changes are verified, or where appropriate validated, before implementation.

### **E1.8700 Processing and Preservation Records**

A record shall be created to document the *Processing* and *Preservation* of tissue. *Processing* and *Preservation* records shall include the following:

- 1) *Processing* dates and responsible *Processing* personnel;

- 2) *Tissue Identification Number(s)* and type(s) of tissue being processed;
- 3) Tissue measurements (e.g., weight, dimensions, volume), as appropriate;
- 4) Expiration where applicable;
- 5) Type and quantity of tissue sampled for *In-Process Controls*;
- 6) Final *Disposition* of each tissue obtained and/or processed; ~~and~~
- 7) Type, *Lot* number, manufacturer (unless recorded in other records), and expiration date, where applicable, of supplies and reagents used to process and/or preserve tissue.; and
- 8) *Identification of equipment used to process and/or preserve tissue.*

## **E4.000 STORAGE**

### **E4.100 Storage Temperatures**

~~(C, V) *Cryopreserved cardiac and vascular Allografts shall be maintained at temperatures of -100°C or colder.*~~

### **E4.120 Frozen and Cryopreserved Tissue**

*(C, V) Cryopreserved cardiac and vascular Allografts shall be maintained at temperatures of -100°C or colder.*

### **E4.141 Storage Conditions for Commonly Transplanted Human Tissue**

Cardiac tissue includes, but is not limited to, *Valved Conduits, Non-Valved Conduits, and Patch Grafts*; vascular tissue includes, but is not limited to, *Arterial Grafts* and vein grafts; musculoskeletal tissue includes, but is not limited to, bone *and cartilage, and soft tissue such as* tendons, ligaments, *nerve,* fascia, *pericardium, amniotic membrane, chorionic membrane, peritoneal membrane, adipose tissue,* and *Dura Mater*.

### **E4.3210 Refrigerated Tissue**

(MS, OA)

The expiration time of refrigerated musculoskeletal tissue shall be 5 days from the date of *Recovery* or established in the *SOPM* using a validated method for determining expiration dating.

(S) Skin *that has not been processed or preserved* shall be stored refrigerated for no longer than 14 days. *NOTE: This standard is currently under review.*

### **E4.3220 Frozen and Cryopreserved Tissue**

(MS, OA)

Expiration dates of frozen and frozen *Cryopreserved* tissue shall not exceed five years from the date of *Processing* unless a longer expiration date has been validated. *NOTE: This standard is currently under review.*

*(C, V) Each tissue bank shall determine a maximum storage period allowable for grafts to be distributed. Limitations imposed by packaging, or by anticipated untoward effects of long term storage on tissue characteristics related to function, shall be validated and taken into account.*

#### **E4.3230 Lyophilized/Dehydrated Tissue**

(MS) Expiration dates of *Lyophilized* or dehydrated tissue shall not exceed five years from the date of initial *Processing* unless a longer expiration date has been validated. *NOTE: This standard is currently under review.*

#### **E4.4300 Segregation of Tissue**

(R) ~~The Director must establish p~~Procedures for storage of tissues from *Client Depositors* or *Directed Donors* whose test results are positive or repeatedly reactive *must be established and maintained.*

## **SECTION F RELEASE AND TRANSFER OF TISSUE**

### **F1.000 TISSUE RELEASE—GENERAL REVIEW REQUIREMENTS**

All necessary information shall be complete and compiled in a standardized format prior to final review and determination of donor suitability and tissue acceptability for transplantation. Each donor record shall contain a ~~release/Disposition/~~*release* statement and signature of both the Medical Director or licensed physician designee who is assuming responsibility for donor suitability determination and, if different, the individual(s) responsible for reviewing all technical and *Quality Control* specifications. If *Processing* was performed, there shall be documentation of a review of all technical and *Quality Control* specifications by ~~the tissue bank Director or his/her designee~~ *designated personnel.* An *SOPM* shall clearly define the responsibilities of each reviewer.

#### **F1.100 Donor Suitability Review**

Although the *Donor Risk Assessment Interview* may be preliminarily reviewed by technical staff to evaluate acceptability for *Collection*, *Recovery* or *Processing*, tissue shall not be released for transplantation without determination of donor suitability by the Medical Director or licensed physician designee. The donor suitability review shall include, but is not limited to:

- 8) All relevant culture results up to and through the completion of *Recovery* (e.g., blood cultures, if performed; ~~pre-processing cultures~~ *Pre-Sterilization/Pre-Disinfection Cultures, if available*);
- 11) Any other information gathered for the purposes of disease screening as required by standards and applicable ~~federal, state, and/or local~~ laws and/or regulations.

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In the case of pediatric donors who have been breastfed within the past 12 months and/or are 18 months of age or less, the birth mother's risk for transmissible disease shall be evaluated for HIV, [HBV, HCV and other infectious agents when indicated](#). See Appendix II.

For all donors one month (28 days) of age or less, the infant and the birth mother shall be screened for risk of Relevant Communicable Disease Agents and Diseases and the mother's blood must be tested.

Once the determination is made, the suitability statement shall be documented, dated, and signed by the Medical Director or licensed physician designee.

### **F1.200 Technical Review**

Tissue may be released for transplantation only with notation in *Processing* records by processing technicians or their supervisor that tissue produced meets technical specifications set forth in the *SOPM* (e.g., dimensions, quality) and that *Processing* was performed according to the *SOPM*. ~~If the Director does not review technical elements,~~ [T](#)here must also be a signature by technical staff indicating that all technical elements were reviewed.

- (A) If autologous tissue is processed, the *Autograft* may be released for transplantation only upon notation in *Processing* records by technicians or their supervisor that *Processing* was performed according to the *SOPM*. ~~If the Director does not review technical elements,~~ [T](#)here must also be a signature by technical staff indicating that all technical elements were reviewed.

## **SECTION G LABELING**

### **G1.000 LABELS AND LABELING**

#### **G1.300 Labeling Integrity**

Labels shall be designed [and qualified to be legible, indelible, and affixed](#) ~~adhere~~ firmly to the container under all anticipated storage conditions [for the shelf life of the tissue](#). Labeling shall be clear, legible, and indelible. Tissue labels and associated *Labeling Materials* applied by tissue bank staff shall not be removed, altered, or obscured except to correct labeling *Errors*.

### **G2.000 LABELING PROCESS**

#### **G2.300 Controls—General**

There shall be appropriate labeling control procedures based upon the system and equipment used in labeling operations. *SOPMs* shall incorporate controls including the review of labels to ensure accuracy and the establishment of checks to prevent transcription and other labeling *Errors*. ~~Computer-assisted~~ [Electronic](#) labeling systems shall possess adequate controls to prevent the erroneous labeling of tissue. There shall be documentation in the records to verify label accuracy and that labeling checks were performed. The labeling area shall be inspected prior to the start of labeling activities to ensure that all labels and packaging materials from previous labeling have been removed.

### **G3.000 LABELING INFORMATION**

#### **G3.200 Summary of Records and Package Insert**

#### **G3.220 Package Insert Content**

The *Summary of Records* may be included in the *Package Insert*. The *Package Insert* shall contain the following information:

21) ~~Date of issue or revision of the *Package Insert*.~~ *Effective date or other traceable version identifier.*

(C, V) Inserts for cardiac and vascular tissue shall contain the following additional information:

2) Statement that the *End User tissue be may not subject the tissue to Sterilization (e.g., DO NOT STERILIZE the allograft by any method. Exposure of the allograft and the packaging to irradiation, steam, ethylene oxide, or other chemical sterilants will render the allograft unfit for use);*

## SECTION H DISTRIBUTION AND DISPENSING

### H1.100 Tissue Distribution and Dispensing Restrictions

#### H1.120 Semen Distribution Restrictions

#### H1.130 Donor Conceived Offspring Limitations

(R) *A written policy addressing limitation of the number of offspring by a gamete donor shall be established. The policy shall include the upper limits deemed acceptable to the Reproductive Tissue Bank and shall describe the methods that will be used to comply.*

### H2.000 TISSUE FOR RESEARCH—GENERAL POLICIES AND PROCEDURES

Facilities providing tissue for research and other non-transplantation purposes shall develop detailed relevant specific policies and procedures. *Informed Consent or Authorization* for research *and/or education* shall be obtained from the donor or *Next of Kin* unless otherwise authorized by law. *See Standards D2.000 and D3.000.*

### H3.000 PACKAGING AND SHIPPING

#### H3.300 Validation and Expiration of Transport Container

If tissue to be shipped requires specific environmental conditions other than ambient temperature, the capability of the transport container to maintain the required environmental conditions shall be demonstrated and documented in a *Validation* study. The length of time that these conditions can be maintained by the transport container, ~~assuming normal handling,~~ shall also be determined and documented. Expiration dates of the transport container shall be noted on the outside of the transport container.

#### H3.400 Quality Control

#### H3.410 Residual Levels in Packaging

(C, V) If ethylene oxide is used to *Sterilize Processing* or packaging components that come in contact with the *Allografts* (e.g., *Disinfection* jars or packaging pouches), residues of ethylene oxide, ethylene glycol, and ethylene chlorohydrin should be evaluated. *Refer to ISO 10993-7.*

#### H3.500 Final Inspection

All packages shall be subjected to a final inspection to ensure that the *Containers* are intact, the *Labels* are accurate, the *Package Insert* is present, and that the final package is appropriate for the type and requirements of the tissue being shipped.

The exterior of the transport container shall be inspected to verify that ~~the name and address and telephone number of the distributing facility and the name and telephone number of the *Consignee* are present.~~ *Verification* that any hazardous materials, type of refrigerant used, transport (shipping) expiration date (if applicable) and prominent identification as “DONATED HUMAN TISSUE,” ~~is clearly visible~~ *requirements in Standard G3.310 are met.* These inspections shall be documented, including identification of staff conducting inspections.

#### **H4.000 RETURN OF TISSUE**

##### **H4.100 Temperature Records**

- (S) Refrigerated skin may be returned to inventory if it has been maintained at ~~1°C~~ *above freezing (0°C)* to 10°C in a closed *Container*.

Frozen/*cryopreserved* skin that has been thawed shall not be returned to the skin bank inventory. Frozen/*cryopreserved* skin shall not be assigned for use to another patient if the package has been opened.

#### **H5.000 RECALLS—GENERAL**

##### **H5.200 Notification Responsibilities**

Upon discovery of the need for *Recall*, the tissue bank shall promptly notify all entities to which affected tissue was distributed or dispensed *as well as the tissue bank that recovered the tissue, if applicable.*

##### **H5.500 Recall Records**

All information relating to the *Recall* of tissue and resulting communications shall be documented and retained on file at least 10 years beyond the date of *Distribution*, the date of transplantation (if known), *Disposition*, or expiration of the tissue, whichever is latest. The file shall include the following information:

- 12) Documentation of review ~~by the Director, the QA staff, and~~ if of a medical nature, review by the Medical Director or licensed physician designee.

### **SECTION J GENERAL OPERATIONS**

#### **J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)**

##### **J1.100 Purpose and Design**

Each tissue bank shall develop written detailed policies and procedures in a standardized written format, which shall be collected into a Standard Operating Procedures Manual (*SOPM*). These shall be *available at all locations for which they are designated, used, or otherwise necessary, and shall be* utilized to ensure that all tissue released for transplantation *is in compliance to these* ~~meet at least minimum requirements, specifications, and established s~~ *Standards* as defined by the American Association of Tissue Banks and applicable federal, state, and/or local laws and/or regulations.

##### **J1.200 Contents**

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The *SOPM* shall specifically include, but shall not be limited to:

- 1) Donor policies and procedures, including *Informed Consent or Authorization*, donor suitability criteria, donor screening methods, notification of confirmed positive test results, information sharing and, if applicable, reconstruction and final disposition of a deceased donor's body (~~Ref. Sections~~ [D2.000](#), [D3.000](#), [D4.000](#) ~~and~~ [D5.000](#));
- 2) Tissue *Collection, Recovery* and handling policies and procedures, including supplies and methods used in all aspects of the operation involving the assessment of the *Recovery Site, Recovery, Processing*, packaging, quarantine, labeling, storage, donor suitability review, and/or release of tissue (~~Ref. Sections~~ [D5.000](#), [D6.000](#) ~~and Sections~~ [E](#) and [F](#));
- 3) Laboratory procedures for tests performed in-house, including establishment of appropriate specifications, standards, and test procedures to assure that tissue is safe; and for contracted laboratory testing, policies and procedures defining which tests shall be performed and how test results shall be received, reviewed, interpreted, and managed (~~Ref. Section~~ [D4.3500](#));
- 4) Policies and procedures for *purchasing controls*, order receipt, unit selection, final inspection of *Container*, and package and shipping of tissue, as well as criteria for returning and reissuing tissue (~~Ref. Sections~~ [K1.300](#), [M3.000](#), [M4.000](#), [M5.000](#) ~~and Section~~ [H](#) ~~and~~ [M5.000](#));
- 5) Record management policies and procedures designed to maintain *Traceability* and facilitate (if necessary) product *Recall* and *Recipient* notification by documentation of each step of tissue production from the point of *Collection, Recovery* and identification to final *Distribution* of the tissue (~~Ref. Sections~~ [C1.000](#), [C1.400](#), [H5.000](#), [L4.000](#) and ~~M36.000~~ [M6.000](#) ~~and~~ [M7.000](#));
- 6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection, Recovery, Processing*, packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including:
  - a) Policies and procedures for monitoring storage temperatures, for defining *Tolerance Limits*, and for describing what, when, and how corrective actions are to be taken for implementing emergency product transfers and determining alternative storage and monitoring methods for tissue units and reagents (~~Ref. Sections~~ [E4.000](#), [F4.200](#) and [M2.000](#));
  - b) Policies and procedures for the investigation, documentation, and reporting of *Accidents, Errors, Complaints*, and *Adverse Outcomes* (~~Ref. Section~~ [K4.000](#));
  - c) Policies and procedures requiring notification in writing of the Director and/or Medical Director and the QA department *Management with Executive Responsibility* of any *Recalls*, investigations, inspection reports, or regulatory actions (~~Ref. Sections~~ [H5.000](#) and [K4.000](#));
  - d) Policies and procedures for the *Recall* of tissue unacceptable for transplantation (~~Ref. Section~~ [H5.000](#), [L6.000](#) and [M6.000](#));
  - e) Policies, procedures and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (~~Ref. Section~~ [J5.000](#));
  - f) Policies and procedures describing the receipt, identification, storage, handling, sampling, testing, and subsequent approval or rejection of *Containers*, packaging materials, labels, reagents, and supplies (~~Ref. Sections~~ [E1.000](#), [E2.000](#), [J5.500](#) and [Section](#) [G](#)); and
  - g) Policies and procedures for monitoring *In-Process Controls* and managing events such as failed test runs and failure of a *Lot* to meet established specifications (~~Ref. Section~~ [K](#)).

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- 7) Policies and procedures for assigning expiration dates (~~Ref. Section E1.000~~ [E4.200, H3.300 and K1.200](#));
- 8) Policies and procedures for handling requests for research tissue (~~Ref. Section H2.000~~);
- 9) Procedures for disposal of medical waste and other hazardous waste (~~Ref. Section J3.000~~);
- 10) Emergency and safety policies and procedures, including reporting of staff injuries and potential exposure to blood-borne pathogens (~~Ref. Section J3.000~~);
- 11) Procedures assigning responsibility for the sanitation of facilities and describing the cleaning schedules, methods, equipment and materials to be used (~~Ref. Section J4.000~~);
- 12) Policies and procedures describing manual methods for tissue banking activities in the event of ~~computer~~ [electronic](#) or equipment malfunctions (~~Ref. Section K6.000~~); and
- 13) Policies and procedures describing requirements of training programs for technical and QA staff (~~Ref. Section J2.000~~).

### **J1.300 Implementation**

The *SOPM* and associated process-*Validation* studies shall be reviewed and approved by ~~either the Director or Medical Director~~ [appropriate individuals](#) as dictated by content. All medically-related portions of the *SOPM* shall be reviewed and approved by the Medical Director. Upon implementation, all portions of the *SOPM* must be followed as written. Minor *Deviations* from the *SOPM* may be authorized in writing by the Director, Medical Director, or QA designee provided the *Deviation* is in compliance with these *Standards*.

### **J1.400 Modifications**

The *SOPM* shall be updated to reflect modifications or changes, [and shall include a description of the change, identification of the affected documents, the signature of the approving individual\(s\), the approval date, and when the change becomes effective.](#)

Prior to implementation, each modification shall be approved by ~~the Director~~ [appropriate individuals](#) or ~~the~~ Medical Director, as dictated by content, and training shall be provided to pertinent staff. Implementation dates shall be recorded for all affected procedures. [Obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.](#)

### **J1.600 Annual Review**

~~The Director or designee shall perform and document a~~ [An](#) annual review of all policies and procedures [shall be performed and documented](#). The Medical Director shall perform and document an annual review of the SOPs for donor suitability and *Adverse Outcomes*.

## **J2.000 TECHNICAL AND QUALITY ASSURANCE STAFF—TRAINING/CONTINUING EDUCATION**

### **J2.100 Training**

Training shall be conducted for technical and QA staff to maintain *Competency* in procedures and familiarity with applicable ~~federal and state~~ regulations and AATB *Standards*. Training shall encompass the following areas, as applicable: new employee orientation; the *SOPM*; technical training; QA; computer *Electronic Systems*; and continuing education. All training activities shall be documented. Training records shall be retained for 16 years after termination of employment or as required by federal, state and/or local law, whichever is longer.

- 1) *As part of their training, personnel shall be made aware of the consequences of the improper performance of their specific jobs.*
- 2) *Personnel who perform Verification and Validation activities shall be made aware of Accidents and Errors that may occur and be encountered as part of their job functions.*

### **J3.000 SAFETY PRACTICES**

#### **J3.100 Work Environment**

Each tissue bank shall provide and promote a safe work environment by developing, implementing, and enforcing safety procedures. These procedures shall be incorporated into the *SOPM* or reside in a specific Safety Manual which is referenced by the *SOPM*. The procedures shall be written in accordance with applicable Occupational Safety and Health Administration (OSHA) regulations, guidelines established by the *CDC*, and applicable ~~federal, state, and local~~ requirements *laws or regulations*. All safety procedures shall be approved and reviewed annually ~~by the Director or designee~~.

### **J4.000 FACILITIES**

#### **J4.400 Security**

Tissue banks shall maintain adequate physical security to safeguard tissue inventory and records as well as to prevent the entry of unauthorized individuals. Such security may be in the form of personnel, electronic *or mechanical* devices *or barriers*, or configuration of the physical plant. Only those personnel (including persons conducting inspections) who are authorized by supervisory personnel shall enter those areas of the building or facility designated as limited-access areas.

### **J5.000 EQUIPMENT**

#### **J5.300 Qualification and Maintenance**

Equipment, laboratory instruments, apparatus, gauges, and recording devices shall be qualified and routinely calibrated, maintained, inspected, monitored, cleaned, *Sterilized*, disinfected, decontaminated, and repaired at appropriate intervals in accordance with the *SOPM* and schedules. *Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on quality.* Where appropriate, *Tolerance Limits* shall be specified. Documentation of such activities shall be made and maintained in equipment files for 10 years. Such records shall include documentation of repairs, rejection, return, and/or disposal of defective equipment.

#### **J5.500 Storage ~~Unit Identification~~ Equipment**

~~Each unit~~ *Equipment* used for storage of tissue shall be identified to facilitate monitoring of temperature and location of in-process, quarantine, and *Distribution* inventory. ~~Each storage unit~~ *Equipment* shall be labeled with the general nature of the contents.

*Storage equipment used for storing tissue, reagents, media, refrigerants, or other laboratory solutions shall not be utilized for the storage of food and/or liquids for human consumption and shall be marked accordingly.*

## SECTION K QUALITY ASSURANCE

### K1.000 QUALITY ASSURANCE PROGRAM

#### K1.100 Basic Elements

QA programs shall include, at a minimum, ~~the following elements:~~

- 2) ~~Require that~~ *Process Validation Studies* ~~and~~ *are performed where the results of a process cannot be fully verified by subsequent inspection and test. Each tissue bank shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each tissue bank shall ensure that validated processes are performed by qualified individual(s). For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented. When changes or process deviations occur, the tissue bank shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented;*
- 3) *Equipment Qualification Studies* are performed as necessary;
- 4) *Purchasing controls are established;*
- 5) ~~Require that appropriate~~ *Procedures are established for implementing* corrective *and preventive* action is taken when results or measurements are outside acceptable limits, assessment of the impact of the excursion on the product, and documented response to this assessment; *appropriate. The procedures shall include requirements for:*
  - a) *Analyzing processes, work operations, concessions, quality audit reports, quality records, errors, accidents, complaints, returns , and other sources of quality data to identify existing and potential causes of nonconforming tissue, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;*
  - b) *Investigating the cause of nonconformities relating to tissue, processes, and the quality system;*
  - c) *Identifying the action(s) needed to correct and prevent recurrence of quality problems;*
  - d) *Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the Finished Tissue;*
  - e) *Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;*
  - f) *Ensuring that information related to quality problems is disseminated to those directly responsible for assuring the quality of Finished Tissue or the prevention of such problems; and*
  - g) *Submitting relevant information on identified quality problems, as well as corrective and preventive*

actions, for management review:

- 6) Review and approval of all ~~QA elements~~ in donor screening, Informed Consent or Authorization, Recovery or Collection, and Processing records prior to release of tissue for transplantation;
- 7) Performance of audit procedures;
- 8) ~~Require that~~ Documentation of formal conclusion of all *Accident, Error, Complaint, Adverse Outcome*, and *Recall* incidents ~~are formally concluded and documented~~;
- 9) Maintenance of ~~specific~~ documentation including, but not limited to:
  - a) Master copy of current *SOPMs*;
  - b) For those authorized to perform or review tasks, records of names, signatures, initials or identification codes and inclusive dates of employment shall be maintained (e.g., by Human Resources, Quality Assurance, or by department);
  - c) Reports and conclusions of process *Validation* and *Equipment Qualification Studies*;
  - d) Records of supply and reagent acceptance or rejection;
  - e) Archived documents; and
  - f) Master lists of preprinted labels.

12) Require a A process for sharing information with other *Tissue Banks* that are known to have recovered and/or received tissue from the same donor.

**K1.300 Purchasing Controls**

Each tissue bank shall establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements. Each tissue bank shall establish and maintain the requirements, including quality requirements that must be met by suppliers, contractors, and consultants. Each tissue bank shall:

- 1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
- 2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
- 3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

Each tissue bank shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement in which the suppliers, contractors, and consultants agree to notify the tissue bank of changes in the product or service so that tissue banks may determine whether the changes may affect quality.

## **K2.000 QUALITY CONTROL PROGRAM**

The QA Program shall ~~define~~ *establish and maintain* QC procedures that include the following:

- 1) Environmental monitoring;
- 2) Equipment maintenance and monitoring;
- 3) *Tolerance Limits*;
- 4) *In-Process Controls* monitoring;
- 5) Reagent and supply monitoring; and
- 6) Laboratory performance monitoring.

The QA program shall require that specific testing procedures are included to identify each tissue unit, and that tissue parameters are met, including clear *Tolerance Limits*, if applicable, and corrective actions.

### **K2.200 Microbiological Tissue Cultures**

#### **K2.220 Final/Pre-Packaging**

(S) Representative *fresh or cryopreserved* skin samples shall be cultured for the presence of fast-growing fungal organisms. *Fresh or cryopreserved* skin shall not be used for transplantation if any one of the following is noted at final culture:

- 1) *Staphylococcus aureus*;
- 2) *Streptococcus pyogenes* (group A strep.);
- 3) *Enterococcus* sp.;
- 4) gram-negative bacilli;
- 5) *Clostridium*; and
- 6) fungi (yeasts, molds).

#### **K2.300 Testing for Residues**

(C, V) Representative samples from *processed* tissue *that have been thawed, rinsed and* prepared *as if* for use (using standard protocols) shall *should* be tested to evaluate the concentration of residuals of ~~*Disinfectants and Cryoprotectant(s)*~~ (if applicable), initially and after any change in ~~*Processing*~~ that involves contact of the tissue with these ~~*Processing*~~ components.

## **K3.000 MICROBIOLOGIC TESTING**

All microbiologic cultures of tissue to be released for transplantation shall be performed by a laboratory that is either certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) or is certified or accredited by another laboratory accrediting organization *that has deemed status for CLIA (the College of American Pathologists, The Joint Commission, certain state licensure)*. *If the services of an outside laboratory are used, the procedures used by that laboratory and results of testing by that laboratory shall be reviewed by the Responsible Person at the tissue bank and recorded in the donor's record. The facility must also have a procedure in their SOPM for determining the acceptability of outside testing laboratories.*

If microbiologic testing is to be performed by the tissue bank, the requirements as outlined in *Standards E1.900-E1.920 (In-House Laboratory Testing, Laboratory Records, and Laboratory Controls)* shall apply *and the Tissue Bank must ascribe to proficiency testing programs and/or certification to appropriate ISO Standards*. *If the services of an outside laboratory are used, the procedures used by that laboratory and results of testing by that laboratory shall be reviewed by the Responsible Person at the tissue bank and recorded in the donor's record. The facility must also have a procedure in their SOPM for determining the acceptability of outside testing laboratories.*

### **K3.210 Quality Control of Growth Medium**

Tissue banks or contracted microbiology laboratories shall follow standards developed by the ~~National Committee on Clinical Laboratory Standards~~ *Clinical and Laboratory Standards Institute (CLSI)* specifying the requirements for *Quality Assurance* testing of culture media (QA for Commercially Prepared Microbiological Culture Media, M22-A).

Media that has been purchased commercially does not require in-house QC testing; however, the testing laboratory should receive, along with each new *Lot* of media purchased from the manufacturer, a statement indicating that the medium meets the standards of the ~~National Committee on Clinical Laboratory Standards~~ *CLSI or any equivalent standards*. These manufacturer's statements shall be retained for at least 10 years as QC records for each batch of medium.

## **K4.000 INVESTIGATIONS**

The QA Program shall provide for the ~~completion~~ *conclusion* of the investigation of *Accidents, Errors, Complaints, and Adverse Outcomes*. ~~The QA Program, in conjunction with the Director or Medical Director, shall approve corrective actions prior to implementation.~~ Precipitating events, recommendations, and *Resolutions* shall be documented in a summary report by the staff involved and reviewed for completeness ~~and Resolution~~ by the QA Program. All reports generated shall be retained on file for 10 years.

### **K4.100 Errors and Accidents**

*Errors and Accidents* *obtaining Informed Consent or Authorization*, in donor screening, *Collection* or tissue *Recovery, Processing*, quarantining, releasing, labeling, storing, and *Distribution* or dispensing, shall be investigated and documented. Potential actions include the review and evaluation of *Errors and Accidents* by the Director or designee and implementation of corrective action(s) designed to prevent recurrence. If the *Error or Accident* has medical consequences or may affect the *Safety* of the tissue, the Medical Director or designee shall also review and evaluate the incident. When tissue may have been contaminated, *Processing* procedures shall be reviewed and other tissue processed simultaneously or from the same donor shall be evaluated.

### **K4.200 Complaints**

## Overview and Updates - 13<sup>th</sup> Edition of AATB *Standards for Tissue Banking*

All written and oral *Complaints* regarding tissue quality, *Safety*, packaging, or effectiveness shall be *expeditiously* investigated to determine whether the *Complaint* is related to an *Error*, *Accident*, *Adverse Outcome*, or other factor, *unless such investigation has already been performed for a similar complaint. If it is determined that no investigation is necessary, the tissue bank shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.* Each investigation shall determine whether associated tissue may be affected. If it is determined that they may be affected, those associated tissue shall be located and *Quarantined* until *Resolution* of the incident (which may involve initiation of a *Recall*). *Complaints* that are medical in nature shall be reviewed by the Medical Director or licensed physician designee.

*When an investigation is made, a record of the investigation shall include:*

- 1) The date the complaint was received;*
- 2) The name of the tissue*
- 3) The unique tissue identifier;*
- 4) The name, address, and phone number of the complainant;*
- 5) The nature and details of the complaint;*
- 6) The dates and results of the investigation;*
- 7) Any corrective action taken; and*
- 8) Any reply to the complainant.*

### **K4.300 Adverse Outcomes**

All reported or suspected *Adverse Outcomes* that are potentially related, directly or indirectly, to an *Allograft* shall be investigated thoroughly and expeditiously. The Medical Director or licensed physician designee shall review all potential *Adverse Outcome* reports and be involved in determination of the impact and *Resolution* of any *Adverse Outcome*. If investigation indicates that the *Adverse Outcome* is related to an *Error* or *Accident*, then procedures for *Errors* and *Accidents* (K4.100) shall also be followed.

### **K4.310 Notifications Reporting**

~~In accordance with applicable federal, state, and local regulations, confirmed e~~Cases of transmissible disease in a *Recipient* attributed to tissue transplantation *the Allograft* shall be reported in writing in a timely fashion to public health authorities, organ procurement organizations and *Tissue Banks* involved in any manner with tissue recovered from the same donor and the physician(s) involved in the transplantation of tissue from that donor. ~~Notifications~~ Reporting shall be documented in the donor's record.

### **K5.000 INTERNAL AUDITS**

All tissue banks shall establish policies and procedures regarding the scope and frequency of routine and focused QA Audits. *The Self-assessment Tool/Audit Report (STAR) must be completed annually and documented on a form provided by, or pre-approved by, the AATB Director of Accreditation (refer to the AATB Accreditation Policies).* The QA Program staff shall perform audits, at least annually, of the major tissue banking operational systems to identify trends or recurring problems in: donor evaluation and acceptance; tissue, *Recovery* or *Collection*, *Processing*, *Preservation* and packaging; donor and tissue testing; quarantining; labeling; storage; *Distribution*; ~~computer operations~~ *electronic systems*; and records management. Focused audits shall be conducted to monitor *Critical Areas* (unless the annual routine audit covers all *Critical Areas*); they shall also be conducted when problems with quality have been identified. If

the routine or focused audit is not conducted by the QA Program staff, the audit shall be performed by persons who do not have direct responsibility for the process being audited. Corrective action(s), including a re-audit of deficiencies, shall be taken when necessary. A report of the results of each quality audit, and re-audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the systems audited. The dates and results of quality audits and re-audits shall be documented.

## **K6.000 ~~COMPUTER/DATA PROCESSING~~ ELECTRONIC SYSTEMS CONTROLS**

### **K6.100 Authorized Access**

Appropriate controls shall be exercised over ~~computer~~ Electronic s~~Systems~~ to assure that general access is limited to authorized personnel and that changes in master production and control records or other records are instituted only by authorized personnel.

### **K6.300 Backup Files**

A backup file should be maintained of all data that are entered into a ~~computer~~ an electronic system and subsequently used for decision-making purposes, and of all data that are not otherwise recorded and accessible.

### **K6.400 Security**

~~Backup systems (e.g., duplicates, tapes, microfilm) designed to assure that backup data are exact and complete shall be implemented and maintained in a secure manner to prevent alteration, inadvertent erasures, and loss.~~ Electronic systems shall be designed to assure data integrity and maintained in a secure manner to prevent alteration or loss.

## **SECTION L TISSUE DISPENSING SERVICES**

### **L1.000 TISSUE DISPENSING SERVICES—GENERAL**

#### **L1.100 ~~Director~~ Responsibilities**

Activities of a *Tissue Dispensing Service* shall be supervised by a physician, dentist, podiatrist, or other qualified medical professional.

### **L3.000 RELEASE**

#### **L3.300 Tissue Disposal**

Tissue that is unused, partially used, or expired, damaged or otherwise unsuitable for *Distribution* shall be disposed of in such a manner as to minimize any hazards to staff or the environment, in conformance with applicable laws and regulations. The *Tissue Dispensing Service* shall notify the tissue bank, or the *Tissue Distribution Intermediary* from whom the tissue was obtained, of the final *Disposition* of the tissue. Documentation of such notification shall be recorded.

- (A) 1) There shall be a written policy for the discard of autologous tissue;
- 2) The ~~director~~ Tissue Dispensing Service, in consultation with the patient-donor's physician, shall approve discard of the tissue, and shall be responsible for documentation of the method

and date of discard;

- 3) Autologous tissue should not be used for transplantation after the expiration date, and should not be retained beyond the expiration date, unless relabeled for research or QC purposes or otherwise indicated by the tissue bank Medical Director;
- (R) For reproductive tissue, tissue discard and disposal shall be authorized by the Reproductive Tissue Bank director, the tissue donor, and/or their designees.

### **L3.400 Return of Tissue**

- (R) *Cryopreserved* donor reproductive tissue that has been released to a physician or designee and subsequently not used and returned to the *Reproductive Tissue Bank* in the frozen state shall not be redistributed for use by any other physician or designee, ~~except as required by applicable local or state regulations.~~

## **Appendix II: CRITERIA FOR PREVENTING TRANSMISSION of RCDADs (Relevant Communicable Disease Agents and Diseases)<sup>1</sup> THROUGH TRANSPLANTATION OF HUMAN TISSUE**

### **Behavior/History Exclusionary Criteria**

- 7) Children born to mothers known to be ~~HIV~~-infected with, or at risk for, HIV, HBV or HCV infection, who are 18 months of age or less and/or have been breastfed ~~in~~ within the preceding 12 months, regardless of the child's (donor's) HIV, HBV or HCV status;  
  
NOTE: Children over 18 months of age born to mothers infected with, ~~HIV~~ or at risk for, HIV, HBV or HCV infection, who have not been breastfed within the preceding 12 months; and whose ~~HIV antibody~~ infectious disease testing, Physical Examination/Physical Assessment, and review of medical records do not indicate evidence of HIV, HBV or HCV infection, may be accepted as donors.
- 8) Persons who have been in a juvenile detention correctional facility, lockup, jail or prison for more than 72 consecutive hours in the preceding 12 months;

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