American Association of Tissue Banks

STANDARDS FOR TISSUE BANKING

by American Association of Tissue Banks

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PREFACE

The American Association of Tissue Banks (AATB) was founded in 1976 as a voluntary, scientific, and educational not-for-profit organization to promote the exchange of information, methods, and procedures that would increase donation and provide safe, transplantable tissues of uniform high quality in quantities sufficient to meet national needs. A year later, a book of Proceedings [1] from the first annual meeting was published that offered a detailed overview of current tissue banking practices and described the ethics of donation and transplantation.

Between 1978 and 1981, provisional ‘Guidelines’ for proposed standards were drafted, discussed, adopted and published. They encompassed specific cells, tissues, and organs divided into the following categories: renal, ocular, cell and tumor tissues, bone marrow, musculoskeletal, semen and skin.

The first edition of AATB’s Standards for Tissue Banking was published in 1984, combining similar, general operational standards from all of these categories. This collection marked the first professional standards ever developed in the field of banking transplantable human tissues, other than ocular. An excerpt from the Scope and Purpose of this inaugural edition reads:

"These general Standards are intended to be applicable to any and all forms of tissue banking: retrieval, storage, and distribution of human tissues for medical use. They represent the current thinking of a diversified group of experienced practitioners of tissue banking who have pooled their efforts to extract general principles and philosophies of banking operations common to all and to highlight specific considerations which pertain to certain categories of tissues."

A voluntary accreditation program for tissue banks was launched in 1986 with inspection and accreditation based upon adherence to these Standards. This first publication of Standards was followed by the publication of a Procedures Manual (1986) aimed at assisting musculoskeletal, skin, and ocular tissue banks to standardize methods being used.

The following year was notable for another AATB publication titled, Technical Manual for Tissue Banking. It contained individual tissue-specific manuals for the banking of musculoskeletal, skin, reproductive, and (living donor) surgical bone. These manuals described step-by-step procedures to facilitate successful tissue banking operations for each tissue type. They were created by their respective councils, which had been formed within the Association.

The Technical Manual was updated with a final publication in 1992. It contained a new section for cardiovascular tissues as well as introducing the ‘Protocol for Reporting an Event with the Potential for Disease Transmission.’ In time, much of the contents of these manuals were incorporated into a subsequent edition of the Standards, since tissue bank accreditation inspections included assessment of compliance with these technical manuals as well as Standards.

In the 1993 sixth edition, a section first appeared in Standards titled, ‘Medical Facility Tissue Storage and Issuance.’ This section was directed at medical facilities to offer structural and functional guidelines for the handling of human tissue allografts and autografts. It required the establishment of
procedures and maintenance of records for tissue storage and disposition to ensure safety and traceability of tissue from receipt through clinical transfer or destruction. Other requirements included: supervision by a licensed physician (or dentist for a dental facility); monitoring of freezers and refrigerators used to store tissue; maintenance of records that included documentation of condition of tissue upon receipt; and steps involved with storage, issuance, return, disposal, recall and handling of adverse outcome reports. These standards were sent to the College of American Pathologists (CAP) as well as The Joint Commission on Accreditation of Hospitals resulting in inclusion of similar tissue handling requirements in their standards and checklists in 1993 and 1996 respectively.

By the seventh edition (1996), the AATB Standards had grown from 21 pages to a book of 108 pages. It included new sections, such as: Records Management; Release and Transfer of Tissues; General Operations (i.e., procedure manual, staff training/competency, safety practices, and facilities/equipment requirements); and, Quality Assurance and Quality Control. The application of a quality systems approach to all tissue banking operations, and the establishment and maintenance of a quality program became required in Standards. Additions to the Standards resembled concepts related to good manufacturing practices (GMPs), which had been adopted by a handful of AATB-accredited tissue banks that were processors of cryopreserved allograft heart valves. At that time, this group of cardiovascular tissue processors was mired in an investigational device exemption (IDE) application with the Food & Drug Administration (FDA). This resulted from FDA’s unforeseen and surprising designation of these tissue banks as a “manufacturer of a replacement heart valve” [3], or better known as a Class III medical device manufacturer, the strictest device classification.

The 10th edition was published in 2002 and was the first edition to be numbered. The 11th edition in 2006 was the first to provide the Standards on a CD-ROM and the style of the publication changed dramatically. The cover was modernized, and the publication size expanded from a 6” x 9” booklet to an 8.5” x 11” notebook with a durable, coiled spine, which allowed the book to lie flat when opened. Three-hole punches along the spine provided an option to maintain the book in a binder and the capability to insert printable updates when issued to the Standards. Frequent revisions became commonplace during modern times and the format changes increased user satisfaction, so this publication style remains.

Similar to the 12th edition (2008), the 13th edition of Standards included a number of guidance documents developed by the Association’s constituency to fill gaps and complement specific standards. For ease of reference regarding expected compliance, the current version of the AATB’s Accreditation Policies for Transplant Tissue Banks was also included.

The 14th edition (2016) of Standards includes three new appendices. To clarify expectations for compliance, three documents previously referred to as “AATB Guidance Documents” each became incorporated as a separate appendix to the Standards. Where their title previously included reference as a “Guidance Document,” the title was changed to reflect they are “Requirements”. Therefore, the following appendices are unambiguous, and compliance is mandatory:

- Appendix III Tissue Donor Physical Assessment Form Requirements (formerly AATB Guidance Document No. 1, v2 Tissue Donor Physical Assessment Form, 6-27-05)

The 14th edition is the first to be published online but the printed book continues to also be available for
purchase. Notice of updates to the 14th edition was provided via publication of two documents; one shows additions and deletions made throughout [4], and another provides a descriptive overview [5].

From the inception of the AATB in 1976 to the present, the passionate dedication of numerous, knowledgeable tissue banking professionals has led to improvements to a variety of published guidelines, manuals, and standards. Their willingness to share experiences and best practices, to educate each other, and their ability to be forward-thinking regarding application of a quality culture to tissue banking operations, has led the way to maintaining a template (the Standards) that continues to be referenced not only by tissue banks, but also by end-user healthcare facilities, other standards-setting associations, and regulators worldwide. Global cooperation and the sharing of information among tissue banking professionals continues today, the same spirit that led to the formation of the AATB and the development of these Standards.

References:
INTRODUCTION

Progress in medical science and cell biology has resulted in the transplantation of human cells and tissue from one human into another, enhancing the quality of life by restoring form and function and facilitating reproduction. For more than 60 years, society has recognized the medical and humanitarian value of donating and transplanting organs and tissues. The universal significance of this is made apparent by the enactment of legislation based on the Uniform Anatomical Gift Act. The American Association of Tissue Banks (AATB), through its constituency, is committed to providing stewardship for gifts of donated human tissue and promoting the public trust in donation and transplantation.

A mission of the AATB is to establish and promulgate standards to provide tissue banks with performance requirements intended to prevent disease transmission and support quality measures that assist clinical performance of transplanted tissue. Furthermore, the AATB fosters education and research, and promotes quality and safety in cell and tissue banking and transplantation.

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 the Association’s Councils (Accredited Tissue Bank, Physicians’, Processing and Distribution, Quality, Recovery and Donor Suitability, and Reproductive) and appropriate standing committees and/or ad hoc task forces, as needed. All revisions are subject to approval by the AATB Board of Governors.

In the Standards, terms and related words with a similar meaning that are defined in A2.000 Definitions of Terms appear in italics [e.g., verification (verify, verified)]. If a word defined in standard A2.000 is used without italics, then the intent is to apply the common meaning of the word and not the strict definition of A2.000.* Additionally, the Standards contain appendices that must be followed.

*Announced 1/31/2020; Effective 7/31/2020

These Standards establish performance requirements for informed consent or authorization, donor eligibility assessment through donor screening and testing, as well as for the recovery, processing, storage, packaging, labeling, and distribution of transplantable human tissue. The Standards are intended to be applied to tissue bank functions that relate to quality, staff, donors, and tissue, but do not encompass the clinical use of tissue. In addition, unless otherwise stated, these Standards apply only to tissue intended for clinical use or transplantation to recipients (including use in assisted reproductive technology procedures).

Accreditation by the AATB is based on verified compliance with these Standards and the Accreditation Policies for Transplant Tissue Banks and is strongly encouraged. Use of the words “shall” or “must” in Standards indicate mandatory compliance, whereas use of the words “should” and “may” indicate recommended compliance. If an accredited tissue bank, or one seeking accreditation, does not comply with any mandatory standard, a written rationale that sufficiently demonstrates equivalency is required. Details regarding the process to request a variance from Standards are specified in Appendix I.

The format of this edition of Standards is that of general requirements applicable to all tissue with subsections delineating donor and tissue standards for:

(A) autologous tissue,

(BT) birth tissue,
(C) cardiac tissue,

(CT) cellular tissue,

(DM) dura mater,

(LD) living donors,

(MS) musculoskeletal tissue,

(OA) osteoarticular graft,

(R) reproductive tissue,

(S) skin,

(SB) living donor surgical bone for allogeneic use, and

(V) vascular tissue.

- For all living donors, (LD) standards apply, then tissue-specific standards apply.
- For tissue that falls into one or more of these categories, both the general and tissue-specific standards apply.
- When a particular numbered item appears in both the general section and tissue-specific subsection, both requirements shall apply unless noted otherwise.
- The tissue-specific standard is not a replacement for the general standard for that item, except as noted.
- For tissue not included in these categories (e.g., parathyroid tissue), the general standards shall apply.
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Appendix I:  REQUEST FOR VARIANCE FROM STANDARDS

Appendix II:  CRITERIA FOR PREVENTING TRANSMISSION OF RCDADs (Relevant Communicable Disease Agents and Diseases) THROUGH TRANSPLANTATION OF HUMAN TISSUE (Last amended on April 9, 2018)
Appendix III: TISSUE DONOR PHYSICAL ASSESSMENT FORM REQUIREMENTS

Appendix IV: PREVENTION OF CONTAMINATION AND CROSS-CONTAMINATION AT RECOVERY: PRACTICES & CULTURE RESULTS REQUIREMENTS

Reference I: AATB ACCREDITATION POLICIES FOR TRANSPLANT TISSUE BANKS

Reference II: AATB GUIDANCE DOCUMENTS

Guidance Document No. 3, Current Good Tissue Practice (June 27, 2006)

Guidance Document No. 4, v2 Providing Service to Tissue Donor Families (March 9, 2015)

Guidance Document No. 5, v2 Microbiological Process Validation & Surveillance Program (July 18, 2016)

Guidance Document No. 7, v2 Evaluation of Body Cooling at Standard D5400 (December 9, 2013)

Guidance Document No. 8, Environmental Controls & Monitoring of a Dedicated Tissue Recovery Site, (date forthcoming)

Guidance Document No.9, Qualification of Packaging and Validation of Shipping/Transport Procedures (announced 10-23-17)

Guidance Document No.10, Training and Competency (announced 12-19-17)

AATB-AOPO-EBAA Guidance Document, Effective Quality Assurance of the DRAI, v2 (September 16, 2013)

SECTION A
GENERAL INFORMATION

A1.000 ACCREDITATION

AATB accredited tissue banks must comply with these Standards, the Accreditation Policies for Transplant Tissue Banks, as well as all applicable laws and regulations.

A1.100 Failure to Comply with Standards

Failure of an accredited tissue bank to comply with Standards and/or the Accreditation Policies for Transplant Tissue Banks shall be reviewed in accordance with the Accreditation Policies for Transplant Tissue Banks. Accreditation may be denied, suspended, or withdrawn upon a determination that significant noncompliance, such as repeated violations, one or more egregious violations, uncorrected violations, or deliberate falsehoods, have occurred.

A1.200 Requesting a Variance to Standards

Tissue banks wishing to implement a variance from current Standards must provide the following information to the AATB Senior Vice President of Policy by using the Request for Variance to AATB Standards Submission Format. The format must be completed in entirety and include:

1) A request for variance or modification including the particular standard number(s) that applies to the request;

2) Justification of the alternative procedure(s), policy or process that assure(s) equivalency to the intent of Standards; and

3) Supporting information such as worksheets, records, data, or other information (e.g., validation of the protocol to be used in the proposed variance, including the scientific data and quality assurance steps).

Until the Board of Governors approves the Variance request, the tissue bank must comply with existing Standards. See Appendix I. A record of the approved variance must be maintained at the requesting tissue bank as well as at any other accredited tissue bank directly affected by the approval. Evidence of approval of the request for variance must be available during an accreditation inspection.

A2.000 DEFINITIONS OF TERMS

Words that are defined here also appear in italics throughout the Standards. Related words with a similar meaning in the form of a noun, verb, or adjective, or in the plural form or as past tense, as applicable, may also be italicized, but are not defined separately. Examples include “recovery/recover/recovered,” “establish/established/establishment (of),” “verification/verify/verified,” “validation/validate/validated” and “distribution/distribute/distributed.” If a word defined in standard A2.000 is used without italics in these Standards, then common usage is intended and the definition in A2.000 does not apply. *

Unless otherwise defined in the tissue-specific standards or otherwise used in another context in these Standards *, the following terms shall be defined as follows:

*Changes announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020

ACCIDENT – Any occurrence, not associated with a deviation from standard operating procedures (SOPs), standards, or applicable laws and regulations, during donor screening or testing, or tissue
recovery, collection or acquisition, processing, quarantining, labeling, storage, distribution, or dispensing that may affect the performance, biocompatibility, or freedom from transmissible pathogens of the tissue or the ability to trace tissue to the donor.

**ACQUISITION (BT)** – The point after delivery at which tissue is under the control of the tissue bank.

**ADEQUATE INFORMATION** – Information sufficient for the donor, the authorizing person or the living donor to make a voluntary decision regarding the gift of tissues for transplantation, therapy, research and/or education. The parameters of what constitutes adequate information must include “Core Elements” contained in D2.400 or D3.400, and such additional information as the donor, authorizing person, or living donor requests or which the donation coordinator reasonably believes the donor, authorizing person or living donor should know. When the donor is authorizing the gift of tissue, publicly available information concerning the scope and use of the gift shall be deemed adequate information.

**ADVERSE OUTCOME** – An undesirable effect or untoward complication in a recipient consequent to or reasonably related to tissue transplantation.

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

**ALLOGRAFT** – Tissue intended for transplantation into a genetically different person.

**ANNUAL** - A frequency of activity defined by each tissue bank as 12 months including reasonable tolerance limits (up to 3 months). Justification for the tolerance limits shall be documented by the tissue bank with consideration for the risk associated with the specific activity scheduled.

**ANONYMOUS DONOR (R)** – A reproductive donor of tissue whose identity is unknown to the recipient (R).

**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.

**ARTIFICIAL INSEMINATION (R)** – The placement of semen within the reproductive tract of a recipient (R).

**ASEPTIC PROCESSING** – The processing of tissue using aseptic techniques where tissue, containers and/or devices are handled in a controlled environment in which the air supply, materials, equipment and personnel are regulated to prevent microbial contamination of tissue.

**ASEPTIC RECOVERY** – The recovery of tissue using methods that restrict or minimize contamination with microorganisms from the donor, environment, recovery personnel, and/or equipment.

**ASSISTED REPRODUCTIVE TECHNOLOGY PROCEDURE (R)** – A medical procedure intended to result in conception, including, but not limited to, therapeutic insemination, in-vitro fertilization (including intracytoplasmic sperm injection), and gamete intrafallopian transfer.

**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 suppliers to evaluate adherence to the written SOPM, standards, applicable laws and regulations.

AUDIT TRAIL - A process that captures details such as additions, deletions, or alterations of information in an electronic record without obliterating the original record. An audit trail facilitates the reconstruction of the course of such details relating to the electronic record. (FDA Guidance for Industry, Computerized Systems Used in Clinical Investigations, May 2007)

AUTHORIZATION – Permission given after adequate information concerning the donation, recovery and use of tissues is conveyed.

AUTHORIZING PERSON – Upon the death of the donor, the person, other than the donor, authorized by law to make an anatomical gift.

AUTOGRAFT (A) – Tissue intended for implantation, transplantation or infusion into the living donor from whom it was recovered.

AUTOLOGOUS – Used as an adjective to modify donation, tissue, donor or recipient when donation is intended only from him/herself and transplantation is intended only to him/herself.

BATCH – A specific quantity of tissue produced according to a single processing protocol during the same processing cycle.

BIOBURDEN – The number of contaminating organisms found on a given amount of material.

BIRTH TISSUE (BT) – gestational tissue donated at the time of delivery of a living newborn. This includes placenta, Wharton’s jelly, amniotic fluid, chorionic membrane, amniotic membrane, placental/chorionic disc, umbilical veins, and umbilical cord tissue.

BLOOD COMPONENT – Any part of a single-donor unit of blood separated by physical or mechanical means.

CARDIAC TISSUE (C) – Tissue type that includes, but is not limited to, valved conduits, non-valved conduits, aortoiliac grafts, and patch grafts.

CELLULAR TISSUE (CT) – viable cells that are autologous or allogeneic, committed or uncommitted, and non-expanded.

CERTIFIED COPY – Relating to a death certificate, an original, authenticated form produced by a governing authority.

CLAIM – Any written or oral communication alleging the quality, durability, reliability, infectious disease risk, or performance of tissue.

CLIENT DEPOSITOR (R) – A person who consents to collection and/or storage of reproductive tissues for artificial insemination or assisted reproductive technology procedures for themself(ves) or a sexually intimate partner; not considered a reproductive tissue donor.
COLD ISCHEMIC TIME (C) – The time interval from subjecting cardiac tissue to cold rinse (or transport) solution at recovery to the beginning of disinfection.

COLD ISCHEMIC TIME (V) – The time interval from subjecting vascular tissue to transport solution and wet ice temperatures at recovery to the beginning of disinfection.

COLLECTION (R) – The acquisition of reproductive tissue from a donor or client depositor by surgical or non-surgical procedures.

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

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

COMPETENCY – The ability of an employee to acceptably perform tasks for which he/she has been trained.

COMPETENCY ASSESSMENT – The evaluation of the ability of an employee to acceptably perform tasks for which he/she has been trained.

CONSIGNEE – Any tissue bank, tissue distribution intermediary, tissue dispensing service, or end-user (whether individual, agency, institution, or organization) that receives finished tissue.

CONTAINER – An enclosure for one finished unit of transplantable tissue.

CONTRACT SERVICES – Those functions pertaining to the recovery, screening, testing, processing, storage, and/or distribution of human tissue that another establishment agrees to perform.

CONTROLLED AREAS – Restricted work areas of low microbial and particulate content in which non-sterile materials are prepared.

CORRECTION – Related to conformity, remedial action to eliminate a detected nonconformity.

CORRECTIVE ACTION – Action to eliminate the cause and prevent recurrence of a nonconformity or other undesirable situation; may be performed in conjunction with preventive action(s).

CRITICAL – Classification of a supply, reagent, material, instrument or equipment that can affect the quality and/or safety of tissue.

CRITICAL AREAS – Restricted work areas where cells, tissue, containers and/or closures are exposed to the environment.

CROSS-CONTAMINATION – The transfer of infectious agents from one tissue to another from either the same donor or a different donor.

CRYOPRESERVED – Frozen with the addition of, or in a solution containing, a cryoprotectant agent such as glycerol or dimethylsulfoxide.

CRYOPROTECTANT – An additive that serves to minimize osmotic imbalances that occur with the progression of freezing fronts through a substance, and is intended to limit the amount of cell damage.
caused by cell shrinkage and intracellular ice formation.

**CRYSTALLOID** – A balanced salt and/or glucose solution used for electrolyte replacement or to increase intravascular volume, such as saline solution, Ringer’s lactate solution, or 5 percent dextrose in water, or total parenteral nutrition (TPN).

**DECONTAMINATION** - Cleaning the environment, facilities, and/or surfaces (sanitation), or instruments, supplies, and equipment (sanitization), with intent to remove or reduce pathogenic microbes.

**DEHYDRATION** – The removal of water from tissue. For example, dehydration methods may include chemical (alcohol), critical/supercritical drying, simple air drying, or drying in a dehydrator.

**DESICCATION** – The removal of water from tissue. For example, desiccation methods may include chemical (alcohol), critical/supercritical drying, simple air drying, or drying in a desiccator.

**DEVIAITION** – An event that is a departure from a procedure or normal practice.

**DIRECTED DONOR (R)** – A reproductive tissue donor who is known to the recipient (R) but is not the recipient’s (R) sexually intimate partner.

**DISINFECTANT** – An agent (e.g., heat or a chemical) capable of reducing the number of viable microorganisms. A disinfectant might not kill spores. Use of antimicrobials in tissue processing is included here.

**DISINFECTION** – A process that reduces the number of viable microorganisms on tissue, but may not destroy all microbial forms, such as spores and viruses. Use of antimicrobials in tissue processing is included here.

**DISINFECTION TIME (C, V)** – The time interval between subjecting tissue to disinfection solution and transferring tissue to rinsing solutions in preparation for preservation.

**DISPENSING SERVICE** – A facility responsible for the receipt, maintenance and delivery to the ultimate user (e.g., transplanting surgeon, surgical center or research facility) of tissue for transplantation or research.

**DISPOSITION** – The final destination of tissue, e.g., use for transplantation, therapy research, education, or discard; also, the final destination of critical supplies, reagents, materials or equipment that can affect the quality and/or safety of tissue, e.g., release for use or discard.

**DISTRIBUTION** – A process that includes receipt of a request for tissue, selection of appropriate finished tissue, preparation for transport, any required inspections, and subsequent shipment and delivery of tissue to another tissue bank, tissue distribution intermediary, tissue dispensing service, or end-user.

**DOCUMENT OF AUTHORIZATION** – Legal record of the gift of tissue, permitting and defining the scope of the postmortem recovery and use of tissues for transplantation, therapy, research and/or education signed or otherwise recorded by the authorizing person, pursuant to law.

**DOCUMENT OF GIFT** – The donor’s legal record of the gift of tissue permitting and defining the scope of the postmortem recovery and use of tissues for transplantation, therapy, research and/or education. It must be signed or otherwise recorded by the donor or person authorized under law to make a gift during the donor’s lifetime.
DOCUMENT OF GIFT/AUTHORIZATION – Term used when the standard refers to both a document of gift and a document of authorization as defined above.

DONATED HUMAN TISSUE – For the purposes of labeling, this is tissue provided for storage or transplantation, either allogeneic or autologous.

DONATION COORDINATOR – A responsible person who seeks authorization from an authorizing person, or who makes notification concerning donation, recovery, and use of the gift, or in the case of a living donor a responsible person who seeks informed consent from a living donor, a birth mother, or a client depositor. For authorization purposes, this person may also be referred to as a “designated requestor.”

DONOR – A living or deceased individual whose body is the source of the tissue.

DONOR ELIGIBILITY ASSESSMENT – The evaluation of all available information about a potential donor to determine whether the donor meets qualifications specified in the SOPM and Standards. See relevant medical records.

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

DONOR REFERRAL SOURCES – Entities such as hospitals, medical examiners, coroners and individual allied health care professionals who identify potential tissue donors and refer them, or their next of kin, to tissue banks.

DONOR REGISTRY – A database established in accordance with law, consisting of legally valid documents of gift.

DOSIMETRIC RELEASE – Tissue release based on dosimetry instead of sterility testing.

DURA MATER (DM) – A type of soft tissue that includes the pachymeninx (thick, membranous) tissue covering the brain.

DYNAMIC – Operational condition during aseptic processing where the controlled environment is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon [ISO 14644-1].

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

ELECTRONIC QUALITY MANAGEMENT SYSTEMS – Software used in the automation or monitoring of an organization’s quality system that may apply, but is not restricted, to the following: product design and development; supply and/or component acceptance; testing; manufacturing; labeling; packaging; distribution; handling of a complaint, CAPA, error, nonconformity; or any other aspect of the Quality Management Systems.

EMBRYO (R) – Pre-implantation, reproductive tissue resulting from the combination of oocyte and
sperm.

**EMBRYO BANK** – A facility that performs cryopreservation or *storage* of embryos intended for use in creating pregnancy.

**EMBRYO CLIENT DEPOSITOR (R)** – A woman and/or man who provides *gametes* or contracts with a *gamete donor(s)* responsible for creation of an *embryo(s)* intended for *transfer* (R).

**EMBRYO DONOR (R)** – *Embryo client depositor(s)* who choose(s) to donate his/her (their) *embryos*. Ownership of the *embryos* is transferred to a new *client depositor(s)* who was (were) not *gamete* providers.

**END-USER** – A health care practitioner who performs *transplantation procedures*.

**ENVIRONMENTAL CONTROL** – Activities performed to control the environment for the purpose of minimizing the potential for contamination or *cross-contamination* of *tissue*.

**ENVIRONMENTAL MONITORING** – Activities performed to systematically observe and *record* data to characterize the environment to identify conditions under which the potential *may* exist for contamination or *cross-contamination* of *tissue*.

**EQUIPMENT QUALIFICATION STUDIES** – Protocols designed to adequately evaluate, prior to use, whether pieces of equipment will perform to expectations, and normally function within the required *tolerance limits*.

**ERROR** – A *deviation* from the *SOPM, Standards*, or applicable laws or regulations.

**ESTABLISH** – Define, document and implement.

**FIELD CORRECTION** – For *distributed tissue*, the repair, modification, adjustment, *relabeling*, destruction, or inspection (including patient monitoring) without its physical removal to some other location. Reference 21 CFR Part 7, 7.3(h).

**FIELD NOTIFICATION** – The provision of additional information pertaining to the *safety, quality*, identification, function and/or use of *distributed tissue*.

**FINISHED TISSUE** – *Tissue* that has been fully *processed*, enclosed in its final *container, labeled*, and released to *distribution* inventory.

**GAMETE (R)** – Mature human germ cell, whether an oocyte or sperm.

**IMAGE(s)** – A representation of the external form of an object, place or person in a photographic, digital, or videographic format. *(Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)*

**INFORMED CONSENT** – Permission given by a *living donor* (LD) or *client depositor* who is presented with a description of the scope, use and any risks or benefits to her or him of the proposed donation, and who has been given the opportunity to ask questions and receive accurate answers. An LD who gives her or his *informed consent* to donation *shall sign* a record of the *informed consent*.

**IN-PROCESS CONTROLS** – Any tests, samples, evaluations, monitoring, or measurements performed during *processing or preservation* that are designed to ensure conformance to specifications in the *SOPM*. 
IN-PROCESS MATERIAL – Any material that is used in the processing of tissue, including, but not limited to, incoming tissue, water, alcohol, acid, containers, and closures.

LABEL – Any written, printed, or graphic material used to identify tissue, cultures, blood specimens or other donor specimens.

LABELING MATERIAL – Any printed or written material, including labels, advertising, and/or accompanying information (e.g., package insert, brochures, and pamphlets), related to the tissue.

LIVING DONOR (LD) – A person who consents to the recovery or collection of his or her tissue, where recovery or collection is to take place while she or he is alive. For all living donors, (LD) standards apply, then tissue-specific standards apply. A living donor is a type of donor and, unless otherwise specified, standards that apply to donors in general apply to living donors.

LOT – Tissue produced from one donor at one time using one set of instruments and supplies. Also refers to a quantity of reagents, supplies, or containers that is processed or manufactured at one time and identified by a unique identification number.

LYOPHILIZED – Tissue dehydrated for storage by conversion of the water content of frozen tissue to a gaseous state under vacuum that extracts moisture.

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.

MARKET WITHDRAWAL – A field correction or removal of distributed tissue that involves a minor violation that would not be subject to legal action by the FDA or that involves no violation (e.g., normal stock rotation practices). Reference 21 CFR Part 7, 7.3(j).

MAY – Used to indicate an acceptable method that is recognized but not essential.

MICROORGANISM – A microscopic organism including bacteria and fungi; viruses, while sometimes included in this classification, are not included here.

MUSCULOSKELETAL TISSUE (MS) – Tissue type that includes, but is not limited to, bone and cartilage, and soft tissue such as tendon, ligament, nerve, fascia, pericardium, peritoneal membrane, adipose, and dura mater.

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

NONCONFORMITY – A finding that identifies non-fulfillment of an accreditation requirement, a standard, policy, process, procedure, or specification.

NON-TERMINAL IRRADIATION – Ionizing radiation used to reduce microbes prior to processing.

NON-VALVED CONDUIT (C) – A length of cardiac outflow tract (aortic or pulmonic) from which the valve structure has been removed or intentionally rendered completely non-functional.

NOTIFICATION (OF GIFT) – Provision and documentation of notice concerning an anatomical gift that was made by the donor during the donor’s lifetime.

OOCYTE DONOR (R) – A person who donates oocytes for use in assisted reproductive technology procedures. An oocyte donor can be further categorized as a directed donor or an anonymous donor but
is not a client depositor.

**OSTEOARTICULAR GRAFT** – A weight bearing *allo*graft with intact articular surfaces, consisting of a joint with associated soft *tissue* and bone.

**PACKAGE** – A *labeled* box, carton, receptacle, or wrapper containing *tissue* and may contain one or more *containers* and accompanying *labeling materials*.

**PACKAGE INSERT** – The written material accompanying an *allo*graft or *auto*graft bearing further information about the *tissue*, directions for use, and any applicable warnings.

**PACKAGING SYSTEM** - The combination of primary package, secondary package, and additional protective packaging, as deemed necessary. *(Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)*

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

**PERFUSION SOLUTION** (V) – A room temperature, sterile isotonic solution such as tissue culture media or PlasmaLyte® utilized to gently perfuse veins at *recovery*. This solution *may* also contain an antithrombotic agent (i.e., sodium heparin).

**PERFUSION TIME** (V) – The time interval from *asystole* to subjecting the *vascular tissue* to *perfusion solution*.

**PHYSICAL ASSESSMENT** – A recent ante-mortem or postmortem documented evaluation of a deceased *donor*’s body that can identify evidence of: high-risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, trauma to the potential *recovery sites*.

**PHYSICAL EXAMINATION** – A recent documented evaluation of a *living donor*’s body to determine whether there is evidence of high risk behavior and that determines overall general health of the *donor*. After a *donor risk assessment interview* is completed and if any history is suspect, the physical examination *should* also encompass a directed examination (of a body part or region).

**PLASMA DILUTION** – A decrease in the concentration of the *donor*’s plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids, e.g., *colloid(s)* and/or *crystalloid(s)*.


**POOLING** – The physical contact or mixing of *tissue* from two or more *donors* in a single receptacle.

**PRE-STERILIZATION/PRE-DISINFECTION CULTURE** - A culture of *tissue* obtained prior to exposure to antibiotics, *disinfecting* chemicals, or *sterilizing* agents.

**PRESERVATION** – The use of chemical agents, alterations in environmental conditions or other means during *processing* to prevent or retard biological or physical deterioration of *tissue*.

**PREVENTIVE ACTION** – Action to eliminate the cause of a potential *nonconformity* or other undesirable situation; *may* be performed in conjunction with *corrective action(s)*.

**PRIMARY PACKAGE** - Layer of packaging in direct contact with tissue. *(Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)*
PROCEDURE – A series of steps, which when followed, is designed to result in a specific outcome.

PROCESS CONTROLS – A system of checks and balances incorporated into standard operating procedures involving critical operations to prevent errors.

PROCESS VALIDATION – Establishing by objective evidence that a process consistently produces a result meeting predetermined specifications.

PROCESSING – Any activity performed on tissue other than donor screening, donor testing, tissue recovery, collection, or acquisition functions, storage, distribution or dispensing. It includes but is not limited to disinfecting, sterilizing, packaging, labeling, and testing tissue.

PROFICIENCY TESTING – The evaluation of an individual laboratory’s performance against pre-established criteria by means of inter-laboratory comparisons. (Adapted from ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing)

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

QUALITY – Conformance to pre-established specifications, attributes, requirements, regulations, and/or standards.

QUALITY AGREEMENT – an agreement that establishes the quality specifications or standards that must be met for defined activities and delineates responsibilities of each entity involved. It may be a separate document or included as part of a written agreement/contract.

QUALITY ASSURANCE (QA) PROGRAM – The policies and environment required to meet standards of quality and safety, and to provide confidence that the processes and tissue consistently conform to quality requirements.

QUALITY CONTROL (QC) – Specific tests defined by the QA program to be performed to monitor recovery, processing, preservation and storage, tissue quality, and test accuracy. These may include but are not limited to, performance evaluations, inspection, testing, and controls used to determine the accuracy and reliability of the tissue bank’s equipment and operational procedures, as well as the monitoring of supplies, reagents, equipment, and facilities.

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.

QUARANTINE – The identification of tissue, reagents, supplies, materials and equipment as not suitable for use, or that has not yet been characterized as being suitable for use.

RECALL – A field correction or removal of distributed tissue initiated to reduce a risk to health posed by the tissue or to remedy a violation of regulatory requirements that may present a risk to health.

RECIPIENT – A person into whom tissue is transplanted.

RECIPIENT (R) – A woman undergoing an assisted reproductive technology procedure. A recipient (R) can be an intended parent, a gestational carrier, or a gestational surrogate.
RECORD - Information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.

RECOVERY – Obtaining tissue other than reproductive tissue from a donor that is intended for use in human transplantation, therapy, research or education.

RECOVERY SITE – The immediate area or room where a tissue recovery takes place (e.g., dedicated tissue recovery site, healthcare facility operating room, autopsy suite).

RELEVANT MEDICAL RECORDS – A collection of documents including a current donor risk assessment interview, a physical assessment/physical examination, laboratory test results (in addition to results of testing for required relevant communicable disease agents), relevant donor records, existing coroner and autopsy reports, a certified copy or verified copy of the death certificate (when applicable), as well as information obtained from any source or records which may pertain to donor eligibility regarding high risk behaviors, and clinical signs and symptoms for any relevant communicable disease agent or disease (RCDAD), and/or treatments related to medical conditions suggestive of such risk.

REMOVAL – The physical removal of distributed tissue from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection. Reference 21 CFR Part 806, 806.2(i).

REPRODUCTIVE TISSUE (R) – Any tissue from the reproductive tract intended for use in assisted reproductive technology procedures. This includes, but is not limited to: oocytes, ovarian tissue, embryos, semen, spermatozoa, spermatids, testicular tissue, and epididymal tissue.

REPRODUCTIVE TISSUE BANK (R) – A tissue bank that collects, processes, stores, and/or distributes human reproductive tissue for use in assisted reproductive technology procedures.

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

RESPONSIBLE PERSON – A person who is authorized to perform designated functions for which he or she is trained and qualified.

SAFETY – A quality of tissue indicating handling according to standards and substantial freedom from the potential for harmful effects to recipients.

SATELLITE FACILITY – A facility operated or owned by the tissue bank and located in a physically separate location from its primary address, and where any tissue banking activities occur or where any tissue banking services are provided.

SECONDARY PACKAGE - The barrier that surrounds the primary package (e.g., the tissue can be sterile tissue inside, aseptically processed tissue, recovered, or acquired tissue.) Refer to Guidance Document No.9, Figures 1 and 2. (Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)

SEMEN (R) – The fluid of man’s reproductive system consisting of spermatozoa and secretions of accessory glands.

SEMEN DONOR (R) – A man who donates semen for use in artificial insemination or assisted reproductive technology procedures where the recipient is not a sexually intimate partner. A semen donor can be further categorized as a directed donor or an anonymous donor but is not a client depositor.
SERIES OF STANDARDS – A group of standards related to a particular topic presented as a capitalized heading (e.g., B2.000) followed by indented subsections (e.g., B2.100, B2.120, B2.121). The heading and everything indented under it are considered part of the series.

SERVICES TO DONOR FAMILIES – A defined policy or support program describing tissue donation follow-up offered to the authorizing person (or party). This may include written communications regarding: potential uses of tissue; recovery outcome information; bereavement information and support; provision of a copy of the document of gift/authorization; and/or guidance describing how to contact the tissue bank if any questions arise regarding the donation. Frequency of follow-up and program maintenance is at the discretion of the tissue bank, however, periodic evaluation of services is required.

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

SHOULD – Used to indicate a recommendation; advisory, indicating a commonly accepted activity for which there may be effective alternatives.

SIGNATURE – A record is signed when it has been authenticated or adopted by the signer by means in writing, or an electronic signature, symbol, sound, process or recording pursuant to applicable law.

SKIN (S) - A membranous soft tissue type that includes, but is not limited to epidermis and dermis.

SKIN PREP - The application of antiseptic solution to decontaminate the skin. This is a continuous process that is performed without delay between steps; it does not include shaving hair, although this can be done if preferred. Unless otherwise qualified/validated, the manufacturer’s written recommendations must be followed, including that the antiseptic solution should remain in place for the recommended contact time and be allowed to air dry completely before the surgical drapes are placed.

STANDARD OPERATING PROCEDURES MANUAL (SOPM) – A group of standard operating procedures (SOPs) detailing the specific policies of a tissue bank and the procedures used by the staff/personnel to carry out the functions of the tissue bank.

STANDARDS – AATB Standards for Tissue Banking

STATIC - At-rest condition during aseptic processing where the controlled environment is complete with equipment installed and operating in a manner agreed upon, but with no personnel present [ISO 14644-1].

STERILE – For tissue, the absence of detectable, viable, microorganisms (refer to ANSI/AAMI ST67:2011). For reagents, supplies, materials and equipment, free from viable microorganisms.

STERILITY ASSURANCE LEVEL (SAL) – The probability of a single viable microorganism occurring on a product after sterilization (refer to ANSI/AAMI ST67:2003).

STERILIZATION – A validated process used to render tissue free from viable microorganisms (refer to ANSI/AAMI ST67:2003) including spores.

STOCK RECOVERY – Retrieval of tissue that has not left the direct control of the tissue bank (manufacturer), i.e., the tissue is located on the premises owned, or under the control of, the tissue bank (manufacturer), and no portion of the affected tissue has been released for use. Reference 21 CFR Part 7, 7.3(k).

STORAGE – The maintenance of tissue for future use.
STRUCTURAL SUPPORT – Those tissue grafts that contribute biomechanical strength to a surgical construct.

SUMMARY OF RECORDS – A condensed version of the donor testing and eligibility determination records. This can be combined with the package insert.

SURGICAL BONE (SB) – Any bone from a living donor for allogeneic use such as a femoral head removed during surgery.

TERMINAL STERILIZATION – A validated process whereby tissue within its final sterile barrier system (e.g., package, container) is sterilized (refer to ANSI/AAMI ST67:2011).

THIRD PARTY RECORDS – Records produced by an entity not involved in tissue recovery, acquisition, or donor screening. Examples of third party records include: hospital medical records; emergency medical services records; coroner/medical examiner records; prenatal records, and police reports.

TISSUE – A functional group of cells. The term is used collectively in Standards to indicate both cells and tissue.

TISSUE BANK – An entity that provides or engages in one or more services involving tissue from living or deceased persons for transplantation purposes. These services include obtaining authorization and/or informed consent, assessing donor eligibility, recovery, collection, acquisition, processing, storage, labeling, distribution and dispensing of tissue.

TISSUE DISPENSING SERVICE – Any entity that receives, stores, and provides tissue directly to an end-user for transplantation. Tissue dispensing services may or may not be tissue banks, depending on what other functions they perform.

TISSUE DISTRIBUTION INTERMEDIARY – An intermediary agent who acquires and stores tissue for further distribution and performs no other tissue banking functions.

TISSUE IDENTIFICATION NUMBER – Any unique combination of letters, numbers, and/or symbols assigned to tissue and linked to a donor, from which the complete history of the recovery, collection or acquisition, processing, packaging, quarantine, labeling, storage, distribution and dispensing of tissue can be traced. Identical tissue processed under the criteria defined in “lot” may be assigned the same tissue identification number.

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

TOTAL ISCHEMIC TIME (C, V) – The time interval from asystole to subjecting tissue to disinfection solution. This is the sum of warm ischemic time and cold ischemic time.

TRACEABILITY – The ability to locate tissue during any step of its donation, recovery, collection, or acquisition, processing, testing, storage, distribution or disposition. It implies the capacity to identify the medical facility receiving the tissue and, at the medical facility, the ability to identify the recipient.

TRANSFER (R) – The placement of human reproductive tissue into a human recipient (R).

TRANSPLANTATION – The transfer of an allograft or autograft to a recipient.
TRANSPORT MEDIUM – Any microbiological medium capable of maintaining cellular viability
during the transport of a culture from field to laboratory.

**TRANSPORT SYSTEM** - The combination of the packaging system and the container utilized to transport tissue. *(Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)*

**VALIDATION** – Confirmation through the provision of documented objective evidence that predefined specifications have been fulfilled and can be consistently reproduced.

**VALVED CONDUIT (C)** – An *allograft* heart valve with an attached length of cardiac outflow tract (aortic or pulmonic).

**VARIANCE** – A departure from *Standards* that is pre-approved by the AATB Board of Governors prior to implementation.

**VASCULAR TISSUE (V)** – *Tissue* type that includes, but is not limited to *arterial grafts* and *vein grafts*.

**VEIN GRAFT (V)** – A segment of vein that is *recovered, processed* and *preserved*.

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

**VERIFIED COPY** - A copy of a death certificate without the raised seal but issued by an authorizing agency.

**VETERINARY USE** – Treatment of a condition or disease in a non-human animal.

**WARM ISCHEMIC TIME (C)** – The time interval from *asystole* to subjecting cardiac *tissue* to cold rinse (or transport) solution at *recovery*.

**WARM ISCHEMIC TIME (V)** – The time interval from *asystole* to subjecting *vascular tissue* to transport solution and *wet ice temperatures* at *recovery*.

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

**WITNESS** – An individual who signifies in writing, or in electronically *recorded* format, that he or she has observed the execution or verbal authorization of the *document of gift/authorization or informed consent*. The *witness’* signification must be contemporaneous with execution and the *witness must* be identified by name, address and/or such other contact information as is relevant and feasible. A *witness should* not be an employee or agent of the *tissue bank* or requesting entity.

**A3.000 ACRONYMS AND ABBREVIATIONS**

The following acronyms and abbreviations are used in *Standards*:

**AAMI** – Association for the Advancement of Medical Instrumentation

**AATB** – American Association of Tissue Banks

**ANSI** – American National Standards Institute

**AORN** – Association of periOperative Registered Nurses

**ASQ** – American Society for Quality
ASTM – ASTM International

CAP – College of American Pathologists

CBER – Center for Biologics Evaluation and Research

CDC – Centers for Disease Control and Prevention

CFR – Code of Federal Regulations. Published by the Office of the Federal Register, National Archives and Records Administration, Washington, DC

e.g. – exempli gratia; for example, such as; the list is not finite

FDA – The United States Food and Drug Administration

i.e. – id est; that is; indicates a finite list

ISO – International Organization for Standardization

USP – United States Pharmacopeia
SECTION B
GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

B1.000 GENERAL INSTITUTIONAL REQUIREMENTS

B1.100 Purpose, Institutional Identity, and Affiliations

The purpose of the tissue bank shall be clearly formulated and documented. The tissue bank shall state whether it is a freestanding entity or part of an institution.

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 laws and regulations, these Standards, and the tissue bank’s SOPM shall be the responsibility of the Governing Body and management with executive responsibility.

B1.300 Medical/Scientific Support

A tissue bank should establish and maintain a mechanism to access medical, technical, and scientific advice as needed. Decisions shall be documented.

B1.400 Satellite Facilities

Satellite facilities shall be operated in accordance with the tissue bank’s SOPM.

B1.500 Written Agreements/Contracts

Each tissue bank shall have written agreements or contracts with all other individuals or organizations that perform or for whom they perform tissue banking activities or services such as, but not limited to:

1) donor referral;
2) authorization;
3) informed consent;
4) donor eligibility assessment;
5) recovery, collection, and/or acquisition;
6) post-delivery functions;
7) laboratory services (see exception at B1.60);
8) testing services;
9) processing;
10) storage;
11) tissue release;
12) distribution; and/or
13) consignment.

For additional controls regarding testing services and other services performed by others, see the series of standards at K1.300.

Written agreements or contracts shall indicate the nature of the relationships, division of tasks performed, division of issues of liability, specific responsibilities of each party and a summary of the protocols and procedures relating to the services provided. The tissue bank shall maintain a copy of each such agreement, which shall be made available for review if requested by AATB inspectors. Compliance with Standards by all parties shall be required and documented in a quality agreement. The following examples provide a few of these expectations:

1) A tissue bank that recovers tissue that is processed and/or distributed by another tissue bank shall be responsible for being in compliance with these Standards for all operations it performs. This includes, but is not limited to, the requirement to have a Medical Director (see B2.220) unless the tissue bank that recovers tissue and the tissue bank responsible for the processing and/or distribution of such tissue have a written agreement that defines the responsibilities of the processing tissue bank’s Medical Director to provide required oversight over donor screening and donor testing*, to follow applicable standards in Section D and Appendix II, and to share records (see D4.300). A tissue bank that recovers tissue is not required to audit its contracted tissue bank processor(s).

*Implementation period extended from 7/31/2019 to 1/31/2020 (Bulletin No.19-5) and from 1/31/2020 to 7/31/2020 (Bulletin No.19-7)

(BT) There shall be a written agreement/contract with the entity that performs post-delivery functions and/or acquisition on behalf of the tissue bank; or, if there is no written agreement or contract, there must be an attestation record from a responsible person that post-delivery protocols and procedures are followed.

2) A tissue bank that processes tissue recovered and/or distributed by another tissue bank shall be responsible for being in compliance with these Standards for all operations it performs. The tissue processing organization must bear the burden of proof, and document in writing, that operations performed by other organizations prior to the receipt of tissue for processing were performed in a manner consistent with these Standards as well as the processing tissue bank’s requirements.

3) A tissue bank that distributes tissue recovered and/or processed by other tissue banks shall be responsible for being in compliance with AATB Standards for all operations it performs. The distributor must also bear the burden of proof, and document in writing, that operations performed by other organizations prior to its receipt of tissue for distribution were performed in a manner consistent with AATB Standards. Any records necessary to demonstrate
compliance *shall* be readily accessible to the *distributing tissue bank*.
4) A tissue bank that determines donor eligibility shall develop and maintain policies and procedures that clearly describe donor records they deem relevant to their operations. Agreements must address how this information is to be communicated in a timely fashion and clearly define expectations and responsibilities of the appropriate entities.

5) A tissue bank that provides another tissue bank with critical supplies, reagents, materials, and/or equipment shall develop and maintain policies and procedures that clearly describe responsibilities for notification of changes and recalls, and both entities should report problems (e.g., defects). The tissue bank providing supplies containing labels is responsible for archiving and notification responsibilities described at G2.330.

6) A tissue bank that distributes tissue for transplantation shall restrict distribution to entities described in Standards (see H1.100). If tissue is provided to a tissue distribution intermediary, the tissue distribution intermediary shall meet the requirements of Section M of these Standards.

If an AATB-accredited tissue 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 tissues imported from entities that do not follow AATB Standards shall be appropriately quarantined throughout import, storage, processing, and export. The 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., informed consent/authorization, donor eligibility assessment, recovery, acquisition, 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.”

B1.510 On-site Inspections

(Refers to any AATB accreditation inspection.)

A tissue bank will be inspected and accredited for the specific activity(ies) or service(s) that it performs. However, if the tissue bank participates jointly with other entities that provide tissue banking activities or services on their behalf, the accredited tissue bank is responsible for providing evidence of compliance to these Standards for all tissue banking activities or services performed by other entities on its behalf.

B1.520 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 *Standards*, laws and regulations. Thereafter, the accredited *tissue bank* is responsible for verifying, at least biennially, that the activity(ies) or service(s) has/have been performed in conformance with applicable *Standards*, laws and regulations. This requirement does not apply to any other AATB-accredited entity. 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 are in compliance with these *Standards*, the written agreement/contract, and applicable laws and regulations. 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*, 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 requirements to be used for a partner performing *recovery* services, refer to Appendix V.

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 *tissue 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 for Donor Infectious Disease Testing**

*Tissue banks* that contract laboratory services for donor infectious disease testing *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. Additionally, all requirements in the *series of standards* at K1.300 *shall* apply. *Tissue banks* that obtain *donor* infectious disease test 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* eligibility or *tissue* suitability assessments. Appropriate management with *executive responsibility* *shall* ensure a *responsible person* understands the principles of bacteriological and/or infectious disease test *procedures* employed by a laboratory as well as the interpretation of results. *Records* of infectious disease laboratory results used to assess *donor* eligibility *shall* become part of the *donor 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.

The *tissue bank must* ensure (and maintain documentation of activities obtained by either paper *audit* or on-site *audit*) that a laboratory performing *donor* infectious disease testing for the
tissue bank is:

1) registered with the FDA as a tissue establishment and lists ‘testing’ as a function;
2) using the appropriate FDA-licensed, approved, or cleared donor screening tests;
3) following manufacturers’ instructions for these tests;
4) certified in accordance with the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services;
5) retaining donor infectious disease test run records for ten years; and
6) aware of the requirement of the tissue bank to comply with D4.240.

B2.000 FUNCTIONAL COMPONENTS OF A TISSUE BANK

B2.100 Management Responsibility

B2.110 Quality Policy

Management with executive responsibility shall ensure the establishment of the tissue bank’s policy and objectives for, and commitment to, quality, and shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

B2.120 Organization

Each tissue bank shall establish and maintain an adequate organizational structure to ensure that all tissue banking activities or services comply with the requirements of these Standards.

B2.121 Responsibilities and Authority

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 Resources

The tissue bank shall have sufficient resources, including the assignment of trained personnel, for management, performance of work, and assessment activities to meet the requirements of these Standards.

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 their 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 Technical Policies and Procedures

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 Quality Assurance Program

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, these Standards, and applicable laws and regulations. A documented annual internal review or audit to ensure compliance must be performed.

B2.160 Contingency Plan

The tissue establishment shall have a contingency plan in place for tissue that remains in inventory and record retention in the event of merger, acquisition or dissolution.

B2.200 Medical Director

B2.210 Qualifications

The tissue bank shall have a Medical Director who maintains a valid medical license from any state or U.S. territory (or for international members, the physician must maintain an equivalent medical license). He/she should have training and experience in evaluating and determining donor eligibility particularly with regard to infectious diseases or use a Medical Advisory Committee or consultants to assist in those areas. An AATB-accredited tissue bank recovering tissue for an AATB-accredited processing tissue bank may fulfill this requirement by securing a written agreement with the processing tissue bank that defines the responsibilities of the processing tissue bank’s Medical Director to provide required oversight over donor screening and donor testing operations conducted by the recovery tissue bank.*

*Implementation period extended from 7/31/2019 to 1/31/2020 (Bulletin No.19-5) and from 1/31/2020 to 7/31/2020 (Bulletin No.19-7)
B2.220 Responsibilities

The Medical Director shall establish, review and approve all policies and procedures of a medical nature. See J1.300, J1.400, J1.600.

B2.221 Donor Eligibility Criteria

The Medical Director shall be responsible for establishing donor eligibility criteria. See the series of standards at D4.000 and Appendix II.

The tissue bank’s donor eligibility criteria may be adopted from criteria used by another organization, provided that the Medical Director has verified the criteria are consistent with, and at least as stringent as, the requirements of these Standards and applicable laws and regulations.

When a tissue bank is responsible for determining donor eligibility, the Medical Director, or licensed physician designee, shall make a determination regarding the eligibility of each donor based on a comparison with predetermined donor criteria as established in the SOPM. This determination must occur prior to the release of tissue for transplantation. See Section F.

B2.222 Adverse Outcomes

The Medical Director shall establish policies and procedures regarding adverse outcomes. See K4.300.

B2.223 Positive Infectious Disease Test Results

The Medical Director shall be responsible for notifying appropriate parties of the availability of positive infectious disease test results, and for reporting positive test results when required, in accordance with D4.232.

B2.300 Technical Staff

B2.310 Qualifications

Staff must possess the educational background, experience, and training sufficient to assure assigned tasks will be performed in accordance with the tissue bank’s established procedures. Staff training shall be documented in individual employee training files.

B2.320 Responsibilities

Staff shall be responsible for implementation of policies and procedures as established by the 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 review.

B2.420 Staff Responsibilities

Quality assurance program personnel shall have responsibility for assuring compliance with the SOPM regulatory requirements. The individual responsible for the quality review shall have the responsibility and authority to approve or reject tissue, as well as discontinue processing and/or release of tissue when deviations from SOPM warrants. Quality assurance personnel shall be responsible for managing audits.
C1.000 RECORDS MANAGEMENT

C1.100 General

Each tissue bank shall develop a donor record management system that will allow the detailed documentation of the tissue banking process(es) for which it is responsible. Documentation must be made concurrent with each significant step and must include, but not be limited to:

1) information from the donor referral source;
2) donor eligibility assessment information;
3) record of informed consent, or document of gift/authorization;
4) donor physical assessment or physical examination, and donor identification;
5) tissue recovery or collection, transport, and processing;
6) quarantine and infectious disease testing;
7) in-process testing;
8) record review;
9) tissue labeling, storage, release, and distribution;
10) quality control; and
11) services to donor families.

Such records shall indicate the responsible party(ies) and must delineate the dates, times, and locations of subsequent procedures as well as the individuals performing them in order to facilitate traceability. The records shall be considered confidential and shall be kept in a location with controlled access; precautions for their safety and security should be evident.

(A) Records shall include, at a minimum, donor identification, and the date and time of recovery.

(R) Names of donors shall be encoded; only designated personnel shall have the authority to link the donor’s name to the identification code. No records shall exist which link the anonymous donor by name to the recipient.

C1.110 Required Processing Documentation

Results of laboratory tests used to determine final release of tissue for transplantation (e.g., sterility testing and testing for residual water, ethylene oxide, residual calcium) shall be maintained by the tissue bank that determines the suitability of the allograft for distribution (“distributor”). All other processing records shall be available to the tissue bank within a reasonable amount of time.
C1.120 Electronic Records

If records are maintained electronically, there shall be an electronic system in place to ensure that data integrity of the electronic records is maintained, and that information is retrievable, and able to be printed as a hard copy. Compliance with K7.000 is expected.

C1.200 Availability for Inspection

Tissue banking records shall be readily accessible for inspection by authorized personnel from accreditation programs and regulatory agencies. Access to donor identity and medical, social, travel, and sexual behavior histories shall be restricted to tissue bank staff with a need for access and to inspectors from accreditation programs and regulatory agencies. Should records be maintained electronically, there must be a system in place to retrieve information, and print a hard copy for review during inspection or for a period as required by applicable laws and regulations.

C1.300 Retention

Records of the informed consent, documents of gift/authorization, and records pertaining to donor eligibility, recovery, collection, acquisition, processing, storage, date of distribution, QA, and identity of person/entity to whom distributed, shall be retained at least 10 years beyond the date of distribution, date of transplantation (if known), date of disposition, or date of expiration of the tissue (whichever is latest) or longer if required by applicable laws and regulations. Records shall be maintained in a manner to preserve their completeness and accuracy over time. Donor eligibility records of dura mater donors shall be retained indefinitely. Tissue banks that have their tissues processed by another agency must assure that processing and QC records are retained for at least ten years.

(R) The reproductive tissue bank should maintain current donor and client depositor addresses until tissues are used or destroyed.

C1.400 Traceability

A tissue bank’s records management system shall identify tissue by use of a unique identifier. Each subsequent entity involved in the process of recovery, collection or acquisition through tissue dispensing shall be required to correlate its donor identifier with the donor identifier of the entity from which it acquired the tissue. Records shall also indicate the dates and the identities of the staff involved in each significant step of the operation from the time of recovery, collection or acquisition through final disposition of the tissue.

Laboratory and QC specimens related to a donor shall also be traceable to the donor. Records shall indicate which specimens were used for testing and shall also permit tracing from the donor to the specimen and from the specimen to the donor.

Whenever an accredited tissue bank consigns tissue to a non-accredited entity, the accredited tissue bank shall:

1) require the non-accredited entity to comply with the requirements of this section; and

2) impose the requirements of this section on all subsequent consignees, up to and including the tissue dispensing service.
C1.500 Revisions

Revisions to paper records shall be made with a single line drawn through the altered text. The revision shall be initialed and dated by the individual making the revision. Additions to a completed record shall be initialed and dated by the individual making the additions.

Records revised electronically must have an audit trail that includes the altered information, date of the revision, and the individual that made the revision. See K7.000.

C2.000 CONSTRUCTION OF RECORDS

Relevant medical records must be reviewed by the responsible person(s) at each tissue bank involved with recovery, collection or acquisition, or the determination of donor eligibility. The content of records that originate or are sourced from outside of a tissue bank (i.e., third party records) is not under control of the tissue bank. The information in these records is considered the best available information. Records that are produced by tissue bank staff must be complete, indelible, legible and accurate. Records must be in English or, if in another language, must be retained and translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document.

Tissue banks shall not utilize documentation related to informed consent/authorization or donor risk assessment interviews that are obtained by unauthorized parties. Authorized parties must be identified in agreements and personnel performing these functions shall be qualified, trained, and competent.

(A) Autologous tissue records shall be maintained either in a separate log, or, if incorporated into general records, in such a manner that the autologous tissue may not be released for non-autologous use.

(C) Records additionally shall include the following information:

1) ABO/Rh, if available;
2) date/time of asystole;
3) date/time of recovery of the heart (time when subjected to cold rinse solution);
4) date/time of subjection of cardiac tissue to disinfection solution;
5) start and stop times when tissue was subjected to disinfection solution; and
6) date/time:
   a) when preservation began; and
   b) when placed in final container.

(V) Records additionally shall include the following information:

1) ABO/Rh, if available;
2) date/time of asystole;
3) date/time vascular tissues subjected to perfusion solution;

4) date/time vascular tissues placed in transport solution and subjected to wet ice temperatures;

5) date/time of subjection of vascular tissue to disinfection solution;

6) start and stop times when tissue was subjected to disinfection solution; and

7) date/time (a) when preservation began and (b) when placed in final container.

C3.000 DONOR RECORDS TO BE MAINTAINED

Tissue Banks shall maintain records of their activities in accordance with these Standards.

(R) Donor records shall include documentation of informed consent, relevant medical records, results of all laboratory screening tests, and outcome of prior assisted reproductive technology procedures (if known) including number of successful pregnancies and any reports that would affect the donor’s eligibility. Records shall also include personal attributes of the donor such as: height, weight, eye color, hair color, complexion, racial group, and/or body type.
SECTION D
AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE
RECOVERY, COLLECTION, AND ACQUISITION

D1.000 GENERAL POLICIES

In addition to the requirements at the series of standards at B1.500, all referral arrangements with organ procurement organizations, donor referral sources and other tissue banks shall be documented.

(LD) Except for a reproductive tissue bank, written procedures for interacting with operating room staff, the patient’s physician, or other sources/facilities shall be established.

D1.100 Monetary Compensation or Other Valuable Consideration

Monetary compensation or other valuable consideration, including goods or services, shall not be offered to a donor, authorizing person, the donor’s estate, or any other third party acting on behalf of the donor, except in the following instances:

1) the tissue bank may reimburse responsible third parties for costs directly associated with a donation; or

2) the tissue bank may reimburse living donors for costs associated with an acceptable donation, including compensation for restoration of lost earnings when directly attributable to donation, if and as authorized by law.

(R) The reproductive tissue bank may provide monetary compensation to donors of reproductive tissue if the compensation is compliant with professional standards of practice.

Donors or their families should not be responsible for any expenses related to the recovery of allogeneic tissue.

D1.200 Tissue for Research

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. See the series of standards at D2.000 and D3.000.

D1.210 Written Requests

All requests for human tissue intended for research use shall be submitted in writing. The request shall indicate the type of tissue requested and how it will be used as well as the name, address and affiliation of the principal investigator accepting responsibility for receipt of the tissue.

D1.220 Review and Approval

Tissue requests for research purposes shall be reviewed and approved based on legal, ethical, and technical considerations defined in the SOPM.

D1.300 Consideration for the Donor
A policy shall be established requiring the donor always be treated with dignity and respect.

D2.000 AUTHORIZATION

D2.100 Requirements

Authorization to acquire tissues and make them available for transplantation, therapy, research or education shall be obtained from a donor or authorizing person in accordance with applicable anatomical gift acts and other laws or regulations. This authorization shall be expressed in a document of gift/authorization, the original or a copy of which shall be maintained in the donor’s record at the tissue bank responsible for recovery, as well as in the donor’s record at the tissue bank whose Medical Director is responsible for the donor eligibility determination. In the case of an electronic or voice recorded document of gift/authorization, the original recording should be maintained in reproducible form.

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful authorization for donation of tissues for transplantation, therapy, research, or education.

D2.200 Conditions

Adequate information concerning the donation and recovery of tissue shall be presented in a language in which the authorizing person is conversant and in terms that are easily understandable by the authorizing person. The donation coordinator should be trained to appropriately answer the questions the authorizing person may have. Neither coercion nor inaccurate information shall be used in any manner to obtain authorization.

D2.300 Signatures and Documentation

D2.310 Document of Gift

In cases where a donor has executed a document of gift it may be acted upon (permits recovery) provided it meets applicable laws and regulations. Acceptable documentation may include a state driver’s license, living will, advanced directive, state ID card, donor card, or photocopy thereof, and documentation that the donor registered in a donor registry.

D2.320 Document of Authorization

When a document of authorization is used it must contain the following signatures and related information:

\(1\) the authorizing person’s signature and:

\(a\) name;

\(b\) mailing address (NOTE: If requested by the authorizing person, only an email address may be documented as the address but, in such cases, the authorizing person should permit its use and should be informed that if the email address changes or if email communication is blocked, there may be no effective forwarding or receipt of information.).
c) phone number; and

d) relationship to the donor;

2) the donation coordinator’s signature and:

a) the date; and

b) identity of their organization;

3) the signature of each witness if witnessing is required by law or regulation;

4) documentation that the Core Elements were used; and

5) a statement granting authorization for tissue recovery.

D2.330 Methods of Obtaining Authorization

Legal authorization can be obtained using different methods. When authorization is obtained:

1) in person, the authorizing person must read and sign the document of authorization.

2) by telephone, the person obtaining the authorization shall read to the authorizing person the document of authorization or, alternatively, shall present each of the Core Elements described in D2.400.

This telephone conversation shall be recorded. There shall be documentation that the authorization was obtained by telephone.

A sampling plan must be adopted that verifies that recordings match the content in the written document of authorization. This verification must be performed by someone other than the donation coordinator or witness. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means is feasible for documenting authorization, the conversation should be witnessed by a third person. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).

3) using a facsimile transmission, a copy of the document of authorization is provided to the authorizing person. The authorizing person shall return the signed document of authorization by facsimile transmission. A donation coordinator shall be available to respond to questions posed by the authorizing person.

A sampling plan must be adopted that verifies signatures received by facsimile. This verification must be performed by someone other than the donation coordinator or witness. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).
4) **using an electronic transmission**, a copy of the *document of authorization* is provided to the *authorizing person*. The *authorizing person shall* electronically respond (e.g., by e-mail) that he/she has read the *document of authorization*, is authorized to grant *authorization*, and is granting such *authorization*. A *donation coordinator shall* be available to respond to questions posed by the *authorizing person*.

A *document of authorization* received by electronic transmission should be verified pursuant to the relevant law on electronic *signatures*, such as the Uniform Electronic Transactions Act of the relevant state. An electronically transmitted, read-only or otherwise protected *document of authorization may be used*.

**D2.400 Core Elements for Authorization**

The *document of authorization shall contain adequate information*. No *document of authorization from an authorizing person shall be acted upon if it does not contain the following Core Elements*. These Core Elements also apply to D2.500.

Core Elements:

1) the name of the *Donor*;

2) the name, mailing address, and telephone number of the *authorizing person*, and his/her relationship to the *donor* (NOTE: If requested by the *authorizing person*, only an email address *may be documented* as the address but, in such cases, the *authorizing person should permit its use and should be informed* that if the email address changes or if email communication is blocked, *there may be no effective forwarding or receipt of information.*);

3) an explanation that the *tissue* is a gift, and that neither the *donor’s estate nor the authorizing person* will receive monetary compensation or valuable consideration for it;

4) a description of the general types of *tissue* to be *recovered*;

5) a description of the permitted use(s) of the *recovered tissues* (i.e., transplant, therapy, research, or education);

6) an explanation that *recovery of tissue* requires the following actions, and the *document of gift/authorization thus specifically authorizes*:

   a) access to, and required disclosure of, the *Donor’s medical and other relevant records*;

   b) testing and reporting for transmissible diseases;

   c) the removal of specimens which *may include*, but are not limited to blood or *tissue samples* for the purposes of biopsy or other testing necessary for determination of *donor eligibility*;

   d) the release to the *tissue bank* of any and all *records* and reports of a Medical Examiner, Coroner or Pathologist (e.g., autopsy report); and
e) such other requirements as may be applicable for the specific donation or tissue bank, such as transport of the donor’s body, archiving of samples, photographic or other imaging, etc.

7) contact information for the organization represented by the donation coordinator; and

8) any additional information required by laws or regulations.

The following information should be provided to an authorizing person:

1) a general description of the recovery e.g., timing, relocation of donor if applicable, contact information, etc.;

2) an explanation that costs directly related to the evaluation, recovery, preservation, and placement of the tissues will not be charged to the family;

3) an explanation regarding the impact the donation process may have on burial arrangements and on appearance of the donor’s body; and

4) an explanation that the document of authorization is available.

Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that tissue may be distributed internationally, must be included.

When an Organ Procurement Organization (OPO), or other entity (e.g., hospital), has initiated the process of obtaining authorization for a potential organ and tissue donation, the tissue bank for which the authorization is being obtained shall request that the OPO or other entity follow the procedure and utilize a document of authorization that satisfies the requirements of D2.000.

For a donor one month (28 days) of age or less, adequate consent pursuant to law shall be obtained for collection of blood from the birth mother that will be used for testing.

D2.500 Notification of Gift

In cases where the gift is authorized by a donor’s own document of gift (i.e., first person consent), including a document of gift recorded in a donor registry (i.e., donor designation), and where law mandates notification, such notification shall be made pursuant to law.

In all other cases, prior to transport of the donor’s body or recovery, the donation coordinator should attempt to notify the person who would have been an authorizing person had no gift been made during the life of the donor or the person who is authorized to make arrangements for final disposition. The information to be provided in the notification should contain, at a minimum, Core Elements of authorization but at no time shall the donation coordinator indicate that the recipient of the information is empowered to revoke or amend the gift made by the donor.

The donation coordinator should inquire during the notification whether the notified person is aware of any revocation or refusal made by the donor.

Notification, if made, shall be documented.
Where good faith efforts to notify an appropriate person of the gift fail to result in actual notification within a time frame compatible with the successful recovery of the tissue, the attempt to notify shall be documented, and recovery may proceed.

D2.600 Services to Donor Families

Services to donor families or referral to a support system must be offered to the authorizing person. Subsequent communications and periodic evaluation of services shall be documented, maintained, and readily available. See AATB Guidance Document No. 4.

D3.000 INFORMED CONSENT

D3.100 Requirements

Except for autologous tissue, informed consent to acquire tissues and make them available for transplantation, therapy, research or education shall be obtained from a living donor or their legal representative, or from a client depositor in accordance with applicable laws or regulations. This informed consent shall be documented in a record of informed consent, the original or a copy of which shall be maintained in the donor’s or client depositor’s record at the tissue bank responsible for recovery, collection or acquisition, as well as in the donor’s record at the tissue bank whose Medical Director is responsible for the donor eligibility determination. In the case of an electronic or voice recorded record of informed consent, the original recording should be maintained in reproducible form.

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful informed consent for donation of tissues for transplantation, therapy, research, or education.

D3.200 Conditions

Adequate information concerning the recovery, collection, or acquisition of tissue shall be presented in a language in which the living donor or their legal representative, or the client depositor is conversant, and in terms that are easily understandable by them. The donation coordinator should be trained to appropriately answer the questions the living donor, their legal representative, or the client depositor may have. Neither coercion nor inaccurate information shall be used in any manner to obtain informed consent.

The potential donor or their legal representative shall not be under the influence of anesthesia or any drug that could influence his/her ability to give informed consent.

Informed consent must be obtained prior to recovery or acquisition, or when not possible and recovery or acquisition has already occurred, as soon as practical before use of the tissue.

D3.300 Signatures and Documentation

The record of informed consent must comply with applicable laws and regulations. It must contain, at a minimum,

1) the living donor’s signature or their legal representative’s signature, or the client depositor’s signature and:
a) name;

b) mailing address (NOTE: If requested by the living donor, their legal representative, or the client depositor, only an email address may be documented as the address but, in such cases, the living donor, their legal representative, or the client depositor should permit its use and should be informed that if the email address changes or if email communication is blocked, there may be no effective forwarding or receipt of information.);

c) phone number;

2) the donation coordinator’s signature and:

a) the date; and

b) identity of their organization;

3) the signature of each witness if witnessing is required by law or regulation;

4) documentation that the Core Elements for informed consent (see D3.400) were used;

5) a statement that the living donor or their legal representative, or the client depositor understands what has been read or explained and is granting informed consent for tissue recovery, collection, or acquisition; and

6) a statement that the living donor or their legal representative, or the client depositor has been informed that his/her name and address, as well as required records, shall be kept on file by the tissue bank or reproductive tissue bank.

D3.310 Methods of Obtaining Informed Consent

Informed consent can be obtained using different methods, if and as authorized by law or regulation. The methods below appear in preferential order. When informed consent is obtained:

1) in person, the living donor, their legal representative, or the client depositor must read and sign the record of informed consent.

2) by telephone, the person obtaining the informed consent shall read to the living donor, their legal representative, or the client depositor the record of informed consent or, alternatively, shall present each of the Core Elements described at D3.400.

This telephone conversation shall be recorded and it shall be documented that the informed consent was obtained by telephone. A sampling plan must be adopted that verifies that recordings match the content in the written record of informed consent. This verification must be performed by someone other than the donation coordinator or witness. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means are feasible for documenting informed consent, the informed consent may be made telephonically and should be witnessed by a third person. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as
the FDA Guide to Inspection of Quality Systems).

3) using a facsimile transmission, a copy of the record of informed consent is provided to the living donor, their legal representative, or the client depositor. The living donor, their legal representative, or the client depositor shall return the signed record of informed consent by facsimile transmission. A donation coordinator shall be available to respond to questions posed by the living donor, their legal representative, or the client depositor.

A sampling plan must be adopted that verifies signatures received by facsimile. This verification must be performed by someone other than the donation coordinator or witness. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).

4) using an electronic transmission, a copy of the record of informed consent is provided to the living donor, their legal representative, or the client depositor. The living donor, their legal representative, or the client depositor shall electronically respond (e.g., by e-mail) that he/she has read the record of informed consent, and is granting such informed consent. A donation coordinator shall be available to respond to questions posed.

A record of informed consent received by electronic transmission should be verified pursuant to the relevant law on electronic signatures, such as the Uniform Electronic Transactions Act, of the relevant state. An electronically transmitted, read-only or otherwise protected record of informed consent may be used.

D3.400 Core Elements for Informed Consent

No informed consent from a living donor, their legal representative, or a client depositor shall be acted upon if it does not contain the following Core Elements.

Core Elements:

1) the name of the living donor or client depositor, or

2) the identity of the person authorized by law to consent on behalf of the living donor or client depositor and his/her relationship to the subject including name, address, and telephone number;

3) if applicable, an explanation that the tissue is a gift, and that the living donor or their legal representative will not receive monetary compensation or valuable consideration for it;

4) a description of the general types of tissue to be recovered, collected, or acquired and any information pertinent to the specific recovery, collection, or acquisition contemplated;

5) a description of the permitted use(s) of the tissues (i.e., transplant, therapy, research, or education);

6) a description of the general purposes for which the tissue may be used;
7) a legally adequate release of the relevant medical records of the living donor, their legal representative (when applicable), or of the client;

8) permission to test for disease, if applicable;

9) a statement that confirmed positive test results will be reported or disclosed if required by law or regulation (e.g., to the living donor, their legal representative, or the client depositor, to the attending physician, to appropriate health officials);

10) contact information for the organization represented by the donation coordinator;

11) information concerning possible risks and benefits to the living donor, their legal representative, or the client depositor, if applicable; and

12) any additional information required by laws or regulations.

Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that tissue may be distributed internationally, must be included.

In the case of a client depositor the record of informed consent shall also include details about costs of tissue cryopreservation, storage, distribution and disposition options.

In the case of an anonymous donor, the record of informed consent shall also include details about monetary compensation. See D1.100.

D3.500 Services Involving Living Donors

(BT) Services shall be developed that provide answers to questions posed by the birth mother after delivery.

D4.000 DONOR SCREENING AND TESTING

D4.100 Donor Screening

Donor screening and donor testing procedures shall be established under the supervision of a contracted licensed physician possessing the qualifications outlined in B2.210. Donor eligibility criteria shall be established by the Medical Director of the tissue establishment responsible for the determination of donor eligibility (ref. Section 1271.50) and shall not conflict with these Standards. Each donor shall be evaluated according to established criteria. If donor screening and testing is under the supervision of a Medical Director other than the Medical Director responsible for final donor eligibility determination, the former shall be available upon request from the latter to provide clarification about results of donor screening and testing if needed.

(A) Donor eligibility shall be documented by a physician caring for the autologous 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.

(BT) Except for autologous donations, the health status of the infant(s) shall be assessed in
regard to information that could affect the quality or safety of the tissue for transplantation. Protocols shall be established for reviewing information at the time of the infant’s delivery. Policies and procedures should be developed to handle information regarding the health status of the infant reported voluntarily after delivery. Written procedures must describe how information is evaluated.

(C) Heart donors shall also be evaluated for the risk of Chagas’ disease.

(LD) Criteria for accepting living donors shall be established by the Medical Director or licensed physician designee.

(R) Criteria for accepting client depositors and potential reproductive tissue donors shall be established by the Medical Director or licensed physician designee.

(S) Potential donors shall be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and skin condition.

D4.110 Age Criteria

The Medical Director and/or tissue bank Medical Advisory Committee shall determine donor age criteria.

(A) There are no age limits for autologous tissue donation.

(BT) There is no age limit for the birth mother, however, policies and procedures shall be written regarding gestational age limits.

(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. Oocyte donors shall be younger than 35 years, unless an exception has been made by the Medical Director with documented agreement of the user physician.

D4.120 Physical Assessment

Prior to the recovery of tissue from a deceased donor, a physical assessment shall be performed by a responsible person. This shall be a recent ante-mortem or postmortem physical assessment to identify evidence of: high risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, signs of trauma or infection to the body where recovery of tissue is planned. If any of the following signs are observed or noted in any other available record, and are deemed to be an indication of these risks, then the tissue shall be rejected:

Note: Each risk type is followed by observational wording in parentheses suggestive of terminology that correlates with each listing. See Appendix III.

1) physical evidence for risk of sexually transmitted diseases such as genital ulcerative disease, herpes simplex, chancroid (genital lesions);

2) physical evidence for risk of, or evidence of, syphilis (genital lesions, rash, skin lesion [non-genital]);
3) for a male donor, physical evidence consistent with anal intercourse including perianal condyloma (insertion trauma, perianal lesions);

4) physical evidence of non-medical percutaneous drug use such as needle tracks (and/or non-medical injection sites), including examination of tattoos (which may be covering needle tracks);

5) disseminated lymphadenopathy (enlarged lymph nodes);

6) unexplained oral thrush (white spots in the mouth);

7) blue or purple spots consistent with Kaposi’s sarcoma (blue/purple [gray/black] spots/lesions);

8) physical evidence of recent tattooing, ear piercing, or body piercing (tattoos/piercings should be described);

9) unexplained jaundice, hepatomegaly, or icterus. Note: Hepatomegaly may not be apparent in a physical assessment unless an autopsy is performed (enlarged liver, jaundice, icterus);

10) physical evidence of sepsis, such as unexplained generalized rash/generalized petechiae, or fever (rash);

11) large scab consistent with recent smallpox immunization (scab);

12) eczema vaccinatum (lesion, scab);

13) generalized vesicular rash, generalized vaccinia (rash);

14) severely necrotic lesion consistent with vaccinia necrosum (lesion); and/or

15) corneal scarring consistent with vaccinial keratitis (abnormal ocular finding, scarring).

The form and instructions in Appendix III must be used to document the tissue donor physical assessment.

(S) The physical assessment shall include documentation of findings and conditions that may affect the quality or quantity of skin recovered.

D4.130 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 licensed 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 D4.120) that would assist with information to determine whether there is evidence of high risk behavior.

(BT) In addition to the (LD) standard above, a physical examination of the birth mother must be performed during admission for delivery or within 14 days prior to delivery.

(R) A physical examination must be performed on all anonymous and directed semen and oocyte donors. A repeat physical examination shall be performed on anonymous semen donors at least every 6 months (180 days) while the donor is actively collecting samples in the program.

*Semen donors shall* not exhibit an infectious skin disease that creates a risk of contamination of the semen.

D4.140 Donor Risk Assessment Interview (DRAI)

A documented dialogue shall be conducted with the donor (if living) or the deceased donor’s next of kin, the nearest available relative, a member of the donor’s household, other individual with an affinity relationship (caretaker, friend, significant life partner) and/or the primary treating physician, using a standardized questionnaire. Questions shall be formulated using these Standards, current federal regulations and guidance.

Questions shall be included that evaluate past medical history for conditions that could constitute a contraindication to the release of tissue for transplantation (e.g., certain infectious diseases, malignancies, and degenerative neurologic disorders), as defined in these Standards (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 (RCDADs) and the birth mother’s blood must be tested. Refer to D4.100 (BT) for expectations to obtain the health status of the infant donor of birth tissue.

The donor risk assessment interview shall document the donor’s name, and the relationship between the donor and the interviewee(s) and shall indicate the name(s) of the interviewer(s) and interviewee(s). The questionnaire shall be maintained as part of the donor’s record.

(A) The tissue bank shall have a policy for obtaining information from the patient’s physician as to whether the autologous donor is at high risk for viral hepatitis or HIV infection.

(BT) The donor risk assessment interview of the birth mother shall be obtained, or previous donor risk assessment interview information verified, no more than 14 days prior to delivery. If this interview is performed after delivery it must be completed within 14 days of delivery.

(LD) Interviews must be administered by trained staff, or if self-administered, a trained staff member must review and verify answers with the donor in order to facilitate comprehension and provision of accurate answers.

(R) The donor’s risk assessment shall include a review of personal alcohol and drug use and sexually transmissible diseases in the donor and partner(s). The
screening process also shall include any history of chemical and/or radiation exposure as well as family medical history and genetic background. An abbreviated donor screening must be obtained at each repeat donation and reviewed by a responsible person. The abbreviated screening must determine and document any changes in the donor’s medical, social, travel, and sexual behavior history (including risk factors) since the previous donation that would make the donor ineligible.

D4.141 Family History and Genetic Background

(BT) If genetic testing has been performed or a genetic history has been obtained and the information is available, it should be considered for the determination of donor eligibility.

(R) A minimum of a three-generation family history shall be elicited from each prospective donor. If a biological family member in the prospective donor’s family is adopted, Medical Director discretion must be made to determine if sufficient family history is provided to determine donor eligibility. The genetic history should be evaluated by an individual with appropriate clinical genetics education and/or training. Any significant condition in a prospective donor or donor’s family history that would pose a risk of producing an offspring with a serious genetic disease or defect greater than the risk in the general population shall disqualify him/her as a donor, with the following exceptions:

1) Anonymous donors whose family history indicates that he/she is at risk for carrying a genetic defect may be accepted only if a test to detect carrier status is performed and is negative for the mutation that is known to occur in the family; or

2) Directed gamete donors and anonymous or directed embryo donors with any family history indicating he/she is at risk for carrying a genetic defect/condition may be accepted, provided the genetic risk to offspring is evaluated in writing and the recipient(s) (R) has reviewed the evaluation, been offered additional genetic testing, and completed an informed consent.

If indicated by medical history, family history, or ethnic background, anonymous donors should be screened for Tay-Sachs disease, thalassemia, sickle cell trait, spinal muscular atrophy, and/or cystic fibrosis.

D4.150 Relevant Medical Records Review

Prior to tissue donation, a preliminary review of readily available relevant medical records shall be conducted by a trained individual.

This review shall include but may not be limited to:

1) evidence of significant active infection at the time of donation for relevant communicable disease agents or diseases (RCDADs) including signs and/or symptoms of viral and fungal infection, bacteremia or sepsis;
2) risk factors for relevant communicable disease agents or diseases (RCDADs) as specified in Appendix I; and

3) additional tissue donor specific criteria as documented in the SOPM and compliant with written agreements/contracts.

(A) Except for skin, autologous donation should not be undertaken when the autologous donor has, or is being treated for, bacteremia or other significant bacterial infection that can be associated with bacteremia, unless such tissue will be secondarily sterilized prior to transplantation or treated in such a manner to minimize microbial contamination.

D4.200 Donor Testing

D4.210 Blood Specimens

Except as otherwise specified for certain reproductive tissue donors, infectious disease testing of donor blood specimens shall be performed for each tissue donor on a specimen collected at the time of donation or within 7 days prior to or after donation. If the donor is one month (28 days) of age or less, a blood specimen from the birth mother must be collected within 7 days prior to or after tissue donation and tested instead of a specimen from the infant donor. There shall be written procedures for all significant steps in the infectious disease testing process, including blood specimen collection (i.e., documentation of date/time of collection, a donor identifier), documentation of the verification of specimen labeling, and use of appropriate blood specimen types, labels, and instructions for specimen handling. Procedures shall conform to the test kit manufacturer’s instructions for use contained in the package inserts. Specimen collection, storage, and handling procedures shall be described in the SOPM.

(R) For anonymous and directed oocyte donors, the blood specimen must be collected within 30 days prior to oocyte collection, or within 7 days post donation. Samples for infectious disease testing of anonymous and directed semen donors must be obtained within 7 days of initial semen collection. See D4.360 for testing requirements for embryo donors.

D4.211 Plasma Dilution

Tissue from a donor who is older than 12 years of age shall be determined to be not suitable for transplantation if blood loss is known or suspected to have occurred and there has been transfusion/infusion of more than 2,000 milliliters (mL) of blood (e.g., whole blood, or red blood cells) or colloids within 48 hours; or more than 2,000 mL of crystalloids within one hour; or any combination thereof, prior to asystole or the collection of a blood specimen, whichever occurred earlier, unless:

1) a pre-transfusion or pre-infusion blood specimen from the tissue donor is available for infectious disease testing; or

2) an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to
ensure that there has not been plasma dilution sufficient to affect test results.

Tissue from a donor who is 12 years of age or less who has been transfused or infused at all, shall be determined to be not suitable for transplantation unless a pre-transfusion or pre-infusion blood specimen from the tissue donor is available for infectious disease testing, or an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to ensure that there has not been plasma dilution sufficient to affect test results.

When the fluids transfused are in the “blood” category (alone, or in combination with colloids and/or crystalloids), a comparison of the total volume of these fluids with the donor’s estimated blood volume shall be performed, in addition to a comparison of the total volume of colloids and/or crystalloids with the donor’s estimated plasma volume. Since every possible clinical situation cannot be described where plasma dilution may affect test results, the SOPM should describe how to address additional circumstances when plasma dilution may have occurred (e.g., large volumes of transfusions/ infusions administered in the absence of blood loss). It may be necessary to use a pre-transfusion/infusion blood specimen or apply an algorithm in those instances.

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

D4.220 Infectious Disease Testing

Results of initial infectious disease and/or confirmatory testing shall be used as one component of determining donor eligibility. Testing used for donor eligibility shall be performed by laboratories that are registered with FDA as a tissue establishment for testing and are either certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

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, and test kit licensing/approval.

FDA-licensed, approved, or cleared donor screening tests must be used, except when testing for Chlamydia or gonorrhea in which case, an FDA-licensed, cleared or approved diagnostic test must be used.

A new test shall be implemented when AATB and/or FDA issues notification to that effect. Prior to that time, use of the new test, even if FDA-licensed, approved, or cleared for donor screening, is voluntary. Tests specifically labeled for use with specimens collected after the donor’s heart has stopped beating instead of a more generally labeled test shall be used when applicable and when available. *

A list of donor screening tests that have been licensed for use with specimens collected after the donor’s heart has stopped beating can be accessed at the FDA/CBER website.

*See AATB Bulletin No. 06-45 “Intent of Update to Standard D4.353.” (Note: this
standard is currently D4.220)

Rapid antigen and/or antibody testing for infectious disease may be performed in addition to the required tests. Results of these tests must be evaluated (see F1.140) and shared (see D4.300) in accordance with policies and procedures.

If a laboratory that performs organ donor testing performs the initial testing in duplicate or triplicate, the tissue bank must obtain and review the results of all individual tests performed. Individual test results shall be shared in accordance with B1.510, D4.300, and K1.100.

All tissue from donors who test repeatedly reactive on a required screening test shall be quarantined and shall not be used for transplantation. There shall be written procedures for all significant steps in the infectious disease testing process that shall conform to the manufacturer’s instructions for use contained in the package inserts for required tests. These procedures shall be readily available to the personnel in the areas where the procedures are performed unless impractical. The manufacturer’s instructions shall be followed in regard to acceptable donor specimens and their handling. Donor sample testing shall be performed, and test results interpreted according to the manufacturer’s instructions in the package insert for the particular infectious disease marker.

Additional testing to confirm or supplement infectious disease test results may be performed at the discretion of the Medical Director using FDA-licensed, confirmatory test kits when commercially available. Results of infectious disease testing shall be evaluated prior to disclosure of availability of positive test results (see D4.232).

**D4.230 Required Infectious Disease Tests**

Excluding autologous, embryo donor, and client depositor tissue, all human tissue intended for transplantation shall be from donors who are tested and found to be negative for:

1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);

2) nucleic acid test (NAT) for HIV-1;

3) hepatitis B surface antigen (HBsAg);

4) nucleic acid test (NAT) for the hepatitis B virus (HBV);

5) total antibodies to hepatitis B core antigen (anti-HBc—total, meaning IgG and IgM);

6) antibodies to the hepatitis C virus (anti-HCV);

7) nucleic acid test (NAT) for HCV; and

8) syphilis (a non-treponemal or treponemal-specific assay may be performed).

Donors of viable leukocyte-rich tissue (e.g., semen, certain (CT)) shall also be tested...
and found to be negative for antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II). Note: HTLV testing of donors of other tissue types may be required by law and/or regulation, including, where applicable, foreign laws and/or regulations.

(LD) For tissue establishments located within the United States (U.S.), all living donors, excluding autologous donors, shall be tested and found to be negative for WNV NAT when recovery, collection, or acquisition occurs from June 1st through October 31st every year. Ref. D4.231 (R)

For tissue establishments located outside the U.S. importing tissues to the U.S., all living donors, excluding autologous donors, shall be tested year-round and found to be negative for WNV NAT.

All test results shall be documented in the donor’s record.

(R) In addition to the infectious disease tests listed above, all anonymous and directed semen and oocyte donors shall undergo testing for Neisseria gonorrhoea and Chlamydia trachomatis. The manufacturer’s requirements for specimens must be met. If the reproductive tissue is collected by a method that ensures freedom from contamination of the tissue by infectious disease organisms that may be present in the genitourinary tract, then these tests are not required.

All anonymous and directed semen donors shall also be tested for total antibody to cytomegalovirus (anti-CMV—total, meaning IgG and IgM).

Required tests for anonymous and directed embryo donors are listed in D4.231.

Client depositors who deposit semen, testicular fluid or tissues, oocytes or ovarian tissue, or embryos, shall be tested prior to use for:

1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);
2) hepatitis B surface antigen (HBsAg); and
3) antibodies to hepatitis C virus (anti-HCV).

D4.231 Repeat Testing of Living Donors

(R) All donated semen from anonymous donors shall be frozen and quarantined for at least 6 months. After such time and prior to release of semen, the donor shall be retested for anti-HIV-1, HIV-1 NAT, anti-HIV-2, HBsAg, anti-HBc, HBV NAT, anti-HCV, HCV NAT, anti-HTLV-I, anti-HTLV-II, syphilis, and for anti-CMV. Anonymous donor semen shall not be made available for use unless results of all tests, excluding CMV and syphilis, are negative or nonreactive. Results of all testing performed must be interpreted as in F1.140. All tests for infectious diseases shall be repeated at least every 6 months while the semen donor remains an active participant in the donor program and after any lapse exceeding 6 months. For repeat semen donors who have already had testing performed and for whom retesting at ≥ 6 months is required, testing at each donation is not required. For such repeat semen
donors, WNV NAT testing shall be performed at the time of, or within 7 days before or after the first donation that is recovered within the June 1st through October 31st testing period, even if an earlier specimen was already collected and tested.

Oocyte donor tissue is not subject to quarantine and the donor is not subject to repeat testing.

For directed or anonymous donation of embryos created by sexually intimate client depositors, the embryos shall be quarantined (stored) for at least 6 months from the date of creation. After the 6-month quarantine and prior to release of the embryo(s) for transfer, appropriate measures should be taken to test the sexually intimate client depositor male and female for anti-HIV-1 anti-HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. In addition, the male should be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II.

For directed or anonymous donation of embryos created using one anonymous or directed egg or sperm donor, embryos shall be quarantined (stored) for at least 6 months from the date of creation. After such time and prior to release of the embryo(s) for transfer, appropriate measures should be taken to test the client depositor for anti-HIV-1, anti-HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. If the client depositor is male, he should also be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II. A Summary of Records for the gamete donor must be provided prior to release.

For directed or anonymous donation of embryos created using both an anonymous or directed egg and sperm donor, a donor summary of records must be obtained for both donors.

“Appropriate measures” means using available resources to accomplish the testing. If the client depositor cannot be tested due to death or inability to locate the person, directed or anonymous donation of the embryos can still be completed.

D4.232 Disclosure and Availability of Positive Infectious Disease Test Results

The donor, if living, shall be provided test results as required by applicable law or regulation. For deceased donors, 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. Positive test results shall be reported to state and/or local health department(s) as required by law or regulation.

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

D4.240 Archived Samples

A policy shall be established to collect and preserve serum, plasma, or hematopoietic tissue samples from donors for an appropriate duration after the recovery, collection, or acquisition date as if prescribed by a quality, safety, and legal risk assessment conducted by the tissue bank to mitigate the establishment’s specific risk exposure. For samples from donors determined to be ineligible/unsuitable, or samples from eligible donors approaching expiration of their preservation term as defined by organizational policy, tissue establishments may have written agreements with third parties for long-term archiving of serum, plasma, or hematopoietic tissue samples for use for possible unforeseen future investigational purposes (e.g., emerging infectious diseases, medical/legal, blood borne pathogen exposure, etc.).

(DM) Appropriate brain tissue specimens (i.e., formalin-fixed brain tissue, histological sections from examination of brain, donor serum) from each donor of dura mater shall be archived under appropriate storage conditions, and for the appropriate duration.

(R) Archived serum or plasma from reproductive donors whose tissue has been stored but subsequently destroyed and never distributed does not require retention.

D4.250 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 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 tissue bank.

Client Depositors: A semen analysis, that includes sperm concentration and motility, at a minimum, shall be performed. The reproductive tissue bank shall make pertinent test results available to the client depositor’s physician.

D4.300 Information Sharing

The tissue bank that recovers tissues must have a procedure(s) for receiving, investigating, evaluating, and documenting donor information as well as how they will share records with all establishments who are known to have also recovered tissues, or to have received recovered tissues, from the same donor:

1) record sharing should occur as new information is received and this must be documented
and included in the records;

2) relevant records that could affect eligibility determinations must be sent without delay to tissue banks that will determine donor eligibility of recovered tissues and/or the donor;

3) the tissue bank that recovers tissue must share tissue recovery culture (pre-sterilization/pre-disinfection culture) information with all tissue banks to which tissue from shared donors was sent. If defined in a written agreement, an eye bank can choose not to receive pre-sterilization/pre-disinfection culture results; and

4) if any tissue bank determines a donor to be ineligible, this determination must be communicated in writing to the tissue bank that recovered tissues, and the tissue bank that recovered tissues must share this information with all establishments that are known to have recovered tissues, or to have received recovered tissues, from the same donor.

Written procedures must describe how this information is received, evaluated, and disseminated in a timely fashion.

Any tissue testing performed after it has been disinfected or subjected to processing (e.g., in-process testing, post-processing microbiological testing, final cultures) is not considered relevant donor records for the tissue bank that recovered tissues and, if such results are reported, would not be expected to be shared with tissue banks who received recovered tissues from a shared donor.

D5.000 RECOVERY, COLLECTION, AND ACQUISITION

Policies and procedures shall be established for the recovery, collection, or acquisition of tissue in accordance with Standards. Reagents, supplies, materials, and equipment shall be of appropriate grade for intended use, and approval for use shall be documented. All tissue must be uniquely identified and traceable to the donor from recovery, collection, or acquisition through transport and receipt at the processing or storage facility. The environment in which tissue can be obtained, and techniques that should be used, shall be specified. Recovery, collection, acquisition and preservation shall occur within a time interval appropriate for retention of tissue quality and shall be compatible with intended use of the tissue. Detailed records of the tissue donation shall be maintained that include information regarding relevant packaging, transportation, and, when applicable, donor reconstruction steps.

D5.100 Reagents, Supplies, Materials, and Equipment

All critical supplies, reagents, materials, and equipment approved for use for recovery, collection, or acquisition shall be identified and specifications (e.g., sterile where applicable) documented. A record shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, lot number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of the staff performing the inspection. The tissue bank shall maintain records of all supplies, reagents, materials, and equipment from receipt through period of time used. All reagents, supplies, materials and equipment shall be used and stored in accordance with manufacturers’ instructions, unless qualified/validated for intended use or storage.

All non-disposable surgical instruments and parts of mechanical/electrical equipment which come in contact with tissue shall be properly cleaned, decontaminated, and sterilized prior to use for recovery, collection, or acquisition according to written procedures prepared to prevent...
contamination or cross-contamination. Records shall be maintained that document sterilization steps. All reagents, supplies, and materials shall be used and stored in accordance with manufacturers’ instructions unless qualified/validated for intended use or storage. Adequate controls must exist to prevent mix-ups between acceptable and unacceptable items.

D5.110 Stock Rotation

Reagents, supplies, and materials with expiration dates or production dates shall be stored in a manner to facilitate inventory rotation. Items not bearing an expiration or production date shall be labeled with the date of acquisition and stored in a manner to facilitate inventory rotation. Older items should be used first and not used if expired or quality has been compromised.

D5.200 Donor Identification

Each donor shall be assigned a unique donor identifier to facilitate tracing of the tissue from the donor and to final disposition of each tissue.

D5.210 Verification Procedures

D5.211 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. Except for autologous tissue, informed consent must be obtained and documented prior to the initial collection from living donors. If informed consent was not obtained prior to recovery (e.g., surgical bone) or acquisition, it must be obtained as soon as practical after recovery or acquisition.

D5.212 Donor Identity

Prior to initiation of tissue recovery, collection, or acquisition the potential donor’s identification shall be verified with the donor’s name as stated on the record of informed consent or document of gift/authorization. Donor identity verification shall be documented in the donor record prior to tissue recovery, collection, or acquisition. Records shall indicate the staff member(s) involved and include the source of the verification information (e.g., hospital wristband, medical examiner number, driver’s license, or government issued identification with photograph).

(A, SB) Identification of the donor shall be the responsibility of the hospital staff involved with the recovery.

(BT) Identification of the birth mother shall be the responsibility of the hospital staff, or the tissue bank staff member involved with acquisition.

D5.300 Tissue Recovery, Collection, and Acquisition

Recovery, collection, or acquisition shall be performed using aseptic or clean techniques appropriate to the specific tissue type and intended use. Tissue must be labeled using a donor
identifier and a description according to the SOPM (see G1.100).

D5.310 Recovery

Recovery shall be performed using aseptic or clean techniques appropriate to the specific tissue recovered and intended use of the tissue. The SOPM shall specify the time limits for the postmortem recovery of tissue consistent with tissue-specific standards, where applicable. If recovery is to be delayed for a deceased donor, the donor’s body should be refrigerated/cooled as specified in the tissue-specific standards. To prevent cross-contamination or mix-ups, recovery from one donor shall be the exclusive activity taking place at one time at a recovery site. Other activities (e.g., embalming, autopsy, another tissue donor recovery) cannot occur simultaneously in the same room as recovery. Tissue recovery shall not occur after embalming procedures have begun (i.e., injection of embalming fluid, application of drying agents either internally or topically).

(LD) Methods for recovery of perioperative tissue shall be safe, aseptic, and ensure accurate identification of tissue.

D5.320 Collection

(R) Collection of anonymous donor semen shall be made at the reproductive tissue bank using a sterile collection container. If the tissue requires transportation to the processing laboratory, it should be transported within a reasonable time period as specified in the SOPM, so as to maintain the utility of the tissue. The collection container shall be labeled with the date of collection and the donor’s identification or, in the case of client depositors or directed donors, the name. The time of collection shall also be recorded.

D5.330 Acquisition

(BT) Methods for acquisition of birth tissue shall be safe, aseptic, and ensure accurate identification of tissue post delivery.

Birth tissue shall be packaged post-delivery using a sterile receptacle/transport package in a controlled environment. Prior to acquisition, the birth tissue receptacle/transport package shall be labeled.

D5.340 Pooling

Pooling tissue from multiple donors shall not occur during recovery, collection, acquisition or storage.

D5.400 Time Limits for Postmortem Tissue Recovery

When recovery of tissue has begun, subsequent recovery steps must proceed without delay.

(C, V) Cardiac tissue and vascular tissue recovery and processing time limits (i.e., warm and cold ischemic time, disinfection time, and the perfusion time [specific to vascular tissues]) shall be established by each individual tissue bank; however, the following upper time limits for initiation of recovery of specific tissue types shall not be exceeded.
Warm ischemic time (C) shall not exceed 24 hours from asystole if the donor’s body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The time limit shall not exceed 15 hours if the donor’s body was not cooled or refrigerated. If the donor’s body is cooled for a period of time then not cooled for a period of time, the time period the donor’s body is not cooled cannot exceed 15 cumulative hours.

(V) 1) Perfusion time shall not exceed 12 hours from asystole; and

2) warm ischemic time (V) shall not exceed 24 hours from asystole if the donor’s body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The time limit shall not exceed 15 hours if the donor’s body was not cooled or refrigerated. If the donor’s body is cooled for a period of time then not cooled for a period of time, the time period the donor’s body is not cooled cannot exceed 15 cumulative hours.

(MS, OA, S)
The skin prep shall begin within 24 hours of asystole provided the donor’s body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The skin prep shall begin within 15 hours of death if the deceased donor’s body has not been cooled or refrigerated. If the donor’s body is cooled for a period of time then not cooled for a period of time, the time period the donor’s body is not cooled cannot exceed 15 cumulative hours.

For expectations when evaluating cooling of a donor’s body, refer to Guidance Document No. 7.

D5.500 Recovery Environment

All tissue shall be recovered in an aseptic or clean fashion using standard surgical preparation with sterile packs, instrumentation, and technique. Prior to recovery, the recovery site must be evaluated for suitability using pre-established criteria designed to control contamination and cross-contamination (see Appendix IV). The recovery site evaluation must be documented, however, if the recovery site is an operating room in a heath care facility, no documented site evaluation is required.

D5.510 Recovery Site Suitability Parameters

These must address the control of:

1) size/space;
2) lighting;
3) plumbing and drainage for the intended use;
4) the physical state of the facility (i.e., state of repair);
5) ventilation;
6) cleanliness of room and furniture surfaces;
7) pests;
8) traffic;
9) location;
10) other activities occurring simultaneously;
11) sources of contamination; and
12) the ability to appropriately dispose of biohazardous waste and handle contaminated equipment.

D5.520 Recovery Cleansing and Preparation

Environment:
An evaluation of the recovery site must be performed to identify potential sources of contamination (see Appendix IV). All working surfaces (e.g., back table, Mayo stand, recovery table) used during recovery must be decontaminated using a bactericidal/antimicrobial agent. All cleansing and disinfecting events performed by tissue bank personnel shall be documented. For guidance, refer to Guideline for environmental cleaning in Guidelines for Perioperative Practice. Denver, CO: AORN, Inc. (current edition).

Technician:
Technician gowning, gloving, and movement shall be accomplished with the same diligence as used routinely for operative procedures. Aseptic technique shall be followed. For guidance, refer to AORN’s Guideline for sterile technique (current edition). Persons performing the surgical recovery shall perform a surgical scrub or wash of their hands and forearms prior to recovery. For guidance, refer to AORN’s for hand hygiene (current edition). A head cover, eye shields and mask shall be worn at the time of scrub, and a Sterile gown and gloves shall be donned after the scrub/wash. For guidance, refer to AORN’s Guideline for surgical attire (current edition).

Donor:
Cleansing, preparing (i.e., skin prep), and draping the skin shall be accomplished with the same diligence as used routinely for operative procedures. Unless otherwise qualified/validated, agents used shall be antimicrobial skin preparation products, as specified in the SOPM, and shall be used in accordance with manufacturers’ guidelines/instructions. For guidance, refer to AORN’s Guideline for preoperative patient skin antisepsis (current edition).

D5.530 Recovery Technique

Specific tissue recovery operations that control contamination and cross-contamination (e.g., sequencing of the tissue recovery, use of well-defined zone recovery techniques, and isolation draping in the presence of trauma; see Appendix IV shall be implemented. Areas of skin that have abrasions or puncture wounds should be avoided. All tissue shall be recovered using aseptic technique.
D5.531 Cultures Obtained at Recovery

(MS, OA, S, SB)
If performed, the technique used to obtain cultures of recovered tissues shall be appropriate for the tissue type and performed according to written instructions.

D5.600 Delivery Environment and Cultures Obtained Prior to Acquisition

D5.610 Delivery Environment

(BT) If the delivery location is an operating room or a designated delivery room in a specialized health care facility, no documented site evaluation is required, however, any other location of delivery must meet the requirements at D5.500 and D5.510. Such an evaluation must be documented. (Amended 1/31/2020)

D5.620 Cultures Obtained Prior to Acquisition

(BT) If performed, the technique used to obtain cultures prior to acquisition shall be appropriate and performed according to written instructions.

D5.700 Records

D5.710 Recovery Records

For allogeneic tissue, details of the tissue donation shall be documented in the recovery record. Recovery records shall include, but not be limited to:

1) name, and address of the recovery agency;
2) date, time and staff involved in all significant steps performed during the recovery (documentation shall be as per C1.100);
3) location and assessment of the suitability of the recovery site;
4) documentation of the physical assessment or physical examination;
5) documentation of any errors, accidents, or deviations that occurred;
6) donor name, age, and sex;
7) the type, lot number, manufacturer, and expiration date of critical reagents, supplies and materials, and the identification of equipment, used to recover, rinse, and/or transport tissue; and
8) specific tissue recovered; and
9) other available relevant medical records.

The tissue bank or agency recovering the tissue shall provide a record of the tissue recovered, date of recovery, name and address of the recovery agency, and name of the donor to the recovery site facility.
(A) The following information regarding autologous tissue recovery shall be documented:

1) name and address of the institution in which the autologous tissue was recovered;

2) date and time the autologous tissue was recovered;

3) name of the physician recovering the autologous tissue;

4) donor name, age, sex, and hospital medical record number and/or social security number; and

5) type of tissue recovered.

D5.720 Delivery and Post-Delivery Records

Details of the delivery and post-delivery time period through acquisition shall be documented in the donor’s record. These records shall include, but not be limited to the:

1) birth mother’s name;

2) infant donor’s gestational age;

3) name and address of the health care facility and the identification of the delivery environment/location;

4) date and time of the delivery;

5) the physician or other authorized practitioner involved with the delivery, or designee as permitted by law;

6) information to allow tracking of critical reagents, supplies and materials provided by the tissue bank;

7) specific tissue(s) acquired;

8) other available relevant medical records; and

9) documentation of any errors, accidents, or deviations that occurred.

D5.800 Packaging, Labeling, and Transport

D5.810 Post Recovery Packaging and Labeling

Immediately following recovery of each individual tissue at the recovery site, recovered tissue shall be individually and aseptically wrapped or enclosed and shall be immediately labeled with the unique donor identifier and the description according to the SOPM (see G1.100). Tissue shall be maintained at defined environmental temperatures until the time of transport to the processing center. Maintenance of such
temperatures shall be documented. The receptacle/transport package must be designed to prevent contamination of the contents and allow for aseptic presentation of the tissue at the time of processing.

(A) Immediately following recovery of the autologous tissue, it shall be individually and aseptically wrapped. The package shall be labeled immediately with definitive autologous donor identifying information such as the patient’s name, hospital registration number, security number, birth date, etc., and shall be prominently labeled “FOR AUTOLOGOUS USE ONLY.”

(C) Recovered cardiac tissue shall be rinsed and packaged in an isotonic, sterile solution such as normal saline, lactated Ringer’s solution, PlasmaLyte®, transplant organ perfusate (e.g., Belzer’s UW solution, Collin’s solution) or tissue culture media, immediately following recovery. The volume of the transport solution should be adequate to cover the entire heart, including the vessels and valves. The type, lot number, manufacturer, and expiration date shall be documented.

(V) Immediately following recovery, vascular tissue shall be gently flushed and packaged in an isotonic sterile solution such as tissue culture media. Normal saline solution should not be used. The type, lot number, manufacturer, and expiration date of all reagents used for recovery and packaging shall be documented.

(S) 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.

D5.820 Post Delivery Packaging and Labeling

(BT) Following delivery, tissue shall be aseptically contained. Labeling that includes a unique donor identifier and the description according to the tissue bank’s SOPM (see G1.100) shall be performed prior to transport. The receptacle/transport package must be designed to prevent contamination of the contents and allow for aseptic presentation of the tissue at the time of processing.

Tissue shall be maintained at defined environmental temperatures until the time of transport to the processing center. Maintenance of such temperatures shall be documented.

D5.830 Tissue Transport

Tissue shall be transported in a manner established by the tissue bank that permits required environmental conditions for the duration of transport necessary to maintain the integrity of the tissue for its intended use. Transportation temperatures do not require verification if the packaging and transport conditions have been validated to maintain the required environmental conditions, including temperatures. The receptacle/transport package must indicate that “DONATED HUMAN TISSUE” is enclosed and must include the name and address of the originating agency and processing center (if
different). All human tissue processed or shipped prior to determination of donor eligibility 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, LD, CT) When wet ice temperatures would be injurious to the tissue recovered, it may be transported at appropriate temperatures and within time limits that maintain the quality of the tissue for its intended use.

(C, V) The transport package shall be transported at wet ice temperatures. Time of acceptance of the tissue into the processing center shall be documented. Cardiac tissue and vascular tissue 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 a time limit established by a validated procedure that maintains tissue quality.

(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 a time limit established by a validated procedure that maintains tissue quality.

(S) If the tissue is to be cryopreserved, the skin transport package shall be transported at wet ice temperatures or packaged by another method that maintains the quality of the tissue for its intended use.

D5.900 Reconstruction of a Deceased Donor’s Body

Unless there is a specific request from a medical examiner, pathologist, or a funeral home, the surgical incision(s) shall be closed in an aesthetic fashion and the deceased donor’s body prepared for the next portion of the recovery or for transportation to an appropriate facility. The donor’s body shall be reconstructed in accordance with the SOPM. Reconstruction should employ techniques consistent with funeral home guidelines and/or medical examiner or pathologist requests. Documentation of donor reconstruction (if applicable) and disposition of the donor’s body shall be maintained in the donor’s record.

D6.000 STORAGE OF TISSUE

Storage, including temporary storage, of recovered, acquired, or collected tissue shall be in conformance with storage temperature and monitoring expectations provided by the tissue bank that will process the tissue. See C1.300, E3.330, E3.331, and E3.340.

D6.100 Quarantine Controls

Adequate controls must exist to prevent mix-ups, contamination, cross-contamination, and ensure tissue is identified as acceptable or unacceptable during all stages of recovery,
receipt, storage, processing and distribution. If physical segregation is deemed unnecessary, justification must be established, and must include a risk assessment and use of a validated electronic system. Considerations for the risk assessment shall include:

1) potential severity of impact if controls fail to prevent mix-up, contamination or cross-contamination;
2) probability of failure to occur;
3) likelihood of identifying a failure before it reaches a customer;
4) existing controls to prevent failure; and
5) back-up plan for failure of validated electronic system.

If physical segregation is deemed necessary, segregated areas must be appropriately labeled.

D6.200 Segregation

The SOPM must address when the segregation of tissue during storage is indicated and how it will be appropriately segregated to avoid contamination, cross-contamination and mix-ups.

Considerations for assessment of risk include, where applicable:

1) donor infectious disease test results are unavailable or this testing will not be performed;

2) the intended use of the tissue is primarily for transplantation or is restricted to research or education;

3) autologous tissue is segregated from allogeneic tissue;

4) the donor has been determined to be ineligible;

5) the ability of packaging and labeling to withstand storage temperatures, and/or

6) the ability to decontaminate storage equipment or the storage area should an accident occur.

Appropriate segregation must include considerations above and storage must be in clearly defined and labeled areas (shelves or compartments) of the storage equipment or storage area.

D6.300 Storage Equipment

Freezers and refrigerators used for storing tissue shall be regularly maintained, calibrated, and monitored according to written QC procedures. See the series of standards at J5.000.
SECTION E
PROCESSING AND STORAGE

E1.000 RECEIPT OF TISSUE AT PROCESSING/STORAGE FACILITY

Approval or rejection of the receipt of tissue into the processing or storage facility must be documented. The receipt and movement into storage, to immediate processing or to removal, shall be documented, including, at a minimum:

1) the condition of the transport package;

2) confirmation each tissue is labeled with a tissue identification number, or other traceable unique identifier;

3) evidence proper environmental conditions were maintained (e.g., presence/absence of ice/coolant). Refer to H3.300;

4) the date and time of receipt and movement; and

5) personnel involved.

E1.100 Tissue Identification

Except for reproductive tissue, each unit of tissue shall be assigned a tissue identification number, which shall serve to relate the tissue to the donor from whom it was recovered or acquired and the associated records at any phase (e.g., quarantined, unprocessed, processed inventory) of the operation. Tissue units shall be assigned the same tissue identification number only if they are identical and processed as a lot.

(R) Reproductive tissue donors and client depositors shall be assigned a unique identifier, which shall be used to identify the tissue during steps of collection, processing, storage, and distribution. The unique identifier can be a directed donor’s or a client depositor’s name. For donors and client depositors giving multiple specimens, a secondary code shall be used to distinguish between dates of collection. The reproductive tissue bank that collects and processes the reproductive tissue shall be identified by name, code, or other identifier on the final container.

E1.200 Pooling

Tissue from multiple donors shall not be pooled during processing, preservation, or storage.

E2.000 PROCESSING

Processing and preservation methods shall be established in accordance with Standards and applicable laws and regulations. All tissue shall be processed, preserved, quarantined, and/or stored pursuant to such methods so as to render them suitable for clinical use.

(A) If autologous tissue is not to be processed, it should be retained in its original wrapping.

(C, V) Processing shall include a disinfection period followed by rinsing, packaging, and preservation.
**E2.100 Tissue Evaluation**

Written criteria for evaluation and assessment of tissue quality must be established.

(C, V, OA)

A standardized evaluation and classification system is required that describes the attributes of each allograft. A detailed description of the condition of the allograft shall be recorded in the permanent donor processing records. The allograft evaluation system shall be made available to the implanting surgeon.

**E2.200 Processing Environment**

Except for reproductive tissue, when tissues are exposed to the environment during processing, these activities shall be consistent with the requirements of aseptic processing. There shall be demonstrated and documented evidence that the chosen environment achieves the quality and safety required for the type of tissue, processing, and intended use.

Without a subsequent validated microbial inactivation process, aseptic processing shall be performed in a certified and qualified bacteriologically and climate-controlled environment.

**E2.210 Environmental Control and Monitoring**

Where environmental conditions could reasonably be expected to cause contamination or cross-contamination of tissue or equipment, or accidental exposure of tissue to communicable disease agents, there must be adequate environmental control and monitoring of viable and non-viable particles under dynamic as well as static conditions. Effectiveness of these controls shall be validated. See AATB Guidance Document No. 5.

Adequate control is defined by justifying and documenting the following:

1) type and frequency of environmental monitoring;
2) when the samples are to be taken (e.g., during or at the conclusion of operations);
3) sampling locations and number of sites to be sampled;
4) sample duration;
5) sample size (e.g., surface area, air volume);
6) action and alert levels for test results; and
7) potential corrective actions when alert and/or action levels are exceeded.

**E2.300 Tissue Contamination**

Written procedures shall be prepared, validated, and followed for control and prevention of contamination or cross-contamination by tissue during processing.

**E2.400 Reagents, Supplies, Materials and Equipment**

All critical supplies, reagents, materials, and equipment approved for use for processing and preservation shall be identified and specifications (e.g., sterile where applicable) documented. It
is expected that the tissue bank has the ability to link all supplies, reagents, materials, and equipment to tissue processed over the period of time they were in use.

A record shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, lot number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of staff performing the inspection. Unless otherwise qualified/validated, all reagents, supplies, materials and equipment shall be used and stored in accordance with manufacturers’ instructions.

All non-disposable surgical instruments and mechanical/electrical equipment used in tissue processing shall be cleaned, decontaminated, and, where applicable sterilized, between use for tissue from different donors according to written procedures. For non-disposable surgical instruments and mechanical/electrical equipment deemed critical, written procedures must be prepared and methods shall be validated, to prevent contamination or cross-contamination during processing. Adequate controls must exist to prevent mix-ups between acceptable and unacceptable items.

**E2.410 Stock Rotation**

Reagents, supplies, and materials with expiration dates or production dates shall be stored in a manner to facilitate inventory rotation. Items not bearing an expiration or production date shall be labeled with the date of acquisition and stored in a manner to facilitate inventory rotation. Older items should be used first and not used if expired or quality is compromised.

**E2.420 Containers**

**E2.421 Physical Properties**

The container shall maintain its integrity, withstand sterilization and storage conditions, not produce toxic residues during storage, and maintain tissue quality through the labeled expiration date. Containers shall not interfere with the effective use of appropriate agents applied to sterilize or disinfect the tissue.

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.

(C, V) Final packaging containers shall be adequate for use at defined storage temperatures and documented to remain stable and impervious to microbial particles under normal environmental conditions at the specified temperature and throughout the recommended thawing regimen.

**E2.422 Receipt of New Shipments**

Containers shall be stored under quarantine until the containers have been tested, sampled, or examined, as appropriate, and released for use. Containers not meeting specifications shall not be used.

**E2.423 Storage**
Unused containers shall be handled and stored to maintain integrity.

**E2.424 Integrity and Sterility**

Sterilized containers shall be handled in a manner to preclude contamination.

**E2.425 Visual Inspection**

Each container shall be examined visually for damage or evidence of contamination prior to use and immediately after filling. Containers not meeting visual criteria shall not be used.

**E2.500 Processing Methods**

Tissue shall be processed using validated methods to prevent contamination and cross-contamination and to maintain tissue quality for its intended use.

**E2.520 Time Limits for Pre-processing, 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 and validated with reference to tissue quality. Additionally, a time limit and temperature for pre-processing quarantine storage that address tissue quality must be established and justified.

(C, V) Disinfection of cardiac and vascular tissue shall be accomplished via a time-specific, validated process (disinfection time). The total ischemic time shall not exceed 48 hours.

(R) After collection, analysis shall be performed within an appropriate time period, and processing, if performed, shall be initiated within a time period appropriate for retention of functional quality, as specified in the SOPM.

(S) When preservation of cellular viability is desired, processing of skin shall be initiated within 10 days of recovery, provided the skin is placed in tissue storage media that is replaced at least every 72 hours. If the media is not changed, processing shall be initiated within 96 hours of recovery.

**E2.530 Prevention of Matrix Deterioration**

(C, V, OA, S) To prevent drying and possible cellular and extracellular matrix deterioration, the tissue shall be kept moist at all times during processing using a sterile solution/medium. If drying does not impact quality for intended use (e.g., decellularized dermis), the requirement to prevent drying is not applicable.

**E2.540 Additives**

When applicable, the type, amount, concentration, and method of incorporation/addition of all media, cryoprotectants, and any other additives used in processing shall be specified in the SOPM. This information about the allograft shall be made available to the implanting/transplanting physician, upon request.
E2.600 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 tissue bank shall determine when, which, and how controls are to be performed (e.g., residual moisture testing, microbial cultures of tissue, solutions, packaging, 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. Procedures and any changes in these procedures shall be reviewed to ensure that such changes are verified, or where appropriate validated, before implementation.

E2.610 Tolerance Limits of Processed Tissue

Tissue banks that process tissue shall include in their SOPM a description of the final types of tissue, any specifically required or specifically prohibited dimensions or characteristics, and the means used to assess these characteristics. At or near the end of processing, tissue shall be evaluated according to these procedures to determine whether it is in conformance with the SOPM. Relevant tissue dimensions or characteristics shall be recorded. All tissue deemed to be out of conformance shall not be released for transplantation.

This inspection, the staff involved, and the disposition of each tissue unit shall be documented.

E2.611 Tissue Measurement

Tissue measurement shall be performed and documented and must include the quantity or other characteristics of the tissue expressed as applicable (e.g. volume, weight, dimensions, cell density, number of viable cells or a combination of these).

(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 the left and right pulmonary arteries shall be recorded in millimeters (mm) or centimeters (cm).

(V) Vascular tissue grafts shall be inspected, evaluated, and sized by diameter and recorded in millimeters (mm).

The length of the vascular segment shall be recorded in centimeters (cm).

(MS, OA)
Radiographic techniques may be used as needed.

E2.612 Calcium Residuals: Demineralized Bone

(MS) Unless bone is treated by a validated process to reduce minerals, representative samples of each lot shall be tested for residual calcium by
a standard method.

Residual calcium content for bone labeled as demineralized shall not exceed 8% by a standard method.

For bone that has been subjected to a demineralization process with a residual calcium content target that exceeds 8% when tested, the tissue must not be labeled as demineralized and should be labeled as partially demineralized to describe the extent of demineralization.

E2.620 In-House Laboratory Testing

If the tissue bank performs laboratory tests and results are used to determine acceptability of tissue for transplantation, the requirements at K2.100 and K2.200 shall apply.

E2.621 Laboratory Records

Records of in-house laboratory testing shall include, at a minimum:

1) sample source and quantity;
2) tissue identification number;
3) test date and identification of the person performing the test;
4) assay methods;
5) calculations, graphs, and charts, if used;
6) test results as well as interpretation of results;
7) testing or standardization of reference standards, reagents, or standard solutions; and
8) record review by an individual other than the operator generating the records to ensure compliance with Standards.

E2.700 Tissue Preservation

E2.710 Lyophilization

Validated procedures for lyophilizing tissue shall be established and described in the SOPM. Each lyophilization cycle shall be monitored and recorded for shelf temperature, condenser temperature, and vacuum. Residual moisture measurement shall not exceed a limit linked to tissue quality. The analytical method selected must be validated for its intended use. The final container shall maintain these moisture requirements for the indicated expiration period.

E2.720 Dehydration/Desiccation

Validated procedures for dehydration or desiccation of tissue shall be established and described in the SOPM. Quality control parameters shall be established and verified for each batch.
If a residual moisture limit has been established for finished tissue, the container shall maintain the limit for the duration of the expiration period. The residual moisture level shall not exceed a limit linked to tissue quality. The analytical method selected must be validated for its intended use.

E2.730 Freezing Tissue

Procedures for freezing tissue shall be established and documented to maintain tissue quality.

E2.740 Cryopreservation

Except for reproductive tissue, tissue to be cryopreserved must be frozen at a controlled and monitored, predetermined rate with compensation for heat of crystallization/latent heat of fusion to a predetermined end-point. Documentation of the concentrations of cryoprotectant and nutrient or isotonic solutions in the cryopreservative solution shall be maintained. When applicable, procedures for cryopreservation shall be established and the method controlled to maintain tissue quality.

(R) Procedures for cryopreservation of reproductive tissue shall be established and documented. If a controlled rate chamber is being utilized, the thermal profile for each cryopreservation cycle shall be logged with the specimen records.

E2.741 Control-Rate Freezing: Surrogate Packages

If surrogates are used for monitoring the freezing program, the packaging shall be regularly inspected and solutions and tissue changed when indicated. Monitoring for deterioration of the packaging shall be performed. The processing center shall have a procedure describing the assembly of such surrogates and a means for monitoring their integrity.

E2.742 Termination of Freezing Program

Upon termination of the freezing program, the cryopreserved tissue shall immediately be placed in storage. Temperature fluctuation and cycling should be avoided.

E2.743 Freezing Profile

If a programmed control-rate freezing method is employed, a record of the freezing profile shall be evaluated and approved and become a permanent part of the processing records.

E2.750 Chemical Preservation

(BT, MS)

Procedures for the preservation of tissue by chemical means shall be validated and documented. When chemical preservation has been used, the package insert shall so indicate.

E2.800 Sterilization/Disinfection of Tissue

Individual processing facilities shall establish, validate, and document disinfection or sterilization
regimens and microbial surveillance methods. The SOPM shall establish a list of organisms that 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 and rendered culture negative).

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

(C, V, CT)  
1) Clostridium;
2) fungi (yeasts, molds); and  
3) Streptococcus pyogenes (group A strep.).

(MS, OA)  
1) Clostridium; and  
2) Streptococcus pyogenes (group A strep.).

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

E2.810 Non-Terminal Irradiation  
A dose is selected to reduce or eliminate bioburden. The selected dose shall be justified and any claims made must be supported by data. The type of irradiation shall be indicated on the container label or package insert of all tissue exposed to non-terminal irradiation.

E2.820 Terminal Sterilization by Irradiation  
The most common sources of ionizing radiation are Cobalt 60, electron beam, and X-ray. Identification of the irradiation source, the dosimetry, and completed certificate of irradiation shall be documented in the processing record. The sterilization dose used must be validated and supported by data. A sterility assurance level (SAL) shall be selected and the sterilization dose must be shown to be capable of achieving that SAL.

Validation methods generally are bioburden-based methods (e.g., AAMI/ISO 11137), but other methods can be justified. The type of irradiation shall be indicated on the container
label or package insert of all tissue exposed to irradiation.

E2.830 Sterilization by Other Methods

*Tissue sterilization* by other methods (other than by irradiation) *shall* be documented in the *processing record*. This includes the type of *sterilization*, the *processing parameters*, and certification of *sterilization*. The process utilized to *sterilize* the tissue *must* be *validated* and supported by data. A *sterility assurance level* (SAL) *shall* be selected and the method *must* be shown to be capable of achieving that SAL. *Validation* methods generally are *bioburden-based* methods (e.g., AAMI/ISO 11137), but other methods can be justified. The type of *sterilization* method used *shall* be indicated on the *container label* or *package insert* of all tissue exposed to the method.

Following ethylene oxide *sterilization*, procedures *shall* be established to ensure appropriate aeration has eliminated residual ethylene oxide and/or its breakdown products.

<table>
<thead>
<tr>
<th>Residual Level in Parts per Million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue Size/Weight</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Very Small (&lt;100 mg)</td>
</tr>
<tr>
<td>Small (&lt;10 grams)</td>
</tr>
<tr>
<td>Medium (10–100 grams)</td>
</tr>
<tr>
<td>Large (&gt;100 grams)</td>
</tr>
</tbody>
</table>

E2.840 Disinfection by Chemical Agents

(MS) Iodophors, ethanol, and other solvent/detergent combinations *may* be used as *disinfectants* of bone in a *validated processing procedure*. In any instance where a chemical *disinfectant* or antibiotic agent is used, the *container label* or the *package insert* *shall* identify presence of possible trace residuals. Refer to G3.120.

E2.850 Other Disinfection Agents

(BT, MS) Other agents such as heat, ultraviolet radiation, or exposure to antibiotics *may* be used as *disinfection* agents. *Procedures* for *processing* with such agents *shall* be documented and *validated* to ensure consistency in *tissue processing*.

E2.900 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) the type, lot number, manufacturer (unless recorded in other records), and expiration date, where applicable, of critical reagents, supplies and materials, and the identification of critical equipment, used to process and/or preserve tissue.

E3.000 STORAGE

E3.100 Quarantine

E3.110 Quarantine Controls

Refer to D6.100 for requirements related to quarantine controls.

E3.120 Situations Requiring Quarantine

Human tissue shall be quarantined until the tissue is either determined to be suitable for processing, transplantation or another appropriate disposition is accomplished. All tissue shall be quarantined until the following criteria for donor eligibility are satisfied:

1) all required infectious disease testing has been completed, reviewed by the responsible person, and found to be negative or non-reactive; and

2) donor screening has been completed, reviewed by the responsible person, and determined to indicate freedom from risk factors for and clinical evidence of HIV, hepatitis B, and/or hepatitis C infection.

Tissue shall be quarantined at any phase of the operation when its release could affect the safety, effectiveness, or quality of the tissue, and subsequently, the health of the recipient.

The following tissue shall be quarantined:

1) tissue that is pending completion of processing, packaging, preservation, or labeling and final-release-approval signature;

2) tissue recovered, collected, or acquired from donors not meeting established donor eligibility criteria, including unacceptable test results;

3) tissue involved in a recall pending investigation, documentation, and resolution;

4) tissue failing to meet technical or quality assurance specifications;

5) tissue pending discard as medical waste; and

6) tissue returned by a consignee, pending evaluation.

E3.130 Labeling Quarantined Tissue

All human tissue processed or shipped prior to determination of donor eligibility must be
under quarantine. Such tissue shall be accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation. Tissue determined to be unsuitable for transplantation and intended for release for other purposes shall be identified accordingly.

E3.140 Quarantine Records

Quarantine records for tissue quarantined post-release shall indicate the reason for quarantine and the final disposition of the tissue. Release dates or disposal dates shall be indicated as well.

E3.200 Segregation of Tissue

(R) Cryopreserved reproductive tissues from untested client depositors shall be stored in a physically separate area clearly defined from those of tested client depositors. Tissues from client depositors known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, or HBsAg or any other test excluding CMV without subsequent negative confirmatory testing as approved by the reproductive tissue bank’s Medical Director shall be stored in a physically separated area clearly identified from tissue of seronegative client depositors. See F2.200 for documentation required for release.

E3.300 Storage Temperatures

Each tissue bank shall establish acceptable temperature-range limits for the storage of tissue before and after processing in accordance with these Standards, applicable laws and regulations and in consideration of tissue quality and the packaging system for the tissue.

(A) Storage temperatures and conditions shall be the same as for comparable allogeneic tissue. Any exception shall require written approval of the Medical Director of the tissue bank.

E3.310 Frozen and Cryopreserved Tissue

(MS, OA) Procedures for storing processed frozen and cryopreserved tissue to ensure graft safety and quality shall be written. Processed frozen or cryopreserved musculoskeletal tissues shall be stored at temperatures of -40°C or colder. Temporary storage of processed frozen or cryopreserved musculoskeletal tissue between -20°C and -40°C is limited to six months total.

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

(R) Reproductive tissues shall be stored either in liquid nitrogen or in the vapor phase of liquid nitrogen.

(S) Frozen or cryopreserved skin shall be stored at ultra-low (-40°C or colder) temperatures.

E3.320 Lyophilized/Dehydrated/Desiccated Tissue

Lyophilized, dehydrated, or desiccated tissue must be stored at ambient temperature or colder.
E3.330 Monitoring Storage Temperatures

A temperature monitoring system shall be utilized to document temperatures and to alert staff when temperatures have strayed outside acceptable limits. Procedures shall be in place for reviewing temperatures. Documentation of such review shall be indicated with the reviewer’s initials and the date. If temperature recording charts are used, they shall be initialed and dated when placed on and also when removed from the storage unit. Completed charts shall be retained for the duration specified in C1.300. If storage utilizes liquid nitrogen, either liquid nitrogen levels or temperature shall be monitored and documented at an interval specified in the SOPM.

E3.331 Storage Conditions for Commonly Transplanted Human Tissue

<table>
<thead>
<tr>
<th>Human Tissue</th>
<th>Storage Conditions</th>
<th>Temperature (°C) *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth tissue (BT)</td>
<td>Frozen, refrigerated, cryopreserved, lyophilized, dehydrated, desiccated</td>
<td>Established by the tissue bank</td>
</tr>
<tr>
<td>Cardiac (C), vascular tissue (V)</td>
<td>Frozen, cryopreserved</td>
<td>-100°C or colder</td>
</tr>
<tr>
<td>Cellular tissue (CT)</td>
<td>Refrigerated</td>
<td>Above freezing (0°C) to 10°C</td>
</tr>
<tr>
<td></td>
<td>Frozen, cryopreserved</td>
<td>Established by the tissue bank</td>
</tr>
<tr>
<td>Musculoskeletal tissue (MS), osteoarticular graft (OA)</td>
<td>Refrigerated</td>
<td>Above freezing (0°C) to 10°C</td>
</tr>
<tr>
<td></td>
<td>Frozen, cryopreserved (temporary storage for 6 months or less)</td>
<td>-20°C or colder to -40°C (this is warmer than -40°C but colder than -20°C)</td>
</tr>
<tr>
<td></td>
<td>Frozen, cryopreserved (long term storage)</td>
<td>-40°C or colder</td>
</tr>
<tr>
<td></td>
<td>Lyophilized, dehydrated, desiccated</td>
<td>Ambient **</td>
</tr>
<tr>
<td>Reproductive tissue (R)</td>
<td>Frozen, cryopreserved</td>
<td>LN₂ (Liquid or Vapor Phase)</td>
</tr>
<tr>
<td>Skin (S)</td>
<td>Refrigerated</td>
<td>Above freezing (0°C) to 10°C</td>
</tr>
<tr>
<td></td>
<td>Frozen, cryopreserved</td>
<td>-40°C or colder</td>
</tr>
<tr>
<td></td>
<td>Lyophilized, dehydrated, desiccated</td>
<td>Ambient **</td>
</tr>
</tbody>
</table>

* Warmest target temperature unless noted to be a range
**Ambient temperature monitoring not required for lyophilized, dehydrated, or desiccated tissue

E3.340 Emergency Transfers

Policies and procedures shall be developed for the emergency transfer of tissue to designated alternative storage facilities and for alternative monitoring methods in the event of mechanical failure or loss of coolant. These shall include specification of tolerance limits or temperatures and time limits after which the initiation of the
emergency transfer is required. Actions to be taken when limits have been exceeded shall also be specified in the SOPM.

E3.400 Expiration Date/Storage Period

The maximum storage period for tissue shall be appropriate to the type of tissue, method of preservation, required storage temperature, packaging, and processing, as well as to its intended application. Expiration dates shall be qualified to demonstrate that the packaging system or container is suitable to maintain tissue quality (e.g., sterility, moisture content) through the expiration date.

(A) The implantaing physician shall be informed of any expiration dates.

E3.410 Refrigerated Tissue

(A) Autologous skin that has not been processed or preserved should be stored refrigerated for no longer than 14 days.
SECTION F
TISSUE RELEASE

F1.000 TISSUE RELEASE

Prior to release of tissue for transplantation, the Medical Director or licensed physician designee shall determine donor eligibility. All necessary information shall be complete and compiled in a standardized format prior to final review and determination of donor eligibility and tissue acceptability for transplantation. Each donor record shall contain a disposition/release statement and signature of both the Medical Director or licensed physician designee who is assuming responsibility for donor eligibility 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 by designated personnel of all technical and quality control specifications. An SOPM shall clearly define the responsibilities of each reviewer.

F1.100 Donor Eligibility Review

The eligibility of each donor shall be determined by the Medical Director or licensed physician designee upon review of all records as specified below and in accordance with the SOPM.

Although the donor risk assessment interview may be preliminarily reviewed by technical staff to evaluate acceptability for recovery, acquisition, collection, or processing, tissue shall not be released for transplantation without determination of donor eligibility by the Medical Director or licensed physician designee.

F1.110 Records for Review

The Medical Director or licensed physician designee shall determine donor eligibility based on a review and evaluation of the donor’s relevant medical records or a summary of these generated by a trained individual. The determination of eligibility shall be based on the SOPM, these Standards and applicable laws and regulations. The donor eligibility review shall include, but is not limited to these records:

1) acceptability of the authorization or informed consent;

2) suitability of the recovery site, delivery environment, or where collection took place;

3) pertinent information from the medical records generated at the time of death, including any pathology and laboratory reports, physician summaries, and transfusion/infusion information;

4) the donor risk assessment interview;

5) all results of laboratory testing relevant to donor eligibility;

6) any plasma dilution calculations used to determine the acceptability of the blood sample used for testing;

7) all relevant culture results up to and through the completion of recovery
(e.g., blood cultures, if performed; *pre-sterilization/pre-disinfection cultures*, if available);

8) applicable time limits for tissue recovery;

9) pertinent circumstantial and donor screening information relayed to tissue bank staff;

10) results of the physical assessment or physical examination;

11) the autopsy report, or a summary of findings, if an autopsy was performed; and

12) any other information gathered for the purposes of disease screening as required by Standards and applicable laws or regulations.

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 (RCDAD) and the mother’s blood must be tested. Refer to D4.100 (BT) for expectations to obtain the health status of the infant donor of birth tissue.

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

**F1.111 Absence of Third Party Records**

When no third party records are available that can be used to establish a likely cause of death, and if no autopsy was performed, a certified copy of the death certificate must be included in the donor record. If it is not possible to obtain a certified copy, a verified copy of the death certificate must be included in the donor record.

When third party records are available that can be used to establish a likely cause of death, or if an autopsy was performed, obtaining a certified copy or verified copy of the death certificate is voluntary.

**F1.112 Autopsy Report**

If an autopsy was performed, the tissue bank’s Medical Director or licensed physician designee shall review the autopsy report or a summary of findings prior to the release of tissue to inventory. If a copy of the autopsy report is not available for the donor’s record, the cause of death and other pertinent autopsy findings shall be documented in the donor’s record.

If it is determined that an autopsy was not performed due to infectious disease risk or, if an autopsy was performed, if any special precautions were taken that would suggest risk of a communicable disease in the donor, this information should be considered.
In the case of suspected Sudden Unexpected Infant Death (SUID), an autopsy should be performed and results reviewed to confirm the cause of death.

(DM) After the dura mater has been recovered, a qualified pathologist shall perform an examination of the donor’s brain. Following fresh examination, the brain should be fixed and sliced, gross examination of the entire brain should be conducted (including multiple cross sections), and multiple specimens of tissue should be obtained (from different parts of the brain, e.g., frontal and occipital lobes) for histological examination. The gross and histologic findings must be assessed for any evidence suggestive of transmissible spongiform encephalopathy (TSE).

F1.120 Infectious Disease Risk Review

Tissue shall not be distributed from a donor who, or a donor whose birth mother, has engaged in behaviors defined as high risk for transmission of relevant communicable disease agents or diseases (RCDADs). This information shall be obtained via a donor risk assessment interview, physical assessment or physical examination, and by review of other available relevant medical records.

The Medical Director or licensed physician designee shall not determine an allogeneic donor eligible with any of the following findings:

1) evidence of significant active infection at the time of donation for relevant communicable disease agents or diseases (RCDADs). These include, but are not limited to: septicemia, viral disease (e.g., HIV, viral hepatitis, West Nile virus, rabies, Ebola virus disease, Zika virus infection, etc.), human transmissible spongiform encephalopathies, untreated syphilis, clinically active tuberculosis, leprosy (Hansen’s disease) or systemic mycosis; and/or

2) risk factors for relevant communicable disease agents or diseases (RCDADs) as specified in Appendix II.

(R) Semen donors shall not exhibit an infectious skin disease that creates a risk of contamination of the semen. For all reproductive tissue donors, there shall not be evidence of infection within the past twelve months with Chlamydia trachomatis and/or Neisseria gonorrhoea unless the reproductive tissues are collected by a method that ensures freedom from contamination of the tissue by infectious disease organisms that may be present in the genitourinary tract.

F1.130 Other Medical Conditions

In addition to the infectious disease risk review, the Medical Director shall establish criteria and evaluate tissue donors for conditions that may adversely affect the safety or utility of the specific types of tissue processed and/or distributed by the tissue bank. Such conditions include, but are not limited to:

1) history of autoimmune diseases;

2) current or prior diagnosis of malignancy and the evaluation shall include the type of malignancy, clinical course, and treatment prior to acceptance;

3) ingestion of, or exposure to, toxic substances;
4) genetic, metabolic, traumatic, or infectious diseases that may adversely affect the quality of specific tissues;

5) previous surgery; and

6) diseases of unknown etiology.

**F1.140 Interpretation of Infectious Disease Test Results**

Disposition of allogeneic tissue shall be based upon the interpretation of all infectious disease test results and shall be as follows:

1) Human tissue shall be determined not to be suitable for transplantation if from a donor whose specimen has tested repeatedly reactive on an FDA-licensed, approved, or cleared donor screening test for anti-HIV-1, anti-HIV-2, HBsAg, anti-HBc, or anti-HCV. When a birth mother’s specimen is used for testing, these same rules apply.

2) Viable leukocyte-rich tissue (e.g., semen) shall be determined not to be suitable for transplantation if from a donor whose specimen has tested repeatedly reactive (RR) on an FDA-licensed, approved, or cleared donor screening test for anti-HTLV-I or anti-HTLV-II.

The eligibility of other human tissue for transplantation from donors whose specimens test RR for anti-HTLV-I or anti-HTLV-II shall be determined by the Medical Director.

Note: Law and/or regulation, including, where applicable, foreign laws and/or regulations, may differ in regard to a RR HTLV antibody test result and how this impacts the suitability of the donor’s tissues for transplantation.

3) Human tissue shall be determined not to be suitable for transplantation if from a donor whose specimen had a final test result of positive, repeat reactive, or repeatedly reactive on a screening test using a NAT assay. When a birth mother’s specimen is used for testing, these same rules apply.

4) If a laboratory that performs organ donor testing performs the initial testing in duplicate or triplicate, the tissue bank must obtain and review the results of all individual tests performed. If any one of those initial tests is reactive or positive, the tissue shall be determined not suitable for transplantation.

5) Tissue from a donor reactive for syphilis using an FDA-licensed, cleared, or approved non-treponemal screening assay may be used for transplantation only if the sample is found to be negative using an FDA-licensed, cleared or approved treponemal-specific confirmatory assay. If initial testing was performed using an FDA-licensed, cleared, or approved treponemal-specific assay and was reactive, the tissue shall not be used for transplantation.

6) If results of additional infectious disease testing are received for tests that are not required, such test results must be included in the donor’s record and any results
from those tests must be considered when determining donor eligibility. Procedure(s) shall be established for the interpretation of additional infectious disease test results.

NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority regarding test kit licensing/approval apply.

(A) Determination of the final disposition of tissue in which a donor’s blood sample tests positive is the responsibility of the autologous donor’s physician. If tissue from a donor who tests positive is to be stored in a tissue bank, refer to F3.200D6.100 and D6.200. (Announced 1/31/2020; Effective 7/31/2020)

(R) Determination of the use of client depositor and/or directed donor reproductive tissues in cases where required test results are positive or repeatedly reactive must be documented according to protocols described at F2.200 (see note for CMV below).

Tissue from an anonymous semen donor who tests reactive for an active, acute infection with cytomegalovirus (CMV) shall not be deemed suitable for use. Tissue from an anonymous semen donor determined to be in a latent CMV status may be acceptable. Each reproductive tissue bank shall develop a procedure for determining eligibility for both anonymous and directed donors. Procedures must also include provisions for communicating CMV status to the end-user physician such that a decision can be made regarding use of tissue from a CMV positive (total IgG plus IgM) donor.

Tissue from a donor testing positive for Chlamydia or Gonorrhea shall not be suitable for use.

F1.200 Technical Review

Tissue may be released for transplantation only with notation in processing records by responsible persons that tissue produced meets technical specifications set forth in the SOPM (e.g., dimensions, quality) and that processing was performed according to the SOPM. There must be a signature by technical staff indicating that all technical elements were reviewed.

For contractual processing arrangements, tissue shall be released for transplantation by the distributing tissue bank only with a signature and written disposition/release statement or equivalent documentation from the processing center indicating that all quality measures were reviewed and determined to be acceptable according to the written SOPM. The written disposition/release statement or equivalent documentation shall indicate that the following conditions, at a minimum, have been met:

1) review of tissue processed for consistency with specific tissue requirements;

2) review of all processing and packaging bacteriologic testing results for completeness and acceptability;

3) review for completeness and acceptability of any test or environmental testing results generated;
4) review of all lot numbers and expiration dates recorded for verification of completeness and that all were within acceptable ranges (e.g., recovery kits, culture media, processing solutions);

5) review of all processing records for completeness and accuracy, and verification that tissue was processed in accordance with the SOPM and met defined specifications;

6) review and comparison of tissue obtained and units produced from each tissue for verification that the disposition of each tissue recovered, acquired, or collected is traceable;

7) verification that all (if any) error and accident reports potentially related to the safety or quality of the tissue to be released are resolved and corrections made where appropriate;

8) verification that all processing was accomplished within time limits specified in the SOPM and within applicable technical specifications in the SOPM (e.g., acceptable residual moisture, irradiation exposure limits, temperatures, and freezing curves); and

9) if tissue was recovered or collected by another entity, verification that the shipment was acceptable when it arrived at the processing center (e.g., with respect to temperature and time limits).

(A) If autologous tissue is processed, the autograft may be released for clinical use only upon notation in processing records by technicians or their supervisor that processing was performed according to the SOPM. There must be a signature by technical staff indicating that all technical elements were reviewed.

F1.300 Quality Review

Except for reproductive tissue, tissue shall not be released for transplantation without a signed disposition/release statement from the responsible person(s) at the site of distribution, indicating that, at some time prior to release, all quality measures were performed and found acceptable according to the written SOPM. The written disposition/release statement or equivalent documentation shall indicate that the following conditions, at a minimum, have been met:

1) review of tissue processed for consistency with specific tissue requirements;

2) review and comparison of tissue obtained and grafts produced from tissue for verification that the disposition of tissue recovered is traceable;

3) verification that all (if any) error and accident reports, potentially related to the safety or quality of the tissue from each donor, are resolved and corrections made where appropriate;

4) verification that all processing was accomplished within time limits specified in the SOPM and within applicable technical specifications in the SOPM (e.g., acceptable residual moisture, irradiation exposure limits, temperatures, and freezing curves);

5) if tissue was recovered by another entity, verification of the acceptability of the shipment upon arrival at the processing center (e.g., with respect to temperature and time limits);

6) verification that the Medical Director or licensed physician designee has made a
decision regarding donor eligibility and that all directives of the Medical Director regarding the donor were implemented; and

7) verification that final labeling of tissue was performed in accordance with SOPM and Standards.

(R) Reproductive tissue shall not be released for clinical use without a signed, written disposition/release statement of the person responsible for authorizing release, at the site of processing, indicating that all quality measures were reviewed and found acceptable according to the written SOPM. This includes, but is not limited to:

1) review of donor age and of tissue processed for consistency with specific tissue requirements;

2) record and verification that all lot numbers and expiration dates were complete and that all were within acceptable ranges (e.g., cryopreservation media);

3) review of all processing records for completeness and accuracy and verification that the tissue was processed in accordance with the SOPM and meets defined technical specifications;

4) review of tissue obtained and specimens produced from each collection for verification that the disposition of each tissue specimen is traceable;

5) verification of resolution of all error or accident reports (if any) potentially related to the safety or quality of the tissue;

6) verification that all processing was accomplished within time limits specified in the SOPM and within applicable technical specifications in the SOPM (e.g., ejaculate volume, sperm motility, concentration, morphology, and post-thaw motility);

7) if reproductive tissue was collected by another entity, verification of the time of receipt at the reproductive tissue bank and condition of the sample upon receipt; and

8) verification that the Medical Director has made a decision regarding donor eligibility and that all directives of the Medical Director regarding the donor were implemented.

F1.310 Review of On-Site Processing Records

If processing was performed on site, there shall also be written documentation that all quality measures were performed and acceptable according to the written SOPM. This includes but is not limited to:

1) review of all processing and packaging bacteriologic testing results for completeness and acceptability;

2) review of all test or environmental testing results generated for completeness and acceptability;

3) review of all lot numbers and expiration dates recorded (e.g., materials such as recovery kits, culture media, processing solutions) for verification that all were
within acceptable ranges; and

4) review of all processing records for: completeness and accuracy; verification that tissue was processed in accordance with the SOPM; and conformance to defined technical specifications.

F2.000 OTHER RELEASE

F2.100 Tissue Release Based on Tissue Utility

Pre-established release criteria based on tissue utility must be developed. If tissue other than reproductive tissue is distributed or dispensed for transplantation, there shall be in each instance, documentation of:

1) donor eligibility and tissue processing information available at the time of release. All donor eligibility requirements in F1.100 must be met with the exception of a review of the autopsy report (if applicable) and pending culture results;

2) Medical Director or licensed physician designee review of all relevant information present;

3) approval of the release by the Medical Director or licensed physician designee;

4) a written statement issued to the end-user physician indicating what information required by the SOPM and/or these Standards is available and what information is not available for review, and when it is expected that the information will be available; and

5) a statement from the end-user physician indicating his/her understanding that the tissue is being released using available information.

Relevant final results shall be forwarded promptly to the end-user physician upon completion of testing. Documentation of the release based on tissue utility shall be maintained in the donor record. These records shall be maintained together or summarized in a log.

F2.200 Special Circumstances in Release of Reproductive Tissues

(R) Release of reproductive tissue may be considered in the special cases of:

1) reproductive tissues from client depositors known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, HBsAg, or any other test, excluding CMV, without subsequent negative confirmative testing as approved by the Medical Director; or

2) reproductive tissues from client depositors that have not been tested or do not meet current Standards; or

3) directed donors who have completed all required testing and screening according to Standard but:
   a) had reactive test results; or
   b) are determined ineligible according to screening criteria.

In the case of release for one of the three circumstances listed above, the following documentation is required (refer to G3.210 and G3.220 for labeling requirements):
1) a written statement signed by a responsible person at the reproductive tissue bank disclosing the deviation(s) from Standards and description of potential risks to the recipient; and

2) acknowledgement from the medical provider indicating he/she:
   a) has received the written statement from the reproductive tissue bank and acknowledges the deviation(s) from Standards;
   b) has had ample opportunity to discuss the implication(s) with a responsible person at the reproductive tissue bank and other medical authorities;
   c) agrees to fully explain the implication(s) to the recipient and provide her ample opportunity to ask questions and consult with experts of her choice; and
   d) will document informed consent from the recipient.

F2.300 Shipping Reproductive Tissue in Quarantine

If donor reproductive tissue is to be released before completion of the donor eligibility assessment, the tissue must be kept in quarantine during shipment. The labeling must include a statement that the donor eligibility assessment, has not yet been completed. It must also include a statement indicating the reproductive tissue must not be transplanted or transferred until the donor eligibility assessment, is complete.

F3.000 TISSUE FAILING REVIEW PROCESS

Tissue failing any portion of the review process shall be maintained in quarantine pending resolution or disposal and shall not be released for transplantation. Unexplained discrepancies or deviations from specifications shall be fully investigated and documented.

F3.100 Ineligible Donors

If a donor is deemed ineligible as a result of donor eligibility assessment or disease screening procedures, the finding shall be specifically stated in the donor record and in the release/disposition decision statement, and this determination must be described and communicated in writing in a timely manner to the tissue bank that recovered tissue. If the tissue is to be made available for nonclinical purposes from a donor who has been determined to be ineligible based on the results of required testing and/or screening, it must be labeled:

1) “For Nonclinical Use Only”; and
2) with the biohazard legend.

(SB) Permanent and temporary deferrals of living surgical bone donors and the reason(s) for such deferral shall be documented in the donor record.

F3.200 Technical or Quality Assurance Assessments

If tissue is deemed unsuitable for release for transplantation for reasons other than donor eligibility, the processing and release/disposition decision records shall specifically describe the reason(s) for the determination. If this tissue is to be made available for nonclinical purposes it
must be labeled ‘‘For Nonclinical Use Only.’’

F4.000 TISSUE TRANSFER

F4.100 Transfer to Distribution Inventory

Before tissue is transferred to distribution inventory, appropriate release documentation shall be verified. Tissue for transplantation may then be placed in distribution inventory. The identification of the tissue transferred, date of transfer, and staff performing the verifications and transfer shall be documented.

F4.200 Transfer to Other Inventory Locations

Disposition of tissue that is transferred shall be documented (e.g., discard, research, further processing). Date of transfer, staff involved, and verification of tissue identity shall also be documented.
SECTION G
LABELING

G1.000 LABELS AND LABELING

G1.100 Nomenclature

Nomenclature used to describe tissue, cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) shall be specified in the SOPM and be applied consistently. For finished tissue, units of measurement and the processing that tissue has received shall also be specified in the SOPM.

G1.200 Label List

A list of labels used shall be maintained, as well as an example of every label that is utilized by the tissue bank. Dates of use (start and discontinuance) shall be recorded. Changes pertaining to labels and communicating changes shall be expected from tissue banks that supply labels to other tissue banks and tissue distribution intermediaries.

G1.300 Labeling Integrity

Labels shall be designed and qualified to be legible, indelible, and affixed firmly to the container under anticipated storage conditions for length of use. See K1.200. Labels applied by tissue bank staff shall not be removed, altered, or obscured except to correct labeling errors. When applicable, this also applies to labeling materials. Suppliers of labels deemed critical are responsible for establishing specifications.

G1.400 Claims

All labeling claims shall be clear, accurate, substantiated, and not misleading.

G2.000 LABELING PROCESS

G2.100 General Requirements

There shall be SOPs established and followed to ensure that approved labels, labeling, and packaging materials are used for tissue. Tissue labeling shall be documented at each step (e.g., unprocessed, in-process quarantined, rejected, released.

G2.200 Relabeling

If tissue is to be relabeled for any reason, such as label detachment or to correct a labeling error, the tissue bank shall establish a relabeling procedure delineating the methods to be utilized, conditions under which tissue may be relabeled, and the staff authorized to perform such activities. The reasons for, and events surrounding, the relabeling of tissue shall be documented in the records. Relabeling methods shall consider storage conditions and label integrity (see G1.300).
G2.300 Controls

Labeling control procedures shall be established to ensure label integrity, legibility and accuracy, and the establishment of checks to prevent transcription and other labeling errors. Electronic labeling systems shall possess adequate controls to prevent the erroneous labeling of tissue. Labeling reviews and checks shall be documented and shall be included in the records. If a sampling plan is used, it must follow a statistically valid method, such as ANSI/ASQ Z1.4: Sampling Procedures and Tables for Inspection by Attributes. 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. The inspection of the area shall be documented and included in the records.

G2.310 Label Inspection

Labels shall meet written specifications and be approved by quality assurance staff prior to release for use by a designated person. Labels not meeting such specifications shall be discarded. Date of receipt, date of inspection, and the names of the staff involved in receipt and inspection shall be documented.

G2.320 Label Storage

The storage area for labels and labeling materials shall be clearly identified. Access should be restricted to authorized personnel only. This is not applicable to labels included in tissue recovery packs.

G2.330 Labeling Process Controls—Obsolete Labels

Procedures shall be established to retrieve obsolete and/or outdated labels and labeling materials from all labeling areas and inventory locations. As each type of label is removed from inventory, one label shall be retained for the archives and the surplus labels shall be discarded. The label list and the SOPM shall be updated accordingly.

G2.340 Tissue and Container Visual Inspection

Prior to labeling a unit of processed tissue, the container shall be inspected for evidence of impurities, defects, broken seals, or contamination that could compromise the quality, or safety of the tissue. A sufficient area of the container shall remain uncovered to permit inspection of the contents whenever possible. Any tissue or container suspected of not meeting specifications shall be quarantined immediately pending further investigation and resolution following established procedures in the SOPM. This review shall be documented.

G3.000 LABELING INFORMATION

G3.100 Container Labels

G3.110 Design

Container labels shall be designed to facilitate the use of uniform labeling techniques for each type of tissue.
G3.120 Content

Except for autologous tissue and reproductive tissue, container labels shall include:

1) the tissue identification number;

2) descriptive name of the tissue and other information necessary for selection or use (e.g., size, right/left, medial/lateral, anterior/posterior);

3) expiration date (if applicable), including the month, day, and year or, if only the month and year are used, the expiration date must be clearly described in labeling as occurring at the beginning or the end of the month;

4) storage conditions, including recommended storage temperature and/or storage temperature range;

5) quantity or other characteristics of tissue expressed as applicable (e.g., volume, weight, dimensions, cell density, number of viable cells or a combination of these);

6) a reference to the package insert.

The following information shall be included on the container label unless space limitations require use of a corresponding insert:

1) disinfection or sterilization procedure utilized (if applicable);

2) preservative (if utilized) and/or method of preservation (if applicable);

3) potential residues of processing agents/solutions (e.g., antibiotics, ethanol, ethylene oxide, dimethylsulfoxide); and

4) name(s) and address(es) of tissue bank(s) responsible for determining donor eligibility. processing and distribution. Should more than two tissue banks be involved, the name of all tissue banks are required but the address is only required for the tissue bank determining donor eligibility.

(A) The following information shall be included on the container label for autologous tissue unless space limitations require use of a corresponding insert:

1) the donor classification statement “AUTOLOGOUS DONOR”;

2) definitive autologous donor identifying information such as the patient’s hospital identification number, social security number, birth date, etc.;

3) a label or attached tag “FOR AUTOLOGOUS USE ONLY”; and

4) if infectious disease testing or donor screening is not complete or has not been performed, a label indicating “NOT EVALUATED FOR INFECTION SUBSTANCES” is required; or

5) if infectious disease testing was performed and any results were positive, or if donor screening was performed and risk factors identified, then labeling
with a “BIOHAZARD” label is required.

(R) Cryocontainers (e.g., vials, straws or ampules) shall be labeled so as to identify:

1) donor or client depositor unique identifier and/or other code that can be used by the reproductive tissue bank to identify the date the specimen was cryopreserved and the stage of development at cryopreservation, where applicable; and

2) name, initials, or other code that can be used to identify the reproductive tissue bank at which the specimen was processed.

G3.200 Summary of Records and Package Insert

Tissue determined to be suitable and released for transplantation shall be accompanied by a summary of records and package insert. A summary of records is not required if a donor eligibility determination is not required (i.e., autologous tissue and certain types of reproductive tissue).

G3.210 Summary of Records Content

A summary of records is required when donor eligibility assessment has been completed and shall include:

1) a statement that the tissue was prepared from a donor determined to be eligible based on the results of screening and testing. All results of relevant communicable disease tests performed on specimens from the donor and used for release of tissue shall be listed. Relevant tests include those tests that are required (see D4.230). For example, the CMV test result used must be listed for reproductive tissue. If a test for anti-HTLV I and/or anti-HTLV II was performed it must be reported;

2) the name and address of the establishment that made the donor eligibility assessment; and

3) a statement that the communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority having jurisdiction apply in regard to required labeling involving donor infectious disease test results.

(R) A statement noting the reason for the determination of ineligibility in the case of tissue from a directed donor who is ineligible based on screening and/or testing.
G3.220 Package Insert Content

The summary of records may be included in the package insert. The package insert shall contain the following information:

1) a statement limiting use to specific health professionals (e.g., physicians, dentists, and/or podiatrists);

2) a statement that the tissue is intended for use in one patient, on a single occasion only, or as is applicable for reproductive tissue;

3) known contraindications (if any) to the use of the tissue;

4) warnings and list of known possible significant adverse reactions;

5) a statement that adverse outcomes potentially attributable to the tissue must be reported promptly to the tissue supplier;

6) presence of known sensitizing agents (if any);

7) a statement that indicates that the tissue may transmit infectious agents;

8) a statement, if applicable, that the tissue may not be sterilized or re-sterilized.

9) dosage information (if applicable);

10) description of how the tissue was supplied (e.g., frozen, lyophilized, irradiated, demineralized or partially demineralized, see E2.612);

11) type of antibiotics present (if applicable);

12) concentration of preservative(s) and/or cryoprotectant(s) in final package solution (if applicable);

13) instructions for opening the package and/or container;

14) instructions for preparation of tissue for transplantation;

15) expiration time of tissue following reconstitution (upon preparation for use);

16) instructions indicating that once a container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded;

17) acceptable storage conditions and tolerance limits;

18) special instructions required for the particular tissue, when applicable (e.g., “DO NOT FREEZE,” “DO NOT X-RAY,” “DO NOT IRRADIATE”);

19) a statement that it is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant and that recipient records must be maintained for the purpose of tracing.
tissue post-transplantation;

20) a statement that the tissue is "DONATED HUMAN TISSUE," when applicable; and

21) effective date or other traceable version identifier.

NOTE: Except for client depositors, directed donors of reproductive tissues, and autologous tissues, the accompanying records required by this section must not contain the donor’s name or other personal information that might identify the donor.

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

1) warning against using a graft if there is evidence that the container has broken or the contents havethawed;

2) statement that the end-user 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);

3) donor age (and blood type, if available);

4) date of dissection or preservation;

5) tissue warm ischemic time;

6) tissue cold ischemic time;

7) graft sizes (e.g., diameter and length);

8) graft physical descriptions and evaluations, including description of imperfections and evaluation criteria;

9) the type of cryoprotectant (if applicable) and clear statement regarding the possibility of residuals;

10) a description of the temperature-sensitive nature of the grafts; and

11) instructions for preparation of tissue for use.

Center-specific protocols shall be established for control of proper thawing, removal of cryoprotectant, and restoration of isotonic balance within the cryopreserved tissue. These protocols shall be provided with each cardiovascular allograft distributed for transplantation.

The preparation instructions shall be sufficiently detailed and unambiguous to allow operating room personnel of average skill to follow and complete the procedure successfully.

(R) See F2.200 for additional requirements that may be applicable in certain directed
donor or client depositor situations.

Reproductive tissue in the following categories require additional information in package inserts as listed below:

1) If the intended recipient is the sexually intimate partner of the gamete provider(s):

   Note: a Summary of records is not required for this category.

   a) For all reproductive tissue, include the statement: “For use by Sexually Intimate Partner Only.”

   b) For all reproductive client depositors who were not tested or screened using all parameters required for either a semen or egg donor, including the required tests and time limits for donor testing, include the statements:

      1. “Not evaluated for Infectious Substances”; and

   c) For all reproductive client depositors who have reactive or positive test results:

      1. biohazard symbol; and
      2. “WARNING: Reactive test results for (insert name of test).”

2) If the intended recipient is NOT the sexually intimate partner of either gamete provider, the following labeling is required in addition to a summary of records:

   a) Directed donors (semen, oocyte, and/or embryo) with reactive test results:

      1. biohazard symbol;
      2. “WARNING: Reactive test results for (insert name of test)”; and

   b) Directed donors (semen, oocyte, and/or embryo) determined to be ineligible based upon risk factors for or clinical evidence of relevant communicable disease agents or diseases, including the physical examination:

      1. biohazard symbol; and
3) If the intended recipient is NOT the sexually intimate partner of either gamete provider, and the tissue is from anonymous or directed embryo donors in cases where the gamete provider(s) was (were) not initially tested as donors, but were re-tested following 6-month quarantine, include the statement: “Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive tissue, but have been performed subsequently.”

(Note: A summary of records is not required for this category, however, a summary of the test results must be included.)

4) If the intended recipient is NOT the sexually intimate partner of a gamete provider who initially cryopreserved reproductive tissue as a client depositor but was subsequently screened and tested as a directed donor in cases where additional collections are unavailable, include the statement: “Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive tissue, but have been performed subsequently.”

5) Reproductive tissue intended for research:
   a) Client depositor reproductive tissue when gamete provider(s) were not tested or screened using all parameters required for either a semen or egg donor, including the required tests and time limits for donor testing, or donor (anonymous or directed) tissue has not completed 6-month quarantine release requirement:
      1. “For Non-Clinical Use Only”; and
      2. “Not evaluated for Infectious Substances.”
   b) Anonymous donor tissue that has completed 6-month quarantine release requirement:
      1. “For Non-Clinical Use Only.”
   c) Client depositor or donor (anonymous or directed) tissue from gamete provider(s) who had reactive test results OR have been determined to be ineligible:
      1. biohazard label;
      2. “For Non-Clinical Use Only”; and
      3. if applicable, “WARNING: Reactive test results for (insert name of test).”

G3.300 Transport Package Label Content

G3.310 Domestic Shipments

The transport package label shall include the following information:
1) name, address and telephone number of the *distribution* facility;

2) name and address of the destination;

3) unless the shipment contains reproductive tissue, prominent identification of contents as “DONATED HUMAN TISSUE.”;

4) recommended storage conditions;

5) *validated* expiration date/time of the transport package when the storage temperature *must* be controlled;

6) type and quantity (when the quantity is applicable) of refrigerant or other hazardous materials enclosed in the transport package; and

7) any special handling instructions, when applicable (e.g., “DO NOT FREEZE,” “DO NOT X-RAY,” “DO NOT IRRADIATE”).

**G3.320 International Shipments**

*Labels for international shipments shall contain all of the information required for domestic shipments; however, information may be modified to meet requirements of the federal government and those of the receiving country.*
SECTION H
DISTRIBUTION AND DISPENSING

H1.000 DISTRIBUTION AND DISPENSING

There shall be SOPs for the following: receipt of tissue orders, unit selection, final container, and/or package inspection, shipping, and transportation of tissue for transplantation.

H1.100 Tissue Distribution and Dispensing Restrictions

Provision of tissue for transplantation shall be restricted to hospitals, free-standing medical facilities, tissue banks, tissue dispensing services, and end-users (e.g., physicians, dentists, podiatrists or other medical professionals) for use in recipients with the veterinary use exception that follows. Human tissue for transplantation shall not be offered, distributed or dispensed for veterinary use unless such use is specifically granted in a document of gift/authorization or in a record of informed consent. If tissue is provided to a tissue distribution intermediary, the tissue distribution intermediary shall meet the requirements of Section M of these Standards. Controls must exist to ensure distribution restrictions are met such as those found on the document of gift/authorization or in a record of informed consent. Distribution restrictions must be communicated to distributors. Periodic verification of activities performed by the tissue distribution intermediary shall be documented (e.g., a paper audit, on-site audit, on-site inspections, etc.). See B1.520.

H1.110 Client Depositor Authorization

(R) Reproductive tissue shall be released for use by the client depositor or the client depositor’s sexually intimate partner only. Prior to release of the specimens, a statement containing a verified signature from the client depositor shall be obtained indicating the relationship between the intended recipient and the client depositor.

Reproductive tissue for potential therapeutic insemination, use in another assisted reproductive technology procedure, or for other specified disposition shall be released as per written authorization of the client depositor, if of legal age or, if not, by that of parent, legal guardian, or his/her legally appointed designee.

H1.120 Reproductive Tissue Distribution Restrictions

(R) A client depositor who requests that his/her reproductive tissue be distributed to a recipient, who is not the client depositor or who is not the sexually intimate partner of the client depositor, shall be treated as a directed donor(s). All directed donor(s) must be fully tested and screened in a manner consistent with donor protocols and these Standards. If additional collections of reproductive tissue are unavailable due to the infertility or health condition of the now directed donor, appropriate measures should be taken to screen and test the directed donor prior to distribution (excluding testing for Neisseria gonorrhoea and Chlamydia trachomatis). Alternatively, the client depositor reproductive tissue may be distributed in quarantine with proper labeling to clearly identify the donor eligibility assessment is not yet complete. See F2.300.
Reproductive tissue shall not be distributed to private individuals unless the request is in the form of a physician’s written order for such distribution.

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.

H1.200 Distributing Tissue to Other Tissue Banks/Dispensing Services

When a tissue bank distributes tissue obtained from another tissue bank or tissue distribution intermediary, all accompanying original labeling materials or other enclosures shall be distributed with the tissue.

H1.210 Consignment Inventory Management

If tissue is provided on consignment, the distributing tissue bank shall maintain procedures to ensure traceability and that appropriate storage conditions are maintained during consignment, transfer or return.

H1.300 Requests for Donor Status and Tissue Processing Information

Donor risk assessment, tissue-related information, and tissue processing details shall be made available to the end-user upon request, except such information that may infringe upon the confidentiality of donor information.

H1.400 Distribution Records

Records shall be maintained by the tissue bank that distributes tissue (including unfinished or as yet unreleased tissue) to other entities. These records shall be designed to permit tissue to be traced from the donor to a consignee or end-user, and from a consignee or end-user back to the donor. Tissue distribution records shall include:

1) date of order placement;
2) name and address of consignee;
3) name of individual placing the order;
4) type and quantity of tissue ordered;
5) information pertaining to tissue shipped including:
   a) identification number(s) of tissue(s);
   b) collection and/or expiration date of tissue;
   c) date of shipment;
   d) type of refrigerant, and quantity of refrigerant when applicable, in the shipment;
e) mode of transportation and/or courier; and
f) name of the staff member filling the order.

6) identifying information, if available, about the intended recipient.

H1.410 Responsibility

The tissue bank shall establish recipient follow-up data collection protocols, and procedures to evaluate information received.

H2.000 TISSUE FOR RESEARCH

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. See the series of standards at D2.000 and D3.000.

H2.100 Written Requests

All requests for human tissue intended for research use shall be submitted in writing. The request shall indicate the type of tissue requested and how it will be used as well as the name, address and affiliation of the principal investigator accepting responsibility for receipt of the tissue.

H2.200 Review and Approval

Tissue requests for research purposes shall be reviewed and approved based on legal, ethical, and technical considerations defined in the SOPM.

H3.000 PACKAGING AND SHIPPING

H3.100 Solutions

Any specifically required solutions not readily available to the end-user that are needed to prepare the tissue for use shall be made available to the utilizing facility.

H3.200 Integrity

Packaging shall be designed to ensure tissue quality and prevent contamination of the contents of the final container(s).

H3.300 Tissue Storage Environment

Maintenance of defined environmental conditions during transit shall be required. Specific environmental conditions shall be in accordance with the SOPM, these Standards and applicable laws and regulations.

H3.400 Validation and Expiration of Transport Package

If tissue to be shipped requires specific environmental conditions other than ambient temperature, the capability of the transport package 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 package shall also be determined and documented. Expiration date (and time if applicable) of the transport package shall be noted on the outside of the transport package.

**H3.500 Quality Control of Reusable Shipping Packages**

If tissue to be shipped requires specific environmental conditions other than ambient temperature, and the transport package can be reused, QC monitoring of the transport packaging must be performed according to the SOPM to verify package integrity has been maintained. These QC checks shall be documented.

**H3.600 Pre-shipping Inspection**

Prior to shipping, packages shall be inspected to ensure the external packaging and labels are undamaged, the tissue is not expired and the tissue being shipped is consistent with the tissue requested. The exterior of the transport package shall be inspected to verify that requirements in G3.310 are met. These inspections shall be documented, including identification of staff conducting inspections.

**H3.700 Transportation**

The mode of transportation selected shall be determined by any special shipping and handling requirements of the tissue and/or shipping refrigerants, by shipping restrictions of commercial carriers, and the urgency of the tissue request.

**H4.000 RETURN OF TISSUE**

A tissue bank shall establish a policy authorizing or prohibiting the return of tissue in its original, unopened container. If returns are permitted, the integrity of the container, package, and labeling shall be examined for evidence of contamination or tampering. If there is any evidence of contamination, tampering, mishandling, or failure to maintain required storage temperatures, tissue shall not be returned to distribution inventory. Information pertaining to the return of tissue shall be recorded in the disposition records for that shipment of tissue as follows:

1) documentation of package and/or container examination;

2) documentation of end-user handling, storage, and shipping conditions;

3) reason for the return;

4) disposition of the returned tissue(s); and

5) date and name of the staff member authorized to evaluate and determine the disposition of the tissue(s).

**H4.100 Temperature Records**

For tissue that requires controlled environmental temperatures, at a minimum, documentation is required that attests the tissue was maintained at required storage temperatures.
H5.000 FIELD CORRECTIONS AND REMOVALS

_Tissue banks shall_ have specific written policies and _procedures_ for the initiation and performance of a _field correction_ or _removal_, if applicable. _Procedures shall_ include, but are not limited to, the following:

1) evaluation and determination by a _responsible person(s)_;  
2) timely identification and management of affected inventory;  
3) assessment of associated health risk;  
4) field communications (e.g., _field notification_);  
5) types of _field corrections_ or _removals_ (e.g., _recall_, _market withdrawal_) and _stock recovery_;  
6) reporting requirements;  
7) evaluation of effectiveness;  
8) termination or closure;  
9) documentation and _record_ requirements; and  
10) review by _management with executive responsibility_.

_Tissue banks_ not directly responsible for conducting _field corrections_ or _removals_, but that perform activities that could lead to the need for a _field correction_ or _removal_ (e.g., _tissue recovery_, _donor screening_, _donor testing_) _shall_ have policies and _procedures_ for the timely notification of all affected parties regarding information related to _tissue safety_ or regulatory requirements.

**H5.100 Circumstances That May Require Field Correction or Removal**

The need to perform a _field correction_ or _removal_ may be identified as a result of a _complaint_, _adverse outcome_, _accident_, _error_, _deviation_, _audit_, or by any other means. An evaluation to determine if _field correction_ or _removal_ is warranted _should_ be made whenever _distributed tissue_ may not meet specifications related to _safety_, _quality_, _traceability_, _identification_, _function_ and/or _use_. This evaluation _must_ consider both risk to health posed by the _tissue_ and applicable regulatory requirements, and be documented.

**H5.200 Notification Responsibilities**

Upon discovery of the need for _field correction_ or _removal_, 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.

**H5.300 Handling of Tissue**

_All_ _tissues_ not already _transplanted_, which are subject to _field correction_ or _removal_, _shall_ be located and _quarantined_ pending _resolution_ of the issue.

**H5.400 Reporting Requirements**

_Tissue banks shall_ comply with all _field correction_ and _removal_ reporting requirements for
applicable federal, state and international government/competent authorities under which they operate or distribute tissue.

For additional information, refer to FDA Guidance for Industry: Product Recalls, Including Removals and Corrections at:
http://www.fda.gov/safety/recalls/industryguidance/ucm129259.htm

**H5.500 Field Correction and Removal Records**

All information relating to the field correction or removal 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:

1) events precipitating the field correction or removal;

2) identification and location of affected tissue, including quarantine steps;

3) associated risk assessment;

4) type of field correction or removal (e.g., recall, market withdrawal) and stock recovery;

5) steps taken to correct or retrieve tissue;

6) documentation of all related communications (e.g., phone calls and/or written correspondence, including copies of field notifications or letters and a list of those to whom notice was sent);

7) final disposition of the tissue;

8) copies of reports to regulatory authorities, accreditation organizations and certification bodies, if required;

9) corrective actions recommended and implemented; and

10) documentation of review; 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)

Each tissue bank shall develop written detailed policies and procedures in a standardized 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 with these Standards and applicable laws or regulations.

J1.100 Identification and Control

Policies and procedures shall establish a document control system for procedures and forms including requirements for:

1) approval prior to use for intent and compliance to relevant regulatory requirements and standards;

2) reviewing revisions and re-approval as needed;

3) identification of the current revision status and of changes to previous revisions;

4) distribution to points of use (i.e., all locations where access to procedures is needed);

5) legibility and ease of identification; and

6) prevention of the unintended use of obsolete documents and suitable identification controls for archived documents.

J1.200 Contents

The SOPM shall specifically include, but shall not be limited to policies and procedures for:

1) informed consent or authorization, donor eligibility criteria, donor screening methods, time limits for tissue recovery, notification of confirmed positive test results, information sharing, construction of records, and, if applicable, reconstruction and final disposition of a deceased donor’s body (series of standards at C2.000, D2.000, D3.000, D4.000 and D5.000);

2) tissue collection, recovery, acquisition and handling, including recovery site assessment, recovery, materials management/supplies management, processing, packaging, quarantine, labeling, storage, donor eligibility review, and release of tissue (series of standards at D5.000, D6.000 and Sections E, F and G);

3) laboratory tests performed in-house, including establishment of appropriate specifications, standards, and test procedures to assure that tissue is safe and quality is addressed; and for contracted laboratory testing defining which tests shall be performed and how test results shall be received, reviewed, interpreted, and managed (B1.600, series of standards at D4.200, series of standards at F1.100, F1.200, F1.300 and F2.000, series of standards at K1.300, series of standards at K2.000);

4) purchasing controls, order receipt, finished tissue selection, final container inspection and packaging
and shipping of tissue, as well as criteria for returning and reissuing tissue (K1.300, series of standards at M3.000, M4.000, M5.000 and Section H);

5) external audits for services, suppliers, contractors, and consultants, when indicated (series of standards at K6.000, and K1.300 and B1.521);

6) record management to maintain traceability, retain records, and facilitate (if necessary) field corrections and removals, 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 (series of standards at C1.000, H5.000, L4.000, M6.000 and M7.000);

7) quality assurance and quality control of supplies, equipment, instruments, reagents, labels, and processes employed in tissue collection, recovery, acquisition, processing, packaging, labeling, storage, distribution, and preparation of tissue for transplantation, including policies or procedures for:

a) labeling of cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) (D4.350, series of standards at D5.000, and Section G);

b) monitoring storage temperatures, for defining tolerance limits, and for describing what, when, and how corrective actions are to be taken for implementing emergency transfers and determining alternative storage and monitoring methods for tissue and reagents (F4.200, series of standards at E4.000 and M2.000);

c) investigating, documenting and reporting accidents, errors, complaints, and adverse outcomes (series of standards at K4.000);

d) performing field corrections, removals, and stock recoveries, if applicable, and the timely notification of affected parties regarding information related to tissue safety or regulatory requirements (series of standards at H5.000, L6.000 and M6.000);

e) of notifying management with executive responsibility of any field corrections, or removals, stock recoveries, investigations, inspection reports, or regulatory actions (series of standards at H5.000 and K4.000);

f) supplies, reagents, materials and equipment and identifying those that are considered critical (D5.100, E1.300, E2.000, J5.100);

g) maintaining equipment management programs that include inspection, maintenance, repair and calibration for the purpose of maintaining equipment (series of standards at J5.000);

h) describing the receipt, identification, storage, handling, sampling, testing, and subsequent approval or rejection of containers, packaging materials, labels, reagents, and supplies (series of standards at D5.000, E1.000, and E2.000, J5.500 and Section G); and

i) monitoring in-process controls and managing events such as failed test runs and failure of a lot to meet established specifications (Section K).

8) assigning time limits and temperature for pre-processing quarantine storage, processing, and expiration dates (E2.520, E3.400, H3.400 and K1.200);
9) handling requests for research tissue (series of standards at D1.200, H2.000);

10) disposing of medical waste and other hazardous waste (series of standards at J3.000);

11) covering emergency and safety including reporting of staff injuries and potential exposure to blood-borne pathogens (series of standards at J3.000);

12) maintaining the sanitation of facilities and describing the cleaning schedules, methods, equipment and materials to be used (series of standards at J4.000 and J5.000);

13) describing the design or arrangement of the physical plant to meet operational needs such as designation of spaces, environmental monitoring, and security (series of standards at J4.000);

14) describing manual methods for tissue banking activities in the event of electronic or equipment malfunction (series of standards at K7.000);

15) describing training program requirements for technical and QA staff (series of standards at J2.000); and

16) identifying and controlling procedures and forms including requirements (J1.100, J1.400).

17) defining appropriate use, confidentiality, security and retention of captured images of the donor and/or tissues. (Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)

J1.300 Implementation

The SOPM and associated process validation studies shall be reviewed and approved by appropriate individuals as dictated by content. All policies and procedures of a medical nature 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 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, justification for 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 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.

J1.500 References

Copies of publications cited in support of policies or procedures shall be maintained at the tissue bank.

J1.600 Annual Review
An annual review of the SOPM, and the safety manual if separate, shall be performed and documented:

1) the Medical Director shall review relevant policies and procedures of a medical nature (e.g., donor eligibility, adverse outcomes);

2) management with executive responsibility, or a responsible person designee, shall review policies and procedures to ensure adequacy in regard to current practice, and applicable standards, laws or regulations; and

3) staff shall review policies and procedures for which they have been trained and are currently responsible.

J1.700 Staff Access and Review

Current copies of the SOPM applicable to specific staff functions shall be in designated locations and available to the staff at all times. New and revised policies and procedures shall be reviewed by applicable staff prior to implementation. Documentation of review and any associated training shall be maintained at least 16 years after termination of employment or as required by applicable laws or regulations, whichever is longer.

J1.800 Inspections

The SOPM shall be made available for inspection upon request by the AATB or authorized regulatory agencies.

J1.900 Archives

A file of archived SOPs shall be maintained in historical sequence for 16 years after discontinuation. The records shall indicate the inclusive dates that each policy and/or procedure (including forms, letters, labels, and other specific documents) was in use.

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 regulations and AATB Standards. Training shall encompass the following areas, as applicable: new employee orientation; the SOPM; technical training; QA; 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 law, whichever is longer.

1) Personnel shall be made aware of their designated functions and of the consequences of the improper performance of their designated functions.

2) Personnel performing verification and validation activities shall be made aware that accidents and errors may occur during the performance of their designated functions.

(SB) Training shall be conducted to maintain competency in procedures and familiarity with appropriate regulations and AATB Standards. Training shall be conducted for all staff whether they are employees of the tissue bank, contracted employees, or other individuals (e.g., hospital staff) who are responsible for determining donor eligibility, or recovering, or packaging the tissue.
J2.200 Competency

Technical staff must demonstrate competency for their designated functions (including a thorough understanding of relevant policies, procedures, process controls, and regulatory requirements).

J2.300 Continuing Education

Technical staff shall participate in continuing education, which may include training courses, technical meetings, and any other educational programs pertaining to designated functions. Such participation shall be documented.

J2.400 Training Records

Training records shall be maintained for each employee with documentation of the following:

1) delineation of functions that each employee is authorized and trained to perform;
2) initial training of new employees;
3) initial training of newly designated functions of existing employees;
4) review and training prior to implementation of new and/or revised sections of the SOPM;
5) annual review of policies and procedures for the employee’s designated functions, including safety procedures (see J1.600);
6) annual safety training; and
7) attendance at workshops, seminars, meetings, or other continuing education programs.

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. Procedures shall be written in accordance with applicable Occupational Safety and Health Administration (OSHA) regulations, guidelines established by the CDC, and applicable laws or regulations. All safety procedures shall be reviewed annually.

J3.200 Procedures

Safety procedures shall include, but are not limited to, the following:

1) instructions for contacting emergency personnel and the establishment of evacuation routes and procedures in the event of fire or disaster;
2) procedures for management of worker injury including possible exposure to hazardous materials or blood-borne pathogens. Such procedures shall require a written report of the incident, including documentation of medical care received, management notification, and actions to prevent
recurrence;

3) delineation of Universal Precautions as defined by the CDC;

4) procedures specifying the proper storage, handling, and utilization of hazardous materials, reagents and supplies, including pertinent Safety Data Sheets; and

5) procedures outlining the steps to be followed in cleaning bio-hazardous spills.

J3.300 Hazardous Materials Training

A training program shall be designed to inform employees about chemical, biological, and, if applicable, radioactive hazards of the workplace as well as the use of personal protective equipment to reduce the risk of exposure to these hazards.

J3.400 Universal Precautions

Universal Precautions, as defined by the CDC, shall be implemented and enforced to reduce the potential exposure of staff to communicable diseases.

J3.500 Immunization

Hepatitis B vaccination shall be offered free of charge to all non-immune personnel whose job-related responsibilities involve the potential exposure to blood-borne pathogens. Personnel files shall include documentation of receipt of vaccination or refusal of immunization with hepatitis B vaccine.

J3.600 Hazardous Waste Disposal

Biohazardous human tissue, medical waste, and other hazardous materials shall be disposed of in accordance with applicable laws or regulations in such a manner as to minimize environmental impact and exposure to personnel. Medical waste and hazardous material tracking records shall be maintained in accordance with the regulations of the regulatory agency charged with management oversight.

J3.700 Personnel

J3.710 Attire

Personnel engaged in the Recovery, Processing, Preservation, or packaging of tissue shall be suitably attired. Attire shall include personal protective equipment to minimize the spread of transmissible pathogens among and between donors, tissue, and staff.

J3.720 Infections

Any staff member shown (either by medical examination or supervisory observation) to have a serious infectious condition (e.g., an apparent illness or open lesion) that may adversely affect the safety of the tissue shall be excluded from the recovery, processing, preservation, or packaging of tissue until the condition is determined to be resolved. All staff members shall be instructed to report, to supervisory personnel, any health conditions that may have an adverse affect on tissues.
J4.000 FACILITIES

J4.100 General

The physical plant shall be designed or arranged to meet operational needs. The premises shall be maintained in a clean, sanitary, and orderly manner with adequate plumbing, drainage, lighting, ventilation, and space. Adequate, clean, and convenient hand washing facilities shall be available for personnel and for donors when applicable. Specific suitability parameters for the recovery site (see D5.500), or where collection of anonymous semen donation takes place, shall be evaluated. Areas of the facility where donor screening and/or obtaining authorization or informed consent takes place should be arranged to prevent errors and maintain confidentiality of information discussed.

J4.200 Designated Space

To prevent errors and/or cross-contamination of tissue, the following critical procedures shall be performed in designated areas of adequate size:
1) donor screening;
2) obtaining authorization or informed consent;
3) processing;
4) quarantine storage of in-process materials;
5) other quarantining;
6) labeling;
7) storage of distributable inventory;
8) quality assurance/control functions;
9) receipt and storage of containers, container labels, supplies, and reagents;
10) storage of medical waste;
11) irradiation and other sterilization procedures; and
12) final product inspection and distribution activities.

J4.210 Routine Decontamination and Record Retention

Facilities used for collection, recovery, processing, or preservation, or for other activities where there is potential for cross-contamination of tissue or exposure to blood-borne pathogens, shall be subjected to routine, scheduled, documented decontamination (sanitation) procedures. Cleaning events performed by tissue bank personnel shall be documented and retained for three (3) years after their creation.
J4.300 Environmental Monitoring

*Environmental monitoring procedures shall* be established, where appropriate, as part of the QA program. Monitoring procedures may include, but are not limited to, *static and dynamic* particulate air samplings (e.g., air bacterial content assays) equipment and personnel monitoring where *tissue* contact occurs, and work-surface cultures. Frequency of sampling *shall* be based on *related industry guidelines*, the results of prior samplings or suitable justification. Procedures *shall* include *tolerance limits* and *corrective actions* to be implemented in the event that *limits* are exceeded. Each monitoring activity *shall* be documented and results trended.

*Environmental monitoring at the recovery site* is not required, however pre-established parameters designed to prevent contamination and *cross-contamination must* be met (see D5.500).

Rooms used for storage of liquid nitrogen tanks *should* be periodically monitored for oxygen levels if not appropriately ventilated.

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. Limited access areas *shall* be established as appropriate, permitting entry of only those personnel (including auditors and inspectors) who are authorized by supervisory personnel.

J5.000 EQUIPMENT AND INSTRUMENTS

J5.100 Selection

Equipment and instruments *should* be of appropriate quality for their intended function and use. Equipment used in the *recovery, processing, preservation, packaging, or storing of tissue* shall be appropriately sized, designed, and located to facilitate use, cleaning, *decontamination*, and maintenance. Equipment *shall* be constructed so that surfaces contacting *tissue* shall not alter the *safety or quality* of the *tissue*. See E1.300.

J5.200 Operation

Equipment *shall* be operated according to manufacturer’s recommendations unless it is demonstrated that modifications to operating procedures will not adversely affect either the *quality of tissue* or personnel safety. Use of instruments *shall* be appropriate for the task.

J5.300 Qualification and Maintenance

Instruments, apparatus, gauges, and recording devices shall be calibrated or verified and routinely maintained, inspected, monitored, cleaned, decontaminated, sterilized (when applicable), and repaired per the manufacturer’s requirements and recommendations. When equipment, instruments, apparatus, gauges, and recording devices are found out of tolerance, there shall be provisions for remedial action to evaluate whether there was any adverse effect on quality.

J5.310 Requalification/Recalibration

Following repairs and system upgrades, equipment should be recalibrated or verified according
to procedures in the SOPM that have been designed to be in compliance with the manufacturer’s requirements and recommendations.

**J5.400 Decontamination**

Equipment and instruments shall be cleaned, or decontaminated, and sterilized (when applicable) at appropriate intervals in accordance with the SOPM to prevent malfunction, contamination, cross-contamination, or accidental exposure of tissue or staff to blood-borne pathogens. Procedures shall be established to track critical instruments that are cleaned and decontaminated with any other instruments. Reusable basins or bath units used for instrument soaks/washes/rinses must be cleaned and decontaminated between uses. See recommendations in AATB Guidance Document No. 3.

Instruments used to recover and/or process dura mater, vertebrae, or ocular tissue that are known to have come in contact with tissue from a donor suspected or confirmed to have a prion-associated disease, must be removed and destroyed. Tissues from other donors for which those instruments were subsequently used for recovery or processing shall be identified, quarantined, withdrawn and/or recalled pending further evaluation.

**J5.500 Sterilization**

Equipment and instruments shall be sterilized if they are intended to come into contact with tissue or if they have the potential of contaminating tissue, if not sterilized. Sterilization must be performed in a manner that is consistent with applicable industry standards.

To ensure that sterilization is successful during routine processing of equipment and instruments, it is important that the following be performed at required or recommended intervals:

1) Regular maintenance of the sterilization equipment: The sterilization equipment manufacturer’s maintenance recommendations must be met.

2) Use of routine lot release controls: Routine lot release controls must be performed according to the specifications, and at the intervals, outlined in the following table.

3) Performance of efficacy monitoring: The specifications and intervals for required efficacy monitoring are outlined in the following table. In addition to the specifications found in the table, additional efficacy monitoring may be necessary, such as leak testing, dynamic air removal testing (DART test), and Bowie-Dick testing, and process challenge device (PCD) testing. Guidance on efficacy monitoring may be found in sterilization equipment manuals, consulting with the sterilization equipment manufacturer, or can be found in applicable industry standards:

   a) steam sterilizers: ANSI/AAMI ST79; or

   b) ethylene oxide sterilizers: ANSI/AAMI ST41.

In the event that routine lot release controls indicate failure of the load to achieve necessary sterilization conditions, the sterilizer load contents must be exposed to a subsequent successful sterilization cycle. Frequent sterilization failures are often indicative of a process problem and should be investigated to determine the cause of failures. Investigation may need to include increased efficacy monitoring.

All sterilization accessories, to include but not limited to biological indicators, commercially available PCDs, wrappers, pouches, and sterilization containers, must be used in a manner consistent with the
accessory manufacturer’s instructions for use or be validated appropriately for the use.

### Table of Common Sterilization Methods, Cycle Parameters, Controls & Monitoring

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle Parameters</th>
<th>Routine Release Controls (for each load)</th>
<th>Efficacy Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Use the recommended parameters (e.g. exposure times, temperatures, pressures, drying times, weight and geometric complexity of load, etc.) specified in the sterilizer manufacturer’s operator’s manual, or validate other cycle parameters in accordance with industry standards.</td>
<td>Verify cycle parameters were met 1. Utilize internal and external chemical indicators 2. Utilize appropriate PCD and verify as negative prior to release of load</td>
<td>Weekly: Utilize appropriate PCD* Daily: Utilize appropriate PCD</td>
</tr>
<tr>
<td>Ethylene Oxide (EO)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaporized Hydrogen Peroxide (VHP)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irradiation (i.e. Gamma, x-ray, electron beam)</td>
<td>Use validated cycle per ISO 11137 Verify cycle parameters were met</td>
<td></td>
<td>Bioburden testing, dose audits and dose mapping per ISO 11137 N/A</td>
</tr>
<tr>
<td>Other (e.g., novel, nontraditional)</td>
<td>Follow manufacturer’s instructions for method selected. Validation is expected if manufacturer’s instructions are not followed.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Weekly use of a PCD is not required if a PCD is already being used in each load as recommended for “Routine Release Controls.”

### J5.600 Storage Equipment

Equipment used for storage of tissue shall be identified to facilitate monitoring of temperature and location of in-process, quarantine, and distribution inventory. 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.

**J5.700 Record Retention**

Documentation of equipment and instrument cleaning, *decontamination*, *sterilization*, qualification, calibration, and maintenance *shall* be maintained in records for 10 years after their creation. Such records *shall* also include documentation of repairs, rejection, return, and/or disposal of defective equipment.
SECTION K
QUALITY ASSURANCE

K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a QA program.

K1.100 Basic Elements

The QA program shall include, at a minimum:

1) designating and managing quality control functions, including:
   a) environmental monitoring at designated intervals;
   b) performing periodic equipment and facility inspections and documenting in maintenance records or logs;
   c) reviewing equipment monitoring records for maintenance within specified tolerance limits, and reviewing records of other equipment or processing functions that have specified tolerance limits;
   d) inspecting and monitoring in-process control results, including collection and testing of representative samples;
   e) performing qualification of reagents, supplies, materials, instruments, or equipment when deemed critical or applicable; and
   f) monitoring laboratory performance, if applicable.

2) performing process validation studies when 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 controlling 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, each tissue bank shall document the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process and the major equipment used. When changes or process deviations occur, the tissue bank shall review and evaluate the process and perform revalidation where appropriate, and shall document these activities.

3) performing equipment qualification studies as necessary;

4) establishing purchasing controls;

5) establishing procedures for implementing corrective action and preventive action and taking action when 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 action 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 action and preventive actions, for management review;

6) reviewing, as applicable at each tissue bank involved, donor screening, informed consent or authorization, recovery, acquisition, or collection, and processing records;

7) approving, as applicable, all processing records and relevant medical records prior to release of tissue for transplantation;

8) auditing;

9) documenting formal conclusions of all accident, error, complaint, adverse outcome, and field correction, removal, or stock recovery incidents;

10) maintaining documentation including, but not limited to:

   a) master copy of current SOPM;

   b) records of names, signatures, initials or identification codes and inclusive dates of employment for those authorized to perform or review tasks (e.g., onsite or at a central location);

   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.

11) evaluating training of personnel and, where required, the competency of personnel, and requiring that staff are appropriately oriented and trained concerning any modifications to
the SOPM;

12) maintaining labeling controls, including all brochures, pamphlets, and promotional materials; and

13) establishing a process for sharing information with other tissue banks that are known to have recovered and/or received tissue from the same donor.

K1.200 Qualification, Verification, and Validation Requirements

Elements or items that must be qualified, verified, or validated shall be determined from a risk assessment that has been approved by the tissue bank’s quality department and the frequency of these activities will be determined by the risk assessment and results of the initial and follow up validations.

Each tissue bank shall:

1) develop, document, and implement protocols for the qualification, verification, or validation of significant components of:
   a) facilities;
   b) processes;
   c) equipment;
   d) reagents;
   e) labels;
   f) containers;
   g) packaging materials;
   h) electronic systems including quality management systems; and
   i) donor eligibility criteria.

2) perform process validations for processes whose results cannot be fully verified by subsequent inspection and test;

3) assess process changes and perform revalidation as appropriate; and

4) evaluate parameters tested and determine the adequacy of the study to demonstrate necessary outcomes.

K1.210 Validation Methods

Where validation is required or desired, evidence supporting validation must be demonstrated. Acceptable methods to demonstrate validation are:

1) studies conducting challenges such as temperature, time, with indicator organisms, as appropriate, and/or other factors determined by the risk assessment that potentially affect tissue quality, as well as studies demonstrating consistency when the steps are repeated lot to lot; or

2) identification of an established procedure or process known to be effective, with implementation of the same procedure or process, without modification; such procedure or process shall be verified, as specified in K1.230. [For example, the implementation of a literature based disinfection process shall include conducting at least method suitability testing (Bacteriostasis/Fungistasis testing) per USP <71> prior to implementation (see AATB Guidance Document No. 5)]. If any steps are modified, all such modifications shall undergo documented evaluation (e.g., through a risk assessment) for potential impact, and a potential result may be that a re-validation is necessary per method 1 of this section.

K1.220 Packaging Qualification and Transport/Shipping Validation

Packaging Systems* used to transport recovered, acquired, collected, or in-process tissue, or to distribute finished tissue shall be designed or qualified for their intended use. Transport System /shipping container* validation is required unless each transport/shipping event is adequately verified and documented. Adequacy of the verification method shall be established and justified. Finished tissue packaging shall be validated to maintain the required conditions to meet the finished tissue quality at the end of its stated expiration date. (For information and guidance see AATB Guidance Document No. 9 Qualification of Packaging and Validation of Shipping and Transport Procedures)*.

*Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020

K1.230 Verification Methods

Where verification is required or desired, evidence supporting verification must be produced by one or more of the following methods:

1) review, examination, inspection, or testing of a defined number of samples (the justification of the number of samples must be documented) in order to establish and document that the tissue, service or system meets specified regulatory or technical standards;

2) verification of the implementation of an established, previously validated, procedure or process without modification; such verification shall be conducted using a defined number of samples/processing events (the justification of the number of samples/processing events must be documented); or

3) a documented review such as when a tissue recovery program must verify that a processor’s donor eligibility criteria is compliant with federal regulations, state law, and AATB Standards.
K1.300 Purchasing Controls

Each tissue bank shall establish and maintain procedures to ensure that all purchased or otherwise received products and services, including testing 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; and

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 the tissue bank can determine whether the changes may affect quality.

For contracted services involving donor screening, donor eligibility, tissue recovery, acquisition, collection, processing, storage, and/or distribution, refer to B1.500 for additional requirements. Also refer to specific information at B1.600 for contracted and non-contracted laboratory services for infectious disease testing.

K1.310 Contracted Testing Services

Contracted testing services may be performed remotely at the contracted laboratory or on-site at the tissue bank, and evaluation of testing services is expected.

K1.311 Types of Testing Services

Examples of contracted testing services include, but are not limited to, the following:

1) donor infectious disease testing (also see B1.600);

2) microbiology testing (e.g., cultures on tissue, bioburden determination);

3) environmental monitoring;

4) sterilization validation;

5) irradiation dose auditing;

6) lot release testing (e.g., residual moisture, residual calcium, endotoxin levels);

7) calibration services (e.g., pipettes, temperature monitoring devices, equipment); and

8) cleanroom certification.
K1.312 Evaluation of Testing Services

Each tissue bank utilizing outside testing services shall ensure the testing facility and test methods are adequate for the intended use of the test results. This evaluation may include, but is not limited to, the following:

1) FDA registration, if required;
2) applicable state licenses, certifications and accreditations;
3) maintenance of an adequate quality assurance program to ensure the validity of results (e.g., test sample integrity, quality control samples, personnel competency, equipment maintenance, materials management);
4) participation in a laboratory proficiency testing program, if available;
5) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP);
6) follow manufacturers’ instructions (e.g., package inserts, equipment manuals, electrical, and/or environmental conditions);
7) appropriate test method selection and validation/qualification;
8) use of traceable reference materials and calibration standards, where applicable; and
9) results from a paper, virtual, or on-site audit.

K2.000 QUALITY CONTROL PROGRAM

The QA program shall 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.

K2.100 Laboratory Proficiency Testing

Laboratories shall participate in relevant proficiency testing programs for all analytes, if available. Proficiency testing shall be conducted in accordance with the laboratories’ normal testing and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.

Procedures shall incorporate a plan for corrective action for poor performance on proficiency
testing.

**K2.200 Laboratory Quality Assurance Program**

Laboratories shall establish and maintain a *quality assurance program* adequate to ensure the validity of test results. The laboratory *quality assurance program shall* include, but is not limited to, the following:

1) appropriate test method selection and *validation/qualification*;

2) monitoring/trending internal *quality control* samples;

3) test sample specifications and integrity (e.g., identification, transportation, type, quantity, rejection criteria, preparation, storage);

4) personnel qualification, training and *competency*;

5) equipment selection, *validation/qualification*, calibration and maintenance;

6) use of traceable reference materials and calibration standards, where applicable;

7) follow manufacturers’ instructions (e.g., package inserts, equipment manuals, electrical and/or environmental conditions);

8) materials management;

9) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP);

10) result *verification*, review and release; and

11) *records/data* management.

**K2.300 Microbiological Tissue Cultures**

**K2.310 Pre-Sterilization/Pre-Disinfection Cultures**

Except for *reproductive tissue banks* and *skin (S)*, each tissue bank shall establish appropriate *pre-sterilization/pre-disinfection culture* methods and sampling strategies to represent all *tissues* received from a particular *donor*. The *pre-sterilization/pre-disinfection culture* results *shall* be documented in the *donor’s record*. See AATB Guidance Document No. 5 for expectations.

If tissue *sterilization* or *disinfection* will not occur a *pre-sterilization/pre-disinfection culture* is not required, however, refer to culture requirement at K2.320.

The Medical Director or his/her physician designee [see exception that follows for (S)] *shall* review these *pre-sterilization/pre-disinfection culture* results prior to release of *tissue* for *transplantation*.

(MS, OA, SB)

*Tissues* with *pre-sterilization/pre-disinfection cultures* positive for *Clostridium,*
Streptococcus pyogenes (group A strep.), or any other microorganisms determined by the processor to be virulent or difficult to eliminate, shall be discarded unless treated with a disinfection or sterilization process validated to eliminate the infectivity of such organisms. Other individual tissues from the same donor that were recovered under conditions that could result in cross-contamination must be discarded unless they will be treated with a disinfection or sterilization process validated to eliminate the infectivity of such organisms.

(BT, C, V, CT)
E2.800 applies.

(S) Cultures shall be obtained prior to processing. Culture methods shall be validated to ensure the suitability of the culture method selected. Inhibitory substances (e.g., skin prep solution(s), transport media, antibiotics, etc.) that may be added to unprocessed skin during recovery or for transport must not interfere with culture results. (i.e., produce false negative results).

Culture results shall be documented in the donor’s record. Cultures positive for microorganisms considered pathogenic, highly virulent must be discarded unless the tissue can be disinfected/sterilized with a validated process (see E2.800). The Medical Director or designee shall review all available pre-processing skin culture results prior to releasing the tissue for transplantation. Skin recovery shall be performed as a separate zone from other tissue types so that culture results can be independently reviewed.

K2.320 Final/Pre-Packaging Cultures

Except for autologous and reproductive tissues, all tissue to be released for human transplantation shall have representative microbiological cultures obtained which includes testing to detect bacteria and fungi. The results must be documented in the donor record, unless dosimetric release has occurred by a validated process according to E2.820. Appropriate final packaging cultures (aerobic and anaerobic) shall be obtained and the results shall meet established parameters defining acceptable final packaging cultures before tissue is released for transplantation. All culture results shall be reviewed prior to release of tissue for transplantation. Any variance in the culture results from established parameters shall be reviewed and approved by the Medical Director or his/her designee prior to release. Except as described for skin (S) below, no allografts contained within the processing batch may be released for transplantation if post-processing final sterility test results show organism contamination. Allograft rework is permitted with an established program validated to eliminate the organism identified.

(A) Except for skin, if autologous tissue is being processed, microbiologic cultures, which includes testing to detect bacteria and fungi, should be obtained immediately prior to processing.

(C, V) Representative cardiac tissue and vascular tissue samples shall be cultured for fungal growth.

(MS, OA, SB, C, V, CT)
Microbiologic testing of processed tissue, which includes testing to detect
bacteria and fungi, shall be performed on each donor lot.

(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 detected 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).

**K2.400 Testing for Residues**

(C, V) Initially, and as required at K1.200, each tissue bank shall thaw, rinse and prepare representative samples from processed tissue as if for use and test them to evaluate the concentration of residual cryoprotectant(s) (if applicable).

**K2.500 Other Quality Control Procedures**

**K2.510 Lyophilized/Dehydrated/Desiccated Tissue**

*QC programs* for monitoring performance of either a lyophilizer, a dehydrator or desiccator shall be established and verified for each batch. When a residual moisture limit has been established, a representative sample that demonstrates the worst-case scenario for that batch shall be tested and shall not exceed the limit. Refer to E2.710 and E2.720.

**K2.520 Calibrations of Storage Devices**

Each tissue bank shall ensure calibrations of devices used for storage are performed according to manufacturer’s requirements and recommendations, but no less frequently than once per year using a National Institute of Standards and Technology-traceable standard. The overall QA program shall include maintenance of calibration records.

**K3.000 MICROBIOLOGIC TESTING**

All microbiologic testing of tissue to be released for transplantation shall be performed by a qualified laboratory using appropriate test methods. If microbiologic testing is to be performed by the tissue bank, the requirements at K2.100 and K2.200 shall apply. If the services of an outside laboratory are used, the requirements at K1.300 and K1.310 shall apply.

NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding qualification of laboratories via accreditation, designation, authorization and/or licensure.
K3.100 Microbiologic Subcultures

The testing lab shall subculture a positive microbiologic culture to identify the organism(s) by genus, and species where appropriate. See Guidance Document No. 5.

K4.000 INVESTIGATIONS

The QA program shall ensure that there is an investigation and review for completeness of accidents, errors, complaints, deviations, and adverse outcomes. Investigation shall include a summary report, precipitating events, recommendations, and resolutions. The QA program shall retain for 10 years all reports generated.

K4.100 Errors and Accidents

The QA program shall ensure a documented investigation of any errors and or accidents in obtaining informed consent or authorization, in donor screening, collection, acquisition, or tissue recovery, processing, quarantining, releasing, labeling, storing, and distribution or dispensing. If the error or accident may affect the safety of tissue to be released or that has been released, the Medical Director or licensed physician designee shall also review and evaluate the incident. When tissue may have been contaminated, the QA program shall ensure the documented review and evaluation both of processing procedures and of any other tissue processed simultaneously or from the same donor.

K4.200 Complaints

The QA program shall ensure that a written and oral complaints regarding tissue quality, safety, packaging, or effectiveness are 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, a responsible person shall document the reason that 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, then those associated tissues shall be located and quarantined until resolution of the incident (which may involve initiation of a recall). The Medical Director or licensed physician designee shall review complaints that are medical in nature.

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 identification number;
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**

The QA program shall ensure that all reported adverse outcomes that are potentially related, directly or indirectly, to an allograft are investigated thoroughly and expeditiously. The Medical Director or licensed physician designee shall review all potential adverse outcome reports and participate 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 the tissue bank shall follow procedures for errors and accidents (see K4.100).

**K4.310 Reporting**

The QA program shall ensure that all cases of transmissible disease in a recipient attributed to the allograft are reported in writing as required by public health authorities, and in a timely fashion to organ procurement organizations and tissue banks involved in any manner with tissue recovered from the same donor and to the physician(s) involved in the transplantation of tissue from that donor. Reporting shall be documented in the donor’s record.

See the Accreditation Policies for Transplant Tissue Banks for other required reporting.

**K5.000 INTERNAL AUDITS**

All tissue banks shall establish policies and procedures regarding the scope and frequency of routine and focused QA audits. The QA program 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, acquisition or collection, processing, preservation and packaging; donor and tissue testing; quarantining; labeling; storage; distribution; electronic systems; and records management. The QA program shall perform focused audits of critical areas (unless the annual routine audit covers all critical areas), and of any area with a pattern of quality problems. All audits shall be performed by persons who do not have direct responsibility for the process being audited. The tissue bank shall take corrective action(s) when necessary, including a re-audit of deficiencies. The QA program staff shall document and report the dates and results of each quality audit (and re-audit) to management responsible for the audited systems, who shall review each report. (Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)

**K6.000 EXTERNAL AUDITS**

External audits may be indicated for certain services, suppliers, contractors, and consultants. See K1.300 and B1.521.

**K7.000 ELECTRONIC SYSTEMS CONTROLS**

**K7.100 Authorized Access**

Each tissue bank shall exercise appropriate controls over electronic systems to limit general access to authorized personnel and to permit only authorized personnel to alter master production and control records or other.
K7.200 Error Reduction

When automated data processing is used for decision-making in processing, adequate procedures shall be designed and implemented to prevent inaccurate input or output of data and programming errors.

K7.300 Backup Files

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

K7.400 Security

Electronic systems shall be designed to assure data integrity and maintained in a secure manner to prevent alteration or loss.

K7.500 Audit Trail

Records revised electronically must have an audit trail that includes the altered information, date of the revision, and the individual that made the revision.
SECTION L
TISSUE DISPENSING SERVICES

L1.000 TISSUE DISPENSING SERVICES

Medical, dental, and hospital facilities, and physician offices that are tissue dispensing services shall establish policies and procedures to ensure the safety and traceability of tissue from receipt through storage and final disposition such as transplantation, further distribution, or destruction.

L1.100 Responsibilities

Activities of a tissue dispensing service shall be supervised by a physician, dentist, podiatrist, or other qualified medical professional.

L2.000 STORAGE

L2.100 General

Tissue storage shall be in conformance with labeling materials.

L2.200 Equipment

Freezers and refrigerators shall be regularly maintained, calibrated, and monitored using QC written procedures.

L2.300 Labeling

Tissue shall not be relabeled. Existing labels shall not be altered.

L3.000 DISPENSING, FURTHER DISTRIBUTION AND DISPOSAL

L3.100 Dispensing

Tissue shall not be dispensed for use in recipients without an order from a physician or other authorized health professional. Human tissue shall not be offered or dispensed for veterinary use. Tissue shall be transported and prepared for transplantation in accordance with labeling materials. All associated labeling material, including the package insert, shall be made available to the end-user physician and/or other qualified medical professionals.

L3.200 Further Distribution

When further distributing tissue, all accompanying original labeling materials or other enclosures shall be forwarded with the tissue. A record shall be made of the type and quantity of tissue, tissue identification number(s), redistribution date and destination.

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. When applicable, 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) Disposal of autologous tissue shall consider the following:

1) there shall be a written policy for the discard of autologous tissue;

2) the tissue dispensing service, in consultation with the autologous donor’s physician, shall approve discard of the tissue, and shall be responsible for documentation of the method and date of discard; and

3) autologous tissue should not be used for transplantation after the expiration date.

(R) There shall be a written policy for discard of reproductive tissue from a client depositor or directed donor. The reproductive tissue bank shall approve discard of reproductive tissue from anonymous donors and shall document the date of discard.

L4.000 RECORDS

Tissue dispensing services shall concurrently record all steps in the receiving, storage, and dispensing of tissue so that all steps can be clearly traced. Records shall be maintained for a minimum of ten years after expiration of the tissue or, in the case of tissue with no expiration date, ten years after dispensing.

L4.100 Tissue Receipt Records

Each tissue specimen shall have a tissue identification number. Tissue receipt records shall contain, at a minimum, the following information:

1) name and address of tissue supplier;

2) description of tissue and quantity received;

3) date of tissue receipt;

4) condition of tissue upon receipt; and

5) expiration date, if applicable, of tissue.

L4.200 Dispensing Records

Disposition of tissue shall be documented. When tissue is dispensed for transplantation, the following information shall be recorded:

1) name, address, and telephone number of the tissue bank (tissue supplier or tissue processor);

2) type and quantity of tissue and unique tissue identification number(s);

3) recipient’s name and medical record number, or social security number or similar unique identifier;

4) transplantation site and date and time of release;
5) name of the ordering physician or other authorized health professional;

6) name of the person dispensing the tissue; and

7) name of the person preparing the tissue(s) for use, if tissue is prepared at the site of dispensing.

This information shall be maintained in the tissue dispensing service records in a log format. The tissue recipient’s medical records shall contain, at a minimum, the first five items to permit tracing of each tissue from the tissue bank (tissue supplier or tissue processor) to each recipient.

The tissue bank’s tissue tracing forms shall be completed, specifying the disposition of the tissue, and returned as instructed in labeling materials.

L5.000 ADVERSE OUTCOMES

Potential adverse reactions, suspected transmission of disease, or other complications, directly or indirectly related to the allograft, shall be reported as instructed in labeling materials and thoroughly investigated and documented.

L6.000 FIELD CORRECTIONS AND REMOVALS

The tissue dispensing service shall have specific written policies and procedures for the performance of a field correction or removal, if applicable. Procedures shall include, but are not limited to, the following:

1) designation of a responsible person(s);

2) location and quarantine of affected inventory, in a timely manner;

3) communication with the tissue bank (tissue supplier or tissue processor);

4) communication with the end-user; and

5) documentation and record requirements.
SECTION M
TISSUE DISTRIBUTION INTERMEDIARIES

M1.000 TISSUE DISTRIBUTION INTERMEDIARIES

An agent who acquires distributed tissue for storage and further distribution shall establish policies and procedures to ensure the safety and traceability of tissue from receipt through storage, clinical use, further distribution, or destruction. See relevant parts of Section B and Section J.

NOTE: When any tissue banking activities are performed beyond the few functions that identify an entity as a tissue distribution intermediary (i.e., an agent that only acquires and stores tissue for further distribution), relevant tissue bank standards apply and compliance is required for accreditation. Tissue bank functions that surpass functions solely under the definition of a tissue distribution intermediary include:

1) designing, creating, maintaining, or controlling the specifications for finished tissue, relevant parts of Section E apply (e.g., the series of standards at E2.600 and E2.421);

2) designing, creating, specifying, or maintaining responsibility for the contents of the label for finished tissue, relevant parts of Section G apply;

3) performing any labeling functions to include the physical application of a label to finished tissue, relevant parts of Section G apply; and/or

4) final review for tissue release, relevant parts of Section F apply (e.g., F1.300, series of standards at F4.000).

M2.000 STORAGE

M2.100 General

Tissue storage shall be in conformance with the package insert and monitoring expectations. See E3.330, E3.331, E3.340, and C1.300.

M2.200 Equipment

Freezers and refrigerators shall be regularly maintained, calibrated, and monitored according to written QC procedures. See the series of standards at J5.000.

M3.000 LABELING

Tissue shall not be relabeled. Existing labels shall not be altered. Additional labels shall not be applied unless pre-approved by the tissue bank processor that applied the original label. Refer to the series of standards at G1.000.

M4.000 DISTRIBUTION

There shall be written procedures for the receipt of tissue orders, unit selection, final container, and/or package inspection, shipping, and transportation of tissue for transplantation. When a tissue distribution intermediary further distributes tissue, all accompanying labeling materials or other enclosures shall be forwarded with the tissue.
M4.100 Tissue Distribution Restrictions

Provision of tissue for transplantation shall be restricted to hospitals, free-standing medical facilities, tissue banks, tissue dispensing services, another tissue distribution intermediary, and end-users (e.g., physicians, dentists, podiatrists or other medical professionals) for use in recipients with the veterinary use exception that follows. Tissue distribution intermediaries shall have procedures that describe evaluation of requests from new customers for tissue. Human tissue for transplantation shall not be offered or distributed for veterinary use unless such use is specifically granted in a document of gift/authorization or in a record of informed consent. Controls must exist to ensure distribution restrictions are met such as those found on the document of gift/authorization or informed consent.

M4.200 Distribution to Another Tissue Distribution Intermediary

If tissue is distributed to another tissue distribution intermediary, that tissue distribution intermediary shall meet the requirements of Section M.

M4.300 Requests for Donor Status and Tissue Processing Information

Donor risk assessment, tissue condition(s), and tissue processing details, with the exception of information that may infringe upon the confidentiality of donor information, shall be made available to the transplanting physician upon request.

M5.000 CONSIGNMENT INVENTORY MANAGEMENT

If tissue is provided on consignment, the tissue distribution intermediary shall maintain procedures to ensure traceability and that appropriate storage conditions are maintained during consignment, further distribution or return.

M6.000 PACKAGING AND SHIPPING

M6.100 Pre-Shipping Inspection

Prior to shipping, packages shall be inspected to ensure the external packaging and labels are undamaged, the tissue is not expired and the tissue being shipped is consistent with the tissue requested. The exterior of the transport package shall be inspected to verify that requirements in G3.310 are met. These inspections shall be documented, including identification of staff conducting inspections.

M6.200 Validation and Packaging Expiration

If tissue to be shipped requires specific environmental conditions other than ambient temperature, the capability of the transport package to maintain the required environmental conditions shall be demonstrated and documented in a validation study. The length of time those conditions can be maintained by the packaging (assuming normal handling) shall also be determined. Expiration dates of the packaging shall be noted on the outside of the transport package.

M6.300 Transportation

The mode of transportation selected shall be determined by any special shipping and handling
requirements of the tissue and/or shipping refrigerants, shipping restrictions of commercial carriers, and the urgency of the tissue request.

**M6.310 Domestic Shipments**

The transport package label shall include the following information:

1) name, address and telephone number of the tissue distribution intermediary;
2) name and address of the consignee or end-user;
3) telephone number of the organization to whom issues related to shipping should be communicated,
4) prominent identification of contents as “DONATED HUMAN TISSUE.” Note: If the reproductive tissue in the shipment was collected from a client depositor, prominent identification as “HUMAN TISSUE”;
5) recommended storage conditions and transport expiration date (if applicable);
6) type and quantity of refrigerant or other hazardous materials enclosed in the transport package;
7) transport (shipping) expiration date (if applicable), and
8) any special handling instructions, when applicable (e.g., “DO NOT FREEZE,” “DO NOT X-RAY,” “DO NOT IRRADIATE”).

**M6.320 International Shipments**

Labels for international shipments shall contain all of the information required for domestic shipments; however, information may be modified to meet requirements of the federal government and those of the receiving country.

**M7.000 RETURN OF TISSUE**

A tissue distribution intermediary shall establish a policy authorizing or prohibiting the return of tissue in its original, unopened container. If returns are permitted, the integrity of the container, transport package, and labeling shall be examined for evidence of contamination or tampering. If there is any evidence of contamination, tampering, mishandling, or failure to maintain required storage temperatures, tissue shall not be returned to distribution inventory. Information pertaining to the return of tissue shall be recorded in the disposition records for that tissue as follows:

1) documentation of container examination;
2) documentation of end-user storage and shipping conditions;
3) reason for the return;
4) disposition of the returned tissue; and
5) date and name of the staff member who evaluated and determined the disposition of the tissue.
M8.000 FIELD CORRECTIONS AND REMOVALS

The need to perform a field correction or removal may be identified as a result of a complaint, adverse outcome, accident, error, deviation, audit, or by any other means. (For applicable quality assurance requirements, see relevant parts of Section K. An evaluation to determine if field correction or removal is warranted should be made whenever distributed tissue may not meet specifications related to safety, quality, identification, function and/or use. This evaluation must consider both risk to health posed by the tissue and applicable regulatory requirements, and be documented.

Tissue distribution intermediaries shall have specific, written policies and procedures for the performance of a field correction or removal. Procedures shall include, but are not limited to, the following:

1) designation of a responsible person(s);
2) location and quarantine of affected inventory, in a timely manner;
3) communication with the tissue bank (tissue supplier or tissue processor);
4) communication with the end-user; and
5) documentation and record requirements.

M8.100 Field Correction and Removal Records

All information relating to the field correction or removal of tissue and resulting communications shall be documented and retained on file for 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, but not be limited to:

1) reason for the field correction or removal;
2) identification and location of affected tissue in a timely manner, including quarantine steps;
3) steps taken to correct or retrieve tissue;
4) documentation of all related communications (e.g., phone calls and/or written correspondence, including copies of field notifications or letters and a list of those to whom notice was sent);
5) final disposition of the tissue;
6) corrective actions recommended and implemented; and
7) documentation of review.

M9.000 RECORDS

The tissue distribution intermediary shall concurrently record all steps in the receiving, storage, and
dispensing of tissue so that all steps can be clearly traced. Records shall be maintained for a minimum of ten years after the expiration date of the tissue, or in the case of tissue with no expiration date, ten years after distribution. See applicable requirements of Section C.

**M9.100 Tissue Receipt Records**

Each finished tissue shall have a tissue identification number. Tissue receipt records shall contain, but not be limited to, the following information:

1) name and address of tissue supplier;
2) description of tissue and quantity received;
3) date of tissue receipt;
4) condition of tissue upon receipt; and
5) expiration date, if applicable, of tissue.

**M9.200 Distribution Records**

Tissue distribution intermediaries shall maintain distribution records. These records shall be designed to permit tissue to be traced from the donor to a consignee or end-user, and from a consignee or end-user back to the donor. Records shall indicate the final disposition of all tissue handled by a tissue distribution intermediary. Tissue distribution records shall include, but not be limited to:

1) date of order placement;
2) name of the site to which the tissue is distributed;
3) name of the individual placing the order;
4) type and quantity of tissue ordered; and
5) information pertaining to tissue selected for shipment, including:
   a) identification number(s) of tissue;
   b) collection or expiration date of the tissue;
   c) date of shipment;
   d) type and amount (if applicable) of refrigerant used for shipment;
   e) mode of transportation; and
   f) name of the person releasing the tissue.

Prior to distribution, the labeled tissue shall be reviewed to verify that tissue has been properly identified and labeled. Such inspection shall be documented.

Any completed tissue tracing forms, specifying the disposition of the tissue, shall be returned
as instructed in *labeling materials*.

**M9.300 Tissue Disposal**

Unused, partially used, or expired *tissue shall* be disposed of in such a manner as to minimize any hazards to staff or the environment in conformance with applicable laws or regulations. The *tissue distribution intermediary shall* notify the *tissue bank* of the final *disposition* of the *tissue* and all actions taken *must* be documented.

**M10.000 ADVERSE OUTCOMES**

Reports of *adverse outcomes*, transmitted disease, or other complications *shall* be documented and reported to the *tissue processor* in a timely fashion and in accordance with applicable laws or regulations.
Appendix I:
REQUEST FOR VARIANCE FROM STANDARDS

Introduction

AATB-accredited tissue banks may request a variance when a policy, process, or procedure is in conflict with requirements in current AATB Standards. A variance request may be submitted for specific AATB standards appearing in this edition or in announced, approved updates to this edition. AATB-accredited tissue bank may request a variance to Standards but may not violate current Standards by implementing the change without first receiving notice of written approval from the AATB Executive Office.

A tissue bank seeking initial AATB accreditation may submit a variance request with a completed application for accreditation. A request for variance to Standards cannot be submitted when noncompliance is discovered during application for re-accreditation, and such a request cannot be used as a corrective action in response to a nonconformity cited at an AATB accreditation inspection.

Requests for variance cannot be acted upon if they are sent by an entity that is not an AATB-accredited tissue bank, or has not applied for AATB accreditation.

The timeline for reviewing a request for variance can be affected by additional requests for information by those who review the submission as well as by the time associated with response(s) by the requestor. The burden is on the tissue bank to provide supporting documentation that adequately describes how the proposed practice will meet the ultimate intent of Standards.

Process

SUBMISSION:

1) Tissue banks requesting a variance from current Standards must provide the following information to the AATB Vice President and Chief Science Officer (VP/CSO) by using the Request for Variance to AATB Standards Submission Format that follows. The format must be completed in entirety and include:

   a) the request for variance, including the particular standard number(s) that apply to the request;
   
   b) justification of the alternative procedure(s), policy or process which assure(s) equivalency to the intent of Standards;
   
   c) supporting information such as worksheets, records, data, or other information (e.g., validation of the process to be used in support of the variance or modification, including the scientific data and quality assurance steps). All data and proprietary information provided to the AATB by the tissue bank in connection with a request for variance shall be treated in accordance with AATB's policy governing confidential and proprietary information.

2) Within thirty (30) days of a request for variance, the AATB VP/CSO and the Chairperson of the Standards Committee will review the information submitted for applicability and completeness. These individuals may:

   a) request more information to complete the submission;
   
   b) consult with officers of appropriate committees and/or councils; and/or
c) determine the submission does not satisfy requirements for a request for variance.

REVIEW:

1) The AATB VP/CSO will forward the request and supportive information to the Standards Committee. These documents may or may not be blinded, depending on the nature of the submission and whether withholding the tissue bank’s identity could adversely affect appropriate review of their submission. This decision will be made in consultation with the person who submitted the variance request.

2) Variances are reviewed without prejudice, and individuals involved in the preparation of the request or who have any conflict relating to the request are to exclude themselves from committee or council discussion. Subject matter experts may be sought for consultation at the discretion of the Standards Committee Chairperson and/or Board of Governors.

3) At the next scheduled meeting, the Standards Committee will review and evaluate the acceptability of the request.
   a) If adequate information has been received, the Standards Committee may vote to approve or disapprove the request. Within thirty (30) days, this recommendation will be forwarded to the Board of Governors.
   b) If additional information is required, the AATB VP/CSO or Chairperson will request information directly from the contact person who submitted the request.

The Standards Committee may determine that the request must be reviewed by another committee or council, or may seek consultation with other subject matter experts. For example, requests of a scientific nature may be forwarded to the Scientific and Technical Affairs Committee for review and recommendation, and those of a medical nature may be forwarded to the Physicians’ Council for review and recommendation.

If consultation with another committee or council has been requested, the recommendation regarding the request shall be sent to the Standards Committee Chairperson and AATB VP/CSO within sixty (60) days of receipt. This time period may be extended if additional supportive information is desired by reviewers, but should be no longer than ninety (90) days from receipt.

Within thirty (30) days of receipt of the recommendation from another committee, a council, or subject matter expert(s), the Standards Committee will forward its recommendation, and rationale that supports the recommendation, to the Board of Governors.

RESPONSE:

1) Within thirty (30) days of its receipt of the Standards Committee’s recommendation, the Board of Governors shall take formal action on the request for variance and shall issue a written response to the tissue bank regarding its request. Requests for variance may be approved, delayed pending receipt of more information requested by the Board of Governors, rejected, or approved in modified form.

2) The Standards Committee shall provide notice of action on a request for variance to the Accreditation Manager for placement in the tissue bank’s file.

The Board of Governor’s action on a request shall be communicated by the AATB VP/CSO to the
Chairperson of each committee and/or council that reviewed the request.

Notice of the grant or rejection of a *variance* from the *Standards* may be included in AATB published materials or reports.

**APPROVED VARIANCES:**

1) A *variance* from *Standards* may not be implemented by the *tissue bank* until the request for *variance* has been approved by the Board of Governors.

2) A *variance* from *Standards* approved by the Board of Governors is applicable only to the *tissue bank* that requested the *variance*. It _may_ also be applicable to a *tissue bank* performing activities directly related to the approved *variance* under written agreement/contract with the requesting *tissue bank*.

3) Should the Standards Committee consider the *variance* to have universal application, the Standards Committee _may_ recommend that the Board of Governors make the approved *variance* applicable to all accredited members under such conditions as _may_ be prescribed.

4) A record of the approved *variance* must be maintained at the requesting *tissue bank* as well as at any other accredited *tissue bank* directly affected by the approval. Evidence of approval of the request for *variance* must be available during an accreditation inspection.

5) Approved *variances* shall remain in effect until:

   a) the *variance* is rescinded;

   b) the applicable standard on which the *variance* is based is amended or deleted thereby rendering the *variance* null and void; or

   c) the *variance* becomes meaningless due to changes in other circumstances.
Request for Variance to AATB Standards (current edition)
— Submission Format —

Standard for which a variance is submitted

Standard number and title:
Enter current text of standard:

Reason
Describe justification of variance request:

Supporting Information
Attach worksheets, records, data, or other documentation that supports your request. List them here by title.

Accredited Tissue Bank Name & Representative
Accredited tissue bank name:
Email address:
Phone number:
Representative (this is the contact person for this request)
Name:
Title:

Statement of Tissue Bank Representative
I request that for purposes of AATB accreditation our tissue bank should be granted a variance from this standard.

Signature: Date Submitted:
Appendix II:  
CRITERIA FOR PREVENTING TRANSMISSION of RCDADs  
(Relevant Communicable Disease Agents and Diseases)  
THROUGH TRANSPLANTATION OF HUMAN TISSUE

Behavior/History Exclusionary Criteria:

1) men who have had sex with another man within the preceding five years;

2) persons who have injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular, and subcutaneous injections;

3) persons who have had sex in exchange for money or drugs in the preceding five years;

4) persons who have had sex in the preceding 12 months with any person described in the 3 items above or with any person who has HIV infection, including a positive test for HIV, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection;

5) persons who have been exposed within the preceding 12 months to known or suspected HIV, HBV, and/or HCV infected blood through percutaneous inoculation (e.g., needlestick) or through contact with an open wound, non-intact skin, or mucous membrane;

6) children born to mothers known to be infected with, or at risk for, HIV, HBV or HCV infection, who are 18 months of age or less and/or have been breastfed 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, or at risk for, HIV, HBV or HCV infection, who have not been breastfed within the preceding 12 months and whose 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.

7) persons who have been in a juvenile correctional facility, lockup, jail or prison for more than 72 consecutive hours in the preceding 12 months;

8) persons with a generic history of hepatitis of an unspecified etiology or a current or past diagnosis of clinical, symptomatic viral hepatitis unless evidence from the time of illness documents that the hepatitis was diagnosed as either hepatitis A or due to cytomegalovirus or Epstein-Barr virus hepatitis. (Note: A verbal history of viral hepatitis occurring before the age of 11 years is acceptable);

9) persons who have lived with (resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection in the preceding 12 months;

10) persons who had or have been treated for syphilis or gonorrhea during the preceding 12 months. Donors may be acceptable if evidence is presented that the treatment occurred more than 12 months ago and was successful;

11) persons who within 12 months prior to donation have undergone tattooing, acupuncture, ear or body piercing in which shared instruments are known to have been used;

12) persons with a diagnosis of any form of Creutzfeldt-Jakob disease (CJD) or known family history (blood relative) of a person with non-iatrogenic CJD;

13) persons with a diagnosis of dementia or any degenerative or demyelinating disease of the central
nervous system (CNS) or other neurological disease of unknown etiology. Note: Tissues from donors with dementia, confirmed by gross and microscopic examination of the brain to be caused by cerebrovascular accident, brain tumor, head trauma, or toxic/metabolic dementia and who are confirmed not to have evidence of transmissible spongiform encephalopathy (TSE) on microscopic examination of the brain, may be acceptable based on an evaluation of this information by the Medical Director;

14) persons who have received injections of human pituitary-derived growth hormone (pit-hGH);

15) persons who are known to have received transplants of human dura mater;

16) persons with encephalitis or meningitis of viral or unknown etiology that is active;

17) persons who have received transfusions of blood or blood products outside of the United States (U.S.) during specific time periods in the following countries:
   a) from 1980 to present: France or the United Kingdom (includes England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, and the Falkland Islands); and/or
   b) after 1977 to present: Central or west Africa (includes Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria);

18) persons determined to be at risk for variant CJD (vCJD) because they are known to meet any of the following criteria:
   a) spent three months or more cumulatively in the United Kingdom (U.K.) from the beginning of 1980 through the end of 1996;
   b) lived cumulatively for 5 years or more in Europe from 1980 until the present (note this criterion includes time spent in the U.K. from 1980 through 1996); and/or
   c) is a current or former U.S. military member, civilian military employee, or dependent of a military member or civilian employee who resided at U.S. military bases in Northern Europe (i.e. Germany, Belgium, and the Netherlands) for 6 months or more from 1980 through 1990, or elsewhere in Europe (i.e. Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more from 1980 through 1996; (Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)

19) persons who, within the previous 120 days, have been told by a healthcare professional that they were suspected or known to have had a West Nile virus (WNV) infection based on symptoms, and/or those who are known to have tested positive for WNV by a NAT assay within this time frame;

20) persons who are known to have risks associated with xenotransplantation (i.e., receipt of a xenotransplantation product or who has had intimate contact with a recipient of a xenotransplantation product);

21) persons who have been permanently deferred as a blood donor for unknown reasons or who have a history of positive infectious disease test results for HIV, HBV, or HCV;

22) persons who, within the past six months, were bitten by an animal suspected to be infected with rabies. Individuals with suspected rabies shall not be accepted as donors under any circumstances (see Title 10 of New York Codes, Rules and Regulations, Section 52-3.4);

23) persons who had known or suspected sepsis at the time of death, or at the time of donation in the case of a living donor,
24) persons who, since 1977, were born in or have lived in any area of **central or west Africa** (includes Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, and Nigeria) and persons known to have had **sexual contact** with any such person;

25) persons who have had a **recent smallpox vaccination** (vaccinia virus) and persons who acquired a clinically recognizable vaccinia virus infection by close **contact** with someone who received the smallpox vaccine;

26) persons whose **cause of death (COD)** cannot be determined and there is likelihood of other exclusionary criteria;

27) persons who are known to have **malaria** or be at risk for malaria;

28) **reproductive donors** who have had or have been treated for **Chlamydia trachomatis** or **Neisseria gonorrhea** infection in the preceding **12 months**. If infection and treatment occurred more than 12 months ago, evidence of successful treatment such as a negative test result must be documented.

29) **living donors** who received a **blood transfusion** within the preceding **12 months** unless approved by the Medical Director in conformance with generally accepted standards of practice (see Title 10 of New York Codes, Rules and Regulations, Section 52-3.4);

30) **birth tissue** donated at **vaginal delivery** when there is significant local viral, parasitic, mycotic, or bacterial infection of the birth canal and, for any delivery, a current **intrauterine infection**;

31) persons with a history of being diagnosed with **Ebola virus disease** or who are at risk based on current **CDC risk information**; and

32) based on current recommendation published in FDA guidance, persons who have been determined to be at **risk** for infection with **Zika virus**.

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1. **RELEVANT COMMUNICABLE DISEASE AGENT OR DISEASE (RCDAD)** - A potentially infectious **microorganism**, virus, or other disease agent that may pose a risk of transmission to **recipients** of, or those who come in contact with, **tissues**. These disease agents/diseases: have sufficient incidence and/or prevalence to affect the potential **donor** population; could be fatal, life-threatening, result in permanent impairment, or necessitate medical or surgical intervention to preclude permanent impairment; and, for which appropriate screening measures have been developed or an appropriate screening test for **donor** specimens has been cleared, approved, or FDA-licensed, and is available. There can also be those disease agents or diseases that could place potential **donors** and/or **recipients** at risk for infection due to accidental or intentional release. **RCDADs** applicable to all **tissue donors** are (but are not limited to): HIV 1/2, HBV, HCV, human TSE, syphilis, communicable disease risks associated with xenotransplantation, WNV, vaccinia, and sepsis. **Donors** of viable, leukocyte-rich **tissues** must additionally consider HTLV I/II, and **donors** of **reproductive tissues** must generally consider **Chlamydia trachomatis** and **Neisseria gonorrhea**.

2. **CLINICALLY ACTIVE HEPATITIS C** - Infection with hepatitis C virus when it is symptomatic. This means that: the person demonstrates related symptoms such as jaundice, icterus, fatigue, abdominal pain, loss of appetite, nausea, vomiting, diarrhea, low grade fever, headache, joint pain, and/or “flu-like symptoms” **AND** HCV infection is suspected or has been diagnosed or anti-HCV (EIA) testing is positive. Also, knowledge of a recent/current positive test for HCV NAT would qualify as a clinically active HCV infection.

3. **Tissue banks** using an HIV test that has been approved by FDA to include a **donor screening claim** for
detection of HIV Group O antibodies are not required to screen for this risk history.

4European countries to be used for deferral of donors based on geographic risk of Bovine Spongiform Encephalopathy (BSE): Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom, or former Yugoslavia, Republic of Macedonia, and Czechoslovakia. (Announced 1/31/2020; Bulletin No.20-2; Effective 7/31/2020)

5XENOTRANSPLANTATION - Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either: (1) live cells, tissues, or organs from a nonhuman animal source; or (2) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs.

6XENOTRANSPLANTATION PRODUCT - Live cells, tissues, or organs used in xenotransplantation. Biological products, drugs, or medical devices sourced from nonliving cells, tissues, or organs from nonhuman animals, including but not limited to porcine insulin and porcine heart valves, are not considered xenotransplantation products.

7XENOTRANSPLANTATION INTIMATE CONTACT - An “intimate contact of a xenotransplantation product recipient” is a person who has engaged in activities that could result in the intimate exchange of body fluids with a xenotransplantation product recipient. Examples of intimate contacts include, but are not limited to, sexual partners, household members who share razors or toothbrushes, and health care workers or laboratory personnel with repeated percutaneous, mucosal, or other direct exposures. Mere sharing of domicile or casual contact, such as hugging or kissing without the exchange of saliva, would not be interpreted as intimate contact.

8CLOSE CONTACT: SMALLPOX - Physical contact with the vaccination site, touching the bandages or covering of the vaccination site, or handling bedding or clothing that had been in contact with an un-bandaged vaccination site.

Sources:


Title 10 (Health) New York Codes, Rules and Regulations, Part 52. February 24, 2007
Appendix III:
TISSUE DONOR PHYSICAL ASSESSMENT FORM REQUIREMENTS

Introduction

This new appendix was derived from a document formerly titled “AATB Guidance Document No 1, v2 Tissue Donor Physical Assessment Form, 6-27-05.” As an appendix, compliance is mandatory. The form and instructions that follow must be used to document the tissue donor physical assessment.

There are specific requirements related to tissue donor identification and physical assessment. Standard D4.120 requires that, “Prior to the recovery of tissue from a deceased donor, a physical assessment shall be performed by a responsible person.” This standard also lists physical findings that may be an indication of infection with, or high risk behavior for, HIV or viral hepatitis, observations that may alert recovery personnel to signs related to an active infection (communicable disease) or to contamination due to trauma or medical intervention, all of which can affect donor eligibility. Other standards related to significant steps of this process are found in Section C and parts of Section D and Section F such as: authorization, relevant medical records review, autopsy report, donor identification verification procedures, and disease screening for infections and conditions that include risk factors and malignancies. These standards cover and exceed expectations in relevant FDA guidance[1].

In 2004, to completely and properly document the physical assessment of a donor, the AATB membership developed a “Tissue Donor Physical Assessment Form” and a corresponding “Standard Operating Procedure (SOP)”. The original version was a guidance document and it was updated once. Version 2 was issued in 2005 after a work group, comprised mostly of the members who created the original version, suggested improvements to the form after it was in use for about a year.

Six years later, new volunteers headed by the officers of the Recovery and Donor Suitability (RADS) Council, began to meet by conference call and online meetings to modernize the form and the instructions. Their expertise provided many improvements and added a page to the form. Review opportunities were provided to the Quality Council, the Processing and Distribution Council, all members of the RADS Council, as well as to the Physicians’ Council, and their comments were deliberated before sending final recommendations to the Standards Committee. The Standards Committee reviewed the updates and sent the recommendations to the Board of Governors who approved it as a new appendix to the Standards.

Tissue banks can adapt and personalize forms and SOPs for use in either paper or electronic format, however, all of the contents of this form must be included in any format used. Tissue donor physical assessment is a significant step in the donor eligibility process therefore staff training and periodic evaluation of competency is expected. Electronic documentation systems shall meet the same requirements for compliance as paper documentation records. Uploads (e.g., photos, documents, etc.) can occur during certain steps of the documentation expectations for physical assessment. The size of the body schematic is important to optimize documentation; the size of the schematic must not be reduced to the point that a reviewer is unable to distinguish the many notations that can be made.

Instructions

The purpose of these instructions is to describe how to properly complete the three-page AATB Tissue Donor Physical Assessment Form. The information contained on these pages and in relevant medical records will be used as an aid to determine donor eligibility in order to proceed with tissue recovery.

This form shall be completed in its entirety, prior to recovery of tissues. Internal findings should also be documented in tissue recovery records but, except for documenting whether lymph nodes appear
abnormal, this aspect is not addresses here. An “internal findings form” may be developed separately.

This record identifies the staff involved in each significant step of the physical assessment procedure, and documents: donor identification and authorization verification procedures; the donor’s appearance and evidence of donation of organs and/or ocular tissues; the status of an autopsy (if any); a description of each finding; whether photos were taken and if consultations occurred; if there were personal effects and their disposition; and, a summary that attests to acceptability to proceed with recovery.

Abbreviations

The following abbreviations are used:
- e.g. - exempli gratia; for example, such as; the list is not finite
- i.e. - id est; that is; indicates a finite list
- ft - feet
- cm - centimeters
- in - inches
- kgs - kilograms
- lbs - pounds
- ET - endotracheal
- ID - identification
- IV - intravenous
- N/A - not applicable
- NG - nasogastric
- Ortho – orthopedic
- UNOS - United Network for Organ Sharing

Materials

- Indelible ink (blue or black);
- AATB Tissue Donor Physical Assessment Form or fully compliant version (paper or electronic substitute); and
- Relevant medical records, including but not limited to: the document of gift or document of authorization, the donor risk assessment interview form, and available, relevant medical records.

Safety

Follow established blood borne pathogen precautions.

Instructions for Completing Page 1

Completion of this page: 1) describes how the donor was identified; 2) describes the donor’s appearance and documents evidence of previous donation of ocular tissues and/or organs; 3) describes the status of an autopsy; 4) documents the recovery team’s physical assessment findings using a required list of potential risk factors; and, 5) identifies personnel who verify donor identification. Information may be derived from available relevant medical records, source documents, and/or personnel involved with the care of the patient/donor.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Document the complete name of the donor as written on the document of gift/authorization.</td>
</tr>
<tr>
<td>2</td>
<td>Document the recovery agency’s unique donor ID.</td>
</tr>
<tr>
<td>3</td>
<td>The manner in which the donor was identified is documented by checking the box next to the</td>
</tr>
</tbody>
</table>
applicable word(s): “ID Band,” “Body/Toe Tag,” or “Other.” If “Other” is selected, it must be described. Multiple identifiers may be checked.

4 Recreate the ID Band/Tag containing the most information. All identifying tags/bands should match. Or check N/A ID not present if there is no ID band/tag present, or check N/A Photo taken/saved if a photo of the ID Band/Tag was taken/saved instead.

5 Check the “Yes” or “No” box to indicate if there is agreement among recovery team personnel that the body’s physical characteristics (e.g., age, gender, race, height, weight, signs associated with the cause of death, or information on the DRAI form) are consistent with available relevant medical records and the identification is consistent with other documents. If “No,” appropriate management shall be contacted for guidance before proceeding with recovery. The SOPM shall include directions when the donor’s identification is discrepant or questionable.

6 On the line provided, print the names or initials of the tissue recovery personnel present that verified the donor’s identification. Document the date and time noting when this step was completed. Identify the appropriate time zone per SOPM.

### Appearance/Evidence of Donation

7 Enter a number for the height of the donor followed by checking a box indicating the appropriate selection designating whether this is inches (in.) or centimeters (cm.).

8 Check the box that indicates the method the team used to obtain the height: use “estimated/team” if estimation by the team’s responsible person(s); use “actual” if direct measurement was performed; use “reported” if relevant medical records (for “source”, enter the specific source). The responsible person(s) of the team must agree upon and document one value for height. Check multiple boxes if the team used multiple methods.

9 Enter a number for the weight of the donor. Check the box for units used [pounds (lbs) or kilograms (kgs)].

10 Check the box that indicates the method the team used to obtain the donor’s weight: use “estimated/team” if estimation by the team’s responsible person(s); use “actual” if direct weighing; use “reported” if relevant medical records (for “source”, enter the specific source). The responsible person(s) of the team must agree upon and document one value for weight. Check multiple boxes if the team used multiple methods.

11 Upon initial body assessment, check the box to describe the state in which the body was found such as: evidence of decomposition (e.g., skin sloughing, putrefaction); or, “cleanliness” (e.g., presence on the body of broken glass, dirt, leaves, grime, road abrasions). If “Poor”, describe condition.

12 Check “No” or “Yes” to document evidence of ocular donation. If “Yes”, then check either “corneas only” or “whole eyes” as appropriate.

13 Check “No” or “Yes” to document evidence of organ donation. If “Yes”, then enter the UNOS #.

### Autopsy Status

14 Check appropriate box to indicate if tissue recovery is “pre” or “post” autopsy, if no autopsy is planned, or, if the autopsy plan is unknown.

15 If an autopsy has been done or is planned, indicate the appropriate type describing it as “full”, “limited (e.g., head only),” “view only,” “toxicology screen only,” or if the plan for autopsy is “unknown.” Check only one. Intent can be met if knowledge of the autopsy plan is documented on a form other than the Tissue Donor Physical Assessment Form, however, the information included on the Tissue Donor Physical Assessment Form must be covered in entirety (i.e., all the options listed must be covered). In cases where some tissue is recovered pre-autopsy (e.g., ocular) and more tissue (e.g., bone) is recovered post-autopsy, the events should be documented in the donor record and reflected on the schematic.”
<table>
<thead>
<tr>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
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<td>17</td>
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<td>26</td>
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<td>27</td>
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<tr>
<td>28</td>
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</tbody>
</table>

Instructions for Completing Page 2 (Schematic)

Completion of this page documents all of the physical assessment findings by team members by recording them on anterior and posterior body diagrams (schematics) using a standardized Key. This will include
those findings documented during assessment on page 1 plus any other observations. Documentation also occurs if no findings are seen on either schematic view. Personnel who perform the physical assessment are identified as well as when it was performed.

1 Document the recovery agency’s unique donor ID.

2 All gross findings are appropriately drawn or otherwise identified (i.e., such as when using electronic records) on the anterior and posterior body schematics using the lettered Key provided. Blank schematic Key spaces are available to document gross findings not listed and/or to provide areas to further describe any listing [e.g., (H), (N)]. Piercing location, body jewelry, and each tattoo’s location and content are important to describe on this form or in additional notes.

3 If no findings are evident on either schematic view, check the appropriate box below to indicate “no observations noted.”

4 Document the name or initials of each team member who performed the physical assessment. Document the date and time noting when this step was performed. Identify the appropriate time zone per SOPM.

**Instructions for Completing Page 3 (Summary)**

Completion of this page documents: 1) if any photos of the body were taken; 2) if consultation occurred regarding physical assessment findings; 3) if personal effects were with the body and if so a description of which ones and their disposition; and, 4) a summary and whether this donor is acceptable or not to proceed with tissue recovery.

1 Document the recovery agency’s unique donor ID.

2 Were photos of the body taken? Check “No” or “Yes”. If “Yes”, then provide relevant information about the photos in the “Notes” section. A process should be established to share photos upon request from the tissue bank determining donor eligibility. This question regarding taking of photos must be addressed but intent is met if this information is captured on a form other than the Tissue Donor Physical Assessment Form.

3 Did consultation of physical assessment findings occur? Check “No” or “Yes”. If “Yes”, then provide relevant information about any consultation in the “Notes” section. This area can also be used for documenting details regarding whether a biopsy was requested and taken.

4 Document if there are no personal effects with the donor body (“No”) or check “Yes” if personal effects are present. Personal effects can be, for example, clothing, a wallet/purse, cash, credit cards, drug paraphernalia, mobile phone, and/or jewelry but, if present, require a description and their disposition. Intent is met if personal effect information is documented on a form other than the Tissue Donor Physical Assessment Form.

5 After a review of available relevant medical records and the physical assessment findings have been completed, a responsible person from the recovery team must indicate “acceptable” or “not acceptable,” then document their name or initials and date of completion of this process. Identify the appropriate time zone per SOPM.

6 After all documentation has been reviewed for legibility, completeness and accuracy, the form is appropriately forwarded.

**Notes Regarding Documentation**

Standard C1.100 requires that “Documentation must be made concurrent with each significant step.” All findings must be documented concurrently with the performance of the physical assessment. Any changes made to the document after the examination must include the date the change was made, initials of the person making the change, and the reason/rationale for the change. Changes to actual findings should be
based on photos that support the change.

The spaces provided on this form for documenting observations may be expanded to meet local policy, such as adding a listing for “lividity” or “rigidity/contractures” in the Key, adding space reserved for documenting more notes, or increasing the space for documenting names, numbers, or identifiers. Other additions may be made but the content of this form must be included in entirety. For example, the letter selected to identify any listing in the Key can be different but all of the listings in the Key to this guidance document must be used. The size of the body schematic is important to optimize documentation; the size of the schematic must not be reduced to the point that a reviewer is unable to distinguish the many notations that can be made.

Proper methods of documentation must be utilized, including revisions to records. Revisions shall be made with a single line drawn through the altered text with the revision initialed and dated by the person making the revision. Additions to a completed record shall be initialed and dated by the individual making the additions (see C1.500). All entries must be legible.

It’s preferred that documentation concerning “time” be based on a 24-hour clock (military time). Use of the notations “pm” and “am” is not preferred. Tissue recovery documentation shall use the time zone appropriate to the time and place of recovery.

Deviations from written procedures shall be documented and shared with all entities that determine donor eligibility and approve release of tissue.

References


Historical Changes

<table>
<thead>
<tr>
<th>Previous Page #</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>New on 2/23/04 (SAB/AM/AG)</td>
<td></td>
</tr>
<tr>
<td>Version 2 effective date 6/27/05 (PA Workgroup/SAB)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Added reference to this being “Version 2”, new date, and address updated</td>
</tr>
<tr>
<td>3</td>
<td>Table of Contents pages and titles updated</td>
</tr>
<tr>
<td>4</td>
<td>Provided listing of standards that are related; verbiage changes and additions made for clarification; reference to staff training and competency added.</td>
</tr>
<tr>
<td>5</td>
<td>Updates made to abbreviations in B.; addition of “available, relevant” to medical records; and punctuation changed in part E.</td>
</tr>
<tr>
<td>6</td>
<td>Verbiage additions and changes made for clarification.</td>
</tr>
<tr>
<td>7</td>
<td>Verbiage additions and changes made for clarification. “Globes” replaced with “whole eyes” to match EBAA terminology.</td>
</tr>
<tr>
<td>8</td>
<td>Removed “icterus” in step 17 and placed it in later step (28); adjusted wording accordingly.</td>
</tr>
<tr>
<td>8</td>
<td>Step 19 amended to document the new observation listing for “tattoos/piercings” to</td>
</tr>
<tr>
<td>Change</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td>8</td>
<td>Removed instruction in step (old 22) that is no longer considered part of physical assessment: “Document by checking the appropriate box, if infectious precautions are known for this patient (“Yes”), or not (“No”).”</td>
</tr>
<tr>
<td>8</td>
<td>Changed “perianal warts” to “perianal lesions” to encompass more possibilities that may be seen.</td>
</tr>
<tr>
<td>8</td>
<td>Added provision for documenting evidence of rash, scab, or skin lesion (non-genital) to accommodate new federal guidance (Donor Eligibility).</td>
</tr>
<tr>
<td>9</td>
<td>Change to step 28 is to address documentation of abnormal ocular findings that was added to accommodate new federal guidance (Donor Eligibility).</td>
</tr>
<tr>
<td>9</td>
<td>Documenting limitations of visualization when it’s restricted is offered as needed.</td>
</tr>
<tr>
<td>9</td>
<td>Body Appearance section amended to report “Cleanliness” instead of “Basic Hygiene” to accurately reflect intent; and, “Body Profile” deleted since height and weight is previously reported.</td>
</tr>
<tr>
<td>9</td>
<td>Step numbers updated and order of last two steps changed.</td>
</tr>
<tr>
<td>10</td>
<td>In step 2, use of blank schematic Key spaces is now described.</td>
</tr>
<tr>
<td>10</td>
<td>Ampersand (&amp;) included in deletion example.</td>
</tr>
<tr>
<td>10</td>
<td>Part G. amended to include general instruction to document/share any deviations from written procedures that occur.</td>
</tr>
<tr>
<td>13</td>
<td>Identification area updated by: 1) adding “/gender” to “sex”; 2) adding checkbox for height measurement in centimeters; 3) addition of “source:” and lines for documenting it for both “reported” height and weight assessments. “Actual” assessment box for height and weight moved to last selection in the row since it likely occurs less often than others. Changed case for capitalizations of measurements.</td>
</tr>
<tr>
<td>13</td>
<td>Evidence of Donation/ Autopsy area changed to list “whole eyes” instead of “globes”.</td>
</tr>
<tr>
<td>13</td>
<td>Recovery Team Assessment area updated by: 1) removal of icterus from first checklist item, then added later in listing for ocular findings; 2) addition of individual checklist item for “tattoo/piercing”; 3) addition of individual checklist item for “rash, scab, skin lesion (non-genital)”; 4) additional individual checklist item for “abnormal ocular finding (i.e. icterus, scarring)” with further checkbox provision for “unable to visualize”, if applicable; 5) limitation for visualization of “oral cavity” removed since there are two scenarios that can occur now. Added “Notes:” to “Explain if unable to visualize…” to clarify intent to document anything relevant in space provided.</td>
</tr>
<tr>
<td>13</td>
<td>In the General Appearance area, deleted “Basic Hygiene” and changed to “Cleanliness”; entirely deleted Body Profile and selections.</td>
</tr>
<tr>
<td>13</td>
<td>Switched order of last two line items.</td>
</tr>
<tr>
<td>14</td>
<td>Added a selection for labeling a ‘scab’ by using the letter W. Changed “for” to “prior to” in Summary.</td>
</tr>
<tr>
<td>15, 16</td>
<td>Added example pages of the sample form completed in entirety for a fictitious donor.</td>
</tr>
<tr>
<td>13–16</td>
<td>Removed all checkboxes and spaced selections appropriately.</td>
</tr>
<tr>
<td>6–8</td>
<td>Changed all references to “checking” or “box” and replaced them with directions to circle appropriate selection or word.</td>
</tr>
</tbody>
</table>

Appendix III (RADS Council Workgroup/SAB)

1  The title was changed from a guidance document to an appendix. This was done to clarify original intent that using this form and following the instructions are mandatory.

3  The list of latest contributors was added.

4  Section listings have been expanded with new subsections; pages and titles updated.

5  The Introduction was expanded to include: a broader description of other standards related to significant steps of the donor eligibility determination process; a description that this method, or an equivalent method, shall be implemented, and that periodic evaluation of
competency is expected for staff performing physical assessment; clarification that electronic documentation systems shall meet the same requirements for compliance as paper documentation records; and, a description of this version’s development and the approval process.

6, 7 The Purpose is described in more detail, more Definitions and Abbreviations were added, and the Materials section updated to clarify that full compliance is expected. It is additionally described that, except for documenting whether lymph nodes appear enlarged/abnormal, this guidance document does not address internal findings and that an “internal findings form” can be developed separately.

8 to 11 On each page, the procedural steps were updated to align with changes to the form in regard to: the new order of the listing of signs in the Assessment box; the switched order of documenting “No” and “Yes” which are now further separated on the form to provide better documentation practice; and, descriptions changed to documenting “No” or “Yes” instead of using directions to “circle appropriate selection or word.”

8 In the Identification box, procedural steps have been revised to meet changes to the form such as: documentation of agreement among recovery team personnel that the body’s physical characteristics and identification are consistent with available relevant medical records; direction provided to contact appropriate management for guidance prior to recovery if there is a discrepancy regarding identification of the body; the procedure describes an expectation that the SOPM shall include directions when the donor’s identification is discrepant or questionable; and, there was an addition made to document not only the date and time when these critical steps were performed but also the appropriate time zone.

9 Procedural steps were updated to describe more detail how the donor’s weight was derived and that the weight documented was agreeable to all recovery personnel, and a new selection was added to the type of autopsy (i.e., toxicology screen only).

10 Procedural steps were updated to describe more detail, especially: when there is an expectation to contact the local Eye Bank and obtain documentation of their ocular assessment; the possible color of spots in the mouth was expanded to include not only white but also yellow; the locations on the body where lymph nodes can be palpated were added; findings of abnormal lymph nodes must be documented but there is not an expectation to identify them on the body schematic; a description was added to provide background on the size of an enlarged lymph node and that abnormal findings can relate to draining pus and/or if it feels hard; and, a reference to the Merck Manual was added. For a few listings that have multiple terms in a listing, a new description states there is no longer an expectation to also circle the word(s) in the listing to indicate which finding(s) were identified, but it (they) must be clearly explained and identified on the schematic.

11 Procedural steps were updated to describe more detail, especially: to allow documentation when the liver cannot be palpated and space to explain why; that there is an expectation to document if a tattoo is suspected to be recent/new and descriptive examples are now provided (i.e., scabbing is present on tattoo, tattoo area is shaved, tattoo has vibrant colors, or if there is inflammation/swelling/redness within the tattoo), and that providing a description (location and content/subject) of any tattoos and the location of piercings and type of body jewelry are also expectations; and, the observation for “perianal lesions or insertion trauma” was changed to “perianal lesions or anal trauma” because referencing “insertion trauma” could be subjective. At “Instructions for Completing Page 2 (Schematic)” it now states that a standardized Key is used, and that documentation also occurs if there are no findings on either schematic view. A summary was added that completion of a new page expects the following additional documentation: 1) if any photos of the body were taken; 2) if consultation occurred regarding physical assessment findings; and 3) if personal effects were with the body. Direction includes that any consultation be explained in the “Notes” section, and that this area can also be used for documenting details.
regarding whether a biopsy was requested and taken. If personal effects are present a description and their disposition is now required documentation.

A new section (Notes Regarding Documentation) gives a description that spaces provided on this form for documenting observations can be expanded to meet local policy and that additions can be made to the form but the content of this form must be included in entirety. It’s now clarified that documentation concerning “time” is preferable when based on a 24-hour clock (military time). Use of the notations “pm” and “am” are now described as not preferred. Documenting the appropriate time zone for the respective region has been added. Documenting and sharing deviations is now required when the deviation can affect the eligibility determination of the donor or release of tissue. The list of references was updated and a few added. The section on Historical Changes was reformatted.

A comment period produced a number of recommendations that were accepted in full, accepted in part, or rejected. Refer to “Compiled Comments & Responses to Tissue Donor Physical Assessment Form”.

The AATB recognizes the efforts of the following individuals who generously donated their time and expertise to creating these requirements.

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Gail Gantt
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## Identification

Name on Document of Gift/Authorization: __________________________  Recovery Agency ID: __________________________

Manner identified by:  
- [ ] ID Band  
- [ ] Body/Toe Tag  
- [ ] Other (describe): __________________________

### Identification Band/Tag:

ID re-created: __________________________  Or:  
- [ ] N/A Photo taken/saved  
- [ ] N/A ID not present

The body’s physical characteristics (e.g., age, gender, race, height, weight, signs associated with the cause of death, or information on the DRAI form) are consistent with available relevant medical records, and the identification is consistent with other documents.

- [ ] Yes  
- [ ] No

If answered “NO,” contact appropriate management for guidance before proceeding with recovery.

Personnel verifying donor ID: __________________________  Date/Time/Zone: ________/______/____

## General Appearance/Evidence of Donation:

Height: _______  
- [ ] in  
- [ ] cm  
Heights:  
- [ ] estimated/team  
- [ ] actual  
- [ ] reported (source : _______)

Weight: _______  
- [ ] lbs  
- [ ] kgs  
Weights:  
- [ ] estimated/team  
- [ ] actual  
- [ ] reported (source : _______)

Cleanliness:  
- [ ] Good  
- [ ] Poor (Describe if poor): __________________________

Ocular Donation:  
- [ ] No  
- [ ] Yes  
If “Yes,”  
- [ ] corneas only  
- [ ] whole eyes

Organ Donation:  
- [ ] No  
- [ ] Yes  
If “Yes,” UNOS # __________________________

## Autopsy Status:

- [ ] Pre-Autopsy Recovery  
- [ ] Post-Autopsy Recovery  
- [ ] No Autopsy Planned  
- [ ] Unknown

### Type:

- [ ] Full  
- [ ] Limited  
- [ ] View only  
- [ ] Toxicology screen only  
- [ ] Unknown

## Assessment:

Are there signs of any of the following? Explain “Yes” answers, or any if “unable to visualize/palpate.”

- [ ] No…Abnormal ocular findings (e.g. icterus, scarring) …  
  - [ ] Yes  
  - [ ] Unable to visualize: __________________________

- [ ] No…White/Yellow spots in the mouth  
  - [ ] Yes  
  - [ ] Unable to visualize: __________________________

- [ ] No…Jaundice  
  - [ ] Yes: __________________________

- [ ] No…Trauma/Infection to tissue recovery areas  
  - [ ] Yes: __________________________

- [ ] No…Rash/Scab/Skin lesion (non-genital)  
  - [ ] Yes: __________________________

- [ ] No…Blue/Purple (gray/black) spots/lesions  
  - [ ] Yes: __________________________

- [ ] No…Non-medical injection site  
  - [ ] Yes: __________________________

- [ ] No…Enlarged/Abnormal lymph node(s)  
  - [ ] Yes: __________________________

- [ ] No…Enlarged liver  
  - [ ] Yes  
  - [ ] Unable to assess: __________________________

- [ ] No…Genital lesions  
  - [ ] Yes: __________________________

- [ ] No…Perianal lesions or Anal trauma  
  - [ ] Yes: __________________________

- [ ] No…Tattoos/piercing  
  - [ ] Yes: __________________________
Tissue Donor Physical Assessment Schematic

Recovery Agency ID: _______________________

☐ Check if no observations noted

Key to Schematic:

(A) Abrasion
(B) Bruise/Contusion/Hematoma
(C) Cast/Ortho device
(D) Dressing/Bandage
(E) ET tube/NG tube
(F) Fracture/Dislocation
(G) IV/IO/Arterial Line
(H) Skin Tag(s)
(I) ID Band/Tag
(J) Laceration/Wound
(K) Autopsy Incision
(L) Needle entry site
(M) Organ Recovery Incision

(N) Body piercing – requires description
(O) Urethral catheter
(P) Skin lesion – requires description
(Q) Scar (surgical/trauma)
(R) Rash
(S) Ocular Donation
(T) Tattoo – requires description (also note if suspected to be new)
(U) Stretch mark(s)
(V) Mole
(W) Team Blood Draw Site

(X) ________________________________
(Y) ________________________________
(Z) ________________________________
(AA) ________________________________

Physical Assessment performed by: __________________________ Date/Time/Zone: _________ / _______ / ___

Page 2 of 3
Tissue Donor Physical Assessment Summary

Recovery Agency ID #: _____________________

☒ No……. Were photos of the body taken?………………………… ☐ Yes

☒ No……. Did consultation of physical assessment findings occur? … ☐ Yes

Notes:
________________________________________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________________________________________

☒ No……. Personal effects with body………☐ Yes

If yes, check only those that apply and describe:

☒ Clothing ………. Describe: ________________________________________________________________

☒ Wallet/purse……… Describe: ________________________________________________________________

☒ Jewelry ……….. Describe: ________________________________________________________________

☒ Other ………….. Describe: ________________________________________________________________

☒ Other ………….. Describe: ________________________________________________________________

☒ Other ………….. Describe: ________________________________________________________________

☒ Other ………….. Describe: ________________________________________________________________

Disposition:
________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________

Summary:
A review of available relevant medical records and physical assessment findings were completed prior to recovery and found to be: ☐ acceptable. ☐ not acceptable.

_____________________________________________ / _________ / ________
Responsible Person Date/Time/Zone
Appendix IV:
PREVENTION OF CONTAMINATION AND CROSS-CONTAMINATION AT RECOVERY: PRACTICES AND CULTURE RESULTS REQUIREMENTS

Introduction

In the spring of 2002, the Board of Governors assembled a Task Force to review reports of recipient infections that were allegedly associated with tissue allografts. In 2003, the Task Force made several recommendations that were considered by the Standards Committee. It was determined that additional steps could be taken to control the possibility of contamination and/or cross-contamination during recovery of tissue from deceased donors, and that the presence of certain microorganisms would necessitate discard of the tissue. The Committee also agreed that the interpretation of associated recovery (pre-processing) cultures from the same donor warrant scrutiny, and that sharing culture results is important.

The Board of Governors decided to include some of these recommendations in the AATB’s Standards for Tissue Banking. Other recommendations were more representative of good practice, and these recommendations were published in the original version of this work when it was titled “Prevention of Contamination and Cross-contamination at Recovery: Practices & Culture Results, Guidance Document (No. 2), October 20, 2004.”

In early 2006, a technical work group was formed to expand the content of the guidance to include another factor that could prevent contamination and cross-contamination at recovery. Suitability of the site where tissue recovery takes place must be evaluated and determined to be acceptable prior to recovery, and revisions were made to D5.500. The goal is to set specific guidelines/suitability parameters that define required controls. There is not an expectation that actual detailed monitoring be performed at each recovery site. Parameters have been developed that, when applied, can ensure that the environment in which recovery occurs meets minimum specifications and should not introduce, transmit, or spread contamination. These additional controls are appropriate and reasonable and have been formulated by this work group from practices tested and used by AATB-accredited tissue banks.

In January of 2007, another work group of subject matter experts was organized to collect information regarding how tissue banks were applying the zone recovery concept and sequencing to their recovery operations. These practices were reviewed for consistency and common practices were added to this work. There is consensus that documentation methods that describe zones and sequencing facilitate tissue suitability determinations. Version 2 of the guidance document was published on May 29, 2007 and included updates for zone recovery and sequencing, and added recovery site suitability parameters along with a sample form.

In 2016, the guidance document became an appendix to the Standards when the 14th edition was published.

Definitions

As used in this appendix, the following definitions apply:

SEQUENCING - A procedure utilized at tissue recovery that documents the order (sequence) that tissues were recovered from one donor.
ZONE RECOVERY - A tissue recovery method by which specific, well-defined areas of the body are identified as zones and from which individual tissues are recovered using the same sterile instrumentation/equipment and sterile gloves. It is recommended that skin recovery be performed as a separate zone so that pre-sterilization/pre-disinfection culture results of other tissues can be independently reviewed.

ISOLATION DRAPING - A method used whereby areas adversely affected by trauma are first segregated (isolated) by entirely covering them to contain potential contamination and prevent cross-contamination to other tissues recovered from the same donor. If tissues from these areas are retrieved, they should be sequenced as the last to be recovered.

Recovery Practices

RECOVERY TECHNIQUES:
Certain tissue recovery practices may be helpful in controlling contamination and cross-contamination of individual tissues. These include recovery techniques such as sequencing of the tissue recovery, use of well-defined zone recovery techniques, and isolation draping in the presence of trauma (see D5.530). Recovery activities should be reviewed to help determine the likelihood of cross-contamination of individual tissues.

RECOVERY SITE QUALIFICATION:
Parts of applicable federal regulations can be referenced (at §1271.190 Facilities, and at §1271.195 Environmental Controls and Monitoring) and used as guides for practical application when determining that a recovery site is satisfactory. The evaluation of the suitability of the site of recovery must be documented and this record shared with entities that receive tissues from the donor [at §1271.160 Quality Program, (b) Functions (2)]. Due to many circumstances related to events that could occur after death, the donor body may be moved to various sites (e.g., dedicated tissue recovery site, healthcare facility operating room, autopsy suite). The room in the building where tissue recovery takes place must offer a level of control that will not increase the potential to introduce contamination or cause cross-contamination. Minimum qualification parameters have been established that should ensure control of this environment and be qualified for tissue recovery.

Prior to recovery, the following evaluations are performed and there must be:

1) adequate floor and tabletop space to allow separation of sterile instrumentation and performance of aseptic recovery procedures (i.e., zone recovery, sequencing, draping, tissue wrapping);
2) adequate lighting to perform physical assessment and tissue recovery;
3) adequate plumbing and drainage for the intended purpose to include access to an adjacent or suitably located hand-washing area that can be used to perform a hand/forearm surgical scrub or wash;
4) a controlled, closed airflow system in the recovery area. This means there is no direct access to the outside of the building from the room at any time during, before, or after tissue recovery (e.g., doors, windows that can open, fans, air conditioners); In addition, all vents appear clean and there is no vented airflow noted to be directed and flowing onto sterile fields;
5) walls, floor, and work surfaces that are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair;
6) no visible signs of insects, rodents, or other pests;
7) an evaluation for any standing fluids or contaminated waste in the room that could be a source of airborne bacteria, mycobacteria, yeasts or fungi, and if present, it must be rectified prior to recovery; and

8) proper preparation of the recovery site by cleaning and decontaminating all working surfaces prior to recovery of tissue;

Concurrent with tissue recovery, the following site parameters must be controlled:

1) human traffic is restricted and all personnel entering the recovery area must be properly outfitted and their movement controlled; and

2) no other activities (i.e. embalming, autopsy, another tissue donor recovery) can occur simultaneously in the same room as this tissue recovery;

After tissue recovery, the following activities must be performed:

1) all contaminated/biohazardous re-usable supplies were decontaminated, and adequately contained for transport, and that contaminated/biohazardous waste was properly disposed, or contained and transported to a disposal site; and

2) all working surfaces and the floor were decontaminated using approved solutions and equipment.

Note: If there is an ability to rectify certain parameters that may not be initially met (e.g., there is a need to cover room furniture, drains, sinks, or walls), this must be described in procedures, and such a scenario warrants review by a designated, responsible person prior to proceeding with recovery. There must be assurance that there is no evidence that the scenario would compromise the suitability of the recovery site by being a source of contamination or cross-contamination.

Recovery personnel must document whether the above parameters have been met, and if the recovery site has been determined to be suitable. See “Sample Tissue Donor Recovery Site Assessment Form” in this appendix.

ZONE RECOVERY AND SEQUENCING:

The primary objective of zone recovery is to reduce the potential spread of microorganisms (cross-contamination) from one region of the body to another by employing isolation techniques. Isolation is accomplished through evaluation of trauma, specific draping if necessary, placement of drapes after the skin prep has occurred, and by using dedicated instruments for each zone. The recovery technician must also make glove changes between zones and may change their gown when indicated (e.g., when it becomes soiled or contaminated, or when sequencing recovery from a zone that is at increased risk for contamination to a zone of lesser risk). By performing these functions and documenting actions this will facilitate suitability determinations made from pre-sterilization/pre-disinfection culture results. These guidelines are reproducible in multiple settings and scenarios and, when followed, can reduce the risk of contamination and cross-contamination at recovery.

A zone is identified as a region of the body. Zones are recovered in a sequence that is recorded, but the sequence order cannot be prescribed due to many possible variables. If preferred, gloves can be changed following each tissue recovered within a zone. In the presence of trauma when isolation draping methods are used, these areas become zones that are prepped and tissue excised only after recovery of all other tissue has occurred.
Some zones (i.e., skin, vertebrae/spine, the pelvis, thoracic cavity, traumatized areas) should be treated as inherently possessing an increased risk for contamination and warrant special consideration when recovering tissue in that zone (e.g., deciding the sequence of zone recovery and whether extra gown changes should occur). Recovery records should include space to document unanticipated zones due to trauma or other factors.

Common zones:
- skin - back, abdomen, left anterior leg, right anterior leg, left posterior leg, right posterior leg;
- ocular - corneas, sclera, wholeglobe;
- intracranial tissue - dura mater, brain;
- mandible;
- thoracic - heart, thoracic aorta, pericardium, ribs, nerves;
- abdomen - abdominal aorta, iliac artery and vein, nerves;
- upper extremity left - rotator cuff, humerus, radius, ulna, metacarpals, nerves;
- upper extremity right - rotator cuff, humerus, radius, ulna metacarpals, nerves;
- lower extremity right - vessels, assorted tendons, fascia lata, femur, tibia (with patellar ligament), tibia, fibula, Achilles tendon with calcaneous, talus, nerves;
- lower extremity left - vessels, assorted tendons, fascia lata, femur, tibia (with patellar ligament), tibia, fibula, Achilles tendon with calcaneous, talus, nerves;
- left hemi-pelvis/ilium - due to proximity of the hemi-pelvis to the viscera, these tissues should be recovered after all other musculoskeletal tissues from the respective extremity have been recovered and packaged;
- right hemi-pelvis/ilium - due to proximity of the hemi-pelvis to the viscera these tissues should be recovered after all other musculoskeletal tissues from the respective extremity have been recovered and packaged; and
- vertebrae/spine - cervical, thoracic, lumbar; due to the proximity of the vertebrae/spine to central nervous system fluids and tissues, these tissues must be considered a separate zone.

DOCUMENTATION:

Practices to control contamination and cross-contamination at recovery must be utilized as described and recovery agencies must document these significant steps. Recovery records (forms) must reflect the sequential recovery of all tissues and there should be a written statement to acknowledge “zone recovery techniques were utilized.” The individual zones for each donor must be identified on the paperwork so all processors can utilize this information along with the results of the pre-sterilization/pre-disinfection cultures. The order of recovery of each zone cannot be prescribed but the sequence of zones must be recorded in the recovery records. It is recommended that order of recovery within a zone be recorded. Any deviation from established protocols for isolation draping, zone recovery, or sequencing, must be approved by a responsible person and details documented.
Records must be maintained and shared demonstrating that pre-established suitability parameters for the recovery site were determined to be acceptable prior to tissue recovery. See “Sample Tissue Donor Recovery Site Assessment Form” in this appendix.

Pre-sterilization/pre-disinfection Cultures Results

RESULTS REPORTING AND SHARING:

To facilitate tissue suitability determinations, pre-sterilization/pre-disinfection cultures results must be provided to recovery agencies by testing laboratories or tissue processors within a reasonable amount of time after recovery.

Knowledge of a donor’s pre-sterilization/pre-disinfection cultures results could affect the eligibility determination made by different processors. Therefore, recovery agencies must share relevant tissue recovery culture information (pre-sterilization/pre-disinfection cultures) with all tissue establishments who are known to have also recovered tissues, or to have received recovered tissues, from the same donor (see D4.300). Procedures must be used that describe how this information is received and disseminated in a timely fashion so that proper tissue disposition decisions can be made. The “Current Good Tissue Practices for Human Cells, Tissues, and Cellular and Tissue-Based Product Establishments; Final Rule” (CGTPs) describes the need for procedures for sharing of results from the same donor that relate to the possible contamination of the product or potential transmission of disease [at §1271.160 Quality Program, (b) Functions (2)]. For details regarding expectations for sharing of results from the same donor, refer to B1.500, D4.300, F3.100, J1.200, and K1.100.

PATHOGENIC, HIGHLY VIRULENT MICROORGANISMS:

Two microorganisms (and others that have been identified for specific tissue types, see E2.800), are considered pathogenic, highly virulent organisms. Individual tissues with culture results yielding Clostridium or Streptococcus pyogenes (group A strep) should be discarded (see K2.310). Other individual tissues from the same donor that were recovered under conditions that could result in cross-contamination should also be discarded unless they can be treated with a validated sterilization process (see K2.320). Tissue establishments (i.e., processors) that determine final donor eligibility may consider that more microorganisms fit this classification.

Considerations

CULTURING METHODS:

There are different pre-sterilization/pre-disinfection culturing methodologies in use. The filter-culturing technique that is used for tissue types such as cardiac tissue (C) and vascular tissue (V) has a sensitivity that is likely higher than that experienced by the swabbing techniques that are most popular for use with musculoskeletal tissue (MS) types. Establishing quantifiable bioburden, actual colony forming units per mL (CFU/mL), can be accomplished via filter-culturing and fluid-extraction techniques but not by limitations of swabbing techniques and protocols used. The low accuracy, sensitivity, and reliability of swab culturing plays heavily upon the decision to discard tissues with positive cultures of pathogenic, highly virulent microorganisms, since the level of bioburden cannot be established. Also, a negative swab culture may be a false negative result and any result can under-represent all organisms present. This is especially suspect if one tissue grows Clostridium or Streptococcus pyogenes yet another tissue sequentially recovered in the same recovery zone does not. Validated sterilization processes must be in place to allow processing tissues meeting this scenario.
PROCESSING METHODS:

Generally, there are two processing methods: disinfection and sterilization. If a tissue type is processed in a fashion where it is not sterilized, only disinfected [e.g., cryopreserved (MS) like tendons, (OA), (C) and (V)], then considerations must be made if there is an associated culture result from that donor that is considered pathogenic, highly virulent. If tissue recovery controls are in place and documented that offer assurance that cross-contamination did not occur, then that tissue may be suitable if its own culture result is acceptable. If such controls are not in use and documented (i.e., sequencing, zone recovery, trauma recovery protocols such as isolation draping), the intent of this appendix is to discard all tissues that were only disinfected (not sterilized).

References


Sample Tissue Donor Recovery Site Assessment Form

Tissue Donor ID #: ____________________ Recovery Site Name:____________________

Recovery Site Location (circle one):
- Dedicated Tissue Recovery Site
- Healthcare Facility Operating Room
- Autopsy Suite
- Other Area (describe): ______________________________________________________

Check the appropriate box. Any “No” answer must be described in detail, rectified if possible, and requires review by a responsible person.

<table>
<thead>
<tr>
<th>Pre-Recovery Evaluation</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>1. Adequate floor and tabletop space to allow separation of sterile instrumentation and performance of aseptic recovery procedures (i.e., zone recovery, sequencing, draping, tissue wrapping) is present.</td>
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<td>2. Adequate lighting to perform physical assessment and tissue recovery is present.</td>
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<tr>
<td>3. Adequate plumbing and drainage for the intended purpose to include access to an adjacent or suitably located hand-washing area that can be used to perform a hand/forearm surgical scrub or wash is present.</td>
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<tr>
<td>4. The recovery area has a controlled, closed airflow system. This means there is no direct access to the outside of the building from the room at any time during, before, or after tissue recovery (i.e., doors, windows that can open, fans, air conditioners, etc.); In addition, all vents appear clean and there is no vented airflow noted to be directed and flowing onto sterile fields.</td>
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<td>5. The walls, floor, and work surfaces are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair.</td>
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<td>6. Signs of insects, rodents, or other pests are not visible.</td>
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<td>7. Standing fluids or contaminated waste in the room, that could be a source of airborne bacteria, mycobacteria, yeasts or fungi, are not present.</td>
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<tr>
<td>8. The recovery room was properly prepared by cleaning and disinfecting all working surfaces prior to recovery of tissue.</td>
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Concurrent with Recovery: | Yes | No |
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<td>1. Human traffic is restricted and all personnel entering the recovery area are properly outfitted and their movement controlled.</td>
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<tr>
<td>2. Other activities (e.g., embalming, autopsy, another tissue donor recovery) did not occur simultaneously in the same room as this tissue recovery.</td>
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Post-Recovery Activities: | Yes | No |
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<td></td>
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<tr>
<td>2. All working surfaces and the floor were cleaned using approved solutions and equipment.</td>
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Comments: ________________________________________________________________

The above parameters have been met and the recovery site has been determined to be suitable (check one): Yes ______ No ______

Completed By: ______________________________ Date/Time: _______________
Document Control No./Date: ________________________________
In conjunction with input provided by members of AATB’s Standards Committee who served during the time when this work was developed, the following members contributed to the original document and a subsequent revision:

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