15th Edition

STANDARDS FOR TISSUE BANKING

American Association of Tissue Banks

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15th Edition (revision 2)

Original announcement Date: July 31, 2024 / AATB Bulletin No. 24-6
Original implementation date: This 15th Edition became effective January 31, 2025.
Revision 2 announcement date: August 11, 2025 / AATB Bulletin No. 25-3
Revision 2 implementation date: revision 2 became effective August 11, 2025.

IMPORTANT NOTICE: AATB Standards are subject to revision at any time pursuant to the Association's procedures. Such revisions may consist of the addition of a new Standard, the rescission of an existing Standard, and/or the partial amendment of a Standard. Notice of each such revision is given by AATB by posting on the Association's website, and distributing via email, a "Bulletin" that announcesthose changes and their respective effective dates. Persons seeking to determine the current provisions of Standards *should* always review the Bulletins for any such announcement of revisions to Standards or may request a current and effective copy of the Standards by sending a request to the AATB mailbox: standards@aatb.org. Please visit https://www.aatb.org/standards-inquiry-form to submit any questions concerning Standards or revisions thereof.

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Guidance Document No. 7, v2 Evaluation of Body Cooling at Standard D5.400 (December 9,2013)

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

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AATB-AOPO-EBAA Guidance Document, Effective Quality assurance of the DRAI, v2 (September16, 2013)

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Library of Congress Catalog Card Number 84-7269

Printed in the United States ofAmerica

Initial development of the AATB Standards for Tissue Banking was partially funded under contract NOO14-84-C-0251,
Naval Medical Research and Development Command,
Naval Medical Command, National Capital Region, Bethesda, Maryland 20814.

DEDICATION

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, embodying the same spirit that led to the formation of the AATB and the development of these Standards.

PREFACE

Progress in medical and biological science 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.

AATB was founded in 1976 as a voluntary, scientific, andeducational 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 qualityin quantities sufficient to meet national needs. A year later, a book of Proceedings 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. From these humble beginnings grew a series of guidelines, technical manuals, and, ultimately, these Standards for Tissue Banking. The history of this evolution is available at https://www.aatb.org/standards-history.

A component of AATB's mission is to establish and promulgate standards to provide tissue banks with performance requirements intended to prevent disease transmission and support quality measures thatassist clinical performance of transplanted tissue. AATB's Standards for Tissue Banking was published in 1984, marking the first professional standards ever developed in the field of banking transplantable human tissues, other than ocular. Furthermore, the AATB fosters education and research, and promotes quality and safety in cell and tissue banking and transplantation. A voluntary accreditation program for tissue banks was launched in 1986 with inspection and accreditation based upon adherence to these Standards.

INTRODUCTION

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 and appropriate standing committees and/or ad hoc task forces, as needed. Information on Councils and Committees can be found at https://www.aatb.org/about/councils-committees. All revisions are subject to approval by the AATB Board of Governors.

Following approval, the Standards are released to membership for implementation by a specified effective date, as of which their provisions become required. This effective date is six months after release unless stated otherwise. Revisions may be implemented at any time between release and effective date. If the effective date of a particular approved revision occurs later than the next publication's specified effective date (e.g., to allow an extended period to prepare for implementation of a major revision), that revision will be distinguishable from text on a routine timeline by inclusion within a text box with its effective date.

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

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: Request for Variance from Standards.

With regards to labeling provisions found in these Standards, required elements of information to be displayed are shown in quotation marks. Periods are not necessary on the label. If required information in Standards is in quotes and all capital letters, then it must appear in all

capital letters on labels. If the required labeling information is not in all capital letters in Standards, then it is at the discretion of the tissue bank regarding what format to use, so long as the words within quotes are exactly as presented in the given standard.

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
(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.

DEFINITIONS OF TERMS

Unless otherwise defined in the tissue-specific *Standards*, the following terms *shall* be defined as follows:

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 H7.710 or H8.300, 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.

APPROPRIATE MEASURES (R) - Using available resources to accomplish screening or testing. May be employed If the donor of reproductive tissue cannot be tested due to death or inability to be located.

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 *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.

AVAILABLE FOR DISTRIBUTION – the status of an HCT/P upon *verifying* and documenting that the HCT/P meets the release criteria on the basis of a review of manufacturing and tracking records pertaining to the HCT/P, documented by a *responsible person* with the date when the determination that the HCT/P is *available for distribution* has been made.

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.

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 and is currently responsible.

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

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.

DEFINED REQUIREMENTS - The broadest set of requirements that are applicable to the *tissue bank*, including the elements described in these *Standards*, applicable requirements from other standards-setting organizations, as well as federal, state, and local requirements.

DEHYDRATION – The removal of liquid water from *tissue* with the purpose of obtaining a *tissue* sufficiently low in water content. For example, *dehydration* methods *may* include chemical (alcohol), *critical*/super*critical* drying, simple air drying, drying in a desiccator, or drying in a dehydrator.

DESICCATION – See *dehydration*.

DEVIATION – An event that is a departure from a regulation, standard, *procedure* or normal practice, see *error*.

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 who is the source of *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 SOURCE – Entity such as a hospital, medical examiner, coroner, or individual allied health care professional 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 [per ISO 14644-1, Edition 2].

ELECTRONIC SYSTEM – Computerized system that creates source documents (electronic *records*).

ELECTRONIC QUALITY MANAGEMENT SYSTEM – 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 System.

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 – An unplanned *deviation* from the *SOPM, Standards*, or applicable laws or regulations, see *deviation*.

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.

GOVERNING BODY – The body within a *tissue bank* in whom policy-making authority resides, unless otherwise provided by the institution of which it is a part. It may consist of a Board of Trustees, Board of Governors, Board of Directors or a designated responsible individual. A Board *shall* consist of individuals from various professions.

IMAGE(s) – A representation of the external form of an object, place, or person in a photographic, digital, or videographic format.

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, collection,* or *acquisition* of his or her *tissue*, where *recovery, collection* or *acquisition* 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.

LYOPHILIZATION (Freeze Drying) –The removal of water from a *tissue* after it is frozen and placed under a vacuum, allowing the ice to change directly from solid to vapor without passing through a liquid phase. The process consists of three separate, unique, and interdependent processes; freezing, primary drying (sublimation), and secondary drying (desorption).

MANAGEMENT WITH EXECUTIVE RESPONSIBILITY (MWER)– Those senior employees of an establishment who have the authority to establish or make changes to the establishment'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 *allograft* 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 *allograft* or *autograft* 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.

PATCH GRAFT (C) – A segment of cardiac *allograft* 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 d*onor'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 site*s.

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 in order to prevent occurrence; *may* be performed in conjunction with *corrective action(s).*

PRIMARY PACKAGE - Layer of packaging in direct contact with *tissue*.

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 the output of a process consistently meets predetermined specification.

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 (i) *disinfecting, (ii) sterilizing*, (iii) *packaging* in *primary package* as defined in *Guidance Document No.9*, (iv) *packaging* in *secondary package*, when used, as defined in *Guidance Document No9*, (v) *labeling*, and (vi) 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 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 level of *quality* of *tissue* that indicates handling according to acceptable standards and assures substantial freedom from the potential for harmful effects to *recipients*. The condition of being protected from risk or injury associated with occupational exposure.

SATELLITE FACILITY – 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.*

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.

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 – The absence of detectable, viable, *microorganisms* (refer to ANSI/AAMI ST67:2011) including spores.

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 a product (e.g., *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 used to render a product (e.g., *tissue)* within its final *sterile* barrier system (e. g., *package, container*) *sterile* (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 receives *finished tissues* for *storage* and/or further *distribution.*

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 track *tissue, critical* supplies, reagents, materials, instruments, and equipment used during any step of donation, *recovery*, *collection*, or *acquisition*, *processing*, testing, *storage*, *distribution,* or *disposition*.

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*.

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.

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

A. Organization and Leadership

A1.000 General

The *tissue bank shall* have a defined structure and leadership, including a *governing body* and *management with executive responsibility (MWER)*.

A1.100 Key Roles

The key roles, functions, responsibilities, and interrelationships *shall* be defined for *quality* and technical activities.

A1.200 Organizational Structure

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*.

A1.300 Purpose

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.

A2.000 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*.

A3.000 Governing Body

The *governing body shall* retain ultimate responsibility and authority for the *tissue bank.*

A3.100 Scope of Activities

This Board or designated individual *shall* determine the scope of activities to be pursued by the *tissue bank*.

A3.200 Management with Executive Responsibility

The *governing body shall* designate one or more senior employees as *MWER*. Issues of liability, ethical considerations, fiduciary responsibility, and compliance with defined requirements, these *Standards*, and the *tissue bank*'s *Standard Operating Procedures Manual (SOPM) shall* be the responsibility of the *governing body* and *MWER*.

A4.000 Mergers, Acquisitions, or Dissolution

The *tissue* establishment *shall* have a contingency plan in place for *tissue* that remains in inventory and for retention of records for traceability in the event of merger, acquisition, or dissolution. The plan *shall* provide for traceability of records for distributed tissue in case of an adverse event or other reason deemed necessary for traceability of tissue or sharing of information.

In the event of a merger or acquisition, tissue remaining in inventory and records for traceability *shall* become part of the merger or acquisition unless other disposition arrangements have been made.

In the event of a dissolution, the contingency plan *shall* also address disposition of tissue that remains in inventory and the mechanism for traceability of records after closure of the tissue establishment. The establishment and its responsible person must ensure that they comply with the record retention requirements (i.e., record traceability) for the duration of their record retention responsibilities.

A5.000 Medical, Technical, and Scientific Support

The *tissue bank shall* establish a mechanism to access medical, technical, and scientific advice as needed.

B. Quality System

B1.000 Scope and Structure

The *tissue bank shall* have a *quality* management system that ensures the *quality* and *safety* of products and services provided by the *tissue bank*.

B1.100 Quality Management System

The *quality* management system *shall* encompass applicable *defined requirements*, including the elements described in these *Standards*, applicable requirements from other standards-setting organizations, and federal, state, and local requirements.

B1.200 Quality Policy

The *quality policy shall* be understood, implemented, and maintained at all levels of the organization.

B2.000 Quality Assurance Program

A *quality assurance (QA)* program *shall* be established and maintained to ensure conformity with the *tissue bank*'s *SOPM*, these *Standards*, and *defined requirements*.

B2.100 Elements

The *QA program shall* include, at a minimum:

1) designating and managing *quality control (QC)* 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) archived documents, and

e) master lists of preprinted *labels;*

11) evaluating training of personnel and, where required, the *competency* of personnel, and requiring that staff be 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*.

B2.200 Qualification, Verification, Validation

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.

B2.210

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.

B2.220

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

B2.240. 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 *revalidation* is necessary per method 1 of this section.

B2.230

*Package*s used to transport recovered *tissue*, to ship *tissue* in-process, or to distribute *finished tissue shall* be *qualified*. The method(s) used *shall* be validated to demonstrate that the *packages* can maintain the required conditions to meet the *finished tissue quality* at the end of its stated expiration date.

B2.240

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*.

B2.300 Investigations and Audits

The QA program *shall* ensure there is an investigation of *accidents*, *errors*, *complaints*, *deviations*, and *adverse outcomes* and review for completeness. Investigation *shall* include a summary report, precipitating events, recommendations, and *resolutions*. The QA program *shall* retain for 10 years all reports generated.

B2.310

The QA program *shall* ensure a documented investigation if any *error* or *accident* in obtaining *informed consent* or *authorization*, in *donor* screening, *collection*, *acquisition*, or *tissue recovery*, *processing*, quarantining, releasing, *labeling*, storing, and *distribution* or dispensing *may* affect the *safety* of *tissue* to be released or that has been released. The Medical Director *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*.

B2.320
The QA program *shall* ensure that written and oral *complaints* regarding *tissue quality*, *safety*, packaging, or effectiveness is 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 *tissues 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*).

B2.330
The Medical Director *shall* review *complaints* that are medical in nature.

B2.340
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 *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 B2.310).

B2.350
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* record.

B2.360
All *tissue banks shall* establish policies and *procedures* regarding the scope and frequency of routine and focused QA *audits*. The QA program staff *shall* perform *audits*, at least *annually*, of the major *tissue* banking operational systems to identify trends or recurring problems in: *donor* evaluation and acceptance; *tissue recovery* or *collection*, *processing*, *preservation*, and packaging; *donor* and *tissue* testing; quarantining; *labeling*; *storage*; *distribution*; *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 *audit*ed. The *tissue bank*

shall take *corrective action(s)* when necessary, including a re-*audit* of deficiencies.

B3.000 Oversight

A management representative appointed by *MWER 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 *MWER* on a defined basis.

B3.100 Quality Reviews

QA program personnel *shall* have responsibility for assuring compliance with the *SOPM* regulatory requirements. A designated individual, generally familiar with, but not having performed, the specific work being reviewed, *shall* be responsible for each *quality* review. 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. *QA* personnel *shall* be responsible for managing *audits*.

B3.200 Audit Reviews

The QA program staff *shall* document and report the dates and results of each *quality audit* (and re-*audit*) to management responsible for the *audit*ed systems, who *shall* review each report.

B3.300 External Audits

External *audits may* be indicated for certain services, suppliers, contractors, and consultants. See B9.200 and F2.000.

B4.000 SOPM and Document Control

The *tissue bank shall* establish policies and *procedure*s that address all *quality* and technical activities necessary to conform to these *Standards*. These policies and *procedures shall* be captured in writing in an *SOPM*.

B4.100 SOPM Availability/Utilization

The policies and *procedures* of the *SOPM shall* be available at all locations where designated, or where policies and *procedures* are 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. Satellite facilities *shall* be operated in accordance with the *tissue bank*'s *SOPM*.

B4.200 Document Control System

The bank *shall* have 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.

B4.300 SOPM Content

The *SOPM shall* specifically include, at a minimum, 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* body;
2) *donor* treatment, requiring that the *donor* always be treated with dignity and respect;
3) *tissue collection*, *recovery*, *acquisition*, and handling, including *recovery site* assessment, *recovery*, materials management/supplies management, *processing*, packaging, *quarantine*, *labeling*, *storage*, *donor* eligibility review, and/or release of *tissue*;
4) 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;
5) 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*;
6) external *audits* for services, suppliers, contractors, and consultants, when indicated;
7) 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 Sections B and G, and H34.000);
8) *QA* and *QC* 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),
    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,
   c) investigating, documenting, and reporting *accidents*, *errors*, *complaints*, and *adverse outcomes*,
   d) performing *field corrections*, removals, and stock recoveries, if applicable, and/or the timely notification of affected parties regarding information related to *tissue safety* or regulatory requirements,
   e) notifying *MWER* of any *field corrections*, or removals, stock recoveries, investigations, inspection reports, or regulatory actions,
   f) supplies, reagents, materials, and equipment and identifying those that are considered *critical*,
   g) maintaining equipment management programs that include inspection, maintenance, repair, and calibration for the purpose of maintaining equipment,
   h) describing the receipt, identification, *storage*, handling, sampling, testing, and subsequent approval or rejection of *containers*, packaging materials, *labels*, reagents, and supplies, and
   i) monitoring *in-process controls* and managing events such as failed test runs and failure of a lot to meet established specifications;
9) assigning time limits and temperature for pre-*processing quarantine storage*, *processing*, and expiration dates;
10) handling requests for research *tissue*;
11) disposing of medical waste and other hazardous waste;
12) emergencies and *safety*, including reporting of staff injuries and potential exposure to blood-borne pathogens;
13) maintaining the sanitation of facilities and describing the cleaning schedules, methods, equipment, and materials to be used;
14) describing the design or arrangement of the physical plant to meet operational needs such as designation of spaces, environmental monitoring, and security;
15) describing manual methods for *tissue banking* activities in the event of electronic or equipment malfunction;
16) describing training program requirements for technical and QA staff;
17) identifying and controlling *procedures* and forms, including requirements; and
18) defining appropriate use, confidentiality, security, and retention of captured *images* of the *donor* and/or *tissues*.

B4.400 Approvals

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*.

B4.500 SOPM Updates
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.

B4.600 Cited Publications
Copies of publications cited in support of policies or *procedures shall* be maintained at the *tissue bank*.

B4.700 SOPM Review
New and revised policies and *procedures shall* be reviewed by applicable staff prior to implementation. A periodic 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) *MWER*, 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.

B4.800 Inspections
The *SOPM shall* be made available for inspection upon request by the AATB or authorized regulatory agencies.

B5.000 Quality and Product Reviews

B5.100 Release 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 H7.000 and H8.000.

B5.110
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*.

B5.120

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

B5.200 Release for Transplantation

Prior to release of *tissue* for transplantation, the Medical Director *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.

B5.210

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

B5.300 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 *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 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 the *SOPM* and *Standards*.

B5.310 Reproductive Tissue Release

(R) *Reproductive tissue shall* not be released for clinical use without a signed, written *disposition*/release statement of the person responsible for authorizing

release, indicating that all *quality* measures were reviewed and found acceptable according to the *SOPM*. This includes, but is not limited to:

1) review of *donor* age and of *tissue* processed for consistency with specific *tissue* requirements;
2) recording 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.

B5.320 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 *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.

B5.330

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 H19.100 *must* be met, with the exception of a review of the autopsy report (if applicable) and pending culture results;
2) Medical Director review of all relevant information present;
3) approval of the release by the Medical Director;
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, and when it is expected that the information will be available; and
5) a statement from the *end-user* physician indicating their 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.

B5.340

(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 antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1, anti-HIV-2), antibodies to the hepatitis C virus (anti-HCV), hepatitis B surface antigen (HBsAg), or any other test, excluding cytomegalovirus (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 *Standards* 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 H29.000 and H30.100 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*.

B5.350
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.

B5.360
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 non-clinical purposes from a *donor* who has been determined to be ineligible based on the results of required testing and/or screening, it *must* be *label*ed:
1) "For Non-Clinical 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.

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 non-clinical purposes, it *must* be *label*ed "For Non-Clinical Use Only."

B6.000 Donor Record
Each *tissue bank shall* develop a *donor* record management system that ensures the detailed documentation of the *tissue* banking process(es) for which it is responsible.

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.

B6.100 Scope of Documentation

Documentation *must* be made concurrent with each significant step and *must* include, but not be limited to:

1) identity of and 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* (including *relabeling*, if necessary), *storage*, release, and *distribution*;
10) *QC*; and
11) *services to donor families*.

B6.200 Document of Authorization

The *donor* record *shall* include a *document of authorization*.

B6.210

The original or a copy of the *authorization shall* be maintained in the *donor* record at the *tissue bank* responsible for *recovery*, as well as in the *donor* 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.

B6.300 Recovery

Each *tissue bank shall* maintain records of *tissue recovery*, which *must* include information about the *donor*, as well as all reagents, supplies, materials, and instruments used in *recovery*.

B6.310

Recovery records *shall* include:

1) inspection of reagents, supplies, and materials prior to use including, as applicable, the type, quantity, manufacturer, *lot* number, date of receipt, and expiration date or manufacturing date (as applicable) [records *must* identify the individual(s) performing the inspection];
2) *sterilization* of surgical instruments and parts of mechanical/electrical equipment that come into contact with *tissue*;
3) documentation of all cleansing and disinfecting events performed by *tissue bank* personnel;
4) name and address of the *recovery* agency;

5) date, time, and staff involved in all significant steps performed during the *recovery*;
6) location of *recovery site* and assessment of the suitability of the *recovery site*;
7) documentation of the *physical assessment* or *physical examination*;
8) documentation of any *errors*, *accidents*, or *deviations* that occurred;
9) *donor* name, age, and sex;
10) 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*;
11) specific *tissue* recovered; and
12) other available *relevant medical records*.

(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* name to the identification code. No records *shall* exist which link the *anonymous donor* by name to the *recipient*.

B6.320

Additional *recovery* record requirements for specific *donors*/*tissues*:

1) *Autologous*
    a) Name and address of the institution in which the *autologous tissue* was recovered;
    b) date and time the *autologous tissue* was recovered;
    c) name of the physician recovering the *autologous tissue*;
    d) *donor* name, age, sex, and hospital medical record number and/or other medical record number; and
    e) type of *tissue* recovered.
2) *Birth*
    a) Birth mother's name;
    b) gestational age at time of delivery of newborn;
    c) name and address of the health care facility and the identification of the delivery environment/location;
    d) date and time of the delivery;
    e) the physician or other authorized practitioner involved with the delivery, or designee as permitted by law; and
    f) specific *tissue*(s) acquired.
3) *Cardiac*
    a) ABO/Rh, if available;
    b) date/time of asystole;
    c) date/time of *recovery* of the heart (time when subjected to cold rinse solution);

d) date/time of subjection of *cardiac tissue* to *disinfection* solution;
e) start and stop times when *tissue* was subjected to *disinfection* solution; and
f) date/time when *preservation* began and when placed in final *container*.

4) *Vascular*
   a) ABO/Rh, if available;
   b) date/time of asystole;
   c) date/time vascular *tissues* subjected to *perfusion solution*;
   d) date/time vascular *tissues* placed in transport solution and subjected to *wet ice temperatures*;
   e) date/time of subjection of vascular *tissue* to *disinfection* solution;
   f) start and stop times when *tissue* was subjected to *disinfection* solution; and
   g) date/time (1) when *preservation* began and (2) when placed in final *container*.

5) *Reproductive*
   a) *Relevant medical records*;
   b) results of all laboratory screening tests;
   c) outcome of prior *assisted reproductive technology procedures* (if known), including number of successful pregnancies and any reports that would affect *donor* eligibility; and
   d) personal attributes of the *donor* such as height, weight, eye color, hair color, complexion, racial group, and/or body type.

B6.330

The *tissue bank* or agency r*ecovering* 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.

B6.400 Processing, Testing, and Preservation Records

The *tissue bank shall* ensure that *processing* records contain the following information:

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*.

B6.410 Processing Evaluation
(C, V, OA) A detailed description of the condition of the *allograft shall* be recorded in the permanent *donor processing* records.

B6.420 In-House Laboratory Records
When testing is performed in-house, laboratory records *shall* include:

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*.

B6.430
When laboratory services are performed by another entity under contract, records *shall* include the name and address of the contracted facility and documentation of the inclusive dates of the contract period.

B6.440 Cryopreservation
Cryopreservation records *shall* include documentation of the concentrations of *cryoprotectant* and nutrient or isotonic solutions in the cryopreservative solution.

If a controlled-rate chamber is being utilized, the thermal profile for each cryopreservation cycle *shall* be logged with the specimen records.

B6.500 Quarantine
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.

B6.600 Release/Donor Eligibility
Each *donor* record *shall* contain a *disposition*/release statement and *signature* of both the Medical Director who is assuming responsibility for *donor* eligibility determination and, if different, the individual(s) responsible for reviewing all technical and *QC* specifications. If *processing* was performed, there *shall* be documentation of a review by designated personnel of all technical and *QC* specifications. Results of laboratory tests used to determine final release of *tissue* for *transplantation must* be included in the *donor* record. The *donor* record *shall* indicate a cause of death. When no third-party records are available that can be used to establish a likely cause of death, H19.300

applies. Once the determination is made, the *donor* eligibility statement *shall* be documented, dated, and signed by the Medical Director.

B6.610 Release – Review of Records

The following information *shall* be reviewed, and the review *shall* be documented. If *processing* was performed on-site, there *shall* also be written documentation that all *quality* measures were performed and acceptable according to the *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.

B6.620 Summary of Records for Release

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 H12.600). For example, the CMV test result used *must* be listed for reproductive tissue. If a test for antibodies to human T-lymphotropic virus type I and/or type II (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 United States, applicable requirements of the government/competent authority having jurisdiction apply in regard to required *labeling* involving *donor* infectious disease test results.

(R) A summary of records shall also include 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.

B6.700 Distribution Records

Distribution 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*.

B6.710 Packaging

Shipping records *shall* include:

1) *QC* check of *packages* to be reused; and
2) inspection prior to shipping.

B6.720 Returns

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);
5) date and name of the staff member authorized to evaluate and determine the *disposition* of the *tissue*(s); and
6) attestation that the *tissue* was maintained at required *storage* temperatures.

B6.730 Field Correction and Removal

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*, *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.

B6.740 Receipt

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*.

B6.750 Dispensing

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.

B6.800 Tissue Distribution Intermediaries

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*.

B6.810

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.

B6.900 Informed Consent

Record of *informed consent 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), and
    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 H8.400) 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 their name and address, as well as required records, *shall* be kept on file by the *tissue bank* or *reproductive tissue bank*.

B7.000 Nonconforming Products and Services

The *quality system shall* define all steps necessary to identify, capture, and prevent the inadvertent release, *distribution*, or use of nonconforming products and services.

B7.100 Process

When products or services are determined to be nonconforming, the *tissue bank shall*:

1) contain the product or service;
2) evaluate the nature and impact of the nonconformity;
3) determine the appropriate *disposition* of the nonconforming product or service, which *may* include, but is not limited to:
    a) *removal* or destruction of the product,
    b) *field corrections* or reworking of the product or service, with appropriate disclosures and approvals, and
    c) suspension of service;
4) monitor and evaluate the outcomes of corrective or *preventive actions* taken.

B7.200 Quarantine, Physical Segregation, and Removal

The bank *shall* have policies and *procedures* for the *quarantine*, physical segregation, and *removal* of *tissues* as appropriate. The *SOPM shall* indicate when *quarantine*, physical segregation, and/or *removal* are indicated, and there *shall* be controls in place to prevent mix-ups and *cross-contamination*.

B7.210

Tissues in *quarantine* and/or subject to physical segregation, and the *storage* areas for such *tissues*, *shall* be clearly identified.

B7.300 Field Correction or Removal

Tissue banks shall have specific written policies and *procedures* for the initiation and performance of a *field correction* or *removal*, if applicable. If the bank is not directly responsible for conducting *field corrections* or removals, the bank *shall* have policies and *procedures* for the timely notification of all affected parties.

B7.310

Procedures for *field correction* or *removal 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 *MWER*.

B7.320
The need to perform a *field correction* or *removal may* be identified as a result of a *complaint*, *adverse outcome*, *accident*, *error*, *deviation*, or *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.

B7.330
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.

B7.340
All *tissues* not already transplanted, which are subject to *field correction* or *removal*, *shall* be located and *quarantined* pending resolution of the issue.

B7.350
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 *Recall*s, Including Removals and *Corrections* (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections).

B7.360
Potential adverse reactions, suspected transmission of disease, or other complications, directly or indirectly related to the *allograft*, *shall* be reported as instructed in *labeling material*s and thoroughly investigated and documented.

B7.370
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.

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.

B8.000 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 records will be shared 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 a shared *donor* 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.

B8.100 Test Results After Processing

Any *tissue* testing performed after *tissue* 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*.

B8.200 Availability to End-User

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.

B9.000 Other Quality System Records
A file of archived standard operating procedures (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.

B9.100 Investigations
Records of investigations undertaken in response to *complaints* when *tissue quality*, *safety*, packaging, or effectiveness is affected *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.

B9.200 Inspections/Audits of Facilities
Inspections/*audits* of facilities providing services to the *tissue bank shall* be documented. Such documentation *shall* itemize all operational systems that were verified to determine compliance with these *Standards*, the agreement/contract, and *defined requirements*.

B10.000 Cleaning, Sanitization, and Safety Records
Routine, scheduled *decontamination* of 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 documented. These records *shall* be retained for 3 years after their creation.

Equipment and instrument cleaning, *decontamination*, *sterilization*, *qualification*, calibration, and maintenance *shall* be documented. Such *records shall* also include documentation of repairs, rejection, return, and/or disposal of defective equipment and *shall* be retained for 10 years after their creation.

Medical waste and hazardous material tracking records *shall* be maintained in accordance with the regulations of the regulatory agency charged with management oversight.

B11.000 Personnel Records
Personnel records *shall* include records of training, continuing education, and *competency* evaluations.

B11.100 Training

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) review of policies and *procedures* for the employee's designated functions, including *safety procedures*;
6) *safety* training; and
7) attendance at workshops, seminars, meetings, or other continuing education programs.

B11.200 Elements

Personnel records *shall* include the names, *signatures*, initials or identification codes, and inclusive dates of employment for those authorized to perform or review tasks.

B12.000 Record Retention Requirements

B12.100 Product and Donor Records

Product and donor *records,* including *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, unless otherwise indicated.

B12.200 Training Records

Records of the review of new and revised policies 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.

B12.300 Other Records

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 10 years.

B12.310

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

C. Personnel

C1.000 General

The bank *shall* have sufficient personnel to ensure that the requirements of these *Standards* are met and to ensure that the bank is able to perform, *verify*, and manage *critical* functions.

C1.100

Personnel *shall* be qualified by training, education, and/or experience.

C1.200

There *shall* be a program to ensure personnel *competency*.

C1.300

The *tissue bank shall* define continuing education needs for personnel and *shall* ensure that these needs are met.

C2.000 Training

The bank *shall* provide training to personnel. The training program *shall* include job- or function-specific training as well as general training on the *SOPM* and the bank, as well as initial/orientation training for new personnel.

C2.100

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:

1) new employee orientation;
2) the *SOPM*;
3) technical training;
4) QA;
5) *electronic systems*; and
6) continuing education.

C2.110

Personnel *shall* be made aware of their designated functions and of the consequences of the improper performance of their designated functions.

C2.120

Personnel performing *verification* and *validation* activities *shall* be made aware that *accidents* and *errors may* occur during the performance of their designated functions.

C2.130

(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*.

C2.200
Technical staff *must* demonstrate *competency* for their designated functions (including a thorough understanding of relevant policies, *procedures*, *process controls*, and regulatory requirements).

C2.300
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.

C3.000 Key Personnel

C3.100 Management with Executive Responsibility

MWER shall be responsible for defining, articulating, and implementing the bank's scope, mission, vision, *quality policy*, and stakeholder orientation. *MWER 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.

C3.110
MWER shall ensure that the *tissue bank* meets applicable *defined requirements*, including those of these *Standards*, and that the *tissue bank* has sufficient personnel and resources to perform, *verify*, and manage every *critical* step within the bank's scope of activities.

C3.120
MWER 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.

C3.130
MWER shall appoint a Management Representative and 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, to be performed at least *annually*, *shall* be documented.

C3.200 Medical Director

The *tissue bank shall* have a Medical Director who maintains a valid U.S. medical license from any state or U.S. territory (or equivalent medical license, if the bank is not located in the United States or subject to U.S. law).

C3.210

The Medical Director *shall* establish, review, and approve all medical policies and *procedures*. In addition, the Medical Director *shall* have responsibility for medical decisions, including, but not limited to, review of abnormal, reactive, or unexpected test results, including infectious disease and culture results, and approval of *donor* eligibility for each *donor*, including exceptions to *donor* eligibility.

D. Facilities, Safety, and Work Environment

D1.000 General

Work described in these *Standards shall* take place in an environment suitable for the work performed.

D1.100 Work Environment

Work environments *shall* be of adequate size, with adequate plumbing, drainage, lighting, and ventilation, with convenient hand washing facilities available.

D1.110

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*.

D1.120

Environmental monitoring procedures shall be established, where appropriate, as part of the QA program. *Environmental monitoring* at the *recovery site* is not required; however, pre-established parameters designed to prevent contamination and *cross-contamination must* be met (see D3.000).

D1.130

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.

D1.140

Rooms used for storage of liquid nitrogen tanks *should* be periodically monitored for oxygen levels if not appropriately ventilated.

D2.000 Controlled Access

The bank *shall* control access to work areas. Only authorized personal *shall* have access to *tissue* and record storage areas.

D2.100 Labels and Labeling Materials

The storage area for *finished tissue labels* and *labeling material*s *shall* be clearly identified. Access *should* be restricted to authorized personnel only.

D3.000 Recovery Site

All *tissue shall* be recovered and processed in an aseptic or clean fashion using standard surgical preparation with *sterile* packs, instrumentation, and technique. Sites used for *recovery*, *processing*, and other *critical* steps *must* be evaluated for suitability using pre-established criteria designed to control contamination and *cross-contamination* (see Appendix IV). These criteria *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.

D3.100 Recovery Site Evaluation

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.

D3.110

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. For guidance, refer to "Guideline for Environmental Cleaning" in AORN's "Guidelines for Perioperative Practice" (current edition). Such an evaluation *must* be documented.

D3.120

If the *recovery* location is an operating room or a designated delivery room in a specialized health care facility, no documented site evaluation is required.

D4.000 Safety

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 *Safety* Manual which is referenced by the *SOPM*. *Safety 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 in accordance with *defined requirements*.

D4.100 Scope

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 and Standard Precautions as defined by OSHA and 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 biohazardous spills.

D5.000 Personnel Considerations

The bank *shall* have measures in place to protect the *safety* of personnel.

D5.100 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.

D5.200 Garb and Aseptic Technique

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 "Guideline 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).

D5.300 Hazardous Material 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.

D5.400 Vaccination

Hepatitis B virus (HBV) 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 HBV vaccine.

D5.500 Health Conditions

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 effect on *tissue*.

D6.000 Disposal

The bank *shall* have policies and *procedures* for the disposal of potentially biohazardous material.

D6.100 Hazardous Material

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.

D6.200 Tissue

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 *defined requirements*.

E. Materials and Equipment

E1.000 Control of Supplies, Reagents, Materials, and Equipment

The bank *shall* ensure that all materials and equipment used in the *recovery*, *acquisition*, *processing*, packaging, and *distribution* of *tissues*, particularly those that come into direct contact with the *tissue*, are appropriately identified and qualified for their intended use.

E2.000 Materials

The bank *shall* have a program to ensure that materials, reagents, and disposables that come into direct contact with the *tissue* are of appropriate grade and sterility for the intended use.

E3.000 Equipment

The bank *shall* ensure that equipment is appropriate for the intended use, and that equipment is used and maintained in a valid operational status.

E3.100 Critical Equipment

The bank *shall* have defined criteria and performance specifications for all *critical* equipment.

E3.200 Manufacturer's Instructions

All equipment *shall* be used in accordance with the manufacturer's written instructions.

E3.300 Cleaning

Equipment *shall* be cleaned, decontaminated, or sterilized at appropriate intervals.

E3.400 Sterilized Container Handling

Equipment known to have come into contact with *tissue* from a *donor* suspected to have prion disease *shall* be removed and destroyed. *Tissue* from any *donor* that comes into contact with this equipment *shall* be identified, *quarantined*, withdrawn, or *recall*ed pending further evaluation.

E3.500 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.

E4.000 Supplies, Reagents, and Materials

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. The *tissue bank shall* maintain records of all supplies, reagents, materials, and equipment from receipt through the 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.

E4.100 Storage

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.

E4.200 Controls

Adequate controls *must* exist to prevent mix-ups between acceptable and unacceptable items.

E5.000 Cleaning, Decontamination, and Sterilization

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.

E5.100 Sterilization Prior to Contact with Tissue

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.

E5.200 Maintenance and Monitoring

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), Bowie-Dick testing, and process challenge device (PCD) testing. Guidance on efficacy monitoring *may* be found in *sterilization* equipment manuals, by consulting with the *sterilization* equipment manufacturer, or 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>
<tr><th colspan="5">Common Sterilization Methods, Cycle Parameters, Controls, and Monitoring</th></tr>
<tr><th rowspan="2">Method
(other methods may be used)</th><th rowspan="2">Cycle Parameters</th><th colspan="2">Routine Release Controls
(for each load)</th><th colspan="2">Efficacy Monitoring</th></tr>
<tr><th>Required</th><th>Recommended</th><th>Required</th><th>Recommended</th></tr>
<tr><td>Steam</td><td rowspan="3">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 rowspan="3">Verify cycle parameters were met</td><td rowspan="3">1. Utilize internal and external chemical indicators

2. Utilize appropriate PCD and verify as negative prior to release of load</td><td rowspan="3">Weekly: Utilize appropriate PCD</td><td rowspan="3">Daily: Utilize appropriate PCD</td></tr>
<tr><td>Ethylene Oxide (EO)</td></tr>
<tr><td>Vaporized Hydrogen Peroxide (VHP)</td></tr>
<tr><td>Irradiation (i.e., gamma, x-ray, electron beam)</td><td>Use validated cycle per ISO 11137</td><td>Verify cycle parameters were met</td><td>N/A</td><td>Bioburden testing, dose audits, and dose mapping per ISO 11137</td><td>N/A</td></tr>
</table>

Common Sterilization Methods, Cycle Parameters, Controls, and Monitoring					
Method (other methods *may* be used)	**Cycle Parameters**	**Routine Release Controls** (for each load)		**Efficacy Monitoring**	
		Required	**Recommended**	**Required**	**Recommended**
Other (e.g., novel, nontraditional)	Follow manufacturer's instructions for method selected. *Validation* is expected if manufacturer's instructions are not followed.				

E6.000 Instruments and Containers

All non-disposable surgical instruments and mechanical/electrical equipment used in *tissue processing shall* be cleaned, decontaminated, and, where applicable, sterilized between uses 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.

E6.100 Container Integrity

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

E6.200 Quarantine Until Released for Use

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.

E6.300 Unused Container Handling

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

E6.400 Sterilized Container Handling

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

E6.500 Sterilization Residues

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.

E6.600 Final Packaging

(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.

E6.700 Evaluating Impact of Instruments Out of Tolerance

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*.

E7.000 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 *label*ed 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.

E7.100 Maintenance of Freezers/Refrigerators

Freezers and refrigerators *shall* be regularly maintained, calibrated, and monitored using *QC* written *procedures*.

F. Agreements and Shared Responsibilities

F1.000 Agreements and Shared Responsibilities

The *tissue bank shall* have policies for entering into agreements to obtain or provide materials, products, or services. The bank *shall* have agreements or contracts with all other external entities involved in the manufacturing of *tissue* products.

F1.100 Verbal Agreements

The bank *shall* retain a record of verbal agreements.

F2.000 Supplier Evaluation and Purchasing Controls

Each *tissue bank shall*:

1) evaluate and select potential suppliers, contractors, and consultants on their ability to meet specified requirements, and the evaluation *shall* be documented; and
2) define the type and extent of control to be exercised based on the evaluation results.

F2.100 Monitoring of Performance

The bank *shall* monitor the performance of suppliers. There *shall* be a mechanism to ensure that agreed-upon requirements are met.

F2.200 Verification of Compliance

Before an entity performs any activity/service under contract, agreement, or other arrangement that has the potential to affect the *quality* and/or *safety* of *tissue* or the ability to comply with *defined requirements*, the accredited *tissue bank must verify* that the entity is in compliance with applicable *quality* and *safety* requirements. It is the responsibility of the *tissue bank* receiving those activities/services to *verify* and document that *procedures* related to the activities/services are in compliance with the written agreement/contract, *Standards*, and applicable laws and regulations. The inspection/*audit* plan, policies, and *procedures* and frequency of *reverification shall* be defined in the *SOPM*. The frequency, *audit*/inspection method (e.g., paper, virtual, or on-site *audit*), and content of all *verification* activities *shall* be risk-based, with the decisions, including consideration of AATB accreditation, being documented. The *verification* of activities or services performed by others *shall* be documented.

F2.300 Discovery of Noncompliance

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.

F2.400 Referral Arrangements with Organ Procurement Organizations
In addition to the requirements at the *series of standards* at F1.000, all referral arrangements with organ procurement organizations, *donor referral sources*, and other *tissue banks shall* be documented.

F2.500 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* 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 products 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 F1.000 for additional requirements. Also refer to specific information at F4.000 for contracted and non-contracted laboratory services for infectious disease testing.

F2.510
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. Examples of contracted testing services include, but are not limited to, the following:

1) *donor* infectious disease testing (also see F4.000);
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.

F3.000 Agreements Pertaining to Traceability
Agreements between banks *shall* clearly indicate the responsibilities of each party, and *shall* address record-keeping and information sharing. Agreements with banks that are responsible for *informed consent*/*authorization* or *donor risk assessment interview*s *shall* identify parties authorized to collect and provide information related to these steps.

F4.000 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; for infectious disease testing, the laboratory *must* be registered with the FDA as a *tissue* establishment and list "testing" as a function;
2) applicable state licenses, certifications, and accreditations; for infectious disease testing, the laboratory *must* be certified in accordance with CLIA (42 U.S.C. 263a) and 42 CFR part 493, or have met equivalent requirements as determined by CMS;
3) maintenance of an adequate *QA program* to ensure the validity of results (e.g., test sample integrity, *QC* 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) following manufacturers' instructions (e.g., *package inserts*, equipment manuals, electrical and/or environmental conditions);
7) appropriate test method selection and *validation/qualification*;
8) use of the appropriate FDA-licensed, -approved, or -cleared *donor* screening tests for infectious disease;
9) use of *traceable* reference materials and calibration standards, where applicable;
10) results from a paper, virtual, or on-site *audit*; and
11) for infectious disease testing services, retaining *donor* infectious disease test run *records* for 10 years (and compliance with sample archival policy).

F5.000 Non-Accredited Tissue Banks Outside of the United States
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, 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 United States. 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 its country for the functions it performs (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.

G. Traceability and Records Management

G1.000 Traceability and Records Management

All *tissues shall* be *traceable* from *donor* source through final *disposition*. Individual banks *shall* ensure that their record system permits *traceability* through all steps for which the bank is responsible, including the receipt of information/records from suppliers and the provision of information to *consignees*.

G1.100 Traceability of Tissues and Samples

The *tissue bank shall* have a record system that ensures *traceability* of *tissues* and *donor* samples from *donor* source through all steps of *processing*, intermediary facilities, and to final *distribution*. Each bank involved in the provision of *tissues shall* ensure that *tissue* remains *traceable* to the *donor* while under the control of the bank.

G1.200 Scope of System

The record system *shall* include pertinent details of each significant step from *recovery*, *collection*, or *acquisition* through *disposition*, including the dates and the identities of the staff involved in each significant step.

G1.300 Record Requirements

Records *shall* be complete, indelible, legible, and accurate.

G1.400 Access Control

The bank *shall* control access to records.

G1.410 Electronic Systems

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.

G1.500 Storage

Records *shall* be stored in a manner that preserves the legibility of the information they contain.

G1.600 Retention Policy

The bank *shall* ensure that records are retained for the appropriate length of time.

G2.000 Unique Identifier

The records management system *shall* identify *tissue* by use of a unique *donor* identifier. In the event that the bank assigns the product a new identifier, the record system *shall* make it possible to link the new identifier to the previously assigned identifier.

G2.100 Correlation of Donor Identifiers
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*.

G2.110
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*.

G3.000 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.

G3.100 Audit Trail for Electronic Records
Records revised electronically *must* have an *audit trail* that includes the altered information, date of the revision, and the individual who made the revision.

G4.000 Traceability in Release to Non-Accredited Entities
Whenever an accredited *tissue bank* consigns *tissue* to a non-accredited entity, the *tissue bank shall* have an agreement with the *consignee* that preserves *traceability* of the *tissue* through any additional *consignees*, if applicable, and through to final *disposition*.

G5.000 Autologous Tissue
The *tissue bank shall* have a system to prevent the release of *autologous tissue* for non-*autologous* use.

G6.000 Electronic Systems and Records
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, accessible, and able to be printed in hard copy.

Electronic systems shall be designed to assure data integrity and maintained in a secure manner to prevent alteration or loss.

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

G7.000 Traceability by Tissue Dispensing Service*s*
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.

G8.000 Notification by Tissue Dispensing Service
Documentation of applicable notification of the final *disposition* of *tissue* made to the *tissue bank* or the *tissue distribution intermediary* from whom the *tissue* was obtained *shall* be recorded.

G8.100 Minimum Required Information
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 following items to permit tracing of each *tissue* from the *tissue bank* (*tissue* supplier or *tissue* processor) to each *recipient*:

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; and
5) name of the ordering physician or other authorized health professional.

G8.200 Completion and Return
The *tissue* bank's *tissue* tracing forms *shall* be completed, specifying the *disposition* of the *tissue*, and returned as instructed in *labeling material*s.

G8.300 Documentation and Retention
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 10 years after the expiration date of the *tissue*, or in the case of *tissue* with no expiration date, 10 years after *distribution*. See applicable requirements of Section B.

G8.310
Any completed *tissue* tracing forms, specifying the *disposition* of the *tissue*, *shall* be returned as instructed in *labeling material*s.

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.

H. Operations

H1.000 General Elements

The bank *shall* have policies and *procedures* that describe every *critical* step or activity performed by the bank and required by these *Standards*.

H1.100 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.

H2.000 Change Control

The bank *shall* ensure that new or revised *procedures* are appropriately reviewed, validated, and/or verified before their implementation.

H3.000 Quality Control

The bank *shall* have a *QC* program to ensure that supplies, equipment, instruments, and reagents meet *defined requirements* and perform as expected.

H3.100 Required Procedures

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.
7) 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.

H3.200 Corrective Action

Procedures shall incorporate a plan for *corrective action* for poor performance on *proficiency testing*.

H3.300 Laboratory Quality Assurance

Laboratories *shall* establish and maintain a *QA* program adequate to ensure the validity of test results. The laboratory *QA* program *shall* include, but is not limited to, the following:

1) appropriate test method selection and validation/*qualification*;
2) monitoring/trending internal *QC* 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) following 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.

H3.400 Lyophilization, Dehydration, and Desiccation
QC programs for monitoring performance of either a lyophilizer, a dehydrator, or a 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 H23.100 and H23.200.

H3.500 Calibration
Each *tissue bank shall* ensure calibration of devices used for *storage* is performed according to the manufacturer's requirements and recommendations. Unless the calibration frequency is otherwise validated, the manufacturer's written recommendations *must* be followed. In the absence of guidance from the manufacturer or unless otherwise validated, the calibration shall be performed at least annually, using a standard traceable to the National Institute of Standards and Technology. The overall QA program *shall* include maintenance of calibration records.

H3.600 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 H3.200 and H3.300 *shall* apply. If the services of an outside laboratory are used, the requirements at F2.000 *shall* apply.

H3.700 Residual Cryoprotectant
(C, V) Initially, and as required at B2.200, 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).

H4.000 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 which, when, 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.

H4.100 Process Control Procedures

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.

H5.000 Quarantine and Physical Segregation

Human *tissue shall* be *quarantined* until the *tissue* is either determined to be suitable for *processing and transplantation,* or another appropriate *disposition* is chosen. 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, HBV, and/or HCV infection.

H5.100 Scope

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 a *donor* 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 *QA* specifications;
5) *tissue* pending discard as medical waste; and
6) *tissue* returned by a *consignee*, pending evaluation.

H5.200 Physical Segregation

The bank's policies and *procedures shall* address when physical segregation of *tissues* is indicated. Physical segregation of *tissues shall* include clear identification of the *storage* device or area in which segregated products are held.

The *pooling* of *tissue* from multiple *donors shall* not occur during *recovery*, *collection*, *acquisition*, *processing*, *preservation*, or *storage.*

H5.210
At a minimum, the bank *shall* ensure the physical segregation of *tissues* in the following circumstances:

1) for products lacking infectious disease test results (i.e., results are unavailable or testing is not performed);
2) when both *autologous* and *allogeneic tissues* are present;
3) when the *donor* of the *tissue* has been determined to be ineligible;
4) when the packaging and *labeling* of the *tissue* may be unable to withstand *storage* temperatures; or
5) when it is not possible to decontaminate *storage* equipment or the *storage* area in the event of an *accident*.

H5.300 Prior to Donor Eligibility Determination
All human *tissue* processed or shipped prior to determination of *donor* eligibility *must* be retained 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.

H5.310
(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 clearly identified area physically separated from *tissue* of seronegative *client depositors*. See B5.340 for documentation required for release.

H5.400 Automated Data Processing Procedures
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*.

H6.000 Donor Eligibility
The Medical Director *shall* be responsible for establishing *donor* eligibility criteria. See the *series of standards* at H9.000 and Appendix II.

H6.100 Medical Director Determination
When a *tissue bank* is responsible for determining *donor* eligibility, the Medical Director *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 B6.000 and H27.000.

H6.200 Procedures for Interactions

(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.

H6.300 Compensation and Expenses

Monetary compensation or other valuable consideration, including goods or services, *shall* not be offered to a *donor*, *authorizing person*, the *donor* 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 a *living donor* 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*.

H7.000 Authorization

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.

H7.100 Communication

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*.

H7.200 Document of Gift

In cases where a *donor* has executed a *document of gift*, it *may* be acted upon (permits *recovery*) provided it meets *defined requirements*.

H7.300 Documentation Types

Acceptable documentation for a *document of gift may* include a state driver's license, living will, advance directive, state ID card, *donor* card, or photocopy thereof, and documentation that the *donor* registered in a *donor registry*.

H7.400 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*.

H7.500 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 H7.710; and
3) 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 email) that they have read the *document of authorization*, are authorized to grant *authorization*, and are granting such *authorization*. A *donation coordinator shall* be available to respond to questions posed by the *authorizing person*.

H7.510

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

H7.520

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 Inspections of Quality Systems").

H7.530

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 Inspections of Quality Systems").

H7.540

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.

H7.600 Information to Be Provided

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);
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* body; and
4) an explanation that the *document of authorization* is available.

Any explanation required by law, such as an explanation that multiple organizations (non-profit 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.

H7.610

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 H7.400.

H7.620

For a *donor* 1 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.

H7.630
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.

H7.640
In all other cases, prior to transport of the *donor* 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*.

H7.650
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*.

H7.660
The *donation coordinator should* inquire during the *notification* whether the notified person is aware of any revocation or refusal made by the *donor*.

H7.670
Notification, if made, *shall* be documented.

H7.680
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.

H7.690
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.

H7.700 Verification of Authorization
No *document of authorization* from an *authorizing person shall* be acted upon if it does not contain the following Core Elements.

H7.710 Core Elements:

1) the name of the *donor*;
2) the name, mailing address, and telephone number of the *authorizing person*, and their 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* 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* 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* 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.

H8.000 Informed Consent

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* or *client depositor's* record at the *tissue bank* responsible for *recovery*, *collection*, or *acquisition*, as well as in the *donor* 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.

H8.100 Circumstances and Timing

The potential *donor* or their legal representative *shall* not be under the influence of anesthesia or any drug that could influence their 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*.

H8.200 Documentation

The record of *informed consent must* comply with *defined requirements*. *Informed consent* can be obtained using different methods, 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 H8.400. 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*.
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 email) that they have read the record of *informed consent* and are granting such informed consent. A *donation coordinator shall* be available to respond to questions posed.

H8.300 Electronic Transmission

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.

H8.400 Core Elements

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:

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 their 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* from the *living donor* or 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.
13) Any explanation required by law, such as an explanation that multiple organizations (non-profit 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.

(R) 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 H6.300.

H8.500 Services Involving Living Donors

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

H9.000 Donor Screening and Testing

H9.100 Autologous Donors

(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.

H9.200 Health of the Newborn

(BT) Except for *autologous* donations, the health status of the newborn(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 regarding the health of the newborn at the time of 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.

H9.300 Chagas' Disease

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

H9.400 Acceptance Criteria

(LD) Criteria for accepting *living donors shall* be established by the Medical Director.

H9.500 Acceptance Criteria

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

H9.600 Age Criteria

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

H9.700 Age Limit

H9.710

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

H9.720

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

H9.730

(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.

H10.000 Donor Risk Assessment Interview (DRAI)

A documented dialogue *shall* be conducted with the *donor* (if living) or the deceased *donor* next of kin, the nearest available relative, a member of the *donor* 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.

H10.100 Content

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).

H10.200 Documented Identities

The *donor risk assessment interview shall* document the *donor* 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* record.

H10.300 Interview

H10.310

(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.

H10.320

(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.

H10.330

(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.

H10.340

(R) The *donor* 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* medical, social, travel, and sexual behavior history (including risk factors) since the previous donation that would make the *donor* ineligible.

H10.350
(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* 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* 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 them as a *donor*, with the following exceptions:

1) *anonymous donor* whose family history indicates that they are 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 donor* and anonymous or directed *embryo donor* with any family history indicating they are 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) 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.

H10.400 Preliminary Review and Medical Director Determination
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.

H10.500 Review Prior to Donation
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 RCDADs as specified in Appendix II; 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.

H11.000 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.

H11.100 Cause for Rejection

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).

H11.200 Documentation
The form and instructions in Appendix III *must* be used to document the *tissue donor physical assessment*.

H11.210
(S) Potential *donors shall* be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and *skin* condition.

H11.220
(S) The *physical assessment shall* include documentation of findings and conditions that *may* affect the *quality* or quantity of *skin* recovered.

H11.300 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 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* 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 (causes for rejection) that would assist with information to determine whether there is evidence of high-risk behavior.

H11.310
(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.

H11.320
(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*.

H12.000 Infectious Disease Testing
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 1 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*. All test results *shall* be documented in the *donor* record.

(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 H12.770 for testing requirements for *embryo donors*.

(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.

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 H13.100).

H12.100 Blood Transfusion/Infusion
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 1 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.

H12.110
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.

H12.120
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* estimated blood volume *shall* be performed, in addition to a comparison of the total volume of *colloids* and/or *crystalloids* with the *donor* 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.

H12.130
Alternative algorithms to evaluate *plasma dilution* can be used if justified.

H12.200 Laboratory Requirements
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 either are certified to perform such testing on human specimens in accordance with CLIA (42 U.S.C. 263a) and 42 CFR part 493, or have met equivalent requirements as determined by CMS.

Note: For international members that do not export *tissues* to the United States, applicable requirements of the government/competent authority having jurisdiction apply regarding establishment registration, laboratory certification, and test kit licensing/approval.

H12.210
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.

H12.300 Implementation of Tests
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 *label*ed for use with specimens collected after the *donor* heart has stopped beating, instead of a more generally *label*ed test, *shall* be used when applicable and when available.

H12.310
A list of *donor* screening tests that have been licensed for use with specimens collected after the *donor* heart has stopped beating can be accessed at the FDA/CBER website.

H12.400 Review of Organ Donor Testing
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 B5.000.

H12.500 Procedures
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.

H12.600 Requirements
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) anti-HIV-1 and anti-HIV-2;
2) nucleic acid test (NAT) for HIV-1;
3) HBsAg;
4) NAT for HBV;
5) total antibodies to hepatitis B core antigen (anti-HBc—total, meaning IgG and IgM);
6) antibodies to anti-HCV;
7) NAT for HCV; and
8) syphilis (a non-treponemal or treponemal-specific assay *may* be performed).

All *tissue* from *donors* who test repeatedly reactive on a required screening test *shall* be *quarantined* and *shall* not be used for transplantation.

H12.610 Requirements
(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 1 through October 31 every year. Ref. H12.750 (R)

(LD) 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.

H12.700 Testing of Viable Leukocyte-Rich Tissue

Donors of viable leukocyte-rich *tissue* (e.g., *semen*, certain cellular tissue (CT)) *shall* also be tested and found to be negative for 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.

H12.710

(R) In addition to the infectious disease tests listed above, all anonymous and directed *semen* and *oocyte donors shall* undergo testing for *Neisseria gonorrhea* 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.

H12.720

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

H12.730

Required tests for anonymous and directed *embryo donors* are listed in H12.770.

H12.740

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

1) anti-HIV-1 and anti-HIV-2;
2) HBsAg; and
3) anti-HCV.

H12.750

(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 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 H19.700. 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.

H12.760
(R) *Oocyte donor tissue* is not subject to *quarantine*, and the *donor* is not subject to repeat testing.

H12.770
(R) 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.

H12.780
(R) 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.

H12.790
(R) For *directed* or *anonymous* donation of *embryos* created using *anonymous* or *directed* egg and sperm *donors*, a *donor summary of records must* be obtained for both *donors*.

H12.800 Sperm Quality Tests
(R) *Semen donor*: 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*.

H12.810
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.

H13.000 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 H13.100.

H13.100 Notification of Donor/Authorizing Person
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. 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.

H13.200 Documentation
Contact regarding availability and/or disclosure of test results *shall* be documented.

H14.000 Archive and Retention Samples
A policy *shall* be established to collect and preserve, according to the individual establishment's *quality*, *safety*, and legal risk assessments, serum, plasma, or hematopoietic *tissue* samples from *donors*. Samples *shall* be retained for appropriate duration after the *recovery*, *collection*, or *acquisition* date, to mitigate the establishment's specific risk exposure according to its *quality*, *safety*, and legal assessments. For samples from *donors* determined to be 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 purposes, blood-borne pathogen exposure, etc.).

H14.100 Dura Mater Tissue Donors
(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.

H14.200 Reproductive Tissue Donors
(R) Archived serum or plasma from *reproductive tissue donors* whose *tissue* has been stored but subsequently destroyed and never distributed does not require retention.

H15.000 Recovery
When a *tissue bank* is responsible for determining *donor* eligibility, this determination *must* occur prior to the release of *tissue* for transplantation. See H6.100 and H27.000.

H15.100 Confirmation of Authorization/Informed Consent
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*.

H15.200 Donor Identity Verification
Prior to initiation of *tissue recovery*, *collection*, or *acquisition*, the potential *donor* identification *shall* be verified with the *donor* 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).

H15.210
(A, SB) Identification of the *donor shall* be the responsibility of the hospital staff involved with the *recovery*.

H15.220
(BT) Identification of the birth mother *shall* be the responsibility of the hospital staff or the *tissue bank* staff member involved with *acquisition*.

H15.300 Control of Contamination and Cross-contamination
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.

H15.310
If *recovery* is to be delayed for a deceased *donor*, the *donor* body *should* be refrigerated/cooled as specified in the *tissue*-specific S*tandards*. 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).

H15.400 Aseptic Technique

Collection or *acquisition shall* be performed using aseptic or clean techniques appropriate to the specific *tissue* type and intended use.

H15.410

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

H15.420

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 unless otherwise qualified/validated. 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. For guidance, refer to AORN's "Guideline for Preoperative Patient Skin Antisepsis" (current edition).

H15.430

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

H15.440

(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 *label*ed with the date of *collection* and the *donor* identification or, in the case of *client depositors* or *directed donors*, the name. The time of *collection shall* also be recorded.

H15.450

(MS, OA, S) The *skin prep shall* begin within 24 hours of asystole provided the *donor* 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 body has not been cooled or refrigerated. If the *donor* body is cooled for a period of time, then not cooled for a period of time, the time period the *donor* body is not cooled cannot exceed 15 cumulative hours.

H15.460
(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.

H15.470
(C) *Warm ischemic time (C) shall* not exceed 24 hours from asystole if the *donor* 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* body was not cooled or refrigerated. If the *donor* body is cooled for a period of time, then not cooled for a period of time, the time period the *donor* body is not cooled cannot exceed 15 cumulative hours.

H15.480
(V) For vascular tissue:

1) *perfusion time shall* not exceed 24 hours from asystole provided that: the *tissue* is recovered within *warm ischemic time* and body cooling parameters defined by these *Standards* (refer to item 2) below; and
2) *warm ischemic time shall* not exceed 24 hours from asystole if the *donor* 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* body was not cooled or refrigerated. If the *donor* body is cooled for a period of time, then not cooled for a period of time, the time period the *donor* body is not cooled cannot exceed 15 cumulative hours.

H15.490
(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.

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

H15.500 Handling of Recovered Tissue
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 *label*ed with the unique *donor* identifier and the description according to the *SOPM*. 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*.

H15.510
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.

H15.520
The type, *lot* number, manufacturer, and expiration date of all reagents used for *recovery* and packaging *shall* be documented.

H15.530
Tissue shall be maintained at defined environmental temperatures until the time of transport to the *processing* center. Maintenance of such temperatures *shall* be documented.

H15.540 Autologous Tissue Recovery
(A) Immediately following *recovery* of the *autologous tissue*, it *shall* be individually and aseptically wrapped. The *package shall* be *label*ed 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 *label*ed "FOR AUTOLOGOUS USE ONLY."

H15.550
(C) Recovered *cardiac tissue shall* be rinsed and *package*d 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.

H15.560
(V) Immediately following *recovery*, vascular *tissue shall* be gently flushed and *package*d in an isotonic *sterile* solution such as *tissue* culture media. Normal saline solution *should* not be used.

H15.570
(S) Recovered *skin tissue shall* be *package*d in a *sterile* solution immediately following *recovery* or *package*d 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*.

H15.580
(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 H15.510) *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*.

H16.000 Transportation
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 monitoring 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").

H16.100 Transport Temperature/Time Limits
(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.

H16.200 Transport Temperature/Time Limits
(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.

H16.300 Transport Temperature/Time Limits
(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*.

H16.400 Transport Temperature/Time Limits

(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*.

H16.500 Transport Temperature/Time Limits
(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.

H17.000 Reconstruction
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* body prepared for the next portion of the *recovery* or for transportation to an appropriate facility. The *donor* 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* body *shall* be maintained in the *donor* record.

H18.000 Post-Recovery
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 B12.000 and H26.000.

H18.100 Adequate Controls
Adequate controls *must* exist to prevent mix-ups, contamination, and *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.

H18.110
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) a back-up plan for failure of validated electronic systems.

H18.200 Labeling of Segregated Areas
If physical segregation is deemed necessary, segregated areas *must* be appropriately *labeled*.

H18.210

Considerations for assessment of risk include the following, 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.

H18.300 Appropriate Segregation

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

H18.400 Documentation of Receipt/Storage

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 that each *tissue* is *label*ed with a *tissue identification number* or other *traceable* unique identifier;
3) evidence that proper environmental conditions were maintained (e.g., presence/absence of ice/coolant) (refer to H34.300);
4) the date and time of receipt and movement; and
5) personnel involved.

H18.500 Traceability

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*.

H18.510

(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 *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*.

H19.000 Determination of Donor Eligibility

When a *tissue bank* is responsible for determining *donor* eligibility, the Medical Director *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.

H19.100 Review

The Medical Director *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 *defined requirements*. 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.

H19.110

In the case of pediatric *donors* who were 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.

H19.120

For all *donors* 1 month (28 days) of age or less, the infant and the birth mother *shall* be screened for risk of RCDADs, and the mother's blood *must* be tested. Refer to H9.000 (BT) for expectations to obtain the health status of the infant *donor* of *birth tissue*.

H19.200 Documentation
Once the determination is made, the *donor* eligibility statement *shall* be documented, dated, and signed by the Medical Director.

H19.300 Cause of Death
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.

H19.400 Autopsy Review/Findings
If an autopsy was performed, the *tissue bank*'s Medical Director *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* record, the cause of death and other pertinent autopsy findings *shall* be documented in the *donor* record.

H19.410
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.

H19.420
In the case of suspected sudden unexpected infant death (SUID), an autopsy *should* be performed, and results reviewed to confirm the cause of death.

H19.500 High-Risk Behavior Review
Tissue shall not be distributed from a *donor* who, or whose birth mother, has engaged in behaviors defined as high risk for transmission of RCDADs. This information *shall* be obtained via a *donor risk assessment interview*, *physical assessment* or *physical examination*, and review of other available *relevant medical records*. 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.

H19.600 Infection Risk Review
The Medical Director *shall* not determine an *allogeneic donor* eligible with any of the following findings:

1) evidence of significant active infection at the time of donation; and/or

2) clinical evidence of, or risk factors for, RCDADs as specified in Appendix II.

H19.610

(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 12 months with *Chlamydia trachomatis* and/or *Neisseria gonorrhea* 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.

H19.700 Test Result Review

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 an RR HTLV antibody test result and how this impacts the suitability of the *donor 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* 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.

H19.800 Anonymous Semen Donors

(R) *Tissue* from an *anonymous semen donor* who tests reactive for an active, acute infection with 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*.

H19.900

Tissue from a *donor* testing positive for chlamydia or gonorrhea *shall* not be suitable for use.

H20.000 Processing

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

H20.100 Tissue Not to be Processed

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

H20.200 Disinfection Period

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

H20.300 Evaluation/Assessment of Tissue Quality

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.

H20.400 Control/Prevention of Contamination/Cross-contamination
The bank *shall* have written *procedures* for control and prevention of contamination or *cross-contamination* by *tissue* during *processing*.

H20.500 Visual Examination of Containers
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.

H20.600 Process Control End Points
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.

H21.000 Post-Recovery Handling of Tissues

H21.100 Disinfection
(C, V) *Disinfection* of cardiac and vascular *tissue shall* be accomplished via a time-specific, validated process (*disinfection time*). The tissue processor shall establish the *cold ischemic time* and thus *total ischemic time* limit for their particular cardiac tissue and vascular tissue processing methods.

H21.200 Quality Analysis
(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*.

H21.300 Preservation of Cellular Viability
(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*.

H21.400 Prevention of Drying
(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.

H21.500 Media, Cryoprotectants, and 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.

H22.000 Assessment of Characteristics
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. If the *tissue bank* performs laboratory tests and results are used to determine acceptability of *tissue* for transplantation, the requirements at F4.000 *shall* apply. All *tissue* deemed to be out of conformance *shall* not be released for transplantation.

H22.100 Documentation
This inspection, the staff involved, and the *disposition* of each *tissue* unit *shall* be documented.

H22.200 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).

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

H22.210
(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).

H22.220
(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).

H22.230
(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 *label*ed 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 *label*ed as demineralized and *should* be *label*ed as partially demineralized to describe the extent of demineralization.

H22.240
Unless processed by a validated method to reduce water levels, each *lot* of *tissue* subjected to *lyophilization* or *dehydration*/*desiccation shall* be tested for residual moisture levels not to exceed a limit linked to *tissue quality*, as established by the *tissue bank*. The analytical method selected *must* be validated for its intended use. The final *container shall* maintain these moisture requirements for the indicated expiration period.

H23.000 Tissue Preservation

H23.100 Procedures for 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, vacuum, and times for cycle steps.

H23.200 Procedures for 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*.

H23.300 Procedures for Freezing
Procedures for freezing *tissue shall* be established and documented to maintain *tissue quality*.

H23.400 Procedures for 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*.

H23.500 Procedures for Cryopreservation
(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.

H23.600 Surrogates for Monitoring Freezing

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.

H23.700 Storage upon Cryopreservation
Upon termination of the freezing program, the *cryopreserved tissue shall* immediately be placed in *storage*. Temperature fluctuation and cycling *should* be avoided.

H23.800 Controlled-Rate Freezing Profile
If a programmed controlled-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.

H23.900 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.

H24.000 Disinfection, Sterilization, and Microbial Surveillance
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).

H24.100 Pathogenic Organisms
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.).

H25.000 Bioburden Reduction
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* record. See AATB Guidance Document No. 5 for expectations.

H25.100 Absence of Sterilization or Disinfection
If *tissue sterilization* or *disinfection* will not occur, a pre-*sterilization*/pre-*disinfection* culture is not required; however, refer to culture requirement at H25.400.

H25.200 Culture Results Review
The Medical Director [see exception that follows for skin (S)] *shall* review these pre-*sterilization*/pre-*disinfection* culture results prior to release of *tissue* for transplantation.

H25.210
(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.

H25.220
(BT, C, V, CT) H24.000 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).

H25.300 Skin Recovery
(S) *Skin recovery shall* be performed as a separate zone from other *tissue* types so that culture results can be independently reviewed.

H25.400 Final 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 H25.500. 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 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.

H25.410

(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*.

H25.420

(C, V) Representative *cardiac tissue* and *vascular tissue* samples *shall* be cultured for fungal growth.

H25.430

(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*.

H25.440

(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*; or
6) fungi (yeasts, molds).

H25.500 Irradiation

When *tissues* are irradiated, a dose *shall* be 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*.

H25.510
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*.

H25.520
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.

H25.600 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 *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.

Residual Level in Parts per Million			
***Tissue* Size/Weight**	**Ethylene Oxide**	**Ethylene Chlorohydrin**	**Ethylene Glycol**
Very small (<100 mg)	2,500	2,500	5,000
Small (<10 g)	250	250	5,000
Medium (10–100 g)	100	100	2,000
Large (>100 g)	25	25	500

(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 the presence of possible trace residuals. Refer to H29.100.

(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*.

H26.000 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* and *defined requirements* and in consideration of *tissue quality* and the *packaging system* for the *tissue*.

Storage* Conditions for Commonly Transplanted Human *Tissue		
Human *Tissue*	***Storage* Conditions**	**Temperature (°C) ***
Birth tissue (BT)	Frozen, refrigerated, *cryopreserved*, *lyophilized*, *dehydrated*, *desiccated*	*Established* by the *tissue bank*
Cardiac (C), *vascular tissue* (V)	Frozen, *cryopreserved*	–100°C or colder
Cellular tissue (CT)	Refrigerated	Above freezing (0°C) to 10°C
	Frozen, *cryopreserved*	*Established* by the *tissue bank*
Musculoskeletal tissue (MS), *osteoarticular graft* (OA)	Refrigerated	Above freezing (0°C) to 10°C
	Frozen, *cryopreserved* (temporary *storage* for 6 months or less)	–20°C or colder to –40°C (this is warmer than –40°C but colder than –20°C)
	Frozen, *cryopreserved* (long-term *storage*)	–40°C or colder
	Lyophilized, dehydrated, *desiccated*	Ambient **
Reproductive tissue (R)	Frozen, *cryopreserved*	LN_2 (liquid or vapor phase)
Skin (S)	Refrigerated	Above freezing (0°C) to 10°C
	Frozen, *cryopreserved*	–40°C or colder
	Lyophilized, dehydrated, *desiccated*	Ambient **
* Warmest target temperature unless noted to be a range ** Ambient temperature monitoring not required for *lyophilized, dehydrated*, or *desiccated tissue*		

NOT EFFECTIVE UNTIL JANUARY 31, 2027. AN IMPLEMENTATION PLAN IS REQUIRED BY JANUARY 31, 2025:

Storage* Conditions for ~~Commonly Transplanted Human~~ *Finished Tissues		
~~Human~~ *Tissue*	***Storage* Conditions**	**Temperature (°C) ***
Birth tissue (BT)	Frozen, refrigerated, *cryopreserved*, *lyophilized*, *dehydrated*, *desiccated*	*Established* by the *tissue bank*
Cardiac (C), *vascular tissue* (V)	Frozen, *cryopreserved*	–100°C or colder
Cellular tissue (CT)	Refrigerated	~~Above freezing (~~>0°C~~)~~ to 10°C
	Frozen, *cryopreserved*	*Established* by the *tissue bank*
Musculoskeletal tissue (MS), *osteoarticular graft* (OA)	Refrigerated	~~Above freezing (~~>0°C~~)~~ to 10°C
	Frozen, *cryopreserved* (temporary *storage* for 6 months or less)	–20°C or colder to –40°C (this is warmer than –40°C but colder than –20°C)
	Frozen, *cryopreserved* (long term *storage*)	–40°C or colder
	Lyophilized, dehydrated, desiccated, or other tissues that do not require refrigerated or frozen storage conditions	~~Ambient~~>0°C to 37°C, or as established by the tissue bank, including excursions **
Reproductive tissue (R)	Frozen, *cryopreserved*	LN_2 (liquid or vapor phase)
Skin (S)	Refrigerated	Above freezing (0°C) to 10°C
	Frozen, *cryopreserved*	–40°C or colder
	Lyophilized, dehydrated, desiccated, or other tissues that do not require refrigerated or frozen storage conditions	~~Ambient~~>0°C to 37°C, or as established by the tissue bank, including excursions **
* Warmest target temperature unless noted to be a range **~~Ambient t~~ Temperature monitoring is not required to be continuous for *lyophilized, dehydrated*, or *desiccated tissue* or other tissues that do not require refrigerated or frozen storage conditions because >0-37°C encompasses the "room" temperature range associated with human comfort. Numeric storage temperature ranges must be included on the container labeling.		

H26.100 Storage Temperatures

(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*.

H26.200 Storage Temperatures

(MS, OA) *Procedures* for storing processed frozen and *cryopreserved tissue* to ensure graft *safety* and *quality shall* be written. Processed frozen or *cryopreserved* musculoskeletal *tissue shall* be stored at temperatures of –40°C or colder.

(MS, OA) Temporary *storage* of processed frozen or *cryopreserved* musculoskeletal *tissue* between –20°C and –40°C is limited to 6 months total.

H26.300 Storage Temperatures
(C, V) *Cryopreserved cardiac tissue* and vascular *tissue allografts shall* be maintained at temperatures of –100°C or colder.

H26.400 Storage Temperatures
(R) *Reproductive tissues shall* be stored either in liquid nitrogen or in the vapor phase of liquid nitrogen.

H26.500 Storage Temperatures
(S) Frozen or *cryopreserved skin shall* be stored at ultra-low (–40°C or colder) temperatures.

H26.600 Storage Temperatures for Lyophilized, Dehydrated, or Desiccated Tissue
Lyophilized, dehydrated, or desiccated *tissue must* be stored at ambient temperature or colder.

NOT EFFECTIVE UNTIL JANUARY 31, 2027. AN IMPLEMENTATION PLAN IS REQUIRED BY JANUARY 31, 2025:

~~**H26.600**~~
~~Lyophilized, dehydrated, or desiccated *tissue* must be stored at ambient temperature or colder.~~

H26.700 Temperature Monitoring System
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 B12.000. If *storage* utilizes liquid nitrogen, either liquid nitrogen levels or temperature *shall* be monitored and documented at an interval specified in the *SOPM*.

H26.800 Emergency Transfer
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*.

H26.900 Maximum 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.

H26.910
(A) The implanting physician *shall* be informed of any expiration dates.

H26.920
(A) *Autologous skin* that has not been processed or preserved *should* be stored refrigerated for no longer than 14 days.

H27.000 Tissue Release
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.

H27.100 Review and Documentation
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 *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).

H27.200 Review and Documentation
(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.

H28.000 Labeling
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. *Tissue banks* that supply *labels* to other *tissue banks* and *tissue distribution intermediaries shall* communicate with recipients when any changes are made.

H28.100 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 B2.200. *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 material*s. Suppliers of *labels* deemed *critical* are responsible for establishing specifications.

H28.200 Claims
All *labeling claims shall* be clear, accurate, substantiated, and not misleading.

H28.300 SOPs
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).

H28.400 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 H28.100).

H28.500 Prevention of Errors

Labeling control *procedures shall* be established to ensure *label* integrity, legibility, and accuracy, and the establishment of checks to prevent transcription *errors* 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.

H28.600 Approval

Labels shall meet written specifications and be approved by *QA* 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.

H28.610

This is not applicable to *labels* included in *tissue recovery* packs.

H28.700 Obsolete/Outdated Labels

Procedures shall be established to retrieve obsolete and/or outdated *labels* and *labeling material*s 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.

H28.800 Tissue 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.

H28.810

For *finished tissue*, units of measurement and the *processing* that *tissue* has received *shall* also be specified in the *SOPM*.

H29.000 Container Labels

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

H29.100 Required 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*.

H29.200 Additional Required Content

The following information *shall* either appear on the *container label* or accompany the tissue (i.e., 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);
4) the name and address of the *tissue bank* that made the donor eligibility determination; and
5) the name and address of the *tissue bank* that determines that the *tissue* meets release criteria and makes the HCT/P available for distribution.

Responsibility for each individual process listed in items 4 through 5 must be borne by the *tissue bank* performing that process. If a different *tissue bank* is responsible for each one of these processes, the labeling or accompanying information should contain the name and address of each *tissue bank* and specify which *tissue bank* performed which function.

H29.300 Container Label Information

(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* prominently stating “NOT EVALUATED FOR INFECTIOUS 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* using a *biohazard legend* is required.

H29.400 Cryocontainer Labels

(R) Cryocontainers (e.g., vials, straws, or ampules) *shall* be *label*ed 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.

H30.000 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*. See B6.600. 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*).

H30.100 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 H22.260);
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., prominently stating "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* name or other personal information that might identify the *donor*.

H30.200 Package Insert Content

(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 have thawed;
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.

H30.300 Thawing Protocols for Cryopreserved Tissue

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.

H30.400 Preparation Instructions
The preparation instructions *shall* be sufficiently detailed and unambiguous to allow operating room personnel of average skill to follow and complete the *procedure* successfully.

H30.500 Package Insert Content
(R) *Reproductive tissue* in the following categories requires additional information in *package inserts* as listed below:

1) If the intended *recipient* is the sexually intimate partner of the *gamete* provider(s), the following *labeling* is required (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
        2. "WARNING: Advise Recipient of Communicable Disease Risks."
    c) For all reproductive *client depositors* who have reactive or positive test results:
        1. "BIOHAZARD" *label* using biohazard legend; 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 donor* (*semen*, oocyte, and/or *embryo*) with reactive test results:
        1. "BIOHAZARD" *label* using biohazard legend; and
        2. "WARNING: Reactive test results for (insert name of test)";
        3. "WARNING: Advise Recipient of Communicable Disease Risks."
    b) *Directed donor* (*semen*, oocyte, and/or *embryo*) determined to be ineligible based upon risk factors for, or clinical evidence of, RCDADs, including the *physical examination*:
        1. "BIOHAZARD" *label* using biohazard legend; and
        2. "WARNING: Advise Recipient of Communicable Disease Risks."
3) If the intended *recipient* is NOT the sexually intimate partner of either *gamete* provider, and the *tissue* is from an anonymous or directed *embryo*

donor in cases where the *gamete* provider(s) was (were) not initially tested as the *donor*, 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* using a *biohazard legend*;
        2. “For Non-Clinical Use Only”; and
        3. if applicable, “WARNING: Reactive test results for (insert name of test).”

H30.510
(R) See B5.340 for additional requirements that *may* be applicable in certain *directed donor* or *client depositor* situations.

H31.000 Transport Package Label

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., prominently stating "DO NOT FREEZE," "DO NOT X-RAY," "DO NOT IRRADIATE").

NOT EFFECTIVE UNTIL JANUARY 31, 2027. AN IMPLEMENTATION PLAN IS REQUIRED BY JANUARY 31, 2025:

H31.000 Transport Package Label

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) 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");
4) recommended *storage* conditions;
5) validated expiration date/time of the transport *package* when the *storage* temperature *must* be controlled (for finished *tissue* requiring specific environmental conditions; does not apply to *lyophilized, dehydrated, desiccated tissue* or other *tissues* that do not require refrigerated or frozen storage conditions);
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., prominently stating "Do Not Freeze," "Do Not X-Ray," "Do Not Irradiate").

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.

H32.000 Distribution

H32.100 SOPs

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.

H32.200 Transfer to Distribution Inventory
Before *tissue* is transferred to *distribution* inventory, appropriate release documentation *shall* be v*erified*. *Tissue* for *transplantation may* then be placed in *distribution* inventory. The identification of the *tissue* transferred, date of transfer, and staff performing the *verification*s and transfer *shall* be documented.

H32.300 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.

H33.000 Release for Transplantation
Provision of *tissue* for *transplantation shall* be restricted to hospitals, freestanding medical facilities, *tissue banks*, *tissue dispensing services*, and *end-user*s (e.g., physicians, dentists, podiatrists, or other medical professionals) for use in *recipient*s 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 applicable requirements 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 F2.200.

H33.100 Reproductive Tissue Release
(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*.

H33.200 Written Authorization
(R) 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 the parent, legal guardian, or their legally appointed designee.

H33.300 Directed Donors
(R) A *client depositor* who requests that their *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*. 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 gonorrhea* 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.

H33.400 Release Before Completion of Donor Eligibility Assessment
(R) 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.

H33.500 Physician's Order
(R) *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*.

H33.600 Limitation of the Number of Offspring
(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.

H33.700 Tissue Obtained from Another Facility
When a *tissue bank* distributes *tissue* obtained from another *tissue bank* or *tissue distribution intermediary*, all accompanying original *labeling material*s or other enclosures *shall* be distributed with the *tissue*.

H33.800 Tissue Provided on Consignment
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.

H34.000 Packaging and Shipping

H34.100 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.

H34.200 Integrity
Packaging *shall* be designed to ensure *tissue quality* and prevent contamination of the contents of the final *container(s)*.

H34.300 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 *defined requirements*.

H34.400 Validation/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 dates (and time, if applicable) of the transport *package shall* be noted on the outside of the transport *package*.

NOT EFFECTIVE UNTIL JANUARY 31, 2027. AN IMPLEMENTATION PLAN IS REQUIRED BY JANUARY 31, 2025:

H34.400 Validation/Expiration of Transport Package
~~If *tissue* to be shipped requires specific environmental conditions other than ambient temperature,~~ ~~t~~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 dates (and time if applicable) of the transport *package shall* be noted on the outside of the transport *package*. This does not apply to finished *lyophilized, dehydrated, desiccated tissue* or other tissues that do not require refrigerated or frozen storage conditions.

H34.500 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.

NOT EFFECTIVE UNTIL JANUARY 31, 2027. AN IMPLEMENTATION PLAN IS REQUIRED BY JANUARY 31, 2025:

H34.500 Quality Control of Reusable ~~Shipping~~ Transport Packages
If ~~tissue to be shipped requires specific environmental conditions other than ambient temperature, and~~ the transport *package* can be reused for finished tissue, QC ~~monitoring of the transport packaging~~ checks must be performed and documented ~~according to the SOPM~~ to *verify package* integrity has been maintained. ~~These QC checks shall be documented.~~

H34.600 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 H31.000 are met. These inspections *shall* be documented, including identification of staff conducting inspections.

H34.700 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 by the urgency of the *tissue* request.

H34.800 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.

H34.810
For *tissue* that requires controlled environmental temperatures, at a minimum, documentation is required that attests the *tissue* was maintained at required *storage* temperatures.

H35.000 Recipient Follow-up
The *tissue bank shall* establish *recipient* follow-up data *collection* protocols, and *procedures* to evaluate information received.

H36.000 Dispensing and Disposal
Activities of a *tissue dispensing service shall* be supervised by a physician, dentist, podiatrist, or other qualified medical professional.

H36.100 Storage
Tissue storage shall be in conformance with *labeling material*s. See requirements for storage temperatures and equipment, including E7.100 and H3.500.

H36.200 Relabeling
Tissue shall not be *relabeled*. Existing *labels shall* not be altered.

H36.300 Orders
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 material*s. All associated *labeling material*, including the *package insert*, *shall* be made available to the *end-user* physician and/or other qualified medical professionals.

H36.400 Further Distribution

When further distributing *tissue*, all accompanying original *labeling material*s 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), re*distribution* date, and destination.

H36.500 Final Disposition

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*.

H36.600 Disposal

(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* 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.

H36.700 Discard

(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. *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 10 years after expiration of the *tissue* or, in the case of *tissue* with no expiration date, 10 years after dispensing.

H37.000 Tissue Distribution

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.

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* (H4.100 and E5.100 apply);
2) designing, creating, specifying, or maintaining responsibility for the contents of the *label* for *finished tissue* (relevant parts of H15.500 apply);
3) performing any *labeling* functions to include the physical application of a *label* to *finished tissue* (relevant parts of H15.500 apply); and/or

4) final review for *tissue* release [relevant parts of Sections B and H apply (e.g., B6.300, H32.000)].

H37.100 Storage
Tissue storage shall be in conformance with the *package insert* and monitoring expectations. See requirements for storage temperatures and equipment, including E3.000, E7.100, H3.500, and H26.000.

H37.200 Relabeling
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 H15.500.

H37.300 Procedure for Orders
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 material*s or other enclosures *shall* be forwarded with the *tissue*.

H37.310
Provision of *tissue* for *transplantation shall* be restricted to hospitals, freestanding medical facilities, *tissue banks*, *tissue dispensing services*, another *tissue distribution intermediary*, and *end-user*s (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.

H37.400 Information Sharing
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.

H37.500 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.

H37.600 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 H31.000 are met. These inspections *shall* be documented, including identification of staff conducting inspections.

H37.700 Transportation Requirements
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.

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*.

NOT EFFECTIVE UNTIL JANUARY 31, 2027. AN IMPLEMENTATION PLAN IS REQUIRED BY JANUARY 31, 2025:

H37.700 Transportation Requirements
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.

~~If tissue to be shipped requires specific environmental conditions other than ambient temperature,~~ ~~t~~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*. This does not apply to finished *lyophilized, dehydrated, desiccated tissue* or other tissues that do not require refrigerated or frozen storage conditions.

H37.800 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.

H37.900 Returns, Field Corrections, and Removals
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*.

The need to perform a *field correction* or *removal may* be identified as a result of a *complaint*, *adverse outcome*, *accident*, *error*, *deviation*, or *audit*, or by any other means. For applicable *QA* requirements, see relevant parts of Section B. 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.

H38.000 Review Prior to Distribution

Prior to *distribution*, the *labeled tissue shall* be reviewed to *verify* that *tissue* has been properly identified and *labeled*. Such inspection *shall* be documented.

Appendix I:
REQUEST FOR VARIANCE FROM STANDARDS

Introduction

AATB-accredited *tissue bank*s *may* request a *variance* when a policy, process, or *procedure* conflicts 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*; and
    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 *QA* 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 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)[1] 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[2] 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*) 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 *donor*.

7) persons who have been in a juvenile *correction*al 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[2] infection in the preceding 12 months;

10) persons who had or have been treated for syphilis or gonorrhea during the preceding 12 months. *Donor 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 *donor* 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)[3].

18) persons determined to be at risk for variant CJD (vCJD) because they are known to meet any of the following criteria:

    a) spent 3 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[4] 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;

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[5] (i.e., receipt of a xenotransplantation product[6] or who has had intimate contact[7] 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 6 months, were bitten by an animal suspected to be infected with rabies. Individuals with suspected rabies *shall* not be accepted as *donor* 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* (as determined by medical record review);

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[3];

25) persons who have had a recent smallpox vaccination (vaccinia virus) and persons who acquired a clinically recognizable vaccinia virus infection by close contact[8] 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 donor* 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 donor* 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 (as determined by medical record review)*;*

31) Persons with a history (ever) of tuberculosis disease (sometimes referred to as "active" or "clinically active" tuberculosis).

32) Persons with a history of latent ("inactive") tuberculosis infection initially diagnosed within the past two (2) years (i.e., the individual has had a positive test for tuberculosis).[9]

33) For tissues intended to ultimately retain viable cells (i.e., all products comprising or containing tissues that are processed in a manner to retain living cells – including reproductive cells), tissues from persons meeting any of the following criteria are not suitable for transplant due to risk of tuberculosis:

    a. aged ≥ 65 (except for cryopreserved skin, where age ≥ 65 is acceptable)
    b. who, within the past 2 years, traveled for ≥3 months or immigrated from a country with most current available tuberculosis incidence of ≥ 20 (rate per 100,000 population) available on WHO TB country profile website: https://worldhealthorg.shinyapps.io/tb_profiles/
    c. with exposure to an individual with tuberculosis disease within the past 2 years
    d. with (latent) tuberculosis infection > 2 years ago (i.e., positive TB test > 2 years ago)
    e. experiencing homelessness housed in shelters or other congregate setting, ≤2 years ago
    f. have been incarcerated ≤2 years ago
    g. with End Stage Renal Disease ([Chronic Kidney Disease (CKD) 5]) with or without dialysis
    h. who have received solid organ transplant

34) Except for cryopreserved skin, which is subject to medical director discretion, tissues intended to ultimately retain viable cells from persons with at least one risk factor from each column below for exposure to, and reactivation of, tuberculosis are not suitable for transplant:

Exposure Risk Factors	Reactivation Risk Factors
who had birth, travel, or residence ≥ 3 months cumulative in a country with most current available tuberculosis incidence of ≥ 20 (rate per 100,000 population) that occurred > 2 years ago	with advanced kidney disease, pre-dialysis— otherwise known as CKD Stage 4, GFR < 30

Exposure Risk Factors	Reactivation Risk Factors
ever experiencing homelessness and were housed in shelters or other congregate settings > 2 years ago	with diabetes mellitus
have been incarcerated ≥ 2 years ago	with cirrhosis or alcoholic liver disease
who have had exposure to an individual with tuberculosis disease > 2 years ago	with alcohol use disorder/ excessive or heavy alcohol use
	who use immunosuppressive medications

[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 *donor* and/or *recipients* at risk for infection due to accidental or intentional release. RCDADs applicable to all *tissue donor* are (but are not limited to): HIV 1/2, HBV, HCV, human TSE, syphilis, communicable disease risks associated with xenotransplantation, WNV, vaccinia, and sepsis. *Donor* of viable, leukocyte-rich *tissues must* additionally consider HTLV I/II, and *donor* 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.

[4]European countries to be used for deferral of *donor* based on geographic risk of Bovine Spongiform Encephalopathy (BSE): Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic/Czechoslovakia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic/Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, former Yugoslavia, and Republic of Macedonia/North Macedonia.

[5]XENOTRANSPLANTATION - 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.

[6]XENOTRANSPLANTATION 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.

[7]XENOTRANSPLANTATION 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.

[8]CLOSE 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.

[9]Tests for tuberculosis include TB skin test (TST; other names used interchangeably—purified protein derivative [PPD] or Mantoux) and Interferon Gamma Release Assay (IGRA) blood tests (e.g., QuantiFERON-TB Gold, T-SPOT)

Sources:
U.S. Department of Health and Human Services, Food and Drug Administration, Eligibility Determination for Donor of Human Cells, Tissues, and Cellular and Tissue-Based Products; Final Rule (69 FR 29785, *May* 25, 2004).

U.S. Department of Health and Human Services, Food and Drug Administration, Final Guidance for Industry: Eligibility Determination for Donor of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) dated August 8, 2007.

U.S. Department of Health and Human Services, Food and Drug Administration, Final Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria dated August 2013. Updated August 2014.

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 H11.000 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 may adapt and personalize forms and SOPs, for use in either paper or electronic format. However, alterations to the content of this form *must* not change the intent. *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.

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* 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* 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*.

Step	**Action**
Identification	
1	Document the complete name of the *donor* as written on the *document of gift/authorization*.
2	Document the *recovery* agency's unique *donor* ID.
3	The manner in which the *donor* was identified is documented by checking the box next to the 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* 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* 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* 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."
Assessment	
16	For each step #17 through # 28 inclusive, check "No" or "Yes". If "Yes", then describe the finding thoroughly. If visualization or palpation is not possible, then check the box and explain why.
17	Are abnormal ocular findings (e.g., icterus, scarring) present? Check "No" or "Yes". If "Yes", then describe. If additional space is needed, then write where to find details (e.g., "see schematic", "see Notes"). If ocular *tissue* was *recovered* prior to this assessment, then check "Unable to visualize" and follow-up with personnel at the local Eye Bank to obtain document.

18	Are white or yellow spots in the mouth present? Check “No” or “Yes”. If “Yes”, then describe. Check “Unable to visualize” if oral cavity is not accessible to visualize and explain why. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
19	Is jaundice present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
20	Are signs of trauma or infection present on the body where *recovery* of *tissue* is planned (*tissue recovery* areas)? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
21	Is a rash, scab, or non-genital *skin* lesion present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
22	Are blue/purple (gray/black) spots/lesions present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
23	Are signs of non-medical injections present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
24	Document if no enlarged lymph/abnormal node(s) is (are) observed (“No”), or if any are observed (“Yes”). Explain any “Yes” findings here or, if space is limited, document where the description can be found (e.g., see schematic, see Notes, etc.). Lymph nodes can be palpated bilaterally just under the skin of the neck, axilla, and groin. When lymph nodes can be visualized and are found to be enlarged/abnormal, such findings *must* be documented in the *recovery records* however there is not an expectation to identify them on the body schematic. An enlarged lymph node can appear swollen [a node that is an inch (2.5 centimeters) or more in diameter in an adult], and abnormal findings can be if it is draining pus or feels hard [2].
25	Is evidence of an enlarged liver (hepatomegaly) present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”). If the liver cannot be assessed, then check “Unable to assess” and explain. If liver is not present, there is an expectation to follow-up to obtain documentation of the description of the liver (e.g., with OPO personnel, a pathologist, a researcher).
26	Are genital lesions present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).
27	Are perianal lesions or anal trauma present upon rectal examination? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).

28	Are tattoos/piercing present? Check “No” or “Yes”. If “Yes”, then describe. If additional space is needed, then write where to find details (e.g., “see schematic”, “see Notes”).

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 it 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 B9.100 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 G3.000). 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

1. U.S. Department of Health and Human Services, Food and Drug Administration, Final Guidance for Industry: Eligibility Determination for Donor of Human Cells, Tissues, and Cellular and Tissue- Based Products (HCT/Ps), August 8, 2007.
2. The Merck Manual, Home Health Handbook for Patients and Caregivers, http://www.merckmanuals.com/home/heart_and_blood_vessel_disorders/lymphatic_disorders/swolle n_lymph_nodes.html (accessed April 30, 2016)

Historical Changes

Previous Page #	Summary of Changes
New on 2/23/04 (SAB/AM/AG)	
1	Added reference to this being "Version 2", new date, and address updated
3	Table of Contents pages and titles updated
4	Provided listing of *Standards* that are related; verbiage changes and additions made for clarification; reference to staff training and competency added.
5	Updates made to abbreviations in B.; addition of "available, relevant" to medical records; and punctuation changed in part E.
6	Verbiage additions and changes made for clarification.
7	Verbiage additions and changes made for clarification. "Globes" replaced with "whole eyes" to match EBAA terminology.
8	Removed "icterus" in step 17 and placed it in later step (28); adjusted wording accordingly.
8	Step 19 amended to document the new observation listing for "tattoos/piercings" to accommodate new federal guidance (*Donor* Eligibility).
8	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")."
8	Changed "perianal warts" to "perianal lesions" to encompass more possibilities that *may* be seen.
8	Added provision for documenting evidence of rash, scab, or skin lesion (non-genital) to accommodate new federal guidance (*Donor* Eligibility).
9	Change to step 28 is to address documentation of abnormal ocular findings that was added to accommodate new federal guidance (*Donor* Eligibility).
9	Documenting limitations of visualization when it's restricted is offered as needed.

Previous Page #	Summary of Changes
9	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.
9	Step numbers updated and order of last two steps changed.
10	In step 2, use of blank schematic Key spaces is now described.
10	Ampersand (&) included in deletion example.
10	Part G. amended to include general instruction to document/share any *deviations* from written *procedures* that occur.
13	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.
13	Evidence of Donation/ Autopsy area changed to list “whole eyes” instead of “globes”.
13	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.
13	In the General Appearance area, deleted “Basic Hygiene” and changed to “Cleanliness”; entirely deleted Body Profile and selections.
13	Switched order of last two line-items.
14	Added a selection for *label*ing a ‘scab’ by using the letter W. Changed “for” to “prior to” in Summary.
15, 16	Added example pages of the sample form completed in entirety for a fictitious *donor*.
13–16	Removed all checkboxes and spaced selections appropriately.
6–8	Changed all references to “checking” or “box” and replaced them with directions to circle appropriate selection or word.
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 *recover*y if there is a discrepancy regarding identification of the body; the *procedure* describes an expectation that the *SOPM shall* include directions when the *donor* 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* 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* are now required documentation.
12	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* are 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.
13	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.

Versions 1 & 2
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Appendix III
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AATB Tissue Donor Physical Assessment Form

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 **Height is:** ☐ estimated/team ☐ actual ☐ reported (source: _____)
Weight: _____ ☐ lb ☐ kgs **Weight is:** ☐ 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: _____

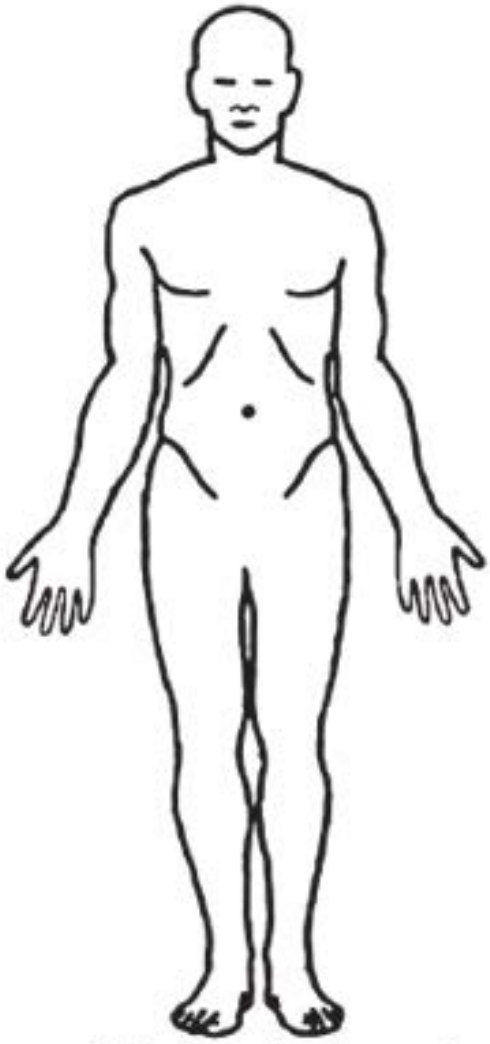
☐ No Genital lesions …… ☐ Yes: _____

☐ No Perianal lesions or Anal trauma …… ☐ Yes: _____

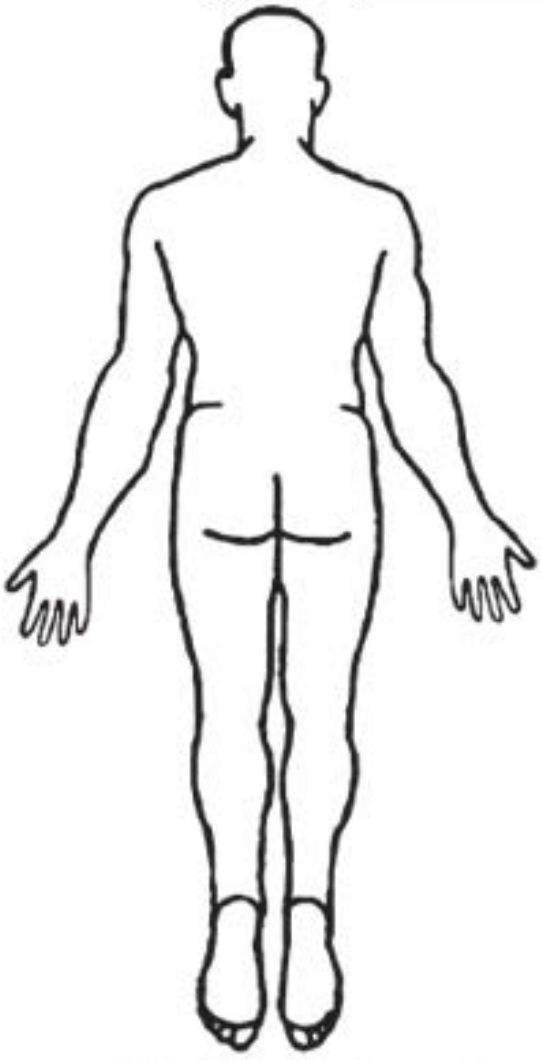
☐ No Tattoos/piercing …… ☐ Yes: _____

Tissue Donor Physical Assessment Schematic

Recovery Agency ID: _____



☐ Check if no observations noted



☐ Check if no observations noted

Key to Schematic:

(A) Abrasion	(N) Body piercing – requires description
(B) Bruise/Contusion/Hematoma	(O) Urethral catheter
(C) Cast/Ortho device	(P) Skin lesion – requires description
(D) Dressing/Bandage	(Q) Scar (surgical/trauma)
(E) ET tube/NG tube	(R) Rash
(F) Fracture/Dislocation	(S) Ocular Donation
(G) IV/IO/Arterial Line	(T) Tattoo – requires description (also note if suspected to be new)
(H) Skin Tag(s)	(U) Mole
(I) ID Band/ Tag	(V) Team Blood Draw Site
(J) Laceration/Wound	(W) _____
(K) Autopsy Incision	(X) _____
(L) Needle entry site	(Y) _____
(M) Organ Recovery Incision	(Z) _____

Physical Assessment performed by: _____ **Date/Time/Zone:** _____ / _____ / ___

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 *donor*, 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. *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, whole globes;
- 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/Pe-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 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 B6.900). *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 Rule1" (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)].

PATHOGENIC, HIGHLY VIRULENT MICROORGANISMS:

Two *microorganisms* (and others that have been identified for specific *tissue* types, see H24.000) are considered pathogenic, highly virulent organisms. Individual *tissues* with culture results yielding *Clostridium* or *Streptococcus pyogenes* (group A strep.) *should* be discarded (see H25.210). 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 H25.400). *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 techniques2 but not by limitations of swabbing techniques and

protocols used. The low accuracy, sensitivity, and reliability of swab culturing3- 11 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 present3-11. 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

1. 21 CFR Part 1271 Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue- Based Product Establishments; Inspection and Enforcement; Final Rule, Department of Health and Human Services, FDA, November 24, 2004.

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10. Mills AR, Roberts MR: “Evaluation of Culturing Methods at Predicting Allograft Sterility for Aseptically Processed Tissue”; AATB Posters and Abstracts, 25th Annual Meeting (2001).

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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*.

Pre-Recovery Evaluation:		Yes	No
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.		
2.	Adequate lighting to perform physical assessment and *tissue* recovery is present.		
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.		
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.		
5.	The walls, floor, and work surfaces are easily cleanable (i.e., non-carpeted, not porous) and in a good state of repair.		
6.	Signs of insects, rodents, or other pests are not visible.		
7.	Standing fluids or contaminated waste in the room, that could be a source of airborne bacteria, mycobacteria, yeasts or fungi, are not present.		
8.	The recovery room was properly prepared by cleaning and disinfecting all working surfaces prior to recovery of *tissue*.		

Concurrent with Recovery:		Yes	No
1.	Human traffic is restricted and all personnel entering the recovery area are properly outfitted and their movement controlled.		
2.	Other activities (e.g., embalming, autopsy, another *tissue donor* recovery) did not occur simultaneously in the same room as this *tissue* recovery.		
Post-Recovery Activities:		Yes	No
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.		
2.	All working surfaces and the floor were cleaned using approved solutions and equipment.		

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

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