Standards # (14th edition)	Standard - Fragment	15th Location
A1.000 Accreditation	AATB accredited tissue banks must comply with these Standards, the Accreditation Policies for Transplant Tissue Banks, as well as all applicable laws and regulations.	B1.100
B1.100 Purpose, Institutional Identity, and Affiliations	The purpose of the tissue bank shall be clearly formulated and documented. The tissue bank shall state whether it is a freestanding entity or part of an institution.	A1.300
B1.200 Governing Body	The tissue bank shall have a Governing Body that may consist of a Board of Trustees, Board of Governors, Board of Directors or a designated responsible individual in whom policy- making authority resides, unless otherwise provided by the institution of which it is a part.	A1.000 (see also Governing Body in Definition of Terms)
B1.200 Governing Body	A Board shall consist of individuals from various professions. This Board or designated individual shall determine the scope of activities to be pursued by the tissue bank.	A3.100
B1.200 Governing Body	The Governing Body shall designate one or more senior employees as management with executive responsibility. Issues of liability, ethical considerations, fiduciary responsibility, and compliance with applicable laws and regulations, these Standards, and the tissue bank's SOPM shall be the responsibility of the Governing Body and management with executive responsibility.	A3.200
B1.300 Medical/Scientific Support	A tissue bank should establish and maintain a mechanism to access medical, technical, and scientific advice as needed. Decisions shall be documented.	A5.000
B1.400 Satellite Facilities	Satellite facilities shall be operated in accordance with the tissue bank's SOPM.	B4.100
B1.500 Written Agreements/Contracts	Each tissue bank shall have written agreements or contracts with all other individuals or organizations that perform or for whom they perform tissue banking activities or services such as, but not limited to:	F1.000
B1.500 Written Agreements/Contracts	1) donor referral; 2) authorization; 3) informed consent; 4) donor eligibility assessment; 5) recovery, collection, and/or acquisition; 6) post-delivery functions; 7) laboratory services (see exception at B1.600); 8) testing services; 9) processing; 10) storage; 11) tissue release; 12) distribution; and/or 13) consignment.	Preempted (see F1.000, F2.200, F2.500)

Standards # (14th edition)	Standard - Fragment	15th Location
B1.500 Written Agreements/Contracts	For additional controls regarding testing services and other services performed by others, see the series of standards at K1.300.	Preempted (see F2.510, F4.000)
B1.500 Written Agreements/Contracts	Written agreements or contracts shall indicate the nature of the relationships, division of tasks performed, division of issues of liability, specific responsibilities of each party and a summary of the protocols and procedures relating to the services provided. The tissue bank shall maintain a copy of each such agreement, which shall be made available for review if requested by AATB inspectors. Compliance with Standards by all parties shall be required and documented in a quality agreement. The following examples provide a few of these expectations:	Preempted (see F1.000, F3.000)
B1.500 Written Agreements/Contracts	1) A tissue bank that recovers tissue that is processed and/or distributed by another tissue bank shall be responsible for being in compliance with these Standards for all operations it performs. This includes, but is not limited to, the requirement to have a Medical Director (see B2.220), to follow applicable standards in Section D and Appendix II, and to share records (see D4.300). A tissue bank that recovers tissue is not required to audit its contracted tissue bank processor(s).	Preempted (see F2.000, F2.600, F2.700)
B1.500 Written Agreements/Contracts	(BT) There shall be a written agreement/contract with the entity that performs post-delivery functions and/or acquisition on behalf of the tissue bank; or, if there is no written agreement or contract, there must be an attestation record from a responsible person that post-delivery protocols and procedures are followed.	Preempted (see F2.200)
B1.500 Written Agreements/Contracts	2) A tissue bank that processes tissue recovered and/or distributed by another tissue bank shall be responsible for being in compliance with these Standards for all operations it performs. The tissue processing organization must bear the burden of proof, and document in writing, that operations performed by other organizations prior to the receipt of tissue for processing were performed in a manner consistent with these Standards as well as the processing tissue bank's requirements.	Preempted (see A1.200, B1.000)
B1.500 Written Agreements/Contracts	3) A tissue bank that distributes tissue recovered and/or processed by other tissue banks shall be responsible for being in compliance with AATB Standards for all operations it performs. The distributor must also bear the burden of proof, and document in writing, that operations performed by other organizations prior to its receipt of tissue for distribution were performed in a manner consistent with AATB Standards. Any records necessary to demonstrate compliance shall be readily accessible to the distributing tissue bank.	Preempted (see A1.200, B1.000, B8.000)
B1.500 Written Agreements/Contracts	4) A tissue bank that determines donor eligibility shall develop and maintain policies and procedures that clearly describe donor records they deem relevant to their operations. Agreements must address how this information is to be communicated in a timely fashion and clearly define expectations and responsibilities of the appropriate entities.	Preempted (see A1.200, B1.000, B8.000)

Standards # (14th edition)	Standard - Fragment	15th Location
B1.500 Written Agreements/Contracts	5) A tissue bank that provides another tissue bank with critical supplies, reagents, materials, and/or equipment shall develop and maintain policies and procedures that clearly describe responsibilities for notification of changes and recalls, and both entities should report problems (e.g., defects). The tissue bank providing supplies containing labels is responsible for archiving and notification responsibilities described at G2.330.	Preempted (see A1.200, B1.000, B8.000)
B1.500 Written Agreements/Contracts	6) A tissue bank that distributes tissue for transplantation shall restrict distribution to entities described in Standards (see H1.100). If tissue is provided to a tissue distribution intermediary, the tissue distribution intermediary shall meet the requirements of Section M of these Standards.	Preempted (see H33.000)
B1.500 Written Agreements/Contracts	If an AATB-accredited tissue bank obtains from and processes tissue for a tissue bank not accredited by the AATB that is located outside of the United States (U.S.), the requirement for compliance with Standards does not apply to the foreign tissue bank if the processed tissues will not be distributed within, or to, the U.S. All tissues imported from entities that do not follow AATB Standards shall be appropriately quarantined throughout import, storage, processing, and export. The AATB-accredited tissue bank must verify that the foreign tissue bank not accredited by the AATB complies with regulations of the governmental authority having jurisdiction in their country for the functions they perform (e.g., informed consent/authorization, donor eligibility assessment, recovery, acquisition, donor testing). Additionally the tissue bank not accredited by the AATB should be verified to be in compliance with existing standards or guidelines, as appropriate. Examples of established standards include the current editions of: Health Canada's ''Safety of Human Cells, Tissues and Organs for Transplantation Regulations;'' the Directive (and Commission Directives) 2004/23/EC of the European Parliament and the Council; or, expectations as described in the World Health Organization's ''Aide Me´moires for Human Cells and Tissues for Transplantation.''	F.5000
B1.510 On-Site Inspections	(Refers to any AATB accreditation inspection.) A tissue bank will be inspected and accredited for the specific activity(ies) or service(s) that it performs. However, if the tissue bank participates jointly with other entities that provide tissue banking activities or services on their behalf, the accredited tissue bank is responsible for providing evidence of compliance to these Standards for all tissue banking activities or services performed by other entities on its behalf.	Preempted (see A1.000, B1.200)
B1.520 Inspections/Audits of Other Facilities	(Refers to inspections/audits that an accredited tissue bank must perform for activities/services rendered by another entity.)	Preempted (see B9.200)
B1.520 Inspections/Audits of Other Facilities	Before an entity performs any activity/service under contract, agreement or other arrangement, the accredited tissue bank must ensure that the entity will comply with applicable Standards, laws and regulations. Thereafter, the accredited tissue bank is responsible for verifying, at least biennially, that the activity(ies) or service(s) has/have been performed in conformance with applicable Standards, laws and regulations. This requirement	F2.200

Standards # (14th edition)	Standard - Fragment	15th Location
	does not apply to any other AATB-accredited entity. The verification of activities or services performed by others shall be documented (e.g., a paper audit, on-site audit, on-site inspections, etc.).	
B1.520 Inspections/Audits of Other Facilities	Regardless of whether the facility performing activities or services for others is accredited, it is the responsibility of the tissue bank receiving those activities/ services to periodically verify that procedures related to the activities/services are in compliance with these Standards, the written agreement/contract, and applicable laws and regulations. The inspection/audit plan, policies, and procedures shall be specified in the SOPM.	F2.200
B1.520 Inspections/Audits of Other Facilities	Documentation that an audit/inspection specific for activities or services performed shall be maintained by the tissue bank. Such documentation shall itemize all operational systems that were verified to determine compliance with these Standards, the agreement/contract and applicable laws and regulations. This itemization of the systems reviewed shall be provided to AATB on-site inspectors upon request. For an audit tool and requirements to be used for a partner performing recovery services, refer to Appendix V.	B9.200
B1.520 Inspections/Audits of Other Facilities	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.	F2.300
B1.600 Contracted and Non-contracted Laboratory Services for Donor Infectious Disease Testing	Tissue banks that contract laboratory services for donor infectious disease testing shall retain in their records the name and address of the contracted facility and documentation of the inclusive dates of the contract period.	B6.430
B1.600 Contracted and Non-contracted Laboratory Services for Donor Infectious Disease Testing	Proof of current laboratory licensure and accreditation must be maintained. Additionally, all requirements in the series of standards at K1.300 shall apply. Tissue banks that obtain donor infectious disease test results from non-contracted laboratory services (e.g., other tissue banks, organ procurement organizations) shall maintain the name, address, licensing and accreditation information for each laboratory from which test results are obtained for the purpose of donor eligibility or tissue suitability assessments. Appropriate management with executive responsibility shall ensure a responsible person understands the principles of bacteriological and/or infectious disease test procedures employed by a laboratory as well as the interpretation of results.	F4.000
B1.600 Contracted and Non-contracted Laboratory Services for Donor Infectious Disease Testing	Records of infectious disease laboratory results used to assess donor eligibility shall become part of the donor record.	B6.600
B1.600 Contracted and Non-contracted Laboratory Services for Donor Infectious Disease Testing	NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding establishment registration, laboratory certification, test kit licensing/approval, and test run record retention.	H12.200

Standards # (14th edition)	Standard - Fragment	15th Location
B1.600 Contracted and Non-contracted Laboratory Services for Donor Infectious Disease Testing	The tissue bank must ensure (and maintain documentation of activities obtained by either paper audit or on-site audit) that a laboratory performing donor infectious disease testing for the tissue bank is: 1) registered with the FDA as a tissue establishment and lists 'testing' as a function; 2) using the appropriate FDA-licensed, approved, or cleared donor screening tests; 3) following manufacturers' instructions for these tests; 4) certified in accordance with the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services; 5) retaining donor infectious disease test run records for ten years; and 6) aware of the requirement of the tissue bank to comply with D4.240.	F4.000
B2.100 Management Responsibility B2.110 Quality Policy	Management with executive responsibility shall ensure the establishment of the tissue bank's policy and objectives for, and commitment to, quality, and shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.	C3.100
B2.120 Organization	Each tissue bank shall establish and maintain an adequate organizational structure to ensure that all tissue banking activities or services comply with the requirements of these Standards.	A1.200
B2.121 Responsibilities and Authority	Each tissue bank shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks in accordance with these Standards. The tissue bank shall ensure that responsibilities and authorities are defined, documented, and communicated within the tissue bank.	A1.100
B2.122 Resources	The tissue bank shall have sufficient resources, including the assignment of trained personnel, for management, performance of work, and assessment activities to meet the requirements of these Standards.	A2.000
B2.123 Management Representative	Management with executive responsibility shall appoint a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for ensuring that quality system requirements are effectively established and effectively maintained. The management representative shall periodically report on the performance of the quality system to management with executive responsibility for their review.	B3.000
B2.130 Management Review	Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of these Standards and the tissue bank's established quality policy and objectives. The dates and results of quality system reviews shall be documented.	C3.130
B2.140 Technical Policies and Procedures	Technical policies and procedures utilized in the operation of the tissue bank must be established and maintained. The tissue bank may adopt current standard procedures, such as those in a technical manual prepared by another organization, provided that the tissue bank	H1.100

Standards # (14th edition)	Standard - Fragment	15th Location
	has verified that the procedures are consistent with, and at least as stringent as, the requirements of these Standards and appropriate for operations.	
B2.150 Quality Assurance Program	A quality assurance (QA) program shall be established and maintained to ensure that the entire operation is in conformity with the tissue bank's SOPM, these Standards, and applicable laws and regulations.	B2.000
B2.150 Quality Assurance Program	A documented annual internal review or audit to ensure compliance must be performed.	C3.130
B2.160 Contingency Plan	The tissue establishment shall have a contingency plan in place for tissue that remains in inventory and record retention in the event of merger, acquisition, or dissolution.	A4.000
B2.200 Medical Director B2.210 Qualifications	The tissue bank shall have a Medical Director who maintains a valid medical license from any state or U.S. territory (or for international members, the physician must maintain an equivalent medical license). He/she should have training and experience in evaluating and determining donor eligibility particularly with regard to infectious diseases or use a Medical Advisory Committee or consultants to assist in those areas.	C3.200
B2.220 Responsibilities	The Medical Director shall establish, review, and approve all policies and procedures of a medical nature. See J1.300, J1.400, J1.600.	C3.210
B2.221 Donor Eligibility Criteria	The Medical Director shall be responsible for establishing donor eligibility criteria. See the series of standards at D4.000 and Appendix II.	H6.000
B2.221 Donor Eligibility Criteria	The tissue bank's donor eligibility criteria may be adopted from criteria used by another organization, provided that the Medical Director has verified the criteria are consistent with, and at least as stringent as, the requirements of these Standards and applicable laws and regulations.	Preempted (see C3.210, H6.000)
B2.221 Donor Eligibility Criteria	When a tissue bank is responsible for determining donor eligibility, the Medical Director, or licensed physician designee, shall make a determination regarding the eligibility of each donor based on a comparison with predetermined donor criteria as established in the SOPM. This determination must occur prior to the release of tissue for transplantation. See Section F.	H6.100
B2.222 Adverse Outcomes	The Medical Director shall establish policies and procedures regarding adverse outcomes. See K4.300.	~~B3.350~~ B2.340
B2.223 Positive Infectious Disease Test Results	The Medical Director shall be responsible for notifying appropriate parties of the availability of positive infectious disease test results, and for reporting positive test results when required, in accordance with D4.232.	H13.000
B2.300 Technical Staff	Staff must possess the educational background, experience, and training sufficient to assure assigned tasks will be performed in accordance with the tissue bank's established procedures.	C1.110
B2.310 Qualifications	Staff training shall be documented in individual employee training files.	~~B2.000~~B11.100
B2.320 Responsibilities	Staff shall be responsible for implementation of policies and procedures as established by the tissue bank. Duties of each staff member shall be described in written job descriptions.	Preempted
B2.320 Responsibilities	Staff must demonstrate competency in the operations to which they are assigned.	C1.2000

Standards # (14th edition)	Standard - Fragment	15th Location
B2.400 Quality Assurance Program B2.410 Staff Qualifications	A designated individual, generally familiar with, but not having performed, the specific work being reviewed, shall be responsible for each quality review.	B3.100
B2.420 Staff Responsibilities	Quality assurance program personnel shall have responsibility for assuring compliance with the SOPM regulatory requirements. The individual responsible for the quality review shall have the responsibility and authority to approve or reject tissue, as well as discontinue processing and/or release of tissue when deviations from SOPM warrants. Quality assurance personnel shall be responsible for managing audits.	B3.100
C1.100 – General	Each tissue bank shall develop a donor record management system that will allow the detailed documentation of the tissue banking process(es) for which it is responsible.	B6.000
C1.100 – General	Documentation must be made concurrent with each significant step and must include, but not be limited to: 1) information from the donor referral source; 2) donor eligibility assessment information; 3) record of informed consent, or document of gift/authorization; 4) donor physical assessment or physical examination, and donor identification; 5) tissue recovery or collection, transport, and processing; 6) quarantine and infectious disease testing; 7) in-process testing; 8) record review; 9) tissue labeling, storage, release, and distribution; 10) quality control; and 11) services to donor families.	B6.100
C1.100 – General	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.	B6.000
C1.100 – General	(A) Records shall include, at a minimum, donor identification, and the date and time of recovery.	B6.310
C1.100 – General	(R) Names of donors shall be encoded; only designated personnel shall have the authority to link the donor's name to the identification code. No records shall exist which link the anonymous donor by name to the recipient.	B6.310
C1.110 Required Processing Documentation	Results of laboratory tests used to determine final release of tissue for transplantation (e.g., sterility testing and testing for residual water, ethylene oxide, residual calcium) shall be maintained by the tissue bank that determines the suitability of the allograft for distribution (''distributor''). All other processing records shall be available to the tissue bank within a reasonable amount of time.	B6.600

Standards # (14th edition)	Standard - Fragment	15th Location
C1.120 Electronic Records	If records are maintained electronically, there shall be an electronic system in place to ensure that data integrity of the electronic records is maintained, and that information is retrievable, and able to be printed as a hard copy. Compliance with K7.000 is expected.	G6.000
C1.200 Availability for Inspection	Tissue banking records shall be readily accessible for inspection by authorized personnel from accreditation programs and regulatory agencies. Access to donor identity and medical, social, travel, and sexual behavior histories shall be restricted to tissue bank staff with a need for access and to inspectors from accreditation programs and regulatory agencies. Should records be maintained electronically, there must be a system in place to retrieve information and print a hard copy for review during inspection or for a period as required by applicable laws and regulations.	D2.000
C1.300 Retention	Records of the informed consent, documents of gift/authorization, and records pertaining to donor eligibility, recovery, collection, acquisition, processing, storage, date of distribution, QA, and identity of person/entity to whom distributed, shall be retained at least 10 years beyond the date of distribution, date of transplantation (if known), date of disposition, or date of expiration of the tissue (whichever is latest) or longer if required by applicable laws and regulations.	B12.100
C1.300 Retention	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 ensure that processing and QC records are retained for at least ten years.	B12.300
C1.300 Retention	(R) The reproductive tissue bank should maintain current donor and client depositor addresses until tissues are used or destroyed.	B12.310
C1.400 Traceability	A tissue bank's records management system shall identify tissue by use of a unique identifier.	G2.000
C1.400 Traceability	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.	G2.100
C1.400 Traceability	Records shall also indicate the dates and the identities of the staff involved in each significant step of the operation from the time of recovery, collection, or acquisition through final disposition of the tissue.	G1.200
C1.400 Traceability	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.	G2.110
C1.400 Traceability	Whenever an accredited tissue bank consigns tissue to a non-accredited entity, the accredited tissue bank shall: 1) require the non-accredited entity to comply with the requirements of this section; and 2) impose the requirements of this section on all subsequent consignees, up to and including the tissue dispensing service.	G4.000

Standards # (14th edition)	Standard - Fragment	15th Location
C1.500 Revisions	Revisions to paper records shall be made with a single line drawn through the altered text. The revision shall be initialed and dated by the individual making the revision. Additions to a completed record shall be initialed and dated by the individual making the additions.	G3.000
C1.500 Revisions	Records revised electronically must have an audit trail that includes the altered information, date of the revision, and the individual that made the revision. See K7.000.	G3.100
C2.000 Construction of Records	Relevant medical records must be reviewed by the responsible person(s) at each tissue bank involved with recovery, collection or acquisition, or the determination of donor eligibility. The content of records that originate or are sourced from outside of a tissue bank (i.e., third party records) is not under control of the tissue bank. The information in these records is considered the best available information.	H19.500
C2.000 Construction of Records	Records that are produced by tissue bank staff must be complete, indelible, legible, and accurate.	G1.300
C2.000 Construction of Records	Records must be in English or, if in another language, must be retained and translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document.	Preempted (to be captured in accreditation program policy)
C2.000 Construction of Records	Tissue banks shall not utilize documentation related to informed consent/authorization or donor risk assessment interviews that are obtained by unauthorized parties. Authorized parties must be identified in agreements and personnel performing these functions shall be qualified, trained, and competent.	F3.000
C2.000 Construction of Records	(A) Autologous tissue records shall be maintained either in a separate log, or, if incorporated into general records, in such a manner that the autologous tissue may not be released for non-autologous use.	G5.000
C2.000 Construction of Records	(C) Records additionally shall include the following information: 1) ABO/Rh, if available; 2) date/time of asystole; 3) date/time of recovery of the heart (time when subjected to cold rinse solution); 4) date/time of subjection of cardiac tissue to disinfection solution; 5) start and stop times when tissue was subjected to disinfection solution; and 6) date/time: a) when preservation began; and b) when placed in final container.	~~B9.320~~ B6.320
C2.000 Construction of Records	(V) Records additionally shall include the following information: 1) ABO/Rh, if available; 2) date/time of asystole;	~~B9.320~~ B6.320

Standards # (14th edition)	Standard - Fragment	15th Location
	3) date/time vascular tissues subjected to perfusion solution; 4) date/time vascular tissues placed in transport solution and subjected to wet ice temperatures; 5) date/time of subjection of vascular tissue to disinfection solution; 6) start and stop times when tissue was subjected to disinfection solution; and 7) date/time (a) when preservation began and (b) when placed in final container.	
C3.000 Donor Records to be Maintained	Tissue Banks shall maintain records of their activities in accordance with these Standards.	Preempted (see G1.200)
C3.000 Donor Records to be Maintained	(R) Donor records shall include documentation of informed consent, relevant medical records, results of all laboratory screening tests, and outcome of prior assisted reproductive technology procedures (if known) including number of successful pregnancies and any reports that would affect the donor's eligibility. Records shall also include personal attributes of the donor such as: height, weight, eye color, hair color, complexion, racial group, and/or body type.	~~B9.320~~ B6.320
D1.000 General Policies	In addition to the requirements at the series of standards at B1.500, all referral arrangements with organ procurement organizations, donor referral sources and other tissue banks shall be documented.	F2.400
D1.000 General Policies	(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.	H6.200
D1.100 Monetary Compensation or Other Valuable Consideration	Monetary compensation or other valuable consideration, including goods or services, shall not be offered to a donor, authorizing person, the donor's estate, or any other third party acting on behalf of the donor, except in the following instances: 1) the tissue bank may reimburse responsible third parties for costs directly associated with a donation; or 2) the tissue bank may reimburse living donors for costs associated with an acceptable donation, including compensation for restoration of lost earnings when directly attributable to donation, if and as authorized by law.	H6.300
D1.100 Monetary Compensation or Other Valuable Consideration	(R) The reproductive tissue bank may provide monetary compensation to donors of reproductive tissue if the compensation is compliant with professional standards of practice.	H6.300
D1.100 Monetary Compensation or Other Valuable Consideration	Donors or their families should not be responsible for any expenses related to the recovery of allogeneic tissue.	H6.300
D1.200 Tissue for Research	Facilities providing tissue for research and other non-transplantation purposes shall develop detailed relevant specific policies and procedures. Informed consent or authorization for research and/or education shall be obtained. See the series of standards at D2.000 and D3.000.	B5.100
D1.210 Written Requests	All requests for human tissue intended for research use shall be submitted in writing. The request shall indicate the type of tissue requested and how it will be used as well as the name,	B5.110

Standards # (14th edition)	Standard - Fragment	15th Location
	address and affiliation of the principal investigator accepting responsibility for receipt of the tissue.	
D1.220 Review and Approval	Tissue requests for research purposes shall be reviewed and approved based on legal, ethical, and technical considerations defined in the SOPM.	B5.120
D1.300 Consideration for the Donor	A policy shall be established requiring the donor always be treated with dignity and respect.	~~B1.300~~ B4.300
D2.000 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.	H7.000
D2.100 Requirements	This authorization shall be expressed in a document of gift/authorization, the original or a copy of which shall be maintained in the donor's record at the tissue bank responsible for recovery, as well as in the donor's record at the tissue bank whose Medical Director is responsible for the donor eligibility determination. In the case of an electronic or voice recorded document of gift/authorization, the original recording should be maintained in reproducible form.	B6.210
D2.100 Requirements	NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful authorization for donation of tissues for transplantation, therapy, research, or education.	H8.000
D2.200 Conditions	Adequate information concerning the donation and recovery of tissue shall be presented in a language in which the authorizing person is conversant and in terms that are easily understandable by the authorizing person. The donation coordinator should be trained to appropriately answer the questions the authorizing person may have. Neither coercion nor inaccurate information shall be used in any manner to obtain authorization.	H7.100
D2.310 Document of Gift	In cases where a donor has executed a document of gift it may be acted upon (permits recovery) provided it meets applicable laws and regulations.	H7.200
D2.310 Document of Gift	Acceptable documentation may include a state driver's license, living will, advanced directive, state ID card, donor card, or photocopy thereof, and documentation that the donor registered in a donor registry.	H7.300
D2.320 Document of Authorization	When a document of authorization is used it must contain the following signatures and related information: 1) the authorizing person's signature and: a) name; b) mailing address (NOTE: If requested by the authorizing person, only an email address may be documented as the address but, in such cases, the authorizing person should permit its use and should be informed that if the email address changes or if email communication is blocked, there may be no effective forwarding or receipt of information.); c) phone number; and d) relationship to the donor;	H7.400

Standards # (14th edition)	Standard - Fragment	15th Location
	2) the donation coordinator's signature and: a) the date; and b) identity of their organization; 3) the signature of each witness if witnessing is required by law or regulation; 4) documentation that the Core Elements were used; and 5) a statement granting authorization for tissue recovery.	
D2.330 Methods of Obtaining Authorization	Legal authorization can be obtained using different methods. When authorization is obtained: 1) in person, the authorizing person must read and sign the document of authorization. 2) by telephone, the person obtaining the authorization shall read to the authorizing person the document of authorization or, alternatively, shall present each of the Core Elements described in D2.400.	H7.500
D2.330 Methods of Obtaining Authorization	This telephone conversation shall be recorded. There shall be documentation that the authorization was obtained by telephone.	H7.510
D2.330 Methods of Obtaining Authorization	A sampling plan must be adopted that verifies that recordings match the content in the written document of authorization. This verification must be performed by someone other than the donation coordinator or witness. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means is feasible for documenting authorization, the conversation should be witnessed by a third person. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).	H7.520
D2.330 Methods of Obtaining Authorization	3) using a facsimile transmission, a copy of the document of authorization is provided to the authorizing person. The authorizing person shall return the signed document of authorization by facsimile transmission. A donation coordinator shall be available to respond to questions posed by the authorizing person.	H7.500
D2.330 Methods of Obtaining Authorization	A sampling plan must be adopted that verifies signatures received by facsimile. This verification must be performed by someone other than the donation coordinator or witness. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).	H7.520
D2.330 Methods of Obtaining Authorization	4) using an electronic transmission, a copy of the document of authorization is provided to the authorizing person. The authorizing person shall electronically respond (e.g., by e-mail) that he/she has read the document of authorization, is authorized to grant authorization, and is granting such authorization. A donation coordinator shall be available to respond to questions posed by the authorizing person.	H7.500
D2.330 Methods of Obtaining Authorization	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	H7.540

Standards # (14th edition)	Standard - Fragment	15th Location
	of the relevant state. An electronically transmitted, read-only, or otherwise protected document of authorization may be used.	
D2.400 Core Elements for Authorization	The document of authorization shall contain adequate information. No document of authorization from an authorizing person shall be acted upon if it does not contain the following Core Elements. These Core Elements also apply to D2.500.	H7.700
D2.400 Core Elements for Authorization	Core Elements: 1) the name of the Donor; 2) the name, mailing address, and telephone number of the authorizing person, and his/her relationship to the donor (NOTE: If requested by the authorizing person, only an email address may be documented as the address but, in such cases, the authorizing person should permit its use and should be informed that if the email address changes or if email communication is blocked, there may be no effective forwarding or receipt of information.); 3) an explanation that the tissue is a gift, and that neither the donor's estate nor the authorizing person will receive monetary compensation or valuable consideration for it; 4) a description of the general types of tissue to be recovered; 5) a description of the permitted use(s) of the recovered tissues (i.e., transplant, therapy, research, or education); 6) an explanation that recovery of tissue requires the following actions, and the document of gift/authorization thus specifically authorizes: a) access to, and required disclosure of, the Donor's medical and other relevant records; b) testing and reporting for transmissible diseases; c) the removal of specimens which may include, but are not limited to blood or tissue samples for the purposes of biopsy or other testing necessary for determination of donor eligibility; d) the release to the tissue bank of any and all records and reports of a Medical Examiner, Coroner or Pathologist (e.g., autopsy report); and e) such other requirements as may be applicable for the specific donation or tissue bank, such as transport of the donor's body, archiving of samples, photographic or other imaging, etc. 7) contact information for the organization represented by the donation coordinator; and 8) any additional information required by laws or regulations.	H7.710
D2.400 Core Elements for Authorization	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's body; and 4) an explanation that the document of authorization is available.	H7.600

Standards # (14th edition)	Standard - Fragment	15th Location
D2.400 Core Elements for Authorization	Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that tissue may be distributed internationally, must be included.	H7.600
D2.400 Core Elements for Authorization	When an Organ Procurement Organization (OPO), or other entity (e.g., hospital), has initiated the process of obtaining authorization for a potential organ and tissue donation, the tissue bank for which the authorization is being obtained shall request that the OPO or other entity follow the procedure and utilize a document of authorization that satisfies the requirements of D2.000.	H7.610
D2.400 Core Elements for Authorization	For a donor one month (28 days) of age or less, adequate consent pursuant to law shall be obtained for collection of blood from the birth mother that will be used for testing.	H7.620
D2.500 Notification of Gift	In cases where the gift is authorized by a donor's own document of gift (i.e., first person consent), including a document of gift recorded in a donor registry (i.e., donor designation), and where law mandates notification, such notification shall be made pursuant to law.	H7.630
D2.500 Notification of Gift	In all other cases, prior to transport of the donor's body or recovery, the donation coordinator should attempt to notify the person who would have been an authorizing person had no gift been made during the life of the donor or the person who is authorized to make arrangements for final disposition.	H7.640
D2.500 Notification of Gift	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.	H7.650
D2.500 Notification of Gift	The donation coordinator should inquire during the notification whether the notified person is aware of any revocation or refusal made by the donor.	H7.660
D2.500 Notification of Gift	Notification, if made, shall be documented.	H7.670
D2.500 Notification of Gift	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.	H7.680
D2.600 Services to Donor Families	Services to donor families or referral to a support system must be offered to the authorizing person. Subsequent communications and periodic evaluation of services shall be documented, maintained, and readily available. See AATB Guidance Document No. 4.	H7.690
D3.000 Informed Consent D3.100 Requirements	Except for autologous tissue, informed consent to acquire tissues and make them available for transplantation, therapy, research, or education shall be obtained from a living donor or their legal representative, or from a client depositor in accordance with applicable laws or regulations. This informed consent shall be documented in a record of informed consent, the original or a copy of which shall be maintained in the donor's or client depositor's record at the tissue bank responsible for recovery, collection, or acquisition, as well as in the donor's record at the tissue bank whose Medical Director is responsible for the donor eligibility	H8.000

Standards # (14th edition)	Standard - Fragment	15th Location
	determination. In the case of an electronic or voice recorded record of informed consent, the original recording should be maintained in reproducible form.	
D3.100 Requirements	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.	H8.000
D3.200 Conditions	Adequate information concerning the recovery, collection, or acquisition of tissue shall be presented in a language in which the living donor or their legal representative, or the client depositor is conversant, and in terms that are easily understandable by them. The donation coordinator should be trained to appropriately answer the questions the living donor, their legal representative, or the client depositor may have. Neither coercion nor inaccurate information shall be used in any manner to obtain informed consent.	H7.100
D3.200 Conditions	The potential donor or their legal representative shall not be under the influence of anesthesia or any drug that could influence his/her ability to give informed consent.	H8.100
D3.200 Conditions	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.	H8.100
D3.300 Signatures and Documentation	The record of informed consent must comply with applicable laws and regulations. It must contain, at a minimum, 1) the living donor's signature or their legal representative's signature, or the client depositor's signature and: a) name; b) mailing address (NOTE: If requested by the living donor, their legal representative, or the client depositor, only an email address may be documented as the address but, in such cases, the living donor, their legal representative, or the client depositor should permit its use and should be informed that if the email address changes or if email communication is blocked, there may be no effective forwarding or receipt of information.); c) phone number; 2) the donation coordinator's signature and: a) the date; and b) identity of their organization; 3) the signature of each witness if witnessing is required by law or regulation; 4) documentation that the Core Elements for informed consent (see D3.400) were used; 5) a statement that the living donor or their legal representative, or the client depositor understands what has been read or explained and is granting informed consent for tissue recovery, collection, or acquisition; and 6) a statement that the living donor or their legal representative, or the client depositor has been informed that his/her name and address, as well as required records, shall be kept on file by the tissue bank or reproductive tissue bank.	B6.900

Standards # (14th edition)	Standard - Fragment	15th Location
D3.310 Methods of Obtaining Informed Consent	Informed consent can be obtained using different methods, if and as authorized by law or regulation. The methods below appear in preferential order. When informed consent is obtained: 1) in person, the living donor, their legal representative, or the client depositor must read and sign the record of informed consent. 2) by telephone, the person obtaining the informed consent shall read to the living donor, their legal representative, or the client depositor the record of informed consent or, alternatively, shall present each of the Core Elements described at D3.400.	H8.200
D3.310 Methods of Obtaining Informed Consent	This telephone conversation shall be recorded, and it shall be documented that the informed consent was obtained by telephone.	H7.510
D3.310 Methods of Obtaining Informed Consent	A sampling plan must be adopted that verifies that recordings match the content in the written record of informed consent. This verification must be performed by someone other than the donation coordinator or witness. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means are feasible for documenting informed consent, the informed consent may be made telephonically and should be witnessed by a third person. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).	H8.200
D3.310 Methods of Obtaining Informed Consent	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.	H7.500
D3.310 Methods of Obtaining Informed Consent	A sampling plan must be adopted that verifies signatures received by facsimile. This verification must be performed by someone other than the donation coordinator or witness. Sampling plans and methods must be established, must be adequate for their intended use, and must be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).	H7.530
D3.310 Methods of Obtaining Informed Consent	4) using an electronic transmission, a copy of the record of informed consent is provided to the living donor, their legal representative, or the client depositor. The living donor, their legal representative, or the client depositor shall electronically respond (e.g., by e-mail) that he/she has read the record of informed consent and is granting such informed consent. A donation coordinator shall be available to respond to questions posed.	H8.200
D3.310 Methods of Obtaining Informed Consent	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.	H8.300

Standards # (14th edition)	Standard - Fragment	15th Location
D3.400 Core Elements for Informed Consent	No informed consent from a living donor, their legal representative, or a client depositor shall be acted upon if it does not contain the following Core Elements.	H8.400
D3.400 Core Elements for Informed Consent	Core Elements: 1) the name of the living donor or client depositor; or 2) the identity of the person authorized by law to consent on behalf of the living donor or client depositor and his/her relationship to the subject including name, address, and telephone number; 3) if applicable, an explanation that the tissue is a gift, and that the living donor or their legal representative will not receive monetary compensation or valuable consideration for it; 4) a description of the general types of tissue to be recovered, collected, or acquired and any information pertinent to the specific recovery, collection, or acquisition contemplated; 5) a description of the permitted use(s) of the tissues (i.e., transplant, therapy, research, or education); 6) a description of the general purposes for which the tissue may be used; 7) a legally adequate release of the relevant medical records of the living donor, their legal representative (when applicable), or of the client; 8) permission to test for disease, if applicable; 9) a statement that confirmed positive test results will be reported or disclosed if required by law or regulation (e.g., to the living donor, their legal representative, or the client depositor, to the attending physician, to appropriate health officials); 10) contact information for the organization represented by the donation coordinator; 11) information concerning possible risks and benefits to the living donor, their legal representative, or the client depositor, if applicable; and 12) any additional information required by laws or regulations.	H8.400
D3.400 Core Elements for Informed Consent	Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that tissue may be distributed internationally, must be included.	H8.400
D3.400 Core Elements for Informed Consent	(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.	H8.400
D3.400 Core Elements for Informed Consent	In the case of an anonymous donor, the record of informed consent shall also include details about monetary compensation. See D1.100.	H8.400
D3.500 Services Involving Living Donors	(BT) Services shall be developed that provide answers to questions posed by the birth mother after delivery.	H8.500
D4.000 Donor Screening and Testing D4.100 Donor Screening	Donor eligibility criteria shall be established by the Medical Director and shall not conflict with these Standards. Each donor shall be evaluated according to established criteria.	H6.000
D4.100 Donor Screening	(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	H9.100

Standards # (14th edition)	Standard - Fragment	15th Location
	interview, or medical history and medical record review for autologous tissue in the tissue bank records.	
D4.100 Donor Screening	(BT) Except for autologous donations, the health status of the infant(s) shall be assessed in regard to information that could affect the quality or safety of the tissue for transplantation. Protocols shall be established for reviewing information at the time of the infant's delivery. Policies and procedures should be developed to handle information regarding the health status of the infant reported voluntarily after delivery. Written procedures must describe how information is evaluated.	H9.200
D4.100 Donor Screening	(C) Heart donors shall also be evaluated for the risk of Chagas' disease.	H9.300
D4.100 Donor Screening	(LD) Criteria for accepting living donors shall be established by the Medical Director or licensed physician designee.	H9.400
D4.100 Donor Screening	(R) Criteria for accepting client depositors and potential reproductive tissue donors shall be established by the Medical Director or licensed physician designee.	H9.500
D4.100 Donor Screening	(S) Potential donors shall be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and skin condition.	H11.210
D4.110 Age Criteria	The Medical Director and/or tissue bank Medical Advisory Committee shall determine donor age criteria.	H9.600
D4.110 Age Criteria	(A) There are no age limits for autologous tissue donation.	H9.710
D4.110 Age Criteria	(BT) There is no age limit for the birth mother, however, policies and procedures shall be written regarding gestational age limits.	H9.720
D4.110 Age Criteria	(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.	H9.730
D4.120 Physical Assessment	Prior to the recovery of tissue from a deceased donor, a physical assessment shall be performed by a responsible person. This shall be a recent ante-mortem or postmortem physical assessment to identify evidence of: high risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, signs of trauma or infection to the body where recovery of tissue is planned.	H11.000
D4.120 Physical Assessment	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]);	H11.100

Standards # (14th edition)	Standard - Fragment	15th Location
	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).	
D4.120 Physical Assessment	The form and instructions in Appendix III must be used to document the tissue donor physical assessment.	H11.200
D4.120 Physical Assessment	(S) The physical assessment shall include documentation of findings and conditions that may affect the quality or quantity of skin recovered.	H11.220
D4.130 Physical Examination	(LD) Except for autologous and embryo donations, prior to the donation of tissue from a potential living donor, a physical examination shall be performed by the Medical Director or licensed physician designee, or by a physician involved with the individual's medical care, or designee as permitted by law. If an examination of a living donor was performed for other reasons, review of the findings of such an examination shall be performed and documented in the donor's record, as well as all other examination findings. After a donor risk assessment interview is completed, if any history is suspect, a directed physical examination shall be performed. The directed examination shall include any of the above applicable items (see D4.120) that would assist with information to determine whether there is evidence of high-risk behavior.	H11.300
D4.130 Physical Examination	(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.	H11.310

Standards # (14th edition)	Standard - Fragment	15th Location
D4.130 Physical Examination	(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.	H11.320
D4.130 Physical Examination	Semen donors shall not exhibit an infectious skin disease that creates a risk of contamination of the semen.	H11.320
D4.140 Donor Risk Assessment Interview (DRAI)	A documented dialogue shall be conducted with the donor (if living) or the deceased donor's next of kin, the nearest available relative, a member of the donor's household, other individual with an affinity relationship (caretaker, friend, significant life partner) and/or the primary treating physician, using a standardized questionnaire. Questions shall be formulated using these Standards, current federal regulations, and guidance.	H10.000
D4.140 Donor Risk Assessment Interview (DRAI)	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).	H10.100
D4.140 Donor Risk Assessment Interview (DRAI)	For all donors one month (28 days) of age or less, the infant and the birth mother shall be screened for risk of relevant communicable disease agents and diseases (RCDADs) and the birth mother's blood must be tested. Refer to D4.100 (BT) for expectations to obtain the health status of the infant donor of birth tissue.	H19.120
D4.140 Donor Risk Assessment Interview (DRAI)	The donor risk assessment interview shall document the donor's name, and the relationship between the donor and the interviewee(s) and shall indicate the name(s) of the interviewer(s) and interviewee(s). The questionnaire shall be maintained as part of the donor's record.	H10.200
D4.140 Donor Risk Assessment Interview (DRAI)	(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.	H10.310
D4.140 Donor Risk Assessment Interview (DRAI)	(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.	H10.320
D4.140 Donor Risk Assessment Interview (DRAI)	(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.	H10.330
D4.140 Donor Risk Assessment Interview (DRAI)	(R) The donor's risk assessment shall include a review of personal alcohol and drug use and sexually transmissible diseases in the donor and partner(s). The screening process also shall include any history of chemical and/or radiation exposure as well as family medical history and genetic background. An abbreviated donor screening must be obtained at each repeat donation and reviewed by a responsible person. The abbreviated screening must determine and document any changes in the donor's medical, social, travel, and sexual behavior history (including risk factors) since the previous donation that would make the donor ineligible.	H10.340

Standards # (14th edition)	Standard - Fragment	15th Location
D4.141 Family History and Genetic Background	(BT) If genetic testing has been performed or a genetic history has been obtained and the information is available, it should be considered for the determination of donor eligibility.	H12.000
D4.141 Family History and Genetic Background	(R) A minimum of a three-generation family history shall be elicited from each prospective donor. If a biological family member in the prospective donor's family is adopted, Medical Director discretion must be made to determine if sufficient family history is provided to determine donor eligibility. The genetic history should be evaluated by an individual with appropriate clinical genetics education and/or training.	H10.350
D4.141 Family History and Genetic Background	Any significant condition in a prospective donor or donor's family history that would pose a risk of producing an offspring with a serious genetic disease or defect greater than the risk in the general population shall disqualify him/her as a donor, with the following exceptions: 1) Anonymous donors whose family history indicates that he/she is at risk for carrying a genetic defect may be accepted only if a test to detect carrier status is performed and is negative for the mutation that is known to occur in the family; or 2) Directed gamete donors and anonymous or directed embryo donors with any family history indicating he/she is at risk for carrying a genetic defect/condition may be accepted, provided the genetic risk to offspring is evaluated in writing and the recipient(s) (R) has reviewed the evaluation, been offered additional genetic testing, and completed an informed consent.	H10.350
D4.141 Family History and Genetic Background	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.	H10.350
D4.150 Relevant Medical Records Review	Prior to tissue donation, a preliminary review of readily available relevant medical records shall be conducted by a trained individual.	H10.500
D4.150 Relevant Medical Records Review	This review shall include but may not be limited to: 1) evidence of significant active infection at the time of donation for relevant communicable disease agents or diseases (RCDADs) including signs and/or symptoms of viral and fungal infection, bacteremia, or sepsis; 2) risk factors for relevant communicable disease agents or diseases (RCDADs) as specified in Appendix II; and 3) additional tissue donor specific criteria as documented in the SOPM and compliant with written agreements/contracts.	H10.500
D4.150 Relevant Medical Records Review	(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.	H10.500
D4.200 Donor Testing D4.210 Blood Specimens	Except as otherwise specified for certain reproductive tissue donors, infectious disease testing of donor blood specimens shall be performed for each tissue donor on a specimen collected at the time of donation or within 7 days prior to or after donation. If the donor is one month (28	H12.000

Standards # (14th edition)	Standard - Fragment	15th Location
	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.	
D4.210 Blood Specimens	(R) For anonymous and directed oocyte donors, the blood specimen must be collected within 30 days prior to oocyte collection, or within 7 days post donation. Samples for infectious disease testing of anonymous and directed semen donors must be obtained within 7 days of initial semen collection. See D4.231 for testing requirements for embryo donors.	H12.000
D4.211 Plasma Dilution	Tissue from a donor who is older than 12 years of age shall be determined to be not suitable for transplantation if blood loss is known or suspected to have occurred and there has been transfusion/infusion of more than 2,000 milliliters (mL) of blood (e.g., whole blood, or red blood cells) or colloids within 48 hours; or more than 2,000 mL of crystalloids within one hour; or any combination thereof, prior to asystole or the collection of a blood specimen, whichever occurred earlier, unless: 1) a pre-transfusion or pre-infusion blood specimen from the tissue donor is available for infectious disease testing; or 2) an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to ensure that there has not been plasma dilution sufficient to affect test results.	H12.100
D4.211 Plasma Dilution	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.	H12.110
D4.211 Plasma Dilution	When the fluids transfused are in the ''blood'' category (alone, or in combination with colloids and/or crystalloids), a comparison of the total volume of these fluids with the donor's estimated blood volume shall be performed, in addition to a comparison of the total volume of colloids and/or crystalloids with the donor's estimated plasma volume. Since every possible clinical situation cannot be described where plasma dilution may affect test results, the SOPM should describe how to address additional circumstances when plasma dilution may have occurred (e.g., large volumes of transfusions/ infusions administered in the absence of blood	H12.120

Standards # (14th edition)	Standard - Fragment	15th Location
	loss). It may be necessary to use a pre-transfusion/infusion blood specimen or apply an algorithm in those instances.	
D4.211 Plasma Dilution	Alternative algorithms to evaluate plasma dilution can be used if justified.	H12.130
D4.220 Infectious Disease Testing	Results of initial infectious disease and/or confirmatory testing shall be used as one component of determining donor eligibility. Testing used for donor eligibility shall be performed by laboratories that are registered with FDA as a tissue establishment for testing and are either certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.	H12.200
D4.220 Infectious Disease Testing	NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding establishment registration, laboratory certification, and test kit licensing/approval.	H12.200
D4.220 Infectious Disease Testing	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.	H12.210
D4.220 Infectious Disease Testing	A new test shall be implemented when AATB and/or FDA issues notification to that effect. Prior to that time, use of the new test, even if FDA-licensed, approved, or cleared for donor screening, is voluntary. Tests specifically labeled for use with specimens collected after the donor's heart has stopped beating instead of a more generally labeled test shall be used when applicable and when available.	H12.300
D4.220 Infectious Disease Testing	A list of donor screening tests that have been licensed for use with specimens collected after the donor's heart has stopped beating can be accessed at the FDA/CBER website.	H12.310
D4.220 Infectious Disease Testing	*See AATB Bulletin No. 06-45 ''Intent of Update to Standard D4.353.'' (Note: this standard is currently D4.220)	H12.310
D4.220 Infectious Disease Testing	Rapid antigen and/or antibody testing for infectious disease may be performed in addition to the required tests. Results of these tests must be evaluated (see F1.140) and shared (see D4.300) in accordance with policies and procedures.	Preempted (see H12.000)
D4.220 Infectious Disease 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 B1.510, D4.300, and K1.100.	H12.400
D4.220 Infectious Disease Testing	All tissue from donors who test repeatedly reactive on a required screening test shall be quarantined and shall not be used for transplantation.	12.600
D4.220 Infectious Disease Testing	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	H12.500

Standards # (14th edition)	Standard - Fragment	15th Location
	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.	
D4.220 Infectious Disease Testing	Additional testing to confirm or supplement infectious disease test results may be performed at the discretion of the Medical Director using FDA-licensed, confirmatory test kits when commercially available. Results of infectious disease testing shall be evaluated prior to disclosure of availability of positive test results (see D4.232).	H12.000
D4.230 Required Infectious Disease Tests	Excluding autologous, embryo donor, and client depositor tissue, all human tissue intended for transplantation shall be from donors who are tested and found to be negative for: 1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2); 2) nucleic acid test (NAT) for HIV-1; 3) hepatitis B surface antigen (HBsAg); 4) nucleic acid test (NAT) for the hepatitis B virus (HBV); 5) total antibodies to hepatitis B core antigen (anti-HBc—total, meaning IgG and IgM); 6) antibodies to the hepatitis C virus (anti-HCV); 7) nucleic acid test (NAT) for HCV; and 8) syphilis (a non-treponemal or treponemal-specific assay may be performed).	H12.600
D4.230 Required Infectious Disease Tests	Donors of viable leukocyte-rich tissue (e.g., semen, certain (CT)) shall also be tested and found to be negative for antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II). Note: HTLV testing of donors of other tissue types may be required by law and/or regulation, including, where applicable, foreign laws and/or regulations.	H12.700
D4.230 Required Infectious Disease Tests	All test results shall be documented in the donor's record.	H12.000
D4.230 Required Infectious Disease Tests	(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.	H12.710
D4.230 Required Infectious Disease Tests	All anonymous and directed semen donors shall also be tested for total antibody to cytomegalovirus (anti-CMV—total, meaning IgG and IgM).	H12.720
D4.230 Required Infectious Disease Tests	Required tests for anonymous and directed embryo donors are listed in D4.231.	H12.730
D4.230 Required Infectious Disease Tests	Client depositors who deposit semen, testicular fluid or tissues, oocytes or ovarian tissue, or embryos, shall be tested prior to use for:	H12.740

Standards # (14th edition)	Standard - Fragment	15th Location
	1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2); 2) hepatitis B surface antigen (HBsAg); and 3) antibodies to hepatitis C virus (anti-HCV).	
D4.231 Repeat Testing of Living Donors	(R) All donated semen from anonymous donors shall be frozen and quarantined for at least 6 months. After such time and prior to release of semen, the donor shall be retested for anti-HIV-1, HIV-1 NAT, anti-HIV-2, HBsAg, anti-HBc, HBV NAT, anti-HCV, HCV NAT, anti-HTLV-I, anti-HTLV-II, syphilis, and for anti-CMV. Anonymous donor semen shall not be made available for use unless results of all tests, excluding CMV and syphilis, are negative or nonreactive. Results of all testing performed must be interpreted as in F1.140. All tests for infectious diseases shall be repeated at least every 6 months while the semen donor remains an active participant in the donor program and after any lapse exceeding 6 months.	H12.750
D4.231 Repeat Testing of Living Donors	Oocyte donor tissue is not subject to quarantine and the donor is not subject to repeat testing.	H12.760
D4.231 Repeat Testing of Living Donors	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.	H12.770
D4.231 Repeat Testing of Living Donors	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.	H12.780
D4.231 Repeat Testing of Living Donors	For directed or anonymous donation of embryos created using both an anonymous or directed egg and sperm donor, a donor summary of records must be obtained for both donors.	H12.790
D4.231 Repeat Testing of Living Donors	“Appropriate measures” means using available resources to accomplish the testing. If the client depositor cannot be tested due to death or inability to locate the person, directed or anonymous donation of the embryos can still be completed.	Definitions of Terms
D4.232 Disclosure and Availability of Positive Infectious Disease Test Results	The donor, if living, shall be provided test results as required by applicable law or regulation. For deceased donors, the authorizing person should be contacted regarding the availability of infectious disease test results that may be of medical significance as determined by the	H13.100

Standards # (14th edition)	Standard - Fragment	15th Location
	Medical Director or licensed physician designee. Contact should include the means by which available test results should be requested. If a document of gift was used (i.e., there is no authorizing person), contact regarding the availability of infectious disease test results should be made to the person who would have been the authorizing person had no gift been made during the life of the donor, or to the person authorized to make arrangements for final disposition of the body. These records should be provided upon written request as permitted by law or regulation. Positive test results shall be reported to state and/or local health department(s) as required by law or regulation.	
D4.232 Disclosure and Availability of Positive Infectious Disease Test Results	Contact regarding availability and/or disclosure of test results shall be documented.	H13.200
D4.240 Archived 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, blood borne pathogen exposure, etc.).	H14.000
D4.240 Archived Samples	(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.	H14.100
D4.240 Archived Samples	(R) Archived serum or plasma from reproductive donors whose tissue has been stored but subsequently destroyed and never distributed does not require retention.	H14.200
D4.250 Semen Analysis	(R) Semen Donors: Prior to enrollment of a donor in the sperm donor program, his semen shall be tested for sperm quality and found acceptable for such parameters as sperm motility, concentration, and post-thaw motility. Donors shall be excluded unless the specimen meets criteria set by the Medical Director and, when appropriate, the Medical Advisory Committee. Criteria for directed donors may differ from those for anonymous donors. Sperm quality tests shall be repeated at a frequency determined by the tissue bank.	H12.800
D4.250 Semen Analysis	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.	H12.810
D4.300 Information Sharing	The tissue bank that recovers tissues must have a procedure(s) for receiving, investigating, evaluating, and documenting donor information as well as how they will share records with all	B8.000

Standards # (14th edition)	Standard - Fragment	15th Location
	establishments who are known to have also recovered tissues, or to have received recovered tissues, from the same donor: 1) record sharing should occur as new information is received, and this must be documented and included in the records; 2) relevant records that could affect eligibility determinations must be sent without delay to tissue banks that will determine donor eligibility of recovered tissues and/or the donor; 3) the tissue bank that recovers tissue must share tissue recovery culture (pre-sterilization/ pre-disinfection culture) information with all tissue banks to which tissue from shared donors was sent. If defined in a written agreement, an eye bank can choose not to receive pre-sterilization/pre-disinfection culture results; and 4) if any tissue bank determines a donor to be ineligible, this determination must be communicated in writing to the tissue bank that recovered tissues, and the tissue bank that recovered tissues must share this information with all establishments that are known to have recovered tissues, or to have received recovered tissues, from the same donor.	
D4.300 Information Sharing	Written procedures must describe how this information is received, evaluated, and disseminated in a timely fashion.	B8.000
D4.300 Information Sharing	Any tissue testing performed after it has been disinfected or subjected to processing (e.g., in-process testing, post-processing microbiological testing, final cultures) is not considered relevant donor records for the tissue bank that recovered tissues and, if such results are reported, would not be expected to be shared with tissue banks who received recovered tissues from a shared donor.	B8.100
D5.000 Recovery, Collection, and Acquisition	Policies and procedures shall be established for the recovery, collection, or acquisition of tissue in accordance with Standards.	B4.300
D5.000 Recovery, Collection, and Acquisition	Reagents, supplies, materials, and equipment shall be of appropriate grade for intended use, and approval for use shall be documented.	E2.000
D5.000 Recovery, Collection, and Acquisition	All tissue must be uniquely identified and traceable to the donor from recovery, collection, or acquisition through transport and receipt at the processing or storage facility. The environment in which tissue can be obtained, and techniques that should be used, shall be specified. Recovery, collection, acquisition, and preservation shall occur within a time interval appropriate for retention of tissue quality and shall be compatible with intended use of the tissue. Detailed records of the tissue donation shall be maintained that include information regarding relevant packaging, transportation, and, when applicable, donor reconstruction steps.	Preempted (see D3.100, D5.200, G1.000)
D5.100 Reagents, Supplies, Materials, and Equipment	All critical supplies, reagents, materials, and equipment approved for use for recovery, collection, or acquisition shall be identified and specifications (e.g., sterile where applicable) documented. A record shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, lot number, date of receipt, and	E4.000

Standards # (14th edition)	Standard - Fragment	15th Location
	expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of the staff performing the inspection. The tissue bank shall maintain records of all supplies, reagents, materials, and equipment from receipt through period of time used. All reagents, supplies, materials and equipment shall be used and stored in accordance with manufacturers' instructions, unless qualified/validated for intended use or storage.	
D5.100 Reagents, Supplies, Materials, and Equipment	All non-disposable surgical instruments and parts of mechanical/ electrical equipment which come in contact with tissue shall be properly cleaned, decontaminated, and sterilized prior to use for recovery, collection, or acquisition according to written procedures prepared to prevent contamination or cross-contamination.	E5.000
D5.100 Reagents, Supplies, Materials, and Equipment	Records shall be maintained that document sterilization steps.	B6.310
D5.100 Reagents, Supplies, Materials, and Equipment	All reagents, supplies, and materials shall be used and stored in accordance with manufacturers' instructions unless qualified/validated for intended use or storage.	E4.000
D5.100 Reagents, Supplies, Materials, and Equipment	Adequate controls must exist to prevent mix-ups between acceptable and unacceptable items.	E5.000
D5.110 Stock Rotation	Reagents, supplies, and materials with expiration dates or production dates shall be stored in a manner to facilitate inventory rotation. Items not bearing an expiration or production date shall be labeled with the date of acquisition and stored in a manner to facilitate inventory rotation. Older items should be used first and not used if expired or quality has been compromised.	E4.100
D5.200 Donor Identification	Each donor shall be assigned a unique donor identifier to facilitate tracing of the tissue from the donor and to final disposition of each tissue.	G2.000
D5.210 Verification Procedures D5.211 Confirmation	Prior to recovery or collection, staff shall confirm that in the case of a deceased donor, authorization for donation has been obtained and documented in a document of gift/authorization. Except for autologous tissue, informed consent must be obtained and documented prior to the initial collection from living donors. If informed consent was not obtained prior to recovery (e.g., surgical bone) or acquisition, it must be obtained as soon as practical after recovery or acquisition.	H15.100
D5.212 Donor Identity	Prior to initiation of tissue recovery, collection, or acquisition the potential donor's identification shall be verified with the donor's name as stated on the record of informed consent or document of gift/authorization. Donor identity verification shall be documented in the donor record prior to tissue recovery, collection, or acquisition. Records shall indicate the staff member(s) involved and include the source of the verification information (e.g., hospital wristband, medical examiner number, driver's license, or government issued identification with photograph).	H15.200

Standards # (14th edition)	Standard - Fragment	15th Location
D5.212 Donor Identity	(A, SB) Identification of the donor shall be the responsibility of the hospital staff involved with the recovery.	H15.210
D5.212 Donor Identity	(BT) Identification of the birth mother shall be the responsibility of the hospital staff, or the tissue bank staff member involved with acquisition.	H15.220
D5.300 Tissue Recovery, Collection, and Acquisition	Recovery, collection, or acquisition shall be performed using aseptic or clean techniques appropriate to the specific tissue type and intended use. Tissue must be labeled using a donor identifier and a description according to the SOPM (see G1.100).	H15.400
D5.310 Recovery	Recovery shall be performed using aseptic or clean techniques appropriate to the specific tissue recovered and intended use of the tissue.	H15.400
D5.310 Recovery	The SOPM shall specify the time limits for the postmortem recovery of tissue consistent with tissue-specific standards, where applicable.	H20.600
D5.310 Recovery	If recovery is to be delayed for a deceased donor, the donor's body should be refrigerated/cooled as specified in the tissue-specific standards. To prevent cross-contamination or mix-ups, recovery from one donor shall be the exclusive activity taking place at one time at a recovery site. Other activities (e.g., embalming, autopsy, another tissue donor recovery) cannot occur simultaneously in the same room as recovery. Tissue recovery shall not occur after embalming procedures have begun (i.e., injection of embalming fluid, application of drying agents either internally or topically).	H15.310
D5.310 Recovery	(LD) Methods for recovery of perioperative tissue shall be safe, aseptic, and ensure accurate identification of tissue.	H15.430
D5.320 Collection	(R) Collection of anonymous donor semen shall be made at the reproductive tissue bank using a sterile collection container. If the tissue requires transportation to the processing laboratory, it should be transported within a reasonable time period as specified in the SOPM, so as to maintain the utility of the tissue. The collection container shall be labeled with the date of collection and the donor's identification or, in the case of client depositors or directed donors, the name. The time of collection shall also be recorded.	H15.440
D5.330 Acquisition	(BT) Methods for acquisition of birth tissue shall be safe, aseptic, and ensure accurate identification of tissue post-delivery.	Preempted (see E1.000, G1.200, D5.000)
D5.330 Acquisition	Birth tissue shall be packaged post-delivery using a sterile receptacle/transport package in a controlled environment. Prior to acquisition, the birth tissue receptacle/transport package shall be labeled.	H15.580
D5.340 Pooling	Pooling tissue from multiple donors shall not occur during recovery, collection, acquisition, or storage.	H5.200
D5.400 Time Limits for Postmortem Tissue Recovery	When recovery of tissue has begun, subsequent recovery steps must proceed without delay.	H15.450

Standards # (14th edition)	Standard - Fragment	15th Location
D5.400 Time Limits for Postmortem Tissue Recovery	(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.	H15.460
D5.400 Time Limits for Postmortem Tissue Recovery	(C) Warm ischemic time (C) shall not exceed 24 hours from asystole if the donor's body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The time limit shall not exceed 15 hours if the donor's body was not cooled or refrigerated. If the donor's body is cooled for a period of time then not cooled for a period of time, the time period the donor's body is not cooled cannot exceed 15 cumulative hours.	H15.470
D5.400 Time Limits for Postmortem Tissue Recovery	(V) 1) Perfusion time shall not exceed 12 hours from asystole; and	H15.480
D5.400 Time Limits for Postmortem Tissue Recovery	2) warm ischemic time (V) shall not exceed 24 hours from asystole if the donor's body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The time limit shall not exceed 15 hours if the donor's body was not cooled or refrigerated. If the donor's body is cooled for a period of time then not cooled for a period of time, the time period the donor's body is not cooled cannot exceed 15 cumulative hours.	H15.480
D5.400 Time Limits for Postmortem Tissue Recovery	(MS, OA, S) The skin prep shall begin within 24 hours of asystole provided the donor's body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of asystole. The skin prep shall begin within 15 hours of death if the deceased donor's body has not been cooled or refrigerated. If the donor's body is cooled for a period of time then not cooled for a period of time, the time period the donor's body is not cooled cannot exceed 15 cumulative hours.	H15.450
D5.400 Time Limits for Postmortem Tissue Recovery	For expectations when evaluating cooling of a donor's body, refer to Guidance Document No. 7.	Preempted – not a standard
D5.500 Recovery Environment	All tissue shall be recovered in an aseptic or clean fashion using standard surgical preparation with sterile packs, instrumentation, and technique.	D3.000
D5.500 Recovery Environment	Prior to recovery, the recovery site must be evaluated for suitability using pre-established criteria designed to control contamination and cross-contamination (see Appendix IV).	D3.100
D5.500 Recovery Environment	The recovery site evaluation must be documented,	D3.100
D5.500 Recovery Environment	however, if the recovery site is an operating room in a heath care facility, no documented site evaluation is required.	D3.100
D5.510 Recovery Site Suitability Parameters	These must address the control of: 1) size/space; 2) lighting; 3) plumbing and drainage for the intended use;	D3.000

Standards # (14th edition)	Standard - Fragment	15th Location
	4) the physical state of the facility (i.e., state of repair); 5) ventilation; 6) cleanliness of room and furniture surfaces; 7) pests; 8) traffic; 9) location; 10) other activities occurring simultaneously; 11) sources of contamination; and 12) the ability to appropriately dispose of biohazardous waste and handle contaminated equipment.	
D5.520 Recovery Cleansing and Preparation	Environment: An evaluation of the recovery site must be performed to identify potential sources of contamination (see Appendix IV). All working surfaces (e.g., back table, Mayo stand, recovery table) used during recovery must be decontaminated using a bactericidal/antimicrobial agent. All cleansing and disinfecting events performed by tissue bank personnel shall be documented. For guidance, refer to Guideline for environmental cleaning in Guidelines for Perioperative Practice. Denver, CO: AORN, Inc. (current edition).	D3.110
D5.520 Recovery Cleansing and Preparation	Technician gowning, gloving, and movement shall be accomplished with the same diligence as used routinely for operative procedures. Aseptic technique shall be followed. For guidance, refer to AORN's Guideline for sterile technique (current edition). Persons performing the surgical recovery shall perform a surgical scrub or wash of their hands and forearms prior to recovery. For guidance, refer to AORN's for hand hygiene (current edition). A head cover, eye shields and mask shall be worn at the time of scrub, and a Sterile gown and gloves shall be donned after the scrub/wash. For guidance, refer to AORN's Guideline for surgical attire (current edition).	D5.200
D5.520 Recovery Cleansing and Preparation	Donor: Cleansing, preparing (i.e., skin prep), and draping the skin shall be accomplished with the same diligence as used routinely for operative procedures. Unless otherwise qualified/validated, agents used shall be antimicrobial skin preparation products, as specified in the SOPM, and shall be used in accordance with manufacturers' guidelines/instructions. For guidance, refer to AORN's Guideline for preoperative patient skin antisepsis (current edition).	H15.420
D5.530 Recovery Technique	Specific tissue recovery operations that control contamination and cross- contamination (e.g., sequencing of the tissue recovery, use of well-defined zone recovery techniques, and isolation draping in the presence of trauma; see Appendix IV shall be implemented. Areas of skin that have abrasions or puncture wounds should be avoided. All tissue shall be recovered using aseptic technique.	H15.300
D5.531 Cultures Obtained at Recovery	(MS, OA, S, SB) If performed, the technique used to obtain cultures of recovered tissues shall be appropriate for the tissue type and performed according to written instructions.	H15.490

Standards # (14th edition)	Standard - Fragment	15th Location
D5.610 Delivery Environment	(BT) If the delivery location is an operating room in a heath care facility, no documented site evaluation is required, however, any other location of delivery must meet the requirements at D5.500 and D5.510. Such an evaluation must be documented.	D3.100
D5.620 Cultures Obtained Prior to Acquisition	(BT) If performed, the technique used to obtain cultures prior to acquisition shall be appropriate and performed according to written instructions.	H15.490
D5.710 Recovery Records	For allogeneic tissue, details of the tissue donation shall be documented in the recovery record.	B6.300
D5.710 Recovery Records	Recovery records shall include, but not be limited to: 1) name, and address of the recovery agency; 2) date, time, and staff involved in all significant steps performed during the recovery (documentation shall be as per C1.100); 3) location and assessment of the suitability of the recovery site; 4) documentation of the physical assessment or physical examination; 5) documentation of any errors, accidents, or deviations that occurred; 6) donor name, age, and sex; 7) the type, lot number, manufacturer, and expiration date of critical reagents, supplies and materials, and the identification of equipment, used to recover, rinse, and/or transport tissue; and 8) specific tissue recovered; and 9) other available relevant medical records.	B6.310
D5.710 Recovery Records	The tissue bank or agency recovering the tissue shall provide a record of the tissue recovered, date of recovery, name and address of the recovery agency, and name of the donor to the recovery site facility.	Preempted (see B6.310)
D5.710 Recovery Records	(A) The following information regarding autologous tissue recovery shall be documented: 1) name and address of the institution in which the autologous tissue was recovered; 2) date and time the autologous tissue was recovered; 3) name of the physician recovering the autologous tissue; 4) donor name, age, sex, and hospital medical record number and/or social security number; and 5) type of tissue recovered.	B6.320
D5.720 Delivery and Post-Delivery Records	Details of the delivery and post-delivery time period through acquisition shall be documented in the donor's record. These records shall include, but not be limited to the: 1) birth mother's name; 2) infant donor's gestational age; 3) name and address of the health care facility and the identification of the delivery environment/location; 4) date and time of the delivery;	~~B9.320~~ B6.320

Standards # (14th edition)	Standard - Fragment	15th Location
	5) the physician or other authorized practitioner involved with the delivery, or designee as permitted by law; 6) information to allow tracking of critical reagents, supplies and materials provided by the tissue bank; 7) specific tissue(s) acquired; 8) other available relevant medical records; and 9) documentation of any errors, accidents, or deviations that occurred.	
D5.800 Packaging, Labeling, and Transport D5.810 Post-Recovery Packaging and Labeling	Immediately following recovery of each individual tissue at the recovery site, recovered tissue shall be individually and aseptically wrapped or enclosed and shall be immediately labeled with the unique donor identifier and the description according to the SOPM (see G1.100). Tissue shall be maintained at defined environmental temperatures until the time of transport to the processing center. Maintenance of such temperatures shall be documented. The receptacle/transport package must be designed to prevent contamination of the contents and allow for aseptic presentation of the tissue at the time of processing.	H15.500
D5.810 Post-Recovery Packaging and Labeling	(A) Immediately following recovery of the autologous tissue, it shall be individually and aseptically wrapped. The package shall be labeled immediately with definitive autologous donor identifying information such as the patient's name, hospital registration number, security number, birth date, etc., and shall be prominently labeled "FOR AUTOLOGOUS USE ONLY.''	H15.540
D5.810 Post-Recovery Packaging and Labeling	(C) Recovered cardiac tissue shall be rinsed and packaged in an isotonic, sterile solution such as normal saline, lactated Ringer's solution, PlasmaLyte®, transplant organ perfusate (e.g., Belzer's UW solution, Collin's solution) or tissue culture media, immediately following recovery. The volume of the transport solution should be adequate to cover the entire heart, including the vessels and valves. The type, lot number, manufacturer, and expiration date shall be documented.	H15.550
D5.810 Post-Recovery Packaging and Labeling	(V) Immediately following recovery, vascular tissue shall be gently flushed and packaged in an isotonic sterile solution such as tissue culture media. Normal saline solution should not be used.	H15.560
D5.810 Post-Recovery Packaging and Labeling	The type, lot number, manufacturer, and expiration date of all reagents used for recovery and packaging shall be documented.	H15.520
D5.810 Post-Recovery Packaging and Labeling	(S) Recovered skin tissue shall be packaged in a sterile solution immediately following recovery or packaged by another method that maintains the integrity of the tissue for its intended use (e.g., decellularized dermis). If in solution, the volume of transport solution must be adequate to cover the entire skin. The type, lot number, manufacturer, and expiration date(s) shall be documented.	H15.570
D5.820 Post-Delivery Packaging and Labeling	(BT) Following delivery, tissue shall be aseptically contained. Labeling that includes a unique donor identifier and the description according to the tissue bank's SOPM (see G1.100) shall be	H15.580

Standards # (14th edition)	Standard - Fragment	15th Location
	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.	
D5.820 Post-Delivery Packaging and Labeling	Tissue shall be maintained at defined environmental temperatures until the time of transport to the processing center. Maintenance of such temperatures shall be documented.	H15.530
D5.830 Tissue Transport	Tissue shall be transported in a manner established by the tissue bank that permits required environmental conditions for the duration of transport necessary to maintain the integrity of the tissue for its intended use. Transportation temperatures do not require 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'').	H16.000
D5.830 Tissue Transport	(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.	H16.100
D5.830 Tissue Transport	(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.	H16.200
D5.830 Tissue Transport	(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.	H16.300
D5.830 Tissue Transport	(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.	H16.400
D5.830 Tissue Transport	(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.	H16.500
D5.900 Reconstruction of a Deceased Donor's Body	Unless there is a specific request from a medical examiner, pathologist, or a funeral home, the surgical incision(s) shall be closed in an aesthetic fashion and the deceased donor's body prepared for the next portion of the recovery or for transportation to an appropriate facility.	H17.000

Standards # (14th edition)	Standard - Fragment	15th Location
	The donor's body shall be reconstructed in accordance with the SOPM. Reconstruction should employ techniques consistent with funeral home guidelines and/or medical examiner or pathologist requests. Documentation of donor reconstruction (if applicable) and disposition of the donor's body shall be maintained in the donor's record.	
D6.000 Storage of Tissue	Storage, including temporary storage, of recovered, acquired, or collected tissue shall be in conformance with storage temperature and monitoring expectations provided by the tissue bank that will process the tissue. See C1.300, E3.330, E3.331, and E3.340.	H18.000
D6.100 Quarantine Controls	Adequate controls must exist to prevent mix-ups, contamination, cross-contamination, and ensure tissue is identified as acceptable or unacceptable during all stages of recovery, receipt, storage, processing, and distribution. If physical segregation is deemed unnecessary, justification must be established, and must include a risk assessment and use of a validated electronic system.	H18.100
D6.100 Quarantine Controls	Considerations for the risk assessment shall include: 1) potential severity of impact if controls fail to prevent mix-up, contamination, or cross-contamination; 2) probability of failure to occur; 3) likelihood of identifying a failure before it reaches a customer; 4) existing controls to prevent failure; and 5) back-up plan for failure of validated electronic system.	H18.110
D6.100 Quarantine Controls	If physical segregation is deemed necessary, segregated areas must be appropriately labeled.	H18.200
D6.200 Segregation	The SOPM must address when the segregation of tissue during storage is indicated and how it will be appropriately segregated to avoid contamination, cross-contamination, and mix-ups.	H5.200
D6.200 Segregation	Considerations for assessment of risk include, where applicable: 1) donor infectious disease test results are unavailable, or this testing will not be performed; 2) the intended use of the tissue is primarily for transplantation or is restricted to research or education; 3) autologous tissue is segregated from allogeneic tissue; 4) the donor has been determined to be ineligible; 5) the ability of packaging and labeling to withstand storage temperatures, and/or 6) the ability to decontaminate storage equipment or the storage area should an accident occur.	H18.210
D6.200 Segregation	Appropriate segregation must include considerations above and storage must be in clearly defined and labeled areas (shelves or compartments) of the storage equipment or storage area.	H18.300
D6.300 Storage Equipment	Freezers and refrigerators used for storing tissue shall be regularly maintained, calibrated, and monitored according to written QC procedures. See the series of standards at J5.000 and K2.50.	E7.100

Standards # (14th edition)	Standard - Fragment	15th Location
E1.000 RECEIPT OF TISSUE AT PROCESSING/STORAGE FACILITY	Approval or rejection of the receipt of tissue into the processing or storage facility must be documented. The receipt and movement into storage, to immediate processing or to removal, shall be documented, including, at a minimum: 1) the condition of the transport package; 2) confirmation each tissue is labeled with a tissue identification number, or other traceable unique identifier; 3) evidence proper environmental conditions were maintained (e.g., presence/absence of ice/coolant). Refer to H3.300; 4) the date and time of receipt and movement; and 5) personnel involved.	H18.400
E1.100 Tissue Identification	Except for reproductive tissue, each unit of tissue shall be assigned a tissue identification number, which shall serve to relate the tissue to the donor from whom it was recovered or acquired and the associated records at any phase (e.g., quarantined, unprocessed, processed inventory) of the operation. Tissue units shall be assigned the same tissue identification number only if they are identical and processed as a lot.	H18.500
E1.100 Tissue Identification	(R) Reproductive tissue donors and client depositors shall be assigned a unique identifier, which shall be used to identify the tissue during steps of collection, processing, storage, and distribution. The unique identifier can be a directed donor's or a client depositor's name. For donors and client depositors giving multiple specimens, a secondary code shall be used to distinguish between dates of collection. The reproductive tissue bank that collects and processes the reproductive tissue shall be identified by name, code, or other identifier on the final container.	H18.510
E1.200 Pooling	Tissue from multiple donors shall not be pooled during processing, preservation, or storage.	H5.200
E2.000 Processing	Processing and preservation methods shall be established in accordance with Standards and applicable laws and regulations. All tissue shall be processed, preserved, quarantined, and/or stored pursuant to such methods so as to render them suitable for clinical use.	H20.000
E2.000 Processing	(A) If autologous tissue is not to be processed, it should be retained in its original wrapping.	H20.100
E2.000 Processing	(C, V) Processing shall include a disinfection period followed by rinsing, packaging, and preservation.	H20.200
E2.100 Tissue Evaluation	Written criteria for evaluation and assessment of tissue quality must be established.	H20.300
E2.100 Tissue Evaluation	(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.	H20.300
E2.200 Processing Environment	Except for reproductive tissue, when tissues are exposed to the environment during processing, these activities shall be consistent with the requirements of aseptic processing.	Preempted (see D1.100)

Standards # (14th edition)	Standard - Fragment	15th Location
	There shall be demonstrated and documented evidence that the chosen environment achieves the quality and safety required for the type of tissue, processing, and intended use.	
E2.200 Processing Environment	Without a subsequent validated microbial inactivation process, aseptic processing shall be performed in a certified and qualified bacteriologically and climate-controlled environment.	Preempted (see D1.110)
E2.210 Environmental Control and Monitoring	Where environmental conditions could reasonably be expected to cause contamination or cross-contamination of tissue or equipment, or accidental exposure of tissue to communicable disease agents, there must be adequate environmental control and monitoring of viable and non-viable particles under dynamic as well as static conditions. Effectiveness of these controls shall be validated. See AATB Guidance Document No. 5.	Preempted (see B10.000, D1.110)
E2.210 Environmental Control and Monitoring	Adequate control is defined by justifying and documenting the following: 1) type and frequency of environmental monitoring; 2) when the samples are to be taken (e.g., during or at the conclusion of operations); 3) sampling locations and number of sites to be sampled; 4) sample duration; 5) sample size (e.g., surface area, air volume); 6) action and alert levels for test results; and 7) potential corrective actions when alert and/or action levels are exceeded	Preempted (see B2.100, D1.100)
E2.300 Tissue Contamination	Written procedures shall be prepared, validated, and followed for control and prevention of contamination or cross-contamination by tissue during processing.	H20.400
E2.400 Reagents, Supplies, Materials and Equipment	All critical supplies, reagents, materials, and equipment approved for use for processing and preservation shall be identified and specifications (e.g., sterile where applicable) documented. It is expected that the tissue bank has the ability to link all supplies, reagents, materials, and equipment to tissue processed over the period of time they were in use.	E4.000
E2.400 Reagents, Supplies, Materials and Equipment	A record shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, lot number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of staff performing the inspection. Unless otherwise qualified/validated, all reagents, supplies, materials, and equipment shall be used and stored in accordance with manufacturers' instructions.	E4.000
E2.400 Reagents, Supplies, Materials and Equipment	All non-disposable surgical instruments and mechanical/electrical equipment used in tissue processing shall be cleaned, decontaminated, and, where applicable sterilized, between use for tissue from different donors according to written procedures. For non-disposable surgical instruments and mechanical/electrical equipment deemed critical, written procedures must be prepared and methods shall be validated, to prevent contamination or cross-contamination during processing. Adequate controls must exist to prevent mix-ups between acceptable and unacceptable items.	E6.000

Standards # (14th edition)	Standard - Fragment	15th Location
E2.410 Stock Rotation	Reagents, supplies, and materials with expiration dates or production dates shall be stored in a manner to facilitate inventory rotation. Items not bearing an expiration or production date shall be labeled with the date of acquisition and stored in a manner to facilitate inventory rotation. Older items should be used first and not used if expired or quality is compromised.	E4.100
E2.420 Containers E2.421 Physical Properties	The container shall maintain its integrity, withstand sterilization and storage conditions, not produce toxic residues during storage, and maintain tissue quality through the labeled expiration date. Containers shall not interfere with the effective use of appropriate agents applied to sterilize or disinfect the tissue.	E6.100
E2.421 Physical Properties	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.	E6.500
E2.421 Physical Properties	(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.	E6.600
E2.422 Receipt of New Shipments	Containers shall be stored under quarantine until the containers have been tested, sampled, or examined, as appropriate, and released for use. Containers not meeting specifications shall not be used.	E6.200
E2.423 Storage	Unused containers shall be handled and stored to maintain integrity.	E6.300
E2.424 Integrity and Sterility	Sterilized containers shall be handled in a manner to preclude contamination.	E6.400
E2.425 Visual Inspection	Each container shall be examined visually for damage or evidence of contamination prior to use and immediately after filling. Containers not meeting visual criteria shall not be used.	H20.500
E2.500 Processing Methods	Tissue shall be processed using validated methods to prevent contamination and cross-contamination and to maintain tissue quality for its intended use.	H20.400
E2.520 Time Limits for Pre-processing, Processing and Preservation Phases	Time limits and/or other valid process control end points or limits for the completion of each phase of processing and preservation shall be established and validated with reference to tissue quality. Additionally, a time limit and temperature for pre-processing quarantine storage that address tissue quality must be established and justified.	H20.600
E2.520 Time Limits for Pre-processing, Processing and Preservation Phases	(C, V) Disinfection of cardiac and vascular tissue shall be accomplished via a time- specific, validated process (disinfection time). The total ischemic time shall not exceed 48 hours.	H21.100
E2.520 Time Limits for Pre-processing, Processing and Preservation Phases	(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.	H21.200
E2.520 Time Limits for Pre-processing, Processing and Preservation Phases	(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.	H21.300

Standards # (14th edition)	Standard - Fragment	15th Location
E2.530 Prevention of Matrix Deterioration	(C, V, OA, S) To prevent drying and possible cellular and extracellular matrix deterioration, the tissue shall be kept moist at all times during processing using a sterile solution/medium. If drying does not impact quality for intended use (e.g., decellularized dermis), the requirement to prevent drying is not applicable.	H21.400
E2.540 Additives	When applicable, the type, amount, concentration, and method of incorporation/addition of all media, cryoprotectants, and any other additives used in processing shall be specified in the SOPM. This information about the allograft shall be made available to the implanting/transplanting physician, upon request.	H21.500
E2.600 In-Process Controls	In-process controls shall be applied as necessary and according to the SOPM during processing and packaging to ensure that each process meets requirements specified in the SOPM. The tissue bank shall determine when, which, and how controls are to be performed (e.g., residual moisture testing, microbial cultures of tissue, solutions, packaging, equipment, pH measurements, or post-thaw sperm quality). Sampling for in-process controls shall be designed to be representative of the materials to be evaluated.	H4.000
E2.600 In-Process Controls	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.	H4.100
E2.610 Tolerance Limits of Processed Tissue	Tissue banks that process tissue shall include in their SOPM a description of the final types of tissue, any specifically required or specifically prohibited dimensions or characteristics, and the means used to assess these characteristics. At or near the end of processing, tissue shall be evaluated according to these procedures to determine whether it is in conformance with the SOPM. Relevant tissue dimensions or characteristics shall be recorded. All tissue deemed to be out of conformance shall not be released for transplantation.	H22.000
	This inspection, the staff involved, and the disposition of each tissue unit shall be documented.	H22.100
E2.611 Tissue Measurement	Tissue measurement shall be performed and documented and must include the quantity or other characteristics of the tissue expressed as applicable (e.g. volume, weight, dimensions, cell density, number of viable cells or a combination of these).	H22.200
E2.611 Tissue Measurement	(C) Allograft heart valve grafts shall be inspected, evaluated, and sized by internal valve annulus diameter, and recorded in millimeters (mm).	H22.210
E2.611 Tissue Measurement	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).	H22.210
E2.611 Tissue Measurement	(V) Vascular tissue grafts shall be inspected, evaluated, and sized by diameter and recorded in millimeters (mm).	H22.220
E2.611 Tissue Measurement	The length of the vascular segment shall be recorded in centimeters (cm).	H22.220
E2.611 Tissue Measurement	(MS, OA) Radiographic techniques may be used as needed	H22.200

Standards # (14th edition)	Standard - Fragment	15th Location
E2.612 Calcium Residuals: Demineralized Bone	(MS) Unless bone is treated by a validated process to reduce minerals, representative samples of each lot shall be tested for residual calcium by a standard method.	H22.230
E2.612 Calcium Residuals: Demineralized Bone	Residual calcium content for bone labeled as demineralized shall not exceed 8% by a standard method.	H22.230
E2.612 Calcium Residuals: Demineralized Bone	For bone that has been subjected to a demineralization process with a residual calcium content target that exceeds 8% when tested, the tissue must not be labeled as demineralized and should be labeled as partially demineralized to describe the extent of demineralization.	H22.230
E2.613 Residual Moisture – Lyophilization/Dehydration/Desiccation	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.	H22.240
E2.620 In-House Laboratory Testing	If the tissue bank performs laboratory tests and results are used to determine acceptability of tissue for transplantation, the requirements at K2.100 and K2.200 shall apply.	H22.000
E2.621 Laboratory Records	Records of in-house laboratory testing shall include, at a minimum: 1) sample source and quantity; 2) tissue identification number; 3) test date and identification of the person performing the test; 4) assay methods; 5) calculations, graphs, and charts, if used; 6) test results as well as interpretation of results; 7) testing or standardization of reference standards, reagents, standard solutions; and 8) record review by an individual other than the operator generating the records to ensure compliance with Standards.	B6.420
E2.700 Tissue Preservation E2.710 Lyophilization	Validated procedures for lyophilizing tissue shall be established and described in the SOPM. Each lyophilization cycle shall be monitored and recorded for shelf temperature, condenser temperature, and vacuum.	H23.100
E2.720 Dehydration/Desiccation	Validated procedures for dehydration or desiccation of tissue shall be established and described in the SOPM. Quality control parameters shall be established and verified for each batch.	H23.200
E2.720 Dehydration/Desiccation	If a residual moisture limit has been established for finished tissue, the container shall maintain the limit for the duration of the expiration period. The residual moisture level shall not exceed a limit linked to tissue quality. The analytical method selected must be validated for its intended use.	H22.280
E2.730 Freezing Tissue	Procedures for freezing tissue shall be established and documented to maintain tissue quality.	H23.300
E2.740 Cryopreservation	Except for reproductive tissue, tissue to be cryopreserved must be frozen at a controlled and monitored, predetermined rate with compensation for heat of crystallization/latent heat of	H23.400

Standards # (14th edition)	Standard - Fragment	15th Location
	fusion to a predetermined endpoint. 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.	
E2.740 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.	H23.500
E2.741 Control-Rate Freezing: Surrogate Packages	If surrogates are used for monitoring the freezing program, the packaging shall be regularly inspected, and solutions and tissue changed when indicated. Monitoring for deterioration of the packaging shall be performed. The processing center shall have a procedure describing the assembly of such surrogates and a means for monitoring their integrity.	H23.600
E2.742 Termination of Freezing Program	Upon termination of the freezing program, the cryopreserved tissue shall immediately be placed in storage. Temperature fluctuation and cycling should be avoided.	H23.700
E2.743 Freezing Profile	If a programmed control-rate freezing method is employed, a record of the freezing profile shall be evaluated and approved and become a permanent part of the processing records.	H23.800
E2.750 Chemical Preservation	(BT, MS) Procedures for the preservation of tissue by chemical means shall be validated and documented. When chemical preservation has been used, the package insert shall so indicate.	H23.900
E2.800 Sterilization/Disinfection of Tissue	Individual processing facilities shall establish, validate, and document disinfection or sterilization regimens and microbial surveillance methods. The SOPM shall establish a list of organisms that necessitate discard, sterilization and/or disinfection of tissue. The list shall be based upon not only the category type of tissue but also the method by which the tissue was processed (e.g., cryopreserved MS tissues that cannot be sterilized and can only be disinfected and rendered culture negative).	H24.000
E2.800 Sterilization/Disinfection of Tissue	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;	H24.100

Standards # (14th edition)	Standard - Fragment	15th Location
	5) Staphylococcus aureus; and 6) Streptococcus pyogenes (group A strep.).	
E2.810 Non-Terminal Irradiation	A dose is selected to reduce or eliminate bioburden. The selected dose shall be justified, and any claims made must be supported by data. The type of irradiation shall be indicated on the container label or package insert of all tissue exposed to non-terminal irradiation.	H25.500
E2.820 Terminal Sterilization by Irradiation	The most common sources of ionizing radiation are Cobalt 60, electron beam, and X- ray. Identification of the irradiation source, the dosimetry, and completed certificate of irradiation shall be documented in the processing record. The sterilization dose used must be validated and supported by data. A sterility assurance level (SAL) shall be selected, and the sterilization dose must be shown to be capable of achieving that SAL.	H25.510
E2.820 Terminal Sterilization by Irradiation	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.	H25.520
E2.830 Sterilization by Other Methods	Tissue sterilization by other methods (other than by irradiation) shall be documented in the processing record. This includes the type of sterilization, the processing parameters, and certification of sterilization. The process utilized to sterilize the tissue must be validated and supported by data. A sterility assurance level (SAL) shall be selected, and the method must be shown to be capable of achieving that SAL. Validation methods generally are bioburden-based methods (e.g., AAMI/ISO 11137), but other methods can be justified. The type of sterilization method used shall be indicated on the container label or package insert of all tissue exposed to the method.	H25.600
E2.830 Sterilization by Other Methods	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 [See table in Stds] Tissue Size/Weight Very Small (<100 mg) Small (<10 grams) Medium (10–100 grams) Large (>100 grams)	H25.600
E2.840 Disinfection by Chemical Agents	(MS) Iodophors, ethanol, and other solvent/detergent combinations may be used as disinfectants of bone in a validated processing procedure. In any instance where a chemical disinfectant or antibiotic agent is used, the container label or the package insert shall identify the presence of possible trace residuals. Refer to G3.120.	H25.600
E2.850 Other Disinfection Agents	(BT, MS) Other agents such as heat, ultraviolet radiation, or exposure to antibiotics may be used as disinfection agents. Procedures for processing with such agents shall be documented and validated to ensure consistency in tissue processing.	H25.600
		B6.400

Standards # (14th edition)	Standard - Fragment	15th Location
E2.900 Processing and Preservation Records	A record shall be created to document the processing and preservation of tissue. Processing and preservation records shall include the following: 1) processing dates and responsible processing personnel; 2) tissue identification number(s) and type(s) of tissue being processed; 3) tissue measurements (e.g., weight, dimensions, volume), as appropriate; 4) expiration, where applicable; 5) type and quantity of tissue sampled for in-process controls; 6) final disposition of each tissue obtained and/or processed; and the type, lot number, manufacturer (unless recorded in other records), and expiration date, where applicable, of critical reagents, supplies and materials, and the identification of critical equipment, used to process and/or preserve tissue.	
E3.000 Storage E3.110 Quarantine Controls	Refer to D6.100 for requirements related to quarantine controls.	Preempted (see H18.200)
E3.120 Situations Requiring Quarantine	Human tissue shall be quarantined until the tissue is either determined to be suitable for processing, transplantation or another appropriate disposition is accomplished. All tissue shall be quarantined until the following criteria for donor eligibility are satisfied: 1) all required infectious disease testing has been completed, reviewed by the responsible person, and found to be negative or non-reactive; and 2) donor screening has been completed, reviewed by the responsible person, and determined to indicate freedom from risk factors for and clinical evidence of HIV, hepatitis B, and/or hepatitis C infection.	H5.000
E3.120 Situations Requiring Quarantine	Tissue shall be quarantined at any phase of the operation when its release could affect the safety, effectiveness, or quality of the tissue, and subsequently, the health of the recipient. The following tissue shall be quarantined: 1) tissue that is pending completion of processing, packaging, preservation, or labeling and final-release-approval signature; 2) tissue recovered, collected, or acquired from donors not meeting established donor eligibility criteria, including unacceptable test results; 3) tissue involved in a recall pending investigation, documentation, and resolution; 4) tissue failing to meet technical or quality assurance specifications; 5) tissue pending discard as medical waste; and 6) tissue returned by a consignee, pending evaluation.	H5.100
E3.130 Labeling Quarantined Tissue	All human tissue processed or shipped prior to determination of donor eligibility must be under quarantine. Such tissue shall be accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation. Tissue determined to be unsuitable for transplantation and intended for release for other purposes shall be identified accordingly.	H5.300

Standards # (14th edition)	Standard - Fragment	15th Location
E3.140 Quarantine Records	Quarantine records for tissue quarantined post-release shall indicate the reason for quarantine and the final disposition of the tissue. Release dates or disposal dates shall be indicated as well.	B6.500
E3.200 Segregation of Tissue	(R) Cryopreserved reproductive tissues from untested client depositors shall be stored in a physically separate area clearly defined from those of tested client depositors. Tissues from client depositors known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, or HBsAg or any other test excluding CMV without subsequent negative confirmatory testing as approved by the reproductive tissue bank's Medical Director shall be stored in a physically separated area clearly identified from tissue of seronegative client depositors. See F2.200 for documentation required for release.	H5.310
E3.300 Storage Temperatures	Each tissue bank shall establish acceptable temperature-range limits for the storage of tissue before and after processing in accordance with these Standards, applicable laws and regulations and in consideration of tissue quality and the packaging system for the tissue.	H26.000
E3.300 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.	H26.100
E3.310 Frozen and Cryopreserved Tissue	(MS, OA) Procedures for storing processed frozen and cryopreserved tissue to ensure graft safety and quality shall be written. Processed frozen or cryopreserved musculoskeletal tissues shall be stored at temperatures of -40°C or colder. Temporary storage of processed frozen or cryopreserved musculoskeletal tissue between -20°C and -40°C is limited to six months total.	H26.200
E3.310 Frozen and Cryopreserved Tissue	(C, V) Cryopreserved cardiac tissue and vascular tissue allografts shall be maintained at temperatures of -100°C or colder.	H26.300
E3.310 Frozen and Cryopreserved Tissue	(R) Reproductive tissues shall be stored either in liquid nitrogen or in the vapor phase of liquid nitrogen.	H26.400
E3.310 Frozen and Cryopreserved Tissue	(S) Frozen or cryopreserved skin shall be stored at ultra-low (-40°C or colder) temperatures.	H26.500
E3.320 Lyophilized/Dehydrated/Desiccated Tissue	Lyophilized, dehydrated, or desiccated tissue must be stored at ambient temperature or colder.	H26.600
E3.330 Monitoring Storage Temperatures	A temperature monitoring system shall be utilized to document temperatures and to alert staff when temperatures have strayed outside acceptable limits. Procedures shall be in place for reviewing temperatures. Documentation of such review shall be indicated with the reviewer's initials and the date. If temperature recording charts are used, they shall be initialed and dated when placed on and also when removed from the storage unit.	H26.700
E3.330 Monitoring Storage Temperatures	Completed charts shall be retained for the duration specified in C1.300. If storage utilizes liquid nitrogen, either liquid nitrogen levels or temperature shall be monitored and documented at an interval specified in the SOPM.	H26.700

<table>
<tr><th>Standards # (14th edition)</th><th>Standard - Fragment</th><th>15th Location</th></tr>
<tr><td>E3.331 Storage Conditions for Commonly Transplanted Human Tissue</td><td>
<table>
<tr><th colspan="3">Storage Conditions for Commonly Transplanted Human Tissue</th></tr>
<tr><th>Human Tissue</th><th>Storage Conditions</th><th>Temperature (°C) *</th></tr>
<tr><td>Birth tissue (BT)</td><td>Frozen, refrigerated, cryopreserved, lyophilized, dehydrated, desiccated</td><td>Established by the tissue bank</td></tr>
<tr><td>Cardiac (C), vascular tissue (V)</td><td>Frozen, cryopreserved</td><td>-100°C or colder</td></tr>
<tr><td rowspan="2">Cellular tissue (CT)</td><td>Refrigerated</td><td>Above freezing (0°C) to 10°C</td></tr>
<tr><td>Frozen, cryopreserved</td><td>Established by the tissue bank</td></tr>
<tr><td rowspan="4">Musculoskeletal tissue (MS), osteoarticular graft (OA)</td><td>Refrigerated</td><td>Above freezing (0°C) to 10°C</td></tr>
<tr><td>Frozen, cryopreserved (temporary storage for 6 months or less)</td><td>-20°C or colder to -40°C (this is warmer than -40°C but colder than -20°C)</td></tr>
<tr><td>Frozen, cryopreserved (long term storage)</td><td>-40°C or colder</td></tr>
<tr><td>Lyophilized, dehydrated, desiccated</td><td>Ambient **</td></tr>
<tr><td>Reproductive tissue (R)</td><td>Frozen, cryopreserved</td><td>LN_2 (Liquid or Vapor Phase)</td></tr>
<tr><td rowspan="3">Skin (S)</td><td>Refrigerated</td><td>Above freezing (0°C) to 10°C</td></tr>
<tr><td>Frozen, cryopreserved</td><td>-40°C or colder</td></tr>
<tr><td>Lyophilized, dehydrated, desiccated</td><td>Ambient **</td></tr>
<tr><td colspan="3">* Warmest target temperature unless noted to be a range
**Ambient temperature monitoring not required for lyophilized, dehydrated, or desiccated tissue</td></tr>
</table>
</td><td>H26.000</td></tr>
<tr><td>E3.340 Emergency Transfers</td><td>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.</td><td>H26.800</td></tr>
<tr><td>E3.400 Expiration Date/Storage Period</td><td>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.</td><td>H26.900</td></tr>
<tr><td>E3.400 Expiration Date/Storage Period</td><td>(A) The implanting physician shall be informed of any expiration dates.</td><td>H26.910</td></tr>
<tr><td>E3.410 Refrigerated Tissue</td><td>(A) Autologous skin that has not been processed or preserved should be stored refrigerated for no longer than 14 days.</td><td>H26.920</td></tr>
</table>

Standards # (14th edition)	Standard - Fragment	15th Location
F1.000 Tissue Release	Prior to release of tissue for transplantation, the Medical Director or licensed physician designee shall determine donor eligibility.	B5.200
F1.000 Tissue Release	All necessary information shall be complete and compiled in a standardized format prior to final review and determination of donor eligibility and tissue acceptability for transplantation. Each donor record shall contain a disposition/release statement and signature of both the Medical Director or licensed physician designee who is assuming responsibility for donor eligibility determination and, if different, the individual(s) responsible for reviewing all technical and quality control specifications. If processing was performed, there shall be documentation of a review by designated personnel of all technical and quality control specifications. An SOPM shall clearly define the responsibilities of each reviewer.	B6.600
F1.100 Donor Eligibility Review	The eligibility of each donor shall be determined by the Medical Director or licensed physician designee upon review of all records as specified below and in accordance with the SOPM.	B5.210
F1.100 Donor Eligibility Review	Although the donor risk assessment interview may be preliminarily reviewed by technical staff to evaluate acceptability for recovery, acquisition, collection, or processing, tissue shall not be released for transplantation without determination of donor eligibility by the Medical Director or licensed physician designee.	H10.400
F1.110 Records for Review	The Medical Director or licensed physician designee shall determine donor eligibility based on a review and evaluation of the donor's relevant medical records or a summary of these generated by a trained individual. The determination of eligibility shall be based on the SOPM, these Standards and applicable laws and regulations. The donor eligibility review shall include, but is not limited to these records: 1) acceptability of the authorization or informed consent; 2) suitability of the recovery site, delivery environment, or where collection took place; 3) pertinent information from the medical records generated at the time of death, including any pathology and laboratory reports, physician summaries, and transfusion/infusion information; 4) the donor risk assessment interview; 5) all results of laboratory testing relevant to donor eligibility; 6) any plasma dilution calculations used to determine the acceptability of the blood sample used for testing; 7) all relevant culture results up to and through the completion of recovery (e.g., blood cultures, if performed; pre-sterilization/pre-disinfection cultures, if available); 8) applicable time limits for tissue recovery; 9) pertinent circumstantial and donor screening information relayed to tissue bank staff; 10) results of the physical assessment or physical examination; 11) the autopsy report, or a summary of findings, if an autopsy was performed; and	H19.100

Standards # (14th edition)	Standard - Fragment	15th Location
	12) any other information gathered for the purposes of disease screening as required by Standards and applicable laws or regulations.	
F1.110 Records for Review	In the case of pediatric donors who have been breastfed within the past 12 months and/or are 18 months of age or less, the birth mother's risk for transmissible disease shall be evaluated for HIV, HBV, HCV and other infectious agents when indicated. See Appendix II.	H19.110
F1.110 Records for Review	For all donors one month (28 days) of age or less, the infant and the birth mother shall be screened for risk of relevant communicable disease agents and diseases (RCDAD) and the mother's blood must be tested. Refer to D4.100 (BT) for expectations to obtain the health status of the infant donor of birth tissue.	H19.120
F1.110 Records for Review	Once the determination is made, the donor eligibility statement shall be documented, dated, and signed by the Medical Director or licensed physician designee.	H19.200
F1.111 Absence of Third-Party Records	When no third-party records are available that can be used to establish a likely cause of death, and if no autopsy was performed, a certified copy of the death certificate must be included in the donor record. If it is not possible to obtain a certified copy, a verified copy of the death certificate must be included in the donor record.	H19.300
F1.111 Absence of Third-Party Records	When third party records are available that can be used to establish a likely cause of death, or if an autopsy was performed, obtaining a certified copy, or verified copy of the death certificate is voluntary.	B6.600
F1.112 Autopsy Report	If an autopsy was performed, the tissue bank's Medical Director or licensed physician designee shall review the autopsy report or a summary of findings prior to the release of tissue to inventory. If a copy of the autopsy report is not available for the donor's record, the cause of death and other pertinent autopsy findings shall be documented in the donor's record.	H19.400
F1.112 Autopsy Report	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.	H19.410
F1.112 Autopsy Report	In the case of suspected Sudden Unexpected Infant Death (SUID), an autopsy should be performed, and results reviewed to confirm the cause of death.	H19.420
F1.120 Infectious Disease Risk Review	Tissue shall not be distributed from a donor who, or a donor whose birth mother, has engaged in behaviors defined as high risk for transmission of relevant communicable disease agents or diseases (RCDADs). This information shall be obtained via a donor risk assessment interview, physical assessment or physical examination, and by review of other available relevant medical records.	H19.500
F1.120 Infectious Disease Risk Review	The Medical Director or licensed physician designee shall not determine an allogeneic donor eligible with any of the following findings: 1) evidence of significant active infection at the time of donation for relevant communicable disease agents or diseases (RCDADs). These include, but are not limited to: septicemia, viral disease (e.g., HIV, viral hepatitis, West Nile virus, rabies, Ebola virus disease, Zika virus	H19.600

Standards # (14th edition)	Standard - Fragment	15th Location
	infection, etc.), human transmissible spongiform encephalopathies, untreated syphilis, clinically active tuberculosis, leprosy (Hansen's disease) or systemic mycosis; and/or 2) risk factors for relevant communicable disease agents or diseases (RCDADs) as specified in Appendix II.	
F1.120 Infectious Disease Risk Review	(R) Semen donors shall not exhibit an infectious skin disease that creates a risk of contamination of the semen. For all reproductive tissue donors, there shall not be evidence of infection within the past twelve months with Chlamydia trachomatis and/or Neisseria 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.	H19.600
F1.130 Other Medical Conditions	In addition to the infectious disease risk review, the Medical Director shall establish criteria and evaluate tissue donors for conditions that may adversely affect the safety or utility of the specific types of tissue processed and/or distributed by the tissue bank. Such conditions include, but are not limited to: 1) history of autoimmune diseases; 2) current or prior diagnosis of malignancy and the evaluation shall include the type of malignancy, clinical course, and treatment prior to acceptance; 3) ingestion of, or exposure to, toxic substances; 4) genetic, metabolic, traumatic, or infectious diseases that may adversely affect the quality of specific tissues; 5) previous surgery; and 6) diseases of unknown etiology	H10.100
F1.140 Interpretation of Infectious Disease Test Results	Disposition of allogeneic tissue shall be based upon the interpretation of all infectious disease test results and shall be as follows: 1) Human tissue shall be determined not to be suitable for transplantation if from a donor whose specimen has tested repeatedly reactive on an FDA-licensed, approved, or cleared donor screening test for anti-HIV-1, anti- HIV-2, HBsAg, anti-HBc, or anti-HCV. When a birth mother's specimen is used for testing, these same rules apply. 2) Viable leukocyte-rich tissue (e.g., semen) shall be determined not to be suitable for transplantation if from a donor whose specimen has tested repeatedly reactive (RR) on an FDA-licensed, approved, or cleared donor screening test for anti-HTLV-I or anti-HTLV-II. The eligibility of other human tissue for transplantation from donors whose specimens test RR for anti-HTLV-I or anti-HTLV-II shall be determined by the Medical Director. Note: Law and/or regulation, including, where applicable, foreign laws and/ or regulations, may differ in regard to a RR HTLV antibody test result and how this impacts the suitability of the donor's tissues for transplantation.	H19.700

Standards # (14th edition)	Standard - Fragment	15th Location
	3) Human tissue shall be determined not to be suitable for transplantation if from a donor whose specimen had a final test result of positive, repeat reactive, or repeatedly reactive on a screening test using a NAT assay. When a birth mother's specimen is used for testing, these same rules apply. 4) If a laboratory that performs organ donor testing performs the initial testing in duplicate or triplicate, the tissue bank must obtain and review the results of all individual tests performed. If any one of those initial tests is reactive or positive, the tissue shall be determined not suitable for transplantation. 5) Tissue from a donor reactive for syphilis using an FDA-licensed, cleared, or approved non-treponemal screening assay may be used for transplantation only if the sample is found to be negative using an FDA-licensed, cleared, or approved treponemal-specific confirmatory assay. If initial testing was performed using an FDA-licensed, cleared, or approved treponemal-specific assay and was reactive, the tissue shall not be used for transplantation. 6) If results of additional infectious disease testing are received for tests that are not required, such test results must be included in the donor's record and any results from those tests must be considered when determining donor eligibility. Procedure(s) shall be established for the interpretation of additional infectious disease test results.	
F1.140 Interpretation of Infectious Disease Test Results	NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority regarding test kit licensing/approval apply.	H12.200
F1.140 Interpretation of Infectious Disease Test Results	(A) Determination of the final disposition of tissue in which a donor's blood sample tests positive is the responsibility of the autologous donor's physician. If tissue from a donor who tests positive is to be stored in a tissue bank, refer to E3.200.	H36.600
F1.140 Interpretation of Infectious Disease Test Results	(R) Determination of the use of client depositor and/or directed donor reproductive tissues in cases where required test results are positive or repeatedly reactive must be documented according to protocols described at F2.200 (see note for CMV below).	H19.700
F1.140 Interpretation of Infectious Disease Test Results	Tissue from an anonymous semen donor who tests reactive for an active, acute infection with cytomegalovirus (CMV) shall not be deemed suitable for use. Tissue from an anonymous semen donor determined to be in a latent CMV status may be acceptable. Each reproductive tissue bank shall develop a procedure for determining eligibility for both anonymous and directed donors. Procedures must also include provisions for communicating CMV status to the end-user physician such that a decision can be made regarding use of tissue from a CMV positive (total IgG plus IgM) donor.	H19.800
F1.140 Interpretation of Infectious Disease Test Results	Tissue from a donor testing positive for Chlamydia or Gonorrhea shall not be suitable for use.	H19.900
F1.200 Technical Review	Tissue may be released for transplantation only with notation in processing records by responsible persons that tissue produced meets technical specifications set forth in the SOPM	H27.000

Standards # (14th edition)	Standard - Fragment	15th Location
	(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.	
F1.200 Technical Review	For contractual processing arrangements, tissue shall be released for transplantation by the distributing tissue bank only with a signature and written disposition/release statement or equivalent documentation from the processing center indicating that all quality measures were reviewed and determined to be acceptable according to the written SOPM. The written disposition/release statement or equivalent documentation shall indicate that the following conditions, at a minimum, have been met: 1) review of tissue processed for consistency with specific tissue requirements; 2) review of all processing and packaging bacteriologic testing results for completeness and acceptability; 3) review for completeness and acceptability of any test or environmental testing results generated; 4) review of all lot numbers and expiration dates recorded for verification of completeness and that all were within acceptable ranges (e.g., recovery kits, culture media, processing solutions); 5) review of all processing records for completeness and accuracy, and verification that tissue was processed in accordance with the SOPM and met defined specifications; 6) review and comparison of tissue obtained, and units produced from each tissue for verification that the disposition of each tissue recovered, acquired, or collected is traceable; 7) verification that all (if any) error and accident reports potentially related to the safety or quality of the tissue to be released are resolved and corrections made where appropriate; 8) verification that all processing was accomplished within time limits specified in the SOPM and within applicable technical specifications in the SOPM (e.g., acceptable residual moisture, irradiation exposure limits, temperatures, and freezing curves); and 9) if tissue was recovered or collected by another entity, verification that the shipment was acceptable when it arrived at the processing center (e.g., with respect to temperature and time limits).	H27.100
F1.200 Technical Review	(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.	H27.200
F1.300 Quality Review	Except for reproductive tissue, tissue shall not be released for transplantation without a signed disposition/release statement from the responsible person(s) at the site of distribution, indicating that, at some time prior to release, all quality measures were performed and found acceptable according to the written SOPM. The written disposition/release statement or	B5.300

Standards # (14th edition)	Standard - Fragment	15th Location
	equivalent documentation shall indicate that the following conditions, at a minimum, have been met: 1) review of tissue processed for consistency with specific tissue requirements; 2) review and comparison of tissue obtained, and grafts produced from tissue for verification that the Disposition of tissue recovered is traceable; 3) verification that all (if any) error and accident reports, potentially related to the safety or quality of the tissue from each donor, are resolved and corrections made where appropriate; 4) verification that all processing was accomplished within time limits specified in the SOPM and within applicable technical specifications in the SOPM (e.g., acceptable residual moisture, irradiation exposure limits, temperatures, and freezing curves); 5) if tissue was recovered by another entity, verification of the acceptability of the shipment upon arrival at the processing center (e.g., with respect to temperature and time limits); 6) verification that the Medical Director or licensed physician designee has made a decision regarding donor eligibility and that all directives of the Medical Director regarding the donor were implemented; and 7) verification that final labeling of tissue was performed in accordance with SOPM and Standards.	
F1.300 Quality Review	(R) Reproductive tissue shall not be released for clinical use without a signed, written disposition/release statement of the person responsible for authorizing release, at the site of processing, indicating that all quality measures were reviewed and found acceptable according to the written SOPM. This includes, but is not limited to: 1) review of donor age and of tissue processed for consistency with specific tissue requirements; 2) record and verification that all lot numbers and expiration dates were complete and that all were within acceptable ranges (e.g., cryopreservation media); 3) review of all processing records for completeness and accuracy and verification that the tissue was processed in accordance with the SOPM and meets defined technical specifications; 4) review of tissue obtained, and specimens produced from each collection for verification that the disposition of each tissue specimen is traceable; 5) verification of resolution of all error or accident reports (if any) potentially related to the safety or quality of the tissue; 6) verification that all processing was accomplished within time limits specified in the SOPM and within applicable technical specifications in the SOPM (e.g., ejaculate volume, sperm motility, concentration, morphology, and post-thaw motility); 7) if reproductive tissue was collected by another entity, verification of the time of receipt at the reproductive tissue bank and condition of the sample upon receipt; and 8) verification that the Medical Director has made a decision regarding donor eligibility and that all directives of the Medical Director regarding the donor were implemented.	B5.310

Standards # (14th edition)	Standard - Fragment	15th Location
F1.310 Review of On-Site Processing Records	If processing was performed on site, there shall also be written documentation that all quality measures were performed and acceptable according to the written SOPM. This includes but is not limited to: 1) review of all processing and packaging bacteriologic testing results for completeness and acceptability; 2) review of all test or environmental testing results generated for completeness and acceptability; 3) review of all lot numbers and expiration dates recorded (e.g., materials such as recovery kits, culture media, processing solutions) for verification that all were within acceptable ranges; and 4) review of all processing records for: completeness and accuracy; verification that tissue was processed in accordance with the SOPM; and conformance to defined technical specifications.	~~B6.320~~ B5.320
F2.000 Other Release F2.100 Tissue Release Based on Tissue Utility	Pre-established release criteria based on tissue utility must be developed. If tissue other than reproductive tissue is distributed or dispensed for transplantation, there shall be in each instance, documentation of: 1) donor eligibility and tissue processing information available at the time of release. All donor eligibility requirements in F1.100 must be met with the exception of a review of the autopsy report (if applicable) and pending culture results; 2) Medical Director or licensed physician designee review of all relevant information present; 3) approval of the release by the Medical Director or licensed physician designee; 4) a written statement issued to the end-user physician indicating what information required by the SOPM and/or these Standards is available and what information is not available for review, and when it is expected that the information will be available; and 5) a statement from the end-user physician indicating his/her understanding that the tissue is being released using available information. Relevant final results shall be forwarded promptly to the end-user physician upon completion of testing. Documentation of the release based on tissue utility shall be maintained in the donor record. These records shall be maintained together or summarized in a log.	~~B3.330~~ B5.330
F2.200 Special Circumstances in Release of Reproductive Tissues	(R) Release of reproductive tissue may be considered in the special cases of: 1) reproductive tissues from client depositors known to be reactive on tests for anti- HIV-1, anti-HIV-2, anti-HCV, HBsAg, or any other test, excluding CMV, without subsequent negative confirmative testing as approved by the Medical Director; or 2) reproductive tissues from client depositors that have not been tested or do not meet current Standards; or 3) directed donors who have completed all required testing and screening according to Standard but: a) had reactive test results; or b) are determined ineligible according to screening criteria.	B5.340

Standards # (14th edition)	Standard - Fragment	15th Location
F2.200 Special Circumstances in Release of Reproductive Tissues	In the case of release for one of the three circumstances listed above, the following documentation is required (refer to G3.210 and G3.220 for labeling requirements): 1) a written statement signed by a responsible person at the reproductive tissue bank disclosing the deviation(s) from Standards and description of potential risks to the recipient; and 2) acknowledgement from the medical provider indicating he/she: a) has received the written statement from the reproductive tissue bank and acknowledges the deviation(s) from Standards; b) has had ample opportunity to discuss the implication(s) with a responsible person at the reproductive tissue bank and other medical authorities; c) agrees to fully explain the implication(s) to the recipient and provide her ample opportunity to ask questions and consult with experts of her choice; and d) will document informed consent from the recipient.	B5.340
F2.300 Shipping Reproductive Tissue in Quarantine	If donor reproductive tissue is to be released before completion of the donor eligibility assessment, the tissue must be kept in quarantine during shipment. The labeling must include a statement that the donor eligibility assessment, has not yet been completed. It must also include a statement indicating the reproductive tissue must not be transplanted or transferred until the donor eligibility assessment, is complete.	H33.400
F3.000 Tissue Failing Review Process	Tissue failing any portion of the review process shall be maintained in quarantine pending resolution or disposal and shall not be released for transplantation. Unexplained discrepancies or deviations from specifications shall be fully investigated and documented.	B6.350
F3.100 Ineligible Donors	If a donor is deemed ineligible as a result of donor eligibility assessment or disease screening procedures, the finding shall be specifically stated in the donor record and in the release/disposition decision statement, and this determination must be described and communicated in writing in a timely manner to the tissue bank that recovered tissue. If the tissue is to be made available for nonclinical purposes from a donor who has been determined to be ineligible based on the results of required testing and/or screening, it must be labeled: 1) ‘‘For Nonclinical Use Only’’; and 2) with the biohazard legend. (SB) Permanent and temporary deferrals of living surgical bone donors and the reason(s) for such deferral shall be documented in the donor record.	~~B6.360~~B5.360
F3.200 Technical or Quality Assurance Elements	If tissue is deemed unsuitable for release for transplantation for reasons other than donor eligibility, the processing and release/disposition decision records shall specifically describe the reason(s) for the determination. If this tissue is to be made available for nonclinical purposes it must be labeled ‘‘For Nonclinical Use Only.’’	~~B6.360~~ B5.360
F4.000 Tissue Transfer	Before tissue is transferred to distribution inventory, appropriate release documentation shall be verified. Tissue for transplantation may then be placed in distribution inventory. The	H32.200

Standards # (14th edition)	Standard - Fragment	15th Location
F4.100 Transfer to Distribution Inventory	identification of the tissue transferred, date of transfer, and staff performing the verifications and transfer shall be documented.	
F4.200 Transfer to Other Inventory Locations	Disposition of tissue that is transferred shall be documented (e.g., discard, research, further processing). Date of transfer, staff involved, and verification of tissue identity shall also be documented.	H32.300
G1.000 Labels and Labeling G1.100 Nomenclature	Nomenclature used to describe tissue, cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) shall be specified in the SOPM and be applied consistently.	H15.510
G1.100 Nomenclature	For finished tissue, units of measurement and the processing that tissue has received shall also be specified in the SOPM.	H28.810
G1.200 Label List	A list of labels used shall be maintained, as well as an example of every label that is utilized by the tissue bank. Dates of use (start and discontinuance) shall be recorded. Changes pertaining to labels and communicating changes shall be expected from tissue banks that supply labels to other tissue banks and tissue distribution intermediaries.	H28.000
G1.300 Labeling Integrity	Labels shall be designed and qualified to be legible, indelible, and affixed firmly to the container under anticipated storage conditions for length of use. See K1.200. Labels applied by tissue bank staff shall not be removed, altered, or obscured except to correct labeling errors. When applicable, this also applies to labeling materials. Suppliers of labels deemed critical are responsible for establishing specifications.	H28.100
G1.400 Claims	All labeling claims shall be clear, accurate, substantiated, and not misleading.	H28.200
G2.000 Labeling Process G2.100 General Requirements	There shall be SOPs established and followed to ensure that approved labels, labeling, and packaging materials are used for tissue. Tissue labeling shall be documented at each step (e.g., unprocessed, in-process quarantined, rejected, released.	H28.300
G2.200 Relabeling	If tissue is to be relabeled for any reason, such as label detachment or to correct a labeling error, the tissue bank shall establish a relabeling procedure delineating the methods to be utilized, conditions under which tissue may be relabeled, and the staff authorized to perform such activities. The reasons for, and events surrounding, the relabeling of tissue shall be documented in the records. Relabeling methods shall consider storage conditions and label integrity (see G1.300).	H28.400
G2.300 Controls	Labeling control procedures shall be established to ensure label integrity, legibility and accuracy, and the establishment of checks to prevent transcription and other labeling errors. Electronic labeling systems shall possess adequate controls to prevent the erroneous labeling of tissue. Labeling reviews and checks shall be documented and shall be included in the records. If a sampling plan is used, it must follow a statistically valid method, such as ANSI/ASQ Z1.4: Sampling Procedures and Tables for Inspection by Attributes. The labeling area shall be inspected prior to the start of labeling activities to ensure that all labels and packaging materials from previous labeling have been removed. The inspection of the area shall be documented and included in the records.	H28.500

Standards # (14th edition)	Standard - Fragment	15th Location
G2.310 Label Inspection	Labels shall meet written specifications and be approved by quality assurance staff prior to release for use by a designated person. Labels not meeting such specifications shall be discarded. Date of receipt, date of inspection, and the names of the staff involved in receipt and inspection shall be documented.	H28.600
G2.320 Label Storage	The storage area for labels and labeling materials shall be clearly identified. Access should be restricted to authorized personnel only.	D2.100
G2.320 Label Storage	This is not applicable to labels included in tissue recovery packs.	H28.610
G2.330 Labeling Process Controls—Obsolete Labels	Procedures shall be established to retrieve obsolete and/or outdated labels and labeling materials from all labeling areas and inventory locations. As each type of label is removed from inventory, one label shall be retained for the archives and the surplus labels shall be discarded. The label list and the SOPM shall be updated accordingly.	H28.700
G2.340 Tissue and Container Visual Inspection	Prior to labeling a unit of processed tissue, the container shall be inspected for evidence of impurities, defects, broken seals, or contamination that could compromise the quality, or safety of the tissue. A sufficient area of the container shall remain uncovered to permit inspection of the contents whenever possible. Any tissue or container suspected of not meeting specifications shall be quarantined immediately pending further investigation and resolution following established procedures in the SOPM. This review shall be documented.	H28.800
G3.000 Labeling Information G3.100 Container Labels G3.110 Design	Container labels shall be designed to facilitate the use of uniform labeling techniques for each type of tissue.	H29.000
G3.120 Content	Except for autologous tissue and reproductive tissue, container labels shall include: 1) the tissue identification number; 2) descriptive name of the tissue and other information necessary for selection or use (e.g., size, right/left, medial/lateral, anterior/posterior); 3) expiration date (if applicable), including the month, day, and year or, if only the month and year are used, the expiration date must be clearly described in labeling as occurring at the beginning or the end of the month; 4) storage conditions, including recommended storage temperature and/or storage temperature range; 5) quantity or other characteristics of tissue expressed as applicable (e.g., volume, weight, dimensions, cell density, number of viable cells or a combination of these); 6) a reference to the package insert.	H29.100
G3.120 Content	The following information shall be included on the container label unless space limitations require use of a corresponding insert: 1) disinfection or sterilization procedure utilized (if applicable); 2) preservative (if utilized) and/or method of preservation (if applicable);	H29.200

Standards # (14th edition)	Standard - Fragment	15th Location
	3) potential residues of processing agents/solutions (e.g., antibiotics, ethanol, ethylene oxide, dimethylsulfoxide); and 4) name(s) and address(es) of tissue bank(s) responsible for determining donor eligibility, processing and distribution. Should more than two tissue banks be involved, the name of all tissue banks are required but the address is only required for the tissue bank determining donor eligibility.	
G3.120 Content	(A) The following information shall be included on the container label for autologous tissue unless space limitations require use of a corresponding insert: 1) the donor classification statement ''AUTOLOGOUS DONOR''; 2) definitive autologous donor identifying information such as the patient's hospital identification number, social security number, birth date, etc.; 3) a label or attached tag ''FOR AUTOLOGOUS USE ONLY''; and 4) if infectious disease testing or donor screening is not complete or has not been performed, a label indicating ''NOT EVALUATED FOR 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 is required.	H29.300
G3.120 Content	(R) Cryocontainers (e.g., vials, straws or ampules) shall be labeled so as to identify: 1) donor or client depositor unique identifier and/or other code that can be used by the reproductive tissue bank to identify the date the specimen was cryopreserved and the stage of development at cryopreservation, where applicable; and 2) name, initials, or other code that can be used to identify the reproductive tissue bank at which the specimen was processed.	H29.400
G3.200 Summary of Records and Package Insert	Tissue determined to be suitable and released for transplantation shall be accompanied by a summary of records and package insert. A summary of records is not required if a donor eligibility determination is not required (i.e., autologous tissue and certain types of reproductive tissue).	H30.000
G3.210 Summary of Records Content	A summary of records is required when donor eligibility assessment has been completed and shall include: 1) a statement that the tissue was prepared from a donor determined to be eligible based on the results of screening and testing. All results of relevant communicable disease tests performed on specimens from the donor and used for release of tissue shall be listed. Relevant tests include those tests that are required (see D4.230). For example, the CMV test result used must be listed for reproductive tissue. If a test for anti-HTLV I and/or anti-HTLV II was performed it must be reported; 2) the name and address of the establishment that made the donor eligibility assessment; and	B6.620

Standards # (14th edition)	Standard - Fragment	15th Location
	3) a statement that the communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority having jurisdiction apply in regard to required labeling involving donor infectious disease test results.	
G3.210 Summary of Records Content	(R) A statement noting the reason for the determination of ineligibility in the case of tissue from a directed donor who is ineligible based on screening and/or testing.	B6.620
G3.220 Package Insert Content	Package Insert Content The summary of records may be included in the package insert. The package insert shall contain the following information: 1) a statement limiting use to specific health professionals (e.g., physicians, dentists, and/ or podiatrists); 2) a statement that the tissue is intended for use in one patient, on a single occasion only, or as is applicable for reproductive tissue; 3) known contraindications (if any) to the use of the tissue; 4) warnings and list of known possible significant adverse reactions; 5) a statement that adverse outcomes potentially attributable to the tissue must be reported promptly to the tissue supplier; 6) presence of known sensitizing agents (if any); 7) a statement that indicates that the tissue may transmit infectious agents; 8) a statement, if applicable, that the tissue may not be sterilized or re-sterilized. 9) dosage information (if applicable); 10) description of how the tissue was supplied (e.g., frozen, lyophilized, irradiated, demineralized or partially demineralized, see E2.612); 11) type of antibiotics present (if applicable); 12) concentration of preservative(s) and/or cryoprotectant(s) in final package solution (if applicable); 13) instructions for opening the package and/or container; 14) instructions for preparation of tissue for transplantation; 15) expiration time of tissue following reconstitution (upon preparation for use); 16) instructions indicating that once a container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded; 17) acceptable storage conditions and tolerance limits; 18) special instructions required for the particular tissue, when applicable (e.g., ‘‘DO NOT FREEZE,’’ “DO NOT X-RAY,” “DO NOT IRRADIATE”);	H30.100

Standards # (14th edition)	Standard - Fragment	15th Location
	19) a statement that it is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant and that recipient records must be maintained for the purpose of tracing tissue post-transplantation; 20) a statement that the tissue is ‘‘DONATED HUMAN TISSUE,’’ when applicable; and 21) effective date or other traceable version identifier. NOTE: Except for client depositors, directed donors of reproductive tissues, and autologous tissues, the accompanying records required by this section must not contain the donor’s name or other personal information that might identify the donor.	
G3.220 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.	H30.200
G3.220 Package Insert Content	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.	H30.300
G3.220 Package Insert Content	The preparation instructions shall be sufficiently detailed and unambiguous to allow operating room personnel of average skill to follow and complete the procedure successfully.	H30.400
G3.220 Package Insert Content	(R) See F2.200 for additional requirements that may be applicable in certain directed donor or client depositor situations.	H30.510
G3.220 Package Insert Content	Reproductive tissue in the following categories require additional information in package inserts as listed below:	H30.500

Standards # (14th edition)	Standard - Fragment	15th Location
	1) If the intended recipient is the sexually intimate partner of the gamete provider(s): Note: a Summary of records is not required for this category. a) For all reproductive tissue, include the statement: ‘‘For use by Sexually Intimate Partner Only.’’ b) For all reproductive client depositors who were not tested or screened using all parameters required for either a semen or egg donor, including the required tests and time limits for donor testing, include the statements: 1.‘‘Not evaluated for Infectious Substances’’; and 2.‘‘WARNING: Advise Recipient of Communicable Disease Risks.’’ c) For all reproductive client depositors who have reactive or positive test results: 1. biohazard symbol; and 2. ‘‘WARNING: Reactive test results for (insert name of test).’’ 2) If the intended recipient is NOT the sexually intimate partner of either gamete provider, the following labeling is required in addition to a summary of records: a) Directed donors (semen, oocyte, and/or embryo) with reactive test results: 1. biohazard symbol; 2.‘‘WARNING: Reactive test results for (insert name of test)’’; 3.‘‘WARNING: Advise Recipient of Communicable Disease Risks.’’ b) Directed donors (semen, oocyte, and/or embryo) determined to be ineligible based upon risk factors for or clinical evidence of relevant communicable disease agents or diseases, including the physical examination: 1.biohazard symbol; and 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 anonymous or directed embryo donors in cases where the gamete provider(s) was (were) not initially tested as donors, but were re-tested following 6-month quarantine, include the statement: ‘‘Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive tissue, but have been performed subsequently.’’ (Note: A summary of records is not required for this category, however, a summary of the test results must be included.) 4) If the intended recipient is NOT the sexually intimate partner of a gamete provider who initially cryopreserved reproductive tissue as a client depositor but was subsequently screened and tested as a directed donor in cases where additional collections are unavailable, include the statement: “Advise recipient that screening and testing of the donor(s) were not performed at the time of cryopreservation of the reproductive tissue, but have been performed subsequently.” 5) Reproductive tissue intended for research:	

Standards # (14th edition)	Standard - Fragment	15th Location
	a) Client depositor reproductive tissue when gamete provider(s) were not tested or screened using all parameters required for either a semen or egg donor, including the required tests and time limits for donor testing, or donor (anonymous or directed) tissue has not completed 6-month quarantine release requirement: 1. ‘‘For Non-Clinical Use Only’’; and 2. ‘‘Not evaluated for Infectious Substances.’’ b) Anonymous donor tissue that has completed 6-month quarantine release requirement: 1. ‘‘For Non-Clinical Use Only.’’ c) Client depositor or donor (anonymous or directed) tissue from gamete provider(s) who had reactive test results OR have been determined to be ineligible: 1. biohazard label; 2. ‘‘For Non-Clinical Use Only’’; and 3. if applicable, ‘‘WARNING: Reactive test results for (insert name of test).’’	
G3.300 Transport Package Label Content G3.310 Domestic Shipments	The transport package label shall include the following information: 1) name, address, and telephone number of the distribution facility; 2) name and address of the destination; 3) 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; 6) type and quantity (when the quantity is applicable) of refrigerant or other hazardous materials enclosed in the transport package; and 7) any special handling instructions, when applicable (e.g., “DO NOT FREEZE,” “DO NOT X-RAY,” “DO NOT IRRADIATE”).	H31.000
G3.320 International Shipments	Labels for international shipments shall contain all of the information required for domestic shipments; however, information may be modified to meet requirements of the federal government and those of the receiving country.	H31.000
H1.000 Distribution and Dispensing	There shall be SOPs for the following: receipt of tissue orders, unit selection, final container, and/or package inspection, shipping, and transportation of tissue for transplantation.	H32.100
H1.100 Tissue Distribution and Dispensing Restrictions	Provision of tissue for transplantation shall be restricted to hospitals, free-standing medical facilities, tissue banks, tissue dispensing services, and end-users (e.g., physicians, dentists, podiatrists or other medical professionals) for use in recipients with the veterinary use exception that follows. Human tissue for transplantation shall not be offered, distributed or dispensed for veterinary use unless such use is specifically granted in a document of gift/authorization or in a record of informed consent. If tissue is provided to a tissue	H33.000

Standards # (14th edition)	Standard - Fragment	15th Location
	distribution intermediary, the tissue distribution intermediary shall meet the requirements of Section M of these Standards. Controls must exist to ensure distribution restrictions are met such as those found on the document of gift/authorization or in a record of informed consent. Distribution restrictions must be communicated to distributors. Periodic verification of activities performed by the tissue distribution intermediary shall be documented (e.g., a paper audit, on-site audit, on-site inspections, etc.). See B1.520.	
H1.110 Client Depositor Authorization	(R) Reproductive tissue shall be released for use by the client depositor or the client depositor's sexually intimate partner only. Prior to release of the specimens, a statement containing a verified signature from the client depositor shall be obtained indicating the relationship between the intended recipient and the client depositor.	H33.100
H1.110 Client Depositor Authorization	Reproductive tissue for potential therapeutic insemination, use in another assisted reproductive technology procedure, or for other specified disposition shall be released as per written authorization of the client depositor, if of legal age or, if not, by that of parent, legal guardian, or his/her legally appointed designee.	H33.200
H1.120 Reproductive Tissue Distribution Restrictions	(R) A client depositor who requests that his/her reproductive tissue be distributed to a recipient, who is not the client depositor or who is not the sexually intimate partner of the client depositor, shall be treated as a directed donor(s). All directed donor(s) must be fully tested and screened in a manner consistent with donor protocols and these Standards. If additional collections of reproductive tissue are unavailable due to the infertility or health condition of the now directed donor, appropriate measures should be taken to screen and test the directed donor prior to distribution (excluding testing for Neisseria 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. See F2.300.	H33.300
H1.120 Reproductive Tissue Distribution Restrictions	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.	H33.500
H1.130 Donor Conceived Offspring Limitations	(R) A written policy addressing limitation of the number of offspring by a gamete donor shall be established. The policy shall include the upper limits deemed acceptable to the reproductive tissue bank and shall describe the methods that will be used to comply.	H33.600
H1.200 Distributing Tissue to Other Tissue Banks/Dispensing Services	When a tissue bank distributes tissue obtained from another tissue bank or tissue distribution intermediary, all accompanying original labeling materials or other enclosures shall be distributed with the tissue.	H33.700
H1.210 Consignment Inventory Management	If tissue is provided on consignment, the distributing tissue bank shall maintain procedures to ensure traceability and that appropriate storage conditions are maintained during consignment, transfer or return.	H33.800

Standards # (14th edition)	Standard - Fragment	15th Location
H1.300 Requests for Donor Status and Tissue Processing Information	Donor risk assessment, tissue-related information, and tissue processing details shall be made available to the end-user upon request, except such information that may infringe upon the confidentiality of donor information.	B8.200
H1.400 Distribution Records	Records shall be maintained by the tissue bank that distributes tissue (including unfinished or as yet unreleased tissue) to other entities. These records shall be designed to permit tissue to be traced from the donor to a consignee or end-user, and from a consignee or end-user back to the donor. Tissue distribution records shall include: 1) date of order placement; 2) name and address of consignee; 3) name of individual placing the order; 4) type and quantity of tissue ordered; 5) information pertaining to tissue shipped including: a) identification number(s) of tissue(s); b) collection and/or expiration date of tissue; c) date of shipment; d) type of refrigerant, and quantity of refrigerant when applicable, in the shipment; e) mode of transportation and/or courier; and f) name of the staff member filling the order. 6) identifying information, if available, about the intended recipient.	B6.700
H1.410 Responsibility	The tissue bank shall establish recipient follow-up data collection protocols, and procedures to evaluate information received.	H35.000
H2.000 Tissue for Research	Facilities providing tissue for research and other non-transplantation purposes shall develop detailed relevant specific policies and procedures. Informed consent or authorization for research and/or education shall be obtained. See the series of standards at D2.000 and D3.000.	B5.100
H2.100 Written Requests	All requests for human tissue intended for research use shall be submitted in writing. The request shall indicate the type of tissue requested and how it will be used as well as the name, address and affiliation of the principal investigator accepting responsibility for receipt of the tissue.	~~B6.110~~ B5.110
H2.200 Review and Approval	Tissue requests for research purposes shall be reviewed and approved based on legal, ethical, and technical considerations defined in the SOPM.	~~B6.120~~ B5.120
H3.000 Packaging and Shipping H3.100 Solutions	Any specifically required solutions not readily available to the end-user that are needed to prepare the tissue for use shall be made available to the utilizing facility.	H34.100
H3.200 Integrity	Packaging shall be designed to ensure tissue quality and prevent contamination of the contents of the final container(s).	H34.200

Standards # (14th edition)	Standard - Fragment	15th Location
H3.300 Tissue Storage Environment	Maintenance of defined environmental conditions during transit shall be required. Specific environmental conditions shall be in accordance with the SOPM, these Standards and applicable laws and regulations.	H34.300
H3.400 Validation and Expiration of Transport Package	If tissue to be shipped requires specific environmental conditions other than ambient temperature, the capability of the transport package to maintain the required environmental conditions shall be demonstrated and documented in a validation study. The length of time that these conditions can be maintained by the transport package shall also be determined and documented. Expiration dates (and time if applicable) of the transport package shall be noted on the outside of the transport package.	H34.400
H3.500 Quality Control of Reusable Shipping Packages	If tissue to be shipped requires specific environmental conditions other than ambient temperature, and the transport package can be reused, QC monitoring of the transport packaging must be performed according to the SOPM to verify package integrity has been maintained. These QC checks shall be documented.	H34.500
H3.600 Pre-shipping Inspection	Prior to shipping, packages shall be inspected to ensure the external packaging and labels are undamaged, the tissue is not expired and the tissue being shipped is consistent with the tissue requested. The exterior of the transport package shall be inspected to verify that requirements in G3.310 are met. These inspections shall be documented, including identification of staff conducting inspections.	H34.600
H3.700 Transportation	The mode of transportation selected shall be determined by any special shipping and handling requirements of the tissue and/or shipping refrigerants, by shipping restrictions of commercial carriers, and the urgency of the tissue request.	H34.700
H4.000 Return of Tissue	A tissue bank shall establish a policy authorizing or prohibiting the return of tissue in its original, unopened container. If returns are permitted, the integrity of the container, package, and labeling shall be examined for evidence of contamination or tampering. If there is any evidence of contamination, tampering, mishandling, or failure to maintain required storage temperatures, tissue shall not be returned to distribution inventory.	H34.800
H4.000 Return of Tissue	Information pertaining to the return of tissue shall be recorded in the disposition records for that shipment of tissue as follows: 1) documentation of package and/or container examination; 2) documentation of end-user handling, storage, and shipping conditions; 3) reason for the return; 4) disposition of the returned tissue(s); and 5) date and name of the staff member authorized to evaluate and determine the disposition of the tissue(s).	B6.720
H4.100 Temperature Records	For tissue that requires controlled environmental temperatures, at a minimum, documentation is required that attests the tissue was maintained at required storage temperatures.	H34.810

Standards # (14th edition)	Standard - Fragment	15th Location
H5.000 Field Corrections and Removals	Tissue banks shall have specific written policies and procedures for the initiation and performance of a field correction or removal, if applicable. ~~Procedures shall include, but are not limited to, the following:~~ ~~1) evaluation and determination by a responsible person(s);~~ ~~2) timely identification and management of affected inventory;~~ ~~3) assessment of associated health risk;~~ ~~4) field communications (e.g., field notification);~~ ~~5) types of field corrections or removals (e.g., recall, market withdrawal) and stock recovery~~ ~~6) reporting requirements;~~ ~~7) evaluation of effectiveness;~~ ~~8) termination or closure;~~ ~~9) documentation and record requirements; and~~ ~~10) review by management with executive responsibility.~~	B7.300
H5.000 Field Corrections and Removals	Procedures shall include, but are not limited to, the following: 1) evaluation and determination by a responsible person(s); 2) timely identification and management of affected inventory; 3) assessment of associated health risk; 4) field communications (e.g., field notification); 5) types of field corrections or removals (e.g., recall, market withdrawal) and stock recovery 6) reporting requirements; 7) evaluation of effectiveness; 8) termination or closure; 9) documentation and record requirements; and 10) review by management with executive responsibility.	B7.310
H5.000 Field Corrections and Removals	Tissue banks not directly responsible for conducting field corrections or removals, but that perform activities that could lead to the need for a field correction or removal (e.g., tissue recovery, donor screening, donor testing) shall have policies and procedures for the timely notification of all affected parties regarding information related to tissue safety or regulatory requirements.	B7.300
H5.100 Circumstances That May Require Field Correction or Removal	The need to perform a field correction or removal may be identified as a result of a complaint, adverse outcome, accident, error, deviation, audit, or by any other means. An evaluation to determine if field correction or removal is warranted should be made whenever distributed tissue may not meet specifications related to safety, quality, traceability, identification, function and/or use. This evaluation must consider both risk to health posed by the tissue and applicable regulatory requirements and be documented.	B7.320

Standards # (14th edition)	Standard - Fragment	15th Location
H5.200 Notification Responsibilities	Upon discovery of the need for field correction or removal, the tissue bank shall promptly notify all entities to which affected tissue was distributed or dispensed as well as the tissue bank that recovered the tissue, if applicable.	B7.330
H5.300 Handling of Tissue	All tissues not already transplanted, which are subject to field correction or removal, shall be located and quarantined pending resolution of the issue.	B7.340
H5.400 Reporting Requirements	Tissue banks shall comply with all field correction and removal reporting requirements for applicable federal, state and international government/competent authorities under which they operate or distribute tissue. For additional information, refer to FDA Guidance for Industry: Product Recalls, Including Removals and Corrections at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections	B7.350
H5.500 Field Correction and Removal Records	All information relating to the field correction or removal of tissue and resulting communications shall be documented and retained on file at least 10 years beyond the date of distribution, the date of transplantation (if known), disposition, or expiration of the tissue, whichever is latest. The file shall include the following information: 1) events precipitating the field correction or removal; 2) identification and location of affected tissue, including quarantine steps; 3) associated risk assessment; 4) type of field correction or removal (e.g., recall, market withdrawal) and stock recovery; 5) steps taken to correct or retrieve tissue; 6) documentation of all related communications (e.g., phone calls and/or written correspondence, including copies of field notifications or letters and a list of those to whom notice was sent); 7) final disposition of the tissue; 8) copies of reports to regulatory authorities, accreditation organizations and certification bodies, if required; 9) corrective actions recommended and implemented; and 10) documentation of review; if of a medical nature, review by the Medical Director or licensed physician designee.	B6.730
J1.000 Standard Operating Procedures Manual (SOPM)	Each tissue bank shall develop written detailed policies and procedures in a standardized format, which shall be collected into a standard operating procedures manual (SOPM).	B4.000
J1.000 Standard Operating Procedures Manual (SOPM)	These shall be available at all locations for which they are designated, used, or otherwise necessary, and shall be utilized to ensure that all tissue released for transplantation is in compliance with these Standards and applicable laws or regulations.	B4.100
J1.100 Identification and Control	Policies and procedures shall establish a document control system for procedures and forms including requirements for:	B4.200

Standards # (14th edition)	Standard - Fragment	15th Location
	1) approval prior to use for intent and compliance to relevant regulatory requirements and standards; 2) reviewing revisions and re-approval as needed; 3) identification of the current revision status and of changes to previous revisions; 4) distribution to points of use (i.e., all locations where access to procedures is needed); 5) legibility and ease of identification; and 6) prevention of the unintended use of obsolete documents and suitable identification controls for archived documents.	
J1.200 Contents	The SOPM shall specifically include, but shall not be limited to policies and procedures for: 1) informed consent or authorization, donor eligibility criteria, donor screening methods, time limits for tissue recovery, notification of confirmed positive test results, information sharing, construction of records, and, if applicable, reconstruction and final disposition of a deceased donor's body (series of standards at C2.000, D2.000, D3.000, D4.000 and D5.000); 2) tissue collection, recovery, acquisition and handling, including recovery site assessment, recovery, materials management/supplies management, processing, packaging, quarantine, labeling, storage, donor eligibility review, and/or release of tissue (series of standards at D5.000, D6.000 and Sections E, F and G); 3) laboratory tests performed in-house, including establishment of appropriate specifications, standards, and test procedures to assure that tissue is safe and quality is addressed; and for contracted laboratory testing defining which tests shall be performed and how test results shall be received, reviewed, interpreted, and managed (B1.600, series of standards at D4.200, series of standards at F1.100, F1.200, F1.300 and F2.000, series of standards at K1.300, series of standards at K2.000); 4) purchasing controls, order receipt, finished tissue selection, final container inspection and packaging and shipping of tissue, as well as criteria for returning and reissuing tissue (K1.300, series of standards at M3.000, M4.000, M5.000 and Section H); 5) external audits for services, suppliers, contractors, and consultants, when indicated (series of standards at K6.000, and K1.300 and B1.520); 6) record management to maintain traceability, retain records, and facilitate (if necessary) field corrections and removals, and recipient notification by documentation of each step of tissue production from the point of collection, recovery and identification to final distribution of the tissue (series of standards at C1.000, H5.000, L4.000, M6.000 and M7.000); 7) quality assurance and quality control of supplies, equipment, instruments, reagents, labels, and processes employed in tissue collection, recovery, acquisition, processing, packaging, labeling, storage, distribution, and preparation of tissue for transplantation, including policies or procedures for: a) labeling of cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) (D4.200, series of standards at D5.000, and Section G);	B4.300

Standards # (14th edition)	Standard - Fragment	15th Location
	b) monitoring storage temperatures, for defining tolerance limits, and for describing what, when, and how corrective actions are to be taken for implementing emergency transfers and determining alternative storage and monitoring methods for tissue and reagents (F4.200, series of standards at E3.000 and M2.000); c) investigating, documenting and reporting accidents, errors, complaints, and adverse outcomes (series of standards at K4.000); d) performing field corrections, removals, and stock recoveries, if applicable, and/or the timely notification of affected parties regarding information related to tissue safety or regulatory requirements (series of standards at H5.000, L6.000 and M6.000); e) of notifying management with executive responsibility of any field corrections, or removals, stock recoveries, investigations, inspection reports, or regulatory actions (series of standards at H5.000 and K4.000); f) supplies, reagents, materials and equipment and identifying those that are considered critical (D5.100, E2.400, E2.000, J5.100); g) maintaining equipment management programs that include inspection, maintenance, repair and calibration for the purpose of maintaining equipment (series of standards at J5.000); h) describing the receipt, identification, storage, handling, sampling, testing, and subsequent approval or rejection of containers, packaging materials, labels, reagents, and supplies (series of standards at D5.000, E1.000, and E2.000, J5.500 and Section G); and i) monitoring in-process controls and managing events such as failed test runs and failure of a lot to meet established specifications (Section K). 8) assigning time limits and temperature for pre-processing quarantine storage, processing, and expiration dates (E2.520, E3.400, H3.400 and K1.200); 9) handling requests for research tissue (series of standards at D1.200, H2.000); 10) disposing of medical waste and other hazardous waste (series of standards at J3.000); 11) covering emergency and safety including reporting of staff injuries and potential exposure to blood-borne pathogens (series of standards at J3.000); 12) maintaining the sanitation of facilities and describing the cleaning schedules, methods, equipment and materials to be used (series of standards at J4.000 and J5.000); 13) describing the design or arrangement of the physical plant to meet operational needs such as designation of spaces, environmental monitoring, and security (series of standards at J4.000); 14) describing manual methods for tissue banking activities in the event of electronic or equipment malfunction (series of standards at K7.000); 15) describing training program requirements for technical and QA staff (series of standards at J2.000); 16) identifying and controlling procedures and forms including requirements (J1.100, J1.400)	

Standards # (14th edition)	Standard - Fragment	15th Location
	17) defining appropriate use, confidentiality, security and retention of captured images of the donor and/or tissues.	
J1.300 Implementation	The SOPM and associated process validation studies shall be reviewed and approved by appropriate individuals as dictated by content. All policies and procedures of a medical nature shall be reviewed and approved by the Medical Director. Upon implementation, all portions of the SOPM must be followed as written. Minor deviations from the SOPM may be authorized in writing by the Medical Director, or QA designee provided the deviation is in compliance with these Standards.	B4.400
J1.400 Modifications	The SOPM shall be updated to reflect modifications or changes, and shall include a description of the change, justification for the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.	B4.500
J1.500 References	Copies of publications cited in support of policies or procedures shall be maintained at the tissue bank.	B4.600
J1.600 Annual Review	An annual review of the SOPM, and the safety manual if separate, shall be performed and documented: 1) the Medical Director shall review relevant policies and procedures of a medical nature (e.g., donor eligibility, adverse outcomes); 2) management with executive responsibility, or a responsible person designee, shall review policies and procedures to ensure adequacy in regard to current practice, and applicable standards, laws or regulations; and 3) staff shall review policies and procedures for which they have been trained and are currently responsible.	B4.700
J1.700 Staff Access and Review	Current copies of the SOPM applicable to specific staff functions shall be in designated locations and available to the staff at all times. New and revised policies and procedures shall be reviewed by applicable staff prior to implementation.	~~B4.800~~ B4.100, B4.700
J1.700 Staff Access and Review	Documentation of review and any associated training shall be maintained at least 16 years after termination of employment or as required by applicable laws or regulations, whichever is longer.	B12.200
J1.800 Inspections	The SOPM shall be made available for inspection upon request by the AATB or authorized regulatory agencies.	B4.800
J1.900 Archives	A file of archived SOPs shall be maintained in historical sequence for 16 years after discontinuation. The records shall indicate the inclusive dates that each policy and/or procedure (including forms, letters, labels, and other specific documents) was in use.	B9.000
J2.000 Technical and Quality Assurance Staff – Training/Continuing Education J2.100 Training	Training shall be conducted for technical and QA staff to maintain competency in procedures and familiarity with applicable regulations and AATB Standards. Training shall encompass the	C2.100

Standards # (14th edition)	Standard - Fragment	15th Location
	following areas, as applicable: new employee orientation; the SOPM; technical training; QA; electronic systems; and continuing education. All training activities shall be documented.	
J2.100 Training	Training records shall be retained for 16 years after termination of employment or as required by law, whichever is longer.	B12.200
J2.100 Training	1) Personnel shall be made aware of their designated functions and of the consequences of the improper performance of their designated functions.	C2.110
J2.100 Training	2) Personnel performing verification and validation activities shall be made aware that accidents and errors may occur during the performance of their designated functions.	C2.120
J2.100 Training	(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.	C2.130
J2.200 Competency	Technical staff must demonstrate competency for their designated functions (including a thorough understanding of relevant policies, procedures, process controls, and regulatory requirements).	C2.200
J2.300 Continuing Education	Technical staff shall participate in continuing education, which may include training courses, technical meetings, and any other educational programs pertaining to designated functions. Such participation shall be documented.	C2.300
J2.400 Training Records	Training records shall be maintained for each employee with documentation of the following: 1) delineation of functions that each employee is authorized and trained to perform; 2) initial training of new employees; 3) initial training of newly designated functions of existing employees; 4) review and training prior to implementation of new and/or revised sections of the SOPM; 5) annual review of policies and procedures for the employee's designated functions, including safety procedures (see J1.600); 6) annual safety training; and 7) attendance at workshops, seminars, meetings, or other continuing education programs.	B11.100
J3.000 Safety Practices J3.100 Work Environment	Each tissue bank shall provide and promote a safe work environment by developing, implementing, and enforcing safety procedures. These procedures shall be incorporated into the SOPM or reside in a specific Safety Manual which is referenced by the SOPM.	D4.000
J3.100 Work Environment	Procedures shall be written in accordance with applicable Occupational Safety and Health Administration (OSHA) regulations, guidelines established by the CDC, and applicable laws or regulations. All safety procedures shall be reviewed annually.	D4.000
J3.200 Procedures	Safety procedures shall include, but are not limited to, the following: 1) instructions for contacting emergency personnel and the establishment of evacuation routes and procedures in the event of fire or disaster;	D4.100

Standards # (14th edition)	Standard - Fragment	15th Location
	2) procedures for management of worker injury including possible exposure to hazardous materials or blood-borne pathogens. Such procedures shall require a written report of the incident, including documentation of medical care received, management notification, and actions to prevent recurrence; 3) delineation of Universal Precautions as defined by the CDC; 4) procedures specifying the proper storage, handling, and utilization of hazardous materials, reagents and supplies, including pertinent Safety Data Sheets; and 5) procedures outlining the steps to be followed in cleaning bio-hazardous spills.	
J3.300 Hazardous Materials Training	A training program shall be designed to inform employees about chemical, biological, and, if applicable, radioactive hazards of the workplace as well as the use of personal protective equipment to reduce the risk of exposure to these hazards.	D5.300
J3.400 Universal Precautions	Universal Precautions, as defined by the CDC, shall be implemented and enforced to reduce the potential exposure of staff to communicable diseases.	D4.100
J3.500 Immunization	Hepatitis B vaccination shall be offered free of charge to all non-immune personnel whose job-related responsibilities involve the potential exposure to blood-borne pathogens. Personnel files shall include documentation of receipt of vaccination or refusal of immunization with hepatitis B vaccine.	D5.400
J3.600 Hazardous Waste Disposal	Biohazardous human tissue, medical waste, and other hazardous materials shall be disposed of in accordance with applicable laws or regulations in such a manner as to minimize environmental impact and exposure to personnel. Medical waste and hazardous material tracking records shall be maintained in accordance with the regulations of the regulatory agency charged with management oversight.	D6.100
J3.700 Personnel J3.710 Attire	Personnel engaged in the Recovery, Processing, Preservation, or packaging of tissue shall be suitably attired. Attire shall include personal protective equipment to minimize the spread of transmissible pathogens among and between donors, tissue, and staff.	D5.100
J3.720 Infections	Any staff member shown (either by medical examination or supervisory observation) to have a serious infectious condition (e.g., an apparent illness or open lesion) that may adversely affect the safety of the tissue shall be excluded from the recovery, processing, preservation, or packaging of tissue until the condition is determined to be resolved. All staff members shall be instructed to report, to supervisory personnel, any health conditions that may have an adverse effect on tissues.	D5.500
J4.000 Facilities J4.100 General	The physical plant shall be designed or arranged to meet operational needs. The premises shall be maintained in a clean, sanitary, and orderly manner with adequate plumbing, drainage, lighting, ventilation, and space. Adequate, clean, and convenient hand washing facilities shall be available for personnel and for donors when applicable. Specific suitability parameters for the recovery site (see D5.500), or where collection of anonymous semen donation takes place, shall be evaluated. Areas of the facility where donor screening and/or	Preempted (see B4.300)

Standards # (14th edition)	Standard - Fragment	15th Location
	obtaining authorization or informed consent takes place should be arranged to prevent errors and maintain confidentiality of information discussed.	
J4.200 Designated Space	To prevent errors and/or cross-contamination of tissue, the following critical procedures shall be performed in designated areas of adequate size: 1) donor screening; 2) obtaining authorization or informed consent; 3) processing; 4) quarantine storage of in-process materials; 5) other quarantining; 6) labeling; 7) storage of distributable inventory; 8) quality assurance/control functions; 9) receipt and storage of containers, container labels, supplies, and reagents; 10) storage of medical waste; 11) irradiation and other sterilization procedures; and 12) final product inspection and distribution activities.	Preempted (see D1.100)
J4.210 Routine Decontamination and Record Retention	Facilities used for collection, recovery, processing, or preservation, or for other activities where there is potential for cross-contamination of tissue or exposure to blood-borne pathogens, shall be subjected to routine, scheduled, documented decontamination (sanitation) procedures. Cleaning events performed by tissue bank personnel shall be documented and retained for three (3) years after their creation.	B10.000
J4.300 Environmental Monitoring	Environmental monitoring procedures shall be established, where appropriate, as part of the QA program. Monitoring procedures may include, but are not limited to, static and dynamic particulate air samplings (e.g., air bacterial content assays) equipment and personnel monitoring where tissue contact occurs, and work-surface cultures. Frequency of sampling shall be based on related industry guidelines, the results of prior samplings or suitable justification. Procedures shall include tolerance limits and corrective actions to be implemented in the event that limits are exceeded. Each monitoring activity shall be documented and results trended.	D1.130
J4.300 Environmental Monitoring	Environmental monitoring at the recovery site is not required, however pre-established parameters designed to prevent contamination and cross-contamination must be met (see D5.500).	D1.120
J4.300 Environmental Monitoring	Rooms used for storage of liquid nitrogen tanks should be periodically monitored for oxygen levels if not appropriately ventilated.	D1.140
J4.400 Security	Tissue banks shall maintain adequate physical security to safeguard tissue inventory and records as well as to prevent the entry of unauthorized individuals. Such security may be in the form of personnel, electronic or mechanical devices or barriers, or configuration of the	Preempted (see D2.000)

Standards # (14th edition)	Standard - Fragment	15th Location
	physical plant. Limited access areas shall be established as appropriate, permitting entry of only those personnel (including auditors and inspectors) who are authorized by supervisory personnel.	
J5.000 Equipment and Instruments J5.100 Selection	Equipment and instruments should be of appropriate quality for their intended function and use. Equipment used in the recovery, processing, preservation, packaging, or storing of tissue shall be appropriately sized, designed, and located to facilitate use, cleaning, decontamination, and maintenance. Equipment shall be constructed so that surfaces contacting tissue shall not alter the safety or quality of the tissue. See E2.400.	E3.100
J5.200 Operation	Equipment shall be operated according to manufacturer's recommendations unless it is demonstrated that modifications to operating procedures will not adversely affect either the quality of tissue or personnel safety. Use of instruments shall be appropriate for the task.	E3.200
J5.300 Qualification and Maintenance	Instruments, apparatus, gauges, and recording devices shall be calibrated or verified and routinely maintained, inspected, monitored, cleaned, decontaminated, sterilized (when applicable), and repaired per the manufacturer's requirements and recommendations.	E3.000
J5.300 Qualification and Maintenance	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.	E6.700
J5.310 Requalification/Recalibration	Following repairs and system upgrades, equipment should be recalibrated or verified according to procedures in the SOPM that have been designed to be in compliance with the manufacturer's requirements and recommendations.	E3.500
J5.400 Decontamination	Equipment and instruments shall be cleaned, or decontaminated, and sterilized (when applicable) at appropriate intervals in accordance with the SOPM to prevent malfunction, contamination, cross-contamination, or accidental exposure of tissue or staff to blood-borne pathogens.	E3.300
J5.400 Decontamination	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.	E5.000
J5.400 Decontamination	Instruments used to recover and/or process dura mater, vertebrae, or ocular tissue that are known to have come in contact with tissue from a donor suspected or confirmed to have a prion-associated disease, must be removed and destroyed.	E3.400
J5.400 Decontamination	Tissues from other donors for which those instruments were subsequently used for recovery or processing shall be identified, quarantined, withdrawn and/or recalled pending further evaluation.	E3.400
J5.500 Sterilization	Equipment and instruments shall be sterilized if they are intended to come into contact with tissue or if they have the potential of contaminating tissue, if not sterilized. Sterilization must be performed in a manner that is consistent with applicable industry standards.	E5.100

Standards # (14th edition)	Standard - Fragment	15th Location
J5.500 Sterilization	To ensure that sterilization is successful during routine processing of equipment and instruments, it is important that the following be performed at required or recommended intervals: 1) Regular maintenance of the sterilization equipment: The sterilization equipment manufacturer's maintenance recommendations must be met. 2) Use of routine lot release controls: Routine lot release controls must be performed according to the specifications, and at the intervals, outlined in the following table. 3) Performance of efficacy monitoring: The specifications and intervals for required efficacy monitoring are outlined in the following table. In addition to the specifications found in the table, additional efficacy monitoring may be necessary, such as leak testing, dynamic air removal testing (DART test), and Bowie-Dick testing, and process challenge device (PCD) testing. Guidance on efficacy monitoring may be found in sterilization equipment manuals, consulting with the sterilization equipment manufacturer, or can be found in applicable industry standards: a) steam sterilizers: ANSI/AAMI ST79; or b) ethylene oxide sterilizers: ANSI/AAMI ST41.	E5.200
J5.500 Sterilization	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.	E5.200
J5.500 Sterilization	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.	E5.200

<table>
<tr><th>Standards # (14th edition)</th><th>Standard - Fragment</th><th>15th Location</th></tr>
<tr><td></td><td>
<table>
<tr><th colspan="6">Table of Common Sterilization Methods, Cycle Parameters, Controls & 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>Recommend -ed</th><th>Required</th><th>Recommend -ed</th></tr>
<tr><td>Steam

Ethylene Oxide (EO)

Vaporized Hydrogen Peroxide (VHP)</td><td>Use the recommended parameters (e.g. exposure times, temperatures, pressures, drying times, weight and geometric complexity of load, etc.) specified in the sterilizer manufacturer’s operator’s manual, or validate other cycle parameters in accordance with industry standards.</td><td>Verify cycle parameters were met</td><td>1. Utilize internal and external chemical indicators

2. Utilize appropriate PCD and verify as negative prior to release of load</td><td>Weekly: Utilize appropriate PCD*</td><td>Daily: Utilize appropriate PCD</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>
<tr><td>Other (e.g., novel, nontraditional)</td><td colspan="4">Follow manufacturer’s instructions for method selected. Validation is expected if manufacturer’s instructions are not followed.</td></tr>
</table>
</td><td>E5.200</td></tr>
<tr><td>J5.500 Sterilization</td><td>* Weekly use of a PCD is not required if a PCD is already being used in each load as recommended for “Routine Release Controls.”</td><td>E5.200</td></tr>
<tr><td>J5.600 Storage Equipment</td><td>Equipment used for storage of tissue shall be identified to facilitate monitoring of temperature and location of in-process, quarantine, and distribution inventory. Equipment shall be labeled with the general nature of the contents.</td><td>E7.000</td></tr>
</table>

Standards # (14th edition)	Standard - Fragment	15th Location
J5.600 Storage Equipment	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.	E7.000
J5.700 Record Retention	Documentation of equipment and instrument cleaning, decontamination, sterilization, qualification, calibration, and maintenance shall be maintained in records for 10 years after their creation. Such records shall also include documentation of repairs, rejection, return, and/or disposal of defective equipment.	~~B11.000~~ B10.000
K1.000 Quality Assurance Program	All tissue banks shall have a QA program.	B2.000
K1.100 Basic Elements	The QA program shall include, at a minimum: 1) designating and managing quality control functions, including: a) environmental monitoring at designated intervals; b) performing periodic equipment and facility inspections and documenting in maintenance records or logs; c) reviewing equipment monitoring records for maintenance within specified tolerance limits, and reviewing records of other equipment or processing functions that have specified tolerance limits; d) inspecting and monitoring in-process control results, including collection and testing of representative samples; e) performing qualification of reagents, supplies, materials, instruments, or equipment when deemed critical or applicable; and f) monitoring laboratory performance, if applicable. 2) performing process validation studies when the results of a process cannot be fully verified by subsequent inspection and test. Each tissue bank shall establish and maintain procedures for monitoring and controlling process parameters for validated processes to ensure that the specified requirements continue to be met. Each tissue bank shall ensure that validated processes are performed by qualified individual(s). For validated processes, each tissue bank shall document the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process and the major equipment used. When changes or process deviations occur, the tissue bank shall review and evaluate the process and perform revalidation where appropriate, and shall document these activities. 3) performing equipment qualification studies as necessary; 4) establishing purchasing controls; 5) establishing procedures for implementing corrective action and preventive action and taking action when appropriate. The procedures shall include requirements for: a) analyzing processes, work operations, concessions, quality audit reports, quality records, errors, accidents, complaints, returns, and other sources of quality data to identify existing and potential causes of nonconforming tissue, or other quality problems. Appropriate	B2.100

Standards # (14th edition)	Standard - Fragment	15th Location
	statistical methodology shall be employed where necessary to detect recurring quality problems; b) investigating the cause of nonconformities relating to tissue, processes, and the quality system; c) identifying the action(s) needed to correct and prevent recurrence of quality problems; d) verifying or validating the corrective action and preventive action to ensure that such action is effective and does not adversely affect the finished tissue; e) implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; f) ensuring that information related to quality problems is disseminated to those directly responsible for assuring the quality of finished tissue or the prevention of such problems; and g) submitting relevant information on identified quality problems, as well as corrective action and preventive actions, for management review; 6) reviewing, as applicable at each tissue bank involved, donor screening, informed consent or authorization, recovery, acquisition, or collection, and processing records; 7) approving, as applicable, all processing records and relevant medical records prior to release of tissue for transplantation; 8) auditing; 9) documenting formal conclusions of all accident, error, complaint, adverse outcome, and field correction, removal, or stock recovery incidents; 10) maintaining documentation including, but not limited to: a) master copy of current SOPM; b) records of names, signatures, initials or identification codes and inclusive dates of employment for those authorized to perform or review tasks (e.g., onsite or at a central location); c) reports and conclusions of process validation and equipment qualification studies; d) records of supply and reagent acceptance or rejection; e) archived documents; and f) master lists of preprinted labels. 11) evaluating training of personnel and, where required, the competency of personnel, and requiring that staff are appropriately oriented and trained concerning any modifications to the SOPM; 12) maintaining labeling controls, including all brochures, pamphlets, and promotional materials; and 13) establishing a process for sharing information with other tissue banks that are known to have recovered and/or received tissue from the same donor.	
K1.200 Qualification, Verification, and Validation Requirements	Elements or items that must be qualified, verified, or validated shall be determined from a risk assessment that has been approved by the tissue bank's quality department and the	B2.200

Standards # (14th edition)	Standard - Fragment	15th Location
	frequency of these activities will be determined by the risk assessment and results of the initial and follow up validations.	
K1.200 Qualification, Verification, and Validation Requirements	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.	B2.210
K1.210 Validation Methods	Where validation is required or desired, evidence supporting validation must be demonstrated. Acceptable methods to demonstrate validation are: 1) studies conducting challenges such as temperature, time, with indicator organisms, as appropriate, and/or other factors determined by the risk assessment that potentially affect tissue quality, as well as studies demonstrating consistency when the steps are repeated lot to lot; or 2) identification of an established procedure or process known to be effective, with implementation of the same procedure or process, without modification; such procedure or process shall be verified, as specified in K1.230. [For example, the implementation of a literature based disinfection process shall include conducting at least method suitability testing (Bacteriostasis/Fungistasis testing) per USP <71> prior to implementation (see AATB Guidance Document No. 5)]; If any steps are modified, all such modifications shall undergo documented evaluation (e.g., through a risk assessment) for potential impact, and a potential result may be that a re-validation is necessary per method 1 of this section.	B2.220
K1.220 Packaging Qualification and Transport/Shipping Validation	Packages 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.	B2.230

Standards # (14th edition)	Standard - Fragment	15th Location
K1.230 Verification Methods	Where verification is required or desired, evidence supporting verification must be produced by one or more of the following methods: 1) review, examination, inspection, or testing of a defined number of samples (the justification of the number of samples must be documented) in order to establish and document that the tissue, service or system meets specified regulatory or technical standards; 2) verification of the implementation of an established, previously validated, procedure or process without modification; such verification shall be conducted using a defined number of samples/processing events (the justification of the number of samples/processing events must be documented); or 3) a documented review such as when a tissue recovery program must verify that a processor's donor eligibility criteria is compliant with federal regulations, state law, and AATB Standards.	B2.240
K1.300 Purchasing Controls	Each tissue bank shall establish and maintain procedures to ensure that all purchased or otherwise received products and services, including testing services, conform to specified requirements. Each tissue bank shall establish and maintain the requirements, including quality requirements that must be met by suppliers, contractors, and consultants.	F2.500
K1.300 Purchasing Controls	Each tissue bank shall: 1) evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented; 2) define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results; and	F2.000
K1.300 Purchasing Controls	3) establish and maintain records of acceptable suppliers, contractors, and consultants. Each tissue bank shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement in which the suppliers, contractors, and consultants agree to notify the tissue bank of changes in the product or service so the tissue bank can determine whether the changes may affect quality.	F2.500
K1.300 Purchasing Controls	For contracted services involving donor screening, donor eligibility, tissue recovery, acquisition, collection, processing, storage, and/or distribution, refer to B1.500 for additional requirements. Also refer to specific information at B1.600 for contracted and non-contracted laboratory services for infectious disease testing.	F2.500
K1.310 Contracted Testing Services	Contracted testing services may be performed remotely at the contracted laboratory or on-site at the tissue bank, and evaluation of testing services is expected.	F2.510
K1.311 Types of Testing Services	Examples of contracted testing services include, but are not limited to, the following: 1) donor infectious disease testing (also see B1.600); 2) microbiology testing (e.g., cultures on tissue, bioburden determination);	F2.510

Standards # (14th edition)	Standard - Fragment	15th Location
	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. Each tissue bank utilizing outside testing services shall ensure the testing facility and test methods are adequate for the intended use of the test results. This evaluation may include, but is not limited to, the following: 1) FDA registration, if required; 2) applicable state licenses, certifications and accreditations; 3) maintenance of an adequate quality assurance program to ensure the validity of results (e.g., test sample integrity, quality control samples, personnel competency, equipment maintenance, materials management); 4) participation in a laboratory proficiency testing program, if available; 5) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP); 6) follow manufacturers' instructions (e.g., package inserts, equipment manuals, electrical, and/or environmental conditions); 7) appropriate test method selection and validation/qualification; 8) use of traceable reference materials and calibration standards, where applicable; and 9) results from a paper, virtual, or on-site audit.	
K2.000 Quality Control Program	The QA program shall establish and maintain QC procedures that include the following: 1) environmental monitoring; 2) equipment maintenance and monitoring; 3) tolerance limits; 4) in-process controls monitoring; 5) reagent and supply monitoring; and 6) laboratory performance monitoring.	H3.100
K2.100 Laboratory Proficiency Testing	Laboratories shall participate in relevant proficiency testing programs for all analytes, if available. Proficiency testing shall be conducted in accordance with the laboratories' normal testing and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.	H3.100
K2.100 Laboratory Proficiency Testing	Procedures shall incorporate a plan for corrective action for poor performance on proficiency testing.	H3.200

Standards # (14th edition)	Standard - Fragment	15th Location
K2.200 Laboratory Quality Assurance Program	Laboratories shall establish and maintain a quality assurance program adequate to ensure the validity of test results. The laboratory quality assurance program shall include, but is not limited to, the following: 1) appropriate test method selection and validation/qualification; 2) monitoring/trending internal quality control samples; 3) test sample specifications and integrity (e.g., identification, transportation, type, quantity, rejection criteria, preparation, storage); 4) personnel qualification, training and competency; 5) equipment selection, validation/qualification, calibration and maintenance; 6) use of traceable reference materials and calibration standards, where applicable; 7) follow manufacturers' instructions (e.g., package inserts, equipment manuals, electrical and/or environmental conditions); 8) materials management; 9) adherence to relevant standards (e.g., CAP, ISO, ASTM, AAMI, USP); 10) result verification, review and release; and 11) records/data management.	H3.300
K2.310 Pre-Sterilization/Pre-Disinfection Cultures	Except for reproductive tissue banks and skin (S), each tissue bank shall establish appropriate pre-sterilization/pre-disinfection culture methods and sampling strategies to represent all tissues received from a particular donor. The pre-sterilization/pre-disinfection culture results shall be documented in the donor's record. See AATB Guidance Document No. 5 for expectations.	H25.000
K2.310 Pre-Sterilization/Pre-Disinfection Cultures	If tissue sterilization or disinfection will not occur a pre-sterilization/pre-disinfection culture is not required, however, refer to culture requirement at K2.320.	H25.100
K2.310 Pre-Sterilization/Pre-Disinfection Cultures	The Medical Director or his/her physician designee [see exception that follows for (S) shall review these pre-sterilization/pre-disinfection culture results prior to release of tissue for transplantation.	H25.200
K2.310 Pre-Sterilization/Pre-Disinfection Cultures	(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.	H25.210
K2.310 Pre-Sterilization/Pre-Disinfection Cultures	(BT, C, V, CT) E2.800 applies.	H25.220
K2.310 Pre-Sterilization/Pre-Disinfection Cultures	(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	H25.220

Standards # (14th edition)	Standard - Fragment	15th Location
	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).	
K2.310 Pre-Sterilization/Pre-Disinfection Cultures	Culture results shall be documented in the donor's record. Cultures positive for microorganisms considered pathogenic, highly virulent must be discarded unless the tissue can be disinfected/sterilized with a validated process (see E2.800). The Medical Director or designee shall review all available pre-processing skin culture results prior to releasing the tissue for transplantation. Skin recovery shall be performed as a separate zone from other tissue types so that culture results can be independently reviewed.	H25.300
K2.320 Final/Pre-Packaging Cultures	Except for autologous and reproductive tissues, all tissue to be released for human transplantation shall have representative microbiological cultures obtained which includes testing to detect bacteria and fungi. The results must be documented in the donor record, unless dosimetric release has occurred by a validated process according to E2.820. Appropriate final packaging cultures (aerobic and anaerobic) shall be obtained and the results shall meet established parameters defining acceptable final packaging cultures before tissue is released for transplantation. All culture results shall be reviewed prior to release of tissue for transplantation. Any variance in the culture results from established parameters shall be reviewed and approved by the Medical Director or his/her designee prior to release. Except as described for skin (S) below, no allografts contained within the processing batch may be released for transplantation if post-processing final sterility test results show organism contamination. Allograft rework is permitted with an established program validated to eliminate the organism identified.	H25.400
K2.320 Final/Pre-Packaging Cultures	(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.	H25.410
K2.320 Final/Pre-Packaging Cultures	(C, V) Representative cardiac tissue and vascular tissue samples shall be cultured for fungal growth.	H25.420
K2.320 Final/Pre-Packaging Cultures	(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.	H25.430
K2.320 Final/Pre-Packaging Cultures	(S) Representative fresh or cryopreserved skin samples shall be cultured for the presence of fast-growing fungal organisms. Fresh or cryopreserved skin shall not be used for transplantation if any one of the following is detected at final culture: 1) Staphylococcus aureus; 2) Streptococcus pyogenes (group A strep.); 3) Enterococcus sp.; 4) gram-negative bacilli; 5) Clostridium; and	H25.440

Standards # (14th edition)	Standard - Fragment	15th Location
	6) fungi (yeasts, molds).	
K2.400 Testing for Residues	(C, V) Initially, and as required at K1.200, each tissue bank shall thaw, rinse and prepare representative samples from processed tissue as if for use and test them to evaluate the concentration of residual cryoprotectant(s) (if applicable).	H3.700
K2.510 Lyophilized/Dehydrated/Desiccated Tissue	QC programs for monitoring performance of either a lyophilizer, a dehydrator or desiccator shall be established and verified for each batch. When a residual moisture limit has been established, a representative sample that demonstrates the worst-case scenario for that batch shall be tested and shall not exceed the limit. Refer to E2.710 and E2.720.	H3.400
K2.520 Calibrations and Storage Devices	Each tissue bank shall ensure calibration of devices used for storage are performed according to 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 otherwise validated, the calibration shall be performed at least annually using a National Institute of Standards and Technology-traceable standard. The overall QA program shall include maintenance of calibration records.	H3.500
K3.000 Microbiologic Testing	All microbiologic testing of tissue to be released for transplantation shall be performed by a qualified laboratory using appropriate test methods. If microbiologic testing is to be performed by the tissue bank, the requirements at K2.100 and K2.200 shall apply. If the services of an outside laboratory are used, the requirements at K1.300 and K1.310 shall apply.	H3.600
K3.000 Microbiologic Testing	NOTE: For international members that do not export tissues to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding qualification of laboratories via accreditation, designation, authorization and/or licensure.	H12.200
K3.100 Microbiologic Subcultures	The testing lab shall subculture a positive microbiologic culture to identify the organism(s) by genus, and species where appropriate. See Guidance Document No. 5.	H25.400
K4.000 Investigations	The QA program shall ensure the there is an investigation and review for completeness of accidents, errors, complaints, deviations, and adverse outcomes. Investigation shall include a summary report, precipitating events, recommendations, and resolutions. The QA program shall retain for 10 years all reports generated.	B2.300
K4.100 Errors and Accidents	The QA program shall ensure a documented investigation of 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 or licensed physician designee shall also review and evaluate the incident. When tissue may have been contaminated, the QA program shall ensure the documented review and evaluation both of processing procedures and of any other tissue processed simultaneously or from the same.	B2.310
K4.200 Complaints	The QA program shall ensure that a written and oral complaints regarding tissue quality, safety, packaging, or effectiveness are expeditiously investigated to determine whether the	B2.320

Standards # (14th edition)	Standard - Fragment	15th Location
	complaint is related to an error, accident, adverse outcome, or other factor, unless such investigation has already been performed for a similar complaint. If it is determined that no investigation is necessary, a responsible person shall document the reason that no investigation was made and the name of the individual responsible for the decision not to investigate. Each investigation shall determine whether associated tissue may be affected. If it is determined that they may be affected, then those associated tissues shall be located and quarantined until resolution of the incident (which may involve initiation of a recall).	
K4.200 Complaints	The Medical Director or licensed physician designee shall review complaints that are medical in nature.	B2.330
K4.200 Complaints	When an investigation is made, a record of the investigation shall include: 1) the date the complaint was received; 2) the name of the tissue; 3) the unique tissue identification number; 4) the name, address, and phone number of the complainant; 5) the nature and details of the complaint; 6) the dates and results of the investigation; 7) any corrective action taken; and 8) any reply to the complainant.	B9.100
K4.300 Adverse Outcomes	The QA program shall ensure that all reported adverse outcomes that are potentially related, directly or indirectly, to an allograft are investigated thoroughly and expeditiously. The Medical Director or licensed physician designee shall review all potential adverse outcome reports and participate in determination of the impact and resolution of any adverse outcome. If investigation indicates that the adverse outcome is related to an error or accident, then the tissue bank shall follow procedures for errors and accidents (see K4.100).	B2.340
K4.310 Reporting	The QA program shall ensure that all cases of transmissible disease in a recipient attributed to the allograft are reported in writing as required by public health authorities, and in a timely fashion to organ procurement organizations and tissue banks involved in any manner with tissue recovered from the same donor and to the physician(s) involved in the transplantation of tissue from that donor. Reporting shall be documented in the donor's record.	B2.350
K5.000 Internal Audits	All tissue banks shall establish policies and procedures regarding the scope and frequency of routine and focused QA audits. The QA program 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	B2.360

Standards # (14th edition)	Standard - Fragment	15th Location
	responsibility for the process being audited. The tissue bank shall take corrective action(s) when necessary, including a re-audit of deficiencies.	
K5.000 Internal Audits	The QA program staff shall document and report the dates and results of each quality audit (and re-audit) to management responsible for the audited systems, who shall review each report.	B3.200
K6.000 External Audits	External audits may be indicated for certain services, suppliers, contractors, and consultants. See K1.300 and B1.520.	B3.300
K7.100 Authorized Access	Each tissue bank shall exercise appropriate controls over electronic systems to limit general access to authorized personnel and to permit only authorized personnel to alter master production and control records or other.	G1.410
K7.200 Error Reduction	When automated data processing is used for decision-making in processing, adequate procedures shall be designed and implemented to prevent inaccurate input or output of data and programming errors.	H5.400
K7.300 Backup Files	A backup file shall be maintained of all data that are entered into an electronic system and subsequently used for decision-making purposes, and of all data that are not otherwise recorded and accessible.	G6.000
K7.400 Security	Electronic systems shall be designed to assure data integrity and maintained in a secure manner to prevent alteration or loss.	G6.000
K7.500 Audit Trail	Records revised electronically must have an audit trail that includes the altered information, date of the revision, and the individual that made the revision.	G6.000
L1.000 Tissue Dispensing Services	Medical, dental, and hospital facilities, and physician offices that are tissue dispensing services shall establish policies and procedures to ensure the safety and traceability of tissue from receipt through storage and final disposition such as transplantation, further distribution, or destruction.	G7.000
L1.100 Responsibilities	Activities of a tissue dispensing service shall be supervised by a physician, dentist, podiatrist, or other qualified medical professional.	H36.000
L2.100 General	Tissue storage shall be in conformance with labeling materials.	H36.100
L2.200 Equipment	Freezers and refrigerators shall be regularly maintained, calibrated, and monitored using QC written procedures.	E7.100
L2.300 Labeling	Tissue shall not be relabeled. Existing labels shall not be altered.	H36.200
L3.100 Dispensing	Tissue shall not be dispensed for use in recipients without an order from a physician or other authorized health professional. Human tissue shall not be offered or dispensed for veterinary use. Tissue shall be transported and prepared for transplantation in accordance with labeling materials. All associated labeling material, including the package insert, shall be made available to the end-user physician and/or other qualified medical professionals.	H36.300

Standards # (14th edition)	Standard - Fragment	15th Location
L3.200 Further Distribution	When further distributing tissue, all accompanying original labeling materials or other enclosures shall be forwarded with the tissue. A record shall be made of the type and quantity of tissue, tissue identification number(s), redistribution date and destination.	H36.400
L3.300 Tissue Disposal	Tissue that is unused, partially used, or expired, damaged or otherwise unsuitable for distribution shall be disposed of in such a manner as to minimize any hazards to staff or the environment, in conformance with applicable laws and regulations. When applicable, the tissue dispensing service shall notify the tissue bank, or the tissue distribution intermediary from whom the tissue was obtained, of the final disposition of the tissue. Documentation of such notification shall be recorded.	H36.500
L3.300 Tissue 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's physician, shall approve discard of the tissue, and shall be responsible for documentation of the method and date of discard; and 3) autologous tissue should not be used for transplantation after the expiration date.	H36.600
L3.300 Tissue Disposal	(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.	H36.700
L4.000 Records	Tissue dispensing services shall concurrently record all steps in the receiving, storage, and dispensing of tissue so that all steps can be clearly traced. Records shall be maintained for a minimum of ten years after expiration of the tissue or, in the case of tissue with no expiration date, ten years after dispensing.	H36.700
L4.100 Tissue Receipt Records	Each tissue specimen shall have a tissue identification number.	G2.000
L4.100 Tissue Receipt Records	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.	B6.740
L4.200 Dispensing Records	Disposition of tissue shall be documented. When tissue is dispensed for transplantation, the following information shall be recorded: 1) name, address, and telephone number of the tissue bank (tissue supplier or tissue processor); 2) type and quantity of tissue and unique tissue identification number(s); 3) recipient's name and medical record number, or social security number or similar unique identifier; 4) transplantation site and date and time of release;	B6.750

Standards # (14th edition)	Standard - Fragment	15th Location
	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.	
L4.200 Dispensing Records	This information shall be maintained in the tissue dispensing service records in a log format. The tissue recipient's medical records shall contain, at a minimum, the first five items to permit tracing of each tissue from the tissue bank (tissue supplier or tissue processor) to each recipient.	G8.100
L4.200 Dispensing Records	The tissue bank's tissue tracing forms shall be completed, specifying the disposition of the tissue, and returned as instructed in labeling materials.	G8.200
L5.000 Adverse Outcomes	Potential adverse reactions, suspected transmission of disease, or other complications, directly or indirectly related to the allograft, shall be reported as instructed in labeling materials and thoroughly investigated and documented.	B7.360
L6.000 Field Corrections and Removals	The tissue dispensing service shall have specific written policies and procedures for the performance of a field correction or removal, if applicable. Procedures shall include, but are not limited to, the following: 1) designation of a responsible person(s); 2) location and quarantine of affected inventory, in a timely manner; 3) communication with the tissue bank (tissue supplier or tissue processor); 4) communication with the end-user; and 5) documentation and record requirements.	B7.370
M1.000 Tissue Distribution Intermediaries	An agent who acquires distributed tissue for storage and further distribution shall establish policies and procedures to ensure the safety and traceability of tissue from receipt through storage, clinical use, further distribution, or destruction. See relevant parts of Section B and Section J.	H36.000
M1.000 Tissue Distribution Intermediaries	NOTE: When any tissue banking activities are performed beyond the few functions that identify an entity as a tissue distribution intermediary (i.e., an agent that only acquires and stores tissue for further distribution), relevant tissue bank standards apply and compliance is required for accreditation. Tissue bank functions that surpass functions solely under the definition of a tissue distribution intermediary include: 1) designing, creating, maintaining, or controlling the specifications for finished tissue, relevant parts of Section E apply (e.g., the series of standards at E2.600 and E2.421); 2) designing, creating, specifying, or maintaining responsibility for the contents of the label for finished tissue, relevant parts of Section G apply; 3) performing any labeling functions to include the physical application of a label to finished tissue, relevant parts of Section G apply; and/or	H37.000

Standards # (14th edition)	Standard - Fragment	15th Location
	4) final review for tissue release, relevant parts of Section F apply (e.g., F1.300, series of standards at F4.000).	
M2.100 General	Tissue storage shall be in conformance with the package insert and monitoring expectations. See E3.330, E3.331, E3.340, and C1.300.	H378.100
M2.200 Equipment	Freezers and refrigerators shall be regularly maintained, calibrated, and monitored according to written QC procedures. See the series of standards at J5.000.	H37.110
M3.000 Labeling	Tissue shall not be relabeled. Existing labels shall not be altered. Additional labels shall not be applied unless pre-approved by the tissue bank processor that applied the original label. Refer to the series of standards at G1.000.	H37.200
M4.000 Distribution	There shall be written procedures for the receipt of tissue orders, unit selection, final container, and/or package inspection, shipping, and transportation of tissue for transplantation. When a tissue distribution intermediary further distributes tissue, all accompanying labeling materials or other enclosures shall be forwarded with the tissue.	H37.300
M4.100 Tissue Distribution Restrictions	Provision of tissue for transplantation shall be restricted to hospitals, free-standing medical facilities, tissue banks, tissue dispensing services, another tissue distribution intermediary, and end-users (e.g., physicians, dentists, podiatrists or other medical professionals) for use in recipients with the veterinary use exception that follows. Tissue distribution intermediaries shall have procedures that describe evaluation of requests from new customers for tissue. Human tissue for transplantation shall not be offered or distributed for veterinary use unless such use is specifically granted in a document of gift/authorization or in a record of informed consent. Controls must exist to ensure distribution restrictions are met such as those found on the document of gift/authorization or informed consent.	H37.310
M4.200 Distribution to Another Tissue Distribution Intermediary	If tissue is distributed to another tissue distribution intermediary, that tissue distribution intermediary shall meet the requirements of Section M.	Preempted
M4.300 Requests for Donor Status and Tissue Processing Information	Donor risk assessment, tissue condition(s), and tissue processing details, with the exception of information that may infringe upon the confidentiality of donor information, shall be made available to the transplanting physician upon request.	H37.400
M5.000 Consignment Inventory Management	If tissue is provided on consignment, the tissue distribution intermediary shall maintain procedures to ensure traceability and that appropriate storage conditions are maintained during consignment, further distribution, or return.	H37.500
M6.100 Pre-Shipping Inspection	Prior to shipping, packages shall be inspected to ensure the external packaging and labels are undamaged, the tissue is not expired and the tissue being shipped is consistent with the tissue requested. The exterior of the transport package shall be inspected to verify that requirements in G3.310 are met. These inspections shall be documented, including identification of staff conducting inspections.	H37.600
M6.200 Validation and Packaging Expiration	If tissue to be shipped requires specific environmental conditions other than ambient temperature, the capability of the transport package to maintain the required environmental	H37.700

Standards # (14th edition)	Standard - Fragment	15th Location
	conditions shall be demonstrated and documented in a validation study. The length of time those conditions can be maintained by the packaging (assuming normal handling) shall also be determined. Expiration dates of the packaging shall be noted on the outside of the transport package.	
M6.300 Transportation	The mode of transportation selected shall be determined by any special shipping and handling requirements of the tissue and/or shipping refrigerants, shipping restrictions of commercial carriers, and the urgency of the tissue request.	H37.700
M6.310 Domestic Shipments	The transport package label shall include the following information: 1) name, address, and telephone number of the tissue distribution intermediary; 2) name and address of the consignee or end-user; 3) telephone number of the organization to whom issues related to shipping should be communicated; 4) prominent identification of contents as ‘‘DONATED HUMAN TISSUE.’’ Note: If the reproductive tissue in the shipment was collected from a client depositor, prominent identification as ‘‘HUMAN TISSUE’’; 5) recommended storage conditions and transport expiration date (if applicable); 6) type and quantity of refrigerant or other hazardous materials enclosed in the transport package; 7) transport (shipping) expiration date (if applicable), and 8) any special handling instructions, when applicable (e.g., “DO NOT FREEZE,” “DO NOT X-RAY,” “DO NOT IRRADIATE”).	H31.000
M6.320 International Shipments	Labels for international shipments shall contain all of the information required for domestic shipments; however, information may be modified to meet requirements of the federal government and those of the receiving country.	H31.000
M7.000 Return of Tissue	A tissue distribution intermediary shall establish a policy authorizing or prohibiting the return of tissue in its original, unopened container. If returns are permitted, the integrity of the container, transport package, and labeling shall be examined for evidence of contamination or tampering. If there is any evidence of contamination, tampering, mishandling, or failure to maintain required storage temperatures, tissue shall not be returned to distribution inventory. Information pertaining to the return of tissue shall be recorded in the disposition records for that tissue as follows: 1) documentation of container examination; 2) documentation of end-user storage and shipping conditions; 3) reason for the return; 4) disposition of the returned tissue; and 5) date and name of the staff member who evaluated and determined the disposition of the tissue.	H37.900

Standards # (14th edition)	Standard - Fragment	15th Location
M8.000 Field Corrections and Removals	The need to perform a field correction or removal may be identified as a result of a complaint, adverse outcome, accident, error, deviation, audit, or by any other means. For applicable quality assurance requirements, see relevant parts of Section K. An evaluation to determine if field correction or removal is warranted should be made whenever distributed tissue may not meet specifications related to safety, quality, identification, function and/or use. This evaluation must consider both risk to health posed by the tissue and applicable regulatory requirements, and be documented.	H37.900
M8.000 Field Corrections and Removals	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.	B7.370
M8.000 Field Corrections and Removals	All information relating to the field correction or removal of tissue and resulting communications shall be documented and retained on file for at least 10 years beyond the date of distribution, the date of transplantation (if known), disposition, or expiration of the tissue, whichever is latest. The file shall include, but not be limited to: 1) reason for the field correction or removal; 2) identification and location of affected tissue in a timely manner, including quarantine steps; 3) steps taken to correct or retrieve tissue; 4) documentation of all related communications (e.g., phone calls and/or written correspondence, including copies of field notifications or letters and a list of those to whom notice was sent); 5) final disposition of the tissue; 6) corrective actions recommended and implemented; and 7) documentation of review.	B6.730
M9.000 Records	The tissue distribution intermediary all steps in the receiving, storage, and dispensing of tissue so that all steps can be clearly traced. Records shall be maintained for a minimum of ten years after the expiration date of the tissue, or in the case of tissue with no expiration date, ten years after distribution. See applicable requirements of Section C.	G8.300
M9.100 Tissue Receipt Records	Each finished tissue shall have a tissue identification number. Tissue receipt records shall contain, but not be limited to, the following information: 1) name and address of tissue supplier; 2) description of tissue and quantity received; 3) date of tissue receipt;	B6.740

Standards # (14th edition)	Standard - Fragment	15th Location
	4) condition of tissue upon receipt; and 5) expiration date, if applicable, of tissue.	
M9.200 Distribution Records	Tissue distribution intermediaries shall maintain distribution records. These records shall be designed to permit tissue to be traced from the donor to a consignee or end-user, and from a consignee or end-user back to the donor. Records shall indicate the final disposition of all tissue handled by a tissue distribution intermediary. Tissue distribution records shall include, but not be limited to: 1) date of order placement; 2) name of the site to which the tissue is distributed; 3) name of the individual placing the order; 4) type and quantity of tissue ordered; and 5) information pertaining to tissue selected for shipment, including: a) identification number(s) of tissue; b) collection or expiration date of the tissue; c) date of shipment; d) type and amount (if applicable) of refrigerant used for shipment; e) mode of transportation; and f) name of the person releasing the tissue.	B6.800
M9.200 Distribution Records	Prior to distribution, the labeled tissue shall be reviewed to verify that tissue has been properly identified and labeled. Such inspection shall be documented.	H38.000
M9.200 Distribution Records	Any completed tissue tracing forms, specifying the disposition of the tissue, shall be returned as instructed in labeling materials.	G8.310
M9.300 Tissue Disposal	Unused, partially used, or expired tissue shall be disposed of in such a manner as to minimize any hazards to staff or the environment in conformance with applicable laws or regulations. The tissue distribution intermediary shall notify the tissue bank of the final disposition of the tissue and all actions taken must be documented.	G8.310
M10.000 Adverse Outcomes	Reports of adverse outcomes, transmitted disease, or other complications shall be documented and reported to the tissue processor in a timely fashion and in accordance with applicable laws or regulations.	B6.810

Revision History

Version	Date	Notes
3	July 28. 2024	Initial version released concurrent with Standards for Tissue Banking, 15th edition
4	October 18, 2024	Corrections to entries in “15th Location” column as tracked