

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

SECTION A - GENERAL INFORMATION

A2.000 DEFINITIONS OF TERMS

Current (13th edition)

LABEL – Any written, printed, or graphic material on or affixed to a container or package of cells, or tissue.

(with amendments)

LABEL – Any written, printed, or graphic material ~~on or affixed to a container or package of~~ used to identify cells, or tissue, cultures, blood specimens or other donor specimens.

(as amended)

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

SECTION B - GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

B1.000 GENERAL INSTITUTIONAL REQUIREMENTS

B1.500 Multi-Facility Tissue Banking

Current (13th edition)

B1.510 Written Agreements/Contracts

Each *Tissue Bank* shall have written agreements or contracts with all other organizations that perform or for whom they perform donor screening, donor acceptability, tissue *Recovery*, *Processing* or *Distribution* for their organization. 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.

- 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 Responsibilities) and to share records (see D4.500 Information Sharing, and K1.100 Basic Elements of a Quality Assurance Program).
- 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.

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

The tissue *Processing* organization must bear the burden of proof, and document in writing, that operations performed by other organizations prior to the receipt of tissue for *Processing* were performed in a manner consistent with these *Standards* as well as the *Processing* tissue bank's requirements.

- 3) A tissue bank that distributes tissue recovered and/or processed by other tissue banks shall be responsible for being in compliance with AATB *Standards* for all operations it performs. The distributor must also bear the burden of proof, and document in writing, that operations performed by other organizations prior to its receipt of tissue for *Distribution* were performed in a manner consistent with AATB *Standards*.
- 4) A tissue bank that determines donor suitability 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.

(with amendments, relevant parts only)

B1.510 Written Agreements/Contracts

Each *Tissue Bank* shall have written agreements or contracts with all other organizations that perform or for whom they perform [Authorization, Informed Consent](#), donor screening, donor acceptability, tissue *Recovery, Processing* or *Distribution* for their organization. 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.

...

- 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 standard G2.330.](#)

(as amended, relevant parts only)

B1.510 Written Agreements/Contracts

Each *Tissue Bank* shall have written agreements or contracts with all other organizations that perform or for whom they perform *Authorization, Informed Consent*, donor screening, donor acceptability, tissue *Recovery, Processing* or *Distribution* for their organization. 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.

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- 5) A tissue bank that provides another tissue bank with *Critical* supplies, reagents, materials,

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

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 standard G2.330.

SECTION D - ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

D4.000 DONOR SUITABILITY

D4.300 Disease Screening

D4.350 Blood Tests

Current (13th edition)

D4.351 Specimens

Except as otherwise specified in tissue-specific standards, infectious disease testing of donor blood specimens shall be performed for each tissue donor (including maternal donors of *Fetal Tissue* or neonatal tissue), on a specimen collected at the time of donation or within seven days prior to or after donation. If the donor is one month (28 days) of age or less, a blood specimen from the birth mother must be collected within seven days prior to or after tissue donation and tested instead of a specimen from the donor. There shall be written procedures for all significant steps in the infectious disease testing process, including collection and use of appropriate blood specimen types and instructions for specimen handling. Procedures shall conform to the manufacturer’s instructions for use contained in the package inserts. Specimen collection, storage, and handling procedures shall be described in the *SOPM*.

- (R) For oocytes, the donor blood specimen must be collected within 30 days prior to oocyte retrieval, or within 7 days post donation. For repeat *Semen Donor* requirements, see D4.360 Repeat Testing of *Living Donors* (R).

(with amendments, relevant part only)

D4.351 Specimens

Except as otherwise specified in tissue-specific standards, infectious disease testing of donor blood specimens shall be performed for each tissue donor (including maternal donors of *Fetal Tissue* or neonatal tissue), on a specimen collected at the time of donation or within seven days prior to or after donation. If the donor is one month (28 days) of age or less, a blood specimen from the birth mother must be collected within seven days prior to or after tissue donation and tested instead of a specimen from the donor. There shall be written procedures for all significant steps in the infectious disease testing process, including collection, [documentation of the verification of specimen labeling](#), and use of appropriate blood specimen

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

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*.

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(as amended, relevant part only)

D4.351 Specimens

Except as otherwise specified in tissue-specific standards, infectious disease testing of donor blood specimens shall be performed for each tissue donor (including maternal donors of *Fetal Tissue* or neonatal tissue), on a specimen collected at the time of donation or within seven days prior to or after donation. If the donor is one month (28 days) of age or less, a blood specimen from the birth mother must be collected within seven days prior to or after tissue donation and tested instead of a specimen from the donor. There shall be written procedures for all significant steps in the infectious disease testing process, including collection, 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*.

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SECTION D - ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

Current (13th edition)

D5.700 Post-Recovery Packaging

Immediately following either Recovery of each individual tissue or Processing at the Recovery Site, tissue obtained shall be individually and aseptically wrapped or enclosed and the receptacle shall be immediately labeled with the unique donor identifier and the type of tissue enclosed (abbreviations may be used if defined in the *SOPM*). Tissue shall be maintained at defined environmental temperatures until the time of transport to the Processing center. Maintenance of such temperatures shall be documented.

- (A) Immediately following *Recovery* of the *Autograft*, the tissue shall be individually and aseptically wrapped in a manner to prevent contamination of the contents, preserve cellular structure and viability, if desired, and to allow for aseptic delivery of the specimen at time of *Processing*, if necessary, or reimplantation. The receptacle shall be labeled immediately with the donor’s name, age, sex, hospital medical record number and/or social security number, and institution name, and shall be prominently labeled “FOR AUTOLOGOUS USE ONLY.”

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

- (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. The transport container should be fluid tight, designed to prevent contamination of the contents, and allow for aseptic delivery of the specimen at the time of *Processing*.
- (V) Immediately following *Recovery*, vascular tissue shall be gently flushed and packaged in an isotonic *Sterile* solution such as tissue culture media. Normal saline solution should not be used. The type, *Lot* number, manufacturer, and expiration date of all reagents used for *Recovery* and packaging shall be documented. The transport container should be fluid tight, designed to prevent contamination of the contents, and allow for aseptic delivery of the specimen at the time of *Processing*.
- (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. If in solution, the transport container must be fluid tight and designed to prevent contamination of the contents.

(with amendments, relevant part only)

D5.700 Post-Recovery Packaging Labeling and Handling

Immediately following ~~either *Recovery* of each individual tissue or *Processing* at the *Recovery Site*, recovered tissue obtained~~ shall be individually and aseptically wrapped or enclosed ~~and the receptacle~~ and shall be immediately labeled with the unique donor identifier and the description according to the SOPM (see G1.100) ~~type of tissue enclosed (abbreviations may be used if defined in the SOPM)~~. Tissue shall be maintained at defined environmental temperatures until the time of transport to the *Processing* center. Maintenance of such temperatures shall be documented.

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(as amended, relevant part only)

D5.700 Post-Recovery Labeling and Handling

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.

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Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

SECTION D - ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

Current (13th edition)

D5.800 Transportation of Tissue Following Recovery

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

Autologous tissue shall be transported to the *Processing*/storage center on wet ice in the time limits appropriate for the particular tissue.

(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 integrity of the tissue for its intended use.

(C, V) The transport container shall be transported at *Wet Ice Temperatures*. Time of acceptance of the tissue into the *Processing* center shall be documented. Cardiac and vascular tissues shall be received at the *Processing* location within sufficient time following *Recovery* to allow for the start of *Disinfection* within the established *Cold Ischemic Time* limit.

(MS) The recovered tissue shall be wrapped in an aseptic fashion with at least one moisture barrier and shall be transported at *Wet Ice Temperatures* or colder. The maximum time that recovered tissue shall remain at *Wet Ice Temperatures*, prior to either *Processing* or freezing, shall be no longer than 72 hours.

(OA) The recovered tissue shall be transported at *Wet Ice Temperatures*. The maximum time that recovered tissue shall remain at *Wet Ice Temperatures* prior to *Processing* shall be no longer than five days.

(S) If the tissue is to be cryopreserved, the skin transportation container shall be transported

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

at *Wet Ice Temperatures* or packaged by another method that maintains the integrity of the tissue for its intended use.

(with amendments, relevant part only)

D5.800 Transportation of Tissue Following Recovery

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

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(as amended, relevant part only)

D5.800 Transportation Following Recovery

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

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SECTION G - LABELING

G1.000 LABELS AND LABELING

Current (13th edition)

G1.100 Nomenclature

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

Nomenclature and units of measurement used to describe tissue and the *Processing* that tissue has received shall be specified in the *SOPM* and be applied consistently.

G1.200 Label List

If preprinted or computer-generated labels are used, a list of them 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.

G1.300 Labeling Integrity

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

G1.400 Claims

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

(with amendments)

G1.100 Nomenclature

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

G1.200 Label List

~~If preprinted or computer-generated labels are used,~~ a *A* list of them *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.*

G1.300 Labeling Integrity

Labels shall be designed and qualified to be legible, indelible, and affixed firmly to the *Container* under all anticipated storage conditions for the shelf life *length of use* of the tissue. Tissue *Labels* and associated ~~*Labeling Materials*~~ applied by tissue bank staff shall not be removed, altered, or obscured except to correct labeling *Errors*. *When applicable, this also*

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

applies to Labeling Materials. Suppliers of labels deemed Critical are responsible for establishing specifications.

G1.400 Claims

All labeling *e*Claims shall be clear, accurate, substantiated, and not misleading.

(as amended)

G1.100 Nomenclature

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

G1.200 Label List

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

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. Labels applied by tissue bank staff shall not be removed, altered, or obscured except to correct labeling *Errors*. When applicable, this also applies to *Labeling Materials*. Suppliers of labels deemed *Critical* are responsible for establishing specifications.

G1.400 Claims

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

SECTION G - LABELING

G2.000 LABELING PROCESS

Current (13th edition)

G2.100 General Requirements

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

There shall be SOPs designed and followed to ensure that correct labels, labeling, and packaging material are used for tissue. Each labeling phase for all tissue (e.g., unprocessed, processed, *Quarantined*, and released for *Distribution*) shall be documented.

G2.200 Re-Labeling

If tissue is to be re-labeled for any reason, such as label detachment or to correct a labeling *Error*, the tissue bank shall establish a re-labeling procedure delineating the methods to be utilized, conditions under which tissue may be re-labeled, and the staff authorized to perform such activities. The reasons for, and events surrounding, the re-labeling of tissue shall be documented in the records.

G2.300 Controls—General

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

G2.310 Label Inspection

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

G2.320 Label Storage

The storage area for labels and *Labeling Materials* shall be clearly identified. Access should be restricted to authorized personnel only.

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 Master Label List and the *SOPM* shall be updated accordingly.

G2.340 Tissue and Container Visual Inspection

Prior to labeling a unit of processed tissue, the *Container* shall be inspected for evidence of

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

impurities, defects, broken seals, or contamination that could compromise the quality, integrity, 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 to be of questionable quality shall be *Quarantined* immediately pending further investigation and *Resolution* following established procedures in the *SOPM*. This review shall be documented.

(with amendments, relevant parts only)

G2.200 Re-Labeling

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

G2.320 Label Storage

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

(as amended, relevant parts only)

G2.200 Re-Labeling

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

G2.320 Label Storage

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

SECTION J - GENERAL OPERATIONS

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

Current (13th edition, relevant parts only)

J1.200 Contents

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

...

- 6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection, Recovery, Processing*, packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:
 - a) for 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 (E4.000, F4.200 and M2.000);
 - b) the investigation, documentation, and reporting of *Accidents, Errors, Complaints*, and *Adverse Outcomes* (K4.000);
 - c) requiring notification of *Management with Executive Responsibility* of any *Recalls*, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);
 - d) for the *Recall* of tissue unacceptable for transplantation (H5.000, L6.000 and M6.000);
 - e) that establish which supplies, reagents, materials and equipment are considered *Critical* (D5.100, E1.300, J5.100);
 - f) and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (J5.000);
 - g) describing the receipt, identification, storage, handling, sampling, testing, and subsequent approval or rejection of *Containers*, packaging materials, labels, reagents, and supplies (D5.000, E1.000, E2.000, J5.500 and Section G); and
 - h) for monitoring *In-Process Controls* and managing events such as failed test runs and failure of a *Lot* to meet established specifications (Section K).

(with amendments, relevant parts only)

J1.200 Contents

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

...

- 6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection, Recovery, Processing*, packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

- a) for labeling of cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) (D4.350, D5.000 and Section G);
- ab) for 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 (E4.000, F4.200 and M2.000);
- bc) the investigation, documentation, and reporting of *Accidents, Errors, Complaints*, and *Adverse Outcomes* (K4.000);
- cd) requiring notification of *Management with Executive Responsibility* of any *Recalls*, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);
- de) for the *Recall* of tissue unacceptable for transplantation (H5.000, L6.000 and M6.000);
- ef) that establish which supplies, reagents, materials and equipment are considered *Critical* (D5.100, E1.300, J5.100);
- fg) and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (J5.000);
- gh) describing the receipt, identification, storage, handling, sampling, testing, and subsequent approval or rejection of *Containers*, packaging materials, labels, reagents, and supplies (D5.000, E1.000, E2.000, J5.500 and Section G); and
- hi) for monitoring *In-Process Controls* and managing events such as failed test runs and failure of a *Lot* to meet established specifications (Section K).

(as amended, relevant parts only)

J1.200 Contents

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

...

6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection, Recovery, Processing*, packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:

- a) for labeling of cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) (D4.350, D5.000 and Section G);
- b) for monitoring storage temperatures, for defining *Tolerance Limits*, and for describing what, when, and how corrective actions are to be taken for implementing emergency

Changes to Standards – Labels and Labeling Involving Tissue Recovery Activities and Services of Processing Tissue Banks

transfers and determining alternative storage and monitoring methods for tissue and reagents (E4.000, F4.200 and M2.000);

- c) the investigation, documentation, and reporting of *Accidents, Errors, Complaints, and Adverse Outcomes* (K4.000);
- d) requiring notification of *Management with Executive Responsibility* of any *Recalls, investigations, inspection reports, or regulatory actions* (H5.000 and K4.000);
- e) for the *Recall* of tissue unacceptable for transplantation (H5.000, L6.000 and M6.000);
- f) that establish which supplies, reagents, materials and equipment are considered *Critical* (D5.100, E1.300, J5.100);
- g) and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (J5.000);
- h) describing the receipt, identification, storage, handling, sampling, testing, and subsequent approval or rejection of *Containers, packaging materials, labels, reagents, and supplies* (D5.000, E1.000, E2.000, J5.500 and Section G); and
- i) for monitoring *In-Process Controls* and managing events such as failed test runs and failure of a *Lot* to meet established specifications (Section K).

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