"Critical" Supplies, Reagents, Materials and Equipment
(with amendments)

For purposes of clarity, text that has been added is underlined, italicized, and appears as blue font (i.e., *Example*), and text that has been deleted utilizes the strikethrough (i.e., ~~Example~~).
Note: For some standards, only relevant parts are reproduced here.

SECTION A
GENERAL INFORMATION

A2.000 Definitions of Terms

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

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

D1.000 GENERAL POLICIES FOR TISSUE RECOVERY OR COLLECTION ORGANIZATIONS

In addition to the requirements at the series of standards at B1.500 Multi-Facility Tissue Banking, ~~A~~all referral arrangements with organ procurement ~~facilities~~ *organizations* ~~and agencies~~, *Donor Referral Sources,* and other tissue banks ~~or facilities should~~ *shall* be documented.

(A) The tissue bank shall establish written or verbal procedures for interacting with operating room staff, the patient's physician, or other sources~~/facilities~~ for autologous tissue donation prior to *Recovery.*

(R) Procedures for accepting *tissue collected from a Client Depositor,* ~~reproductive cells and tissues~~ and for recruiting, accepting or excluding potential reproductive tissue donors, shall be established by the Medical Director.

D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

~~The *Tissue Bank* shall establish~~ ~~p~~Policies and procedures *shall be established* for the *Recovery* or *Collection* of tissue in accordance with *Standards*. *Reagents, supplies, materials, and equipment shall be of appropriate grade for intended use, and approval for use shall be documented. All tissue must be uniquely identified and traceable to the donor from recovery or*

collection through transport and receipt at the processing or storage facility. The ~~tissue bank shall specify the site where tissue is to be obtained and the~~ environment *in which tissue can be obtained, and techniques that should be used, shall be specified*. *Recovery, Collection* and *Preservation* shall occur within a time interval appropriate for retention of biological functions and shall be compatible with ~~the~~ intended use of the tissue. *Detailed records of the tissue donation shall be maintained that include information regarding relevant packaging, transportation, and donor reconstruction steps.*

~~**D5.100 Verification Procedures**~~

~~**D5.110 Confirmation**~~

~~**D5.120 Donor Identity**~~

D6*5*.100 Reagents, ~~and General~~ Supplies, *Materials, and Equipment*

All Critical supplies, reagents, materials, and equipment approved for use for Recovery or Collection shall be identified and specifications (e.g., Sterile where applicable) documented A record shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, Lot number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of the staff performing the inspection. The tissue bank shall maintain records of all supplies, reagents, materials, and equipment from receipt through period of time used..

~~All instruments, solutions, and supplies used to recover human tissue used for transplantation shall be *Sterile*, unless otherwise indicated.~~ All non-disposable surgical instruments and parts of mechanical/ electrical equipment which come in contact with tissues ~~during tissue~~ shall be properly cleaned, disinfected, and *Sterilized* ~~between~~ *prior to use for* ~~donor~~ *Recovery or Collection* according to written procedures ~~prepared to control the~~ prepared to prevent~~ion of infectious disease~~ contamination or *Cross-Contamination* ~~by tissues~~. *Records shall be maintained that document sterilization steps. All* reagents*, supplies, and materials* shall be used and stored in accordance with manufacturers' instructions.

D6*5*.110 Stock Rotation

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

D5.200 Donor Identification ~~Number~~

Each donor shall be assigned a unique donor ~~identification number~~ *identifier* to facilitate tracing of the tissue from the donor and *to* ~~the~~ final *Disposition* of each tissue ~~derived from the donor~~.

(R) At the time of *Collection*, the collection container shall be labeled with the date and time of *Collection* and the donor's identification or, in the case of *Client Depositors*, the name.

D5.~~1~~0*21*0 Verification Procedures

D5.~~1~~10*211* Confirmation

D5.~~1~~10*212* Donor Identity

D5.300 Tissue Recovery *and Collection* —General

Recovery shall be performed using aseptic or clean techniques appropriate to the specific tissue recovered and ~~the~~ intended use of the tissue. The *SOPM* shall specify the time limits for the postmortem *Recovery* of tissue consistent with tissue-specific standards, where applicable. If *Recovery* is to be delayed for *a* deceased donor~~s~~, the 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).

D5.600 Recovery Records

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

1) Name, and address of the *Recovery* agency;

2) Date, time and staff involved in the *Recovery* (documentation shall be as per C1.100 General— Records Management);

3) Location and assessment of the suitability of the *Recovery Site* (see D5.500 Recovery Environment);

4) Donor name, age, and sex;

5) T*he t*ype, *Lot* number, manufacturer, and expiration date of *Critical* ~~supplies and~~ reagents*, supplies and materials, and the identification of equipment,* used to recover, rinse, and*/or* transport tissue; and

6) Specific tissue recovered.

When applicable, the *Recovery* agency shall provide pertinent recovery record information to the *Recovery Site* facility and/or the relevant Pathologist, Medical Examiner, or Coroner.

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 ~~identification number~~ *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.

(followed by A-, C-, V-, and S-specific standards that remain unchanged)

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SECTION E
PROCESSING, PRESERVATION, QUARANTINE, AND STORAGE

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

E1.300 Reagents, ~~and General~~ Supplies, *Materials, and Equipment*

~~The reagents used in *Processing* and *Preservation* shall be of appropriate grade for the intended use and *Sterile*, if indicated. Selection criteria used to qualify must be documented~~. *All Critical supplies, reagents, materials, and equipment approved for use for Processing and Preservation shall be identified and specifications (e.g., Sterile where applicable) documented. It is expected that the tissue bank has the ability to link all supplies, reagents, materials, and equipment to tissue processed over the period of time they were in use.*

A record shall be made of all reagents*,* ~~and~~ 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).* ~~The inspection of reagents and supplies~~ *Inspection* shall be documented, including identification of ~~the~~ staff performing the inspection. *All reagents, supplies, materials and equipment shall be used and stored in accordance with manufacturers' instructions.*

(C, V, MS, OA, S)
~~All instruments, solutions, and supplies used to process human tissue used for transplantation shall be *Sterile*.~~ All non-disposable surgical instruments and mechanical/electrical equipment used in tissue *Processing* shall be cleaned, disinfected, and *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 should be Validated*, ~~and followed for~~ *to* prevent~~ion of infectious disease~~ contamination or *Cross-Contamination* ~~by tissue~~ during *Processing*.

E1.310 Stock Rotation

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

~~**E1.311 Storage**~~

~~Reagents shall be stored in accordance with manufacturer's instructions.~~

~~**E1.320 Non-Disposable Supplies**~~

~~Non-disposable supplies shall be cleaned, disinfected, or *Sterilized* between donors according to written procedures prepared, validated, and followed for prevention of infectious disease contamination or *Cross-Contamination* by tissue during *Processing*.~~

E1.700 Processing and Preservation Records

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

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

2) *Tissue Identification Number(s)* and type(s) of tissue being processed;

3) Tissue measurements (e.g., weight, dimensions, volume), as appropriate;

4) Expiration where applicable;

5) Type and quantity of tissue sampled for *In-Process Controls*;

6) Final *Disposition* of each tissue obtained and/or processed; *and*

7) T*he t*ype, *Lot* number, manufacturer (unless recorded in other records), and expiration date, where applicable, of *Critical* ~~supplies and~~ reagents*, supplies and materials, and the identification of Critical equipment,* used to process and/or preserve tissue*.*~~; and~~

~~8) Identification of equipment used to process and/or preserve tissue.~~

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SECTION J
GENERAL OPERATIONS

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

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) ~~Policies and procedures~~ for monitoring storage temperatures, for defining *Tolerance Limits*, and for describing what, when, and how corrective actions are to be taken for implementing emergency transfers and determining alternative storage and monitoring methods for tissue and reagents (E4.000, F4.200 and M2.000);

   b) ~~Policies and procedures~~ for the investigation, documentation, and reporting of *Accidents*, *Errors*, *Complaints*, and *Adverse Outcomes* (K4.000);

   c) ~~Policies and procedures~~ requiring notification of *Management with Executive Responsibility* of any *Recalls*, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);

   d) ~~Policies and procedures~~ 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);

~~e~~f) ~~Policies, procedures~~ and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (J5.000);

~~f~~g) ~~Policies and procedures~~ 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

~~g~~h) ~~Policies and procedures~~ for monitoring *In-Process Controls* and managing events such as failed test runs and failure of a *Lot* to meet established specifications (Section K).

J5.000 EQUIPMENT

J5.100 Selection

Equipment and instruments should be of appropriate quality for their intended function. Equipment used in the *Recovery*, *Processing*, *Preservation*, packaging, or storing of tissue shall be appropriately sized, designed, and located to facilitate use, cleaning, and maintenance. Equipment shall be constructed so that surfaces contacting tissue shall not alter the *Safety* or quality of the tissue. *See E1.300.*

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SECTION K
QUALITY ASSURANCE

K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a QA Program.

K1.100 Basic Elements

QA programs shall include, at a minimum:

1) Designation and management of *Quality Control* functions, including:

   a) Environmental monitoring at designated intervals;

   b) Performance and documentation in maintenance records or logs of periodic equipment and facility inspections;

c) Review of equipment monitoring records for maintenance within specified *Tolerance Limits*, and reviewing records of other equipment or *Processing* functions that have specified *Tolerance Limits*;

d) Inspection and monitoring *In-Process Control* results, including collection and testing of representative samples;

e) Performing ~~acceptability determinations~~ *qualification* of ~~supplies and~~ reagents*, supplies, materials, or equipment when deemed Critical or applicable*; and

f) Monitoring laboratory performance, if applicable.

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