

**“Critical” Supplies, Reagents, Materials and Equipment
(as amended)**

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.

**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, all referral arrangements with organ procurement organizations, Donor Referral Sources, and other tissue banks 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 for autologous tissue donation prior to *Recovery*.
- (R) Procedures for accepting tissue collected from a *Client Depositor*, 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

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 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 intended use of the tissue. Detailed records of the tissue donation shall be maintained that include information regarding relevant packaging, transportation, and donor

“Critical” Supplies, Reagents, Materials and Equipment (as amended)

reconstruction steps.

D5.100 Reagents, 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 non-disposable surgical instruments and parts of mechanical/electrical equipment which come in contact with tissue shall be properly cleaned, disinfected, and *Sterilized* prior to use for *Recovery* or *Collection* according to written procedures prepared to prevent contamination or *Cross-Contamination*. Records shall be maintained that document sterilization steps. All reagents, supplies, and materials shall be used and stored in accordance with manufacturers’ instructions.

D5.110 Stock Rotation

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

D5.200 Donor Identification

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

- (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.

D5.210 Verification Procedures

D5.211 Confirmation

D5.212 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 intended use of the tissue. The *SOPM* shall specify the

“Critical” Supplies, Reagents, Materials and Equipment (as amended)

time limits for the postmortem *Recovery* of tissue consistent with tissue-specific standards, where applicable. If *Recovery* is to be delayed for a deceased donor, the 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) 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
- 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 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.

**“Critical” Supplies, Reagents, Materials and Equipment
(as amended)**

**SECTION E
PROCESSING, PRESERVATION, QUARANTINE, AND STORAGE**

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

E1.300 Reagents, Supplies, Materials, and Equipment

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

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

(C, V, MS, OA, S)

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* to prevent contamination or *Cross-Contamination* during *Processing*.

E1.310 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.

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;

**“Critical” Supplies, Reagents, Materials and Equipment
(as amended)**

- 2) *Tissue Identification Number(s)* and type(s) of tissue being processed;
- 3) Tissue measurements (e.g., weight, dimensions, volume), as appropriate;
- 4) Expiration where applicable;
- 5) Type and quantity of tissue sampled for *In-Process Controls*;
- 6) Final *Disposition* of each tissue obtained and/or processed; and
- 7) The type, Lot number, manufacturer (unless recorded in other records), and expiration date, where applicable, of *Critical* reagents, supplies and materials, and the identification of *Critical* equipment, used to process and/or preserve tissue.

**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) 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) for 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);

“Critical” Supplies, Reagents, Materials and Equipment (as amended)

- 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).

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.

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;

**“Critical” Supplies, Reagents, Materials and Equipment
(as amended)**

- 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 qualification of reagents, supplies, materials, or equipment when deemed *Critical* or applicable; and
- f) Monitoring laboratory performance, if applicable.

...