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**Part 52**  
**TISSUE BANKS AND NONTRANSPLANT ANATOMIC BANKS**

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## **SUBPART 52-1 DEFINITIONS**

**Section 52-1.1 Definitions.** For purposes of this Part, unless the context indicates otherwise, the following terms shall have the following meanings:

- (a) *Acquisition* means any activity, including solicitation, retrieval, and donor selection and testing, which is necessary to obtain tissue for transplantation, transfer, artificial insemination or implantation, or to obtain nontransplant anatomic parts for research or education.
- (b) *Allogeneic tissue collection* means the retrieval of tissue from a donor for the purpose of transplantation or transfer into another individual, including tissue provided by a donor for transplantation, artificial insemination, implantation or transfer into a designated recipient.
- (c) *Aseptic processing* means the handling, preservation and packaging of tissue not intended for viral inactivation, using methods designed to prevent contamination with pathogenic organisms.
- (d) *Aseptic retrieval* means the recovery of tissue in a clean surgical field, using standard operating room techniques.
- (e) *Autogeneic tissue collection* means the retrieval of tissue from a donor for subsequent reimplantation into that same donor.
- (f) *Clinical laboratory* means a laboratory operating under a permit issued pursuant to article V, Title 5 of the Public Health Law and/or which meets the requirements of the state in which it is located and of the Federal government (see clinical laboratory improvement amendments of 1988), and is acceptable to the Commissioner as specified herein.
- (g) *Clinical use* means the use of tissue for allogeneic or autogeneic transplantation, transfer, artificial insemination or implantation.
- (h) *Commissioner* means the Commissioner of the New York State Department of Health.
- (i) *Controlling interest* means the ability to direct or control the operation or management of a tissue bank, tissue processing facility or tissue storage facility (herein referred to as a facility), including, but not limited to, the ability or authority, expressed or reserved, to:
  - (1) amend or change the corporate or operating identity (e.g., joint venture agreement or unincorporated business status) of the facility;
  - (2) approve operating and capital budgets of the facility;
  - (3) adopt, approve or direct facility fiscal operating policies and procedures;
  - (4) approve debt necessary to finance the facility's costs of compliance with operational or plant standards required by law;
  - (5) approve contracts for management of facility services;
  - (6) hire or dismiss the medical director or tissue bank director and nontechnical personnel;
  - (7) maintain and control the books and financial records of the facility;
  - (8) control any of the assets of the facility;

- (9) encumber the assets of the facility by way of mortgage or other indebtedness; and
- (10) dissolve the facility or arrange for the sale or transfer of the facility to new ownership or control.
- (j) *Department* means the New York State Department of Health.
- (k) *Direct ownership interest* means the possession of stock, equity in the capital, or any interest in the profits of the facility.
- (l) *Distribution* means any activity necessary to distribute tissue for transplantation, transfer, artificial insemination or implantation from the tissue bank to the transplantation facility or insemination/implantation site, including allocation and transportation, but shall not include transportation within the transplantation facility. Distribution shall also include distribution of nontransplant anatomic parts from the bank to the research or education facility.
- (m) *Donor* means, except as otherwise defined in this Part, a human being, living or dead, who is the source of tissue or nontransplant anatomic parts for transplantation, transfer, artificial insemination, implantation, education or research purposes.
- (n) *FDA* means the Food and Drug Administration of the United States Department of Health and Human Services.
- (o) *Indirect ownership interest* means the possession of stock, equity in the capital, or any interest in the profits of an entity with a direct or indirect ownership interest in the facility. For example, if an entity owns ten percent of the stock in a corporation that owns 80 percent of the stock in a facility, that entity's interest equates to an eight percent indirect ownership interest.
- (p) *Medical advisory committee* means a panel composed of at least five members with experience and expertise in the fields specified in the Subpart specific to the category or categories of tissue services provided, who are responsible for monitoring the medical efficacy of the tissue bank, and setting operating policies and procedures. At least one member of the medical advisory committee shall possess expertise in microbiology, clinical pathology or infectious disease.
- (q) *Medical director* means a physician who meets the requirements of section 52-2.5(a)(3) of this Part.
- (r) *Nontransplant anatomic bank* means any person or facility that solicits, retrieves, performs donor selection and/or testing, preserves, transports, allocates, distributes, acquires, processes, stores or arranges for the storage of nontransplant anatomic parts, including whole bodies, body segments, organs or tissues from living or deceased donors, for education and/or research purposes specifically authorized by Public Health Law section 4302. The following shall not constitute a nontransplant anatomic bank:
  - (1) Any person or entity that stores nontransplant anatomic parts, except whole bodies and body segments, solely for purposes of research and/or education conducted by such person, provided the person or entity maintains on its premises a properly executed anatomical gift consent document consistent with section 52-11.3 of this Subpart, and:

- (i) such person or entity is a legal donee pursuant to Public Health Law section 4302 and obtains all organs/tissues from a tissue bank or nontransplant anatomic bank licensed by the department; or
- (ii) is a general hospital conducting pathology services or research on nontransplant anatomic parts including whole bodies, recovered from within the facility from a living or deceased source;
- (2) Any person or entity whose activities within the State of New York are limited to distribution of nontransplant anatomic parts to a tissue bank or nontransplant anatomic bank licensed by the department;
- (3) Any person or entity that uses prepared slides and/or human-derived cell lines for purposes of education and/or research; and
- (4) An employee of the federal government, provided an anatomical gift consent document has been executed in accordance with Public Health Law section 4301 and section 52-11.3(d) of this Subpart.
- (s) *Owner* means a person, persons, or an entity with direct or indirect ownership interest in a facility.
- (t) *Person* means an individual, corporation, government or governmental subdivision or agency, business trust, estate trust, partnership or association, or any other legal entity, other than the Office of Mental Health.
- (u) *Principal stockholder* means any person who owns (whether of record or as beneficiary), holds or has the power to vote, 10 percent or more of any class of securities issued by a corporation.
- (v) *Processing* means any activity necessary to prepare, preserve for storage, remove from storage and/or conduct laboratory testing to assure the potency, quality and/or sterility of bodies, body parts, organs or tissue for research or education purposes, or tissue for transplantation, transfer, artificial insemination or implantation.
- (w) *Procure* means to perform any activity which is necessary for the procurement of organs or tissue for transplantation, artificial insemination, implantation, research, education, therapy, fertilization, or autogeneic purposes, including solicitation, retrieval, donor selection and testing, clinical laboratory testing, including typing, preservation, transportation, allocation, distribution, storage, and payment activities.
- (x) *Recipient* means a patient who receives tissue through transplantation, artificial insemination, transfer or implantation.
- (y) *Service area* means a geographic area for acquisition and/or distribution services approved by the United States Secretary of Health and Human Services or, in the absence of such approval, by the department pursuant to the standards established in this Subpart.
- (z) *Storage* means any activity necessary to store tissue for transplantation, transfer, artificial insemination or implantation, or nontransplant anatomic parts for research and/or education purposes.
- (aa)(1) *Tissue bank* means any person or facility which solicits, retrieves, performs donor selection and/or testing, preserves, transports, allocates, distributes, acquires, processes, stores or arranges for the storage of human tissues for transplantation, transfer, therapy, artificial insemination

or implantation, including autogeneic procedures. Tissue banks shall be issued a license in the specific category of tissue and type of tissue services provided as described in subdivision (ad) of this section, and shall be required to comply with the standards applicable to the category or categories of tissue acquired, processed, stored and/or distributed. Categories of tissue and their definitions are:

- (i) *Cardiovascular tissue* means human heart valves, aorta, great vessels, pericardium, saphenous vein, umbilical vein, or any other cardiovascular tissue for transplantation.
- (ii) *Musculoskeletal tissue* means human bone, tendon, ligament, muscle, fascia, cartilage, dura, or any other musculoskeletal tissue for transplantation.
- (iii) *Skin* means any human skin tissue for transplantation.
- (iv) *Eye* means a human cornea or any other ocular tissue for transplantation.
- (v) *Reproductive tissue* means any tissue from the reproductive tract intended for use in artificial insemination or any other assisted reproductive procedure. This includes, but is not limited to, semen, oocytes, embryos, spermatozoa, spermatids, ovarian tissue, testicular tissue and epididymal aspirates.
- (vi) *Human milk* means human milk for ingestion by a child other than the mother's own.
- (vii) *Hematopoietic progenitor cells* means human precursor or progenitor hematopoietic cells derived from bone marrow, peripheral blood or other tissue sources (see Subpart 58-5 of this Title).

(2) The following exceptions shall apply to the definition of tissue bank in this subdivision:

- (i) An organ procurement organization shall not constitute a tissue bank solely by virtue of storing or arranging for the storage of heart valves.
- (ii) An entity that uses tissue or fluids exclusively for diagnostic purposes, after removal or withdrawal of these materials in the course of standard medical practice, shall not constitute a tissue bank.
- (iii) A hospital whose tissue banking activities are limited to requesting organs and/or tissue donations, or referring potential donors or next of kin to licensed comprehensive tissue procurement services pursuant to Public Health Law article 43-A, shall not constitute a tissue bank.

(ab) *Tissue bank compliance officer* means an employee of a tissue transplantation facility who is responsible for communicating all department requirements pertinent to transplantation services to each transplantation service director in the facility and for responding to inquiries from the department regarding compliance with this Part.

(ac) *Tissue bank director* means a person who is appointed by the owner of a

tissue bank and meets the requirements of section 52-2.5(a)(2) of this Part, who may be the medical director, and has responsibility for the operation of the tissue bank.

- (ad) *Tissue services* means the type and extent of services provided by tissue banks acquiring, processing, storing and/or distributing tissues for transplantation, transfer, artificial insemination or implantation. Types of tissue services sites and their definitions are:
- (1) *Comprehensive tissue procurement service* means a facility or organization that engages in donor selection, solicitation and retrieval activities related to tissues from living and/or cadaveric donors.
  - (2) *Limited tissue procurement service* means a facility or organization whose tissue acquisition activities are limited to donor selection and solicitation by its own staff or the provision of staff, training or equipment for tissue acquisition activities to assist a comprehensive tissue procurement service in retrieving tissue. Retrieval of tissues on the premises of a limited tissue procurement service shall be performed by the staff or agents of a comprehensive tissue procurement service. Hospitals whose tissue banking activities are limited to requesting organ and/or tissue donations, or referring potential donors or next of kin to licensed comprehensive tissue procurement services are not subject to the licensure requirements in Subpart 52-2.
  - (3) *Tissue processing facility* means a facility or organization that engages in any or all activities associated with processing, storage and/or distribution of human tissues for transplantation, transfer, artificial insemination or implantation.
  - (4) *Tissue storage facility* means a facility that engages in any or all activities associated with storage and distribution of human tissues for transplantation, transfer, artificial insemination, and/or implantation, except insemination/implantation sites storing, for less than six months, semen collected and processed by a semen bank appropriately licensed by the department.
  - (5) *Tissue transplantation facility* means a facility which temporarily stores and transplants tissue, except for tissue intended for autogeneic transplantation, provided such tissue does not leave the operating room for processing and/or storage.
  - (6) *Tissue transplantation service* means a unit within a tissue transplantation facility that is independently supervised and transplants one or more types of tissue.
  - (7) *Insemination/implantation site* means a location at which artificial insemination or assisted reproductive procedures are performed, using reproductive tissue from anonymous donors, directed donors and/or client-depositors. Semen processing, limited to washing, concentrating and storing semen from patients of physicians associated with the licensed insemination/implantation site or from the patients' regular sexual partners, and limited storage (less than six months' duration) may be undertaken without additional licensure.

- (ae) *Transplantation service director* means a physician who directs a tissue transplantation service.
- (af) *Viral inactivation* means a process that subjects tissue to sterilization using ethylene oxide gas, gamma irradiation, or other sterilization method generally accepted by leading authorities in transplant medicine.

## SUBPART 52-2

### TISSUE BANKS AND NONTRANSPLANT ANATOMIC BANKS - LICENSURE

#### SECTION

- 52-2.1 Licensure
- 52-2.2 Provisional licensure
- 52-2.3 Ownership or controlling interest reporting requirements
- 52-2.4 Special criteria for tissue bank licensure
- 52-2.5 License issuance and denial
- 52-2.6 Financial disclosure and fees for services
- 52-2.7 Administration and direction
- 52-2.8 Administration of a tissue transplantation facility
- 52-2.9 Required records
- 52-2.10 Compliance with standards

#### **Section 52-2.1 Licensure.**

- (a) Any person who plans to operate a tissue bank or nontransplant anatomic bank or distribute tissue or nontransplant anatomic parts in New York State shall submit a completed, signed application to the department and obtain a license from the department prior to the operation of such a tissue bank or nontransplant anatomic bank, or conduct of such activity, unless otherwise specified in this Part.
- (b) The department shall provide, upon request, an application for licensure as a tissue bank which may require information including, but not limited to, the following:
  - (1) the name, address and telephone number of the bank;
  - (2) the days and hours of bank operation;
  - (3) the type of organization sponsoring the bank, i.e., proprietary, municipal or nonprofit;
  - (4) the type of ownership, i.e., individual, partnership, corporation or government;
  - (5) if ownership is individual, corporation or partnership: the name and principal office address of the entity, and the name, title, home address and Social Security number and Federal employer identification number, if any, of the owner, officers of the corporation or the partners;
  - (6) if government-operated: the name, principal office address of the government entity, and the name(s), title(s) and addresses of the administrator responsible for the operation of the bank in conjunction with the director;
  - (7) except for facilities established pursuant to Public Health Law article 28, for any person or entity with a direct or indirect ownership interest in the tissue bank of five percent or more, or any owner who is a licensed health

professional and is authorized by law to prescribe tissue services and/or perform tissue transplantation services, or principal stockholder or any person or entity with a controlling interest:

- (i) name, home address, and Social Security number and employer identification number, if any, of such persons, or for a corporation, the corporate name, principal place of business, corporate executive office address and employer identification number;
  - (ii) the manner in which the person or entity has an ownership interest or a controlling interest, and the percentage of such ownership interest;
  - (iii) any existing or prior direct or indirect ownership interest or status as a person or entity with a controlling interest in any other tissue bank, laboratory, funeral firm or health care facility holding a New York State or New York City license, permit or certificate of operation, and the name and address of such tissue bank, laboratory, firm or facility, and whether such bank, laboratory, firm or facility has had its permit or license denied, revoked, suspended, limited or annulled, or currently has an enforcement proceeding pending against it; and
  - (iv) whether the person or entity has been convicted of, or pled guilty to, a criminal offense related to the operation of a bank, laboratory or health care facility, or of any programs established pursuant to title XVIII, XIX or XX of the Federal Social Security Act; and
- (8) the category or categories of tissue, and the type or types of tissue services to be provided;
  - (9) a description of the tissue bank premises and equipment;
  - (10) any other employment of the tissue bank director and/or medical director, including the position and number of hours worked;
  - (11) the name, position, qualifications, duties and work schedule of all technical personnel;
  - (12) a copy of all existing tissue acquisition and/or processing agreements;
  - (13) a description of the tissue bank's proposed or existing service area for acquisition and/or distribution of tissue;
  - (14) a description of educational programs, including those programs designed to encourage tissue donation;
  - (15) donor and recipient selection and testing criteria;
  - (16) a copy of each protocol or procedure required in this Subpart and in the Subpart for each category of tissue;
  - (17) any information required in the Subpart for each category of tissue;
  - (18) for a corporation: a copy of the existing certificate of incorporation, by-laws and any certificates of doing business under an assumed name, or for a partnership: a copy of the partnership agreement and any certificates of doing business under an assumed name;
  - (19) for the tissue bank director and medical director, if applicable, the following information:
    - (i) name;
    - (ii) work and home addresses and work telephone number;
    - (iii) educational background; and

- (iv) work experience, including all places of employment and positions held for the ten years immediately preceding the date of the application; and
  - (20) the name, title, work address and telephone number of the tissue bank compliance officer and tissue transplantation service director(s), if such personnel are required pursuant to this Part.
- (c) An application for licensure as a limited tissue procurement service shall require the information specified in paragraphs (1) through (8) of subdivision (b) above, and:
- (1) a list of all tissue banks performing tissue acquisition activities on the premises of a limited tissue procurement service; and
  - (2) the name, title and business telephone number of the person with primary responsibility for compliance with Public Health Law article 43-B.
- (d) An application for licensure as a nontransplant anatomic bank shall require the information specified in paragraphs (b) (1) through (8) of this section, and:
- (1) a list of all the types of nontransplant anatomic parts banked;
  - (2) a list of all facilities that provide nontransplant anatomic parts to the nontransplant anatomic bank;
  - (3) a list of all facilities in New York State to which nontransplant anatomic parts are distributed;
  - (4) the name, title and business telephone number of the person with primary responsibility for compliance with Public Health Law article 43-B; and
  - (5) an affirmation that the tissue will be distributed only to a legal donee as designated in Public Health Law section 4302 and will only be used by the bank for the purposes authorized by Public Health Law section 4302.
- (e) Any dentist or physician whose use of tissue is limited to virally inactivated tissue shall not be required to be separately licensed pursuant to this Part, provided he or she is licensed by, and currently registered with, the State Education Department.
- (f) Shipping of any tissue from an out-of-state facility shall constitute distribution and shall require a license, unless the tissue is:
- (1) avascular eye tissue or hematopoietic progenitor cells shipped to a licensed comprehensive tissue procurement service, provided the licensed comprehensive tissue procurement service shall be responsible for:
    - (i) the safety and appropriateness of the imported tissue as specified in Subparts 52-3 and 52-7 of this Part, and Subpart 58-5 of this Title; and
    - (ii) obtaining documentation that valuable consideration has not been paid to the out-of-state facility transferring the tissue. Documentation that the transferring out-of-state facility is a nonprofit organization shall create a presumption that valuable consideration has not been paid.

- (2) subjected to viral inactivation by a process accepted by leading authorities in the field of transplantation medicine and a written exception to the requirements of this subdivision has been granted by the department on the basis of documentation submitted by the applicant, including a detailed description of the viral inactivation methodology and procedure, and data showing the amount of virus introduced and the effectiveness of the method in destroying the virus; or
  - (3) from fully screened and tested donors; has been extensively processed and altered by such means as culturing over many generations, and combined with nontissue components, so that the original human tissue constitutes a small percentage of the final product; and a written exception to the requirements of this section has been granted by the department on the basis of documentation submitted by the applicant. Such documentation shall include a detailed description of the processing and donor screening performed to ensure that the tissue is free of pathogens listed in sections 52-3.4(c)(4), 52-4.7(a), 52-5.7(a), 52-6.7(a) and 52-7.7(a), as applicable to the type of tissue procured.
- (g) All changes in the tissue bank director, medical director, owner or persons with a controlling interest shall be reported as specified in section 52-2.3(a) and (b) of this Subpart.

**52-2.2 Provisional licensure.**

- (a) The department may issue a provisional license which shall be valid for a period determined by the department to be sufficient to enable the department to assess the compliance of the tissue bank or nontransplant anatomic bank with this Part. The provisional license may be renewed pending issuance or denial of a license.
- (b) Except for a limited tissue procurement service, a tissue bank initially applying for a license may be issued a provisional license provided it meets the following conditions:
  - (1) a valid and complete license application has been filed;
  - (2) unless the site is a tissue transplantation facility or insemination/implantation site or a tissue storage facility whose tissue storage activity is limited to virally inactivated tissue, a medical advisory committee, consisting of at least five individuals with experience in tissue banking and/or transplantation medicine, including at least one member with expertise in infectious diseases, has been designated;
  - (3) if the tissue bank has been inspected by the department, the tissue bank has provided satisfactory evidence of correction of any deficiencies found; and
  - (4) the owners and/or persons with a controlling interest, tissue bank director, medical director, tissue bank compliance officer and transplantation service director, as required, meet the requirements of this Part and possess the education and experience necessary to ensure that the tissue

bank is operated in substantial compliance with this Part.

- (c) A nontransplant anatomic bank or a limited tissue procurement service initially applying for a license may be issued a provisional license provided it submits a complete application.
- (d) A provisional license may be withheld if the director, medical director, tissue bank compliance officer, any owner, or any person with a controlling interest applying for a provisional license has ever directed, owned or controlled a health care facility, laboratory, tissue bank, funeral directing firm, or nontransplant anatomic bank which has had its permit or license denied, revoked, suspended, limited or annulled, or which has an enforcement proceeding against it pending at the time of application for a provisional license.
- (e) A provisional license may be denied or terminated, without a hearing, if the department finds that the tissue bank or nontransplant anatomic bank is not operated in substantial compliance with the applicable provisions of section 52-2.5 of this Subpart.
- (f) The valid provisional license shall be conspicuously posted within the facility.

**52-2.3 Ownership or controlling interest reporting requirements.**

- (a) Except for a tissue bank owned and operated by a facility established pursuant to Public Health Law, article 28, any change in the direct or indirect ownership status of five percent or more or in a controlling interest in a tissue bank or nontransplant anatomic bank, shall be reported to the department on a new application within 30 days of the change. Such application shall be reviewed in accordance with section 52-2.5 of this Subpart. Any change in the direct or indirect ownership status or of a person with a controlling interest which requires Public Health Council approval pursuant to Public Health Law, article 28, shall be reported to the department within 30 days of the change.
- (b) All changes in tissue bank director, medical director, nontransplant anatomic bank director, or tissue bank compliance officer shall be reported to the department in writing within five days of the change, and a new application reflecting all changes since the prior application must be submitted within 30 days of the change. Such application shall be reviewed in accordance with section 52-2.5 of this Subpart.
- (c) If any person or corporation with an ownership or controlling interest in a tissue bank or nontransplant anatomic bank of five percent or more has been convicted of a criminal offense related to the operation of such a bank, a laboratory or of any programs established by title XVIII, XIX or XX of the Federal Social Security Act, such conviction shall be disclosed within 30 days

of its occurrence. Conviction does not necessarily bar ownership; the department shall review the conviction under the requirements of the Public Health Law to determine whether the conviction may affect the ability of the bank to operate in compliance with Public Health Law, article 5, title V and article 43-B, and applicable state and federal regulations regarding the operation of tissue banks.

- (d) Ownership of or controlling interest in any other tissue bank, nontransplant anatomic bank, laboratory or health care facility holding a New York State or New York City license shall be disclosed within 30 days of any change in such status.
- (e) Failure to comply with the reporting and application requirements of this section shall result in termination of the license.

#### **52-2.4 Special criteria for tissue bank licensure.**

- (a) Prior to approving an application for a license to operate a tissue bank, other than a limited tissue procurement service or a tissue transplantation facility, which acquires, processes, stores and/or distributes tissue for transplantation, transfer, artificial insemination or implantation, the department shall consider:
  - (1) the applicant's ability and intent to arrange for the acquisition, processing, storage and/or distribution of usable donated tissue within the designated geographic area of service;
  - (2) the applicant's ability to establish and maintain effective agreements for tissue acquisition with hospitals;
  - (3) the applicant's ability to engage and participate in systematic efforts, including professional and public education, to acquire usable tissue;
  - (4) the applicant's ability to establish and meet quality standards for the acquisition, processing, storage and/or distribution of tissue;
  - (5) the applicant's ability to arrange for the selection and testing of donors, and/or testing and processing of donated tissue;
  - (6) the character and competence of the tissue bank operator, the bank's officers, directors, principal stockholders and any persons with a controlling interest, including the quality of care or professional services provided by themselves or through any health care entity or business operated or controlled by such persons; and
  - (7) with respect to tissue banks created after June 1, 1991, the existence and activities of other tissue banks in the geographic area to be served by the applicant, and the statewide need for tissue to be distributed by the applicant, as determined by a review of the following factors, as applicable:
    - (i) the current and projected population characteristics of the service area, including relevant health status indicators;
    - (ii) normative criteria for age-specific and sex-specific rates of tissue utilization;
    - (iii) procedures to assure that tissues are distributed based on medical

- need and not preferentially distributed according to the donor or recipient's membership in a category based on race, color, creed, national origin, marital status, social organization or income, except if medically indicated; and
- (iv) the need of the population served or to be served for the types of tissue services proposed for each category of tissue, and the extent to which all residents in the service area will have access to those services. The population need analysis for each proposal shall include a determination of the appropriate service area for distribution of tissues. After reviewing the evidence, the commissioner may determine that the proposed service area is not acceptable and may direct, as a condition of licensure, that additional, fewer, or different areas be served.
- (b) Prior to approving an application for a license to operate a tissue transplantation facility, the department shall consider the special criteria listed in subdivision (a) of this section except for paragraphs (1), (2), (3), (5) and (7).
  - (c) Prior to approving an application for a license to operate a limited tissue procurement service, the department shall consider the special criteria listed in subdivision (a) of this section except for paragraphs (1), (2), (5) and (7).

**52-2.5 License issuance and denial.**

- (a) A tissue bank, other than a tissue transplantation facility, tissue storage facility or a limited tissue procurement service, shall be issued a license for one or more tissue categories, provided that:
  - (1) the owner(s) and/or an authorized representative have submitted a license application pursuant to this Subpart;
  - (2) a tissue bank director has been appointed who:
    - (i) is a physician licensed and currently registered to practice medicine in New York State or in the state in which he or she practices, and has at least two years' training or experience in the category or categories of tissue, or in a related field, as determined by the department; or
    - (ii) is a person with a doctoral degree in an appropriate biological science, and has a minimum of two years' tissue banking experience in the category or categories of tissue, or in a closely related field, as determined by the department; or
    - (iii) is a person with a master's degree in an appropriate biological science, and has a minimum of four years' tissue banking experience in the category or categories of tissue, or in a closely related field, as determined by the department; or
    - (iv) is a person with a bachelor's degree in an appropriate biological science, and has a minimum of six years' tissue banking experience in the category or categories of tissue, or in a closely related field, as

- determined by the department; and
- (v) holds a current certificate of qualification from the department, in the category or categories of testing, if laboratory testing is performed by the tissue bank;
  - (3) the medical director is a physician licensed and currently registered to practice medicine in New York State or in the state in which he or she practices. The tissue bank director may serve as the medical director if he or she is a physician licensed and currently registered to practice medicine in New York State or in the state in which he or she practices;
  - (4) for tissue banks other than insemination/implantation sites, the medical advisory committee is found acceptable by the department;
  - (5) the department has found that the tissue bank owners, any parties with a controlling interest, medical director and tissue bank director have the character and competence to ensure that the tissue bank is competently staffed, properly equipped, and operated in accordance with the law, and that such tissue bank will be so operated. In making such a determination, the department shall consider the factors listed in subdivision (e) of this section with respect to the tissue bank, the director, medical director, and owner(s) of the tissue bank, and any affiliated person, including parties with a controlling interest; and
  - (6) the tissue bank has corrected deficiencies found on any inspection conducted by the department and any deficiencies noted by the department in the standard operating procedures manual submitted with the application.
- (b) A tissue transplantation facility shall be issued a license for one or more tissue categories, provided that:
- (1) the owner(s) and/or authorized representative have submitted a license application pursuant to this Subpart;
  - (2) a tissue bank compliance officer has been appointed;
  - (3) a director who is a physician licensed and currently registered to practice medicine in New York State is appointed for each tissue transplantation service within the tissue transplantation facility;
  - (4) the tissue transplantation facility is established pursuant to Public Health Law, article 28, or is the private office of a physician licensed and currently registered to practice medicine in New York State;
  - (5) the department has found no evidence that the tissue bank compliance officer and director of each tissue transplantation service within the tissue transplantation facility lack the character and competence to ensure that the tissue transplantation facility is competently staffed, properly equipped and operated in accordance with the law, and that such tissue transplantation facility will be so operated. In making such a determination, the department shall consider the factors listed in subdivision (e) of this section with respect to the tissue transplantation facility, the tissue bank compliance officer and the director of each tissue transplantation service within the tissue transplantation facility; and

- (6) the tissue transplantation facility has corrected any deficiencies noted by the department in the written standard operating procedure manual or records of tissue issuance and, if inspected, the tissue transplantation facility has corrected any deficiencies found.
- (c) A tissue storage facility shall be issued a license provided:
- (1) the owner(s) and/or authorized representative(s) have submitted a license application pursuant to this Subpart;
  - (2) a director has been appointed who has at least two years' experience in the storage of tissue or in a related field, as determined by the department;
  - (3) the medical director is a physician licensed and currently registered to practice medicine in New York State or in the state in which he or she practices. The tissue storage facility director may serve as the medical director only if he or she is a physician licensed and currently registered to practice medicine in New York State or in the state in which he or she practices;
  - (4) if inspected, the facility has corrected any deficiencies found; and
  - (5) the department has found that the tissue bank owners and any parties with a controlling interest, medical director and tissue bank director have the character and competence to ensure that the facility is competently staffed, properly equipped and operated in accordance with the law, and that such tissue bank will be so operated. In making such a determination, the department shall consider the factors listed in subdivision (e) of this section with respect to the facility, the director(s) and owner(s) of the facility, and any affiliated person, including parties with a controlling interest.
- (d) A nontransplant anatomic bank or limited tissue procurement service shall be issued a license provided:
- (1) the owner(s) and/or authorized representative(s) have submitted a license application pursuant to this Subpart;
  - (2) if inspected, the bank has corrected any deficiencies found; and
  - (3) the bank is competently staffed, properly equipped and operated in accordance with the law. In making such a determination, the department may consider the factors listed in subdivision (e) of this section with respect to the bank, the director(s) and owner(s) of the bank, and any affiliated person, including parties with a controlling interest.
- (e) In determining whether to deny a license, the department may consider the following factors with respect to the tissue bank or nontransplant anatomic bank director(s) and owner(s), and any affiliated person, including parties with a controlling interest:
- (1) false representation or omission of a material fact in filing the license application or during inspection;
  - (2) failure to supply further information necessary to process the license application, within three months of the department's written request,

- without satisfactory explanation;
- (3) conviction of any crime or sustained charges of administrative violations of state or federal laws, rules and regulations, related to the operation of a site performing health care services or a funeral directing firm, including, but not limited to, the Public Health Law or related statutes;
  - (4) the employment of unqualified technical personnel or an insufficient number of such personnel or support personnel;
  - (5) a pattern of deficiencies on onsite inspection, especially in areas of quality assurance, management, and handling of regulated medical waste and radioactive materials, including:
    - (i) refusal or inability to produce records or reports as requested by department employees;
    - (ii) failure to correct deficiencies from inspection to inspection;
    - (iii) deviation from regulations and/or accepted standards so as to jeopardize the quality of tissue services provided or pose a hazard to employees, donors, recipients or the public; and
    - (iv) refusal to provide department employees with access to the premises;
  - (6) knowing acceptance of tissue requisitions from or provision of tissue services or tissue to a person or persons not authorized by law to provide such services, or possess or use such tissue;
  - (7) failure of the director to be on the premises for an adequate amount of time and adequately supervise technical personnel to ensure the proper performance of all tissue services provided;
  - (8) failure to establish and follow procedures for disposal or handling of tissue or infectious or radioactive medical waste, as determined by the governing state and federal agencies, or disposal in a manner which endangers the public, the employees or the environment; and
  - (9) whether the bank is in compliance with the technical requirements specified in this Subpart, Subpart 52-3 of this Part and/or the Subpart specific to each category of tissue.
- (f) License denial.
- (1) If the department proposes to deny a license to a tissue bank or nontransplant anatomic bank, the bank shall be given written notice of the proposed denial, stating the reason or reasons for the denial. Such notice shall be sent by certified mail and shall be a final determination to be effective 30 days from the date of the notice unless reconsideration is requested pursuant to paragraphs (3), (4) and (5) of this subdivision.
  - (2) Denial of a license shall preclude the applicant from operating a tissue bank or nontransplant anatomic bank in New York State, either directly or indirectly through any other person.
  - (3) If the department gives notice of proposed denial of a license, the applicant may request reconsideration of the proposed denial by submitting a written request for reconsideration to the department within 30 days of the date of the notice. Submission of a request for

- reconsideration within 30 days shall stay any action to deny a license, pending the department's decision regarding such reconsideration.
- (4) The written request for reconsideration shall include all information the applicant wishes to be considered, including any written documentation which would controvert the reason for the denial or disclose that the denial was based upon a mistake of fact.
  - (5) Within 90 days of receipt of the request for reconsideration, the department shall review its initial determination to deny a license and shall issue a written determination after reconsideration. The determination after reconsideration may affirm, revoke, or modify the proposed denial, allow issuance of a license conditional on maintenance of corrective action, or require that the applicant take corrective action. Such determination shall be the final decision of the department.
  - (6) No license application shall be considered for any applicant who is substantially the same as an applicant who has been denied a license within six months of the final determination of the department denying such application. In the event an applicant has received two successive license denials, no license application shall be considered for that applicant within two years of the last final determination of the department denying a previous application.
  - (7) In addition to any penalties provided under the Public Health Law and Penal Law, falsification or failure to make full disclosure on a license application shall be deemed to constitute, in itself, a bar to obtaining a tissue bank or nontransplant anatomic bank license in New York State.
- (g) A tissue bank license shall list the categories of tissue and types of tissue services offered, as defined in section 52-1.1 (aa) and (ad) of this Subpart, respectively. Such license shall be conspicuously posted on the premises of the bank.

#### **52-2.6 Financial disclosure and fees for services.**

- (a) Each tissue bank or non-transplant anatomic bank shall establish and maintain complete and accurate books, financial records, documents and accounts, which shall be kept for a period of at least seven years. The department shall have access to all such records and any financial statements and audits of the bank, during normal business hours at an office of the bank located within the State of New York or, if no such office is available, at a mutually agreeable and reasonable venue for the purposes of inspection, auditing and copying.
- (b) Upon request, a tissue bank or non-transplant anatomic bank shall provide the department with:
  - (1) a statement of the expenses of the bank, including, but not limited to, salaries, rents, equipment, utilities and travel;
  - (2) a statement of the revenues of the bank, including fees, grants, endowment funds and any other revenues; and
  - (3) a list of fees charged for all tissue services, tissues, and nontransplant

anatomic parts provided by the bank.

- (c) No tissue bank or nontransplant anatomic bank shall sell or otherwise transfer tissue for valuable consideration. Fees charged shall reflect only reasonable costs incurred in the provision of specific services, which shall include the fair market value of the overhead and salaries directly related to the provision of such services, actual transportation costs when transportation is provided, and other documented expenses directly related to the provision of services.

**52-2.7 Administration and direction.**

- (a) Every tissue bank other than a tissue transplantation facility or limited tissue procurement service shall have a tissue bank director. The tissue bank director shall develop and implement policies and procedures for the operation of the bank, consistent with this Subpart and the Subparts for each category of tissue. If the tissue bank director is not a physician, a medical director who is a physician shall be retained.
- (b) Except for transplantation facilities, insemination/implantation sites, and limited tissue procurement services, every tissue bank shall have a medical advisory committee, composed of persons with training and experience in tissue banking or a closely related field, as well as at least one member with infectious disease expertise, and with the qualifications specified in the Subpart(s) for each category of tissue, if any.
- (c) Medical direction of a tissue bank, other than a tissue transplantation facility or limited tissue procurement service, shall be provided by a physician, designated as the medical director, in consultation with the medical advisory committee, if applicable.
- (d) The tissue bank director, if one is required, in consultation with the medical director, if not the same person, and the medical advisory committee, if one is required, shall monitor the medical efficacy of the tissue banking program and shall, as a minimum, develop:
  - (1) medical criteria for allogeneic donor participation;
  - (2) quality control and quality assurance standards; and
  - (3) procedures to assure that tissues from allogeneic donors are distributed based on medical need and not preferentially distributed according to the donor's or recipient's membership in a category based on race, color, creed, national origin, marital status, social organization or income, except if medically indicated.
- (e) The tissue bank director shall be responsible for donor selection and the technical/scientific operation of the bank, including recruitment of sufficient numbers, training, and supervision of all personnel performing tissue acquisition, processing, storage or distribution activities.

- (f) The tissue bank director shall be responsible for ensuring that the tissue transplantation facility or insemination/implantation site performing each transplant, artificial insemination, transfer, or implantation is advised of the donor's applicable medical history and tissue processing methods used, so that recipient counseling may be provided if indicated.
- (g) The medical director of each insemination/implantation site shall be responsible for ensuring that the individual performing each artificial insemination, transfer or implantation is advised of the donor's significant medical history.
- (h) The tissue bank director, medical director and owner(s) shall be responsible for compliance with this Part.

**52-2.8 Administration of a tissue transplantation facility.**

- (a) Each tissue transplantation service director shall develop and implement policies and procedures for operation of the tissue transplantation service consistent with this Subpart and the Subparts for each category of tissue.
- (b) The tissue transplantation service director shall, at a minimum, develop:
  - (1) quality assurance procedures and standards; and
  - (2) procedures to assure that tissues are issued for transplantation based on medical need and not preferentially distributed according to the donor's or recipient's membership in a category based on race, color, creed, national origin, marital status, social organization or income, except if medically indicated.
- (c) The tissue transplantation service director shall be responsible for ensuring that the physician performing each transplant or transfer is advised of the donor's significant medical history if provided by the tissue bank supplying the tissue, and the processing methods used, so that recipient counseling may be provided if indicated.

**52-2.9 Required records.**

- (a) Complete and accurate records of tissue and nontransplant anatomic parts released shall be kept by the tissue banks or nontransplant anatomic banks distributing the tissue. Such records shall be open to inspection by the department. For all donated tissue and nontransplant anatomic parts, the donor's name, address, and any other information which would directly or indirectly identify the donor shall not be disclosed or released by the bank to any person or entity, except upon the written consent of the donor or the person authorized by law to make the donation, or to authorized employees of the department, or as permitted by law. The recipient's name, address, and any other information which would directly or indirectly identify the recipient shall not be disclosed or released by the tissue bank to any person or entity, except upon the written consent of the recipient, or except to authorized

employees of the department, or as permitted by law.

- (b) Complete and accurate records of tissue and nontransplant anatomic parts released for transplantation, transfer, artificial insemination, implantation, research and education shall be kept by the tissue transplantation facility or insemination/implantation site. Such records shall be open to inspection by the department and shall be kept for at least seven years after transplantation or six months after the expiration date of the tissue, whichever is longer. In cases of reproductive tissue transfer/artificial insemination/implantation, records shall be kept for at least seven years after the release of tissue not resulting in live births and 25 years for tissue resulting in live births. Nontransplant anatomic banks shall retain records for five years after release of nontransplant anatomic parts for research or education purposes. The recipient's name, address, and any other information which would directly or indirectly identify the recipient shall not be disclosed or released by the tissue transplantation facility or insemination/implantation site to any person or entity, except upon the written consent of the recipient, or except to authorized employees of the department, or as permitted by law.
- (c) The following donation records shall be kept by each comprehensive tissue procurement service:
  - (1) donor's full name, address at time of donation, identification code, date of birth or age, and date and time of death, if a cadaveric donor;
  - (2) documentation of evaluation of physical condition, if a cadaveric donor;
  - (3) pertinent donor medical history, including, but not limited to, autopsy reports, donation questionnaires, and other donor solicitation materials;
  - (4) documentation of donor informed consent or consent of the person authorized by law to consent to the donation, if applicable, including such person's address, unless this record is retained by a limited tissue procurement service;
  - (5) date and time of collection, and description and quantity of tissue retrieved;
  - (6) any reported changes in donor health status, if applicable;
  - (7) outcome of transplantation, transfer, artificial insemination and implantation procedures, if known, and any reports from facilities using the tissue, which would affect the donor's acceptability;
  - (8) records specified in the Subpart specific to each category of tissue; and
  - (9) documentation of staff training, certification and continuing education.
- (d) The following records shall be kept by each limited tissue procurement service:
  - (1) a record of each referral to a comprehensive tissue procurement service, including the donor's name or other identification, the date and time of referral, the name of the person making the referral, the name of the comprehensive tissue procurement service, and whether the records specified in paragraphs (2) and (3) of this subdivision have been

- transferred to the comprehensive tissue procurement service;
- (2) medical and social history information obtained from the donor, donor's family, and other individuals, including the names of the persons obtaining and giving the information, unless this record is transferred to a comprehensive tissue procurement service; and
  - (3) documentation of donor informed consent or consent of the person authorized by law to consent to the donation, if applicable, including such person's address, unless this record is transferred to a comprehensive tissue procurement service.
- (e) The following records shall be kept by each tissue processing facility:
- (1) an acquisition log or other similar record indicating:
    - (i) donor's identification code and/or unique tissue product number;
    - (ii) name and address of the tissue bank from which the tissue was acquired;
    - (iii) date of receipt of the tissue; and
    - (iv) tissue location in the storage chamber;
  - (2) description of tissue received for processing;
  - (3) methods used for acquisition, processing, distribution and storage of the tissue;
  - (4) air quality measurements for critical and controlled work areas, if applicable;
  - (5) disposition of the tissue, including, but not limited to, distribution records, destruction logs, and autoclaving or incineration records;
  - (6) results of all laboratory tests performed on donors and donated tissue, including documentation of review of test results prior to release of the tissue;
  - (7) documentation of labeling and packaging inspection prior to tissue transport to a tissue transplantation facility or release for transplantation, transfer, artificial insemination or implantation;
  - (8) records specified in the Subpart specific to each category of tissue; and
  - (9) documentation of staff training, certification and continuing education.
- (f) The following records shall be kept by each tissue storage facility:
- (1) an acquisition log or other similar record indicating:
    - (i) donor's identification code and/or unique tissue product number;
    - (ii) date of receipt of tissue;
    - (iii) name and address of tissue bank providing the tissue; and
    - (iv) location of the tissue in the storage chamber; and
  - (2) a record of the disposition of the tissue, including, but not limited to, distribution records, destruction logs, and autoclave or incineration records.
- (g) The following records shall be kept by each tissue transplantation facility or insemination/implantation site:
- (1) the name of the tissue bank providing the tissue, and unique tissue

- product number;
  - (2) a description of the tissue;
  - (3) results of any laboratory tests performed;
  - (4) a log of the disposition of the tissue, including, but not limited to, name or identification code of recipient, tissue product return records, destruction logs, and autoclaving or incineration records;
  - (5) condition of the tissue upon receipt, including any loss noted of liquid nitrogen, dry ice, or other coolant;
  - (6) date of transplant, transfer, artificial insemination, or implantation;
  - (7) quantity of tissue used;
  - (8) outcome of the transplantation, artificial insemination, transfer or implantation procedure, including, but not limited to, any adverse outcome or infectious disease in the recipient, which shall be reported to the tissue bank from which the tissue was obtained; and
  - (9) records specified in the Subpart specific to each category of tissue.
- (h) Records shall be kept by insemination/implantation sites as specified in Subpart 52-8 of this Part.
- (i) Nontransplant anatomic banks which solicit, retrieve, release or store nontransplant anatomic parts shall keep the following information:
- (1) if known, donor's full name, address at the time of donation, identification code, date of birth or age, and date and time of death if a cadaveric donor;
  - (2) documentation of donor informed consent or consent of the person authorized by law to consent to the donation, if applicable, including such person's address;
  - (3) records of distribution of all nontransplant anatomic parts;
  - (4) if applicable, name and address of the nontransplant anatomic bank from which the nontransplant anatomic part was acquired;
  - (5) if applicable, date of receipt of the nontransplant anatomic part from the nontransplant anatomic bank;
  - (6) location of nontransplant parts in storage, including documentation tracing nontransplant anatomic parts to specific donors; and
  - (7) if known, disposition of the nontransplant anatomic parts once their use in education or research is ended, including the names of the funeral directors, cemeteries or crematories involved in disposition.

**52-2.10 Compliance with standards.** Tissue banks, including tissue transplantation facilities, insemination/implantation sites, human milk transfer stations and nontransplant anatomic banks, shall allow admission to representatives of the department for the purpose of inspecting the premises and evaluating the operating procedures, equipment and records, including financial records and lists of physicians or facilities to whom or to which human tissue is released, to determine compliance with the standards in this Part. No tissue bank or nontransplant anatomic bank may acquire, process, store or distribute tissue or nontransplant anatomic parts in New York State unless the bank has been issued a license by the department, or as otherwise specified in this Part. If the commissioner

determines that a bank's failure to comply with the standards set forth in this Part creates a significant likelihood that the health, safety and welfare of potential patients and other persons in contact with tissue or nontransplant anatomic parts from the bank is in jeopardy, the department may require that tissue not be released pending a hearing. The hearing shall commence within 15 days of any suspension pursuant to this section.

## SUBPART 52-3

### GENERAL TECHNICAL STANDARDS FOR TISSUE BANKS

#### SECTION

- 52-3.1 Compliance with FDA regulations and manufacturers' instructions
- 52-3.2 Sterilization of instruments
- 52-3.3 Qualifications of donors
- 52-3.4 Selection and testing requirements for tissue donors
- 52-3.5 Quality assurance and safety requirements
- 52-3.6 HIV antibody testing and notification
- 52-3.7 Reporting requirements
- 52-3.8 Special circumstances

#### **Section 52-3.1 Compliance with FDA regulations and manufacturers' instructions.**

- (a) All antisera, reagents, devices, methods and procedures for tissue processing or transplantation-related testing shall be approved by the FDA, if such approval is available for the particular class or type of antiserum, reagent, device, method or procedure.
- (b) All reagents shall be stored in labeled containers under conditions appropriate for each reagent as directed by the manufacturer and shall be removed from use after the expiration date. The reactivity, specificity and potency of each reagent shall be determined whenever a new lot is employed. All methods shall conform to the manufacturer's instructions unless otherwise approved by the department upon submission of evidence that another method is equal or superior to the method described in the manufacturer's instructions.

**52-3.2 Sterilization of instruments.** All instruments, including collection containers, used for both sterile and clean, non-sterile retrieval of tissues shall be either licensed by the FDA for single use or be sterilized prior to each use. Heat sterilization shall be by autoclaving at 121.5 degrees Celsius for 15 minutes after the chamber of the autoclave has been evacuated and has reached that temperature, or by dry heat for two hours at 170 degrees Celsius, or by such other procedures as may be approved by the department upon submission of evidence that such other procedures are at least equally effective.

#### **52-3.3 Qualifications of donors.**

- (a) A comprehensive or limited tissue procurement service shall obtain a signed informed consent from the living donor of tissue for clinical use.
- (b) For potential cadaveric donors who have not left a signed, witnessed organ/tissue donor card (see section 4303 of the Public Health Law) or a will, the procurement service shall obtain informed consent to an anatomical gift from the next of kin or guardian of the decedent, as required by section 405.25

of this Title, before retrieving tissue. Informed consent forms shall clearly specify the tissues and/or nontransplant anatomic parts to be retrieved. Consent obtained by telephone shall be recorded or documented in writing by the tissue procurement service requesting the donation.

- (c) The acceptability of a cadaveric donation shall be determined by medical history information obtained from medical records, attending physicians or other health care professionals, and from interviewing a family member and/or other person close to the decedent. In the event that no family member or other person close to the decedent is available, eye tissue may be accepted, provided that the final tissue container or accompanying paperwork is clearly labeled to alert the transplanting surgeon that such interview was not conducted. An evaluation of the donor's condition shall be made by a qualified tissue retrieval team member, including an examination for signs of injected drug use, infection, or trauma at the site of donation that may affect the quality of the donated tissue.
- (d) The acceptability of a donation from a living donor shall be determined by a physical examination of and health history interview with the donor.
- (e) A trained, qualified supervisor shall determine whether a donor is suitable for tissue retrieval on the day of the retrieval, according to criteria developed by the medical director in consultation with the medical advisory committee. The medical director, as defined in Subpart 52-1 of this Part, shall be responsible for determining whether:
  - (1) the living donor and his/her donated tissue are acceptable, prior to the retrieval of the tissue, according to criteria developed by the medical director in consultation with the medical advisory committee; and
  - (2) the cadaveric donor and his/her donated tissue are acceptable, prior to the release of tissue, according to criteria developed by the medical director in consultation with the medical advisory committee.

#### **52-3.4 Selection and testing requirements for tissue donors.**

- (a) Except as specifically approved by the medical director of the comprehensive tissue procurement service and in conformance with generally accepted standards of practice, allogeneic tissue for clinical use shall not be released from donors with any of the following conditions:
  - (1) evidence of infection at the site of donation or generalized sepsis on physical examination, by history or by autopsy;
  - (2) except for donors of eye tissue, evidence of autoimmune disease or malignant disease;
  - (3) history of hepatitis B or C, or hepatitis of unknown etiology;
  - (4) history of a confirmed positive test or treatment for syphilis within the past 12 months;
  - (5) degenerative or infectious neurological disease, such as Creutzfeldt-Jacob disease, multiple sclerosis and Alzheimer's disease, or encephalitis of

- unknown etiology;
- (6) history of receipt of pituitary-derived human growth hormone;
  - (7) transfusion within 48 hours, with four or more units of blood or blood components in adults, or any transfusions within 48 hours in children under 12 years of age, unless:
    - (i) a pretransfusion blood sample is available for testing;
    - (ii) a testing technology unaffected by plasma dilution and approved by the department is used for all analytes; or
    - (iii) plasma dilution is determined to be insufficient to alter test results, according to an algorithm submitted to and approved by the department.
  - (8) history of behavior or factors which place the donor at high risk for human immunodeficiency virus (HIV) infection, including:
    - (i) nontherapeutic injected drug use within the preceding five years;
    - (ii) men who have engaged in anal intercourse or oral sex with another man at any time within the preceding five years;
    - (iii) recipients of factor VIII or factor IX concentrate which was not heat-treated or otherwise virally inactivated;
    - (iv) individuals with evidence of HIV infection;
    - (v) individuals who have engaged in other behavior determined as high risk for HIV infection by the United States Public Health Service (USPHS);
    - (vi) individuals who have been inmates of correctional facilities for 72 consecutive hours or longer within the preceding 12 months;
    - (vii) individuals who, within the preceding 12 months, have been heterosexual partners of HIV-positive individuals or of individuals who fit within any of the above categories; and
    - (viii) men and women who have engaged in prostitution at any time within the preceding five years, and individuals who have been their heterosexual partners within the past 12 months;
  - (9) except for donors of eye tissue, significant exposure to a substance that may be transferred in toxic doses, such as lead, mercury and gold;
  - (10) acquisition, within the previous 12 months, of a tattoo or other skin piercing in which shared instruments which were not sterilized between uses are known to have been used;
  - (11) within the preceding six months, receipt of a bite from an animal suspect of rabies; and
  - (12) for living donors, receipt of a blood transfusion within the preceding 12 months.
- (b) Individuals with suspected rabies or evidence of HIV infection shall not be accepted as donors under any circumstances.
- (c) All required clinical laboratory testing shall be performed by a laboratory operating under a permit issued by the department. For out-of-state tissue acquisitions by New York State-licensed banks, all required clinical

laboratory testing shall be performed by a laboratory which is approved by that state's regulatory authority, the United States Health Care Financing Administration or by the department.

- (1) Blood samples from all allogeneic donors of tissue for clinical use, except oocyte donors tested in accordance with section 52-8.6(h) of this Part shall be tested for evidence of infection with HIV-1, HIV-2, hepatitis B virus (HBV), including hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) and, except for donors of eye tissue or tissue to be virally inactivated, human T-lymphotropic virus type I (HTLV-I), for purposes of donor selection. If available, aliquots of residual serum or plasma shall be frozen for retrospective testing of donors in the event that new or improved tests become available prior to the distribution of donated tissue.
- (2) All laboratory testing and donor medical history reports shall be reviewed and approved by the medical director or by the medical director's designee, according to criteria determined by the medical director, prior to release of tissue for distribution.
- (3) Results of required testing shall be affixed to the final tissue product container or included in a product circular for tissue intended for clinical use.
- (4) Except in a life-threatening emergency documented and approved by the medical director and the director of the tissue transplantation service using the tissue, tissue shall not be made available for clinical use unless the donor's blood reacts negatively to approved tests for HIV-1, HIV-2, HBsAg, HCV and, except for eye tissue or tissue to be subjected to viral inactivation, HTLV-I.

### **52-3.5 Quality assurance and safety requirements.**

(a) Quality assurance.

- (1) Records shall document that the following quality control procedures are in place at the tissue bank, except for a limited tissue procurement service:
  - (i) preventive maintenance, periodic inspections and testing for proper operation of equipment, including annual calibration of thermometers used to monitor the temperature of tissue in storage, against a National Institute of Standards and Technology (NIST)-certified thermometer, or a thermometer that has been tested against and found to be in agreement with an NIST-certified thermometer;
  - (ii) monitoring of all temperature-controlled spaces and equipment to assure proper performance;
  - (iii) validation of computer systems, microprocessor-controlled equipment and associated software;
  - (iv) validation of processing and testing methodologies; and
  - (v) supervisory review of test results prior to labeling of the tissue.
- (2) Processing, laboratory and storage facilities shall be maintained in a clean and orderly manner, and shall be of suitable size, construction and location to assure tissue and personnel safety.
- (3) All reagents and solutions shall be in-date, stored properly and labeled to

indicate identity and, as appropriate, titer, strength or concentration, recommended storage requirements, preparation or expiration date, and other pertinent information. All such materials shall be removed from use on the expiration date. Materials of substandard reactivity and deteriorated materials shall be discarded regardless of expiration date.

- (4) All specimens for testing accompanying the retrieved tissue shall be sufficiently stable to provide accurate and precise test results suitable for clinical interpretation. The tissue bank shall ensure that specimens are collected, preserved, and transported to the laboratory in such a manner as to meet this requirement. Specimens for analysis shall be identified fully and accessioned in a logbook. The accessioning system shall be designed to trace the tissue to a specific donor and to identify the date and, if applicable, the time of retrieval.
- (5) Control samples and standards shall be assayed regularly in order to validate test results on patient samples and to monitor reagents, operating characteristics of instruments and accuracy of volumetric equipment. The frequency required for such testing shall be determined by the nature of the testing. Records of test procedures, reagents, calibrations, and results with control samples and standards shall be maintained and be available at all times for use by processing laboratory personnel and inspection by the department. As appropriate, these records shall document the precision required for every method, automated or manual, and its restandardization schedule. Control limits for standards and reference samples shall be recorded and shall indicate when test results are outside acceptable limits. Values for quantitative assays shall be reported only if the analytical run of which they are a part is an acceptable run as determined by a protocol approved by the laboratory director. If the analytical error exceeds limits established by the laboratory's quality control program, remedial action shall be taken and documented, and the patient specimen, if available, retested. Whether or not the specimen is available for retesting, the initial result shall be reported as invalid.
- (6) Current standard operating procedure manuals or other procedural guides specific to the facility shall be available at all times in the immediate work area of personnel engaged in tissue retrieval, processing, testing, storage and distribution activities. There shall be a written procedure for each tissue collection, processing, storage and distribution activity performed at the facility. Manuals shall contain a protocol for writing, maintaining and periodic review of standard operating procedures by user personnel and management staff. Procedure manuals shall have the following features:
  - (i) a standardized format;
  - (ii) a system of numbering and/or entitling individual procedures;
  - (iii) a clearly written description of purpose for each procedure;
  - (iv) a reference section listing appropriate scientific literature and industry and/or corporate standards espoused by the tissue bank;
  - (v) clearly defined areas of personnel responsibility by title;
  - (vi) documented approval of procedures and procedural modifications by

- the tissue bank director, and annual review by the tissue bank director or authorized supervisor;
- (vii) instructions for the completion of reports and forms, including examples;
  - (viii) authorship and effective date, and date of review for each procedure; and
  - (ix) a system of archiving earlier versions of procedures and forms.
- (7) The policies and procedures specified in the current standard operating procedures manual shall be followed at all times. If deviations or deficiencies are identified, appropriate corrective action shall be taken and documented.
- (8) The tissue bank director shall establish and maintain a planned and periodic internal review program for monitoring and evaluating the quality and appropriateness of the banking activities conducted. Included in the program shall be a system for designing and implementing corrective action for any problems identified. Quality assurance deficiencies shall be documented, and evidence shall be available that problems are reported to supervisory personnel in a timely manner and that corrective action is implemented, documented and subsequently followed-up.
- (b) Safety. The tissue bank shall implement written safety and infection control policies and procedures to ensure protection from unnecessary physical, chemical and biological hazards.
- (1) Decontamination and disposal techniques for regulated medical waste shall be utilized. All hazardous and regulated waste materials shall be handled, stored and discarded pursuant to Part 70 of this Title, or in the case of out-of-state banks, in accordance with the hazardous waste disposal requirements of the state in which the disposal occurs.
  - (2) If autoclave equipment is used for sterilization, the pressure, temperature, and duration of each cycle shall be recorded, and such records maintained for one year. For each run, these parameters shall be within the manufacturer's recommended operating standards. If any one or more of these parameters fall outside the manufacturer's standards, all material shall be reautoclaved. Chemical, biological and physical detection systems should be used in conjunction with these other measurements of performance.
  - (3) Eating, drinking, smoking, or the application of cosmetics or contact lenses shall not be permitted in work areas. Refrigerators or freezers used for storing tissue, specimens or reagents shall not be used for any other purpose.
  - (4) Gloves and laboratory coats, gowns or other protective clothing shall be worn as necessary while handling specimens or tissues. Such protective clothing shall not be worn outside the work area and shall be disposed of in an appropriate receptacle.
  - (5) A tissue bank performing tissue processing or laboratory testing shall have written policies and procedures in the following areas:

- (i) infection control;
- (ii) biosafety;
- (iii) chemical safety and, if radioactive materials are used, radiological safety;
- (iv) emergency response to worksite accidents; and
- (v) waste disposal.

**52-3.6 HIV antibody testing and notification.** No tissue bank shall inform any tissue donor or consenting next of kin of the results of HIV antibody testing solely on the basis of the enzyme-linked immunosorbent assay (ELISA) or other screening test for HIV antibodies unless such results are negative. Any reactive screening test shall be repeated in duplicate. If two or more separate screening tests are reactive, the sample shall be considered repeatedly reactive. Notification that a donor is positive shall be made only if the results have been reactive or equivocal for more than one screening test and the confirmatory HIV test has been unequivocally reactive. HIV test results that are substantiated as positive shall be reported to living donors. Equivocal or negative results based on confirmatory testing may be reported to the donor, if living, or person legally authorized to consent on behalf of such donor, provided that the person is not informed that the donor is seropositive. Appropriate counseling of living donors or the consenting next of kin regarding the significance of all test results shall be made available or arranged for by the comprehensive tissue procurement service. Reporting of any HIV results to living donors or consenting next of kin, other than results of negative screening tests, shall be conducted in person, unless repeated efforts to encourage the individual(s) to come in have failed, in which case notification may be made by certified restricted delivery mail.

**52-3.7 Reporting requirements.**

- (a) The tissue bank shall have a written procedure for documenting errors or accidents in retrieval, testing, processing, storage or distribution of tissue that may affect the safety of any product. If the error or accident is not detected prior to issuance of the tissue, specimens, or test results to a hospital or other tissue bank, transplantation facility or insemination/implantation site, the error or accident shall be reported immediately to the receiving facility. All such errors and accidents shall also be reported to the department's Wadsworth Center within seven calendar days of discovery.
- (b) All New York State-licensed tissue banks that directly perform or arrange for the performance of transmissible disease testing of donors shall:
  - (1) make the results of such testing available, upon request, to other tissue banks receiving tissue from the same donor; and
  - (2) report, within 24 hours, all positive test results that affect donor suitability to the comprehensive tissue procurement service, if a different facility, except that positive culture results need not be reported if contamination can be traced to a specific step in tissue processing not affecting other tissues processed from the same donor.

- (c) The comprehensive tissue procurement service shall report significant positive test results, as determined by the medical director, to facilities receiving tissues from the same donor so that decisions on quarantining and/or physician notification may be made in a timely and appropriate manner.
- (d) When requested, a tissue bank shall submit reports to the department containing such information and data concerning its activities as may be required by this Part. Such reports shall be signed by the director of the tissue bank.
- (e) Comprehensive tissue procurement services that terminate operations shall submit, for approval by the department, a plan for the continued storage of donor records for the minimum time periods specified in this Part.

**52-3.8 Special circumstances.**

- (a) The department may exempt a tissue bank from a specific standard contained in this Part, provided:
  - (1) the tissue bank has applied to the department for an exemption for limited circumstances prior to the noncompliance with the standard; and
  - (2) the tissue bank has demonstrated to the department that application of the standard to the bank under the limited circumstances for which an exemption is sought:
    - (i) is inconsistent with the provision of the particular service, as documented in properly conducted current medical or scientific research, or current scientific literature;
    - (ii) is incompatible with a requirement imposed by a Federal or other state's government unit which is similar to the standard for which an exemption is sought, and the department determines that the requirement imposed by the Federal or other state's governmental unit's requirement adequately protects the public health, safety, and welfare, based upon commonly accepted medical standards, properly conducted medical or scientific research, or current scientific literature; or
    - (iii) would prevent provision of services necessitated by a medical emergency or special medical conditions. Persons seeking an exemption pursuant to this subparagraph shall describe the nature of the emergency or special medical conditions and the exemption requested, for review on a case-by-case basis by the department. All such emergencies or special medical conditions shall be documented in the medical record, and any action taken in response which is contrary to the requirements of this Part shall be approved by the director of the tissue transplantation service.
- (b) A copy of the department's approval for an exemption shall be maintained by the tissue transplantation facility and the tissue bank releasing the tissue.

## SUBPART 52-4

### CARDIOVASCULAR TISSUE BANKS

#### SECTION

- 52-4.1 Definitions
- 52-4.2 Construction
- 52-4.3 Tissue procurement services
- 52-4.4 Donor qualifications
- 52-4.5 Retrieval of tissue
- 52-4.6 Tissue processing facilities
- 52-4.7 Required laboratory tests on donors and donated tissue
- 52-4.8 Processing and storage of tissue
- 52-4.9 Distribution of tissue products
- 52-4.10 Required records of tissue acquisition, testing, processing and storage
- 52-4.11 Records to be kept by a tissue transplantation facility
- 52-4.12 Disposition of unused tissue
- 52-4.13 Tissue storage facilities

**Section 52-4.1 Definitions.** For the purposes of this Subpart, unless the context indicates otherwise, the following terms shall have the following meanings:

- (a) *Cardiovascular tissue donor* means a human being, living or dead, who is the source of cardiovascular tissue for transplantation, including autogeneic tissue.
- (b) *Critical work area* means an area where sterile tissue containers or aseptically retrieved tissue are exposed to the environment.
- (c) *Critical surface* means a surface which comes into contact with aseptically retrieved tissue, sterile tissue containers or sterile container covers.

**52-4.2 Construction.** Terms not defined in this Subpart are defined in Subpart 52-1 of this Part. Cardiovascular tissue banks shall apply for licensure and otherwise comply with Subpart 52-2 of this Part, and shall meet all general technical standards for tissue banks specified in Subpart 52-3 of this Part.

**52-4.3 Tissue procurement services.**

- (a) A facility that engages in donor selection and solicitation, and retrieval of cardiovascular tissue shall be licensed by the department as a comprehensive tissue procurement service.
- (b) A facility whose tissue acquisition activities are limited to donor selection and solicitation by its own staff shall be licensed by the department as a limited tissue procurement service.

- (c) Comprehensive tissue procurement services retrieving cardiovascular tissue from cadaveric donors shall maintain written standard operating procedures that assure that the retrieval environment, including, but not limited to, walls, floors and permanent equipment, is suitable for retrieval and adequate to prepare an aseptic field. A working sink shall be available.
- (d) Cardiovascular tissue retrieval shall be performed only by trained retrieval technicians under the supervision of the director of a licensed comprehensive tissue procurement service. The director of the licensed comprehensive tissue procurement service shall be responsible for developing policies, procedures and standards for the educational background, training, certification and continuing education of retrieval technicians. Documentation of compliance with this requirement and the standards developed shall be maintained.

**52-4.4 Donor qualifications.**

- (a) In addition to all the requirements of this Subpart, limited tissue procurement services and comprehensive tissue procurement services shall comply with the donor qualification requirements in Subpart 52-3 of this Part.
- (b) Unless specifically authorized by the tissue bank medical director, cardiovascular tissue shall not be released for allogeneic transplant from donors with any of the following conditions:
  - (1) a disease of unknown etiology;
  - (2) malaria within the last three years or travel to a malarially endemic area within the last six months;
  - (3) active or untreated tuberculosis;
  - (4) history or presence of bacterial endocarditis or semilunar valvular heart disease, except for mitral valve prolapse;
  - (5) previous cardiac valvular surgery, if donation of the affected valve is considered;
  - (6) insulin-dependent diabetes mellitus;
  - (7) death due to drowning, if immersion was for longer than six hours; or
  - (8) history of rheumatic fever.
- (c) In addition to the exclusions outlined in subdivision (b) of this section, saphenous veins shall not be released from donors with any of the following conditions:
  - (1) varicose veins or other conditions of chronic venous stasis;
  - (2) trauma to saphenous veins; or
  - (3) significant phlebitis.
- (d) Social history as recorded in the medical chart of the donor, or as provided by a friend or family member shall be considered in the donor selection process.
- (e) The medical director of the comprehensive tissue procurement service shall

be responsible for determining that the donor and the donated cardiovascular tissue are acceptable based on medical history information and established donor selection criteria as specified in this Part, and a physical examination.

- (f) A written policy shall specify the range of acceptable donor age limits for allogeneic cardiovascular tissue donation. This policy shall be determined by the tissue bank medical director in consultation with the medical advisory committee of the comprehensive tissue procurement service.
- (g) Written criteria for acceptance of donors of autogeneic tissue shall be specified by the transplantation service director of the tissue transplantation facility, unless such criteria have been specified already by the medical director of a comprehensive tissue procurement service.

#### **52-4.5 Retrieval of tissue.**

- (a) Cardiovascular tissue shall be retrieved using aseptic technique in an operating room or other aseptic premises approved by the tissue bank medical director.
- (b) Retrieval of cardiovascular tissue from a cadaveric donor shall occur within a time limit after cessation of cardiac function specified in written policies approved by the medical director of the comprehensive tissue procurement service.
- (c) Cardiovascular tissue shall be stored and transported to the tissue processing facility at a temperature between one and 10 degrees Celsius.
- (d) Aseptic processing of cardiovascular tissue shall begin within 48 hours of cessation of cardiac function.
- (e) If an ante mortem blood sample is not available from a cadaveric donor, a post mortem sample of sufficient quantity to perform required laboratory testing shall be drawn via a cardiac insertion or from a large vein or artery.
- (f) Tissue specimen containers and packaging materials shall be sterile and non-toxic.
- (g) Each tissue and blood specimen container shall be labeled legibly at the time of retrieval with the tissue bank identification, and donor identification code or unique tissue identification number. The date, time and anatomic site of retrieval shall be recorded on accompanying documents.
- (h) Unless a sample for culture is to be collected at the tissue processing facility, a segment or sample of contiguous heart or vascular tissue shall be placed in a separate, appropriately labeled sterile container intended for culturing for aerobic and anaerobic contamination.

- (i) Tissue and blood specimen containers shall be labeled so as to maintain cardiovascular tissue identification throughout all phases of processing, storage and distribution, in a manner not subject to significant deterioration under conditions of transport and storage.

**52-4.6 Tissue processing facilities.**

- (a) A facility which processes cardiovascular tissue shall be licensed by the department as a tissue processing facility. Such facilities shall make available to the department a statement of the procedures used in the preparation, testing and preservation of the tissue or tissues distributed, or offered for use. The premises, equipment, procedures, records, circulars of instruction and tissues shall be available for inspection and/or testing by the department as required. Copies of all brochures and other informational materials and instructions, including descriptions of methods of tissue handling, shall be available to the department. Each container of tissue shall be clearly labeled with the donor identification code or a unique tissue identification number, unit size and expiration date, if applicable.
- (b) Aseptic processing of cardiovascular tissue shall be performed in separately defined work areas with:
  - (1) floors, walls and ceilings with nonporous smooth surfaces that are easily cleaned;
  - (2) temperature and humidity controls;
  - (3) an air supply filtered through high efficiency particulate air filters with positive pressure differentials between rooms;
  - (4) a system for monitoring environmental conditions;
  - (5) a system for cleaning and disinfecting a room and equipment to produce aseptic conditions; and
  - (6) adequate space for staff, and storage of garments and equipment.
- (c) Critical work areas in which sterile tissue containers or aseptically retrieved cardiovascular tissue are exposed to the environment shall have an air quality of no more than 100 particles (less than or equal to 0.5 micron) per cubic foot of air and no more than one bacterial colony forming unit per 10 cubic feet of air. Critical work areas shall have a positive pressure gradient greater than or equal to 0.05 inches of water relative to an adjacent less clean area. Critical surfaces shall be sterile and shall not interact with the tissue so as to affect the quality of the tissue adversely.

**52-4.7 Required laboratory tests on donors and donated tissue.** All required clinical laboratory testing shall be performed by a laboratory operating under a permit issued by the department. For out-of-state cardiovascular tissue procurements, all required clinical laboratory testing shall be performed by a laboratory which is approved by that state's regulatory authority, the United States Health Care Financing Administration, or by the department.

- (a) Blood samples from all allogeneic cardiovascular tissue donors shall be tested

for antibodies to human immunodeficiency virus type 1 (HIV-1), human immunodeficiency virus type 2 (HIV-2), human T-lymphotropic virus type I (HTLV-I), and hepatitis C virus (HCV), as well as for hepatitis B surface antigen (HBsAg) and for syphilis, for purposes of donor selection.

- (b) Testing of each cardiovascular tissue unit for aerobic and anaerobic contamination from each retrieval site shall be performed prior to final packaging, using standard laboratory procedures. Whenever fresh tissue is transplanted, the results of cultures shall be made available to the transplantation surgeon on a daily basis until the final reading has been completed.
- (c) All cardiovascular tissue from living donors intended for allogeneic use shall be quarantined for six months. After such time and prior to distribution of the tissue for transplantation, the donor shall be retested for HBsAg and antibodies to HCV, HIV-1 and HIV-2 and tested for antibodies to hepatitis B core antigen (anti-HBc).

#### **52-4.8 Processing and storage of tissue.**

- (a) Fresh cardiovascular tissue shall be stored in an isotonic storage medium demonstrated to maximize tissue viability in a sealed, sterile container at a temperature between one and 10 degrees Celsius for a period not to exceed 24 hours from retrieval. Storage shall take place in a refrigerator reserved for cardiovascular or other tissue intended for transplantation, equipped with a thermometer calibrated at least annually against a National Institute of Standards and Technology (NIST)-certified thermometer, or a thermometer that has been tested against, and found to be in agreement with, an NIST-certified thermometer. The temperature shall be visually monitored and recorded daily unless the refrigerator is equipped with a calibrated mechanical temperature monitor and alarm system to detect an increase in temperature to above 10 degrees Celsius or a decrease in temperature to below one degree Celsius.
- (b) Cardiovascular tissue processing for cryopreservation shall be initiated under aseptic conditions within 24 hours of retrieval. Until processing, tissue shall be stored at between one and 10 degrees Celsius. Once processed, cardiovascular tissue shall be stored frozen at a target temperature of minus 100 degrees Celsius or lower with a suitable cryoprotectant in labeled containers until distributed or issued for use, in either:
  - (1) a freezer reserved for cardiovascular or other tissue intended for transplantation, equipped with an audible alarm to detect an increase in temperature to above the limit established by the director and a recording thermometer calibrated at least annually against an NIST-certified thermometer, or a thermometer that has been tested against, and found to be in agreement with, an NIST-certified thermometer; or
  - (2) a liquid nitrogen tank reserved for cardiovascular or other tissue intended

for transplantation.

- (c) Storage equipment shall have clearly defined and labeled areas for all cardiovascular tissue stored, and untested tissue shall be maintained in a quarantine area segregated from tissue awaiting distribution.
- (d) Thermometers shall be visually monitored daily or temperatures shall be continuously monitored mechanically, and, if applicable, liquid nitrogen levels shall be checked at least twice a week for fluctuations potentially affecting the quality of the cardiovascular tissue. Temperature records and, if applicable, liquid nitrogen level records shall be available for inspection by the department for the entire period of storage and for one year afterwards.

**52-4.9 Distribution of tissue products.**

- (a) Except as provided in section 52-3.4 of this Part, cardiovascular tissue shall not be made available for allogeneic transplantation if:
  - (1) the donor's blood tests repeatedly reactive in approved screening tests for HBsAg, or antibodies to HIV-1, HIV-2, HTLV-I or HCV; or
  - (2) the donor's blood reacts positively to approved tests for syphilis, unless confirmatory testing is negative.
- (b) Cardiovascular tissue shall be transported by the tissue bank or its agents, or by staff or agents of the tissue transplantation facility. A signed form shall be kept on file at the tissue bank documenting the identification of tissue distributed, including the names of both the person(s) releasing the tissue and the person(s) receiving the tissue.
- (c) Frozen cardiovascular tissue in transit from a tissue processing or storage facility to a tissue transplantation facility shall be maintained at a temperature of minus 70 degrees Celsius or lower. Tissue stored at a tissue transplantation facility shall be maintained at the appropriate storage temperature until immediately prior to transplantation.
- (d) Cardiovascular tissue and its labeling and packaging shall be visually inspected prior to its distribution by the tissue processing facility. The tissue shall be inspected by the tissue transplantation facility immediately upon receipt and again after thawing, if frozen. If the physical appearance is abnormal, or there is indication or suspicion of overt microbial contamination, the tissue shall not be utilized for transplantation. In the case of frozen tissue, the period of time between thawing and use shall not exceed 24 hours if tissue is refrigerated at between one and 10 degrees Celsius, or four hours if not refrigerated.
- (e) Cardiovascular tissue shall be issued by the tissue transplantation facility only upon a written order by a licensed physician, or person authorized by law to order such issuance pursuant to section 52-4.11(b) of this Subpart.

Documentation of such order shall be on a dedicated tracking record or on the recipient's medical record. Issuance of cardiovascular tissue shall be recorded in a disposition log and shall allow accurate tracking of tissue to each recipient.

**52-4.10 Required records of tissue acquisition, testing, processing and storage.**

Each cardiovascular tissue bank shall maintain donation records as required by Subpart 52-2 of this Part.

**52-4.11 Records to be kept by a tissue transplantation facility.**

- (a) The director of each tissue transplantation service shall be responsible for records kept by the tissue transplantation facility. In addition to the records specified in Subpart 52-2 of this Part, the following records shall be kept, separate from recipient records, by the tissue transplantation facility:
  - (1) if performed, results of testing for bacterial and fungal contamination after tissue thawing and prior to engraftment;
  - (2) a disposition log allowing accurate tracking of tissue to each recipient; and
  - (3) records of appropriate storage and temperature monitoring of cardiovascular tissue.
- (b) A copy of the order for issuance of the cardiovascular tissue, including the name and signature of the ordering physician or person authorized by law to order such issuance, shall be kept by the tissue transplantation facility. A record in the patient's chart shall be satisfactory documentation of such order for issuance.

**52-4.12 Disposition of unused tissue.**

- (a) Thawed cardiovascular tissue that is not used by the tissue transplantation facility within 24 hours of thawing shall be used for education or research purposes authorized by Public Health Law section 4302, or discarded pursuant to Part 70 of this Title. Packaging of cardiovascular tissue for destruction shall be designed to obscure the contents.
- (b) Cardiovascular tissue returned by the tissue transplantation facility for possible reissuance shall meet all storage and transport requirements of this Part. The cardiovascular tissue bank shall not reissue tissue returned by the tissue transplantation facility, unless written criteria approved by the tissue bank medical director are met.

**52-4.13 Tissue storage facilities.**

- (a) A facility which stores cardiovascular tissue shall be licensed by the department as a tissue storage facility. The cardiovascular tissue bank shall keep the department fully informed of the number and type of tissue storage facilities operating under its direction.

- (b) All cardiovascular tissue shall be stored and monitored in accordance with the provisions of sections 52-4.8, and 52-4.9(b), (c) and (d) of this Subpart.
- (c) Temperature records or liquid nitrogen level records shall be available for inspection by the department for the entire period of cardiovascular tissue storage and for one year afterwards.
- (d) Cardiovascular tissue products shall be distributed in accordance with the requirements of this Part, and all records related to the inspection, distribution and transport of tissues shall be open to inspection by the department and shall be kept for at least seven years or six months after the expiration date of the tissue, whichever is the longer time.

## SUBPART 52-5

### MUSCULOSKELETAL TISSUE BANKS

#### SECTION

- 52-5.1 Definitions
- 52-5.2 Construction
- 52-5.3 Tissue procurement services
- 52-5.4 Donor qualifications
- 52-5.5 Retrieval of tissue
- 52-5.6 Tissue processing facilities
- 52-5.7 Required laboratory tests on donors and donated tissue
- 52-5.8 Processing and storage of tissue
- 52-5.9 Distribution of tissue products
- 52-5.10 Required records of tissue acquisition, testing, processing and storage
- 52-5.11 Records to be kept by a tissue transplantation facility
- 52-5.12 Disposition of unused tissue
- 52-5.13 Tissue storage facilities

**Section 52-5.1 Definitions.** For the purposes of this Subpart, unless the context indicates otherwise, the following terms shall have the following meanings:

- (a) *Batch* means a specific quantity of tissue that is intended to have uniform characteristics and quality within specific limits, and is produced according to the same processing protocol and during the same processing cycle.
- (b) *Musculoskeletal tissue donor* means a human being, living or dead, who is the source of musculoskeletal tissue, including autogeneic tissue, for transplantation.
- (c) *Critical work area* means an area where sterile tissue containers or aseptically retrieved tissue are exposed to the environment.
- (d) *Critical surface* means a surface which comes into contact with aseptically retrieved tissue, sterile tissue containers or sterile container covers.
- (e) *Controlled work area* means an area where unsterilized tissue, in-process materials and tissue containers are handled.

**52-5.2 Construction.** Terms not defined in this Subpart are defined in Subpart 52-1 of this Part. Musculoskeletal tissue banks shall apply for licensure and otherwise comply with Subpart 52-2 of this Part, and shall meet all general technical standards for tissue banks specified in Subpart 52-3 of this Part.

**52-5.3 Tissue procurement services.**

- (a) A facility that engages in donor selection and solicitation, and retrieval of musculoskeletal tissue shall be licensed by the department as a comprehensive tissue procurement service.
- (b) A facility whose tissue acquisition activities are limited to donor selection and solicitation by its own staff shall be licensed by the department as a limited tissue procurement service.
- (c) Comprehensive tissue procurement services retrieving musculoskeletal tissue aseptically from cadaveric donors shall maintain written standard operating procedures that assure that the retrieval environment, including, but not limited to, walls, floors and permanent equipment, is suitable for retrieval and adequate to prepare an aseptic field. A working sink shall be available.
- (d) Musculoskeletal tissue retrieval shall be performed only by trained retrieval technicians under the supervision of the director of a licensed comprehensive tissue procurement service. The director of the licensed comprehensive tissue procurement service shall be responsible for developing policies, procedures and standards for the educational background, training, certification and continuing education of retrieval technicians. Documentation of compliance with this requirement and the standards developed shall be maintained.

**52-5.4 Donor qualifications.**

- (a) In addition to all the requirements of this Subpart, limited tissue procurement services and comprehensive tissue procurement services shall comply with the donor qualification requirements in Subpart 52-3 of this Part.
- (b) Unless specifically authorized by the tissue bank medical director, musculoskeletal tissue shall not be released for allogeneic transplant from donors with any of the following conditions:
  - (1) evidence of rheumatoid arthritis;
  - (2) a disease of unknown etiology; or
  - (3) malaria within the last three years or travel to a malarially endemic area within the last six months.
- (c) Social history as recorded in the medical chart of the donor, or as provided by a friend or family member shall be considered in the donor selection process.
- (d) The medical director of the comprehensive tissue procurement service shall be responsible for determining that the donor and the donated musculoskeletal tissue are acceptable based on medical history information and established donor selection criteria as specified in this Part, and a physical examination.
- (e) A written policy shall specify the range of acceptable donor age limits for allogeneic musculoskeletal tissue donation. This policy shall be determined

by the tissue bank medical director in consultation with the medical advisory committee of the comprehensive tissue procurement service.

- (f) Written criteria for acceptance of donors of autogeneic tissue shall be specified by the transplantation service director of the tissue transplantation facility, unless such criteria have been specified already by the medical director of a comprehensive tissue procurement service.

#### **52-5.5 Retrieval of tissue.**

- (a) Musculoskeletal tissue, including tissue for which assurance of sterility cannot be maintained, such as mandible, shall be retrieved using aseptic technique in an operating room or other aseptic premises approved by the tissue bank medical director.
- (b) Retrieval of musculoskeletal tissue from cadaveric donors shall occur within a time limit after cessation of cardiac function specified in written policies approved by the medical director of the comprehensive tissue procurement service.
- (c) Musculoskeletal tissue retrieved from cadaveric donors shall be transported to the tissue processing facility at a temperature of 10 degrees Celsius or lower.
- (d) If an ante mortem blood sample is not available from a cadaveric donor, a post mortem sample of sufficient quantity to perform required laboratory testing shall be drawn via a cardiac insertion or from a large vein or artery.
- (e) Tissue specimen containers and packaging materials shall be sterile and non-toxic.
- (f) Each tissue and blood specimen container shall be labeled legibly at the time of retrieval with the tissue bank identification, and donor identification code or unique tissue identification number. The date, time and anatomic site of retrieval shall be recorded on accompanying documents.
- (g) A segment or sample of musculoskeletal tissue that is not intended for viral inactivation shall be placed in a separate, appropriately labeled sterile container intended for culturing for aerobic and anaerobic contamination.
- (h) Tissue and blood specimen containers shall be labeled so as to maintain musculoskeletal tissue identification throughout all phases of processing, storage and distribution, in a manner not subject to significant deterioration under conditions of transport and storage.

#### **52-5.6 Tissue processing facilities.**

- (a) A facility which processes musculoskeletal tissue shall be licensed by the department as a tissue processing facility. Such facilities shall make available

to the department a statement of the procedures used in the preparation, testing and preservation of the tissue or tissues distributed, or offered for use. The premises, equipment, procedures, records, circulars of instruction and tissues shall be available for inspection and/or testing by the department as required. Copies of all brochures and other informational materials and instructions, including descriptions of methods of tissue handling, shall be available to the department. Each container of tissue shall be clearly labeled with the donor identification code or a unique tissue identification number, unit size, and expiration date, if applicable.

- (b) Aseptic processing of musculoskeletal tissue shall be performed in separately defined work areas with:
  - (1) floors, walls and ceilings with nonporous smooth surfaces that are easily cleaned;
  - (2) temperature and humidity controls;
  - (3) an air supply filtered through high efficiency particulate air filters with positive pressure differentials between rooms;
  - (4) a system for monitoring environmental conditions;
  - (5) a system for cleaning and disinfecting a room and equipment to produce aseptic conditions; and
  - (6) adequate space for staff, and storage of garments and equipment.
  
- (c) Processing of musculoskeletal tissue intended for viral inactivation shall occur in controlled work areas. These areas shall have an acceptable microbial and particulate quality to minimize contaminants in final tissue preparation prior to sterilization and to ensure effectiveness of sterilization. Air shall have a particulate (less than or equal to 0.05 micron) count of less than or equal to 100,000 per cubic foot in the vicinity of the exposed tissue during periods of processing activity, and no more than 25 bacterial colonies per 10 cubic feet. Air flow shall achieve 20 air exchanges per hour and a pressure differential greater than or equal to 0.05 inches of water relative to an adjacent less clean area. Compressed air shall be free of demonstrable oil vapors.
  
- (d) Critical work areas in which sterile tissue containers or aseptically retrieved musculoskeletal tissue are exposed to the environment shall have an air quality of no more than 100 particles (less than or equal to 0.5 micron) per cubic foot of air and no more than one bacterial colony forming unit per 10 cubic feet of air. Critical work areas shall have a positive pressure gradient greater than or equal to 0.05 inches of water relative to an adjacent less clean area. Critical surfaces shall be sterile and shall not interact with the tissue so as to affect the quality of the tissue adversely.

**52-5.7 Required laboratory tests on donors and donated tissue.** All required clinical laboratory testing shall be performed by a laboratory operating under a permit issued by the department. For out-of-state musculoskeletal tissue procurements, all required

clinical laboratory testing shall be performed by a laboratory which is approved by that state's regulatory authority, the United States Health Care Financing Administration, or by the department.

- (a) Blood samples from all allogeneic musculoskeletal tissue donors shall be tested for antibodies to human immunodeficiency virus type 1 (HIV-1), human immunodeficiency virus type 2 (HIV-2), and hepatitis C virus (HCV), as well as for hepatitis B surface antigen (HBsAg) and for syphilis, and, unless the tissue is to be virally inactivated, antibodies to human T-lymphotropic virus type I (HTLV-I), for purposes of donor selection.
- (b) Testing of each musculoskeletal tissue unit for aerobic and anaerobic contamination shall be performed prior to final packaging, using standard laboratory procedures. Whenever fresh tissue is transplanted, the results of cultures shall be made available to the transplantation surgeon on a daily basis until the final reading has been completed.
- (c) All musculoskeletal tissue from living donors intended for allogeneic use shall be quarantined for six months. After such time and prior to distribution of the tissue for transplantation, the donor shall be retested for HBsAg and antibodies to HCV, HIV-1 and HIV-2 and tested for antibodies to hepatitis B core antigen (anti-HBc).

#### **52-5.8 Processing and storage of tissue.**

- (a) Fresh musculoskeletal tissue shall be stored in an isotonic storage medium demonstrated to maximize tissue viability in a sealed, sterile container at a temperature between one and 10 degrees Celsius for a period not to exceed 14 days from retrieval. Storage shall take place in a refrigerator reserved for musculoskeletal or other tissue intended for transplantation, or blood intended for transfusion, equipped with a thermometer calibrated at least annually against a National Institute of Standards and Technology (NIST)-certified thermometer, or a thermometer that has been tested against, and found to be in agreement with, an NIST-certified thermometer. The temperature shall be visually monitored and recorded daily unless the refrigerator is equipped with a calibrated mechanical temperature monitor and alarm system to detect an increase in temperature to above 10 degrees Celsius or a decrease in temperature to below one degree Celsius.
- (b) Musculoskeletal tissue processing for freezing shall be performed under aseptic conditions within 48 hours of retrieval. Until processing, tissue shall be stored at between one and 10 degrees Celsius. Once processed, musculoskeletal tissue shall be stored frozen at a target temperature of minus 40 degrees Celsius or lower in labeled containers until released for use, in either:
  - (1) a freezer reserved for musculoskeletal or other tissue intended for transplantation, or blood intended for transfusion, equipped with an audible alarm to detect an increase in temperature to above the limit

established by the director and a recording thermometer calibrated at least annually against an NIST-certified thermometer, or a thermometer that has been tested against, and found to be in agreement with, an NIST-certified thermometer; or

- (2) a liquid nitrogen tank reserved for musculoskeletal or other tissue intended for transplantation.
- (c) Freeze-dried musculoskeletal tissue shall be processed in a manner that meets the minimum standards of the manufacturer of the freeze-drier. The freeze-drier shall be equipped with a temperature recording device unless another mechanism for recording temperature is in place, and documentation shall allow tracing of each tissue product to a specific batch. Sterility testing of each freeze-dried tissue unit shall be performed using a properly validated method of 100 percent nondestructive testing, or another method approved by the medical director of the tissue bank in consultation with the medical advisory committee and approved by the department. Testing for residual moisture shall be performed on one representative sample from each freeze-dried batch for each type of musculoskeletal tissue, such as cartilage, ligament and bone. Freeze-dried tissue shall be stored at room temperature or lower.
- (d) If musculoskeletal tissue is sterilized by ethylene oxide, testing for ethylene oxide, ethylene glycol and ethylene chlorhydrin residue shall be performed on each type of tissue within a batch. Residue amounts shall not exceed:

**Parts per Million**

<b>Tissue Quantity</b>	<b>Ethylene Oxide</b>	<b>Ethylene Chlorhydrin</b>	<b>Ethylene Glycol</b>
Small (<10 g)	250	250	5,000
Medium (10-100 g)	100	100	2,000
Large (>100 g)	25	25	500

- (e) Storage equipment shall have clearly defined and labeled areas for all musculoskeletal tissue stored, and untested tissue shall be maintained in a quarantine area segregated from tissue awaiting distribution.
- (f) Thermometers shall be visually monitored daily, or temperatures shall be continuously monitored mechanically, and, if applicable, liquid nitrogen levels shall be checked at least twice a week for fluctuations potentially affecting the quality of the musculoskeletal tissue. Storage shall be at a target temperature of minus 40 degrees Celsius or lower. Temperature records and, if applicable, liquid nitrogen level records shall be available for inspection by the department for the entire period of storage and for one year afterwards.

- (g) Musculoskeletal tissue from two or more donors shall not be pooled.
- (h) The age and sex of the donor, and, if the musculoskeletal tissue is from a living donor, the patient's orthopedic diagnosis shall be made available to the transplanting surgeon, upon request.

**52-5.9 Distribution of tissue products.**

- (a) Except as provided in section 52-3.4 of this Part, musculoskeletal tissue shall not be made available for allogeneic transplantation if:
  - (1) the donor's blood tests repeatedly reactive in approved screening tests for HBsAg, or antibodies to HIV-1, HIV-2, HCV or, unless the tissue is to be virally inactivated, antibodies to HTLV-I; or
  - (2) the donor's blood reacts positively to approved tests for syphilis, unless confirmatory testing is negative.
- (b) Freeze-dried processed musculoskeletal tissue distributed by a processing or storage facility shall be visually inspected for cracks, contamination, or extraneous material prior to distribution. If tissue container seals are broken or there is evidence that proper temperature has not been maintained, tissue shall not be distributed for transplantation. Container vacuums shall be determined to be satisfactory by testing with a spark generator.
- (c) Musculoskeletal tissue shall be transported by the tissue bank or its agents, or by staff or agents of the tissue transplantation facility. A signed form shall be kept on file at the tissue bank documenting the identification of tissue distributed, including the names of both the person(s) releasing the tissue and the person(s) receiving the tissue.
- (d) Musculoskeletal tissue in transit from a tissue processing or storage facility to a tissue transplantation facility shall be maintained at the applicable storage temperature specified in section 52-5.8 of this Subpart. Tissue stored at a tissue transplantation facility shall be maintained, until immediately prior to transplantation, at minus 20 degrees Celsius or lower for a maximum of six months, and minus 40 degrees Celsius for longer periods. Storage shall be in a freezer reserved for musculoskeletal or other tissue intended for transplantation, or blood intended for transfusion.
- (e) Musculoskeletal tissue and its labeling and packaging shall be visually inspected prior to its distribution by the tissue processing facility. The tissue shall be inspected by the tissue transplantation facility immediately upon receipt and again after thawing, if frozen. If the physical appearance is abnormal, or there is indication or suspicion of overt microbial contamination, the tissue shall not be utilized for transplantation. In the case of frozen tissue, the period of time between thawing and use shall not exceed 24 hours if tissue is refrigerated at between one and 10 degrees Celsius, or four hours if not refrigerated.

- (f) Musculoskeletal tissue shall be issued by the tissue transplantation facility only upon a written order by a licensed physician or other person authorized by law to order tissue. Documentation of such order shall be on a dedicated tracking record or on the recipient's medical record. Issuance of musculoskeletal tissue shall be recorded in a disposition log and shall allow accurate tracking of tissue to each recipient.

**52-5.10 Required records of tissue acquisition, testing, processing and storage.**

In addition to the recordkeeping requirements of Subpart 52-2 of this Part, each musculoskeletal tissue bank shall maintain tissue records which include:

- (a) spark testing for vacuum in the case of freeze-dried tissue; and
- (b) if the tissue is sterilized by ethylene oxide, amount of ethylene oxide, ethylene glycol and ethylene chlorhydrin residue for each type of musculoskeletal tissue within a batch.

**52-5.11 Records to be kept by a tissue transplantation facility.**

- (a) The director of each tissue transplantation service shall be responsible for records kept by the tissue transplantation facility. In addition to the records specified in Subpart 52-2 of this Part, the following records shall be kept, separate from recipient records, by the tissue transplantation facility:
  - (1) if performed, results of testing for bacterial and fungal contamination after tissue thawing and prior to engraftment;
  - (2) a disposition log allowing accurate tracking of tissue to each recipient; and
  - (3) records of appropriate storage and temperature monitoring of musculoskeletal tissue.
- (b) A copy of the order for issuance of the musculoskeletal tissue, including the name and signature of the ordering physician or person authorized by law to order such issuance, shall be kept by the tissue transplantation facility. A record in the patient's chart shall be satisfactory documentation of such order for issuance.

**52-5.12 Disposition of unused tissue.**

- (a) All musculoskeletal tissue determined to be unsuitable for transplantation, or education or research purposes authorized by Public Health Law section 4302 shall be discarded pursuant to Part 70 of this Title. Packaging of musculoskeletal tissue for destruction shall be designed to obscure the contents.
- (b) Musculoskeletal tissue returned by the tissue transplantation facility for possible reissuance shall meet all storage and transport requirements of this Part. The musculoskeletal tissue bank shall not reissue tissue returned by the tissue transplantation facility, unless written criteria approved by the tissue bank medical director are met.

**52-5.13 Tissue storage facilities.**

- (a) A facility which stores musculoskeletal tissue shall be licensed by the department as a tissue storage facility. The musculoskeletal tissue bank shall keep the department fully informed of the number and type of tissue storage facilities operating under its direction.
- (b) All musculoskeletal tissue shall be stored and monitored in accordance with the provisions of sections 52-5.8, and 52-5.9(b), (c), (d) and (e) of this Subpart.
- (c) Temperature records or liquid nitrogen level records shall be available for inspection by the department for the entire period of musculoskeletal tissue storage and for one year afterwards.
- (d) Musculoskeletal tissue products shall be distributed in accordance with the requirements of this Part, and all records related to the inspection, distribution and transport of tissues shall be open to inspection by the department and shall be kept for at least seven years or six months after the expiration date of the tissue, whichever is the longer time.

## SUBPART 52-6

### SKIN BANKS

#### SECTION

- 52-6.1 Definitions
- 52-6.2 Construction
- 52-6.3 Tissue procurement services
- 52-6.4 Donor qualifications
- 52-6.5 Retrieval of tissue
- 52-6.6 Tissue processing facilities
- 52-6.7 Required laboratory tests on donors and donated tissue
- 52-6.8 Processing and storage of tissue
- 52-6.9 Distribution of tissue products
- 52-6.10 Required records of tissue acquisition, testing, processing and storage
- 52-6.11 Records to be kept by a tissue transplantation facility
- 52-6.12 Disposition of unused tissue
- 52-6.13 Tissue storage facilities

**Section 52-6.1 Definitions.** For the purposes of this Subpart, unless the context indicates otherwise, the following terms shall have the following meanings:

- (a) *Skin donor* means a human being, living or dead, who is the source of skin tissue, including autogeneic tissue, for transplantation.
- (b) *Transplantation* means the grafting of skin from a donor to a recipient, including the grafting of skin that has been manipulated and integrated into an artificial skin substitute, and the grafting of skin from an autogeneic donor.

**52-6.2 Construction.** Terms not defined in this Subpart are defined in Subpart 52-1 of this Part. Skin banks shall apply for licensure and otherwise comply with Subpart 52-2 of this Part, and shall meet all general technical standards for tissue banks specified in Subpart 52-3 of this Part.

#### **52-6.3 Tissue procurement services.**

- (a) A facility that engages in donor selection and solicitation, and retrieval of skin shall be licensed by the department as a comprehensive tissue procurement service.
- (b) A facility whose tissue acquisition activities are limited to donor selection and solicitation by its own staff shall be licensed by the department as a limited tissue procurement service.
- (c) Comprehensive tissue procurement services retrieving skin from cadaveric donors shall maintain written standard operating procedures that assure that

the retrieval environment, including, but not limited to, walls, floors and permanent equipment, is suitable for aseptic retrieval and adequate to prepare an aseptic field. A working sink shall be available.

- (d) Skin retrieval shall be performed only by trained retrieval technicians under the supervision of the director of a licensed comprehensive tissue procurement service. The director of the licensed comprehensive tissue procurement service shall be responsible for developing policies, procedures and standards for the educational background, training, certification and continuing education of retrieval technicians. Documentation of compliance with this requirement and the standards developed shall be maintained.

#### **52-6.4 Donor qualifications.**

- (a) In addition to all the requirements of this Subpart, limited tissue procurement services and comprehensive tissue procurement services shall comply with the donor qualification requirements in Subpart 52-3 of this Part.
- (b) Unless specifically authorized by the tissue bank medical director, skin shall not be released for allogeneic transplant from donors with any of the following conditions:
  - (1) a disease of unknown etiology;
  - (2) malaria within the last three years or travel to a malarially endemic area within the last six months; or
  - (3) drowning as a terminal event.
- (c) Social history as recorded in the medical chart of the donor, or as provided by a friend or family member shall be considered in the donor selection process.
- (d) The medical director of the comprehensive tissue procurement service shall be responsible for determining that the donor and the donated skin are acceptable based on medical history information and established donor selection criteria as specified in this Part, and a physical examination.
- (e) A written policy shall specify the range of acceptable donor age and weight limits for allogeneic skin donation. This policy shall be determined by the tissue bank director in consultation with the medical director and medical advisory committee of the comprehensive tissue procurement service.
- (f) Written criteria for acceptance of autogeneic tissue shall be specified by the transplantation service director of the tissue transplantation facility, unless such criteria have been specified already by the medical director of a comprehensive tissue procurement service.

#### **52-6.5 Retrieval of tissue.**

- (a) Skin shall be retrieved using aseptic technique in an operating room or other aseptic premises approved by the tissue bank medical director. In all cases, a

vigorous surgical scrub and disinfectant solution nontoxic to epithelial cells shall be used in preparing the donation site for skin retrieval in accordance with standard operating room practice.

- (b) Retrieval of skin from cadaveric donors shall occur within a time limit after cessation of cardiac function specified in written policies approved by the medical director of the comprehensive tissue procurement service.
- (c) If an ante mortem blood sample is not available from a cadaveric donor, a post mortem sample of sufficient quantity to perform required testing shall be drawn via a cardiac insertion or from a large vein or artery.
- (d) Skin specimen containers and packaging materials shall be sterile and nontoxic.
- (e) Each skin and blood specimen container shall be labeled legibly at the time of retrieval with the tissue bank identification, and donor identification code or unique tissue identification number. The date, time and anatomic site of retrieval shall be recorded on accompanying documents.
- (f) Fresh-cut skin shall be maintained in a sterile, isotonic solution or other nutrient medium during the skin removal procedure, and transported to the tissue processing facility at the completion of the procedure.
- (g) Skin samples for testing for microbial contamination shall be recovered from each anatomical site and placed in a separate, appropriately labeled container.
- (h) Skin and blood specimen containers shall be labeled so as to maintain identification throughout all phases of processing, storage and distribution, in a manner not subject to significant deterioration under conditions of transport and storage.

**52-6.6 Tissue processing facilities.** A facility which processes skin shall be licensed by the department as a tissue processing facility. Such facilities shall make available to the department a statement of the procedures used in the preparation, testing and storage of the tissue or tissues distributed, or offered for use. The premises, equipment, procedures, records, circulars of instruction and tissues shall be available for inspection and/or testing by the department as required. Copies of all brochures and other informational materials and instructions, including descriptions of methods of tissue handling, shall be available to the department. Each container of tissue shall be clearly labeled with the donor identification code or a unique tissue identification number, unit size and expiration date, if applicable.

**52-6.7 Required laboratory tests on donors and donated tissue.** All required clinical laboratory testing shall be performed by a laboratory operating under a permit issued by the department. For out-of-state skin procurements, all required clinical laboratory

testing shall be performed by a laboratory which is approved by that state's regulatory authority, the United States Health Care Financing Administration, or by the department.

- (a) Blood samples from all allogeneic skin donors shall be tested for antibodies to human immunodeficiency virus type 1 (HIV-1), human immunodeficiency virus type 2 (HIV-2), and hepatitis C virus (HCV), as well as for hepatitis B surface antigen (HBsAg) and for syphilis, and, unless the tissue is to be virally inactivated, antibodies to human T-lymphotropic virus type I (HTLV-I), for purposes of donor selection.
- (b) Microbial testing of skin from each anatomical site for aerobic and anaerobic contamination shall be performed using standard laboratory procedures. Whenever fresh skin is transplanted, the results of cultures shall be made available to the transplantation surgeon on a daily basis until the final reading has been completed.
- (c) All skin tissue from living donors intended for allogeneic use shall be quarantined for at least six months. After such time and prior to the distribution of the tissue for transplantation, the donor shall be retested for HBsAg and antibodies to HCV, HIV-1 and HIV-2 and tested for antibodies to hepatitis B core antigen (anti-HBc).

#### **52-6.8 Processing and storage of tissue.**

- (a) Fresh skin shall be stored in a sealed, sterile container with an isotonic solution or nutrient medium demonstrated to maximize tissue viability, at a temperature between one and 10 degrees Celsius for a period not to exceed 14 days from retrieval. Storage shall take place in a refrigerator reserved for skin or other tissue intended for transplantation, or blood intended for transfusion, equipped with a thermometer calibrated at least annually against a National Institute of Standards and Technology (NIST)-certified thermometer, or a thermometer that has been tested against, and found to be in agreement with, an NIST-certified thermometer. The temperature shall be visually monitored daily unless the refrigerator is equipped with a calibrated mechanical temperature monitor and alarm system to detect an increase in temperature to above 10 degrees Celsius or a decrease in temperature to below one degree Celsius.
- (b) If performed, skin processing for cryopreservation shall occur under aseptic conditions within three days of retrieval. Until processing, skin shall be stored at between one and 10 degrees Celsius. Once processed, skin shall be stored frozen at a target temperature of minus 40 degrees Celsius or lower with a suitable cryoprotectant in labeled containers until released for use, in either:
  - (1) a freezer reserved for skin or other tissue intended for transplantation, or blood intended for transfusion, equipped with an audible alarm to detect an increase in temperature to above the limit established by the director and a thermometer calibrated at least annually against an NIST-certified

thermometer, or a thermometer that has been tested against, and found to be in agreement with, an NIST-certified thermometer; or

- (2) a liquid nitrogen tank reserved for skin or other tissue intended for transplantation.
- (c) If performed, skin processing for freeze-drying shall take place within seven days of tissue procurement and in a manner that meets the minimum standards of the manufacturer of the freeze-drier. If sterilized by ethylene oxide, testing for ethylene oxide, ethylene glycol and ethylene chlorhydrin residue shall be performed on each batch of skin sterilized. Freeze-dried skin shall be stored at between one and 30 degrees Celsius.
- (d) Storage devices shall have clearly defined and labeled areas for all skin stored, and untested tissue shall be maintained in a quarantine area segregated from tissue awaiting distribution.
- (e) Thermometers shall be visually monitored daily, or temperatures shall be continuously monitored mechanically, and, if applicable, liquid nitrogen levels shall be checked at least twice a week for fluctuations potentially affecting the quality of the skin. Storage shall be at a target temperature of minus 40 degrees Celsius or lower. Temperature records and, if applicable, liquid nitrogen level records shall be available for inspection by the department for the entire period of storage and for one year afterwards.
- (f) Skin from two or more donors shall not be pooled.

**52-6.9 Distribution of tissue products.**

- (a) Except as provided in section 52-3.4 of this Part, skin shall not be made available for allogeneic transplantation if:
  - (1) the donor's blood tests repeatedly reactive in approved screening tests for HBsAg, or antibodies to HIV-1, HIV-2, HCV or, unless the tissue is to be virally inactivated, antibodies to HTLV-I; or
  - (2) the donor's blood reacts positively to approved tests for syphilis, unless confirmatory testing is negative.
- (b) Skin shall be transported by the tissue bank or its agents, or by staff or agents of the tissue transplantation facility. A signed form shall be kept on file at the skin bank documenting the identification of tissue distributed, including the names of both the person(s) releasing the tissue and the person(s) receiving the tissue.
- (c) Skin in transit from a tissue processing or storage facility to a tissue transplantation facility shall be maintained at the applicable storage temperature specified in section 52-6.8 of this Subpart. Tissue stored at a tissue transplantation facility shall be maintained at a target temperature of

minus 40 degrees Celsius or lower until immediately prior to transplantation. Storage shall be in a freezer or liquid nitrogen tank reserved for skin or other tissue intended for transplantation, or blood reserved for transfusion.

- (d) Skin and its labeling and packaging shall be visually inspected prior to its release by the tissue processing facility. The tissue shall be inspected by the tissue transplantation facility immediately upon receipt and again after thawing, if frozen. If the physical appearance is abnormal, or there is indication or suspicion of overt microbial contamination, the skin shall not be utilized for transplantation.
- (e) Skin shall be issued by the tissue transplantation facility only upon a written order by a licensed physician or other person authorized by law to order tissue. Documentation of such order shall be on a dedicated tracking record or on the recipient's medical record. Issuance of skin shall be recorded in a disposition log and shall allow accurate tracking of tissue to each recipient.

**52-6.10 Required records of tissue acquisition, testing, processing and storage.**

Each skin bank shall maintain donation records as required by Subpart 52-2 of this Part.

**52-6.11 Records to be kept by a tissue transplantation facility.**

- (a) The director of each tissue transplantation service shall be responsible for records kept by the tissue transplantation facility. In addition to the records specified in Subpart 52-2 of this Part, the following records shall be kept, separate from recipient records, by the tissue transplantation facility:
  - (1) a disposition log allowing accurate tracking of tissue to each recipient;
  - and
  - (2) records of appropriate storage and temperature monitoring of skin.
- (b) A copy of the order for issuance of the skin, including the name and signature of the ordering physician or person authorized by law to order such issuance, shall be kept by the tissue transplantation facility. A record in the patient's chart shall be satisfactory documentation of such order for issuance.

**52-6.12 Disposition of unused tissue.**

- (a) Skin that is not used by the tissue transplantation facility immediately after thawing may be refrigerated at between one and 10 degrees Celsius in isotonic or nutrient medium demonstrated to maximize tissue viability for a period of up to seven days. Such skin may be issued for transplantation to the same patient to whom the skin was originally assigned, but shall not be refrozen. Thawed skin that is not used within seven days shall be discarded, or used for education or research purposes authorized by Public Health Law section 4302.
- (b) Skin determined to be unsuitable for transplantation, or education or research purposes shall be discarded pursuant to Part 70 of this Title. Packaging of skin for destruction shall be designed to obscure the contents.

- (c) Skin returned by the tissue transplantation facility for possible reissuance shall meet all storage and transport requirements of this Part. The skin bank shall not reissue tissue returned by the tissue transplantation facility, unless written criteria approved by the tissue bank medical director are met.

**52-6.13 Tissue storage facilities.**

- (a) A facility which stores skin shall be licensed by the department as a tissue storage facility. The skin bank shall keep the department fully informed of the number and type of tissue storage facilities operating under its direction.
- (b) All skin shall be stored and monitored in accordance with the provisions of sections 52-6.8, and 52-6.9(b), (c) and (d) of this Subpart.
- (c) Temperature records or liquid nitrogen level records shall be available for inspection by the department for the entire period of skin storage and for one year afterwards.
- (d) Skin products shall be distributed in accordance with the requirements of this Part, and all records related to the inspection, distribution and transport of skin shall be open to inspection by the department, and shall be kept for at least seven years or six months after the expiration date of the tissue, whichever is the longer time.

## SUBPART 52-7

### EYE BANKS

#### SECTION

- 52-7.1 Definitions
- 52-7.2 Construction
- 52-7.3 Tissue procurement services
- 52-7.4 Donor qualifications
- 52-7.5 Retrieval of tissue
- 52-7.6 Tissue processing facilities
- 52-7.7 Required laboratory tests on donors and donated tissue
- 52-7.8 Processing and storage of tissue
- 52-7.9 Distribution of tissue products
- 52-7.10 Required records of tissue acquisition, testing, processing and storage
- 52-7.11 Laboratory tests to be performed prior to tissue transplantation
- 52-7.12 Records to be kept by a tissue transplantation facility
- 52-7.13 Disposition of unused tissue

**Section 52-7.1 Definitions.** For the purposes of this Subpart, unless the context indicates otherwise, the following terms shall have the following meanings:

- (a) *Eye donor* means a human being, living or dead, who is the source of ocular tissue intended for transplantation.
- (b) *Enucleation* means the removal of the whole eye globe.
- (c) *Corneal excision* means the *in situ* or laboratory removal of the cornea or corneal-scleral rim.

**52-7.2 Construction.** Terms not defined in this Subpart are defined in Subpart 52-1 of this Part. Eye banks shall apply for licensure and otherwise comply with Subpart 52-2 of this Part, and shall meet all general technical standards for tissue banks specified in Subpart 52-3 of this Part.

**52-7.3 Tissue procurement services.**

- (a) A facility that engages in donor selection and solicitation, and retrieval of ocular tissue shall be licensed by the department as a comprehensive tissue procurement service.
- (b) A facility whose tissue acquisition activities are limited to donor selection and solicitation by its own staff shall be licensed by the department as a limited tissue procurement service.
- (c) Comprehensive tissue procurement services retrieving ocular tissue

aseptically from cadaveric donors shall maintain written standard operating procedures that assure that the retrieval environment, including, but not limited to, walls, floors and permanent equipment, is suitable for enucleation or excision, and adequate to prepare a clean surgical field. A working sink shall be available.

- (d) Ocular tissue retrieval shall be performed only by trained retrieval technicians under the supervision of the director of a licensed eye bank. The director of the licensed eye bank shall be responsible for developing policies, procedures and standards for the educational background, training, certification and continuing education of retrieval technicians. Documentation of compliance with this requirement and the standards developed shall be maintained.

#### **52-7.4 Donor qualifications.**

- (a) In addition to all the requirements of this Subpart, limited tissue procurement services and comprehensive tissue procurement services shall comply with the donor qualification requirements in Subpart 52-3 of this Part.
- (b) Unless specifically authorized by the tissue bank medical director, ocular tissue shall not be released for transplant from donors with any of the following conditions or factors:
  - (1) evidence of disseminated malignant disease, such as lymphoma or leukemia;
  - (2) malignant disease of the eye;
  - (3) active hepatitis B or C, or hepatitis of unknown etiology;
  - (4) syphilis within the past 12 months;
  - (5) any disease of unknown etiology;
  - (6) congenital rubella;
  - (7) subacute sclerosing panencephalitis;
  - (8) Reye's syndrome; or
  - (9) bacterial or fungal endocarditis.
- (c) The medical director of the comprehensive tissue procurement service shall be responsible for determining that donors and donated ocular tissue are acceptable based on medical history information, the tissue bank's established donor selection criteria and the factors specified in this Part.
- (d) A written policy shall specify the range of acceptable donor age limits for eye donation. This policy shall be determined by the tissue bank medical director in consultation with the medical advisory committee of the comprehensive tissue procurement service.
- (e) Unless intended for lamellar grafts or epikeratoplasty, corneal tissue shall not be released from donors with prior intraocular or anterior segment surgery affecting the corneal endothelium or from donors with intrinsic eye disease affecting the corneal endothelium.

**52-7.5 Retrieval of tissue.**

- (a) Prior to enucleation, eyes shall be maintained in accordance with procedures approved by the tissue bank medical director. Eyes shall be kept moist during the interval between cessation of circulatory function and enucleation.
- (b) Enucleation and corneal excision shall be performed in a clean surgical field using standard operating room technique.
- (c) Enucleation and/or corneal excision shall occur within 12 hours after cessation of circulatory function unless otherwise specifically authorized by the tissue bank medical director.
- (d) Eyes shall be stored and transported to the tissue processing facility at a temperature between two and six degrees Celsius.
- (e) If an ante mortem blood sample is not available from a cadaveric donor, a post mortem sample of sufficient quantity to perform required laboratory testing shall be drawn via a cardiac insertion or from a large vein or artery.
- (f) Tissue specimen containers and storage solutions shall be sterile and nontoxic.
- (g) Each tissue and blood specimen container shall be labeled legibly at the time of retrieval with the tissue bank identification, and donor identification code or unique tissue identification number. The date, time and anatomic site of retrieval shall be recorded on accompanying documents.
- (h) Tissue and blood specimen containers shall be labeled so as to maintain tissue identification throughout all phases of processing, storage and distribution, in a manner not subject to significant deterioration under conditions of transport and storage.

**52-7.6 Tissue processing facilities.** A facility which processes ocular tissue shall be licensed by the department as a tissue processing facility. Such facilities shall make available to the department a statement of the procedures used in the preparation, testing and preservation of the tissue or tissues distributed, or offered for use. The premises, equipment, procedures, records, brochures and other informational materials, instructions, manufactured media and tissues shall be available for inspection and/or testing by the department as required. Copies of all general circulars of information and instructions, including descriptions of methods of tissue handling, shall be available to the department. Each container of tissue shall be clearly labeled with the donor identification code or a unique tissue identification number and collection date.

**52-7.7 Required laboratory tests on donors and donated tissue.** All required clinical laboratory testing shall be performed by a laboratory operating under a permit issued by the department. For out-of-state tissue procurement, all required clinical laboratory testing shall be performed by a laboratory which is approved by that state's regulatory

authority, the United States Health Care Financing Administration, or by the department.

- (a) Blood samples from all allogeneic ocular tissue donors shall be tested for antibodies to human immunodeficiency virus type 1 (HIV-1), human immunodeficiency virus type 2 (HIV-2) and hepatitis C virus (HCV), as well as for hepatitis B surface antigen (HBsAg), for purposes of donor selection.
- (b) All ocular tissue from living donors, except corneal tissue, shall be quarantined for six months. After such time and prior to the distribution of the tissue for transplantation, the donor shall be retested for HBsAg and antibodies to HCV, HIV-1 and HIV-2 and tested for antibodies to hepatitis B core antigen (anti-HBc).

**52-7.8 Processing and storage of tissue.**

- (a) Until processing, eyes shall be stored at a temperature of between two and six degrees Celsius.
- (b) The corneal-scleral segment shall be examined grossly for clarity, epithelial defects, foreign objects, contamination and scleral color for evidence of jaundice.
- (c) Slit-lamp examination of whole eyes or the corneal-scleral rim of excised tissue shall be performed to detect epithelial and stromal pathology, including edema, cell density, opacities, scars and guttata. A system, as determined by the tissue bank medical director, shall be in place to categorize tissue adequacy for transplantation.
- (d) Eyes and ocular tissue shall be preserved using aseptic technique, in:
  - (1) a moist chamber kept at a temperature of between two and six degrees Celsius;
  - (2) a short-term preservation medium stored and used in accordance with the manufacturer's instructions and/or with written procedures approved by the tissue bank director;
  - (3) a long-term culture medium used in accordance with written procedures approved by the tissue bank director;
  - (4) a frozen or dehydrated state, if corneal tissue is used for epikeratoplasty;
  - (5) the frozen state, as scleral grafts immersed in antibiotic solution; or
  - (6) any other method, in accordance with written procedures approved by the tissue bank medical director and currently accepted by leading authorities in eye transplant medicine.
- (e) Thawed tissue that has been refrozen shall not be issued for transplantation.
- (f) The duration of storage subsequent to application of each preservation method above shall be clearly specified in written procedures approved by the tissue bank medical director.

- (g) Tissue shall be maintained aseptically at a temperature appropriate to the method of preservation utilized. The tissue bank director shall determine the appropriate temperature based upon the method of preservation utilized, manufacturers' instructions, standards set forth in this Part and standards in current scientific literature. The refrigeration device used for storage shall be reserved for ocular and other tissue and related supplies, with clearly defined and labeled areas for all tissues stored. Quarantined tissue awaiting test results shall be segregated from tissue ready for distribution. Unless an alternative mechanism is in place for immediate notification and action to be taken in the event of a power failure, the refrigeration device shall be equipped with an audible alarm to detect temperature deviations above and below the established limits of storage, and a thermometer calibrated at least annually against a National Institute of Standards and Technology (NIST)-certified thermometer, or a thermometer that has been tested against, and found to be in agreement with, an NIST-certified thermometer.
- (h) Thermometers shall be visually monitored daily or temperatures shall be continuously monitored mechanically for fluctuations potentially affecting the quality of the tissue. Temperature records shall be available for inspection by the department for the entire period of storage and for one year afterwards.
- (i) If whole eye is stored in a moist chamber, corneal excision shall occur within 12 hours, and tissue shall be transplanted within a time period established in written policy by the tissue bank medical director and the medical advisory committee.

**52-7.9 Distribution of tissue products.**

- (a) Except as specified in section 52-3.4 of this Part, ocular tissue shall not be made available for transplantation if the donor's blood tests repeatedly reactive in approved screening tests for HBsAg or antibodies to HIV-1, HIV-2 or HCV.
- (b) The eye bank shall distribute tissue for transplantation only to another eye bank or to a licensed tissue transplantation facility in possession of a written order by a licensed physician.
- (c) Tissue shall be transported by the eye bank or its agents, or by staff or agents of the tissue transplantation facility. A signed form shall be kept on file at the eye bank documenting the identification of tissue distributed, including the names of both the person(s) releasing the tissue and the person(s) receiving the tissue.
- (d) Tissue in transit from a tissue processing or storage facility to a tissue transplantation facility shall be maintained at the appropriate storage temperature specified in section 52-7.8 of this Subpart. Tissue stored at a transplantation facility shall be maintained at the appropriate storage

temperature until immediately prior to transplantation.

- (e) Tissue shall be visually inspected prior to use by the transplant surgeon, who shall determine the suitability of the tissue for transplantation.
- (f) Tissue shall be issued by the tissue transplantation facility only upon a written order by a licensed physician or other person authorized by law to order tissue for transplant. Documentation of such order shall be on a dedicated tracking record or on the recipient's medical record. Documentation shall allow accurate tracking of tissue to each recipient.

**52-7.10 Required records of tissue acquisition, testing, processing and storage.**

In addition to the record keeping requirements of Subpart 52-2 of this Part, each eye bank must maintain tissue records which include:

- (a) documentation of gross ocular tissue evaluation; and
- (b) documentation of slit-lamp examination.

**52-7.11 Laboratory tests to be performed prior to tissue transplantation.**

The tissue transplantation service shall culture the corneal-scleral rim at the time of tissue transplantation for aerobic and anaerobic bacterial contamination.

**52-7.12 Records to be kept by a tissue transplantation facility.**

- (a) The director of each tissue transplantation service shall be responsible for records kept by the tissue transplantation facility. In addition to the records specified in Subpart 52-2 of this Part, the following records shall be kept, separate from recipient records, by the tissue transplantation facility:
  - (1) results of bacterial culture;
  - (2) records of appropriate storage and temperature monitoring of ocular tissue; and
  - (3) a dedicated record allowing accurate tracking of tissue to each recipient.
- (b) A copy of the order for issuance of the tissue, including the name and signature of the ordering physician or person authorized by law to order such issuance, shall be kept by the tissue transplantation facility. A record in the patient's chart shall be satisfactory documentation of such order for issuance.

**52-7.13 Disposition of unused tissue.**

- (a) All tissue unsuitable for transplantation, education, or research purposes authorized by Public Health Law section 4302 shall be discarded pursuant to Part 70 of this Title. Packaging of tissue for destruction shall be designed to obscure the contents.
- (b) If tamper-resistant seals are broken or proper temperature has not been maintained, tissue shall not be issued for transplantation.

- (c) Tissue returned by the tissue transplantation facility for possible reissuance shall meet all storage and transport requirements of this Part. The tissue bank shall not reissue tissue returned by the tissue transplantation facility, unless written criteria approved by the tissue bank medical director are met.

## SUBPART 52-8

### REPRODUCTIVE TISSUE BANKS

#### SECTION

- 52-8.1 Definitions
- 52-8.2 Licensure
- 52-8.3 Administrative responsibility
- 52-8.4 Direction and medical direction
- 52-8.5 Donor qualifications
- 52-8.6 Required laboratory tests
- 52-8.7 Collection, storage and disposition of reproductive tissue
- 52-8.8 Informed consent
- 52-8.9 Required records
- 52-8.10 Quality assurance and safety
- 52-8.11 Compliance with standards

**Section 52-8.1 Definitions.** As used in this Part:

- (a) *Anonymous donor* means a donor whose identity is unknown to the recipient.
- (b) *Artificial insemination* means the placement of semen within the body of a recipient.
- (c) *Assisted reproductive procedure* means a medical procedure intended to result in conception, including, but not limited to, *in vitro* fertilization (including intracytoplasmic sperm injection), embryo transfer and gamete intrafallopian transfer.
- (d) *Client-depositor* means a man who deposits reproductive tissue prior to intended or potential use in artificial insemination or assisted reproductive procedures performed on his regular sexual partner, or a woman who deposits reproductive tissue for processing into embryos and subsequent implantation into the same woman.
- (e) *Directed donor* means a donor who is known to the recipient and who directs his or her reproductive tissue for use by a particular recipient. This includes a man providing semen to a surrogate, but who is not the regular sexual partner of the recipient.
- (f) *Donor* means a person who provides reproductive tissue for use in artificial insemination or assisted reproductive procedures performed on recipients other than that person or that person's regular sexual partner, and includes directed donors.

- (g) *Reproductive tissue bank* means a facility which acquires, processes, stores, distributes and/or releases reproductive tissue to an insemination/implantation site for use in artificial insemination or assisted reproductive procedures. Reproductive tissue banks include, but are not limited to, semen banks, oocyte donation programs and embryo banks.
- (h) *Insemination/implantation site* means a location at which artificial insemination or assisted reproductive procedures are performed, using reproductive tissue from anonymous donors, directed donors and/or client-depositors. Licensed insemination/implantation sites may undertake, without additional licensure, semen processing, limited to washing, concentrating and storing of semen from patients of physicians associated with the licensed insemination/implantation sites or the patients' regular sexual partners, as well as limited semen storage (less than six months' duration).
- (i) *Recipient* means a woman who receives reproductive tissue from a donor or client-depositor.
- (j) *Semen processing facility* means a tissue processing facility that processes semen for use by other licensed reproductive tissue banks and insemination/implantation sites.

**52-8.2 Licensure.** Reproductive tissue banks, insemination/implantation sites and semen processing facilities shall not operate unless licensed as tissue banks pursuant to Subpart 52-2 of this Part.

**52-8.3 Administrative responsibility.** The reproductive tissue bank director shall assume overall responsibility for operation of the reproductive tissue bank. The reproductive tissue bank director shall meet the requirements of section 52-2.5(a)(2) of this Part. The training and/or experience requirements specified in section 52-2.5 of this Part shall be in the field of reproductive endocrinology, andrology, human fertility or a closely related field. The reproductive tissue bank director shall develop and implement policies and procedures consistent with this Subpart for the operation of the bank. If the reproductive tissue bank director is not a physician, a medical director who meets the requirements of section 52-2.5(a)(3) of this Part shall be retained. Except for insemination/implantation sites, reproductive tissue banks shall have a medical advisory committee, composed of at least five members with experience and expertise in the fields of human fertility, infectious disease, clinical pathology or related fields, who shall be responsible for monitoring the medical efficacy of the reproductive tissue bank and reviewing operating policies and procedures. If the bank acquires reproductive tissue from donors, a qualified microbiologist, clinical pathologist or infectious disease specialist, and a geneticist shall serve either as members of or consultants to the committee.

**52-8.4 Direction and medical direction.**

- (a) Medical direction of a reproductive tissue bank shall be provided by the

medical director in consultation with the medical advisory committee, if applicable.

- (b) Except for insemination/implantation sites, the reproductive tissue bank director, in consultation with the medical director, if not the same person, and the medical advisory committee shall monitor the efficacy of the reproductive tissue banking program and shall, as a minimum, develop:
  - (1) medical criteria for donor participation;
  - (2) quality standards for sperm, oocytes, embryos and other reproductive tissue, as applicable; and
  - (3) guidelines for determining a maximum number of offspring per donor to minimize the probability of consanguinity.
- (c) The reproductive tissue bank director shall be responsible for selection of donors who meet the medical criteria and for the technical/scientific operation of the reproductive tissue bank, and shall make available to the physician performing each artificial insemination or assisted reproductive procedure the donor's medical history and other pertinent nonidentifying characteristics of the donor, so that recipient counseling may be provided.
- (d) Artificial insemination and all assisted reproductive procedures shall be ordered only by a licensed physician, physician's assistant or nurse practitioner. Artificial insemination procedures shall be performed only by:
  - (1) a licensed physician;
  - (2) a licensed physician's assistant;
  - (3) a licensed nurse practitioner; or
  - (4) a licensed registered nurse who has been trained in the technical aspects of artificial insemination by a licensed physician, licensed physician's assistant or licensed nurse practitioner employed by the insemination/implantation site, and is supervised by such a physician, physician's assistant or nurse practitioner.

**52-8.5 Donor qualifications.**

- (a) The reproductive tissue bank shall initially screen and periodically assess donors for conditions that may adversely affect the quality of reproductive tissue or impair the recipient's and/or the offspring's health. Reproductive tissue donor screening shall, except as provided in Section 52-8.6(g), be performed prior to the initial collection of reproductive tissue for clinical use, and shall include a physical examination, as well as an examination for indications of sexually transmissible diseases.
- (b) A complete medical history, both individual and family, including first-degree and second-degree relatives, shall be obtained from each reproductive tissue donor prior to any collection of tissue for clinical use, and shall include, but not be limited to, incidence of the following:
  - (1) major malformations of complex cause that result in serious functional or

- cosmetic defects, including, but not limited to spina bifida or heart malformations;
- (2) major genetic disorders, including:
    - (i) autosomal dominant or X-linked disorders for which age of onset extends beyond the age of the donor;
    - (ii) autosomal dominant disorders with reduced penetrance; and
    - (iii) autosomal recessive disorders;
  - (3) for semen donors, systemic disease which may affect the decision to use the semen;
  - (4) for semen donors, infectious skin disease that may create a risk of contamination of the semen;
  - (5) history of sexually transmissible disease, including herpes simplex virus type 2;
  - (6) more than one sexual partner within the last six months;
  - (7) previous exclusion from blood donation for reasons of infectious disease;
  - (8) receipt of a blood transfusion within the past year;
  - (9) for semen donors, known episodes of trichomoniasis in a sexual partner;
  - (10) history of an occupation with increased risk of radiation or chemical exposure, or known such exposure;
  - (11) known history of alcohol abuse;
  - (12) history of behavior or factors which place the donor at increased risk for human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) infection, as determined by the United States Public Health Service (USPHS);
  - (13) all conditions listed in section 52-3.4(a) of this Part; and
  - (14) other conditions as determined by the reproductive tissue bank director, medical director and medical advisory committee.
- (c) Except for those factors currently identified by the USPHS as posing an increased risk for HIV infection, the factors in subdivision (b) of this section need not necessarily exclude a donor, but the reproductive tissue bank medical director or the attending physician shall counsel the recipient about potential associated risks if such a donor's reproductive tissue is accepted. Persons with an HIV risk factor identified by the USPHS shall not be accepted as anonymous donors.
- (d) Recipients' physicians shall be notified if a semen donor's age at the time of donation is older than 44 years. Recipients' physicians shall be notified if an oocyte donor's age at the time of donation is older than 34 years.
- (e) Potential anonymous donors with a history of behavior or factors which place them at increased risk for HIV infection or other infectious diseases, pursuant to section 52-3.4(a)(8) of this Part, shall be excluded.

#### **52-8.6 Required laboratory tests.**

- (a) For reproductive tissue banks located within New York State, all required

clinical laboratory testing shall be performed by a laboratory operating under a permit issued by the department. For out-of-state reproductive tissue banks, all required clinical laboratory testing shall be performed by a laboratory which is approved by that state's regulating authority, the United States Health Care Financing Administration, or by the department.

- (b) The following laboratory tests shall be performed prior to donor acceptance and, except as specified in paragraph (g) of this section, initial collection of donor semen for clinical use:
  - (1) Blood shall be tested for:
    - (i) determination of ABO and Rh blood groups; and
    - (ii) antibodies to HIV-1, human immunodeficiency virus type 2 (HIV-2), human T-lymphotropic virus type I (HTLV-I), hepatitis B core antigen (HBc), and to hepatitis C virus (HCV), and for hepatitis B surface antigen (HBsAg) and syphilis.
  - (2) Semen or a urethral specimen shall be tested for infection with *Neisseria gonorrhoeae*, and urine or a urethral specimen shall be tested for infection with *Chlamydia trachomatis* using a method that meets standards generally accepted by leading authorities in laboratory medicine.
  - (3) Semen shall be tested for sperm quality as measured against criteria set by the director in consultation with the medical director and medical advisory committee, including such parameters as ejaculate volume and sperm motility, concentration, morphology and cryosensitivity, including a post-thaw analysis. Sperm quality tests shall be repeated at a frequency determined by the director.
- (c) All tests for infectious diseases shall be repeated at least every six months for as long as a donor is participating in the semen banking program, or whenever a donor reenters the program after an absence of longer than six months.
- (d) Any semen stored from a donor testing repeatedly reactive for antibodies to HIV-1, HIV-2, HCV or HTLV-I, for syphilis infection or for HBsAg, shall be destroyed unless such semen is to be used for research studies authorized by section 4302 of the Public Health Law and approved by the appropriate institutional review board, in which case all semen samples from the donor shall be labeled, "For research use only," and immediately sequestered from other donor samples. Testing for antibody to hepatitis B core antigen (anti-HBc) shall be negative for donor acceptance. For semen donors testing positive for any indicator of HIV infection, the director shall advise the department and the attending physicians of all recipients who received semen that was collected any time after six months prior to the last negative test.
- (e) Subsequent to testing as required in subdivision (b) of this section, all donated semen shall be frozen and quarantined for six months. After such time and prior to release of the semen for artificial insemination or assisted reproductive procedures, the donor shall be retested for HBsAg and antibodies

to HIV-1, HIV-2, HCV and HBc. If the semen to be released originates from a directed donor, the recipient may be given the opportunity to waive the quarantine period in writing after being advised by the director, his/her designee, or the physician performing the insemination of the risks involved in doing so. In such cases, each of the tests required in paragraphs (a)(1), (2) and (3) of this section, except tests for ABO and Rh blood groups, must have been performed after a date one month prior to the first donation and every three months thereafter, while the donor is engaged in donation.

- (f) Semen shall not be made available for artificial insemination or assisted reproductive procedures if:
  - (1) the donor's blood is repeatedly reactive in approved screening tests for HBsAg or antibodies to HIV-1, HIV-2, HTLV-I or HCV;
  - (2) the donor's blood is repeatedly reactive in approved screening tests for antibodies to HBc;
  - (3) the donor's blood tests positively in approved tests for syphilis, unless a confirmatory test is negative;
  - (4) the donor's semen or urethral specimen tests positive in approved tests for *Neisseria gonorrhoeae*; or
  - (5) the donor's urine or urethral specimen reacts positively to approved tests for *Chlamydia trachomatis*.
  
- (g) A client-depositor who wishes to direct stored semen for use by a specific recipient, other than his current or active regular sexual partner, shall first be fully evaluated and tested in accordance with the requirements of sections 52-8.5, 52-8.6(b), (c), (d) and (f) of this Subpart. Tissue from such client-depositors shall not be released unless stored for at least six months prior to such testing.
  
- (h) Reproductive tissue donors who, based on their racial/ethnic background or family history, have been identified at increased risk of being carriers of Tay-Sachs disease, thalassemia, cystic fibrosis and/or sickle cell disease shall be tested for such carrier states. The reproductive tissue bank medical director, in consultation with the medical advisory committee, shall establish a policy specifying any other conditions that should be tested for, the testing to be performed on donors with particular racial/ethnic backgrounds and family histories, and the analytes to be tested for.
  
- (i) Testing requirements for oocyte donors shall be specified in a written policy approved by the reproductive tissue bank medical director in consultation with the medical advisory committee. At a minimum, donors shall, within one month of each donation, be tested and found negative for HBsAg, and for antibodies to HCV, HIV-1 and HIV-2. Oocytes and embryos stored from donors who test repeatedly reactive for antibodies to HIV-1, HIV-2, or HCV or for HBsAg, shall be destroyed, unless such tissue is to be used for research studies authorized by section 4302 of the Public Health Law and approved by

the appropriate institutional review board, in which case all tissue samples from the donor shall be labeled, "For research use only," and immediately sequestered from the donor samples. For donors testing positive for any indicator of HIV infection, the director shall advise the department and the attending physicians of all recipients who received tissue that was collected at any time after six months prior to the last negative test.

- (j) Male and female contributors to donated embryos shall be tested as specified in section 52-8.6(i) of this Subpart prior to release of embryos for clinical use by others.
- (k) Results of all donor testing shall be made available, upon request, to the donors and to physicians using the donors' reproductive tissue in artificial insemination and assisted reproductive procedures.
- (l) Accurate, written donor profiles or other descriptions of pertinent donor characteristics shall be provided upon request to physicians ordering reproductive tissues.

**52-8.7 Collection, storage and disposition of reproductive tissue.**

- (a) Semen collection containers shall be clean and non-toxic to sperm.
- (b) Each semen collection container shall be labeled legibly prior to collection with the donor's or client-depositor's name or identification code, unless another system is used to ensure absolute identification, and shall also be labeled at the time of collection with the date and time of collection.
- (c) Semen storage containers and support vehicles shall be labeled so as to maintain identification throughout all phases of processing, storage and distribution, in a manner not subject to deterioration at low temperatures. Such containers and/or vehicles shall be labeled with the reproductive tissue bank identification and semen specimen collection date, donor's identification code or, in the case of a client-depositor, his name and semen specimen collection date. Semen shall be frozen with a suitable cryopreservative and stored continuously until placed in either a freezer section reserved for semen, equipped with a thermometer, or a liquid nitrogen storage tank. The thermometer shall be calibrated at least annually against a National Institute of Standards and Technology (NIST)-certified thermometer, or a thermometer that has been tested against, and found to be in agreement with, an NIST-certified thermometer. Thermometers shall be either visually monitored daily or continuously monitored mechanically, and, if applicable, liquid nitrogen levels shall be checked at least twice a week for fluctuations in temperature potentially affecting the quality of the semen. Storage shall be at a temperature of minus 130 degrees Celsius or lower. Semen from client-depositors shall be stored in a freezer section or tank separate from that for donor semen, and shall not be exposed to ambient air unless absolutely

necessary. Temperature records or liquid nitrogen level records shall be available for inspection by the department for the entire period of storage and for one year afterward.

- (d) Frozen semen in transit from a reproductive tissue bank to an insemination/implantation site shall be maintained in liquid nitrogen or vapor until immediately prior to the artificial insemination or assisted reproductive procedure. Frozen semen shall be transported by the bank or its agents, the staff of the insemination/implantation site, or the recipient with the written authorization of her physician.
- (e) The insemination/implantation site shall inspect semen samples for proper labeling and appearance immediately after thawing. If the physical appearance is abnormal or there is indication or suspicion of overt microbial contamination, the semen shall not be utilized for artificial insemination or other assisted reproductive procedures.
- (f) Reproductive tissue stored for a client-depositor shall not be destroyed or released for other purposes as a result of nonpayment of storage fees or for any other reasons, without documentation that the client-depositor was given at least 30-days' written notice by certified mail, return receipt requested.
- (g) Oocytes shall be collected, processed and stored as oocytes or embryos according to written procedures approved by the reproductive tissue bank director in consultation with the medical director and the medical advisory committee. Storage containers and support vehicles shall be labeled or segregated so as to maintain tissue identification throughout all phases of processing, storage and distribution, in a manner not subject to deterioration at low temperatures. Final embryo containers shall be labeled with the identification code or name of the source of both the component oocyte and spermatozoan.
- (h) Embryos shall not be created for donation by fertilizing donor oocytes with donor semen, except at the request of a specific patient who intends to use such embryos for her own treatment.
- (i) Embryos shall not be created using semen or oocytes of client-depositors or directed donors who are blood relatives of the other gamete provider to a degree that their sexual contact would constitute incest under New York State law.

#### **52-8.8 Informed consent.**

- (a) Reproductive tissue banks shall obtain written informed consent from the donor for participation in the donation program, after the director or a designee has provided information to the donor on the procedures for collection, storage and use of semen, oocytes or embryos, and the risks of any

drugs, surgical procedures and/or anesthesia administered. The informed consent shall include:

- (1) a statement that the donor has been informed that his or her name and address will be kept on file by the reproductive tissue bank, and advised of the restrictions on release of donor-identifying information specified in section 52-8.9 of this Subpart;
  - (2) authorization for performance of genetic and infectious disease marker testing, consistent with statutory requirements for genetic testing;
  - (3) notification of all currently known ways in which the donor's reproductive tissue and resulting embryos may be used. If the reproductive tissue bank accepts reproductive tissue with restrictions on the manner in which embryos created may be used, the consent also shall include a statement that the reproductive tissue bank has informed the donor that it will make a good faith effort to ensure that the donor's restrictions are respected, but that it cannot guarantee that the recipients of the reproductive tissue will abide by the donor's restrictions;
  - (4) authorization for disclosure of the donor's medical history information to potential recipients and their physicians, consistent with statutory requirements for the disclosure of genetic and other medical information;
  - (5) an explanation of the oocyte donor's extent of responsibility for any costs of any medical complications associated with oocyte donation; and
  - (6) a statement that the reproductive tissue donor has the right to withdraw his/her consent to donation up until such time that a specific recipient has begun an assisted reproduction cycle in reliance on the availability of tissue from that donor.
- (b) Reproductive tissue banks shall obtain written informed consent from the client-depositor for participation in the semen, oocyte or embryo storage program, after the director or a designee has provided information to the client-depositor on the procedures for collection/storage and retrieval of semen, oocytes or embryos, and the risks of any drugs, surgical procedures and/or anesthesia administered, as well as procedures for payment for semen, oocyte or embryo storage. The informed consent shall include the male client-depositor's specific instructions for disposition of frozen semen upon his death. The reproductive tissue bank shall maintain and adhere to written procedures for ensuring that the client-depositor's instructions are followed.
- (c) The insemination/implantation site shall obtain written informed consent from the recipient for receipt of donated reproductive tissue, after a physician has explained the risks and benefits of the procedure, made available details of the medical history of the donor or donors, and, if applicable, notified the recipient that reproductive tissue bank records are required to be kept for the periods of time specified in section 52-8.9(a) of this Subpart and that the outcome of the procedure is required to be reported to the reproductive tissue bank.

### **52-8.9 Required records.**

- (a) Reproductive tissue bank records shall be open to inspection by the department and shall be kept for at least seven years after release of reproductive tissue for artificial inseminations or assisted reproductive procedures not resulting in a live birth, and 25 years for inseminations or assisted reproductive procedures known to have resulted in a live birth. For all donated reproductive tissue, the donor's name, address, and any other information which would directly or indirectly identify the donor shall not be disclosed or released by the reproductive tissue bank to any person or entity, except upon the written informed consent of the donor, or except to authorized employees of the department or as permitted by law. The recipient's name, address, and any other information which would directly or indirectly identify the recipient shall not be disclosed or released by the insemination/ implantation site to any person or entity, except upon the written informed consent of the recipient, or except to authorized employees of the department, or as permitted by law.
- (b) In addition to the recordkeeping requirements of section 52-2.9(c) of this Part, each reproductive tissue bank shall maintain applicable donor/client-depositor records which include:
  - (1) for donors, pertinent family history of any genetic disorders;
  - (2) documentation of donor and client-depositor written informed consent;
  - (3) for semen donors, outcome of any prior artificial insemination or other assisted reproductive procedures, if known, including number of successful pregnancies, if any, and any reports from insemination/implantation sites which would affect the donor's acceptability; and
  - (4) documented approval of the reproductive tissue bank director, or his/her designee, of the acceptability of the donor.
- (c) In addition to the recordkeeping requirements of section 52-2.9(e) and (f) of this Part, each reproductive tissue bank shall maintain applicable records which include:
  - (1) donor's identification code or client-depositor's name;
  - (2) for semen donations, documentation of laboratory cryosensitivity testing, and, if performed, results of viability checks after thawing and during storage, if any;
  - (3) the name of the insemination/implantation site, the physician or other person authorized by law to perform artificial insemination or assisted reproductive procedures, and/or receive reproductive tissue, and the name of the person communicating the order for distribution of the tissue;
  - (4) the recipient's name, if the name has been provided to the reproductive tissue bank with her informed consent, or the recipient's identification code, if used;
  - (5) documentation of training, certification, licensure, if required by law, and continuing education for each staff member; and

- (6) any adverse outcomes, including infectious diseases in recipients or their offspring and genetic defects in offspring, which shall be reported to the donors if there is any possibility that the donor's reproductive tissue contributed to the adverse outcome.
  
- (d) The following records shall be kept, separate from the recipient's records, by an insemination/implantation site for each insemination or assisted reproductive procedure performed:
  - (1) donor's identification code or name, if the reproductive tissue originates from a client-depositor;
  - (2) evidence that reproductive tissue from donors and/or client-depositors has been obtained from a reproductive tissue bank licensed pursuant to Subpart 52-2 of this Part;
  - (3) disposition of the reproductive tissue, including, but not limited to, the name or identification code of the recipient, destruction logs, and autoclaving or incineration records;
  - (4) the name and signature of the ordering physician or other person authorized by law to order issuance of the reproductive tissue;
  - (5) results of sperm viability checks, if performed; and
  - (6) signature of the person receiving the sample and condition of the sample upon receipt.
  
- (e) The insemination/implantation site shall document the outcome of the artificial insemination or assisted reproductive procedure, including, but not limited to, any known adverse outcome in the infant or infectious disease in the recipient, as well as any known successful pregnancies. This information shall also be reported to the reproductive tissue bank releasing the tissue, even if the reproductive tissue bank is the same entity as the insemination/implantation site.

**52-8.10 Quality assurance and safety.** The requirements of section 52-3.5 of this Part shall be met.

**52-8.11 Compliance with standards.** A reproductive tissue bank shall allow admission to representatives of the department for the purpose of inspecting the premises and evaluating operating procedures, equipment, and records, including lists of physicians or facilities to whom or to which reproductive tissue has been released, to determine compliance with the standards in this Part. If the Commissioner determines that a significant likelihood exists that adequate safeguards are not implemented at a reproductive tissue bank, the department may require that reproductive tissue not be released pending a hearing. Such hearing shall commence within 15 days of any suspension pursuant to this section.

## SUBPART 52-9

### HUMAN MILK BANKS

#### SECTION

- 52-9.1 Definitions
- 52-9.2 Construction
- 52-9.3 Administrative responsibility
- 52-9.4 Medical direction
- 52-9.5 Donor qualifications
- 52-9.6 Collection and storage of human milk
- 52-9.7 Maintenance of records
- 52-9.8 Distribution of human milk

**Section 52-9.1 Definitions.** As used in this Part:

- (a) *Human milk bank* means an organized service for the selection of donors and the collection, processing, storage or distribution of human breast milk for infants or children other than the donor's own infant.
- (b) *Donor* means a lactating woman who voluntarily contributes milk to a human milk bank for use by an infant or child other than her own. A donor shall not receive remuneration for the donation of milk.
- (c) *Human milk transfer station* means the location at which containers of human breast milk are held temporarily between the donation site and the human milk bank.

**52-9.2 Construction.** Terms not defined in this Subpart are defined in Subpart 52-1 of this Part. Human milk banks shall apply for licensure and otherwise comply with Subpart 52-2 of this Part, and shall meet all general technical standards for tissue banks specified in Subpart 52-3 of this Part.

**52-9.3 Administrative responsibility.** The director of a human milk bank shall ensure the development and implementation of policies and procedures consistent with this Part for the operation of the bank, and the appointment of a medical director and a medical advisory committee composed of physicians with experience in pediatrics, neonatology, blood banking, nutrition and/or other appropriate fields, including at least one member with expertise in infectious diseases, as well as other allied health personnel.

**52-9.4 Medical direction.**

- (a) Medical direction of a human milk bank shall be provided by a physician, who may also be the director of the bank, in consultation with the medical advisory committee. Such physician shall be licensed and currently registered with the New York State Education Department, and possess a minimum of

four years' experience in neonatology, pediatrics, blood banking or a related field.

- (b) The medical director and the medical advisory committee shall establish operating procedures and monitor the medical efficacy of milk banking services, and shall, consistent with this Part, develop:
  - (1) medical criteria for donor participation;
  - (2) quality standards for the milk, including methodologies and criteria for heat-processing; and
  - (3) policies for priority distribution of milk when demand exceeds the supply.

#### **52-9.5 Donor qualifications.**

- (a) The human milk bank shall initially screen and periodically assess the donor for conditions and behavior that may affect the quality or nutritional value of milk, or impair the donor's health, including, but not limited to, the donor qualification requirements in Subpart 52-3 of this Part, and for:
  - (1) the use of medications, tobacco, alcohol and/or other substances in quantities likely to be harmful if transmitted through human milk to a recipient;
  - (2) systemic chronic diseases or nutritional deficiencies;
  - (3) acute and chronic infectious diseases;
  - (4) emotional conditions and/or behavioral disturbances;
  - (5) history of jaundice in the donor's own infant after one week of age;
  - (6) sources of exposures which may be associated with environmental contaminants;
  - (7) duration of breast feeding; and
  - (8) general ability to understand and follow directions regarding sanitary collection and storage of the milk, and contraindications to donation.
- (b) Donors with a history or behavior which places them at high risk for human immunodeficiency virus (HIV) infection or other infectious diseases (see Subpart 52-3 of this Part) shall be permanently excluded from donation.
- (c) The human milk bank shall have evidence available that the donor has been tested within one month prior to the first donation and found negative for hepatitis B virus, including hepatitis B surface antigen (HBsAg) and antibody to hepatitis B core antigen (anti-HBc); hepatitis C virus; human immunodeficiency virus type 1 (HIV-1); human immunodeficiency virus type 2 (HIV-2); and to human T-lymphotropic virus type I (HTLV-I); and for syphilis and tuberculosis, and that the donor is immune to rubella. Testing for cytomegalovirus shall also be performed, unless donated milk is subjected to the Holder pasteurization method. All laboratory tests shall be performed by a laboratory operating under a permit issued by the department. For out-of-state milk donations, all required laboratory testing shall be performed by a laboratory which is approved by that state's regulating authority, the United States Health Care Financing Administration, or by the department. Except

for rubella and tuberculosis, testing shall be repeated every six months while the donor is participating in the milk banking program, and the donor shall be found negative prior to any subsequent donations. Milk from a donor testing positive for anti-HBc shall not be made available for clinical use.

- (d) The milk bank shall obtain the informed signed consent of the donor for participation in the milk banking program.
- (e) The milk bank shall implement a donor education program, including, but not limited to:
  - (1) the purpose of milk banking and responsibilities of the donor;
  - (2) operating policies and procedures of the milk bank;
  - (3) guidelines for sanitary collection and storage of milk;
  - (4) medical conditions, diseases, and medications or other substances contraindicating use of the milk;
  - (5) diet and nutrition;
  - (6) smoking and alcohol consumption; and
  - (7) breast care and common problems associated with breast feeding and milk donation.

#### **52-9.6 Collection and storage of human milk.**

- (a) The human milk bank shall supply presterilized, leak-proof containers and container seals to the donor.
- (b) Containers shall be accompanied by an affixed tag which shall show the donor's identification number, and the date and time the milk was collected. When frozen milk is held at a transfer station, this tag shall also identify the station, and the date and time of receipt and transport of the milk.
- (c) Milk shall be transported and stored so that it is protected from contamination, thawing and refreezing. Milk in liquid form shall be maintained at a temperature between one and six degrees Celsius, but shall be stored in liquid form for no longer than 48 hours. If milk is frozen, it shall be maintained at minus 20 degrees Celsius or below for a maximum storage period of six months, unless the medical advisory committee specifically approves a longer storage period. Household freezers with automatic defrost cycles shall not be used for such storage. Frozen milk shall be utilized within 48 hours of thawing and discarded thereafter if not utilized.
- (d) The physical facilities of the human milk bank shall minimize the potential for contamination, as follows:
  - (1) the human milk bank shall be located in a distinct, identifiable area with a separate refrigerator and/or freezer provided for human milk; and
  - (2) refrigerators and freezers shall be equipped with a thermometer calibrated at least annually against a National Institute of Standards and Technology (NIST)-certified thermometer, or with a thermometer that has been tested

against, and found to be in agreement with, an NIST-certified thermometer. The thermometer shall be either visually or mechanically monitored daily for fluctuations in temperature affecting the quality of the milk. Temperature records shall be maintained and made available for inspection for at least one year after collection of the milk.

**52-9.7 Maintenance of records.**

- (a) The human milk bank shall maintain an individual file on each milk donor. For all donated human milk, the donor's name, address and any other information which would directly or indirectly identify the donor shall not be disclosed or released by the human milk bank to any person or entity except upon the written consent of the donor or except to the department. Records to be kept by the human milk bank shall include, but not be limited to, those required in Subpart 52-2 of this Part and documentation of instructions given to the donor for collecting, storing and preserving the wholesomeness of donated milk.
- (b) Records of milk donations shall be filed by donor identification number and shall include, but not be limited to:
  - (1) information from the identification tag affixed to the container at the time of collection, showing the date and time of collection, amount collected, and, if applicable, the identification of the transfer station with recorded date, and time of receipt and transport of the milk;
  - (2) results of all clinical laboratory tests performed on the donor preparatory to and during participation in the milk banking program;
  - (3) the date of pasteurization of the milk, if applicable; and
  - (4) the date the milk was distributed or used, and, if applicable, identifying information regarding milk pooled from multiple donors.
- (c) Records shall be maintained on each recipient, including, but not limited to:
  - (1) the infant's or child's age, birth weight and/or weight history, and diagnosis indicating the medical need for human milk;
  - (2) the dates the milk banking service began and terminated;
  - (3) identification by donor identification number of the source of all milk given to the recipient;
  - (4) documentation that the risks of consumption by an infant or child of donated milk have been disclosed to the person(s) legally responsible for such infant or child;
  - (5) recipient health status at the time of discontinuation of milk banking service and reason for such discontinuation.
- (d) Donor and recipient records shall be maintained for at least three years after a recipient's age of majority (18 years) or for at least six years after a recipient's death.

**52-9.8 Distribution of human milk.** Facilities shall distribute human milk only upon receipt of a written order from a licensed physician.

## SUBPART 52-10

### HEMATOPOIETIC PROGENITOR CELL BANKS

#### SECTION

52-10.1 Definitions

52-10.2 Licensure and compliance with standards

#### **Section 52-10.1 Definitions.** As used in this Part:

- (a) *Bone marrow* means the human tissue filling cavities of bone, consisting of fully mature and precursor hematopoietic cells intended for hematopoietic reconstitution.
- (b) *Hematopoietic progenitor cells* means human precursor hematopoietic cells derived from bone marrow, peripheral blood or other tissue sources.
- (c) *Hematopoietic progenitor cell bank* means hematopoietic progenitor cell procurement service, hematopoietic progenitor cell processing facility, hematopoietic progenitor cell storage facility or hematopoietic progenitor cell transplantation facility.
- (d) *Bone marrow transplantation service* means a coordinated program of inpatient and outpatient care in a hospital approved by the commissioner as a provider of bone marrow transplantation services pursuant to section 709.8 of this Title. Such services may accept only stem cells collected in substantial compliance with the criteria established in this Part and Subpart 58-5 of this Title, except in documented emergencies.
- (e) *Department* means the New York State Department of Health.

**52-10.2 Licensure and compliance with standards.** No hematopoietic progenitor cell bank shall operate in New York State unless licensed by the department under Subpart 52-2 of this Part. All of the provisions of Subparts 52-1 and 52-2 of this Part shall apply to a hematopoietic progenitor cell bank, except for the recordkeeping requirements contained in section 52-2.9 of this Part. All hematopoietic progenitor cell banks shall comply with the standards and requirements set forth in Subpart 58-5 of this Title.

## SUBPART 52-11

### NONTRANSPLANT ANATOMIC BANKS

#### SECTION

52-11.1	Definitions
52-11.2	Construction
52-11.3	Informed consent
52-11.4	Retrieval and acquisition of nontransplant anatomic parts
52-11.5	Use of nontransplant anatomic parts
52-11.6	Disposition of nontransplant anatomic parts
52-11.7	Safety
52-11.8	Reporting requirements

**Section 52-11.1 Definitions.** For the purposes of this Subpart, unless the context indicates otherwise, the following terms shall have the following meanings:

- (a) *Whole body* means the intact corporeal remains of an individual after the time of death.
- (b) *Whole body acquisition service* means a nontransplant anatomic bank that solicits, retrieves, performs donor selection, preserves, transports, allocates, distributes, acquires, processes, stores, or arranges for the storage of whole bodies or body segments, solely for education and/or research purposes.
- (c) *Whole body user* means a nontransplant anatomic bank located in New York State that obtains whole bodies and/or body segments from a whole body acquisition service. A whole body user shall store and/or use whole bodies or body segments solely for education and/or research purposes, under the direct oversight of the legally authorized donee. A whole body user may not transfer whole bodies or body segments to any other entity, except as authorized in writing by the whole body acquisition service.
- (d) *Body segment* means a portion of a whole body detached for purposes of study, evaluation, education and/or research. Body segments consist of contiguous mixed tissues whose relationships have been altered only at the segment boundaries.

**52-11.2 Construction.** Terms not defined in this Subpart are defined in Subpart 52-1 of this Part. Nontransplant anatomic banks shall apply to the department for licensure and otherwise comply with all applicable provisions of Subpart 52-2 of this Part.

#### **52-11.3 Informed consent.**

- (a) Nontransplant anatomic banks that recover bodies, body segments, organs or tissues from deceased donors, including whole body acquisition services, shall obtain documented informed consent to the donation from a person authorized to consent to such donation in accordance with Public Health Law section 4301, or, for recoveries outside New York State, applicable statutes in the state where the nontransplant anatomic parts were recovered.
- (b) Nontransplant anatomic banks that recover body segments, organs or tissues from living donors shall obtain documented informed consent from the

- donors.
- (c) If specific direction is not provided in the consent document, it shall be presumed that whole bodies, body segments, and other nontransplant anatomic parts have been donated to entities authorized to receive the bodies of deceased persons pursuant to subdivision (1) of Public Health Law section 4211 and in accordance with the priorities established therein. Such entities may transfer or authorize the transfer of whole bodies, body segments and other nontransplant anatomic parts to other donees specified in subdivisions (1) and (2) of Public Health Law section 4302 for purposes of:
    - (1) medical or dental education;
    - (2) medical or dental research; and/or
    - (3) the advancement of medical or dental science, therapy or transplantation.
  - (d) The documentation of informed consent to a donation shall identify the donee, indicate whether the gift is of the whole body or is limited to specified identifiable body segments, organs or tissues, and clearly specify the authorized uses of such donated body, body segments, organs, and/or tissues. Consent obtained by telephone shall be electronically recorded or documented in writing by the nontransplant anatomic bank. Electronically recorded telephone consent shall be put in the form of written documentation of consent for donation prior to using whole bodies, body segments, organs and tissues in education and/or research.
  - (e) Except as provided in subdivision (c) above, no nontransplant anatomic bank shall use or transfer bodies, body segments or other nontransplant anatomic parts for any purpose not specified in the consent.

#### **52-11.4 Retrieval and acquisition of nontransplant anatomic parts.**

- (a) The retrieval of nontransplant anatomic parts shall only be performed on: (1) the premises of a general hospital; (2) the premises of a whole body acquisition service licensed in accordance with this Subpart; or (3) for nontransplant anatomic parts other than whole bodies and body segments, the premises of a comprehensive tissue procurement service licensed in accordance with Subpart 52-2 of this Part.
- (b) No body, body segment, or other nontransplant anatomic part shall be retrieved, acquired, distributed, transported, or used for a purpose not authorized by Public Health Law section 4302. For the purposes of this Subpart, the term “research” as used in Public Health Law section 4302 shall be limited to research conducted in accordance with accepted research protocols designed to improve the public health, safety and welfare.
- (c) Whole body acquisition services.
  - (1) A whole body acquisition service shall employ the following staff:
    - (i) a nontransplant anatomic bank director who holds a graduate degree in anatomy or the health sciences, or who has been serving as director of a nontransplant anatomic bank licensed by the department prior to the adoption of this provision;
    - (ii) an appropriately trained technician, morgue attendant, diener,

or licensed funeral director responsible for the preparation, care and maintenance of whole bodies and body segments; and

- (iii) at least one support staff person, other than the nontransplant anatomic bank director, but who may be the technician, morgue attendant, diener, or licensed funeral director, who shall be responsible for record keeping.

(2) Facilities requirements. A whole body acquisition service shall have a dedicated, secure and restricted space for preparation of whole bodies and body segments for research and/or education purposes. Access to such space shall be limited to individuals directly associated with receipt and preparation of whole bodies or body segments.

Preparation and storage space shall include:

- (i) a working sink and adequate counter space for preparation of whole bodies or body segments;
- (ii) suitable space for storage of chemicals/materials used in preparation of whole bodies or body segments, as applicable;
- (iii) counters, tables, and cabinetry built of material that may be easily disinfected and cleaned;
- (iv) a refrigerated storage room, walk-in cooler, or cadaver drawer cooler, dedicated solely to storage of whole bodies or body segments. Such storage areas shall have lockable access doors, and alarms to signal intrusion or unacceptable temperature deviation;
- (v) a U.S. Occupational Safety and Health Administration (OSHA)-approved device for handling, lifting, and internal transportation of whole bodies or body segments;
- (vi) OSHA-approved eye wash stations;
- (vii) if embalming is performed, a morgue compliant with federal and state standards; and
- (viii) if cremation is performed, a crematory compliant with federal and state standards.

(3) Records. In addition to the records required in section 52-2.9(i) of this Subpart, a whole body acquisition service shall maintain complete and accurate records of all donations, including:

- (i) identification of the whole body, and, in the case of a body segment, a description and source of the body segment;
- (ii) documentation of unclaimed acquisitions, death certificates, and burial transit permits associated with receipt and use of whole bodies or body segments;
- (iii) facilities/institutions to which the whole bodies or body segments are transferred, or documentation of any other disposition; and
- (iv) a copy of any contract or letter of agreement between the whole body acquisition service and the whole body user, and documentation of the method of intended final disposition of

the whole body or body segment.

(d) Transfer.

- (1) Any transfer of whole bodies, body segments or other nontransplant anatomic parts shall be conducted in compliance with existing state standards for such transfer. The burial transit permit(s) issued by the registrar of vital statistics (in the case of a whole body transfer), or written documentation of the source and a description of the body segment(s) or anatomic parts, shall accompany whole bodies, body segments, or nontransplant anatomic parts.
- (2) In the case of a whole body transfer, a copy of the properly executed burial transit permit shall be maintained by the whole body acquisition service.

**52-11.5 Use of nontransplant anatomic parts.**

- (a) Whenever a whole body is donated for educational purposes, unless another lawful donee is specified in the donor consent, the whole body user shall be an entity authorized to receive the bodies of deceased persons pursuant Public Health Law section 4211 in accordance with the priorities established therein.
- (b) A whole body user shall not transfer the whole body or body segment to any other entity, except as authorized in writing by the whole body acquisition service from which the whole body or body segment was obtained.
- (c) A whole body user shall have at least one staff member with a graduate degree in the health sciences, and training specific to human dissection or to the activity to be performed.
- (d) In addition to the records required in section 52-2.9(i) of this Subpart, a whole body user shall maintain complete and accurate records of receipt, use and disposition of whole bodies, body segments, organs and tissues. These records shall include, but not be limited to:
  - (1) identification of the whole body, or, in the case of a body segment, a description and source of the body segment;
  - (2) a copy of any contract or letter of agreement between the whole body acquisition service and whole body user, and documentation of the method of final disposition of whole bodies or body segments; and
  - (3) in the case of whole body transfers, a copy of a properly executed burial transit permit.
- (e) The dissection and/or other authorized use of whole bodies and body segments shall occur only in dedicated rooms on the premises of the facility identified on the license or at an off-site location approved by the director of the whole body acquisition service from which whole bodies and/or body segments were obtained. Such rooms shall feature:
  - (1) lockable doors with access restricted to individuals directly associated with the dissection and/or other authorized use;
  - (2) isolation from public view;
  - (3) sufficient size, and construction and equipment suitable to ensure safe and respectful handling of whole bodies and body segments;
  - (4) tables designed for dissection of whole bodies or other work spaces

- appropriate for the specific authorized activity to be performed;
  - (5) a working sink and adequate counter space to ensure the safety of individuals involved in using whole bodies and body segments in dissection or other authorized use;
  - (6) surfaces constructed of nonporous materials;
  - (7) OSHA-approved eye wash stations; and
  - (8) facilities for storage of chemicals, if any, in accordance with OSHA guidelines.
- (f) Other nontransplant anatomic banks.
- (1) All other nontransplant anatomic banks shall conduct authorized activities in spaces that feature:
    - (i) lockable doors with access restricted to individuals directly associated with the education and/or research activities conducted;
    - (ii) isolation from public view;
    - (iii) sufficient size, and construction and equipment suitable to ensure safe and respectful handling of the organs and/or tissues;
    - (iv) a working sink and adequate work space to ensure the safety of individuals involved in using organs and/or tissues in education and/or research; and
    - (v) surfaces constructed of nonporous materials.
  - (2) Nontransplant anatomic banks using nontransplant anatomic parts that are not whole bodies or segments shall maintain complete and accurate records of receipt, use and disposition of organs and tissues. These records shall include the source and a full description of each organ or tissue.

**52-11.6 Disposition of nontransplant anatomic parts.**

- (a) All users of nontransplant anatomic parts, including whole body users, shall dispose of whole body remains, body segments, organs and tissue in accordance with existing state standards for such disposition. Users may return whole bodies or body segments to the whole body acquisition service from which the material was originally obtained.
- (b) Disposition of whole bodies and body segments shall be consistent with instructions provided in the consent document.

**52-11.7 Safety.** A nontransplant anatomic bank shall implement written safety and infection control policies and procedures to ensure protection from unnecessary physical, chemical and biological hazards.

- (a) Decontamination and disposal techniques for regulated medical waste shall be utilized. All hazardous and regulated waste materials shall be handled, stored and discarded pursuant to Part 70 of this Title and/or Title 6 Subpart 360-10 as appropriate, or in the case of out-of-state banks, in accordance with the hazardous waste disposal requirements of the state in which the disposal occurs.

- (b) If autoclave equipment is used for sterilization, the pressure, temperature, and duration of each cycle shall be recorded, and such records maintained for one year. For each run, these parameters shall be within the manufacturer's recommended operating procedures. If any one or more of these parameters fall outside the manufacturer's standards, all material shall be reautoclaved. Chemical, biological, and physical detection systems shall be used in conjunction with these other measurements of autoclave performance.
- (c) Eating, drinking, smoking, and the application of cosmetics or contact lenses shall not be permitted in work areas. Refrigerators and freezers used for storing nontransplant anatomic parts, specimens, or reagents shall not be used for any other purpose.
- (d) Gloves and laboratory coats, gowns or other protective clothing shall be worn while handling nontransplant anatomic parts or specimens, sufficient to protect against the transmission of disease and exposure to toxic substances. Such protective clothing shall not be worn outside the work area and shall be disposed of in an appropriate receptacle.

**52-11.8 Reporting requirements.** Whenever requested, a nontransplant anatomic bank shall submit reports to the department containing such information and data concerning its activities as may be required by this Part. Such reports shall be signed by the director of the nontransplant anatomic bank.