

Effective July 21, 2004

**Subpart 58-5  
Hematopoietic Progenitor Cell Banks**

Statutory Authority: Public Health Law, section 3121(5)

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**Section 58-5.1 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 transplantation.

(b) *Hematopoietic progenitor cells* means human precursor hematopoietic cells derived from bone marrow, peripheral blood or other tissue sources, such as cord blood obtained from the placenta or umbilical cord.

(c) *Hematopoietic progenitor cell bank* means hematopoietic progenitor cell procurement service, hematopoietic progenitor cell processing facility or hematopoietic progenitor cell transplantation facility.

(d) *Hematopoietic progenitor cell procurement service* means a facility which performs donor selection and bone marrow aspiration or other hematopoietic progenitor cell collection, and pre-processing storage of hematopoietic progenitor cells from autogeneic and/or allogeneic donors.

(e) *Hematopoietic progenitor cell processing facility* means a facility which processes bone marrow or other hematopoietic progenitor cell samples, including purging, storage, and distribution of hematopoietic progenitor cells from autogeneic and/or allogeneic donors.

(f) *Hematopoietic progenitor cell transplantation facility* means a facility which temporarily stores and transplants hematopoietic progenitor cells, and includes facilities which infuse autogeneic hematopoietic progenitor cells and bone marrow transplantation services approved by the commissioner pursuant to section 709.8 of this Title.

(g) *Hematopoietic progenitor cell transplantation service* means a specific unit conducting hematopoietic progenitor cell transplantation within a hematopoietic progenitor cell transplantation facility. Such a service shall be independently supervised by a qualified director.

(h) *Department* means the New York State Department of Health.

(i) *Commissioner* means the Commissioner of the New York State Department of Health.

#### **58-5.2 General requirements.**

(a) A hematopoietic progenitor cell procurement service shall possess a license issued under Subpart 52-2 of this Title in the category of either limited tissue procurement service or comprehensive tissue procurement service, and operate under standards established by this Subpart, Subpart 52-2 except section 52-2.9, and one or more licensed hematopoietic progenitor cell transplantation facilities. Unless the procurement service and the transplantation facility are operated by the same institution, a hematopoietic progenitor cell procurement service shall have a written agreement with the transplantation facility, which specifies that hematopoietic progenitor cells collected and stored by the hematopoietic progenitor cell procurement service are acceptable for transplantation by the hematopoietic progenitor cell transplantation facility. Collection of hematopoietic progenitor cells performed at facilities outside New York State shall follow policies and procedures consistent with this Subpart. Documentation of such policies and procedures shall be maintained by each associated hematopoietic progenitor

cell transplantation facility. Hematopoietic progenitor cells collected outside New York State shall be approved for use in New York State, in writing, by the director of the hematopoietic progenitor cell transplantation facility or by a physician designated by the director.

(b) A hematopoietic progenitor cell processing facility shall possess a license issued under Subpart 52-2 of this Title in the category of tissue processing facility, and be associated with and operating under standards established by one or more licensed hematopoietic progenitor cell transplantation services.

(c) A hematopoietic progenitor cell transplantation facility shall possess a license issued under Subpart 52-2 of this Title in the category of tissue transplantation facility.

(d) Hematopoietic progenitor cell procurement services, hematopoietic progenitor cell processing facilities and hematopoietic progenitor cell transplantation facilities may operate independently, or together as part of the same organization.

(e) The director of a hematopoietic progenitor cell procurement service and/or processing facility shall ensure the development and implementation of policies and procedures consistent with this Subpart for the operation of the service and the appointment of a medical director and a medical advisory committee.

(1) The director of a hematopoietic progenitor cell procurement service collecting hematopoietic progenitor cells from peripheral blood shall be a physician and have at least one year's experience in apheresis, including or supplemented by experience in the performance or supervision of at least twenty-five (25) peripheral blood hematopoietic progenitor cell collection procedures. The director of a hematopoietic progenitor cell procurement service collecting bone marrow shall be a physician and have at least one year's experience in bone marrow collection, including or supplemented by experience in the performance or supervision of at least twelve (12) bone marrow collection procedures. The director of a hematopoietic progenitor cell procurement service collecting cord blood only shall be a physician and have at least one year's experience in hematopoietic progenitor cell collection, including or supplemented by experience in the performance or supervision of at least twenty-five (25) hematopoietic progenitor cell collection procedures. Such director shall also demonstrate satisfactory knowledge in the area of hematopoietic progenitor cell collection, with particular emphasis on the unique characteristics of cord blood collection. A person who has been approved by the department to direct a hematopoietic progenitor

cell procurement service as of the effective date of these amendments shall be deemed to qualify as director.

(2) The director of a hematopoietic progenitor cell processing facility shall possess a doctoral degree in the biological sciences and have at least three (3) years' laboratory experience, including at least six (6) months' experience in a clinical laboratory or blood bank. In addition, the director of a hematopoietic progenitor cell processing facility shall have one year's experience in hematopoietic progenitor cell processing, including or supplemented by experience in the performance or supervision of at least twenty-five (25) hematopoietic progenitor cell processing procedures. A person who has been approved by the department to direct a hematopoietic progenitor cell processing facility as of the effective date of these amendments shall be deemed to qualify as director.

(f) Medical direction of a hematopoietic progenitor cell procurement service and/or processing facility shall be provided by a physician in consultation with the medical advisory committee. Such physician shall be licensed and currently registered with the New York State Education Department or in the state or jurisdiction of practice. The medical director of a hematopoietic progenitor cell procurement service shall have two (2) years' experience or training in clinical hematology/oncology that includes experience in bone marrow transplantation or two (2) years' experience or training in transfusion medicine, in addition to either one year's experience in hematopoietic progenitor cell collection, or performance or supervision of at least twenty-five (25) hematopoietic progenitor cell collection procedures for each anatomic site (bone marrow, peripheral blood, cord blood or other site) to be used as a source of hematopoietic progenitor cells. The medical director of a hematopoietic progenitor cell processing facility shall have two (2) years' experience in clinical hematology/oncology that includes bone marrow transplantation experience, or two (2) years' experience or training in laboratory medicine or transfusion medicine, in addition to either one year's experience in hematopoietic progenitor cell processing, or experience in the performance or supervision of at least twenty-five (25) hematopoietic progenitor cell processing procedures. A person who has been approved by the department as medical director of a hematopoietic progenitor cell bank as of the effective date of these amendments shall be deemed to qualify as medical director.

(g) The hematopoietic progenitor cell transplantation service director shall be a physician who shall be responsible for compliance with section 52-2.8 of this Title, and shall

monitor the medical efficacy of the hematopoietic progenitor cell transplantation program.

(h) The medical advisory committee, which may be the in-house transfusion committee or transplantation committee, shall include experts in the areas of infectious disease, hematology, oncology, histocompatibility and transfusion medicine, as well as physicians representing associated hematopoietic progenitor cell transplantation facilities. The committee shall meet at least annually.

(i) The medical director of a hematopoietic progenitor cell procurement service, in consultation with the medical advisory committee shall monitor the medical efficacy of the program, and in conjunction with the associated hematopoietic progenitor cell transplantation facility shall, as a minimum, develop medical criteria for donor participation.

(j) The medical director of a hematopoietic progenitor cell procurement service shall be responsible for all aspects of donor qualification, as described in section 58-5.4 of this Subpart.

(k) The director of a hematopoietic progenitor cell procurement service and/or processing facility shall be responsible for the technical and scientific operation of the facility, and shall develop quality standards for hematopoietic progenitor cells.

### **58-5.3 Hematopoietic progenitor cell procurement.**

(a) Facilities where allogeneic or autogeneic hematopoietic progenitor cells are collected shall be adequately lighted, ventilated and equipped, and be operated in a manner which conforms to current medical standards generally accepted by leading authorities in transplantation medicine.

(b) Each hematopoietic progenitor cell procurement service, except for such facilities collecting cord blood only, shall document association with a hematopoietic progenitor cell transplantation facility and compliance with the procedures, protocols and record keeping requirements for collection as established by the transplantation facility, as well as all requirements of this Subpart.

(c) All required clinical laboratory testing shall meet the standards of Article 5, Title V of the Public Health Law.

(d) For bone marrow harvesting procedures, adequate facilities shall be available for the administration of anesthesia and for emergency resuscitation. A qualified

anesthesiologist shall be on the premises at all times during harvesting procedures.

(e) Emergency services shall be immediately available to any donor who manifests an adverse reaction.

(f) A physician shall explain the hazards of the donation procedure to the donor in such a manner that the donor is offered an opportunity to refuse consent. The donor shall be advised of the risks of hematopoietic progenitor cell donation and of the anesthesia method to be used, the potential need for transfusional support and possible side effects of each procedure, and options for disposition of hematopoietic progenitor cells no longer needed by the intended recipient. All this information shall be provided to each prospective donor in written form. The written informed consent of the prospective donor shall then be obtained. Autogeneic donors shall also be informed of the risks associated with hematopoietic progenitor cell collection.

(g) Informed consent for collection of cord blood shall be obtained from the donor's mother before stem cells are placed in inventory. In all cases of *in utero* cord blood collection, consent shall be obtained prior to collection.

(h) Hematopoietic progenitor cells from autogeneic donors shall not be destroyed or released for purposes other than infusion into the intended patient without written authorization from the director of the facility storing the hematopoietic progenitor cells and:

(1) if the donor/patient is deceased, written documentation of death; or

(2) if the donor/patient is living, written authorization from the physician currently responsible for treating the patient for the underlying disorder for which the hematopoietic progenitor cells were collected; and documented informed consent from the donor/patient or donor/patient's guardian, unless it is documented that no response was received within sixty (60) days to at least two (2) written requests for such consent sent at least thirty (30) days apart. Documentation of such written requests shall be maintained.

(i) Hematopoietic progenitor cells from allogeneic donors shall not be destroyed or released for purposes other than transplantation into the originally intended recipient without the written authorization of the intended recipient's physician and documentation that the intended recipient, if living, has been notified that the cells will not be available.

**58-5.4 Donor qualifications.**

(a) Except in the case of an autogeneic donation, a complete donor history shall be obtained prior to hematopoietic progenitor cell donation. A summary of the donor history obtained by a hematopoietic progenitor cell procurement service shall be provided to the physician performing the transplant for a determination of the cells' suitability for transplantation. The donor history, or in the case of cord blood donation, the history of the donor's biologic mother and, if available, the donor's biologic father, shall include, but not be limited to, information concerning:

- (1) any acute respiratory disease;
- (2) any infectious skin disease that creates a risk of contamination of the hematopoietic progenitor cells;
- (3) any disease transmissible by hematopoietic progenitor cells insofar as can be determined by donor history;
- (4) active tuberculosis or history of therapy therefor;
- (5) history of malaria or travel to or residence in malarially endemic areas for periods of time considered to bear increased risks for malaria exposure, as determined by criteria established by the procurement or collection facility, consistent with criteria developed by the United States Public Health Service;
- (6) known coagulation or platelet disorders;
- (7) any medical condition which may be affected adversely by the collection procedure;
- (8) any medical condition, including a malignancy, that would adversely affect the quality of hematopoietic progenitor cells collected;
- (9) receipt of an organ transplant or a transfusion of blood or blood components within the past twelve (12) months;
- (10) indications of drug or alcohol abuse; and
- (11) other medical conditions or circumstances as determined by the medical advisory committee and medical director of the procurement service.

(b) Except in the case of an autogeneic donation or cord

blood donation, a complete physical examination of the donor shall be performed by the medical director of the procurement service or another qualified physician.

(c) For autogeneic donations, testing for syphilis, hepatitis B surface antigen (HBsAg), antibody to human immunodeficiency virus type 1 (anti-HIV-1) and antibody to human immunodeficiency virus type 2 (anti-HIV-2) shall be performed, unless already performed within the previous thirty (30) days, or unless the hematopoietic progenitor cells are collected, processed and transfused at the same facility and a system is in place to ensure disposition to the intended recipient.

(d) For allogeneic hematopoietic progenitor cell donations in New York State, specimens of blood shall be collected from the donor, or in the case of umbilical cord blood, from the donor's mother, and the following tests shall be performed in a clinical laboratory under permit by the department. For out-of-state donations, all required clinical laboratory testing shall be performed by a laboratory which is approved by the regulatory authority in the state or jurisdiction where the laboratory is located, or by the department:

(1) within thirty (30) days prior to or seventy-two (72) hours after donation, and prior to initiation of the transplant conditioning regimen in the recipient:

(i) direct tests for indicators of infection with syphilis and cytomegalovirus (CMV);

(ii) HBsAg;

(iii) antibody to hepatitis B core antigen (anti-HBc), antibody to hepatitis C virus (anti-HCV), anti-HIV-1, anti-HIV-2, and antibody to human T-cell lymphotropic virus type I (anti-HTLV-I); and

(iv) except for cord blood donation, peripheral blood cell enumeration (red, white and platelet) and differential blood smear evaluation.

(2) prior to ablation of the recipient, major histocompatibility antigens (HLA-A, B and DR) and other minor histocompatibility antigens, including mixed lymphocyte culture or DNA typing, as indicated.

(e) Except for allogeneic donors confirmed positive for any indicator of HIV infection, the decision as to the acceptability of hematopoietic progenitor cells shall be made by the hematopoietic progenitor cell transplantation service director. Hematopoietic progenitor cells from allogeneic donors

confirmed positive for any indicator of HIV infection may not be used in any case.

#### **58-5.5 Sterilization of instruments.**

Syringes, needles, lancets, or other phlebotomy or hematopoietic progenitor cell collection devices capable of transmitting infection from one person to another and licensed for single use by the Food and Drug Administration shall be appropriately discarded after such use. Reusable devices shall be heat-sterilized prior to each use. Heat sterilization shall be by autoclaving at 121.5 degrees Celsius for fifteen (15) minutes after the chamber of the autoclave has been evacuated and has reached that temperature, or by dry heat for two (2) hours at 170 degrees Celsius, or by such other similarly acceptable procedure in accordance with current medical standards generally accepted by leading authorities in transplantation medicine.

#### **58-5.6 Collection and handling of hematopoietic progenitor cells.**

(a) All hematopoietic progenitor cell specimens obtained by bone marrow aspiration shall be collected by the medical director of the procurement service or other qualified physician, physician's assistant, or a nurse practitioner under the supervision of the medical director. Hematopoietic progenitor cells obtained by peripheral blood apheresis shall be collected by an individual trained in pheresis in accordance with the requirements of section 58-2.15 of this Part. Cord blood collection shall be performed by staff with documented training, experience and proficiency in the techniques utilized.

(b) Hematopoietic progenitor cell collection apparatus and containers shall be clean, pyrogen-free and sterile.

(c) Phlebotomy and bone marrow aspiration puncture sites shall be prepared by a procedure which conforms to current medical standards generally accepted by leading authorities in transplantation medicine.

(d) Hematopoietic progenitor cell collection systems shall meet the following minimum requirements:

(1) hematopoietic progenitor cells shall be collected under aseptic conditions using an approved system adequately protected against contamination;

(2) additives shall be used as required to ensure the continued suitability of hematopoietic progenitor cells for transplantation and retention of viability. All changes in additives shall be validated on-site, and such validation shall be documented;

(3) each container shall be legibly labeled or tagged at the time of collection with:

(i) the donor's identification code and date of collection; and

(ii) if known, the recipient/patient's name, the name of the hospital where the patient is to be transplanted, and the patient's hospital registration number, Social Security number, birth date or similar identifying information;

(4) each final container shall be legibly labeled or tagged at the time of issuance with:

(i) if performed, the results of laboratory tests for syphilis, HBsAg, and antibodies to HBV, HCV, HIV-1, HIV-2, HTLV-I and CMV, unless the results were forwarded to the hematopoietic progenitor cell transplantation service in advance or included in records accompanying the hematopoietic progenitor cells; and

(ii) a biohazard label, if the donor has tested reactive or positive for any of the tests required in section 58-5.4(c) or (d)(1) of this Subpart; and

(5) if microbial culturing is performed, suspected contamination shall be reported to the transplantation service.

(e) Prior to collection of cord blood, an access agreement/acknowledgment shall be consummated between the administration of the hospital or other collection site and the licensed cord blood bank.

#### **58-5.7 Hematopoietic progenitor cell processing facilities.**

(a) If hematopoietic progenitor cells are to be frozen, the following requirements apply:

(1) unless otherwise specifically authorized in writing by the director of the hematopoietic progenitor cell processing facility, hematopoietic progenitor cells shall be frozen within forty-eight (48) hours of collection using cryopreservation techniques generally accepted by experts in transplantation medicine and meeting the requirements of this Subpart;

(2) until used, hematopoietic progenitor cells shall be stored continuously within a temperature range of minus 196 degrees Celsius to minus 80 degrees Celsius, under one of the following conditions:

(i) in a mechanical freezer reserved for hematopoietic progenitor cells, equipped with an automatic temperature recording device, an audible alarm and a back-up system in the event of unexpected mechanical failure; or

(ii) in a liquid nitrogen freezer reserved for hematopoietic progenitor cells, equipped with an automatic liquid nitrogen level monitor, an audible alarm and a back-up system in the event of unexpected liquid nitrogen loss;

(3) frozen hematopoietic progenitor cells in transit from a processing facility to a transplantation facility or other facility shall be:

(i) maintained, at a minimum, on dry ice or in a liquid nitrogen dry shipper. Storage/transport procedures for the frozen hematopoietic progenitor cells shall be validated, and such validation shall be documented;

(ii) transported as fast as reasonably possible and without any unnecessary delay; and

(iii) used immediately upon arrival or stored as required in paragraph (2) of this subdivision until thawed for use; and

(4) hematopoietic progenitor cell specimens shall be inspected visually at the time of freezing and thawing. If the color or physical appearance is abnormal, the cells shall not be released for transplantation unless authorized, in writing, by the transplantation service director.

(b) Hematopoietic progenitor cells stored in the liquid state shall be maintained at a temperature and for a period of time specified in a protocol approved by the director of the hematopoietic progenitor cell procurement service and/or processing facility.

(c) Storage temperature records for hematopoietic progenitor cells shall be maintained as required in section 58-5.8(c) and (d) of this Subpart, and be made available for inspection by the department for the entire period of storage and for one year afterward.

(d) Unless needed to meet a medical emergency, hematopoietic progenitor cells shall be transported in a leak-resistant, crush-resistant and puncture-resistant container featuring a prominent label which:

(1) identifies the contents as "human blood," "human hematopoietic progenitor cells" or "human bone marrow";

(2) describes the contents, the packing agent, if any, and any special precautions necessary in handling such contents; and

(3) contains the name, address and twenty-four (24)-hour telephone number of the person or entity to be contacted in the event that the container is found leaking or damaged, or is misdirected.

#### **58-5.8 Required records.**

(a) Complete and accurate records of hematopoietic progenitor cells released for transplantation shall be kept for seven (7) years by the hematopoietic progenitor cell procurement service, processing facility and transplantation service using the sample. Such records shall be open to inspection by the department. For all donated hematopoietic progenitor cells, the donor's name, address, and any other information that 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 that would directly or indirectly identify the recipient shall not be disclosed or released by the hematopoietic progenitor cell 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) Records to be kept by the hematopoietic progenitor cell procurement service shall include, but not be limited to, the following information:

(1) donor's full name, address, age, sex, and identification code, as well as documentation of donor or donor's mother informed consent;

(2) date and volume of hematopoietic progenitor cells collected;

(3) any adverse reaction of the donor and its outcome;

(4) medical history and results of all required clinical laboratory tests and of the physical examination performed;

(5) disposition of hematopoietic progenitor cells;

(6) documentation of sterility testing and viability and recovery checks, if performed; and

(7) medical director's authorization for the collection.

(c) Records to be kept by the hematopoietic progenitor cell processing facility shall include, but not be limited to, the following information:

(1) donor's identification code, date and amount of cells collected;

(2) results of all clinical laboratory tests performed;

(3) methods used for processing, preserving, storage and transport of the hematopoietic progenitor cells, including manufacturer's name and lot numbers of all reagents used in processing or preserving the cells;

(4) temperature records of the storage chamber;

(5) records of visual inspection of the hematopoietic progenitor cell specimens at the time of freezing and thawing;

(6) specimen location in the storage chamber;

(7) methods used for hematopoietic progenitor cell preservation, storage and transport; and

(8) disposition of the cells.

(d) Whenever hematopoietic progenitor cells are released for transplantation, the following records shall be maintained by the hematopoietic progenitor cell transplantation facility:

(1) name of the hematopoietic progenitor cell bank providing the cells, description of the specimen, and condition of the cells and shipping container upon receipt, including any loss noted of liquid nitrogen, dry ice or other coolant;

(2) if applicable, any extenuating circumstances that warrant acceptance of hematopoietic progenitor cells from donors who test positive;

(3) medical history and results of all tests, and of the physical examination performed on the donor, if applicable;

(4) disposition of the hematopoietic progenitor cells, including date and time released, and name of recipient;

(5) outcome of the transplantation procedure,

including, but not limited to, any adverse outcome or infectious disease in the recipient; and

(6) if applicable, records documenting storage and temperature monitoring of hematopoietic progenitor cells, in accordance with the requirements in section 58-5.7 of this Subpart.

#### **58-5.9 Quality assurance and safety requirements.**

(a) Quality assurance.

(1) The hematopoietic progenitor cell procurement service and hematopoietic progenitor cell processing facility shall keep records which indicate that a quality assurance program is maintained in the following areas:

(i) preventive maintenance, periodic inspections and testing for proper operation of equipment;

(ii) monitoring of all temperature-controlled spaces and equipment to ensure proper performance;

(iii) validation of microprocessor-controlled equipment and associated software, including test plan protocols, results of parallel testing and supervisory review; and

(iv) validation of hematopoietic progenitor cell processing and testing methodologies.

(2) Hematopoietic progenitor cell 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 product 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 and/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 accompanying the collected hematopoietic progenitor cells shall be sufficiently stable to provide accurate and precise test results suitable for clinical interpretation. The hematopoietic progenitor cell procurement service 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 log book. The accessioning system shall be

designed to allow tracing of the hematopoietic progenitor cells to a specific donor, and to identify the date and, if applicable, the time of retrieval.

(5) Current standard operating procedure manuals specific to the facility shall be available at all times in the immediate work area of personnel engaged in retrieval, processing, testing, storage, distribution, or other hematopoietic progenitor cell procurement activity. There shall be a written protocol for all procedures performed. Manuals shall contain a protocol for development, maintenance, and periodic review of standard operating procedures by facility personnel and management staff. Procedure manuals shall have the following features:

(i) a standardized format for procedures;

(ii) a system of numbering and/or titling 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 hematopoietic progenitor cell procurement service and/or processing facility;

(v) clearly defined areas of employee or technical staff responsibility by position/title;

(vi) documented approval of procedures and procedural modifications, including annual review by the director of the hematopoietic progenitor cell procurement service and/or processing facility, or authorized supervisor;

(vii) instructions for the completion of reports and forms, including examples;

(viii) effective date and date of review for each procedure; and

(ix) a system for archiving earlier versions of procedures and forms.

(6) The policies and procedures specified in the procedure manual shall be followed at all times. If deviations or deficiencies are identified, appropriate corrective action shall be taken and documented.

(7) The director of the hematopoietic progenitor cell

procurement service and/or processing facility shall establish and maintain a planned and periodic internal review program for monitoring and evaluating the quality and appropriateness of the hematopoietic progenitor cell banking services. Included in the program shall be systems for evaluating errors, and designing, implementing and documenting corrective action for any deficiencies identified. Quality assurance deficiencies shall be documented, and evidence shall be available that any operational or procedural problems are reported to supervisory personnel in a timely manner, and that corrective action is implemented, documented and subsequently followed-up.

(8) The director of the hematopoietic progenitor cell procurement service and/or hematopoietic progenitor cell processing facility shall be responsible for developing policies, procedures and/or standards for the qualifications, training, certification and continuing education of technical staff. Documentation of compliance with this requirement and with the policies developed shall be maintained.

(b) Safety.

(1) The hematopoietic progenitor cell procurement service and/or processing facility shall implement written safety and infection control policies and procedures to ensure protection from unnecessary physical, chemical and biological hazards, as follows:

(i) Decontamination and disposal techniques for regulated medical waste shall be utilized. All hazardous and regulated medical waste materials shall be handled, stored and discarded pursuant to Part 70 of this Title.

(ii) If sterilization equipment is used, 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(s) outside the manufacturer's standards, all material shall be resterilized. Chemical, biological and physical detection systems should be used in conjunction with these other measurements of performance.

(iii) Eating, drinking, smoking, or the application of cosmetics or contact lenses shall not be permitted in work areas. Refrigerators or freezers used for storing specimens or reagents shall not be used for any other purpose.

(iv) Gloves and laboratory coats, gowns or other protective clothing shall be worn as necessary while handling

blood specimens or hematopoietic progenitor cell tissue. Such protective clothing shall not be worn outside the work area and shall be disposed of in an appropriate receptacle.

(2) The hematopoietic progenitor cell procurement service and/or processing facility shall have written policies and procedures in the following areas:

- (i) infection control;
- (ii) biosafety;
- (iii) chemical and radiological safety;
- (iv) emergency response to worksite accidents; and
- (v) medical waste disposal.

(3) The safe collection of peripheral blood hematopoietic progenitor cells by apheresis shall be the responsibility of the medical director of the apheresis service. Collection shall be performed in full compliance with section 58-2.15 of this Part.

(4) Hematopoietic progenitor cell transplantation facilities shall report suspected cases of infectious disease transmission in recipients to the hematopoietic progenitor cell bank providing the tissue.

(5) The hematopoietic progenitor cell bank shall have a written procedure for documenting any errors or accidents in retrieval, testing, processing, storage or disposition of hematopoietic progenitor cells that may affect the safety of the cells, and for reporting such errors or accidents to the medical advisory committee of the bank. If the error or accident is detected after issuance of the cells, the error or accident shall be reported to the receiving facility immediately upon detection by the distributing facility. All errors with the potential for serious adverse effects on the recipient shall also be reported to the department's Wadsworth Center within seven (7) calendar days of discovery.

#### **58-5.10 Compliance with standards.**

58-5.10 Compliance with standards. (a) Hematopoietic progenitor cell procurement services and/or processing facilities shall allow admission to representatives of the department for the purpose of inspecting the premises and evaluating operating procedures, equipment, and records, including financial records and lists of physicians or facilities to whom or to which hematopoietic progenitor cells are released, to determine compliance with the standards in this

Subpart. If the Commissioner determines that a significant likelihood exists that adequate safeguards are not implemented, the department may require that cells not be released pending a hearing. Such hearing shall commence within fifteen (15) days of any suspension pursuant to this section.

(b) Whenever requested, a hematopoietic progenitor cell bank shall submit to the department reports containing such information and data concerning the bank's activities as may be required by this Subpart. Such reports shall be signed by the director of the hematopoietic progenitor cell bank.

#### **58-5.11 Licensure.**

No person shall own or operate a hematopoietic progenitor cell procurement service, processing facility or transplantation facility in New York State unless licensed by the department under Subpart 52-2 of this Title. All provisions of Subpart 52-2 of this Title shall apply to a hematopoietic progenitor cell procurement service, processing facility and/or transplantation facility, except for the record keeping requirements contained in section 52-2.9 of this Title.

#### **58-5.12 Special circumstances.**

(a) The department may exempt a hematopoietic progenitor cell bank from a specific standard contained in this Subpart, provided:

(1) the hematopoietic progenitor cell bank has requested an exemption under limited circumstances prior to the noncompliance with the standard; and

(2) the hematopoietic progenitor cell bank has demonstrated to the department that application of the standard to such bank under the limited circumstances for which the 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 the exemption is sought, and the department determines that the requirement imposed by the federal or other state's governmental unit 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 or impair the provision of

services necessitated by a medical emergency or special medical condition. Hematopoietic progenitor cell banks seeking an exemption pursuant to this subparagraph shall describe the nature of the emergency or special medical condition 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 Subpart shall be approved by the director of the hematopoietic progenitor cell transplantation service.

(b) A copy of the department's approval for an exemption shall be maintained by the hematopoietic progenitor cell transplantation facility and the hematopoietic progenitor cell bank releasing the cells.