SUBPART 58-2
BLOOD BANKS

Effective November 7, 2007

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Section 58-2.1 Definitions. As used in this Subpart:

(a) **Blood bank** means a facility for the collection, processing, storage or distribution of human blood, human blood components or blood derivatives, or the performance of reinfusion procedures. A blood bank shall employ a qualified director for administrative purposes and, if blood collection is performed, a qualified medical director.

(b) **Blood donation center** means a facility, fixed or mobile, that is operated by a blood bank and used for the collection of blood, plasma or cytapheresis products, or separation of whole blood into components.

(c) **Donor or blood donor** means a person who provides his/her blood or plasma for transfusion of whole blood, blood components or derivatives.

(d) **Blood components** means those preparations separated from a single donation of whole blood, or collected by apheresis, intended for direct use in transfusion, including but not limited to plasma, fresh frozen plasma, red blood cells, washed red blood cells, leukocyte-reduced red blood cells, platelets, granulocytes, and cryoprecipitate.

(e) **Derivatives** means those preparations separated from plasma derived from multiple donors, including but not limited to albumin, immune globulin, plasma protein fraction and clotting factor concentrates.

(f) **Blood products** means whole blood, blood components or derivatives.

(g) **Plasmapheresis** means the withdrawal of blood to obtain plasma with subsequent or simultaneous reinfusion into the donor of his/her own red blood cells.

(h) **Serial plasmapheresis** program means a program of individual donor donations on a regular basis by plasmapheresis yielding three liters or more of plasma per consecutive four-week period.

(i) **Cytapheresis** means the separation and collection of blood cells or other formed elements by hemapheresis for the purpose of obtaining a transfusable blood component.

(j) **Intraoperative blood recovery** means recovery of blood from a surgical field and processing of recovered blood for direct reinfusion, storage or infusion into a cardiopulmonary bypass pump. Intraoperative blood recovery does not include performance of perioperative normovolemic hemodilution procedures. Postoperative blood recovery means recovery of blood from a wound following surgery, and processing of recovered blood for direct reinfusion or storage. Intraoperative blood recovery was formerly termed intraoperative blood salvage.
(k) **F.D.A.** means the Food and Drug Administration of the United States Department of Health and Human Services.

(l) **Limited transfusion service** means a facility, home care services agency, physician’s office, or other entity which administers blood or blood components, and may temporarily store blood or blood components, and distribute them within its own organization, but relies on a blood bank holding a permit in blood services-transfusion to perform laboratory tests required under section 58-2.17 of this Subpart.

(m) **Holding facility** means a facility at which blood is temporarily stored but which does not offer any other blood banking services.

(n) **Transfusion service** means a service which issues blood, blood components or blood derivatives for administration into a person, but does not include a limited transfusion service.

(o) **Institution** means a hospital or other facility operating a transfusion service under a permit issued by the department.

(p) **Allogeneic collection** means the removal and storage of blood or blood components from a donor for transfusion into another person, and includes blood donated for directed donation to another person, or donated for autogeneic use and subsequently crossed-over in whole or in part for use by others. Allogeneic collection was formerly termed homologous collection.

(q) **Autogeneic collection** means the removal and storage of blood or blood components from a donor for subsequent reinfusion into that same person, and includes preoperative hemodilution procedures if at any time the blood leaves the operating room in which surgery is performed. Autogeneic collection was formerly termed autologous collection.

(r) **Directed donation** means an allogeneic collection in which blood from a particular donor is designated for use by a specified recipient.

(s) **Medical director** means a qualified physician who is employed by a blood bank, and is responsible for donor selection and safety.

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

(u) **Reinfusion procedure** means the withdrawal of a small amount of blood or a component thereof from a patient, its processing by addition of substances or by culturing, and administration of the product so obtained, in whole or in part, into the same patient for diagnostic or therapeutic purposes. Reinfusion procedures shall include, but not be limited to, radioisotopic tagging, and genetic and immunologic manipulation, but shall not include processing of whole blood units into components for autogeneic reinfusion, such as platelet concentrates, packed red blood cells and plasma.
(v) *Normovolemic hemodilution* means the collection of blood prior to surgery, and includes fluid replacement and reinfusion during or after surgery for purposes of reducing red cell loss during surgery.

(w) *Limited reinfusion service* means a facility, home care services agency, physician’s office or other non-hospital entity that performs reinfusion procedures.

(x) *Clinical laboratory technician* means a clinical laboratory practitioner who performs clinical laboratory procedures and examinations, pursuant to established and approved protocols of the department, which require limited exercise of independent judgment, and are performed under the supervision of a clinical laboratory technologist, laboratory supervisor, or director of a clinical laboratory.

(y) *Clinical laboratory technologist* means a clinical laboratory practitioner who, pursuant to established and approved protocols of the department, performs clinical laboratory procedures and examinations and any other tests or procedures conducted by a clinical laboratory, including maintaining equipment and records, and performing quality assurance activities related to examination performance, which require the exercise of independent judgment and responsibility.

(z) *Health care provider*, for the purposes of this Subpart, means a physician, physician assistant or nurse practitioner.

(aa) *Nurse practitioner* means a registered professional nurse licensed and currently registered, under the Laws of the State of New York, to diagnose illness and physical conditions, and perform therapeutic and corrective measures, in accordance with a collaborative agreement with a physician qualified to collaborate in the specialty involved.

(bb) *Physician* means an allopathic or osteopathic physician licensed and currently registered, under the Laws of the State of New York or in the state of practice, to practice medicine.

(cc) *Physician assistant* means a person licensed and currently registered, under the Laws of the State of New York, to practice medicine under the supervision of a physician.

(dd) *Physician designee* means a physician designated by the medical director to be responsible for one or more routine or special tasks.

58-2.2 Qualifications of donors.

(a) The medical director shall be responsible for the determination that blood may be collected safely from a donor and that the donor’s blood is acceptable for collection. This determination shall be made by the medical director or trained staff members under the medical director’s supervision on the day of collection of the blood. In
addition, autogeneic collections prior to anticipated surgery or other medical procedure
shall require the written authorization of the donor's health care provider and written
consent of the donor. If autogeneic blood is to be subsequently used for allogeneic
transfusion, all requirements in subdivision (f) of this section must be met.

(b) Only those persons may be accepted as donors of blood for allogeneic
use who are in good health as indicated by:

(1) freedom from acute respiratory diseases;

(2) freedom from infectious skin lesions at the phlebotomy site
and from any infectious skin disease generalized to an extent that creates a risk of
contamination of the blood;

(3) freedom from any disease transmissible by blood transfusion,
insofar as can be determined by history and examinations required in this Subpart;

(4) freedom from active tuberculosis. A person with a history of
tuberculosis may be accepted as a blood donor following completion of drug therapy;

(5) freedom from syphilis. However, blood for plasma fractionation
into heat-treated or pathogen-inactivated derivatives may be accepted;

(6) freedom from a history of viral hepatitis for a duration specified by
the United States Public Health Service;

(7) freedom from a history of malaria or travel to or residence in
malarially endemic areas for periods of time considered to increase risks for malaria
exposure, as determined by the United States Public Health Service. However, plasma for
transfusion or fractionation may be accepted from donors with a history of malaria or travel
to a malarially endemic area;

(8) freedom from signs and symptoms of human immunodeficiency
virus (HIV) infection; and

(9) freedom from other medical contraindications.

(c) For allogeneic collections, a person may not be accepted as a blood
donor:

(1) whose health may be affected adversely by the bleeding;

(2) who has received a transfusion of blood or blood components
within the past year, with the exception of autogeneic transfusion;

(3) who is under 17 years of age, except that donors who are 16
years of age may be accepted, if they have presented written permission specific to the occasion from a parent or guardian;

(4) who is more than 75 years of age, except that donors over 75 may be accepted after satisfactory case-by-case review by the medical director or physician designee;

(5) who is known to use or presents indications of having used illegal injectable drugs;

(6) whose oral temperature exceeds 37.5 degrees Celsius (99.5 degrees Fahrenheit);

(7) whose pulse after resting is faster than 110 or slower than 45 beats per minute, except if the donor is an athlete with high exercise tolerance; or whose pulse exhibits pathologic irregularities;

(8) whose systolic blood pressure exceeds 180 millimeters of mercury, or whose diastolic pressure exceeds 100 millimeters;

(9) whose weight is less than 50 kilograms (110 pounds), except that a donor whose weight is between 40 kilograms (88 pounds) and 50 kilograms (110 pounds) may donate a volume proportionate to the donor’s weight, provided that the anticoagulant is proportionately reduced and the container is appropriately labeled;

(10) whose hemoglobin content is less than 12.5 grams per deciliter or whose hematocrit is less than 38 percent, as determined by techniques found by the department to meet medical standards generally accepted in New York State;

(11) who is known ever to have received pituitary-derived human growth hormone; or

(12) who falls into a category of individuals determined by the United States Public Health Service to be unsuitable for blood donation.

(d) For allogeneic collection:

(1) All donors shall be given educational materials on risk activities for HIV infection and shall be advised that persons at risk for HIV infection should refrain from donating blood.

(2) Each donor shall be provided the opportunity to indicate confidentially that blood collected is unsuitable for transfusion.

(e) For autogeneic collection only:

(1) There are no age limits.
(2) The hemoglobin concentration of the donor-patient should be no less than 11 grams per deciliter, or the hematocrit, if substituted, should be no less than 33 percent, unless otherwise approved in writing by the medical director of the blood bank or other physician designated by such medical director.

(3) The frequency of phlebotomy for autogeneic transfusion shall be determined by the medical director of the blood bank and the donor-patient’s physician. Phlebotomy of the donor-patient within 72 hours of the time of the anticipated surgery or transfusion must be authorized in writing by the medical director or other physician designated by the medical director.

(4) Donation for autogeneic transfusion should not be undertaken if medically contraindicated.

(f) Blood withdrawn for autogeneic transfusion may not be used for allogeneic transfusion unless the donor meets all the criteria set forth in subdivision (b), and paragraphs (c)(2), (5) and (6) of this section, and the unit meets the requirements set forth in section 58-2.3(a) of this Subpart. The minimum hemoglobin concentration for such a unit shall be 12.5 grams per 100 milliliters or a hematocrit of 38 percent, and the minimum volume for such a unit shall be 405 milliliters.

(g) Blood withdrawn in order to promote the health of a donor otherwise qualified under the provisions of this section shall not be used for transfusion unless the container label indicates the donor’s disease that necessitated withdrawal of blood, except that, in the case of a donor with hemochromatosis, blood without such labeling may be used for transfusion, provided that the blood bank has demonstrated that therapeutic phlebotomy is available free of charge to hemochromatosis patients and that all other requirements of this Subpart have been met.
completed, all blood and blood components shall be stored in a separate refrigerator or
prominently labeled separate area of the refrigerator reserved for quarantined units.
However, in an emergency requiring release for transfusion prior to receipt of such report,
the results shall be recorded subsequently on the recipient’s chart. Any unacceptable blood
unit identified, as well as all of its components, shall be removed immediately from the
quarantine area and disposed of or moved to a separate area reserved for such units. Units
unacceptable for transfusion, which are retained for other purposes, shall be labeled with
pertinent test results.

(b) All test runs for required tests for infectious disease markers that
generate numeric readings shall include a weakly reactive control. If the results of this
weakly reactive control or any other control do not fall within the predetermined acceptable
range, results from that run shall not be reported until the run is repeated. Results of all
tests shall be verified by a second staff member to preclude errors in transcription or
interpretation. In a manual system, examination of the original instrument tape shall be
conducted by the second staff member. Except for results of tests performed on samples
from autogeneic donors, as specified in section 58-2.23 of this Subpart, incomplete test
results shall not be reported to donors, including any initially reactive test results not yet
repeated in duplicate. Release of blood units from quarantine shall be based on examination
of a signed and verified hard copy, or electronic equivalent, of all test results. The director
of the laboratory conducting the testing shall be responsible for ensuring that testing is
performed in accordance with this Subpart. The blood bank director shall be responsible for
development of algorithms for test result interpretation and shall approve, in writing, the
laboratory procedures to be used.

(c) Plasma collected for fractionation purposes only need not be tested for
HTLV-I.

(d) If platelets are donated by the infant’s mother to an infant with
alloimmune neonatal thrombocytopenia, the donor’s blood need not be tested as required
in subdivision (a) of this section. In such case, the donor requirements specified in section
58-2.2 of this Subpart may also be waived with the written authorization of the medical
director of the blood bank or physician designee.

(e) If multiple patient-dedicated blood components are donated by a single
donor to support a particular patient, that donor’s blood may be screened for all analytes
specified in subdivision (a) of this section every 30 days, rather than at each donation.

(f) For both allogeneic and autogeneic collection, the ABO and Rh groups of
every donor shall be determined in accordance with procedures approved by the
department. The determination shall be made by:

(1) testing the blood cells with anti-A and anti-B grouping sera;
testing the serum or plasma from the blood with known group A and group B red blood
cells; and
(2) testing the blood with anti-Rho (anti-D) grouping serum, including, in the case of initially negative testing with anti-Rho (anti-D), a method designed to detect weak D.

(g) For allogeneic collection, required tests for detecting unexpected alloantibodies:

1) All donor blood shall be tested for unexpected alloantibodies using reagent red blood cells that meet F.D.A. standards and are intended for this purpose.

2) Methods of testing for alloantibodies shall be those that demonstrate sensitizing and hemolytic antibodies.

(h) Errors or accidents in collecting, testing or processing of donor blood that may affect the safety or purity of any product or health of the donor or recipient shall be reported to the department’s Wadsworth Center within seven calendar days of such an error or its discovery.

58-2.4 Collection of blood.

(a) Prior to collection of blood for testing, a signed form must be obtained from the donor or person legally authorized to consent on behalf of such donor, in which the donor or the person legally authorized to consent acknowledges that he/she has been provided with written materials stating that HIV testing for donor screening purposes shall be performed in conjunction with all donations.

(b) Quantity limitations. Allogeneic and autogeneic donors may give a maximum of 550 milliliters of whole blood in addition to pilot samples of up to 30 milliliters.

(c) Frequency limitations. No allogeneic blood donor may donate more than 550 milliliters of whole blood within an eight-week period, unless approved to do so by a physician who examines the potential donor at the time of the proposed second donation. In no event may an allogeneic blood donor donate more than twice within a sixteen-week period. The foregoing prohibition on donations does not apply to allogeneic blood donors diagnosed with hemochromatosis. For autogeneic collections, the frequency of donation shall be as specified in section 58-2.2(e)(3) of this Subpart.

58-2.5 Sterilization of instruments. For both allogeneic and autogeneic transfusions, syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another, shall either be licensed by the F.D.A. for single use or be heat-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 procedure as may be approved by the department.

58-2.6 Collection and handling of blood for subsequent allogeneic or autogeneic transfusion.

(a) Every blood donation shall be obtained under the direction of the medical director. Medical services for emergency care of the donor shall be available. Collection of blood for transfusion may be conducted only at blood banks with a permit in blood services-collection and at blood donation centers approved by the department.

(b) Phlebotomy apparatus and blood containers shall be clean, pyrogen-free and sterile. Anticoagulants shall be placed in containers prior to sterilization.

(c) Phlebotomy sites shall be prepared by a procedure found by the department to meet medical standards generally accepted in New York State.

(d) Blood collection systems shall meet the following minimum requirements:

(1) Blood shall be collected under aseptic conditions using an approved closed system or a vented system if adequately protected against contamination.

(2) Anticoagulant solutions shall be sterile and pyrogen-free. F.D.A.-approved formulae such as anticoagulant citrate dextrose (ACD) (21-day storage), citrate phosphate dextrose (CPD) (21-day storage), trisodium citrate (48-hour storage), heparin (48-hour storage), citrate phosphate dextrose adenine-1 (CPDA-1) (35-day storage), and other safe and effective formulae and storage periods, of such length as to assure the blood’s continued effectiveness for transfusion and retention of its safety, purity and potency, as approved by the department, may be employed.

(3) Labeling requirements.

(i) For allogeneic collection, the container and the attached pilot blood specimens shall be legibly labeled at the time of collection with the associated unit’s identification code. The container label shall indicate the date of expiration. As soon as available, the results of ABO and Rh grouping tests shall be affixed to component containers.

(ii) With the exception of units collected in an operating room which never leave the immediate proximity of the patient, for autogeneic collection, the following information shall appear on a label or tag attached to the blood container:

(a) the identification of the collecting facility;
(b) the patient’s name and if available, the name of the hospital where the patient is to be transfused and the patient’s hospital registration number or, if unavailable, social security number, birth date or similar identifying information. This tag shall be removed if the unit is subsequently used for allogeneic transfusion;

(c) ABO and Rh group;

(d) date of expiration;

(e) if the unit does not qualify for allogeneic transfusion, a prominent label to read “For autologous use only” or similar wording;

(f) an autogeneic unit from a donor who has tested positive or reactive on any of the tests required in section 58-2.3(a) of this Subpart within the previous 30 days shall be labeled as a biohazard unless confirmatory testing has been negative. The exterior of the shipping container shall not contain any information identifying the donor; and

(g) a label bearing the donor classification statement "Autologous donor" shall be permanently affixed to the unit.

(e) For allogeneic and autogeneic collections, adequate specimens of blood sufficient for all testing to be performed shall be taken.

(f) The blood shall be collected in the manner appropriate for the container employed. Following collection, the container shall be sealed securely. If a container is opened or entered in any way, the blood component must be transfused within 24 hours or discarded, unless a sterile connecting device which maintains a functionally closed system has been utilized for entry. After deglycerolizing, frozen red blood cells shall be transfused or refrozen within 24 hours, or shall be discarded. If a refrozen unit is subsequently rethawed and deglycerolized, a notation indicating such previous thawing and deglycerolizing shall be made on a label or tag attached to the blood unit, or on accompanying paperwork. After thawing of fresh frozen plasma, the blood component shall be transfused immediately or stored at between one and six degrees Celsius. Plasma stored in the liquid state for more than 24 hours shall be released only for medical indications other than replacement of labile coagulation factors. Cryoprecipitate intended for factor VIII replacement must be transfused within six hours after thawing.

(g) Until issued, whole blood and red cell components shall be stored continuously in a refrigerator either with a fan for circulating air, or of a capacity and design to ensure that the proper temperature is maintained throughout, and equipped with automatic temperature recording and an audible alarm. Storage shall be at a temperature of not less than one degree Celsius nor more than six degrees Celsius. No items other than specimens, tissue, or reagents shall be stored in a refrigerator in which whole blood and red blood cell components are stored. Temperature records shall be available for inspection for at least five years. Blood in transit shall be refrigerated at a temperature between one
degree Celsius and 10 degrees Celsius, preferably between four degrees Celsius and six degrees Celsius, with the exception of units from which platelets will be separated. Units which will be used as a source of platelets shall be stored at room temperature, preferably at 20 to 24 degrees Celsius, until platelets are separated, but for no more than eight hours. Autogeneic units shall be stored in a separate, specifically designated portion of the refrigerator.

(h) Until issued, cryoprecipitate, fresh frozen plasma and cryoprecipitate-poor plasma shall be stored continuously at a temperature not higher than minus 18 degrees Celsius in a freezer equipped with automatic temperature recording and an audible alarm. Storage time shall not exceed one year. Such components shall not be relabeled as different components and released for transfusion, but may be used for fractionation into derivatives. Freezer temperature records shall be available for inspection for at least five years.

(i) Until issued, platelets shall be stored at 20 to 24 degrees Celsius and shall be continuously rotated on a rotator designed for such use. Temperature records shall be available for inspection for at least five years.

(j) Until issued, frozen red blood cells shall be stored at a temperature no higher than minus 65 degrees Celsius in a freezer equipped with automatic temperature recording and audible alarm, or in liquid nitrogen. Liquid nitrogen levels must be mechanically or visually monitored daily. Storage time shall not exceed ten years. Freezer temperature or liquid nitrogen level records shall be available for inspection for at least five years. After thawing, blood shall be transfused within 24 hours or discarded.

(k) Whenever blood is irradiated, a protocol for such irradiation, approved by the director of transfusion services or the director of the blood bank, must be followed. Maintenance and operation of blood irradiators must conform to the manufacturer’s instructions. Whenever irradiation of blood is medically indicated because of a blood relationship between donor and recipient, such irradiation shall be performed by the blood bank collecting the blood unless the hospital notifies in writing the facility collecting the blood that the hospital will be responsible for irradiation, in which case such blood shall be identified as requiring irradiation on a tag or paperwork accompanying the units. Blood that has been irradiated shall be identified as "Irradiated" on a label or tag attached to the unit.

(l) Fresh frozen plasma, cryoprecipitate and frozen red blood cells shall be thawed only in a water bath at a temperature not exceeding 38 degrees Celsius or in another device specially designed for such thawing. If a water bath is used for thawing, its temperature shall be recorded each day of such use. Temperature records shall be available for inspection for at least five years. Maintenance and operation of all equipment for processing or preparation of blood components shall conform to the manufacturer’s instructions and shall follow a protocol approved by the director of transfusion services.

(m) Except for blood recovered intraoperatively or postoperatively, or collected for use in a reinfusion procedure, all blood intended for transfusion shall upon
collection become the responsibility of the blood collection service. Disposition of blood collected by phlebotomy shall be at the discretion of the director of the collection service until the blood is transferred to a transfusion service, at which time its disposition shall be at the discretion of the director of transfusion services. The director of the blood bank shall ensure that during any transport blood is packed and handled appropriately and only by authorized individuals. No directed or autogeneic blood unit or component shall be transported to a transfusion service unless the director of the receiving transfusion service or his/her designee has authorized such transport. A transfusion service which has granted standing authorization for receipt of blood shall be given specific notice prior to each shipment. Disposition of blood recovered intraoperatively or postoperatively shall be at the discretion of the intraoperative or postoperative blood collection service, unless the blood is transferred to the hospital blood bank for storage, at which time its disposition shall be at the discretion of the director of transfusion services. Blood banks shall not release blood components or blood intended for transfusion to any site in New York State not permitted as a collection service or transfusion service, or approved as a limited transfusion service.

(n) The premises, equipment, procedure manuals, records, circulars of information, and all blood, blood components and derivatives shall be available for inspection, review and approval by the department during normal business hours.

58-2.7 Immunohematology testing.

(a) Labeling of specimens intended for pre-transfusion testing shall include the patient’s name, patient’s identification number, and date of collection. Identification of the person collecting the specimen shall be recorded.

(b) All tests, including, but not limited to, ABO and Rho(D) grouping, antibody detection and identification, and compatibility testing, shall employ methods, techniques or procedures which have been approved or recommended for the particular reagent in use by the F.D.A. or the American Association of Blood Banks, and which have been demonstrated to be effective in a manner acceptable to the department, in conformance with generally accepted laboratory principles. All grouping antisera, reagents, devices, methods, and procedures for blood unit processing or transfusion-related testing shall be approved by the F.D.A. or conform to the recommended minimum requirements of the F.D.A.

(c) 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 their expiration date. The reactivity and specificity of each reagent shall be determined whenever a new lot is employed. All methods shall conform to manufacturers’ instructions unless otherwise approved by the department.

(d) Negative controls run on each day of use are not required for anti-human globulin and antibody screening cells, provided manufacturers’ instructions are followed. New lots of reagents shall be thoroughly evaluated, but antibody identification cell panels
need not be tested with a known antibody. All test procedures to be used shall be determined by the blood bank director and shall be documented in the standard operating procedure manual. If no negative reactions are observed on a given test run, an investigation shall be performed and controls run. Such quality control records shall be accessible to laboratory personnel engaged in immunohematology testing and to the department.

(e) Centrifuges used for testing of red blood cell agglutination shall undergo revolutions per minute (RPM) and timer checks quarterly. Functional calibration that determines optimal centrifugation conditions shall be performed prior to initial use, after adjustments or repairs, and at least annually thereafter, and shall be documented. The procedure shall specify the speed and duration of centrifugation to be used. A microscope shall be located in the work area designated for immunohematology testing, if use of a microscope is specified by the facility’s standard operating procedure manual or by a test kit manufacturer’s package insert. Microscopic examination shall be performed for red blood cell agglutination tests whenever indicated for the procedure in use.

58-2.8 Standard operating procedures.

(a) 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 the collection, processing, testing, storage, distribution and administration of blood, blood components or derivatives for autogeneic or allogeneic use, and for therapeutic, prophylactic or diagnostic purposes. There shall be a written protocol for all procedures 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:

(1) a standardized format;

(2) a system of numbering and/or entitling individual procedures;

(3) a clearly written description of purpose for each procedure;

(4) a reference section listing appropriate scientific literature;

(5) clearly defined areas of personnel responsibility by title;

(6) documented approval of procedures and procedural modifications by the director, and annual review by the director or authorized supervisor;

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

(8) effective date and date of review for each procedure; and
(9) a system of archiving earlier versions of procedures and forms. Discontinued procedure documents and forms shall be retained and be available for inspection for at least seven years. Dates of initial use and discontinuance shall be recorded.

(b) The procedure manual shall include a written procedure for documenting errors or accidents in collection, testing, processing, storage or distribution that may affect the safety or purity of any product, or health of the donor or recipient. If the error or accident is not detected prior to issuance of the blood, blood components or derivatives, 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.

(c) The procedure manual shall include written policies and protocols regarding the following, for activities performed at the site:

(1) use and maintenance of blood warming devices;

(2) type of infusion sets and filters for all components;

(3) inspection of components prior to issuance;

(4) type of personnel who may remove components;

(5) for collecting facilities, obtaining blood or components from other institutions during emergency situations;

(6) prenatal and neonatal testing;

(7) evaluation of reported transfusion reactions; and

(8) emergency release of uncrossmatched blood;

(9) method validation requirements;

(10) professional qualifications of personnel who may collect blood specimens for pretransfusion testing; and

(11) specimen and labeling requirements for pretransfusion samples.

(d) The policies and procedures specified in the procedure manual shall be followed at all times. If deviations are identified, appropriate corrective action shall be taken and documented.
(e) The blood bank director or the director of transfusion services shall establish and maintain a planned and periodic internal review program for monitoring and evaluating the quality and appropriateness of standard operating procedures in the performance of blood bank and transfusion service activities. 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 the appropriate individuals in a timely manner and that corrective action is implemented and subsequently followed-up.

58-2.9 Issuance of blood, blood components and derivatives.

(a) Unless they are needed to meet a medical emergency, blood and blood components 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" or "biomedical product";

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

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

(b) Except in an emergency or except as indicated in section 58-2.3(c) or (d) of this Subpart, blood and blood components shall not be made available for allogeneic transfusion, unless a donor blood sample reacts negatively to tests required in section 58-2.3(a) of this Subpart, and testing specified in section 58-2.3(f) of this Subpart has been completed. Untested or incompletely tested blood, including blood from directed donations and cytapheresis collections, shall not be issued if a fully tested blood component is available, except in the case of autogeneic donations, as specified in section 58-2.3(a) of this Subpart. Cytapheresis units for which testing has not been completed may be distributed to a hospital by the facility collecting the units, but such components may not be issued by a transfusion service until testing is complete, except in the case of a life-threatening emergency. The release of cytapheresis components from a donor found to have a positive result for anti-HBc may be permitted upon the authorization of the health care provider ordering the transfusion and the written authorization of the medical director or physician designee, provided that such authorization documents the indication and justification for such release. Such components shall be labeled with all positive test results. Blood from a donor whose blood specimen reacts positively in a test for syphilis and is nonreactive in confirmatory testing shall be appropriately labeled and may be used for plasma fractionation. Blood from a donor whose blood specimen reacts positively in tests for anti-HBc shall be appropriately labeled and may be used for plasma fractionation. Blood from a donor whose blood specimen reacts positively in tests for HbsAg, HIV or HCV nucleic acid or antibodies to HCV, HIV-1, HIV-2, or HTLV-I/II shall be appropriately
labeled and may not be used for allogeneic transfusion or for fractionation. Blood from a donor whose blood sample reacts positively in tests for HBsAg or antibodies to HIV-1 and/or HIV-2 may not be used for autogeneic transfusion without the written authorization of the patient’s physician and, if drawn by another facility, the director of the transfusion service receiving the unit.

(c) Blood components and derivatives shall be issued only if ordered by a licensed physician or other person authorized by law. Recipients shall receive whole blood of the same ABO group or compatible red blood cells. Rho (D)-negative recipients shall receive Rho (D)-negative blood except for reasonable exempting circumstances as determined by the director of transfusion services. Rho (D)-positive recipients may receive Rho (D)-positive or Rho (D)-negative whole blood or red blood cells. In an emergency, appropriately documented in the records, blood may be released for transfusion prior to the completion of compatibility tests. Any transfusion service which issues blood for transfusion at a limited transfusion service shall perform the required tests on its own premises unless the limited transfusion service holds the required permit issued by the department to perform such tests.

(d) Whole blood, red blood cells, plasma or other blood components and derivatives shall be inspected visually immediately prior to issuance. If the color or physical appearance is abnormal or there is indication or suspicion of microbial contamination, the unit or units of whole blood, blood components or derivatives shall not be issued for transfusion.

(e) Blood, blood components or derivatives may not be made available for transfusion beyond the designated expiration date, except that whole blood may be used to prepare plasma within nine days after the designated expiration date, provided that it meets the inspection standards required in subdivision (d) of this section.

(f) An established protocol for processing or pooling of blood components prior to issuance must be in place.

(g) Except in emergency situations, or in cases in which the patient has multiple vascular access lines and more than one unit will be transfused simultaneously, or in case of release to an operating room with a monitored refrigerator, only one unit of red cells at a time may be issued within a hospital for a particular patient, unless otherwise authorized in writing by the director of transfusion services.

(h) If an unused, unopened unit is returned to the blood bank, the time, date and condition of the unit must be recorded.

(i) A sample of red cells or whole blood from each red cell product issued for transfusion shall be retained for a minimum of seven days after the transfusion for further testing in the event of an adverse reaction.

(j) After issuance, red blood cells may be stored at room temperature for up to one hour or by refrigerating at between one and six degrees Celsius. Red blood cells
kept at room temperature for more than one hour may not be returned to the blood bank and later reissued for transfusion unless the temperature of the component is documented not to have risen above ten degrees Celsius. If refrigerated, red blood cells shall be stored in a refrigerator designed for the purpose of storing blood, except that a cooler with suitable coolant may be used for refrigeration, provided that the temperature of the blood is maintained at between one and ten degrees Celsius.

(k) Blood or blood components shall not be identified or labeled or preferentially distributed according to the donor’s membership in a category based on age, race, color, creed, national origin, sex, marital status or social organization, except for purposes of phenotyping of blood units. The sequence of issuance by a transfusion service of blood donated for designated recipients shall not be based on factors other than medical considerations.

(l) Blood or blood components from a donor who had been determined in the past to be unsuitable for subsequent donation shall not be released for transfusion unless the donor has been approved for reentry into the donor pool by the director of the blood bank.

58-2.10 Required records and confidentiality.

(a) Complete and accurate records of blood, blood components and derivatives released for allogeneic or autogeneic transfusion shall be kept for seven years or six months after the expiration date of the individual product, whichever is later, by the blood bank preparing the product and by the institution using the product. Such records shall be open to inspection by the department and by the institution using the product. Such records shall be open to inspection by the department and shall include the information specified in sections 58-2.11 and 58-2.12 of this Subpart. For all collected or distributed blood, blood components and derivatives, the donor’s name, address, telephone number, social security number and any other information which would directly or indirectly identify the blood donor of any specific unit shall not be disclosed by the blood bank to any person or entity except upon the written consent of the donor or except to the department and other agencies which issue clinical laboratory and/or blood bank permits to the facility whose records are requested.

(b) Blood banks and transfusion services shall file a Blood Services Activity Report annually with the department.

(c) Records shall be maintained of all tests, controls, reagents and current procedures, in a manner acceptable to the department in conformance with generally accepted laboratory principles.

58-2.11 Records to be kept when blood is collected for autogeneic or allogeneic transfusion.
(a) Every blood bank shall maintain a record of each container of blood or blood components collected or prepared therein. The record shall contain the following information:

(1) donor's full name, address, age, sex and identifying code;

(2) date and amount of blood collected;

(3) any adverse reaction of the donor;

(4) signature of the phlebotomist;

(5) results of all tests performed on a sample from the donor or a unit;

(6) disposition of the blood or blood components;

(7) for autogeneic donation, documentation of written or verbal consent of the donor-patient’s health care provider if donation takes place prior to anticipated surgery or medical procedure, of the physician responsible for collection or his/her designee, and of the donor-patient. If the blood is to be considered for allogeneic use, the donor shall sign a consent form giving consent for such use, specifying procedures for release of the unit by the health care provider, and stating that to the best of the donor’s knowledge, the blood is safe for use by others; and

(8) if a donor is determined to be unsuitable for donation based on donor history, laboratory test results or implication in a case of transfusion-transmitted disease according to the protocol of the blood collection service, a record of the donor’s name and identifying information. Blood from such a donor shall not be released, even if results of testing on subsequent donations are negative, unless the donor has been approved for reentry into the donor pool by the director of the blood bank.

(b) Blood banks and transfusion services shall file a Blood Services Activity Report annually with the department.

58-2.12. Records to be kept when blood, blood components or derivatives are issued for allogeneic or autogeneic transfusion.

(a) For blood and blood components, logbook records of the following information, where relevant, shall be kept in the blood bank and made available to the department for inspection:

(1) source;

(2) donor identification code;
(3) ABO and Rh groups;

(4) expiration date;

(5) results of compatibility tests;

(6) disposition of the unit, including recipient's name if administered;

(7) signature or initials of the person removing the unit;

(8) date and time of issue; and

(9) results of all tests associated with the investigation of all transfusion reactions, with the conclusions reached and the report signed, or approved by electronic equivalent, by the director of the blood bank or a qualified physician designated by the director of the blood bank.

(b) For coagulation factor concentrates, logbook records of the following information shall be kept and made available to the department for inspection:

(1) manufacturer;

(2) lot number;

(3) expiration date;

(4) disposition, including recipient's name if administered; and

(5) date of issue.

(c) For all derivatives, records associated with the investigation of all reactions, with the conclusions reached and the report signed, or approved by electronic equivalent, by the director of the blood bank or a qualified physician designated by the director of the blood bank, shall be kept and made available to the department for inspection.

(d) These recordkeeping requirements shall also apply to blood issued to limited transfusion services.

(a) A blood bank may maintain blood donation centers at fixed sites provided written approval is obtained from the department for the establishment of each such center.

(b) Each blood donation center shall be under the supervision of the director of the blood bank, and shall be adequately lighted and ventilated, and equipped and operated in a manner satisfactory to the department.

(c) Other activities, including preparation of components, storage, distribution and donor qualification laboratory testing shall not be performed at blood donation centers without prior written approval of the department.

(d) The blood bank shall inform the department, upon request, of the number and type of mobile units active under its direction, and the provisions made for the handling of medical emergencies.


(a) The standards that apply to whole blood collection and processing shall apply to serial plasmapheresis except as otherwise specified. Whenever the plasma is not intended for transfusion, or for the preparation of fractions for transfusion, the criteria for donor selection may be limited to those designed for the safety of the donor. In such instances, the plasma unit shall be prominently labeled, "NOT FOR TRANSFUSION", or similar language.

(b) Direction. The director of a serial plasmapheresis program shall be a physician who must demonstrate satisfactory training in all aspects of hemapheresis, including a minimum of two years' experience.

(c) Informed consent. The consent of a prospective serial plasmapheresis donor shall be obtained in writing after a licensed physician explains the hazards of the procedure to the donor in such a manner that he/she is offered an opportunity to refuse consent. The donor shall be told of the risks of serial plasmapheresis, including the possibility of a hemolytic transfusion reaction if he/she is given someone else's red cells, risks of any medications or sedimenting agents to be used, and, if he/she is to be immunized or hyperimmunized, of the hazards involved. For example, in the case of immunization with human blood components, the donor shall be told specifically about the risk of viral hepatitis, as well as about the increased risk of receiving incompatible blood if he/she ever needs a transfusion. A prospective donor who is to be deliberately exposed to an antigen shall also be given a general description of the immunization program, including the nature of the material to be injected. All of this information shall also be given to each prospective donor in written form, and the donor’s consent shall be signed and witnessed on a form approved by the department.
(d) **Donor qualification.** A donor may not be accepted for serial plasmapheresis unless the criteria in section 58-2.2(b) and (c) of this Subpart, with the exception of sections 58-2.2(b)(5) and (7), and 58-2.2(c)(10) and (11), are met.

(e) **Care of serial plasmapheresis donors.** A qualified, licensed physician shall be available within fifteen minutes' travel time of the premises at which serial plasmapheresis is performed, immediately available for personal or telephone consultation in the treatment of a donor who manifests an adverse reaction, and responsible for all phases of plasmapheresis conducted. A physician or a registered nurse designated by the medical director shall be available on the premises at all times. The floor supervisor shall be a registered nurse, physician assistant, or person with at least two years' experience performing plasmapheresis procedures, and shall have completed a plasmapheresis training program that includes documented satisfactory performance of donor plasmapheresis procedures. Persons performing manual plasmapheresis procedures shall be licensed practical nurses, registered nurses, clinical laboratory technologists, physician assistants, or persons with at least two years' experience performing manual plasmapheresis procedures. Persons performing automated plasmapheresis procedures shall be licensed practical nurses, registered nurses, clinical laboratory technologists, clinical laboratory technicians or physician assistants, or persons with at least six months' experience in collecting whole blood for transfusion. All persons performing plasmapheresis procedures shall have one year's experience performing plasmapheresis procedures or shall have completed a training program in plasmapheresis procedure technique. The training program must include training in donor screening, venipuncture techniques, instrument operation, prevention of and initially addressing donor reactions, and proper documentation of all completed procedures. At the end of the training program, each plasmapheresis operator must be able to:

1. safely and effectively operate the cell separator systems in use at the facility;
2. harvest plasma which meets quality standards;
3. manage fluid volumes safely;
4. prevent, and when necessary, initially address adverse reactions;
5. develop the ability to work independently, utilizing the floor supervisor as a resource when necessary; and
6. provide support to the donor while maintaining control of the operation of the instrument. The director shall establish an agreement with an accredited hospital in the vicinity of the plasmapheresis center for the admission of donors who sustain adverse reactions and require hospital care.

(f) **Laboratory testing.** A serologic test for syphilis shall be performed within 24 hours on a specimen collected at the time of the first donation and at four-month intervals thereafter. A donor with a reactive serologic test for syphilis shall not be
plasmapheresed again until the donor’s serum is nonreactive in confirmatory testing, except that donors with reactive tests for syphilis may be plasmapheresed to obtain plasma to be used for manufacturing control serum for serologic tests for syphilis. Approved tests for HbsAg and antibodies to HCV, HIV-1 and HIV-2 shall be performed on the retained plasma or on a specimen obtained from the donor at the time of donation. If the plasma is intended for transfusion, all tests required in section 58-2.3(a) of this Subpart shall be performed.

(g) Return of red blood cells to donor. If it is not possible to return red blood cells to a plasmapheresis donor, or if whole blood is donated, the donor shall not be plasmapheresed again for eight weeks, unless the donor’s extracorporeal red blood cell volume during the procedure is not expected to exceed 100 milliliters.

(h) Manual plasmapheresis procedures. Containers and anticoagulants shall meet the standards for whole blood. Before the blood container is separated from the donor for processing, it shall bear two separate and independent means of identification to enable both the donor and the phlebotomist to determine without doubt that the contents originate from the donor. Plasmapheresis shall be performed aseptically under conditions that avoid air embolism. During their separation, the red blood cells shall be maintained at a temperature not exceeding 37 degrees Celsius and under conditions known to assure the sterility and viability of these cells upon their return to the donor. The identity of the donor and the container shall be confirmed by at least two technical staff members prior to reinfusion of the red blood cells. Red blood cells shall be returned to the donor within two hours of the phlebotomy. If plasmapheresis is to be performed using equipment dissimilar to blood bags used for the collection of blood so that the standards for containers and anticoagulants for whole blood do not apply, specific approval from the department is required.

(i) Automated plasmapheresis procedures. Plasmapheresis shall be performed aseptically under conditions that avoid air embolism and maintain sterile technique. If plasmapheresis is to be performed using equipment dissimilar to blood bags used for the collection of blood so that the standards for containers and anticoagulants for whole blood do not apply, specific approval from the department is required.

(j) Records. All institutions performing plasmaphereses shall maintain records of all plasmaphereses performed, and the clinical and laboratory information pertinent thereto. These records shall include complete information on each donor, signed consent of the donor, his/her identification code, and the amount of plasma removed. When immunizations are performed, the antigen and the procedures employed shall be identified and recorded, and the donor shall give specific consent for the immunization. These records shall be available for inspection for at least seven years after each plasmapheresis.

58-2.15 Collection of blood components by apheresis.
(a) **Selection of donors.** The standards that apply to whole blood donation shall apply in the selection and care of the donor for apheresis, unless otherwise specified.

(b) **Informed consent.** The consent of a prospective donor shall be obtained in writing after a qualified and specially trained individual explains the hazards of the procedure in such a manner that the donor is offered an opportunity to refuse consent. The donor shall be informed of the risks of apheresis and the risks of any sedimenting agents or medications to be used.

(c) **Qualifications and care of the donor.**

(1) Only those persons may be accepted as blood donors for apheresis who are in good health as indicated by the qualifications of a whole blood donor specified in section 58-2.2 of this Subpart, with the following exceptions:

   (i) Ingestion of aspirin-containing medications within three days of donation shall preclude donation of platelets.

   (ii) Cytapheresis of donors who do not meet the requirements of this subsection shall be performed only if the harvested cells are expected to be of particular value to an intended recipient, and only if the supervising physician has confirmed in writing the particular value of these cells and has certified that the donor's health permits cytapheresis.

   (iii) Medications or sedimenting agents to facilitate cytapheresis shall not be used in donors whose medical history suggests that these may exacerbate previous or intercurrent disease. Guidelines for use of such agents shall be established by the medical director.

(2) The medical director, who must demonstrate satisfactory training in all aspects of apheresis, including one year of experience, shall be responsible for all phases of apheresis conducted. Persons performing apheresis procedures shall be registered nurses, licensed practical nurses, clinical laboratory technologists, clinical laboratory technicians or physician assistants, or persons with at least six months' experience collecting blood for transfusion. All persons performing apheresis procedures shall have at least one year's experience performing apheresis procedures or shall have completed a training program in apheresis procedure technique. The training program must include training in donor screening, venipuncture techniques, instrument operation, prevention of and initially addressing donor reactions, and proper documentation of all completed procedures. At the end of the training program, each apheresis operator must be able to:

   (i) safely and effectively operate the cell separator systems in use at the facility;

   (ii) harvest blood components which meet quality standards;
(iii) manage fluid volumes safely;

(iv) prevent, and when necessary, initially address adverse reactions;

(v) develop the ability to work independently, utilizing the floor supervisor as a resource when necessary; and

(vi) provide support to the donor while maintaining control of the operation of the instrument.

(3) The floor supervisor shall be a:

(i) registered nurse;

(ii) physician assistant;

(iii) person with at least two years’ experience performing apheresis procedures; or

(iv) person with at least one year of experience supervising allogeneic blood collection.

(4) The floor supervisor shall have completed an apheresis training program that includes documented satisfactory performance of donor apheresis procedures.

(5) A person specifically trained in recognizing and addressing reactions that may occur in association with the procedures being performed shall be immediately available on the premises at all times during an apheresis procedure. A qualified licensed physician shall be immediately available, at least for telephone consultation, during all procedures.

(d) Volume and frequency of apheresis. Extracorporeal blood volume shall not exceed 15 percent of the donor’s estimated blood volume. No more than 12.0 liters of plasma shall be removed per year from a donor weighing 175 pounds or less, and no more than 14.4 liters shall be removed per year from a donor weighing more than 175 pounds. The interval between procedures shall be at least 48 hours. The above volume and frequency requirements may be waived upon written authorization of the supervising physician, provided the donor meets all other eligibility requirements. Red blood cell loss shall not exceed 300 milliliters per eight weeks, unless the following requirements are met:

(1) for male donors, the donor’s weight is at least 130 pounds;
(2) for female allogeneic donors, the donor’s weight is at least 150 pounds;

(3) for female autogeneic donors, the donor’s weight is at least 130 pounds;

(4) the allogeneic donor’s hemoglobin content is 13.3 grams per deciliter or greater or hematocrit is 40 percent or greater;

(5) the autogeneic donor’s hemoglobin content is 12.0 grams per deciliter or greater or hematocrit is 36 percent or greater;

(6) the volume of packed red blood cells removed does not exceed 550 milliliters; and

(7) the volume removed is replaced with at least 225 milliliters of normal saline.

Following a red cell apheresis procedure in which red blood cell loss exceeds 300 milliliters, the allogeneic donor shall not donate whole blood or undergo another apheresis procedure for a minimum of 16 weeks. For autogeneic donors, frequency and volume to be removed shall be determined by the medical director of the blood bank in conformance with recommendations of the manufacturer of the apheresis device.

(e) **Return of red blood cells to donor.** If it is not possible to return red blood cells to a donor, or if whole blood is donated, the donor shall not undergo apheresis again for eight weeks, unless the donor’s extracorporeal red blood cell volume during the procedure will not exceed 100 milliliters.

(f) **Procedures for collection of blood components by apheresis and their processing.** Such procedures shall follow a written protocol approved by the medical director. Containers and anticoagulants shall meet the standards for whole blood. Apheresis shall be performed aseptically under conditions that prevent air embolism, and assure sterility and viability of cells returned to the donor.

(g) **Required records.** All facilities performing apheresis shall maintain records of all such procedures performed, and the clinical and laboratory information pertinent thereto. These records shall include complete information on the donor, volume of blood removed, anticoagulants used, duration of the procedure, volume of components obtained, medications and sedimenting agents used, including manufacturer, lot number, expiration date and amount administered, and any adverse reactions and their management. These records shall be available to the department for inspection for at least seven years after each procedure.

58-2.16 **Required standards for transfusions.**
(a) Transfusion services. Every institution which performs transfusions or supplies blood to limited transfusion services shall designate a physician who is a member of the staff as director of transfusion services. Such physician must be licensed and currently registered in New York State. The director of the blood bank, if a physician, may be so designated. The premises, equipment, procedure manuals, records, and all blood, blood components and derivatives shall be available for inspection by the department.

(1) It shall be the responsibility of the chief executive officer or other person in charge of each institution and of the director of transfusion services to determine that:

   (i) the rules and regulations of the Council on Human Blood and Transfusion Services and the Administrative Rules and Regulations of the department and related requirements are complied with;

   (ii) attending and other staff members and nurses are properly instructed regarding all required procedures;

   (iii) records required by the aforesaid rules and regulations are maintained;

   (iv) serious unexpected reactions and incidents involving transfusions are reported to the department’s Wadsworth Center, with sufficient detail to facilitate evaluation and investigation, within seven calendar days of the reaction or incident or its discovery; and

   (v) a written policy exists regarding use of blood components negative for cytomegalovirus antibody, irradiated components, leukocyte-reduced components and other specialty components. Such a policy shall include recommended indications for component use and a protocol for component processing and issuance. There shall also be a written policy on recommended indications for transfusion of whole blood, fresh frozen plasma and platelets.

(2) The institution shall report annually to the department the name(s) of the physician(s) in charge of the transfusion service.

(3) If blood is issued to a limited transfusion service, the director of transfusion services of the issuing facility and the director of the limited transfusion service performing the transfusion shall ensure compliance with all requirements of this Part.

(b) Each facility which transfuses blood or supplies blood to limited transfusion services shall have a transfusion committee which meets at least quarterly or more frequently as required by the department. The committee shall:
(1) be composed of at least five members, a majority of whom are present at each meeting;

(2) include members with expertise in transfusion medicine and qualified to review the appropriateness and technical aspects of a transfusion, such as, but not limited to, the director of transfusion services, blood bank supervisor or pathologist; and

(3) review transfusions of all blood and blood products issued by the facility for all sites at which transfusions are performed, including all intraoperative and postoperative recovery procedures.

(c) Each institution, through its transfusion committee, shall establish guidelines for reservation (compatibility or crossmatching) of blood for each elective surgical procedure which has been performed there more than five times in the preceding calendar year and shall set the maximum number of hours that crossmatched blood will be held on reserve.

(d) Whole blood, red blood cells, plasma, or other components and derivatives shall be prepared and administered by methods generally accepted by the F.D.A. or American Association of Blood Banks and/or by other methods approved by the department as in conformance with generally accepted laboratory principles. For blood and blood components, the person initiating the transfusion shall be a physician, registered nurse, physician assistant, nurse practitioner, licensed practical nurse or board-certified cardiovascular perfusionist (intraoperatively). A licensed practical nurse shall initiate transfusions only following satisfactory completion of a transfusion training program meeting criteria specified by the department and by the New York State Education Department and only when a registered nurse, physician assistant, or a physician is immediately available on site. A filter meeting F.D.A. requirements shall be incorporated into the intravenous administration set to be used for blood or blood component transfusions.

(e) No medications except physiologic saline for intravenous use shall be added to or mixed with blood for transfusion unless they have been approved for this use by F.D.A. and there is documentation available to show that the addition is safe and does not adversely affect the blood component.

(f) In a health care setting, following comparison of the blood product label with all accompanying information, the person initiating the transfusion shall, at the patient’s side, immediately prior to initiating the transfusion, positively identify the recipient and the blood product to be transfused or infused, using the patient’s name and a unique numerical or alphanumerical identifier. For administration of a blood component, one additional person, who must be a physician, registered nurse, physician assistant, nurse practitioner, licensed practical nurse or board-certified cardiovascular perfusionist (intraoperatively), shall also so identify the recipient and the blood component, unless another procedure to ensure accurate identification is used, in which case a single
identification is sufficient. At least one person identifying the patient and blood component at the patient’s side shall be a physician, registered nurse, physician assistant, nurse practitioner, or board-certified cardiovascular perfusionist (intraoperatively). Each identification procedure shall be documented in writing by each participant. Two persons authorized to initiate blood transfusions shall be immediately available during a blood component transfusion and for 30 minutes afterward, except for transfusion of a patient enrolled in a chronic transfusion program who has no history of adverse reactions. A blood component recipient’s vital signs shall be serially recorded, in accordance with written policies and procedures. If the person recording the vital signs is a licensed practical nurse, all measurements outside of established parameters shall be reported to a registered nurse, physician, physician assistant, or nurse practitioner for assessment and action. Such notification shall be documented.

(g) For transfusions outside a health care setting, including in patient homes, the person initiating the transfusion and monitoring the patient shall be a physician, registered nurse, physician assistant, or nurse practitioner. Following comparison of the blood product label with all accompanying information, this person shall, at the patient’s side, immediately prior to initiating the transfusion, positively identify the recipient and the blood product to be transfused or infused, using the patient’s name and a unique numerical or alphanumerical identifier. Such identification procedure shall be documented in writing. The person administering the transfusion and another competent adult, other than the recipient, shall be immediately available at all times during a transfusion. Both persons shall be available for 30 minutes afterwards, except for transfusions of patients enrolled in a chronic transfusion program who have no history of adverse reactions. The recipient’s vital signs shall be monitored and documented, in accordance with written policies and procedures.

(h) Every facility or limited transfusion service performing transfusions shall provide 24-hour-a-day post-transfusion patient coverage by telephone as necessary.

(i) Each institution, through its transfusion committee, shall develop and implement procedures to encourage the use of autogeneic blood whenever medically indicated. These procedures shall include a mechanism for informing staff physicians of the risks and benefits of autogeneic blood and the options for autogeneic blood transfusion available at the institution. These procedures shall also include a mechanism to encourage physicians to inform their patients of such options whenever medically indicated.

(j) If blood is warmed prior to transfusion, the warming system shall be equipped with a visible thermometer and an alarm to ensure that the blood is not warmed above the temperature specified by the director of the blood bank, in conformance with the system manufacturer’s instructions. Blood warmer temperature shall be monitored and recorded on each day of use, and such records shall be available for inspection for at least five years. Maintenance and operation of blood warmers must conform to the manufacturer’s instructions.
58-2.17 Laboratory tests to be performed prior to allogeneic or autogeneic transfusion.

(a) Tests shall be performed to determine the ABO and Rho (D) groups of each recipient and each unit to be transfused in accordance with procedures approved by the department pursuant to this Subpart. ABO grouping tests shall include both forward and reverse grouping except in the case of hospital transfusion services verifying a blood group determination performed elsewhere, in which case forward grouping alone may be performed. Prior to transfusion, the ABO group of all units of whole blood and red blood cell components, as well as the Rh group of all such units labeled as Rh-negative, shall be confirmed using a sample obtained from an attached segment or using a validated computer system. Any discrepancies shall be reported in writing to the collecting facility and resolved prior to issuance of the blood for transfusion purposes.

(b) All recipient blood shall be tested for unexpected alloantibodies using reagent red blood cells that meet F.D.A. standards, are intended for this purpose and are not pooled. Methods of testing for unexpected alloantibodies shall demonstrate sensitizing and hemolytic antibodies.

(c) Except in cases necessitating emergency release of group-compatible blood or except in the case of transfusion of a volume of blood or blood components exceeding the recipient’s expected normal blood volume in a 24-hour period, compatibility between recipient and donor blood shall be determined. If a clinically significant antibody has been detected, or if there is a history of presence of such an antibody, the compatibility test shall include an antiglobulin phase crossmatch. If no clinically significant antibody has been detected, and there is no known history of presence of such an antibody, the procedure to be used may be determined by the director of transfusion services, but shall, at minimum, consist of an immediate spin test or verification of the blood group of the recipient, and of the blood or blood component to be transfused.

(d) In the case of patients requiring repeated blood transfusions, or those pregnant or transfused with allogeneic red blood cell-containing components within the previous three months, fresh blood specimens shall be drawn for compatibility testing and antibody screening at intervals of not more than three days prior to the day of transfusion, except for neonates, to whom no time limits apply.

(e) The procedure to be used for compatibility testing shall be determined by the blood bank director, but shall, at minimum, consist of an immediate spin, or verification of the blood group of the recipient and of the blood or blood component to be transfused. Antiglobulin phase compatibility testing is required if a clinically significant antibody is detected during the antibody screen or if there is a history of presence of such an antibody. Laboratory procedure manuals shall be revised to reflect any changes in such procedures.

(f) A pre-transfusion sample of recipient blood, including serum or plasma, shall be retained for seven days after each transfusion for further testing in the event of an adverse reaction.
58-2.18 Records to be kept when blood or blood component transfusions are performed. The following information shall be included on the recipient’s chart or in records maintained in the blood bank:

(a) donor’s identification code;
(b) donor’s ABO and Rh groups;
(c) date of the transfusion and quantity of material transfused;
(d) time of starting and time of completing the transfusion;
(e) description of the blood product;
(f) description of any adverse reaction and the results of investigations related to this reaction;
(g) name(s) of the person(s) who performed the transfusion and who attended the recipient during the transfusion; and
(h) in the case of emergency issuance of uncrossmatched blood, the signature of the physician authorizing such emergency release.

58-2.19 Records to be kept when plasma derivatives are infused. The following information shall be included on the recipient’s chart or in records maintained in the blood bank or pharmacy:

(a) product name, lot number, and expiration date;
(b) date of infusion and quantity of material infused; and
(c) description of any adverse reaction and the results of investigations related to this reaction.

58-2.20 Neonatal transfusions.

(a) Transfusions of neonates shall comply with the provisions in this Part governing transfusions in general.

(b) Donor qualifications shall meet the standards required in section 58-2.2 of this Subpart, and donations shall be documented as indicated in section 58-2.11 of this Subpart.
(c) Taking and handling of blood for neonatal transfusions shall meet the requirements established by sections 58-2.4 to 58-2.6 of this Subpart.

(d) Each neonatal transfusion shall require laboratory tests specified in sections 58-2.3 and 58-2.17 of this Subpart. Compatibility tests may utilize serum from the neonate’s mother, provided that donor red cells are of a group expected to be compatible with the serum of both the mother and the child.

(e) Records to be kept when blood is collected and when blood, blood components or derivatives are released for transfusion to neonates shall meet the requirements of section 58-2.11 and 58-2.12 of this Subpart.

58-2.21 Limited transfusion services.

(a) Limited transfusion services shall comply with the provisions in this Part governing transfusions in general.

(b) Limited transfusion services shall have a written agreement with an issuing facility holding a permit in blood services-transfusion. The agreement shall specify the division of responsibilities for assuring conformity with the provisions of this Part. The agreement shall be subject to the prior approval of the department. An inspection may be conducted prior to departmental approval. The agreement must include:

(1) the written approval of the issuing facility's director of transfusion services and the director of the limited transfusion service;

(2) the procedures for transport and storage of blood and means to assure compliance with such procedures;

(3) a description of the transfusion committee of the issuing facility, its responsibilities and composition;

(4) procedures for training of personnel at the limited transfusion service;

(5) requirements for handling adverse reactions, including training of personnel, availability of a physician, 24-hour coverage, and reporting and investigation of such reactions;

(6) procedures for administration of transfusions, including staffing requirements; and

(7) recordkeeping procedures as required in sections 58-2.12, 58-2.18 and 58-2.19 of this Subpart, clearly describing responsibility for maintenance of records and their location.
(c) Transfusions may be performed outside of hospitals only if the patient is cooperative, is able to respond to verbal commands and give informed consent and does not have a history of hemolytic or anaphylactic reactions. The initial transfusion for a given patient shall not be performed in the home setting, and subsequent transfusions may be performed in a patient’s home only if physical limitations or hardships exist which would impede transportation to or transfusion in a hospital or ambulatory care setting.

(d) A qualified licensed physician must supervise personnel administering transfusions by limited transfusion services and must be responsible for ensuring that such personnel have adequate training and experience.

(e) A licensed physician, physician assistant, or nurse practitioner must be immediately available for personal or telephone consultation during the transfusion and for 30 minutes afterward.

(f) Any site at which a transfusion is performed by a limited transfusion service must have available an accessible working telephone to allow communication in case of an adverse reaction. All medications, equipment and supplies necessary for the management of adverse reactions must be immediately available on the premises. Infectious waste disposal must be undertaken using containers and procedures found acceptable by the department pursuant to Part 70 of this Title.

(g) Referral of a patient for out-of-hospital transfusion therapy must be approved by the director of the limited transfusion service or his/her designee. Each such transfusion must be ordered by a licensed physician, physician assistant, or nurse practitioner, and a copy of the order must be provided to both the limited transfusion service and the facility issuing the blood.

58-2.22 Holding facilities. Issuance of a permit to a facility which holds blood for forwarding to a transfusion service, but does not perform any laboratory tests itself, shall be conditional upon filing of the annual statistical report required under Public Health Law, section 3124.

58-2.23 HIV-1 and HIV-2 antibody testing results. No blood bank shall inform any blood or plasma donor or his/her health care provider of the results of HIV-1, HIV-2 or HIV-1/HIV-2 combination antibody screening tests unless such results are negative, with the exception of autogeneic donors, whose health care provider may be informed of screening test results if there is insufficient time prior to surgery for completion of supplemental testing, provided that such health care provider is instructed that the donor may not be informed that he or she is positive for HIV-1 or HIV-2 antibodies based on the incomplete results. Initial reactive screening tests shall be repeated in duplicate. If two of three screening tests are reactive, the sample shall be considered repeatedly reactive, and supplemental testing shall be performed. Notification that a donor is positive shall be made
only if the results have been reactive for more than one screening test, and the supplemental HIV antibody test result has been unequivocally positive. Appropriate counseling of donors regarding the significance of all test results must be available. HIV results must be reported to donors if the results are substantiated as positive, or upon supplemental testing show an increased likelihood of representing seroconversion to positive, as determined by the director of the laboratory performing the supplemental testing. This report must be made in person unless repeated efforts to encourage a donor to come in have failed, in which case notification may be made by certified restricted delivery mail. HIV results that are substantiated as negative, or upon supplemental testing are indeterminate but do not show an increased likelihood of representing seroconversion to positive, as determined by the director of the laboratory performing the supplemental testing, may be reported to donors by mail, provided that such donors are not informed that they are seropositive. Any notification of HIV results to donors who were repeatedly reactive on initial screening tests, regardless of the results of supplemental testing, must include an offer of appropriate counseling.

58-2.24 Disposal of untransfused and expired blood units. Units deemed unsuitable for transfusion, those not transfused for any reason, and those designated for disposal for any reason, shall be disposed of by an appropriate method in accordance with all applicable regulations and requirements. All expired blood components shall be transferred to a separate storage location within 24 hours of expiration. All such components shall be destroyed, discarded, or removed for non-transfusion purposes within 72 hours of expiration, or returned to the collection facility within one week of expiration.

58-2.25 Intraoperative and postoperative blood recovery and normovolemic hemodilution.

(a) Blood recovered intraoperatively or postoperatively from a person or collected for normovolemic hemodilution shall not be transfused into another person.

(b) Methods for intraoperative or postoperative recovery of blood and for normovolemic hemodilution shall be safe and aseptic, and shall ensure accurate identification of all blood collected. The equipment used shall be operated according to the manufacturer’s instructions, shall be pyrogen-free, shall include a filter capable of retaining particles potentially harmful to the recipient, and shall prevent air embolism. If the blood is warmed prior to reinfusion, the warming system shall be equipped with a visible thermometer and an alarm to ensure that the blood is not warmed above the temperature specified in a written protocol, in conformance with the system manufacturer’s instructions.

(c) A complete written protocol for collection and processing of recovered blood and for normovolemic hemodilution, approved by the director of transfusion services, shall be maintained and followed. The protocol shall include criteria for selection of suitable
patients and determination of dosage of ancillary agents used, as well as procedures for prevention and management of adverse reactions.

(d) If recovered blood or blood collected for normovolemic hemodilution is removed from the immediate premises for processing or storage, identification procedures shall be in place to ensure its transfusion into the intended recipient.

(e) If not immediately transfused, recovered blood shall be stored under one of the following conditions:

1. at one to 24 degrees Celsius for up to six hours after initiating the collection; or

2. at one to six degrees Celsius under monitored conditions for up to 24 hours, provided that storage at one to six degrees Celsius is begun within six hours of initiating the collection and the blood is washed under sterile conditions.

(f) Blood collected for normovolemic hemodilution shall be stored under one of the following conditions prior to initiation of transfusion:

1. at one to 24 degrees Celsius for up to eight hours after initiating the collection; or

2. at one to six degrees Celsius under monitored conditions for up to 24 hours, provided storage at one to six degrees Celsius is begun within eight hours of initiating the collection.

(g) Untested recovered blood and blood collected for normovolemic hemodilution which are kept in the blood bank shall be stored in a specially designated area separate from other units and prominently labeled with the patient’s name and a label "Caution: Untested Blood" or similar wording.

(h) Transfusion of blood recovered postoperatively or from post-traumatic patients shall commence within six hours of the initiation of the collection, or if not, the blood shall be discarded.

(i) All records of transfusions of blood recovered intraoperatively or postoperatively shall be available to the department for inspection for at least seven years after each transfusion. Summary records, listing the patient’s name, the medical record number and procedures performed, shall be kept of all such procedures, separate from the patient’s chart.

58-2.26 Exceptions.
(a) When, for indications generally accepted by the medical community, an allogeneic donor who would not otherwise qualify to donate blood or blood components is found to be uniquely suited to meet a given patient's needs, exceptions may be made to the requirements in sections 58-2.2(b) and (c), 58-2.3(a), 58-2.4(c), and 58-2.15(c), (d) and (e) of this Subpart. Such exceptions shall be approved in writing by both the medical director of the blood bank collecting the blood or his/her physician designee, and the director of the transfusion service transfusing the blood or his/her physician designee. If donation under such circumstances presents an increased risk to the donor's health or safety, the donor shall be informed of the risk and must consent in writing to such donation. If the donation presents an increased risk to the recipient's health or safety, the written authorizations of the recipient's health care provider and the recipient or person legally authorized to consent on behalf of the recipient are also required. All such exceptions granted shall be reported to the department annually in a format designated by the department.

(b) Exceptions to the requirements of this Subpart, other than the exception specified in subdivision (a) of this section, may be granted by the department on a case-by-case basis and for a limited time only, if necessitated by a medical emergency or special medical conditions. Persons seeking an exception shall apply to the department as soon as possible and shall describe the nature of the emergency or special medical conditions and the exception requested. All such emergencies or special medical conditions must be documented in the medical record, and any action taken in response which is contrary to the requirements of this Subpart must be approved by the director of transfusion services. If it is not possible to request an exception in advance or if the department has not responded before an action contrary to the requirements of this Subpart had to be taken, the director of transfusion services must report the action taken to the department as soon as possible thereafter but not later than the end of the next business day after the action was taken.

58-2.27 Reinfusion procedures.

(a) All reinfusion procedures shall comply with written protocols approved by the director of transfusion services and the transfusion committee of the facility where the reinfusion is to be performed, the director of the hospital department where the product is reinfused, and the hospital department or facility where processing for the reinfusion procedure is performed, if different. These protocols shall include procedures for collection, labeling, handling, processing and reinfusion of the product.

(b) All reinfusion procedures performed in hospitals shall be reviewed by the hospital transfusion committee. Out-of-hospital reinfusion procedures shall be performed only by a limited reinfusion service which meets the standards in this Subpart and has been approved by the department.

(c) The syringe, tube, bag, or other container into which the blood or component thereof is collected for reinfusion, shall be labeled at the time of collection with
two forms of identification, one of which shall be the patient's name. The person drawing
the blood or component shall initial or sign the records pertaining to the collection and
 certify that the identification on the blood or component and on the pertinent records is
correct.

(d) During shipment, processing and storage, reinfusion products shall be
 maintained at a temperature between one and 38 degrees Celsius, except as otherwise
 required in a protocol approved by the director of the service performing the reinfusion.
Red cell reinfusion products shall not be exposed to a temperature above six degrees
Celsius for more than six hours. While in transit, the container and shipping box for such
products shall be appropriately labeled as containing human blood products.

(e) Any container into which the blood or component is transferred from
another container during reinfusion processing shall be labeled prior to the transfer with
two forms of identification, one of which shall be the patient's name or identification code.
The person performing the transfer shall initial or sign the records pertaining to reinfusion
processing of the blood or component and shall certify that the container identification was
transcribed correctly. All final containers shall be labeled with the patient's name,
description of the contents, expiration date and dosage, if applicable.

(f) All facilities preparing reinfusion products shall hold a valid department
permit in the category of blood services - transfusion. Such facilities shall be open for
inspection by the department during normal business hours and shall allow representatives
of the department access to all protocols and records pertinent to reinfusion procedures
performed in New York State.

(g) No reinfusion of a processed product shall be performed unless two
individuals other than the patient have confirmed the identity of the recipient and the
product to be reinfused as matching in name and in at least one additional identifier. This
confirmation shall be documented in writing.

(h) All errors or accidents during processing or reinfusion procedures, which
may pose a substantial risk to the patient, shall be reported to the department's
Wadsworth Center, with sufficient detail to facilitate evaluation and investigation, within
seven calendar days of the error or accident, or its discovery.

(i) All records pertaining to reinfusion procedures shall be retained for a
minimum of seven years.