

CHAPTER 8

COLLECTION, PROCESSING, STORAGE AND DISTRIBUTION OF BLOOD

Authority

N.J.S.A. 26:1A-7 and 26:2A-7.

SUBCHAPTER 1. GENERAL PROVISIONS

8:8-1.1 Compliance

(a) Persons, known as licensees, for the purpose of this chapter, shall operate blood banks in this State and shall meet the qualifications and conduct blood banks in accordance with N.J.S.A. 26:2A-2 et seq. and all rules in this chapter.

(b) Failure to comply with N.J.S.A. 26:2A-2 et seq. and with this chapter shall be cause for revocation of license and imposition of penalties as prescribed by N.J.S.A. 26:2A-2 et seq.

8:8-1.2 Definitions

For the purpose of this chapter, the terms listed below shall be defined and interpreted as follows:

“AABB Standards” means the “Standards for Blood Banks and Transfusion Services,” 23rd Edition (2004), incorporated herein by reference as amended and supplemented and the “Standards for Cord Blood Cellular Therapy Product Services,” First Edition (2004), incorporated herein by reference as amended and supplemented, both of which publications are published by the American Association of Blood Banks, 8101 Glenbrook Road, Bethesda, MD 20814-2749, (301) 907-6977, www.aabb.org.

“Accident” means a non-preventable occurrence.

“Additive solution system” means blood preservative systems designed primarily for the extended storage of red blood cells. These systems utilize a second preservative solution for red cell storage in addition to the anticoagulant solution necessary for whole blood collection.

“Allogeneic” means the collection of blood or blood components for subsequent transfusion to an individual other than the donor. The term “allogeneic” is also known as homologous.

“Autologous donation/transfusion” means the collection of blood and blood components from a donor/recipient for subsequent reinfusion into the same individual. The term “autologous” is also known as autogeneic.

“Blood bank” means any commercial or noncommercial activity involving the handling of blood or plasma, intended to be used for therapeutic or prophylactic purposes, which participates in any of the

following operations: collection, processing, storage, distribution or administration of blood.

“Blood components” means those preparations that are separated from whole blood and are intended for use as final products for therapeutic purposes, for further manufacturing, or as products used for in vitro testing.

“Broker” means procuring, selling and distributing of blood, blood components or blood products without engaging in processing, alteration or other manipulation of the blood component.

“Center for Biologics Evaluation and Research (CBER)” means the U.S. Food and Drug Administration (FDA), Department of Health and Human Services.

“Clinical practitioner” means a physician currently licensed to practice in New Jersey; an advanced practice nurse currently certified under the New Jersey Advanced Practice Nurse Certification Act; or a physician assistant licensed under the Physician Assistant Licensing Act, acting within the rules governing those professions. Where authorized under this chapter, clinical practitioners shall be permitted to order transfusions and procedures related to the collection or donation of blood and blood products. Advanced practice nurses shall order only according to specific written joint protocols established with the collaborating physician and physician assistants, according to specific protocols established with the supervising physician.

“Closed system” means a system in which the blood container is not entered or air introduced.

“Code of Federal Regulations” means the current Code of Federal Regulations, as amended and supplemented, Title 21, parts 600 through 640.

“Collection” means the procedure for obtaining blood by donor or recipient phlebotomy.

“Commissioner” means the Commissioner of New Jersey State Department of Health and Senior Services or his or her duly authorized agent.

“Crossing over” means the transfusion of a donation of blood and/or blood components, originally collected for autologous transfusion, to a recipient other than the original donor/recipient.

“Cytapheresis” means the procedure in which blood is removed from the donor, certain cellular elements are separated, and the remaining formed elements and residual plasma are returned to the donor.

“Department” means the New Jersey State Department of Health and Senior Services.

“Designated donor” means a donor that is selected by a recipient for transfusion to this recipient at a later date.

“Designee” means an individual designated by the blood bank director and who is qualified by education, training and/or experience to assume the blood bank

director's duties and authority for specific aspects of the blood bank.

“Directed donation” means an allogeneic donation where the blood or blood component is collected from a designated donor.

“Distribution” means the transfer of blood or blood components from one blood bank facility to any other location for processing or storage or for the purpose of providing the blood for therapeutic, prophylactic or in vitro purposes.

“Donor” means and includes any individual from whom blood or components are collected by a blood bank.

“Error” means a preventable occurrence.

“FDA regulations” means 21 C.F.R. Parts 600 through 680, incorporated herein by reference, as amended and supplemented.

“Health system” means a multidivisional hospital with a blood bank and no more than three satellite blood bank facilities.

“Hemapheresis” means the process of separating freshly drawn whole blood into various blood components and products, some of which are retained while the remainder are reinfused into the donor.

“HIV antigen” means the Human Immunodeficiency Virus antigen.

“HIV-1” means the Human Immunodeficiency Virus type 1.

“HIV-2” means the Human Immunodeficiency Virus type 2.

“Industrial manufacturer” means any person engaged in collection and/or procurement of blood and blood components for manufacture or preparation of biological products or reagents.

“Key person” means individuals designated by the blood bank director.

“Licensee” means a person holding a license in accordance with N.J.S.A. 26:2A-2 et seq. and this chapter.

“Mobile unit” means a moveable, transient unit that is used to collect blood and/or blood components from donors not at the blood bank permanent location.

“Person” means a natural person, partnership, association, corporation, institution, agency, or other similar type entity responsible for the operation of a blood bank as defined by N.J.S.A. 26:2A-2 et seq. and this chapter.

“Phlebotomist” means a person who obtains blood from donors by venipuncture.

“Plasmapheresis” means the procedure in which blood is removed from the donor, the plasma is separated

from the formed elements and at least the red blood cells are returned to the donor.

“Preparation” means the method used to manufacture blood and blood components.

“Processing” means all tests and procedures required to prepare and identify the blood and blood products as to their suitability for therapeutic, prophylactic or other in vivo or in vitro purposes.

“Proficiency testing” means the structured evaluation of laboratory methods that assesses the accuracy and reliability of processes, procedures, equipment, supplies and reagents.

“Pyrogen-free” means a system free from any material capable of causing a febrile response.

“Reagent” means a substance used for any in vitro purpose.

“Recipient” means any person who receives a transfusion of whole blood or blood components.

“Satellite blood bank” means a facility, which is part of a health system and does emergency or limited blood banking activities.

“Service” means any of the functions outlined in the Blood Bank License Application form supplied by the Department.

“Significant step” means any step that would be necessary to reconstruct, from the record alone, the procedures performed and who performed them.

“Standard operating procedures (SOP)” means a collection of written individual instructions and policy guidelines with a specific step by step description of how an activity is to be performed.

“Standards of the American Association of Blood Banks” means the current standards, as amended and supplemented, of the American Association of Blood Banks, National Office, 8101 Glenbrook Rd., Bethesda, MD 20814-2749.

“Storage” means the holding of blood or blood components in connection with collection, and/or processing prior to distribution or transfusion.

“System” means the organizational structure, responsibilities, policies, processes, procedures, and resources established by the licensee to achieve the requirements of these rules.

“Therapeutic phlebotomy” means the removal of whole blood from a donor for the purpose of medical treatment.

8:8-1.3 Licensure

(a) Application for an initial license to conduct a blood bank, as required under the provisions of N.J.S.A. 26:2A-2 et seq., commonly known as the Blood Bank Licensing Act and

this chapter, shall be made on forms provided for that purpose by the Department.

(b) A blood bank license shall be obtained whenever any function related to the collection, processing, storage, distribution or the administration of blood and blood components is performed.

(c) A separate blood bank license shall be obtained for each permanent location of a blood bank even if the location is owned and operated by the same licensee. No more than one blood bank license shall be issued for each location. However, a licensed blood bank may permit representatives of another licensed blood bank to provide services within its facility that are within the scope and consistent with the provisions of this chapter provided that the licensed blood bank director has reviewed and approved the SOP for that service.

(d) Renewal of the license shall be on an annual basis on or before November 10th of each year on forms provided for that purpose by the Department.

(e) Amendments to the license shall be as follows:

1. A license renewal shall be obtained 30 days prior to a change in the location or the name of the blood bank.

2. The Department shall be notified in writing, 30 days prior to a change, whenever the ownership, corporate structure, director, and/or services of a blood bank change.

(f) The blood bank shall perform only those services, related to this chapter for which they specifically request and receive licensure. In the case of new services, written approval shall be received from the Department prior to initiating the new service.

(g) Blood and blood components for therapeutic purposes shall only be distributed to a New Jersey licensed blood bank unless a nonsurgical situation exists which could not be anticipated and blood and blood components are necessary on an emergency basis to treat a life-threatening situation as specified in N.J.A.C. 8:8-12.3(c).

(h) Pursuant to N.J.S.A. 26:2A-4, the following blood bank licensure fees shall be effective November 1, 1992:

1. Transfusion Services:

Number of Transfusions	Fee
0-1000	\$200.00
1001-2,000	300.00
2,001-3,000	400.00
3,001-4,000	500.00
4,001-5,000	600.00
5,001-+	700.00

2. Collection Centers:

Number of Collections	Fee
0-200	\$250.00
201-1,500	500.00
1,501-3,000	750.00
3,001-5,000	1,000.00
5,001-10,000	1,250.00
10,001-15,000	1,500.00
15,001-25,000	1,600.00
25,001-35,000	1,700.00
35,001-50,000	1,800.00
50,000-+	1,900.00

3. Other Blood Bank Services:

Type	Fee
Collection Site	\$100.00
Broker	200.00
Industrial Blood Bank	200.00
Home Transfusion Service	200.00

8:8-1.4 Inspection

(a) Blood bank facilities and operations shall be made available for inspection upon request by any authorized representative of the Department during normal working hours.

(b) Reports of inspections of blood banks made by the Center for Biologics Evaluation and Research may be accepted for purposes of approving and issuing renewal of licenses.

8:8-1.5 Proficiency testing

(a) Blood banks shall successfully participate in Department approved proficiency testing surveys.

(b) Records of all proficiency testing results shall be maintained, including results and interpretations.

(c) Proficiency test results shall be periodically reviewed and evaluated by the blood bank director.

(d) Proficiency testing shall be performed in accordance with the proficiency testing requirements specified in N.J.A.C. 8:44.

integral part of the clinical laboratory, this shall be considered one facility.

3. The director shall spend an adequate amount of time in the blood bank to direct and supervise the technical performance of the staff. The director shall be readily available for personal or telephone consultation.

4. The director shall be responsible for the blood bank personnel's in-service training and their adherence to established policies and procedures.

5. If the director is to be absent, the director must arrange for a qualified substitute director.

6. The director may delegate his or her responsibilities for administering the licensed activities of the blood bank to a properly qualified and trained designee. If the director appoints a designee, the director shall be responsible for the proper performance of all the designee's duties and these duties shall be outlined in the SOP.

(c) Qualifications of the blood bank director shall be as follows:

1. The blood bank director shall be a physician licensed to practice medicine in the State of New Jersey. The physician requirement shall be waived for industrial manufacturers and/or brokers.

2. The blood bank director shall have four years of fulltime experience and/or training appropriate to the services provided by the blood bank, as described in (c)3 below. For new and developing procedures performed by the blood bank, the blood bank director shall have at least two years of relevant experience.

3. Appropriate experience shall include, but shall not be limited to:

i. Evaluation of donor suitability;

ii. Donor and recipient testing;

iii. Blood and blood component collection, preparation, storage, processing and distribution; and

iv. Administration of blood and blood components for therapeutic purposes.

8:8-2.3 Blood bank personnel

(a) The blood bank shall have one or more supervisors who under the general direction of the blood bank director supervise all functions related to the collection, processing, testing, storage and distribution of blood and blood components, and in the absence of the blood bank director are responsible for proper performance of these procedures.

(b) General provisions for donor/transfusion related personnel are:

1. Each blood bank during the collection or transfusion of blood shall have a responsible individual

8:8-1.6 Brokers

(a) Brokers shall obtain a blood bank license.

(b) Brokers shall maintain records in accordance with all applicable standards and procedures set forth in this chapter.

8:8-1.7 Waivers

The Department is empowered to waive such of these regulations as may be necessary for purposes of research, experimentation and new methodologies in blood banking activities, provided requests for such activities, are received in writing and approved by the Department prior to initiation of the activity.

8:8-1.8 Public Health Council

The Public Health Council on the advice of the Commissioner may promulgate, enforce and may amend or repeal these regulations that at any given time shall be no less stringent than the complete interim or revised Code of Federal Regulations in effect at that time. In administering the Blood Bank Licensing Act, the Department can seek the advice and recommendations of an advisory committee.

SUBCHAPTER 2. PERSONNEL

8:8-2.1 General

The licensee shall be responsible for obtaining a qualified blood bank director and qualified technical staff.

8:8-2.2 Blood bank director

(a) The blood bank director and the licensee shall be responsible for compliance with N.J.S.A. 26:2A-2 et seq. and the rules set forth in this chapter.

(b) The blood bank director shall administer the licensed activities of the blood bank as follows:

1. The director shall be responsible and shall have authority for all procedures and policies relating to all phases of donor and recipient testing as well as the collection, processing, storage, and distribution of all blood and blood components. Procedures and policies for the administration of blood and blood components shall be established in consultation with the blood bank director.

2. The director shall not individually serve as director or co-director of more than three blood banks, laboratories or one health system. If the blood bank is an

on the premises who, according to N.J.A.C. 8:8-2.3(d), shall be qualified to provide emergency care and in out-of-hospital transfusion situations performs the transfusion.

2. An adequate number of personnel shall be available.

3. Personnel associated with donor or transfusion related functions shall be suitably trained through a formal training program and supervised in the performance of their prescribed tasks. Personnel shall demonstrate their competency to the satisfaction of the director of the blood bank.

(c) The personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components shall be adequate in number, educational background, training and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions and to ensure adherence to this chapter. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the procedures or control operations they perform, the necessary training or experience, and adequate information concerning the application of pertinent provisions of the rules in this chapter as they relate to their respective duties and responsibilities.

(d) Donor or transfusion emergency care personnel qualifications shall be as follows:

1. A physician licensed in the State or a registered nurse (R.N.) holding a current certificate of registration who has fulfilled the following requirements:

i. Has taken an eight hour course in cardiopulmonary resuscitation (CPR) for health care providers and holds a current CPR certification.

(e) A phlebotomist shall be properly trained or supervised for six months and be proficient in the collection of blood from a donor.

(f) The blood bank supervisor shall meet the requirements of N.J.A.C. 8:44 or possess a Specialist in Blood Banking (SBB) with two years experience subsequent to graduation. The two years of experience shall be waived if the individual was a blood bank supervisor prior to obtaining the SBB.

(g) The blood bank shall have a process for identifying the training needs and monitoring the training for personnel who are performing activities which affect the quality of blood and blood components.

(h) The blood bank shall evaluate the competency of personnel at specified intervals.

SUBCHAPTER 3. FACILITIES, EQUIPMENT AND CONTAMINATED MATERIAL

8:8-3.1 Facilities and equipment

(a) Quarters, environment, and equipment shall be provided to maintain safe and acceptable standards for handling of human blood and blood components.

(b) Blood donor facilities shall consist of at least a waiting room, private screening area for donor questioning, bleeding area, donor recovery area, lavatory facilities and the proper equipment for collection and immediate storage of blood.

(c) The blood bank shall also provide a processing laboratory as follows:

1. The laboratory shall have appropriate equipment for donor and/or recipient testing, component preparation, record keeping, storage and distribution of blood and blood components.

2. All laboratory tests required for proper donor blood processing, not performed by the collecting facility, shall be referred to a laboratory or blood bank licensed in New Jersey or hold an applicable Federal certificate or license.

3. The blood bank shall identify all equipment that is critical to the provision of blood and blood components with unique identification and shall provide a schedule to ensure that all critical equipment is monitored and maintained as required by the manufacturer and in accordance with this chapter.

8:8-3.2 Contaminated material

Contaminated material shall be disposed in a manner consistent with the rules of the New Jersey Department of Health and Senior Services and the New Jersey Department of Environmental Protection at N.J.A.C. 7:26-3A.

SUBCHAPTER 4. MANAGEMENT

8:8-4.1 Quality control and quality assurance

(a) All blood banks shall have quality control and quality assurance programs which shall be in compliance with these rules, and shall be sufficiently comprehensive to ensure that blood and blood components, reagents and equipment perform as expected.

(b) The quality control and the quality assurance programs shall include at least the following:

1. Written procedures that include all policies and procedures developed for use;

2. Evidence of validation of methods;

3. Evidence of periodic evaluation of reagents and equipment including the date of performance;

4. Evidence of periodic evaluation of blood and blood components in accordance with, whichever is more stringent, the current Code of Federal Regulations and/or the current Standards of the American Association of Blood Banks;

5. Evidence of periodic evaluation to determine that policies and procedures are appropriate and are followed;

6. Evidence of daily review of computer maintained error correction records by the blood bank director or supervisor.

7. Evidence of appropriate and timely corrective action; and

8. Review by the supervisor or the director;

9. Evidence of self-evaluation of the clinical appropriateness of licensed activities; and

10. Documented evidence of monitoring of the transfusion which shall include:

- i. The type of the component;
- ii. The blood unit identification number;
- iii. The pre-transfusion, 15-minute and post-transfusion vital signs;
- iv. The volume transfused;
- v. The identities of the transfusionist and the reviewing staff; and
- vi. Notation of any suspected transfusion reaction.

(c) The requirements of (b)10iii and iv above shall not apply to blood and blood component transfusions performed in the operating room under emergency situations as that term is defined at N.J.A.C. 8:8-9.4(a).

8:8-4.2 Standard operating procedures

(a) All policies and procedures developed for use in the blood bank and required by this chapter shall be detailed in a manual(s) of SOP.

(b) Each procedure shall have a current pertinent literature reference.

(c) The actual test procedures used shall coincide with the manufacturers' current product insert or written documentation from the manufacturer.

(d) The most current edition of the manufacturer's product inserts shall be available.

(e) The manual(s) of SOP shall be reviewed by the blood bank director annually and this review shall be documented by date and the blood bank director's signature.

(f) All significant changes to procedures shall be reviewed, dated and signed by the blood bank director.

8:8-4.3 Documented review

(a) When blood or blood components are collected and/or prepared, a key individual in the operation of the blood bank shall conduct a documented review prior to the release and final labeling of blood and blood components to ensure that blood from unsuitable donors shall not be distributed for transfusion or further manufacture. If this function is performed by computer, validation of the computer programs,

as outlined in N.J.A.C. 8:8-5.1(e) shall be performed. This review procedure shall be in writing and the procedure shall include tracking of all collected and/or prepared blood and blood components, to assure that:

1. The sequence of the numbers of the blood and blood components drawn are verified and donor numbers for which no donations are available are accounted for;

2. All required testing, as outlined in N.J.A.C. 8:8-7.2, Testing, is performed on all blood and blood components, with specimens drawn from the donor at the time of collection, before release for transfusion. For granulocytes, the specimen may be drawn up to 10 days prior to collection;

3. Blood or blood components with positive or questionable test results are not released for allogeneic transfusions;

4. Blood or blood components collected from donors that shall be deferred are not released for allogeneic transfusion or for further manufacture;

5. If required tests are performed by the blood bank, the testing is performed correctly and properly interpreted as determined by at least the following criteria:

i. Personnel are following the blood bank's established procedures for the test;

ii. Equipment is correctly set-up for test method specific adjustments;

iii. Test results on the machine printout can be traced to the worklist;

iv. Test runs, that are unacceptable by the criteria specified in the manufacturers' product insert, are repeated;

v. Appropriate repeat testing is performed; and

vi. Review of the interpretation of all final test results to assure that the interpretation complies with state requirements, when applicable, or the manufacturers' product insert;

6. If required tests are performed by personnel outside the blood bank, the criteria used to determine a final reactive or nonreactive result coincides with the blood bank's own policy of interpreting results used to discard blood and blood components for transfusion; and

7. That all blood and blood components from donations that have positive or questionable test results are quarantined until their final disposition is determined or they are destroyed.

(b) Final disposition/destruction of records shall be completed at the time of disposition/destruction and documented review shall verify that records accurately reflect that disposition/destruction.

8:8-4.4 Errors and accidents

(a) If an error occurs and any component prepared from a unit improperly tested, not tested, or tested properly but improperly interpreted for ABO or infectious diseases is labeled and released for transfusion, fractionation, reagent production, research or other use, immediate effort shall be made to locate and quarantine all components until satisfactory resolution occurs.

(b) If an accident occurs and any component is released, which is not suitable for transfusion, fractionation, reagent production, research or other use, immediate effort shall be made to locate and destroy all components.

(c) If a whole blood unit or any blood component has been transfused prior to recognition of the error or accident, the medical director of the blood collection facility shall be immediately notified and shall take immediate appropriate action to resolve the problem. If the error or accident has resulted in the transfusion of blood or blood components that could result in infectious disease or other harmful consequences, appropriate medical staff from the collection facility shall notify the patient/recipient's hospital blood bank director who shall document that the patient/recipient's physician is notified of the error or accident and advised that it is his or her responsibility to notify the patient/recipient or his or her representative. Thorough and complete documentation shall be made as to these actions.

SUBCHAPTER 5. RECORDS AND REPORTING REQUIREMENTS

8:8-5.1 Records

(a) Suitable legible records prepared with indelible material shall be maintained for a period of not less than five years. Records needed to trace a unit of blood or blood component from its source to final disposition shall be kept for at least 10 years after transfusion or five years after the latest expiration date for the individual product, but in no case for less than 10 years.

1. The blood bank shall have a policy addressing the confidentiality of donor and recipient records.

(b) All corrections to errors made in the records shall:

1. Not conceal the original entry;
2. Document the reason for the correction; and
3. Include the date the change was made and the initials of the person making the change.

(c) Worklists or loadlists that list the sequence of specimens tested shall be prepared prior to testing.

(d) Workrecords of tests shall be maintained and these records shall indicate final results together with all corresponding instrument readings and calculations. Where instrumentation produces tracings or printouts of results, these tracings or printouts shall be retained in a readily traceable manner and may serve as the workrecord.

(e) If records are maintained on computer systems, the following apply:

1. Prior to use or when modifications are made to the program, validation of all computer programs, including, but not limited to, those dealing with processing, labeling, and distribution of blood and blood components, shall be required as follows:

- i. To determine if software consistently performs as required and within pre-established limits; and
- ii. To include review of confidentiality of donor information, security of data and system documentation.

2. Adequate provisions shall be made to safeguard against the eventuality of unexpected electronic loss of data from the computer storage medium.

3. A system shall be in existence which maintains duplicate records on electronic storage media, updates these duplicates continuously and/or transfers electronically stored data periodically to hard copy such as prints or microfiche.

4. Written procedures shall be available for describing each of the blood bank's methods for performing requirements in (e)1 through 3 above.

5. The computer shall automatically note, at the time of correction, when corrections are made to verified results.

6. The computer record shall maintain the original verified entry, including the date, time and the identity of the person performing the test. When corrections to verified results are made, both the original and corrected entries shall show the date, time and identity of the person performing the original and corrected records.

7. Records maintained on computer shall comply with all requirements of this chapter.

8. The computer shall list donor collection records by the sequential donor numeric or alphanumeric identifier.

(f) The records shall:

1. Include all data secured and developed by blood banks concerning donor and/or recipient testing, donor identification, medical qualifications, registration as well as the processing, storage and distribution and final disposition of blood and blood components;

2. Make it possible to trace a unit of any blood or blood component by a sequential numeric or alphanumeric identifier from source (donor collection facility) to final disposition (for example transfused, shipped, autoclaved);

3. Be readily available for review;

4. Be made available on forms provided by the Department for the purpose of preparing the State's Statistical Summary of Blood Use report annually by January 31, of each year;

5. Include the actual result of each test observed recorded immediately, and the final interpretation recorded upon completion of testing.

6. Include all the significant steps of the process and who performed them; and

7. Include written documentation of any verbal instructions including the identity of all involved individuals.

(g) Before blood is issued for transfusion, test results for each recipient sample shall be compared with the following:

1. Past records of previous ABO and Rh typing results for the past 12 months; and

2. Past records of all patients known to have significant unexpected antibodies; severe adverse reactions to transfusion, and/or difficulty in blood typing.

(h) If computers are used, an alternate method shall be available and used which allows access to the information required in (g) above in the case of computer failure.

(i) Records shall include at least the following:

1. Donor records:

i. An annual record of each unit of blood and blood component, listed by sequential numeric or alphanumeric identifier, as to its source bank and final disposition;

ii. Donor history, examination, consent, deferral, reactions and also the result of required laboratory tests performed on all blood donors;

iii. An annual alphabetical file of donor registration cards or a cross index system;

iv. Blood and component labelling, including initials of person responsible for such labelling;

v. Storage temperatures of components, including dated and initialled temperature recording charts;

vi. Results of visual inspection of blood;

vii. Results of blood processing, including results and interpretation of all tests and retests;

viii. Component preparation, including all relevant dates and times;

ix. Documentation of separation and pooling of recovered plasma;

x. Documentation of units included in pooled products;

xi. Reissue records, including records of proper temperature maintenance; and

xii. A system that relates a donor with each previous donation.

2. Recipient records shall include:

i. An alphabetical file of the recipient and all units administered;

ii. Each recipient's ABO and Rh type available for immediate reference for at least the past 12 months;

iii. Patients known to have significant unexpected antibodies, adverse reactions to transfusion and/or difficulty in blood grouping and typing available for immediate reference for at least the past five years;

iv. Transfusion request records;

v. Test results, interpretations and release or issue date for compatibility testing;

vi. Emergency release of blood including written or validated electronic signature of the requesting physician and the type of blood and/or blood component.

3. List of therapeutic bleedings, including signed request by physician, donor's disease and disposition of units;

4. Detailed procedure manual including all policies and procedures developed for use in the blood bank and required by this chapter;

5. Evidence of annual review of the procedure manual by the blood bank director;

6. A data sheet for each cytopheresis procedure and the following information recorded: volume of blood processed; anticoagulants given; duration of procedure; volume of product; drugs given; identity of the donor; any reactions that occurred and how they were treated and any other information necessary to ensure the proper preparation of the component and the safety of the donor.

7. Quality control and quality assurance records, including, but not limited to: periodic evaluation of personnel, blood and blood components, reagents, equipment, including dates of performance; tests performed; observed results; interpretations; identification of personnel performing the tests; any appropriate corrective action taken; and review by the supervisor and/or director.

8. Antibody identification records;

9. Reports of adverse reactions and laboratory investigations of suspected transfusion reactions;

10. Lot numbers of supplies and reagents.

11. A method to identify persons performing each significant step in collecting, processing, compatibility testing and distributing blood or blood components; and

12. Shipping records from the blood distributor with written documentation that indicates that, at the time of blood and blood component receipt, components listed on the shipping record were verified as received.

8:8-5.2 Reporting requirements

(a) Blood banks shall report transfusion reactions to the Department as follows:

1. Hemolytic and/or delayed hemolytic and other known or suspected life-threatening transfusion reactions within 10 days of the occurrence, using the form at chapter Appendix A, incorporated herein by reference; and

2. Known and/or suspected fatal transfusion reactions by telephone call to (609) 292-0522 by the next working day after the day the event occurs, with written follow-up within 10 days of the occurrence, using the form at chapter Appendix A, incorporated herein by reference.

(b) Blood banks shall report in writing to the Blood Bank Program, Clinical Laboratory Improvement Service, of the Department, at PO Box 361, Trenton, NJ 08625-0361, known and/or presumed cases of HIV infection and/or AIDS associated with a transfusion within 10 days of the date on which the case is brought to the attention of the blood bank.

(c) Blood banks shall report prospective donors testing positive for hepatitis B, hepatitis C, syphilis and infectious diseases that are reportable pursuant to N.J.A.C. 8:57-1 to the Communicable Disease Service of the Department or the local health agency in accordance with N.J.A.C. 8:57-1.

(d) Blood banks shall report prospective donors testing positive for HIV-1 and/or HIV-2 to the Division of HIV/AIDS Services of the Department in accordance with N.J.A.C. 8:57-2.

(e) Blood banks shall report to the Department the occurrence of errors and accidents described at N.J.A.C. 8:8-4.4 within 15 working days of the recognition of the error, using the form at chapter Appendix B, incorporated herein by reference.

(f) Blood banks shall report to the Department the occurrence of errors and accidents that result in the wrong blood or blood component being transfused that results in no harm to the recipient within 15 working days of the recognition of the error, using the form at chapter Appendix B, incorporated herein by reference.

(g) Appendices A and B are available on request from the Blood Bank Program of the Clinical Laboratory Improvement Service of the Department and are available for download from the Department's forms page at <http://nj.gov/health/forms>.

8:8-5.3 (Reserved)

8:8-5.4 (Reserved)

8:8-5.5 (Reserved)

SUBCHAPTER 6. CRITERIA FOR DONOR SELECTION

8:8-6.1 Donor identification

(a) Blood donors shall be identified by an identification card or another form of authorized identification.

(b) The type of identification used shall be written on the donor registration card at the time of each blood donation.

8:8-6.2 Medical history; physical examinations; bleeding limitations

Medical history, physical examinations, and bleeding limitations of the donor shall be consistent with, whichever is more stringent, the most recent Code of Federal Regulations or the most recent Standards of the American Association of Blood Banks. If necessary, these documents may be reviewed at the Department of Health and Senior Services, Clinical Laboratory Improvement Services, Health and Agriculture Building, Room 401, Trenton, New Jersey 08625-0361. In addition, for emerging issues, the most recent FDA guidelines shall be followed. These documents are available at www.fda.gov/cber/guidelines.htm.

8:8-6.3 Donor selection; deferral records; deferral notice to donor

(a) Blood bank personnel trained to conduct donor eligibility screening in accordance with AABB Standards, the Code of Federal Regulations, and the blood bank's policies and procedures shall evaluate each prospective donor's history on the day of donation to ensure that the prospective donor meets the criteria for blood donation contained in the AABB Standards and the Code of Federal Regulations, and shall defer any person who does not meet these criteria.

(b) Blood banks shall adhere to the Code of Federal Regulations in the maintenance of records with respect to the temporary and permanent deferral of persons from donating blood.

(c) If, as a result of laboratory testing of donated blood, a blood bank determines that a donor meets criteria for permanent deferral, the blood bank shall transmit written notice to the donor informing the donor that he or she is permanently deferred and cannot donate blood for allogeneic use and that the blood bank will maintain his or her name in the blood bank's record of persons permanently deferred from donating blood.

8:8-6.4 Information provided to the donor

(a) Consent shall be obtained in writing from the prospective donor after the procedure has been explained in terms the donor can understand and after the donor has had an opportunity to ask questions and refuse consent. Consent shall include information on significant risks of the procedure and tests performed to reduce the risks of infectious disease to the recipient.

(b) The donor must be instructed in post phlebotomy care and cautioned as to possible adverse reactions.

(c) The blood bank director shall be responsible for a mechanism for notifying the donors of the cause of rejection.

8:8-6.5 AIDS screening requirements

(a) All blood and blood components collected in New Jersey are subject to the requirements of this section.

(b) Educational material shall be given to the blood donors prior to the collection of blood which will allow donors to determine whether or not they have engaged in high risk behavior.

(c) All donors including those utilized in hemapheresis, shall be screened by history for the early signs and symptoms of AIDS.

(d) The collecting agency shall ensure that all blood and blood components collected in New Jersey, including those obtained by hemapheresis, be tested for HIV-1 and HIV-2 as specified in N.J.A.C. 8:8-7.2. Laboratory tests not performed by the collecting facility shall be referred to a blood bank or laboratory licensed to perform HIV testing by the Department as specified in N.J.A.C. 8:8-3.1(c)2. It shall be the responsibility of the receiving blood bank to assure that any blood brought in from out-of-state sources shall be tested for HIV types 1 and 2 in accordance with testing methods specified in AABB Standards and FDA regulations. If the blood is used for allogeneic transfusion, it shall be tested as all other blood and blood components.

(e) Blood and blood components that are positive, as defined by Centers for Disease Control (CDC) in the "Morbidity and Mortality Weekly Report" of August 14, 1987, in "Laboratory Evidence for or Against HIV Infection," as amended and supplemented, incorporated herein by reference, to serologic tests for HIV types 1 and 2 or collected from a donor known to be positive to serologic tests for HIV types 1 and 2 shall either be discarded or used for research purposes only.

(f) Prior to a donation of blood or blood component each donor shall be notified in writing and shall have signed a written statement confirming that:

1. The blood or blood components shall be tested for evidence of the probable causative agent of acquired immune deficiency syndrome.

2. Donors found to have serologic evidence of HIV shall be placed on a confidential internal deferral list and may, if deemed appropriate by the Department, a confidential statewide deferral list.

3. The donor shall be notified of the test results in accordance with requirements described in (i) below.

4. Blood or blood components shall not be donated for transfusion purposes by a person if the person has reason to believe that he or she has engaged in high risk behavior.

(g) All blood banks shall notify the donor of results when there is serologic evidence of the probable causative agent of AIDS as currently outlined by the Department.

(h) Reactive donors shall be notified and counseled in person. Every effort shall be made to accomplish face to face notification and counseling.

(i) Blood banks shall maintain records pertaining to all HIV requirements and test results. These records shall be kept in a confidential manner.

(j) Testing facilities shall participate in a proficiency program acceptable to the Department.

SUBCHAPTER 7. BLOOD AND BLOOD COMPONENTS

8:8-7.1 General criteria

(a) The procedure for the collection, processing, storage, and distribution of blood and blood components shall meet the requirements of this chapter.

(b) Blood banks shall establish criteria for collection, processing, storage, and distribution, according to current standards, acceptable to the Department.

(c) Sale or exchange of blood and/or blood products positive for HIV and/or HBsAg shall not be made without the express permission, in writing, of the Department.

(d) Blood banks distributing blood and blood components shall:

1. Have available an information circular with each product explaining its proper indications and usage (thawing, dosage, stability, side effects, adverse reactions, hazards, etc.);
2. Provide accurate expiration dates and hours on the container label for all blood and blood components; and
3. Meet licensed expiration dates for the product.

(e) The preparation and processing of all blood and blood components shall be consistent with, whichever is more stringent, the Code of Federal Regulations, as amended or supplemented, or the Standards of American Association of Blood Banks, as amended or supplemented. If necessary, these documents may be reviewed at the Department of Health and Senior Services, Clinical Laboratory Improvement Services, Health and Agriculture Building, Room 401, Trenton, New Jersey 08625-0361.

8:8-7.2 Testing

(a) All laboratory tests shall be made on specimens of blood taken from the donor at the time of phlebotomy in properly identified tubes. For granulocytes, the specimen may be drawn 10 days prior to collection.

(b) When available, FDA licensed reagents shall be used for screening tests.

(c) Required infectious disease testing includes a serologic test for syphilis (STS), Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C Virus (HCV), HCV RNA, Hepatitis B Core Antibody (HBcAb), antibody to Human Immunodeficiency Virus Type I (HIV-1), HIV-1 RNA, antibody to Human Immunodeficiency Virus Type 2 (HIV-2)

and antibody to Human T-Lymphotropic viruses I/II (HTLV I/II).

(d) Testing shall be performed as required in N.J.A.C. 8:8-7.2 and shall adhere to FDA regulations.

(e) The blood or blood components shall not be used for therapeutic purposes unless results of test(s) are clearly negative except where delay occasioned by testing may result in serious threat to the health and well-being of the recipient.

(f) In instances where untested units are transfused, the attending physician shall attest in writing to the existence of an emergency and if the test is subsequently positive, the recipient's physician shall be notified.

(g) Determination of ABO group shall be as follows:

1. Each container of blood shall be properly identified and labeled as to its blood group.

2. The ABO group of each blood donation shall be determined by testing the red cells of the donor using known Anti-A and Anti-B reagents, and by testing the serum or plasma for expected antibodies using known A₁ and B red blood cells. The two methods of testing shall be recorded and be in complete agreement before any label or release can be effected for the unit of blood.

3. All Anti-A and Anti-B reagents shall meet the Code of Federal Regulations minimum requirements, and the procedures used shall follow the manufacturer's directions.

4. Previous records of ABO group shall not serve as identification of units subsequently given by the same donor. New determinations shall be made for each collection.

(h) Determination of Rh type shall be as follows:

1. The Rh type of each container of donor blood shall be determined with Anti-D reagent.

2. If the blood is Rh negative, it shall be tested using a technique designed to detect weak D.

3. Only reagents meeting the Code of Federal Regulations minimum requirements for the products shall be used and the technique of typing shall be that recommended by the manufacturer.

(i) Determination of antibodies shall be as follows:

1. Each container of blood shall be tested for unexpected antibodies using a screening cell suspension which meets the Code of Federal Regulations minimum requirements.

2. The techniques employed shall be those which shall detect clinically significant antibodies and shall include the anti human globulin test.

3. Blood in which antibodies are found shall be used in a manner not detrimental to the recipient.

(j) Repeat testing: The facility at which the transfusion is administered shall confirm the ABO group, on a sample

obtained from the integral attached segment, of all units of whole blood and red blood cells, and the Rh type of all Rh negative units of whole blood and red blood cells.

(k) Performance of any additional testing for product quality and patient safety is permitted under this chapter. This testing shall comply with all applicable requirements of this chapter.

8:8-7.3 (Reserved)

8:8-7.4 (Reserved)

8:8-7.5 (Reserved)

8:8-7.6 (Reserved)

8:8-7.7 (Reserved)

8:8-7.8 (Reserved)

8:8-7.9 (Reserved)

8:8-7.10 (Reserved)

8:8-7.11 (Reserved)

8:8-7.12 (Reserved)

8:8-7.13 (Reserved)

8:8-7.14 (Reserved)

SUBCHAPTER 8. COLLECTION OF BLOOD

8:8-8.1 General criteria

(a) Blood banks wishing to employ the techniques set forth in this subchapter shall file their protocol and a request in writing to the Department, prior to initiation of this service.

(b) The techniques set forth in this subchapter can be employed upon receipt of written approval from the Department.

8:8-8.2 Donor's emergency care

(a) Blood shall be drawn from donors only when a physician or donor emergency care personnel are available on the premises.

(b) The blood bank director may determine on a case-by-case basis with each blood collection drive, as a means to increase the availability of the State's blood supply, that a particular blood collection drive is exempt from the emergency care personnel requirement in (a) above, so long as prior to making that determination the blood bank has made a reasonable effort, in the manner specified in the blood bank's standard operating procedures which are required under (c) 1 below, to schedule a physician or nurse for that blood drive

and has determined that one is not available and so long as the conditions set forth in (c) below are met.

(c) Each of the following conditions shall be met in order for the blood bank director to authorize an exemption under (b) above:

1. The blood bank shall draft a standard operating procedure outlining the requirements for granting an exemption from the emergency care personnel requirement in (a) above;
2. The blood bank director shall conduct the blood collection drive in accordance with the blood bank's standard operating procedure;
3. Alternative emergency care personnel shall be present at the site of the blood collection drive who meet training, education and experience requirements established by the blood bank director and who, at a minimum, possess current CPR and standard first aid certifications, and have readily available either land line or cell phone communications to immediately call 9-1-1 for assistance in the event of a medical emergency;
4. The blood bank shall maintain accurate records documenting all occurrences when the blood bank director has authorized an exemption under (b) above, including the date and location of the blood collection drive, the name and signature of the blood bank director who authorized the exemption and the rationale for the blood bank director's determination that the blood collection drive is exempt from the emergency care personnel requirement in (a) above; and
5. Notwithstanding any of the provisions of this chapter to the contrary, the blood bank director shall not grant an exemption under (b) above under any of the following circumstances:
 - i. When blood is to be collected from a group predominantly made up of high school aged students; or
 - ii. When blood is to be collected for the express purpose of autologous collection or maternal/fetal collection that is not conducted in a general hospital.

(d) The Commissioner or his or her designee may, on his or her own initiative, in accordance with the purposes and intent of this chapter, temporarily waive, for a period not to exceed 30 days, the emergency care personnel requirement in (a) above, when the Commissioner or his or her designee has determined that an emergent condition exists and that strict compliance with the emergency care personnel requirement in (a) above would prevent, hinder, or delay necessary action by the State to address the emergent condition, and would increase the health threat to the population.

(e) The Commissioner or his or her designee may renew a waiver established in accordance with (d) above, provided he or she applies the same standard when making the determination to renew the waiver as is applied to the initial waiver determination under (d) above, namely, that an emergent condition exists and that strict compliance with the emergency care personnel requirement in (a) above would prevent, hinder, or delay necessary action by the State to address the emergent condition, and would increase the health threat to the population.

(f) During every blood collection drive, conspicuously displayed at the donor registration desk shall be a sign, placard or other type of signage informing the donors of the name and qualifications (e.g. licenses, certifications, and/or training) of the emergency care personnel on duty and on site at the time of the blood collection drive.

(g) The qualifications of donor emergency care personnel and the procedures for implementation of donor selection and donor care standards shall be approved by the Department.

(h) This rule shall not waive the requirements for physicians' attendance at a location where plasmapheresis is being performed in an opened system.

(i) If home transfusions are performed, a second responsible person shall be available on the premises to help with emergency situations.

(j) Subsections (b) through (f) above shall not be effective after February 1, 2011.

8:8-8.3 Medical contingency plan

(a) Each location for collection or the transfusion of blood and blood components shall have a current medical contingency plan specific for that location which shall include:

1. Immediate access to an identified land line telephone for notification of 9-1-1 or other emergency care services; and

2. A detailed SOP developed by the blood bank director outlining the circumstances under which 9-1-1 or other emergency care services shall be immediately notified.

(b) A copy of the Medical contingency plan for each location shall be maintained on file on the premises of each licensed blood bank for a period of not less than five years.

8:8-8.4 Donor protection

(a) Preparation of the donor's skin for phlebotomy shall be adequate to afford protection from infection to the donor and to the future recipient.

(b) All equipment used in the collection of blood, such as syringes, needles, lancets or other blood letting devices, capable of transmitting infection to donor or recipient, shall be sterile and pyrogen free.

(c) Disposable thermometers or other temperature checking device maintained in a sanitary manner shall be used.

(d) All personnel concerned with the collection of blood shall be instructed in appropriate first aid procedures in the event of donor reaction.

(e) Suitable drugs, supplies and instructions for use shall be immediately available at all times.

8:8-8.5 Method of blood and blood component collection

(a) Immediately prior to collection of the blood or blood component, a unique sequential numeric or alphanumeric identification shall be placed on all material related to that donation, such as the blood component label, the donor medical history record and pilot tubes. This number shall identify all material related to the particular blood donation.

(b) The method employed for the removal of blood from the donor shall conform to accepted standards of asepsis.

(c) Blood containers and donor sets shall be sterile and pyrogen-free.

(d) A closed system shall be used except for blood cell separation instruments that use an open system.

(e) If more than one venipuncture is needed, another set and container shall be used.

(f) The container into which the blood is collected at one venipuncture shall be the final container.

(g) During bleeding, the anticoagulant solution and the blood shall be thoroughly mixed.

(h) The outside of the container shall be kept clean.

(i) Immediately after bleeding, the blood shall be placed in temporary storage having sufficient refrigeration capacity to cool the blood continuously toward a range between one to six degrees Centigrade unless platelets are to be harvested.

(j) The volume of blood collected from the donor shall be in accordance with FDA regulations and AABB Standards.

8:8-8.6 Pilot samples

(a) At the time of collection, the integral donor tubing shall be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent tests for serologic compatibility.

(b) The integral donor tubing segments shall be separable from the container without breaking the sterility of the container.

(c) At the time of collection, additional blood may be collected for laboratory tests provided containers are properly labeled before or at the time of collection, accompany the blood container, and are re-identified with the blood container immediately after filling.

8:8-8.7 Blood containers

(a) Containers for whole blood and blood components used by licensed establishments, shall be identified by recording the manufacturer's lot numbers and shall be sterile and pyrogen-free.

(b) The containers shall be sufficiently colorless and transparent to permit visual inspection of blood.

(c) The blood containers shall be provided with closures which maintain a hermetic seal and prevent contamination of the contents.

(d) The container and the closure shall not interact with the contents under customary conditions of storage and use.

(e) The anticoagulant solution and additive solution systems shall be sterile, pyrogen-free in the amount prescribed for the volume of blood collected, and prepared according to the Code of Federal Regulations.

8:8-8.8 Labeling

(a) Labeling shall be consistent with the most recent Code of Federal Regulations.

(b) Blood and blood components shall be labelled to include conspicuous notation of incomplete testing and when applicable positive or abnormal test results.

(c) Untested autologous blood collected from a donor/recipient, who has been tested in the last 30 days, shall not be labeled according to standards for uniform labeling of allogeneic blood. It shall be labeled as follows:

1. With a statement that the blood was collected from a donor known to be tested for FDA-required tests; and
2. The date that the donor recipient was tested.

8:8-8.9 Sterility testing

(a) Sterility testing shall be performed at regular intervals and not less than once monthly, where blood is collected or prepared in an open system. Such tests shall not be done on blood intended for transfusion.

(b) Culture techniques shall be in accordance with the most recent Code of Federal Regulations.

(c) Permanent records of sterility tests, with evidence that the tests have been performed according to the most recent Code of Federal Regulations, and the results shall be kept.

8:8-8.10 Autologous collection/transfusion

(a) Blood banks wishing to employ the techniques set forth in this section shall file their protocol and a request in writing to the Department, prior to initiation of the service.

(b) The techniques set forth in this section can be employed upon receipt of written approval from the Department.

(c) Autologous collection/transfusion shall be done only at the written request of the physician or clinical practitioner, whichever is more consistent with the AABB Standards. A telephone request shall be followed by written confirmation within seven calendar days.

(d) Testing and labelling requirements for autologous donations shall be consistent with, whichever is more stringent, this chapter or the Code of Federal Regulations.

(e) Donor processing for autologous transfusion shall be as follows:

1. Donor qualifications for autologous transfusion may vary from standard donor criteria but this entire procedure shall be arranged by consultation between the blood bank director and the donor-patient's physician or clinical practitioner, whichever is more consistent with the AABB Standards.

2. If the patient-donor and/or donated unit do not meet the criteria for donor selection listed in this Chapter to protect the recipient, the unit shall be labeled "For Autologous Use Only", segregated, and used solely for this purpose.

3. "Crossing over" shall not be allowed.

4. Blood and blood components that test positive or abnormal and are transfused to the donor/recipient shall be labelled with a Biohazard label.

(f) Criteria for donation shall be as follows:

1. Volume of blood shall comply with the Code of Federal Regulations.

2. There are no age limits for autologous transfusion procedures.

3. The hemoglobin concentration of patient-donor shall be no less than 11 gms. per dl. The packed cell volume, if substituted, shall be no less than 33 percent.

4. Frequency of phlebotomy for autologous transfusion shall be determined by competent medical decision but blood shall not be collected from the patient within 72 hours of the anticipated procedure.

5. Phlebotomy concurrent with transfusion of previously collected autologous units shall not be undertaken more frequently than once every three days.

(g) Pretransfusion testing of blood and blood components for autologous transfusion shall be subject to the following:

1. ABO group shall be determined by the collection facility. If the transfusion facility is different from the collecting facility, the ABO group shall be confirmed.

2. Other factors tested for routine transfusion are optional.

3. Compatibility testing is optional.

(h) If "Autologous Use Only" blood is drawn, all satellite bags shall be labeled "Autologous Use Only" immediately prior to or at the time of the collection.

(i) Crossmatched autologous units that are tested can be stored on the same shelf with the crossmatched allogeneic and/or directed units for the same recipient.

8:8-8.11 Directed donation

(a) Blood banks wishing to employ the techniques set forth in this section shall file their protocol and a request in writing to the Department, prior to initiating the procedure.

(b) Such techniques can not be employed until written approval is received from the Department.

(c) All requirements of this chapter related to allogeneic donations shall be followed.

(d) Directed donations shall be initiated only at the written request of the intended recipient's clinical practitioner or a transfusion facility. A telephone request shall be followed by written confirmation within seven calendar days.

8:8-8.12 Perioperative autologous blood collection and administration

(a) Facilities that perform perioperative autologous blood collection and administration shall obtain a blood bank license to operate in New Jersey.

(b) Facilities shall submit SOP to the Department and receive written approval prior to initiation of the service.

(c) Standards of the American Association of Blood Banks related to perioperative procedures, as amended or supplemented, shall be followed when performing perioperative autologous transfusion procedures.

8:8-8.13 Therapeutic phlebotomy

(a) Any person who performs a therapeutic phlebotomy shall obtain a blood bank license before offering the service.

(b) Therapeutic phlebotomy shall be done only at the written request of the patient's physician or clinical practitioner, whichever is more consistent with AABB Standards.

(c) There shall be a written procedure describing the technique used.

(d) Records shall be maintained which include patient identification, diagnosis, therapeutic procedure, volume of plasma and cells removed, volume replaced, nature of the replacement fluids, any adverse actions, and a record of the administered medications.

(e) Informed consent of the patient shall be obtained.

(f) There shall be provisions for the management of reactions.

(g) If therapeutic phlebotomy procedures and recordkeeping are not entirely performed by blood bank personnel, there shall be a written agreement that specifies the division of responsibilities for assuring compliance with this chapter.

(h) Any blood or blood component withdrawn from a patient for therapeutic purposes shall be clearly indicated as such on the blood label.

(i) Blood or blood components obtained from therapeutic phlebotomy may be used for allogeneic transfusion using the following criteria:

1. Waiver approval from the FDA shall be received and the approved procedures and protocols shall be followed;
2. It shall be performed at no expense to the donor;
3. The donor diagnosis shall be hereditary hemochromatosis; and
4. The donor shall meet all the allogeneic donation criteria except for donation interval and hematocrit.

8:8-8.14 Plasmapheresis

(a) Facilities that perform plasmapheresis procedures shall obtain a blood bank license before offering the service.

(b) Facilities shall submit SOP to the Department and receive written approval prior to initiation of the service.

(c) The procedures used shall include as a minimum the following requirements:

1. Within one week prior to the first plasmapheresis, the donor shall be examined and certified to be in good health by a clinical practitioner.
2. A licensed physician on the premises shall supervise the performance of manual plasmapheresis collection. This requirement shall not be applicable to automated plasmapheresis collection which meets the following conditions:
 - i. N.J.A.C. 8:8-8.2, Donor's emergency care, shall be strictly followed;
 - ii. Donor emergency care personnel, as required under N.J.A.C. 8:8-2.3(d), shall be on the premises; and
 - iii. A contingency plan to assure that a physician is available for emergency purposes during the procedure shall be in use. The physician response time shall be no longer than 15 minutes.
3. Prior to each procedure, records shall be made and maintained of the major pertinent elements of each donor's physical condition and shall also include a determination of the donor's total protein.
4. A donor shall not serve as a source of plasma unless his or her total protein is within normal limits.
5. Quality control records of the total protein determinations shall be maintained.
6. If a second plasmapheresis is to be performed within 30 days of the first procedure, laboratory tests shall be done on samples of the donor's serum to determine that the protein level and ratio of the various

protein components, as shown by electrophoresis, fall within normal limits.

7. A donor shall not serve as a source of plasma while there is any significant change in his health, or in the values of these initial determinations.

8. Periodic determinations shall be made as frequently as necessary and at least every four months to monitor these evaluations.

9. The amount of plasma withdrawn shall be consistent with the current Code of Federal Regulations.

10. A plasmapheresis donor may donate a unit of whole blood if 48 hours have lapsed since the last plasmapheresis, but at least eight weeks shall elapse after a regular whole blood donation before starting a donor in a plasmapheresis program.

11. Plasmapheresis donors shall, on each occasion of plasmapheresis satisfy all requirements of whole blood donors outlined in N.J.A.C. 8:8-6, Criteria for Donor Selection.

(d) Plasmapheresis shall be performed in accordance with AABB standards.

8:8-8.15 Cytapheresis

(a) Facilities that perform cytapheresis procedures shall obtain a blood bank license before offering the service.

(b) Facilities shall submit SOP to the Department and receive written approval prior to initiation of the service.

(c) A licensed physician on the premises shall supervise the performance of manual cytapheresis collection. This requirement shall not be applicable to automated cytapheresis collection which meets the following conditions:

1. N.J.A.C. 8:8-8.2, Donor's emergency care, shall be strictly followed;
2. Donor emergency care personnel, as required under N.J.A.C. 8:8-2.3(d), shall be on the premises; and
3. A contingency plan to assure that a physician is available for emergency purposes during the procedure shall be in use. The physician response time shall be no longer than 15 minutes.

(d) The interval between procedures shall be at least 48 hours, and the amount of plasma collected shall not exceed the amount cleared by the FDA for the device.

(e) If a cytapheresis donor donates a unit of whole blood, at least eight weeks shall elapse before a subsequent cytapheresis procedure unless the extracorporeal red cell volume of the apheresis machine does not exceed 100 ml.

(f) If it becomes technically impossible to return the donor's red blood cells during apheresis, at least eight weeks shall elapse before a subsequent apheresis procedure, unless the red cell loss was less than 200 ml.

(g) The blood bank or transfusion service shall ensure that donor red cell losses during any eight-week period, as

well as the preceding 12 months, do not exceed the loss of red cells permitted for whole blood collections.

(h) Donors may receive drugs before or during leukapheresis.

1. Such drugs shall not be used for donors whose medical history suggests that they may exacerbate previous intercurrent disease.

2. The blood bank director is responsible for setting appropriate written guidelines in such circumstances.

(i) For a two-unit red cell collection, the volume of red cells removed from apheresis donors shall not exceed a volume predicted to result in donor hematocrit of less than 30 percent or hemoglobin of less than 10 grams per deciliter (g/dL) after volume replacement, and no additional collections shall be performed in the following 16 weeks.

(j) In the case of multiple concurrent apheresis collections, the volume limits of red cells and plasma removed from the donor shall follow the FDA-cleared device criteria.

8:8-8.16 Immunized donor

(a) If specific immunization of a donor is to be performed, the selection and scheduling of the injection of the antigen, and the evaluation of each donor's clinical response, shall be by a qualified physician.

(b) Any material used for immunization shall be either a product licensed under Section 351 of the Public Health Service Act for such purpose or one specifically approved by the Director, Center for Biologics Evaluation and Research.

(c) Immunization procedures shall be on file at each plasmapheresis center where immunizations are performed.

(d) Each donor to be immunized shall be instructed regarding possible hazards associated with use of his blood at other blood banks and each shall agree that he will not donate blood elsewhere without first divulging his immunization status.

(e) Informed consent of the donor shall be obtained.

SUBCHAPTER 9. RECIPIENT BLOOD TESTING

8:8-9.1 General provisions

(a) The requirements in this section must apply to both hospital and out-of-hospital transfusion of blood for therapeutic purposes.

(b) Forms and request for blood and blood components and forms accompanying recipient blood samples shall have sufficient information for the positive identification of the recipient.

(c) The recipient's full name, as it appears on the identification band, and a traceable identification number are

required. If more than one identification number is needed to establish the positive identification of the recipient, all the numbers shall be documented on all blood bank documents used for recipient testing.

(d) Incomplete or illegible forms shall not be accepted.

(e) The intended recipient and the blood sample shall be identified at the time of collection by a mechanism which positively identifies the recipient. Use of an armband is considered the method of preference. The Department shall approve any other method prior to use.

(f) The sample for compatibility testing shall be:

1. Identified by a label firmly attached to the sample before leaving the side of the recipient;

2. Labeled at the time of the collection with at least the recipient's full name, as it appears on the identification band, traceable identification number, the identity of the person drawing the sample and the date the sample was drawn;

3. Obtained within three days of the scheduled transfusion when the recipient has been transfused or pregnant in the preceding three months or this information is not known;

4. Examined by a qualified person, before a specimen is used for typing or compatibility testing, to confirm that all information on the request form is in agreement with that on the specimen label. In the case of a discrepancy or doubt, another specimen shall be obtained and used for these procedures; and

5. Labeled so that if it is necessary for the blood bank to affix a second label, the second label could be peeled off so that personnel performing the compatibility testing can verify that the information on the original and secondary labels match. The second label shall be affixed in a manner that it does not obscure the full name of the recipient and the traceable identification number.

(g) Testing of the recipient's blood shall include at least the following:

1. Determination of ABO group:

i. ABO grouping shall be performed on each sample of recipient blood as in N.J.A.C. 8:8-7.2(g).

ii. For neonates, only anti-A and Anti-B reagents are required.

2. Rh typing:

i. Anti-D reagent shall be used to determine whether the recipient shall receive Rh positive or Rh negative blood.

ii. The test for weak D is unnecessary when testing recipient red cells.

iii. To avoid incorrect designation of an Rh negative recipient as Rh positive, a control system appropriate to the Anti-D reagent in use is required.

3. Detection of unexpected antibodies:

- i. Each blood sample submitted with a request for potential transfusion shall be tested prior to, or concurrently with, the performance of compatibility testing.
- ii. Methods for testing for unexpected antibodies shall be those which demonstrate clinically significant antibodies and shall include an antiglobulin test.

4. Compatibility testing:

- i. Compatibility testing requirements shall be consistent with the most recent Code of Federal Regulations and shall include a method to verify the ABO group of the donor unit and the recipient.
- ii. For compatibility testing, the sample used shall be from an originally attached Whole Blood or Red Blood Cell component segment.
- iii. If a computer system is used to detect ABO incompatibility, the following requirements shall be met:

(1) On-site validation of the computer to ensure that only ABO compatible whole blood and red blood cells components are selected for transfusion.

(2) Performance of two determinations of the recipient's ABO group as specified in N.J.A.C. 8:8-7.2(g). One of the determinations shall be on a current sample and the second shall be by one of the following methods: retesting the same sample; testing of a second current sample; or comparison with previous records.

(3) The computer system shall contain the donor unit number, component name; ABO group and Rh type of the component, the confirmed ABO group, the two unique recipient identifiers, recipient ABO group, Rh type, and antibody screening results.

(4) The computer system shall contain logic to alert the user to discrepancies between the donor ABO group and Rh type on the unit label and those determined by blood group confirmatory tests, and ABO incompatibility between the recipient and the donor unit.

(5) There shall be a method to verify correct entry of data before release of blood and blood components for transfusion.

5. A control system using red blood cells sensitized with IgG shall be used with each negative antiglobulin test.

(h) Selection of compatible blood and blood components for transfusion for special circumstances shall follow AABB Standards, as amended and supplemented.

1. There shall be a mechanism to ensure that patients with special transfusion requirements receive the correct component as clinically indicated.

2. The blood bank shall have a policy regarding transfusion of cellular components selected or processed to reduce Cytomegalovirus (CMV) transmission and transfusion of irradiated components for patients at risk for transfusion-associated graft-vs-host disease.

8:8-9.2 Suspected transfusion reactions

(a) Each blood bank and transfusion service shall have a system for detecting and evaluating suspected adverse reactions to transfusion.

(b) All suspected transfusion reactions shall be evaluated promptly.

(c) In the event of a suspected transfusion reaction, the staff attending the patient shall:

1. Immediately notify the blood bank and the responsible clinical practitioner. All instructions for the evaluation of the suspected reaction shall be documented; and

2. Note the reaction in the patient's medical record and on the blood transfusion documentation.

(d) If an acute hemolytic transfusion reaction is suspected, the transfusion shall be discontinued and the blood bank staff shall:

1. Check labels on the blood container and all other records associated with the transfusion to detect clerical errors in identification;

2. Retype the post transfusion reaction sample for ABO group and Rh typing and compare the results to the pretransfusion results;

3. Inspect the post reaction plasma or serum for evidence of hemolysis and compare the appearance with the pretransfusion sample and record results;

4. Perform Direct Antiglobulin Test (DAT). If the result is positive, compare the result with the pretransfusion sample; and

5. If discrepancies or adverse results are identified in (d)1 through 4 above, notify the blood bank director immediately.

(e) The blood bank shall have a written procedure that specifies the additional tests that need to be performed when discrepancies or adverse results exist.

(f) The blood bank shall have a procedure in place to ensure that blood is not released for transfusion while the suspected transfusion reaction investigation is in progress, unless approval is received from the blood bank director and this approval is documented.

8:8-9.3 Operative blood order schedules

(a) If type and screen procedure is used, there shall be prompt availability of ABO compatible blood to meet unexpected transfusion requirements.

(b) If this blood is needed before compatibility testing is completed, an immediate spin crossmatch shall be performed before the blood can be released.

1. Testing shall be completed promptly and the results documented.

8:8-9.4 Urgent requirement for blood and blood components

(a) Urgent requirements for blood are situations in which delay in provision of blood may unduly jeopardize the patient, therefore, blood may be issued before completion of routine tests.

(b) The following standards shall apply to urgent situations:

1. Recipients whose ABO group and Rh type have been determined by the transfusing facility without reliance on previous records may receive type-specific blood before required tests have been completed.

2. Recipients whose ABO group is not known shall receive type O red blood cells.

3. The record shall contain a statement of the requesting physician indicating that the clinical situation was sufficiently urgent to require release of blood before completion of required testing and shall include the written or validated electronic signature of the requesting physician.

4. The tag or label shall indicate in a conspicuous fashion that required testing had not been completed at the time of issue.

5. Required tests shall be completed promptly.

6. The identification number required in N.J.A.C. 8:8-9.1 and N.J.A.C. 8:8-10.1 shall be traceable.

SUBCHAPTER 10. ISSUE AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS FOR TRANSFUSION

8:8-10.1 Issue of blood

(a) Issue and administration of blood and blood components shall be at the request of a clinical practitioner.

(b) A blood transfusion request form indicating the recipient's full name, as it appears on the identification band, traceable identification number and the type and quantity of component shall be completed.

(c) A label or tag with the appropriate information to identify the unit with the intended recipient shall be attached to the blood container before its release from the laboratory for transfusion.

(d) At the time the blood or blood component is released from the blood bank for transfusion, the person receiving the blood shall present a written request with sufficient information for the positive identification of the recipient.

(e) The technologist who issues the blood shall perform an identification check along with the person picking up the blood. This identification check shall involve active participation by both individuals in a review of the identifying information on the blood bag and the requisition slip. At a minimum, this review shall include the recipient's full name, as it appears on the identification band, traceable identification number, the type of component requested, and the date of transfusion.

(f) The blood bank shall record the unit number and the type of component issued.

(g) Retention of blood samples shall be as follows:

1. A stoppered or sealed sample of each donor blood, and a similar sample of the recipient's blood, shall be stored at 1 to 6°C for at least seven days after transfusion.

8:8-10.2 Administration of blood and blood components

(a) Blood or blood components for transfusion shall be prescribed by a clinical practitioner.

(b) Identification of the recipient and the blood container shall be as follows:

1. Each transfusion service must have a written procedure for the positive identification of the recipient and the blood container.

2. At the bedside, immediately prior to transfusion, two qualified individuals (whose qualifications are determined and verified by the medical institution or the transfusing facility in consultation with the blood bank director) shall simultaneously check and match all information identifying the container with the identifying information on the person of the intended recipient and the compatibility testing request slip. If the information does not match, the initiation of transfusion shall be suspended until the discrepancy is adequately investigated and resolved.

3. At the bedside, immediately after the identifying information in N.J.A.C. 8:8-10.2(b)2. is matched, and before the transfusion is initiated, the two qualified individuals that checked this information shall sign the transfusion form to attest that this information was checked and that it matched.

4. All identification attached to the container shall remain attached at least until the transfusion has been completed.

(c) Blood transfusions shall be conducted as follows:

1. Blood and components shall be transfused through a sterile, pyrogen-free transfusion set equipped with a filter appropriate to the component.

2. Warming of blood shall be consistent with AABB Standards and FDA regulations.

3. Irradiation of blood shall be consistent with current acceptable standards of the American Association

of Blood Banks or current guidelines issued by the Food and Drug Administration, whichever is more stringent.

4. The recipient shall be observed periodically during the transfusion and for an appropriate time thereafter for potential adverse reactions. At least the pretransfusion, 15 minute, and the post transfusion vital signs shall be recorded on transfusion documentation.

8:8-10.3 Reissue of blood and blood components

(a) Blood or blood components which have been returned to the blood bank shall not be reissued for use unless the following conditions have been met:

1. The container closure or seal has not been punctured or tampered with;
2. The blood has been continuously stored and shipped under controlled conditions, which maintain acceptable temperatures for the product, or it is returned to the blood bank within a pre-determined time, set by the blood bank, which is acceptable to the Department;
3. Whole blood and red blood cells have not been allowed to warm above 10 degrees Centigrade or cool below one degree Centigrade;
4. Original identification labels and tags are attached and unaltered;
5. The original pilot sample has not been removed or tampered with and at least one sealed segment of the integral donor tubing remains attached to the container;
6. If applicable, the blood has been allowed to settle long enough to permit reinspection of the plasma; and
7. The records indicate the blood was reissued with documentation of the time it was returned and reissued.

8:8-10.4 (Reserved)

8:8-10.5 (Reserved)

8:8-10.6 (Reserved)

8:8-10.7 (Reserved)

SUBCHAPTER 11. STORAGE OF BLOOD

8:8-11.1 General provisions

(a) The equipment used for the storage of blood or blood components shall be kept clean and individual compartments used only for the storage of blood and blood components, blood bank reagents, pilot and patient samples.

(b) No food or potentially contaminated material shall be stored in the equipment used for storage of blood or blood components.

(c) Written procedures shall be readily available containing directions on how to maintain blood and blood

components within permissible temperatures and including instructions to be followed in the event of power failure or other disruption of refrigeration.

8:8-11.2 Refrigerators for the storage of blood and blood components

(a) The refrigerator for the storage of blood shall maintain the blood at a temperature between 1-6°C.

(b) Refrigerators for blood or blood component storage shall be provided with a fan for circulating air or be of a design to ensure that the proper temperature is maintained throughout.

(c) Liquid temperature shall be monitored.

(d) The liquid medium used shall reflect the actual temperature of blood in storage.

8:8-11.3 Freezers for the storage of blood and blood components

(a) Freezers for blood and blood components stored frozen shall maintain the blood and blood components at a temperature below -18 degrees Centigrade.

(b) Liquid nitrogen freezers used to store blood and blood components shall maintain them at a gas phase temperature below -120 degrees Centigrade.

8:8-11.4 Room temperature storage

(a) Components for room temperature storage shall be maintained at a temperature of 20 to 24 degrees Centigrade.

(b) If components are stored in an open storage area, the ambient temperature shall be recorded every four hours during storage.

8:8-11.5 Temperature monitoring systems

(a) All equipment used to store blood and blood components shall have a system to record temperature continuously. In the event of equipment failure, the blood and blood component storage temperature shall be recorded at least every four hours.

(b) The temperature recording device shall be calibrated periodically, inspected at least daily and written records of the temperatures shall be kept on file.

(c) Alarms shall be attached to the blood and blood component storage equipment and shall be subject to the following:

1. Visual and audible alarm systems shall be attached to the equipment to indicate whenever the temperature is outside acceptable ranges.

2. Alarms shall be installed in locations to provide 24 hour coverage by night personnel or switchboard operators.

3. The alarms shall be set to activate at a temperature which shall allow proper action to be taken before the blood or blood components reach undesirable temperatures.

4. When the alarm is activated, the licensee shall initiate a process for immediate investigation and appropriate corrective action shall be documented.

(d) There shall be a written procedure posted prominently for staff to follow in case of electrical or equipment failure.

8:8-11.6 Inspection of stored blood and blood components

(a) Stored blood and/or blood components shall be inspected daily and records maintained during the entire period of storage and immediately prior to issue or use.

(b) If the color or physical appearance is abnormal or there is any indication or suspicion of contamination, the unit of blood or blood components shall not be issued for transfusion purposes.

(c) There shall be methods to limit and detect bacterial contamination in all platelet components in accordance with AABB Standards.

8:8-11.7 Expiration dates of blood and blood components

(a) The expiration date shall be the last day on which the blood and blood components are considered suitable for transfusion purposes.

(b) Expiration dates shall be in accord with the Code of Federal Regulations, as amended or supplemented.

8:8-11.8 Packaging and transportation

(a) Processed whole blood, modified whole blood and all liquid red blood cell components shall be transported in a manner that will maintain temperatures of one to 10 degrees Centigrade.

(b) Components ordinarily stored at 20 to 24 degrees Centigrade shall be transported at this temperature.

(c) Components ordinarily stored frozen shall be transported in a manner designed to keep them frozen.

(d) Immediately upon arrival, the receiving facility shall transfer the blood to temperature controlled equipment for further storage.

SUBCHAPTER 12. OUT-OF-HOSPITAL TRANSFUSIONS

8:8-12.1 General provisions

(a) A facility that intends to perform out-of-hospital transfusion shall obtain a blood bank license to offer the service in New Jersey.

(b) Any facility that issues blood and blood components to an Out-of-Hospital Transfusion (OOHT) service shall be a blood bank licensed in accordance with this chapter to perform "Transfusion Services" and "Processing (Routine)".

(c) The OOHT service and the New Jersey licensed "Transfusion Service" shall have a written agreement that specifies the division of responsibilities for assuring compliance with this chapter. If the OOHT service performs no function other than transfusion of the blood, the New Jersey licensed transfusion service shall agree in this written

document to perform recipient testing required in N.J.A.C. 8:8-9.1 and N.J.A.C. 8:8-9.2, and to provide technical consultation when necessary.

(d) Blood banks wishing to employ the techniques set forth in this subchapter shall file their protocol and a request in writing with the Department, prior to initiation of the procedure.

(e) Such techniques shall only be employed upon receipt of written approval from the Department.

(f) The procedures used shall be acceptable to the Department and ensure that there is compliance with this Chapter.

8:8-12.2 Out-of-hospital transfusions (OOHT)

(a) Out-of-hospital transfusions (OOHT) shall be done under medical supervision, and the patient shall be observed during the transfusion and for an appropriate time thereafter for suspected adverse reactions. Specific instructions concerning possible adverse reactions shall be provided in writing for the patient.

(b) Blood or blood components for transfusion shall be prescribed by a clinical practitioner.

(c) OOHT services shall be licensed to transfuse blood and blood components, in accordance with this chapter.

(d) Recipient safety shall be assured by at least the following:

1. If a physician is not present, the transfusionist shall be a person able to administer emergency care and shall be a registered nurse (R.N.) holding a current certificate of registration who has fulfilled the following requirements:

i. Has taken an eight hour course in cardiopulmonary resuscitation within three years and successfully passed a practical and written exam on the subject matter.

2. A second responsible person shall be available on the premises to help with emergency situations and to provide the second check required in N.J.A.C. 8:8-10.2.

3. Adherence to N.J.A.C. 8:8-8.3, Medical contingency plan.

(e) The procedures used shall comply with N.J.A.C. 8:8-4, Management, N.J.A.C. 8:8-5, Records and Reporting Requirements, N.J.A.C. 8:8-10.2, Administration of blood and blood components, and N.J.A.C. 8:8-11.1, 8:8-11.4 and 11.8, Storage of blood.

(f) Blood banks functioning only as OOHT services shall also comply with N.J.A.C. 8:8-2, Personnel, N.J.A.C. 8:8-3.2, Contaminated material, N.J.A.C. 8:8-7.1(a), (b) and (d), Blood and blood components, and N.J.A.C. 8:8-9.1, Recipient blood testing.

8:8-12.3 Out-of-hospital transfusions (OOHT) in emergency situations

(a) Facilities not routinely using blood and blood components for therapeutic purposes that can anticipate that they may use them on an emergency basis to treat a life-threatening situation, shall be licensed as outlined in N.J.A.C. 8:8-1.3, Licensure. This licensure requirement shall not be applicable to ambulatory surgery centers that are not required to be licensed by the Department.

(b) The facilities described in (a) above shall comply with N.J.A.C. 8:8-5, Records and Reporting Requirements, N.J.A.C. 8:8-9, Recipient Blood Testing and N.J.A.C. 8:8-10.1, Administration of blood and blood components.

(c) If a nonsurgical situation exists, which could not be anticipated and blood or blood components for therapeutic purposes are necessary on an emergency basis to treat a life-threatening situation, a licensed blood bank shall be permitted to release blood and blood components to an entity not licensed as a blood bank provided that:

1. The attending physician shall attest in writing to the existence of the emergency and the licensed blood bank shall maintain this documentation as required in 8:8-5.1, Records.

2. N.J.A.C. 8:8-9, Recipient Blood Testing and N.J.A.C. 8:8-10.1, Administration of blood and blood components are followed.

SUBCHAPTER 13. HEMATOPOIETIC PROGENITOR CELLS

8:8-13.1 Compliance

(a) Persons, known as licensees, for the purpose of this chapter, operating blood banks involved in the collection, processing, storage, distribution and/or transplantation of hematopoietic progenitor cells (HPC), shall meet the qualifications and conduct blood banks in accordance with N.J.S.A. 26:2A-2 et seq., the rules in this subchapter and the provisions of N.J.A.C. 8:8-1 and 3.

8:8-13.2 Definitions

For the purpose of this subchapter, the terms listed below shall be defined and interpreted as follows:

“Allogeneic” means the collection of HPC for subsequent transplantation to a recipient other than the donor. The term “allogeneic” is also known as homologous.

“Autologous” means the removal and storage of HPC from a donor for subsequent reinfusion into the same person. The term “autologous” is also known as autogeneic.

“Collection and processing service” means an organizational entity that collects or processes HPC or performs both functions.

“Cord blood” means blood in the placenta and umbilical cord that may be rich in HPC.

“Designee” means an individual designated by the medical and/or laboratory director in writing, who is qualified by education, training and/or experience to assume his/her duties for specific aspects of the collection/processing service.

“First degree blood relative” means a parent, child, or sibling.

“Hematopoietic progenitor cells (HPC)” means pluripotential cells that may be capable of self-renewal and differentiation into any mature blood cells, which are present in peripheral blood and placental/cord blood.

“Hematopoietic progenitor cell blood bank” means an operation engaged in HPC collection, processing, storage, distribution and/or transplantation that shall be referred to as blood banks or HPC blood banks in N.J.A.C. 8:8-13.

“Human leukocyte antigens (HLA)” are proteins located on the surface of the white blood cells and other tissues of the body that are used for typing in allogeneic transplants to determine histocompatibility between donor and intended recipient.

“Manipulated HPC” means HPC obtained after one or more processes have been performed to intentionally purge or enrich the starting material.

“Processing” means all tests and procedures required in preparing and identifying the HPC products as to their suitability for therapeutic, prophylactic or other in vivo or in vitro purposes.

“Recipient” means any person who receives a transplantation of HPC.

“System” means the organizational structure, responsibilities, policies, processes, procedures, and resources established by the licensee to achieve the requirements of these rules.

8:8-13.3 Personnel

(a) The licensee shall be responsible for obtaining a qualified HPC blood bank medical director, laboratory director and qualified technical staff.

(b) The medical director shall:

1. Be a physician who is appropriately licensed to practice medicine in New Jersey and is board certified in one or more of the following specialties: Hematology; Oncology; Pediatric Hematology/Oncology; Immunology and/or Pathology;

2. Have at least two years of documented experience or training in the relevant field, and have supervised at least 10 HPC collection and/or transplantation procedures for which they have direct authority;

3. Acquire proficiency in new procedures as they are developed with appropriate study, training, supervision, and/or certification;

4. Be responsible and have the authority for providing oversight of the entire HPC process, and shall specifically assure that each portion of the collection, processing, administration and storage comply with this subchapter;

5. Be responsible for adherence with N.J.S.A. 26:2A-2 et seq. and this subchapter;

6. Be responsible for the employment of qualified HPC personnel, their in-service training and their adherence to established policies and procedures.

7. A qualified medical director may serve in the dual capacity of medical director and laboratory director with full responsibility for all HPC services and duties listed in this subchapter and (c) below.

(c) The Laboratory director shall:

1. Hold a doctoral degree in a biological science;

2. Have one year of HPC processing training or two years of HPC processing experience, and shall have supervised at least 10 processing procedures for which he or she has direct authority;

3. Provide written confirmation of his or her training or experience from the Director of the Program of the department or institution in which he or she obtained his or her training or experience. The laboratory director shall acquire proficiency in new procedures as they are developed with appropriate study, training, supervision, and/or certification;

4. Be responsible for all administrative operations of HPC processing facility, including compliance with this chapter;

5. Be responsible for supervision of the technical staff, and for ensuring that the staff shall have capabilities and training appropriate to the services offered;

6. Have the responsibility and authority for all technical aspects of those portions of the program that he or she supervises;

7. Be responsible for adherence with N.J.S.A. 26:2A-2 et seq. and this subchapter;

8. Be responsible for the employment of qualified HPC personnel, their in-service training and their adherence to established policies and procedures; and

9. Where the laboratory director does not qualify as the medical director, there shall be a medical director in accordance with (b) above.

(d) The following concern HPC technical staff:

1. The HPC blood bank shall have one or more supervisors who under the general direction of the medical director and/or laboratory director supervise all functions related to HPC, and in the absence of the medical director or laboratory director shall be responsible for proper performance of these procedures set forth in this chapter.

2. There shall be a sufficient number of properly trained and qualified technical staff per the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) P.L. 100-578, amending 42 U.S.C. § 263a and N.J.A.C. 8:44 to meet the volume and complexity of technical procedures performed by the HPC blood bank.

3. All other personnel associated with the functions related to the collection, processing, testing, cryopreservation, storage and distribution of HPCs shall be suitably trained and supervised in the performance of their prescribed tasks with training records available for review.

4. Personnel shall qualify as the general supervisor.

8:8-13.4 Quality management

(a) HPC collection, processing, and administration service(s) shall establish and maintain a program or programs for quality control, quality assurance and quality assessment, which shall be in accordance with N.J.A.C. 8:8-4.1. The ultimate responsibility for the implementation of an adequate quality management program shall reside with the medical director.

1. There shall exist a written method for evaluating product specifications, specimen collection, storing, processing, usage, administration policies, and ability of services to meet patient needs.

(b) HPC collection, processing, storage and administration service(s) shall maintain a SOP manual or manuals describing, in a standardized format, all policies and procedures for activities performed by those services.

1. Policies and procedures shall include, but not be limited to, all aspects of the operation. When the following activities are performed, policies and procedures shall be available for them: donor screening, consent, collection, processing, quality control and proficiency testing, storage, labeling, dispensing, transportation, preparation for and actual administration of HPC and clinical research protocols.

(c) HPC collection, processing, and administration services shall have a system for detecting, evaluating, documenting, and reporting errors, accidents, suspected adverse reactions, nonconformance and deviations from the SOP manual(s).

1. Any deviations from standards, regulations, or the SOP manual(s) shall be documented and reviewed subsequently by the medical director and/or laboratory director dependent upon whether the deviation is medical or technical in nature.

2. Corrective actions shall be documented and reviewed promptly by the medical director and shall be made available to the patient's physician and all directors of facilities separately cooperating in provision of services.

3. If HPC has been transplanted prior to recognition of the error or accident, the medical director shall take immediate appropriate action to resolve the problem. If

the error or accident has resulted in the transplantation of the HPC that could result in infectious disease or other harmful consequences, appropriate staff shall notify the patient/recipient's physician. Thorough and complete documentation shall be made as to these actions.

8:8-13.5 Records

(a) Suitable and legible records shall be maintained for a period of not less than five years. Records to trace a unit of HPC from source to final disposition shall be kept for at least 10 years after transplantation. Written records shall be prepared with indelible material. All records stored off-site shall be retrievable within 24 hours.

(b) All corrections made in the HPC records shall not conceal the original entry; shall document the reason for the correction; and shall include the date the change was made and the initials of the person making the change.

(c) Complete records for all aspects of HPC activities performed shall be maintained. Records shall include the identity of the personnel who performed each significant step, quality control and when applicable donor history, medical examination, consent, deferral, reactions and laboratory test results; storage temperature; labeling, issue, and administration of HPC and its final disposition.

(d) Records maintained on computer shall comply with all the requirements of this chapter as set forth in N.J.A.C. 8:8-5.1(e).

(e) All records of HPC donors that do not meet the donor suitability criteria shall be kept for a period of 10 years.

8:8-13.6 Reporting requirements

(a) Any error in collection, processing, testing or administration of HPC that results in an adverse clinical event shall be reported on forms provided by the Department within 15 working days of occurrence.

(b) All prospective donors found to test positive for hepatitis B surface antigen and hepatitis C virus antibody shall be reported to the Department within 10 calendar days on forms provided for this purpose. These donors shall be considered ineligible for transplantation purposes as long as they continue to be identified on current lists of interdicted donors supplied by the Department, unless approved by the medical director and the recipient's physician.

(c) All prospective donors who test positive for communicable diseases shall be reported to the Department in accordance with N.J.A.C. 8:57.

(d) Corrective actions shall be documented and reviewed promptly by the medical director/laboratory director dependent upon whether the corrective action in this case is of medical or technical nature.

(e) Any errors, as set forth in N.J.A.C. 8:8-4.4(a), that result in the availability of unsuitable HPC products shall be reported to the Department on forms provided for that purpose.

8:8-13.7 Criteria for donor identification

(a) HPC donor shall be identified by an identification card or another form of authorized identification that provides a mechanism to positively identify prospective donors.

(b) The type of identification used shall be written on the donor registration card at the time of each HPC donation.

8:8-13.8 Criteria for donor selection

(a) When establishing the suitability of HPC donors for collection, the criteria used for medical history; physical examinations; bleeding limitations and the applicable requirements as prescribed by N.J.A.C. 8:8-6.2 shall be followed and shall be consistent with FDA regulations.

(b) When selecting donors for suitability, the applicable requirements as prescribed by N.J.A.C. 8:8-6.3 shall be followed and shall be consistent with FDA regulations and AABB Standards.

(c) The recipient's physician shall write a request for collection and processing before HPC are collected.

(d) The licensee shall obtain an informed consent of the peripheral blood donor prior to collection.

(e) Informed consent for cord blood donors shall:

1. Be obtained from birth mother, preferably both parents and if applicable, the legal custodian(s), according to N.J.A.C. 8:8-6.4(a) and the AABB Standards;

2. Not be obtained during active labor or while the mother is under the influence of sedation;

3. Be obtained prior to collection in cases of in utero collection; and

4. Begin before collection and be completed within 48 hours of collection.

(f) The requirements for qualifying the peripheral blood donor shall include:

1. Physician's approval of donor suitability; and

2. Written approval by the Medical Director and the recipient's physician for any exceptions to the donor qualification process.

(g) The licensee shall provide medical provisions for care of donors in case of adverse events and for a licensed physician to supervise when drugs, growth factors, pharmacologic or biologic agents are administered to a donor of peripheral blood.

(h) Donor acceptance shall be at the discretion of the transplant physician based on the degrees of ABO and HLA incompatibility.

(i) The cord blood service shall establish criteria for accepting birth mothers of autologous and related allogeneic donors that are acceptable to the Department.

(j) Birth mothers shall qualify with the allogeneic donor suitability requirements.

8:8-13.9 Collection of HPC

Collection of HPC shall be in accordance with N.J.A.C. 8:8-8

8:8-13.10 Collection of cord blood

(a) The cord blood service shall have policies and procedures for acceptable collection methods. Collections of cord blood shall be initiated within 10 minutes of the birth of the infant.

(b) The collection method shall:

1. Ensure the safety of the birth mother and the infant;
2. Ensure the positive identification of the donor (infant) by verifying the identification of the mother and the associated placenta;
3. Ensure retention of adequate sterility and stem cell viability;
4. Not result in any deviation from normal obstetric procedures;
5. Conform to accepted standards of asepsis; and
6. Be performed by the obstetrician or allied health care professional, responsible for the delivery of the infant, for in utero (prior to placental delivery) collection procedure.

(c) Staff shall have documented training and experience in venipuncture, infection control, and handling of biohazardous materials.

8:8-13.11 Processing

(a) The medical director of the facility shall approve HPC processing procedures in writing.

(b) The facility shall use methods known to result in acceptable viability, recovery, and sterility.

(c) Cryopreservation, manipulation or other processing procedures shall be performed as per the SOP that are well established in the medical literature or, if experimental, shall be approved by an institutional review board.

(d) Aseptic techniques shall be used to prevent bacterial contamination.

(e) Appropriate quality control tests and measures shall be in place to demonstrate adequate targeted cell yields, microbial sterility and viability of the product.

(f) After processing, the product shall be stored at acceptable temperatures in accordance with N.J.A.C. 8:8-13.16.

(g) Relevant information that can affect the safety, efficacy and potency of the product shall be communicated to the recipient's physician.

(h) The licensee shall ensure that the HPC are not exposed to gamma irradiation, inappropriate temperatures and other conditions known to compromise the safety or the efficacy of the HPC unit.

(i) The facility shall maintain records of:

1. Lot numbers and expiration dates of all disposables and reagents used in processing;
2. Processing procedures for each unit and the person performing each procedure; and
3. Processing tests on each unit shall include CD34 analysis, total nucleated cell count, percent viability, ABO group, Rh type, and microbial culture.

(j) The processing record for each unit shall be reviewed by the medical or laboratory director in a timely manner after completion of processing.

8:8-13.12 Cryopreservation

(a) Cryopreservation methods known to preserve HPC viability, recovery, and potency shall be used.

(b) The following records shall be maintained for each cryopreserved unit:

1. Starting product and volume;
2. Relevant cell count;
3. Cell viability;
4. Name, volume and concentration of cryoprotectant, anticoagulants and/or additives;
5. Cooling record from controlled-rate freezing, if applicable;
6. Endpoint temperature of cooling; and
7. Location of HPC and stored test aliquots.

8:8-13.13 Testing of donors

(a) For products originating in the United States, all required tests on the prospective donors prior or at the time of the donation shall be performed by a New Jersey licensed laboratory/blood bank and/or CMS certified laboratory. This information shall be available to the recipient's physician and the cell processing laboratory.

(b) All allogeneic donors are subject to the testing required by the Food and Drug Administration (FDA).

(c) The blood bank director shall communicate abnormal results in writing to the donor.

(d) Prior to the collection/transplantation, the transplant physician shall review the results to determine compatibility.

(e) Current results shall be compared with previous results, if any, for ABO group, Rh type and HLA type. Any discrepancies shall be resolved prior to issue of the HPC.

(f) The following tests shall be performed:

1. ABO group and Rh type;

2. Major histocompatibility antigens, HLA-A; -B and -DR (For allogeneic donors only);

3. Tests for unexpected antibodies to red cell antigens. Serum or plasma from donors with a history of transfusion or pregnancy shall be tested for unexpected antibodies to red cell antigens using methods that demonstrate clinically significant red cell antibodies within 30 days of donation. (For allogeneic donors only); and

4. Required infectious disease testing for allogeneic and autologous transplantation include a serologic test for syphilis (STS); Hepatitis B Surface Antigen (HBsAg); antibody to Hepatitis C Virus (HCV); Hepatitis B Core Antibody (HBcAb); antibody to Human Immunodeficiency Virus type 1 (HIV-1) and type 2 (HIV-2); antibody to Human T-Lymphotropic Viruses I/II (HTLV I/II); Cytomegalovirus (CMV) for allogeneic only and any other tests licensed by the FDA for donor testing within 30 days of availability.

i. This testing is waivable only in accordance with 21 CFR Part 1271-Human Cells, Tissues, and Cellular and Tissue-Based Products, incorporated herein by reference, as amended and supplemented.

(g) Cord blood testing shall be done on a sample from donor's birth mother within 48 hours of cord blood collection.

8:8-13.14 Labeling

(a) The labeling for HPC shall be in accordance with the N.J.A.C. 8:8-8.8 and AABB standards as amended and supplemented.

(b) There shall be documented evidence that the label used can withstand the conditions under which the specimen is stored.

(c) During intermediate processing steps, the container label shall contain at least the name of the component and the unique alphanumeric identifier.

(d) Prior to storage, issue, or transport, the container label(s) shall have at least the following information:

1. The name of the component, the date of collection, the alphanumeric identifiers, the recipient's name, if known, the collection facility and when applicable the donor registry's identifier, the approximate volume of the component, the names and volumes of the anticoagulants and additives, any manipulation process, the recommended storage temperature, if applicable, the expiration date and time or the statement "No expiration date", and the ABO group and Rh type of the donor; and

2. A biohazard label if the donor has tested confirmed positive for infection with syphilis, Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C virus antibody, anti-HIV-1, anti-HIV-2 and antibody to Human T-cell lymphotropic virus types I and II.

8:8-13.15 Expiration dates

Expiration dates for HPC shall be in accordance with the FDA regulations and the AABB Standards, as amended or supplemented.

8:8-13.16 Storage

(a) The storage of HPC shall be in accordance with N.J.A.C. 8:8-11.3.

(b) HPC stored in a liquid state shall be maintained at a temperature and for a period of time specified in a written procedure approved by the laboratory director. Appropriate documentation shall be available to support these specifications.

(c) HPC stored in a frozen state shall be within a temperature range as determined to be appropriate for the cryoprotectant used.

(d) For HPC components immersed in liquid nitrogen, written procedure to minimize the risk of microbial cross contamination of components shall be defined in the SOP and followed.

(e) The storage device shall be located in a secure area with available locking capability for use.

(f) Liquid nitrogen freezers shall have a mechanism to ensure that levels of nitrogen are maintained.

(g) An inventory control system shall be operational to locate any HPC component or quality control vial from that component, if available.

8:8-13.17 Issue

(a) A blood transplantation request form indicating the recipient's name, traceable identification number, and ABO group and Rh type shall be completed for each unit of HPC.

(b) A label or tag with the appropriate information to identify the HPC unit with the intended recipient shall be attached to the HPC container before its release from the HPC blood bank or laboratory for transplantation.

(c) At the time the HPC is released from the blood bank for transplantation within the facility, the person receiving the HPC shall present a written request with sufficient information for the positive identification of the recipient. When the HPC are issued within the facility, the technologist who issues the HPC shall perform an identification check along with the person picking up the HPC. This identification check shall involve active participation by both individuals in a review of the identifying information on the HPC container and the requisition slip. At a minimum the recipient's first and last names, traceable identification number, the HPC requested, and the date of transplantation shall be included. The blood bank shall write the unit number of the issued HPC on the request slip. When the HPC are issued outside the facility, the technologist who packages the HPC for shipping shall perform an identification check. The review process shall be documented.

(d) There shall be SOP for the management of abnormal appearance, broken container and any variance from acceptable ranges.

(e) A duly licensed physician shall request the release of HPC preparations from storage in writing.

(f) The identity of the intended recipient, the location (hospital) where the product is to be administered and the shipping date shall be documented.

(g) The following information shall also be documented and records shall be maintained indicating:

1. The type of HPC;
2. The alphanumeric identification for each collection;
3. The date and time of the expected infusion;
4. The recipient name and identification number;
5. The facility and person to whom the cells were dispensed; and
6. The integrity of the container and label.

(h) There shall be a contact person to whom HPC was issued or contact person for the transplant program when HPC is issued for transplantation outside of the facility in which the blood bank is located.

8:8-13.18 Reissue

(a) There shall be SOP for return to inventory of HPC issued for infusion and subsequently not infused. This shall include verification of the integrity of the container and verification that the HPC was maintained under appropriate storage conditions.

(b) The SOP shall address the need for authorization by the medical director or laboratory director or their designee, in consultation with the patient's transplant physician, to accept components for return and shall stipulate criteria for disposition of the component including possible reissue or discard.

(c) Documentation of the events requiring return, the results of inspection upon return, and subsequent action to insure component safety and viability shall be maintained in the blood bank/laboratory record.

8:8-13.19 Packaging and transportation

(a) The packaging and transportation of HPC shall follow this chapter and the AABB Standards.

(b) Prior to transportation, each container shall be inspected to ensure the container is intact and the label is complete, secure, and legible.

(c) HPC in transit to outside facilities shall be:

1. Packaged and shipped according to blood bank policies to ensure product integrity and maintenance of product temperature within limits set by the licensee;
2. Temperatures shall be recorded at the beginning and end of transport to document maintenance of acceptable temperatures set by the licensee;

3. Shipped using appropriate modes of transportation to ensure delivery to meet the urgency of the request for HPC;

4. Labeled prominently to:

i. Identify the contents with industry nomenclature specific to the product;

ii. Describe the contents, the packing agent, if any, and any precautions necessary in handling such contents; and

iii. Contain the name, address, and 24-hour telephone numbers of the person or entity to contact in the event that the container is found leaking or damaged, or is misdirected; and

5. Used immediately upon arrival or stored in a temperature environment specified in the SOP until thawed for use.

8:8-13.20 Administration

(a) Identification of the recipient and the HPC container shall be as follows:

1. Each transplantation service shall have a written procedure for the positive identification of the recipient and the HPC container.

2. At the bedside, immediately prior to transplantation, two qualified individuals (as specified in the SOP whose qualifications are determined and verified by the medical institution or the transplantation facility in consultation with the medical director) shall simultaneously check and match all information identifying the container with the identifying information on the person of the intended recipient and the request slip. If the information does not match, the initiation of transplantation shall be suspended until the discrepancy is adequately investigated and resolved.

3. At the bedside, immediately after the identifying information in N.J.A.C. 8:8-10.2 is matched, and before the transplantation is initiated, the two qualified individuals that checked this information shall sign the transplantation form to attest that this information was checked and that it matched.

4. All identification attached to the container shall remain attached at least until the transplantation has been completed.

(b) An administration record shall be completed and shall include:

1. The recipients name and unique identifying number;

2. The date and time of the infusion;

3. The identity of the persons administering the infusion;

4. Documentation of each HPC component, including any deviations from acceptable limits;

5. Inspection of each HPC component;

6. Authorization to use each HPC component;
7. The ABO group and Rh type;
8. A unique donor identifier; and
9. The identity of the medical staff involved with the infusion

(c) The record shall indicate that the HPC component has not been irradiated or undergone leukocyte filtration.

(d) Deviation from the infusion SOP shall be approved by the medical director and the recipient's physician and the approvals shall be documented.