"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 an individual who obtains blood from donors and/or patients by venipuncture.

"Plasmapheresis" means the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and the formed elements 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.

Amended by R.1987 d.111, effective February 17, 1987.
See: 18 N.J.R. 2280(a), 19 N.J.R. 356(b).
Added definition HIV.
Amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
"Autologous donation/transfusion" amended.
Definitions added for "Crossing over", "Designated donor", "Directed donation", "Homologous donation", "HIV", "Key person", "Mobile unit", "Preparation", "Service", "Significant step", "Stationary collection site", "Subsidiary blood bank", "Surrogate testing".
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Added "AABB Standards" , "Allogeneic", "Center for Biologics Evaluation and Research (CBER)", "Clinical practitioner", "Designee", "FDA regulations", "Industrial manufacturer", "Licensee", "Person", "Proficiency testing", "Standard operating procedures (SOP)" and "System" definitions; rewrote "Autologous donation/transfusion", "Blood bank", "Directed donation", "Mobile unit", "Phlebotomist", "Plasmapheresis", "Satellite blood bank" and "Storage" definitions; substituted the term "Broker" for "Brokerage" and rewrote the definition; deleted "Homologous or allogenic donation" and "Office of Biologics" definitions.

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
-1,000	$200.00
1,001-2,0000	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 Transfusions	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

Amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
License requirement for subsidiary blood bank added; service requirements amended.
Amended by R.1992 d.427, effective October 19, 1992.
See: 24 N.J.R. 2508(a), 24 N.J.R. 3725(c).
Blood bank licensure fee scheduled added at (f).
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In (a) and (d), substituted "Department" for "State of New Jersey" following "purpose by the"; rewrote (c); in (d), substituted "shall" for "will" following "license" and substituted "Department" for "State of New Jersey" at the end.

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.

Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In (b), substituted "Center for Biologics Evaluation and Research" for "Office of Biologics" following "made by the".

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.

Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Rewrote (a); added (d).

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.

Recodified from 8:8-1.7 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Repeal of rule concerning quality control program.
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Added (a); former section recodified as (b) and rewritten.

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.

Recodified from 8:8-1.8 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In rule heading, substituted "Waivers" for "Exemptions"; added "prior to initiation of the activity" following "by the Department".

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.

Recodified from 8:8-1.9 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In rule heading, substituted "Public Health Council" for "Waivers"; substituted "advice" for "advise" following "Council on the".

SUBCHAPTER 2. PERSONNEL

8:8-2.1 General

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

New Rule by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Former N.J.A.C. 8:8-2.1 recodified as 2.2 and amended.

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 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.

Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Recodified from N.J.A.C. 8:8-2.1 and amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Former N.J.A.C. 8:8-2.2 recodified as N.J.A.C. 8:8-2.3.
Rewrote the section.

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 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 cardio-pulmonary 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

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.

New Rule, R.1987 d.111, effective February 17, 1987.
See: 18 N.J.R. 2280(a), 19 N.J.R. 356(b).
Recodified from 8:8-5.5 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Requirement to test autologous blood deleted. Self-deferral system requirements added.
Requirement to produce HIV statistics added.
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In (b), (c), (g)-(i), substituted "shall" for "must"; rewrote (d) and (e); in (h), also substituted "counseling" for "counselling".

Case Notes

Enhanced-risk theory applied to negligence claim against trade association of voluntary blood banks based on alleged failure to recommend surrogate testing to eliminate blood contaminated with human immunodeficiency virus from supply. Snyder v. American Ass'n of Blood Banks, 282 N.J.Super. 23, 659 A.2d 482 (A.D.1995).

Blood bank which supplied AIDS contaminated blood was not strictly liable to patient who received blood. Snyder v. Mekhjian, 244 N.J.Super. 281, 582 A.2d 307 (A.D.1990), appeal granted 126 N.J. 318, 598 A.2d 879, appeal dismissed 126 N.J. 305, 598 A.2d 870, affirmed 125 N.J. 328, 593 A.2d 318.

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.

Recodified from 8:8-6.1 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Blood banks required to establish criteria. Labeling requirements added. Rule on donor's emergency care recodified to N.J.A.C. 8:8-8.2.
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In (e), added "and processing" preceding "of all blood" and rewrote the zip code as "08625-0361".

Case Notes

Trade association of voluntary blood banks that set standards for blood banks owed duty of care to transfusion recipient who brought negligence action against association after receiving blood that was contaminated with Human Immunodeficiency Virus and thereafter contracting Acquired Immune Deficiency Syndrome. Snyder v. American Ass'n of Blood Banks, 144 N.J. 269, 676 A.2d 1036 (1996).

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-Lymphotrophic 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 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 A 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.

Amended by R.1987 d.111 effective February 17, 1987.
See: 18 N.J.R. 2280(a), 19 N.J.R. 356(b).
(b)3 added; old (b)3.-7. renumbered (b)4.-7.
Recodified from 8:8-6.2 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Compliance with CFR and industry standards added. Surrogate testing for non-A, non-B Hepatitis added. Rule on medical contingency plan recodified to N.J.A.C. 8:8-8.3.
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Rewrote (a)-(d) and (f)-(j).

8:8-7.3 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.4.

8:8-7.4 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.5.

8:8-7.5 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.6.

8:8-7.6 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.7.

8:8-7.7 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.8.

8:8-7.8 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.10.

8:8-7.9 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.12.

8:8-7.10 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.13.

8:8-7.11 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.14.

8:8-7.12 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.15.

8:8-7.13 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Text recodified to N.J.A.C. 8:8-8.16.

8:8-7.14 (Reserved)

Repealed by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
This section was previously sterility testing.

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.

New Rule, R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on general provisions recodified to N.J.A.C. 8:8-9.1.
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).

8:8-8.2 Donor's emergency care

(a) Blood shall be drawn from donors only when donor emergency care personnel are available on the premises in accordance with N.J.A.C. 8:8-2.3(d).

(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 exemp-

tion 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 (for example, 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 procedures for implementation of donor selection and donor care standards shall be consistent with the provisions of this chapter.

(h) This rule shall not waive the requirements for physicians' attendance at a location where plasmapheresis is being performed in an open 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 March 31, 2008.

Recodified from 8:8-7.1 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on operative blood order schedules recodified to N.J.A.C. 8:8-9.2.
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Rewrote (a) and (b); in (c), rewrote "opened" as "open".
Amended by R.2006 d.134, effective April 17, 2006.
See: 37 N.J.R. 3765(a), 38 N.J.R. 1732(a).
Added (b)-(f) and (j); recodified former (b)-(d) as (g)-(i).

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.

Recodified from 8:8-7.2 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on urgent requirement for blood recodified to N.J.A.C. 8:8-9.3.
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.1995 d.25, effective January 17, 1995.
See: 26 N.J.R. 3141(b), 27 N.J.R. 343(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Rewrote (a); deleted former (b); recodified former (c) as (b) and substituted "shall" for "must".

(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.

Recodified from 8:8-9.1 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Identification requirements added at (c).
Rule on refrigerators for the storage of blood recodified to N.J.A.C. 8:8-11.2.
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Added (a); recodified former (a) as (b) and rewrote subsection; recodified former (b) as (c); recodified former (c) as (d)-(f) and rewrote new (e) and (f); recodified former (d) as (g).

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 shall 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(a)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.

Recodified from 8:8-9.2 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on freezers for blood components recodified as 8:8-11.3.
Amended by R.1994 d.350, effective August 1, 1994.
See: 26 N.J.R. 1057(a), 26 N.J.R. 3171(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
Rewrote the section.

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.

New Rule, R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on room temperature storage recodified to N.J.A.C. 8:8-11.4.
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In rule heading, added "and blood components"; in (a), added 3 and recodified former 3 as 4, recodified and rewrote former 4 as 5, and recodified former 5 and 6 as 6 and 7.

8:8-10.4 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on temperature monitoring systems recodified to N.J.A.C. 8:8-11.5.

8:8-10.5 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on inspection of stored blood recodified to N.J.A.C. 8:8-11.6.

8:8-10.6 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on expiration rates of blood and blood components recodified to N.J.A.C. 8:8-11.7.

8:8-10.7 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on packaging and transportation recodified to N.J.A.C. 8:8-11.8.

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.

New Rule, R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In (a), added "or blood components" preceding "shall be kept" and substituted "bank reagents" for "banking sera"; in (b), deleted "refrigeration" preceding "equipment" and added "used for storage of blood or blood components" following "equipment".

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.

Recodified from 8:8-10.1 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In rule heading, added "and blood components".

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.

Recodified from 8:8-10.2 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Amended by R.2005 d.283, effective October 3, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).
In rule heading, added "the storage of blood and" preceding "blood components"; substituted "degrees Centigrade" for "°C" in (a) and (b); in (a), added "blood and" preceding "blood components" and added "and blood" following "maintain the blood"; in (b), substituted "blood and blood components" for "red blood cells".

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.