CHAPTER 8

COLLECTION, PROCESSING, STORAGE AND DISTRIBUTION OF BLOOD

Authority

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

Source and Effective Date

R.2005 d.283, effective August 1, 2005.
See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).

Chapter Expiration Date

Chapter 8, Collecting, Processing, Storage and Distribution of Blood, expires on August 1, 2010.

Chapter Historical Note

Chapter 8, Collection, Processing, Storage and Distribution of Blood, was filed and became effective prior to September 1, 1969.

Pursuant to Executive Order No. 66(1978), Chapter 8, Collection, Processing, Storage and Distribution of Blood, was readopted as R.1989 d.246, effective April 12, 1989. See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).

Pursuant to Executive Order No. 66(1978), Chapter 8, Collection, Processing, Storage and Distribution of Blood, was readopted as R.1994 d.229, effective April 12, 1994. See: 26 N.J.R. 1057(a), 26 N.J.R. 2025(a). Pursuant to Executive Order No. 66(1978), Chapter 8 expired on April 12, 1999.

Chapter 8, Collection, Processing, Storage and Distribution of Blood, was adopted as new rules by R.1999 d.288, effective August 16, 1999. See: 31 N.J.R. 947(a), 31 N.J.R. 2373(c).

Chapter 8, Collecting, Processing, Storage and Distribution of Blood, expiration date was extended by gubernatorial directive from February 12, 2005 to February 12, 2006, in accordance with N.J.S.A. 52:14B-5.1d. See: 37 N.J.R. 774(a).

Chapter 8, Collecting, Processing, Storage and Distribution of Blood, was readopted by R.2005 d.283, effective August 1, 2005. See: Source and Effective Date. See, also, section annotations.

Subchapter 13, Hematopoietic Progenitor Cells, was adopted as new rules by R.2005 d.283, effective October 3, 2005. See: 36 N.J.R. 4261(a), 37 N.J.R. 3815(a).

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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.

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).

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 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.

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 cytapheresis 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.

Recodified from 8:8-4.1 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on donor identification previously at N.J.A.C. 8:8-5.1 recodified to N.J.A.C. 8:8-6.1.
Requirements added concerning record maintenance, corrections, work records, computer systems, written procedures, reporting requirements, quality control and identification of staff involved in blood processing.
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), added 1; in (f), deleted "and" at the end of 4, replaced ";" for "." at the end of 5, and added 6 and 7; in (i), substituted "all blood" for "plasmapheresis and cytapheresis" in 1ii, substituted "pooled product" for "pooling of source plasma" in 1x, rewrote 2vi, substituted "corrective" for "correction" and added "the" preceding "supervisor" in 7, and substituted "investigations" for "investigation" and "suspected" for "suspect" in 9.

8:8-5.2 Reporting requirements

(a) Transfusion reactions shall be reported to the Department as follows:

1. Any hemolytic or delayed hemolytic and other known or suspected life-threatening transfusion reaction shall be reported on forms provided by the Department within 10 days of occurrence.

2. Any known or suspected fatal transfusion reaction shall be reported by telephone by the next working day of the event, with written follow-up on forms provided by the Department within 10 days of occurrence.

(b) Transfusion associated AIDS shall be reported as follows:

1. Any known or presumed case of transfusion associated AIDS brought to the attention of a blood bank shall be reported to the Department within 10 days on forms provided for this purpose.

(c) All prospective donors found to test positive for hepatitis B surface antigen and antibody to hepatitis C virus shall be reported to the Department within 10 days on forms provided for this purpose and shall be considered ineligible for transfusion purposes as long as they continue to be identified on current lists of interdicted donors supplied by the Department.

(d) Errors, as outlined in N.J.A.C. 8:8-4.4(a), that result in the availability of unsuitable blood and blood components for transfusion or distribution, shall be reported on forms provided by the Department within 15 working days of the recognition of the error.

(e) Errors that result in the wrong blood or blood component being transfused, regardless of harm to the recipient, shall be reported on forms provided by the Department within 15 working days of the recognition of the error.

Recodified from 8:8-4.2 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on medical history, physical exam and bleeding limitations previously at N.J.A.C. 8:8-5.2 recodified to N.J.A.C. 8:8-6.2. Requirements added for the reporting of transfusion-associated AIDS and of errors in shipment.
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), added "to the Department" following "reported" in the introductory paragraph, rewrote 1, and added "known or suspected" preceding "fatal transfusion" in 2; in (b), recodified 2 as (c) and added "and antibody to hepatitis C virus" following "surface antigen"; recodified former (c) and (d) as (d) and (e) and substituted "15 working" for "10" in both subsections.

Case Notes

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.

8:8-5.3 (Reserved)

Recodified by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on donor selection previously at N.J.A.C. 8:8-5.3 recodified to N.J.A.C. 8:8-6.3.

8:8-5.4 (Reserved)

Amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on information to donor previously at N.J.A.C. 8:8-5.4 recodified to N.J.A.C. 8:8-6.4.

8:8-5.5 (Reserved)

Amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on AIDS screening previously at N.J.A.C. 8:8-5.5 recodified to N.J.A.C. 8:8-6.5.

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.

Recodified from 8:8-5.1 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on general criteria recodified to N.J.A.C. 8:8-7.1.

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.

Recodified from 8:8-5.2 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Rule on processing recodified to N.J.A.C. 8:8-7.2. Address changed. Criteria clarified.
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 "and" preceding "bleeding limitations", changed the zip code to "08625-0361", and added the last two sentences.

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).

8:8-6.3 Donor selection

(a) On the day of donation the prospective donor's history shall be evaluated and the donor examined by qualified blood bank personnel trained to follow guidelines acceptable to the Department in order to determine that blood donation will not be detrimental to the donor and to determine that the donor has no evidence of disease transmissible by blood transfusion.

(b) Donors shall be excluded from donating blood for transfusion while their names appear in the latest revision of publications supplied to the blood bank by the Department which prohibit them from serving as a donor.

(c) Before blood or blood components are issued for distribution, permanent deferral records, which include reason for deferral for donor past medical history and all tests required in N.J.A.C. 8:8-7.2. Testing shall be reviewed to determine if the blood and blood components meet all the requirements for allogeneic use. Blood and blood components, which do not meet these requirements, can not be used for allogeneic transfusion.

Recodified from 8:8-5.3 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Requirements for homologous use 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 (c), substituted "allogeneic" for "homologous" throughout.

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 shall 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.

Recodified from 8:8-5.4 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.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 "shall" for "must".

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).
Administrative correction.
See: 38 N.J.R. 2800(b).

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 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 (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".

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.