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Repealed by R.1989 d.246, effective May 15, 1989.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 procedures for implementation of donor selection and donor care standards shall be consistent with the provisions of this chapter.

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

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

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".

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".

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.

Recodified from 8:8-7.3 by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).

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.

Recodified from 8:8-7.4 and amended by R.1989 d.246, effective May 15, 1989.
See: 21 N.J.R. 407(a), 21 N.J.R. 1412(a).
Exception to closed system added.
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).
In (b), (d), and (e), substituted "shall" for "must"; rewrote (i); added (j).

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.

Recodified from 8:8-7.5 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 (a) and (b), substituted "shall" for "must"; in (c), added "immediately" preceding "after filling".