56 NJR 11(2)
November 18, 2024
Filed October 24, 2024

ADOPTIONS SECTION

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

CLINICAL LABORATORY IMPROVEMENT SERVICES

Notice of Readoption

Collection, Processing, Storage, and Distribution of Blood

Readoption with Technical Changes: N.J.A.C. 8:8

Authority: N.J.S.A. 26:1A-7 and 26:2A-1 et seq., especially 26:2A-7; and Reorganization Plan No. 003-2005.

Authorized By: Kaitlan Baston, MD, MSc, DFASAM, Commissioner, Department of Health, in consultation with the Public Health Council.

Effective Dates: October 15, 2024, Readoption;
November 18, 2024, Technical Changes.

New Expiration Date: October 15, 2031.

Take notice that pursuant to N.J.S.A. 52:14B-5.1, N.J.A.C. 8:8, Collection, Processing, Storage, and Distribution of Blood (also known historically as Chapter X of the State Sanitary Code) was scheduled to expire on December 18, 2024.

Reorganization Plan No. 003-2005, 37 N.J.R. 2735(a), continued and transferred the functions, powers, and duties of the Public Health Council to the Commissioner and recast the role of the Public Health Council as being of an advisory and consultative nature.

N.J.A.C. 8:8 establishes standards for the licensure and operation of blood banks, and requirements for the collection, processing, storage, distribution, administration, and transplantation of blood, blood components, and hematopoietic stem cells. Subchapter 1, General Provisions, establishes general provisions, including compliance and licensure standards and definitions of terms that the chapter uses. Subchapter 2, Personnel, establishes personnel standards. Subchapter 3, Facilities, Equipment, and Contaminated Material, establishes minimum standards for facility layout, environment, and disposal of contaminated material. Subchapter 4, Management, establishes standards addressing blood bank management, including required programs and procedures related to quality control and assurance, standard operating procedures, documented review of collected blood and blood components, and procedures to address errors and accidents. Subchapter 5, Records and Reporting Requirements, establishes standards for record creation, storage, and retention, and blood bank obligations to report transfusion reactions, certain communicable diseases, and errors and accident incidents. Subchapter 6, Criteria for Donor Selection, establishes standards by which blood banks are to identify, select, and defer donors, provide information to donors, screen donors for HIV infection, and test donated blood and blood components for the presence of HIV. Subchapter 7, Blood and Blood Components, establishes general criteria to which blood banks must adhere in testing and labeling donated blood and blood components, and required procedures, equipment, and materials for testing donated blood and blood components for the presence of the causative organisms for certain communicable diseases and certain antibodies, and to determine blood group and Rh factor. Subchapter 8, Collection of

Blood, addresses the collection of blood from donors, required processes and procedures, including the establishment of a medical contingency plan, required emergency care for donors, collection, labeling, and sterility testing for collection of blood components, and processing requirements for autologous collection, directed, donation, therapeutic phlebotomy, and other blood collection contexts. Subchapter 9, Recipient Blood Testing, establishes standards for testing of the recipient blood and for compatibility with the unit(s), identification of and response to suspected blood transfusion reactions, scheduling operative blood orders, and procedures for transfusion in urgent situations. Subchapter 10, Issue and Administration of Blood and Blood Components for Transfusion, establishes standards for the issuance of blood or blood components by a blood bank, and for the administration of blood or blood components in the context of transfusion. Subchapter 11, Storage of Blood, establishes standards for storage, temperature monitoring, inspection, expiration, packaging, and transportation of blood and blood components. Subchapter 12, Out-of-Hospital Transfusions, establishes standards for routine and emergency out-of-hospital transfusions. Subchapter 13, Hematopoietic Progenitor Cells, establishes standards for the collection, processing, storage, distribution, and transplantation of hematopoietic progenitor cells.

The Department of Health (Department) is developing a rulemaking to revise and update existing N.J.A.C. 8:8 and anticipates filing this rulemaking with the Office of Administrative Law for processing in the ordinary course. However, this rulemaking will not be concluded prior to the expiration of existing N.J.A.C. 8:8. Therefore, the Department is readopting the chapter with technical changes to maintain its

effectiveness, pending the completion of the rulemaking in development. The Department is making technical changes throughout the chapter to correct grammar, update a cross-reference and the names of publications and appendices that are incorporated by reference, update references to the name of the Department pursuant to N.J.S.A. 26:1A-2 and 2.1, and names, contact information, and website addresses of Department subunits and other entities to which the chapter refers. The Department is updating the telephone number to be used when contacting the Department's Blood Bank program on the Transfusion Reaction Report form (N.J.A.C. 8:8 Appendix A) and on the Error/Accident Report form (N.J.A.C. 8:8 Appendix B).

The Commissioner has reviewed N.J.A.C. 8:8 and determined that, pending the conclusion of the rulemaking in development, described above, the existing chapter remains necessary, proper, reasonable, efficient, understandable, and responsive for the purposes for which it was originally promulgated and should be readopted. Therefore, pursuant to N.J.S.A. 52:14B-5.1.c(1), N.J.A.C. 8:8 is readopted and shall continue in effect for seven years.

Full text of the technical changes follows (additions indicated in boldface, **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

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] **34th** Edition ([2004] **2024**), incorporated herein by reference**,** as

amended and supplemented**,** and the "Standards for Cellular Therapy [Product] Services," [First] **11th** Edition ([2004] **2023**), incorporated herein by reference**,** as amended and supplemented, both of which publications are published by the [American] Association **for the Advancement** of Blood [Banks] **& Biotherapies (also known as "AABB")**, [8101 Glenbrook Road] **4550 Montgomery Avenue, Suite 700, North Tower**, Bethesda, MD 20814-2749, (301) 907-6977, www.aabb.org.

…

"Clinical practitioner" means a physician currently licensed to practice in New Jersey; an advanced practice nurse currently certified [under] **pursuant to** the [New Jersey] Advanced Practice Nurse Certification Act**, N.J.S.A. 45:11-45 et seq.**; or a physician assistant licensed [under] **pursuant to** the Physician Assistant Licensing Act**, N.J.S.A. 45:9-27.10 et seq.**, acting within the rules governing those professions. Where authorized [under] **pursuant to** 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.

...

"Commissioner" means the Commissioner of **the** New Jersey [State] Department of Health [and Senior Services]**,** or his or her duly authorized agent.

...

"Department" means the New Jersey [State] Department of Health [and Senior Services].

...

["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.]

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SUBCHAPTER 3. FACILITIES, EQUIPMENT**,** AND CONTAMINATED MATERIAL

8:8-3.2 Contaminated material

Contaminated material shall be disposed **of** in a manner **that is** 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) (No change.)

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

1.-3. (No change.)

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] **AABB** Standards [of the American Association of Blood Banks];

5.-10. (No change.)

(c) (No change.)

SUBCHAPTER 5. RECORDS AND REPORTING REQUIREMENTS

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 **Transfusion Reaction Report** form **(CL-44)** at chapter Appendix A, incorporated herein by reference; and

2. Known and/or suspected fatal transfusion reactions by telephone call to (609) [292-0522] **718-8084** by the next working day after the day the event occurs, with written follow-up within 10 days of the occurrence, using the **Transfusion Reaction Report** form **(CL-44)** at chapter Appendix A, incorporated herein by reference.

(b)-(c) (No change.)

(d) Blood banks shall report prospective donors testing positive for HIV-1 and/or HIV-2 to the Division of [HIV/AIDS] **HIV, STD, and TB** Services of the Department in accordance with N.J.A.C. [8:57-2] **8:65**.

(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 **Error/Accident Report** form **(CL-21)** 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

Error/Accident Report form **(CL-21)** at chapter Appendix B, incorporated herein by reference.

(g) (No change.)

SUBCHAPTER 6. CRITERIA FOR DONOR SELECTION

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 **AABB** 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] **Public Health, Environmental, and Agricultural Laboratory, 3 Schwarzkopf Drive, Ewing, NJ 08628-1620**. In addition, for emerging issues, the most recent FDA guidelines shall be followed. These documents are available at [www.fda.gov/cber/guidelines.htm] **https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances**.

SUBCHAPTER 7. BLOOD AND BLOOD COMPONENTS

8:8-7.1 General criteria

(a)-(d) (No change.)

(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 **AABB** 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, **Public** Health**, Environmental,** and [Agriculture Building, Room 401, Trenton, New Jersey 08625-0361] **Agricultural Laboratory, 3 Schwarzkopf Drive, Ewing, NJ 08628-1620**.

SUBCHAPTER 8. COLLECTION OF BLOOD

8:8-8.12 Perioperative autologous blood collection and administration

(a)-(b) (No change.)

(c) **The AABB** 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.

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

8:8-10.2 Administration of blood and blood components

(a)-(b) (No change.)

(c) Blood transfusions shall be conducted as follows:

1.-2. (No change.)

3. Irradiation of blood shall be consistent with [current acceptable standards of the American Association of Blood Banks] **AABB Standards** or current guidelines issued by the Food and Drug Administration, whichever is more stringent.

4. (No change.)

APPENDIX A

New Jersey Department of Health
Clinical Laboratory Improvement Service
PO Box 361
Trenton, NJ 08625-0361

TRANSFUSION REACTION REPORT

INSTRUCTIONS:

1. *Pursuant to N.J.A.C. 8:8-5.2, blood banks must report hemolytic and/or delayed hemolytic and other known or suspected life-threatening transfusion reactions within 10 days of the occurrence using this form; and must report known and/or suspected fatal transfusion reactions by telephone call to 609-718-8084 by the next working day after the day the event occurs, with written follow-up within 10 days of the occurrence, using this form.*
2. *Forward the original copy of the report to the address listed above; retain a copy for your records.*
3. *If there are any questions, contact the Blood Bank Unit at 609-718-8084.*
4. *Briefly summarize the events leading to the reaction below. Attach copies of the transfusion reaction work-up performed.*
5. *Describe corrective action(s) taken to prevent error from recurring.*

Name of Blood Bank		Telephone Number
Date of Transfusion	Time of Transfusion	Day, Date and Time of Reaction
Amount of Blood Transfused	Patient ABO Group	Donor ABO Group
Location of Patient at Time of Reaction		
Patient Name	Patient Age	Diagnosis

Type of Reaction

- ☐ Fatal ☐ Non-Fatal
  - ☐ Hemolytic
  - ☐ Anaphylactic
  - ☐ Delayed Hemolytic
    - ☐ a. Amount of time after transfusion _____
    - ☐ b. Specify antibody, if applicable _____
  - ☐ Bacterial (List Organism) _____

Describe Events Leading to the Reaction and Corrective Action Taken (If more space is needed attach additional sheets.)

Date Reported	Name of Blood Bank Director	Signature of Blood Bank Director

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Forward completed Report to address listed above; retain a copy for your records.

APPENDIX B

New Jersey Department of Health
Clinical Laboratory Improvement Service
PO Box 361
Trenton, NJ 08625-0361

ERROR / ACCIDENT REPORT

INSTRUCTIONS:

1. *Pursuant to N.J.A.C. 8:8-5.2, blood banks must 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 recognition of the error, using this form.*
2. *Keep a copy for your records and forward the original report to the above address. If more space is needed, attach additional sheets.*
3. *If there are any questions, contact the Blood Bank unit at (609) 718-8084.*

Name of Blood Bank	Telephone Number
Name of Person Completing the Form	Telephone Number
Date of Error	Date Error Detected

Type of Error

- ☐ Infectious Disease Testing,
  - Specify Test: _____
    - ☐ Improperly Tested
    - ☐ Not Tested
    - ☐ Properly Tested but Improperly Interpreted or Labeled
- ☐ ABO,
  - Specify: _____
- ☐ Permanent Deferral,
  - Specify: _____
- ☐ Confidential Unit Exclusion
- ☐ Transfusion-Related Septicemia
- ☐ Other, Specify: _____

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Page 1 of 2 Pages.

ERROR / ACCIDENT REPORT, Continued

Name of Blood Bank
Donation Number (s)
Components Prepared from each Donation Number
Components Transfused (List by Number)
Successful Recall(s) (List by Number)
Describe the Error
Describe Corrective Action(s) taken to prevent error from recurring.
Name of Blood Bank Director (Print)

Signature of Blood Bank Director	Date Reported

Forward completed Report to address listed above; retain a copy for your records

CL-21