

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: Blood Labeling Code
- 2) Code Citation: 77 Ill. Adm. Code 460
- 3)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
460.10	Repeal
460.100	Repeal
460.110	Repeal
460.130	Repeal
460.140	Repeal
460.150	Repeal
460.410	Repeal
460.500	Repeal
- 4) Statutory Authority: Blood Labeling Act [210 ILCS 20]
- 5) A Complete Description of the Subjects and Issues Involved: The Blood Labeling Code is being repealed because its statutory authority, the Blood Labeling Act, was repealed by Public Act 87-1269. Blood labeling is now regulated under the Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25].

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? No
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rulemaking will not create a state mandate.

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- 12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after this issue of the *Illinois Register* to:

Elizabeth Paton
Assistant General Counsel
Department of Public Health
Division of Legal Services
535 W. Jefferson St., 5th Floor
Springfield, Illinois 62761
(217)782-2043
e-mail: dph.rules@illinois.gov

- 13) Initial Regulatory Flexibility Analysis:

- A) Types of small businesses, small municipalities and not for profit corporations affected: None
- B) Reporting, bookkeeping or other procedures required for compliance: None
- C) Types of professional skills necessary for compliance: None

- 14) Regulatory Agenda on which this rulemaking was summarized:

This rule was not included on either of the two most recent Regulatory Agendas because the need for the rulemaking was not known at the time the latest Regulatory Agendas were drafted.

The full text of the Proposed Rule/Amendment begins on the next page:

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TITLE 77: PUBLIC HEALTH

CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER d: LABORATORIES AND BLOOD BANKS

PART 460
BLOOD LABELING CODE

SUBPART A: DEFINITIONS

Section
460.10 Definitions

SUBPART B: CRITERIA FOR DONOR SELECTION

Section
460.100 Identification Required
460.110 Minimum Requirements
460.120 Disease
460.130 Donor Requirement Guide
460.140 Donors and Donor Blood/Identification of Donor Blood
460.150 Directed Blood Donations

SUBPART C: PURCHASED BLOOD

Section
460.410 Justification and Charting Requirements for the Transfer and Administration of
Purchased Blood Effective July 1, 1973

SUBPART D: HIV CONTAMINATED BLOOD

Section
460.500 Handling and Disposal of HIV Contaminated Blood

AUTHORITY: Implementing and authorized by The Blood Labeling Act (Ill. Rev. Stat. 1985, ch. 111½, pars. 620-1 et seq.)

SOURCE: Filed September 20, 1972, effective October 1, 1972; amended at 2 Ill. Reg. 24, p. 22, effective June 6, 1978; amended at 4 Ill. Reg. 33, p. 224, effective August 6, 1980; codified

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at 8 Ill. Reg. 7274; amended at 10 Ill. Reg. 10697, effective June 3, 1986; amended at 12 Ill. Reg. 9998, effective May 27, 1988; repealed at 39 Ill. Reg. _____, effective _____.

SUBPART A: DEFINITIONS

Section 460.10 Definitions

"Act" means "The Blood Labeling Act", approved August 18, 1972 and effective October 1, 1972 (Ill. Rev. Stat. 1981, ch. 111½, pars. 620-1 et seq.).

"Department" means the Illinois Department of Public Health.

SUBPART B: CRITERIA FOR DONOR SELECTION

Section 460.100 Identification Required

Blood donations shall be accepted only from individuals who present positive identification and evidence of a fixed address. With identification established, the following rules shall be applied on the day of donation by suitably trained persons and the results shall be appropriately recorded.

Section 460.110 Minimum Requirements

It shall be determined that the making of the blood donation will not be detrimental to the donor. The following minimum requirements shall apply:

- a) Prospective donors with a history of chronic diseases of the heart, kidneys, lungs, liver, etc., or with a history of cancer, except minor skin cancer, abnormal bleeding tendencies, or of convulsions after infancy shall be excluded subject to evaluation by a qualified physician on the day of donation.
- b) Except for reasonable qualifying circumstances, the interval between individual donations of whole blood should be at least 8 weeks.
- c) For plasmapheresis not more than 1200 ml. of plasma to be removed in one week.
- d) Whole blood donation must be deferred for at least 48 hours after plasmapheresis.

Section 460.120 Disease

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The donor shall be free of disease transmissible by blood transfusion as ascertained at the time of collection in accordance with the guide for donor requirements.

Section 460.130 Donor Requirement Guide

A guide for donor requirements follows:

- a) General Appearance
The donor shall appear to be in good health and free from acute respiratory diseases.
- b) Age
Blood donor shall be between the ages of 17 through 75 (up to 76th birthday) provided:
 - 1) that the donor is 17 years of age or older
 - 2) after the 76th birthday, donors may be accepted at the discretion of the blood bank director if they have specific written consent from a physician within two (2) weeks before the date of donation, and provided that they meet all other criteria for acceptability.
- c) Temperature
The oral temperature shall not exceed 99.6°F. (37.5°C.).
- d) Hemoglobin or hematocrit

The measurement of either value is acceptable.
 - 1) The hemoglobin shall be no less than 12.5 grams per 100 ml. for female donors, and no less than 13.5 grams per 100 ml. for male donors.
 - 2) The hematocrit value shall be no less than 38 percent for females, and no less than 41 percent for males.
- e) Pulse
The pulse shall reveal no pathological cardiac irregularity and should be between

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50 and 100 beats per minute.

- f) Blood pressure
The systolic blood pressure should be between 90 and 180 mm of mercury, and the diastolic should not exceed 100 mm of mercury. Prospective donors with diastolic blood pressure readings between 100 and 110 mm of mercury and donors with abnormal differences between their systolic and diastolic pressures may be accepted only after evaluation by a qualified physician.
- g) Pregnancy
Known existing pregnancy shall exclude a donor. Except for exceptional qualifying circumstances a donor shall be excluded for 6 weeks postpartum.
- h) Dental surgery
Tooth extraction or other minor oral surgery during the preceding 72 hours shall exclude a donor.
- i) Receipt of blood, blood components
Donors who during the preceding six months have received blood or those human blood components known to be a possible source of hepatitis shall be excluded.
- j) Infectious diseases
A donor shall be free from infectious diseases known to be transmissible by blood insofar as can be determined by usual examinations.
 - 1) Viral Hepatitis
 - A) Donors with a history of viral hepatitis as well as those who within six months have had close contact with an individual having the disease shall be excluded.
 - B) A donor shall be excluded permanently:
 - i) If his were the only unit of blood, blood component, or derivative administered to a patient who within six months developed post/transfusion hepatitis and who received no other icterogenic blood fractions, or

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- ii) If his blood has ever been known to contain Hepatitis B antigen.
 - C) When hepatitis has developed after transfusion of blood, blood components, or derivatives from multiple donors, those donors who have not been previously suspected of hepatitis need not be rejected as future donors of whole blood. Each situation should be evaluated individually by the facility physician. The possible presence of the agent of viral hepatitis in donors cannot at present be detected with certainty by any available means including history, physical examination and laboratory tests (including a test for the presence of Hepatitis B antigen).
- 2) Malaria
- Travelers who have been in areas considered endemic for malaria by Malaria Program, Center for Disease Control, U.S. Department of Health, Education and Welfare, may be accepted as regular blood donors six months after return to the non/endemic area, providing they have been free of symptoms and have not taken antimalarial drugs. Prospective donors who have had malaria shall be deferred for three years after becoming asymptomatic and after cessation of therapy. Prospective donors who have taken anti/malarial prophylaxis or who have been military personnel in an endemic area shall be deferred for three years after cessation of therapy or after departure from the area if they have been asymptomatic in the interim. Immigrants or visitors from endemic areas may be accepted as blood donors three years after departure from the area, if they have been asymptomatic in the interim. Donations to be used for the preparation of plasma, plasma components or fractions devoid of intact red blood cells are exempted from these restrictions.
- 3) Syphilis
- A positive serologic test for syphilis is cause for donor rejection. Donors may be acceptable when they become seronegative provided the previous positive result was not due to a condition which would result in continued exclusion.
- 4) Tuberculosis
- Prospective donors with clinically active tuberculosis are unacceptable.

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Donors with a positive tuberculin skin test, but without other abnormality, may be accepted if they have not taken prophylactic medication during the preceding 48 hours.

- 5) HIV Infection
 - A) Blood and blood components which have been found reactive when tested for evidence of infection with the human immunodeficiency virus (HIV) or any other identified causative agent of AIDS shall be rejected for blood donation in accordance with Section 460.140(e).
 - B) Prospective donors who request that their blood be tested for evidence of infection with HIV shall be referred to a HIV Counseling and Testing Center designated by the Illinois Department of Public Health.
- k) Immunizations or vaccinations:
 - 1) Symptom-free donors who have been immunized with toxoids, or killed viral, bacterial or rickettsial vaccines are acceptable after 24 hours. This includes tetanus, typhoid, paratyphoid, cholera, diphtheria, typhus, Rocky Mountain spotted fever, influenza, polio (Salk), plague and prophylactic rabies duck embryo vaccines.
 - 2) Smallpox: Donors are acceptable either after the scab has fallen off or two weeks after an immune reaction.
 - 3) Measles (rubeola), mumps, yellow fever, oral polio vaccine and animal serum products: Donors are acceptable two weeks after their last immunization or last antigenic dose. German measles (rubella): Donors are acceptable three months after their last injection.
 - 4) Rabies: Donors will be deferred until one year after their last injection.
- l) Donor skin

The skin at the venipuncture site shall appear free of lesions. History of a tattoo performed any place on the body within six months of donation shall be cause for

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rejection.

- m) Alcohol, narcotics
Obvious stigmata of narcotic or alcoholic habituation or intoxication shall exclude a donor.
- n) Allergy
Prospective donors with symptoms of bronchial asthma should be deferred.
- o) Oral medication
History of recent drug therapy should be evaluated by a physician since the indication for such treatment may be cause for donor rejection. Exceptions to this requirement include ingestion of vitamins or oral contraceptives.
- p) Therapeutic bleedings
Any blood withdrawn from a person for a therapeutic purpose and intended for future homologous transfusion shall be labeled to indicate the donor's disease. Therapeutic bleedings shall be performed only at the written request of a person's physician. The facility physician must decide whether he will accept the responsibility of bleeding the person in the facility. The use of this blood for transfusion purposes shall be submitted for the consideration of the physician in charge of the facility and of the physician attending the prospective recipient.
- q) Weight and amount of blood
Donors weighing 110 lbs (50 kg) or more may ordinarily give 450 plus or minus 45 ml of blood, in addition to pilot samples which shall not exceed 30 ml. Donors weighing less than 110 lbs may be bled proportionately less in a reduced volume of anticoagulant, provided the regulations outlined in Section 450.835 are met. Prospective donations of blood exceeding the recommended amounts shall be subject to evaluation by a qualified physician.
- r) Medical discretion
Any of the above criteria may be waived or modified by the facility physician in charge and the donor's physician, for certain medical indications related to the therapy of the donor. This waiver privilege extends to pregnancy and/or the products of the donor's conception.
- s) Fasting

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Fasting prior to blood donation is unnecessary.

- t) Before any blood is collected, all donors shall be informed that:
 - 1) Each unit of donated blood will be tested for the presence of antibodies to HIV or any other identified causative agent of AIDS.
 - A) All donors shall be informed about the following:
 - i) the meaning of the HIV test results, such as the purpose, potential use, limitations of the test and test results; the use of additional confirmatory testing and the related notification procedures; and the availability of referrals for further information and counseling.
 - ii) The opportunity to refuse HIV testing. If testing is refused, then the person will not be accepted as a donor.
 - B) Collection of a donor's blood is not permitted without signed written consent of the donor allowing disclosure of the test results to the donor. However, the written informed consent required by P.A. 85-677 and 85-679, effective September 21, 1987 and 77 Ill. Adm. Code 697.120 is not necessary because blood donors are specifically required by law to be tested.
 - 2) Persons infected with the HIV virus are potentially infectious to persons with whom they have contact through sexual relations or the sharing of blood or blood components. Persons with increased risk (high risk) of being infected with HIV must not donate blood, except for purposes of autologous transfusion. High risk persons include the following:
 - A) persons who have signs and symptoms suggestive of Acquired Immunodeficiency Syndrome (AIDS) (e.g. a combination of two or more of the following: unexpected weight loss of greater than 10% of body weight, chronic fever, chronic lymphadenopathy, night sweats or chronic diarrhea);
 - B) persons who have had sexual contact with HIV infected persons;

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- C) males who have had sexual contact with a male anytime since 1977;
 - D) persons who have immigrated from countries where heterosexual activity is thought to play a major role in transmission of HIV infection, such as Central Africa and Haiti anytime since 1977 as recognized by the Centers for Disease Control;
 - E) persons who are (were) present (past) intravenous drug users by self injection;
 - F) hemophiliacs; or
 - G) current or former sexual partners of any of the above.
- 3) Confirmed, available, test results showing evidence of HIV infection (e.g. Western blot assay or Indirect Fluorescent Antibody tests) will be disclosed in a confidential manner to the donor's physician or the donor no later than 55 days after the date of donation as described in Section 460.840(e).

Section 460.140 Donors and Donor Blood/Identification of Donor Blood

- a) Routine Labeling
The following information shall appear in clear, readable letters on a label firmly attached to the container:
 - 1) Name of component
 - 2) The amount of blood and the kind and amount of anticoagulant
 - 3) The serological test used for syphilis and the result.
 - 4) The required storage temperature
 - 5) The identification number

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- 6) The expiration date
 - 7) The ABO and Rh types in conspicuous lettering. Subsections (b) and (c) of this Section shall be followed.
 - 8) The results of tests for significant unexpected antibodies (see subsection (d) of this Section).
 - 9) The nonreactive results of an FDA approved test for Hepatitis B antigen.
 - 10) The name and address of the facility which conducted the tests.
 - 11) The following instructions and cautions:
 - A) The requirement for administration only to recipients who have been demonstrated compatible by crossmatch.
 - B) The need for a filter.
 - C) No medication shall be added to the blood prior to or during a transfusion.
 - D) A statement of the possible presence of the agent of viral hepatitis (see Section 450.830 (c)(10)(A))
 - E) Federal law prohibits dispensing without a prescription.
 - F) Mix thoroughly before transfusion.
 - G) Do not vent plastic containers.
- b) Determination of ABO type
ABO type shall be determined by testing the red blood cells with anti/A and anti/B serums which meet United States Food and Drug Administration (FDA) standards (21 CFR 600-680)(1986), and by testing the serum or plasma for expected antibodies with a pool of known type A (or single subtype A 1) and known type B cells. The blood shall not be released unless the tests are in agreement.

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- c) **Routine determination of Rh type**

The Rh type shall be determined with anti/Rh o (D) typing serum which meets FDA standards (21 CFR 600-680)(1986). If the blood is typed as Rh o (D) negative, it shall be tested using a technique designed to detect Rh o variants (D u). Routine testing for additional blood types is not recommended. The label shall indicate:

 - 1) Rh positive when the red cells are reactive for Rh o (D) or Rh o variants (D u).
 - 2) Rh negative when the red cells are nonreactive for Rh o (D) and Rh o variants (D u).
- d) **Test for detecting antibodies**
 - 1) All donor blood shall be tested for both expected and unexpected antibodies. This shall be done with Reagent Red Blood Cells that meet FDA standards (21 CFR 600-680)(1986), and are intended for this use.
 - 2) Methods of testing for unexpected antibodies shall be those that will demonstrate hemolyzing, agglutinating, and coating antibodies.
 - 3) Blood in which significant unexpected antibodies have been detected should not be used unless transfused as Red Blood cells. (see Section 450.848(b))
- e) **HIV Testing**
 - 1) All donor blood shall be tested for evidence of infection with HIV by using a test approved by the United States Food and Drug Administration (FDA) (e.g. an enzyme-linked immunosorbent assay (ELISA)). A unit of blood which is found to be reactive by two or three ELISA tests (according to the package insert – product circular) shall not be used for transfusion or for production of components for transfusion or injection. All units of blood which are found to be reactive shall be retested using a confirmatory test approved by FDA or the Department (e.g. Western blot assay or Indirect Fluorescent Antibody tests).

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- 2) In the event that blood is transfused before completion of the tests for evidence of HIV infection and if the tests are subsequently confirmed positive, the recipient's physician must be notified within 24 hours.
- 3) A donor whose blood has yielded a positive confirmatory result (e.g. Western blot assay or Indirect Fluorescent Antibody tests) shall be notified of that test result in accordance with the following requirements in Section 450.840 (e)(4).
- 4) Notification Requirements:
 - A) The donor shall be advised to contact the facility which conducted the testing for an appointment to discuss the results of the tests. If initial notification is made by mail, the correspondence must be general in nature (e.g. no references to specific diseases or test procedures shall be made). If the donor does not respond to the initial notification by mail, or if the donor chooses not to use such initial notification procedures, the donor shall be advised through certified mail with restricted delivery, messenger or personal visit to contact the facility which conducted the testing for an appointment to discuss the test results.
 - B) The medical director of the facility which conducted the testing or the medical director's designee who is knowledgeable about HIV infection including the possible medical and psychosocial aspects of such infection shall be available for a scheduled appointment with the donor at the earliest possible date requested by the donor and shall present and explain the results of HIV testing only in a person to person interview;
 - C) If the donor has not contacted the facility which conducted the testing for an appointment as described in Section 450.840 (e)(4)(A) above or if the donor has failed to follow through with the scheduled appointment, the confirmed test results(s) shall be sent to the donor by certified mail with restricted delivery, messenger or personal visit accompanied by explanatory and referral information which has been provided by the Department or

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equivalent information;

- D) The above-described available test results shall be released to the donor or the donor's physician no later than 55 days after the date of donation;
 - E) If the donor expressly so requested in writing and provides the name and address of his or her physician, the results shall be sent to the physician by certified mail;
 - F) HIV test results shall be treated as confidential and shall be disclosed as authorized in writing by the donor or as otherwise authorized by the AIDS Confidentiality and Testing Code, 77 Ill. Adm. Code 697.140.
- f) Serological test for syphilis
An FDA approved serological test for syphilis shall be made on a specimen of the blood (21 CFR 600-680)(1986). The blood shall not be used for transfusion unless the test is negative. Blood may be issued in an emergency situation without performing a serological test for syphilis provided the label and the records so indicate. An emergency situation is one which requires the transfusion of blood in order to preserve life prior to the completion of the required tests. If the test is subsequently positive, the recipient's physician shall be notified.
- g) Test for Hepatitis B antigen (HB Ag)
All donor blood shall be tested for HB Ag using reagents and technics specified by FDA (21 CFR 600-680)(1986). The unit of whole blood or blood component shall not be used for transfusion unless the test is nonreactive. In an emergency, blood may be transfused before completion of the test for Hepatitis B antigen. An emergency situation is one which requires the transfusion of blood in order to preserve life prior to the completion of the required tests. If the test is subsequently positive, the recipient's physician shall be notified. The medical director shall be responsible for notification of the donor and/or the donor's physician of a positive test for Hepatitis B antigen.
- h) Repeat testing
Determination of the ABO and Rh types shall be repeated whenever the facility performing the compatibility test is not affiliated with the collecting facility.

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Discrepancies shall be resolved before issue of the blood for transfusion purposes. The other tests required by this section do not have to be repeated.

- i) Previous records
A donor's previous record of ABO and Rh types shall not serve for identification of units of blood subsequently given by the same donor; new determinations shall be made for each collection.
- j) Retention of blood samples
All pilot samples shall be stored at 1 to 6 degrees Centigrade for at least seven days after transfusion or expiration date of the blood. When the blood is discarded the pilot tube need not be saved.
- k) Laboratory records
The actual results observed with each test as well as the final interpretation shall be recorded.
- l) Control of serologic testing
 - 1) Equipment
The temperature of water baths, heating blocks, Rh view boxes and incubators should be checked daily. Centrifuges used for serologic testing and for separation of blood components shall be calibrated periodically to determine optimum time and force required to produce desired results. (See Subpart E of this Part).
 - 2) Reagents
All antisera and test cells of each lot of each shipment shall be evaluated periodically to demonstrate their capacity to detect the corresponding antigens and antibodies. (See Subpart K of this Part).

Section 460.150 Directed Blood Donations

- a) *Each blood bank licensed under the Blood Bank Act and each hospital licensed under the Hospital Licensing Act shall allow a recipient of blood to designate a donor of his choice under the following conditions:*
 - 1) *The recipient or someone on his behalf, has solicited the donors;*

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- 2) *The designated donor consents to such donation;*
- 3) *The designated donor's blood may be obtained in sufficient time to meet the health care needs of the recipient;*
- 4) *The designated donor is qualified to donate blood under the Criteria for Donor Selection (See Section 460.130 and 77 Ill. Adm. Code 450.830); and*
- 5) *The blood of the donor is acceptable under the requirements of Section 460.140 and for the patient's medical needs.*
- b) *Blood donated for such designated use shall be reserved for the designated recipient; however, if it has not been used within 7 days from the day of donation, it may be used for any other medically appropriate purpose as determined by the blood bank director or hospital consistent with this Part.*
- c) This section shall not limit other procedures blood banks or hospitals may establish to enable directed donations.
- d) This Section is automatically repealed as of September 21, 1989.

SUBPART C: PURCHASED BLOOD

Section 460.410 Justification and Charting Requirements for the Transfer and Administration of Purchased Blood – Effective July 1, 1973

- a) Effective July 1, 1973, "purchased" blood may be acquired and transferred for transfusion purposes in Illinois in the following instances:
 - 1) There is no potentially compatible donor available other than from an individual whose blood group and Rh type qualifies him for listing on the recognized rare donor registries.
 - 2) The attending physician explicitly directs the transfusion service to acquire purchased blood for any reason.

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- b) In either of the situations described in paragraph (a)(1) above, the attending physician must comply with Section 5, para. 1 of the Act, which states:

After July 1, 1973, no blood initially acquired by purchase may be administered by transfusion in Illinois unless:

- 1) *The physician in charge of the treatment of the patient to whom the blood is to be administered has directed that such purchased blood be administered to that patient, and*
- 2) *The physician has specified in the patient's medical record his reason for such action*

c)

- 1) Records of transfusions administered by the utilization of "purchased" blood shall be recorded in separate blood bank records and available to the Department for review. This separate record shall contain the following information:
 - A) Unit identification number;
 - B) Date of collection;
 - C) Blood group and Rh type;
 - D) Reason for purchase.
- 2) Neither the attending physician nor the recipient need be identified in these records.

- d) Falsification or manipulation of situations involving the utilization of purchased blood for transfusion purposes in Illinois shall imply a violation of the intent of this Act.

SUBPART D: HIV CONTAMINATED BLOOD

Section 460.500 Handling and Disposal of HIV Contaminated Blood

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- a) *Any blood or blood components showing exposure to HIV* as evidenced by two or three reactive ELISA test results (according to the package insert – product circular) *or any other identified causative agent of AIDS* or originating from a patient diagnosed with AIDS or AIDS-Related Complex (ARC) as defined in 77 Ill. Adm. Code 693.20, *shall be disposed of* in accordance with the provisions of this Section, *unless a research facility licensed by the state requests, in writing, the use of such blood for AIDS research.* (Section 3.1 of the Act.) Any such blood or human tissue shall be disposed of in accordance with Section 460.500 (b) when no longer being used for research purposes.
 - 1) A research facility, for the purposes of this Section, shall mean any clinical laboratory licensed under the Clinical Laboratory Act (Ill. Rev. Stat. 1987, ch. 111½, par. 621 et seq.), any blood bank licensed under the Illinois Blood Bank Act (Ill. Rev. Stat. 1987, ch. 111½, par. 601-101 et seq.) or any hospital licensed under the Hospital Licensing Act (Ill. Rev. Stat. 1987, ch. 111½, par. 142 et seq.).
 - 2) *Any person delivering such blood or blood components to research facilities pursuant to such a request shall file with the Department a report which shall include at least the following information:*
 - A) *a copy of the request for blood or blood components;*
 - B) *the quantity of blood or blood components delivered;*
 - C) *the name and location of the research facility to which the blood or blood components was delivered; and*
 - D) *the date and time of delivery.* (Section 620-3.1 of the Act.)
- b) Any such blood or blood components or any materials or paraphernalia exposed to or contaminated by such blood or blood components shall be disposed of in accordance with the following provisions:
 - 1) Cultures and specimens to be discarded, and all other potentially infectious materials, shall be completely incinerated or sterilized or sealed in order to render the materials innocuous before disposal or removal from the premises.

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- 2) The incineration of materials shall be done in accordance with the requirements of the Illinois Environmental Protection Agency concerning the operation of an incinerator. (35 Ill. Adm. Code 700).
- 3) The sterilization of materials shall be done by autoclaving the materials in accordance with the manufacturer's recommendations, and the effectiveness of the autoclave shall be verified and documented at least weekly with a biological spore assay containing *B. stearothermophilus*.
- 4) The disposal or removal of materials outside of the facility shall be done in the following manner:
 - A) Incinerated or sterilized materials shall be disposed of through routine waste disposal methods without precautions against possible contamination.
 - B) Materials which have not been incinerated or sterilized shall be disposed of by a waste hauler with a proper permit from the Illinois Environmental Protection Agency. (35 Ill. Adm. Code 809). The materials which have not been sterilized must be sealed, transported and stored in biohazard containers. These containers shall be marked "Biohazard", bear the universal biohazard symbol, and be orange, orange and black or red. The containers shall be rigid and puncture resistant such as a secondary metal or plastic can with a lid that can be opened by a step-on-pedal. These containers shall be lined with one or two high density polyethylene or polypropylene plastic bags with a total thickness of at least 2.5 mil. or equivalent material. The containers which are marked "Biohazard" shall be sealed before being removed from the laboratory.