DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED REPEALER

1) Heading of the Part: Illinois Blood Bank Code

2) Code Citation: 77 Ill. Adm. Code 490

3)

Section Numbers:	Proposed Action:
490.10	Repeal
490.20	Repeal
490.30	Repeal
490.40	Repeal
490.210	Repeal
490.220	Repeal
490.230	Repeal
490.310	Repeal
490.320	Repeal
490.330	Repeal
490.410	Repeal
490.420	Repeal
490.430	Repeal
490.440	Repeal
490.510	Repeal
490.520	Repeal
490.610	Repeal
490.620	Repeal
490.710	Repeal
490.720	Repeal
490.730	Repeal
490.740	Repeal
490.750	Repeal
490.760	Repeal
490.770	Repeal
490.780	Repeal
490.790	Repeal
490.810	Repeal
490.820	Repeal
490.830	Repeal
490.840	Repeal
490.910	Repeal
490.APPENDIX A	Repeal
490.EXHIBIT A	Repeal
490.EXHIBIT B	Repeal

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4) Statutory Authority: Illinois Blood Bank Act [210 ILCS 10]

5) A Complete Description of the Subjects and Issues Involved: The Illinois Blood Bank Code is being repealed because its statutory authority, the Illinois Blood Bank Act, was repealed by Public Act 87-1269. Blood banks are 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 does not create a state mandate.

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

DEPARTMENT OF PUBLIC HEALTH

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(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 Repealer begins on the next page:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED REPEALER

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER d: LABORATORIES AND BLOOD BANKS

PART 490
ILLINOIS BLOOD BANK CODE

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490.10 Definitions
490.20 Application and License
490.30 Blood Banks required to be Licensed
490.40 Incorporated Materials

SUBPART B: DIRECTORS OF BLOOD BANKS

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490.220 Operational Participation of the Director
490.230 Number of Blood Banks Permitted to Operate

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Section
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490.520 Preventive Maintenance of Equipment and Instruments

SUBPART F: PROFICIENCY TESTING AND INSPECTION OF FACILITIES

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490.770 Preparation of Blood Components
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SUBPART H: PROHIBITED PRACTICES

Section
490.810 Terms Not to be Used in Names of Blood Banks
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SUBPART I: RECORDS

490.910 Records

490.APPENDIX A License Application for Blood Banks
490.EXHIBIT A Initial License Application for Blood Banks

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED REPEALER

490.EXHIBIT B Renewal License Application for Blood Banks

AUTHORITY: Implementing and authorized by the Illinois Blood Bank Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 601-101 et seq.).

SOURCE: Adopted at 13 Ill. Reg. 14409, effective September 1, 1989; repealed at 39 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL

Section 490.10 Definitions

"Accredited Institution" or "Accredited College or University" means a college or university located in the United States which has been accredited by one of the regional accreditation programs recognized by the U.S. Commissioner of Education or a college or university located outside the United States where the individual provides documentation that the individual's education is equivalent to that provided in the United States by: documenting that the foreign degree has been accepted by an accredited institution in the United States at which the person is or was enrolled in a graduate program; or having the individual's credentials evaluated by the Credentials Evaluation Service, Inc., Los Angeles, California.

"Act" means the Illinois Blood Bank Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 601-101 et seq. as now and hereafter amended.)

"Approved Blood Bank" means, for purposes of personnel qualifications, a blood bank directed by a physician licensed to practice medicine in the state in which the blood bank is located and which is licensed by FDA (21 CFR 600-680)(1987).

"Approved Clinical Laboratory" means, for purposes of personnel qualifications, a clinical laboratory – with a director at the doctoral level – of a hospital, health department, university, medical research institution; or a clinical laboratory licensed under the Illinois Clinical Laboratory Act (Ill. Rev. Stat. 1987, ch. 111½, par. 621-101 et seq.); or a blood bank licensed under the Blood Bank Act; or a clinical laboratory licensed under the Clinical Laboratories Improvement Act of 1967 (42 U.S.C. 201 et seq. as amended by the Clinical Laboratory Amendments of 1988, P.L. 100-578, October 31, 1988) or, a clinical laboratory approved under 42 CFR 405, Subpart M, (1987).

"Demonstration of proficiency" means the blood bank meets the standards for acceptable proficiency testing as stated in Section 490.620(f) by means of on-site analysis of specimens sent to the blood bank by agencies approved by the Department for that purpose (See Section 490.620 of this Part).

"Department" means the Illinois Department of Public Health.

"Drawing Station" means a facility in a permanent location under the direction of licensed blood bank only for the collection and transient storage of blood prior to shipment to a licensed blood bank for processing, distribution, and/or administration of blood or its component parts.

"FDA" means the Food and Drug Administration.

"Full-time experience" means experience in the field being referred to consisting of a least 35 hours per week conducting activities required by the specific position or field such biological, microbiological, serological, chemical, immunohematological, radioimmunological, hematological, biophysical, cytological, pathological, toxicological or other examination of materials derived from the human body for the purposes of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of, the health of humans including determining drug use by humans, shall constitute acceptable experience.

"Hospital Licensing Act" means the Hospital Licensing Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 142 et seq. as now and hereafter amended).

"Illinois Clinical Laboratory Act" means the Illinois Clinical Laboratory Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 621-101 et seq. as not and hereafter amended.)

"Medical Practice Act of 1987" means the Medical Practice Act of 1987 (Ill. Rev. Stat. 1987, ch. 111, pars. 4400-01 et seq., as now and hereafter amended).

"Physician" means a person licensed in Illinois to practice medicine in all of its branches.

"Technician" means an individual who meets the educational and experience

requirements set forth in Section 490.430 of this Part and who functions only under the direct supervision of a director, supervisor or technologist.

"Technologist" means an individual who meet the educational and experience requirements set forth in Section 490.420 of this Part and who performs tests requiring the exercise of judgment and responsibility with minimal supervision by the director or supervisor only in those areas of testing in which the technologist is qualified by education, training and experience.

Section 490.20 Application and License

a) All applications shall be submitted on forms provided by the Department; shall be signed by the owner(s) or authorized officer(s) of the corporation and the director(s) and shall be notorized and include all information requested on the form (See Appendix A, Exhibits A and B of this Part).

b) If during the one year period for which the license or renewal thereto has been issued, there is a change of owner, location, or name of the blood bank, the Department shall be notified in writing at least 10 days prior to such change or the license application shall require an initial application fee.

c) If a license is to be issued to an individual or two or more persons who are co-owners, all such persons shall be identified upon the application for license and all such persons shall sign the application and it shall be notarized.

d) An application for a license, where the owner is a corporation, shall clearly disclose all persons or other entities owning 5% more of the shares in the corporation. An authorized officer(s) of the corporation shall sign the application and it shall be notarized.

e) A program and services form shall be completed to permit the Department to determine the fields of science represented by the services of the blood bank and the tests performed.

f) Licenses may be revoked for the causes set forth in Article IV and Article VIII of the Act. All hearings and appeals shall be conducted in accordance with the procedures set forth in Article VIII of the Act and the Department's Rules of Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100). Any

person holding 5% or more of the ownership in a blood bank and was convicted or violated Section 8-101 of the Act, shall constitute grounds for denial or revocation of a license.

Section 490.30 Blood Banks required to be Licensed

a) The following are required to be licensed pursuant to the Act:

1) all blood banks located within the State of Illinois except as otherwise provided in subsection (b) of this Section; and

2) blood banks located in hospitals licensed under the Hospital Licensing Act but in which the blood bank is not operated by the governing authority of such hospital, including blood banks operating under a lease arrangement with another entity.

b) The following are not required to be licensed under the Act:

1) blood banks operated by the United States Government;

2) blood banks located in hospitals licensed under the Hospital Licensing Act which are operated by the governing board of such hospitals, owned by the exact same entity identified as owner/operator of the hospital as indicated on the last hospital license application filed with the Department, located at the same site and contiguous with the hospital, subject to the regulations and hospital by-laws, and where the entity which receives payment for blood bank services is the same entity that owns the hospital; and

3) places used as drawing locations for mobile unit collections by a licensed blood bank on a temporary basis, and not as a regularly constituted substation of the blood bank, provided, they are used only for the collection and the transient storage of blood prior to shipment to a licensed blood bank.

Section 490.40 Incorporated Materials

The following materials are incorporated or referenced in this Part:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED REPEALER

a) State of Illinois Statutes

1) Illinois Clinical Laboratory Act (Ill. Rev. Stat. 1987, par. 621-101 et seq. as amended by P.A. 85-1025, effective June 30, 1988; P.A. 85-1202, effective August 25, 1988; P.A. 85-1251, effective August 30, 1988.)
(Section 490.10)

2) Illinois Blood Bank Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 601-101 et seq.)
(Section 490.10)

3) Hospital Licensing Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 142 et seq.)
(Section 490.10)

4) Medical Practice Act of 1987 (Ill. Rev. Stat. 1987, ch. 111, pars. 4400 et seq.)
(Section 490.10)

5) Blood Labeling Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 620-1 et seq.)
(Section 490.330(f)(1))

6) The Illinois Nursing Act (Ill. Rev. Stat. 1987, ch. 111, pars. 3501 et seq.)
(Section 490.440(b))

b) State of Illinois Regulations:

1) 35 Ill. Adm. Code 307
(Section 490.330(d)(5))

2) 35 Ill. Adm. Code 724
(Section 490.330(e)(3))

3) 35 Ill. Adm. Code 809
(Section 490.330(e)(3)(C))

4) 77 Ill. Adm. Code 450
(Sections 490.750(d)(3) and 490.750(d)(4))

5) 77 Ill. Adm. Code 697
(Sections 490.720(d)(1) and 490.750(b)(4)(F))

c) Federal Guidelines, Statutes, and Federal Regulations:

1) 42 CFR 405, Subpart M (1988)
(Section 490.10)

2) 21 CFR 600-800 (1988)
(Section 490.10)

3) 21 CFR 606
(Section 490.710(e), 490.740, 490.910(a) and 490.750(a))

4) 21 CFR 610
(Section 490.750(a))

5) 21 CFR 640
(Section 490.720(c)(2)(B), 490.730(a), 490.760(b), 490.770 and 490.780)

6) Laboratory Personnel Qualification Appraisal Form Health Care Financing Authority (HCFA)
HCFA-3084-OMB No. 0938-0049
(See Section 490.410(b), 490.420(a), 490.430 and 490.440)

7) Standard for Blood Bank and Transfusion Services, 13th Edition (1989) American Association of Blood Banks, 1117 N. Nineteenth Street, No. 600, Arlington, VA, 22209 (Section 490.610(c) and 490.760(a)(5)

d) All incorporations by reference of federal regulations and the standards of nationally recognized organizations refer to the regulation and standards on the date specified and do not include any additions or deletions subsequent to the date specified.

SUBPART B: DIRECTORS OF BLOOD BANKS

Section 490.210 Qualifications of the Blood Bank Director

The Director of a blood Bank must be:

a) a physician certified or determined board eligible by the American Board of Pathology or the American Osteopathic Board of Pathology in Clinical Pathology and has completed not less than one year of post-graduate training and experience in blood banking methods in an approved blood bank, or

b) a physician who has completed not less than two years of post-graduate training and experience in blood banking methods in an approved blood bank with at least one year in a supervised trainee ("Resident", "Fellow", or similar) status, or

c) any individual who is director of an independent blood bank on July 1, 1988 (effective date of P.A. 85-279), may continue as medical director of that blood bank.

Section 490.220 Operational Participation of the Director

a) The blood bank director must be present in the blood bank each week and follow the weekly schedule established by the director to assess the activities of the blood bank by personnel observation, evaluation, and review of reports and procedures; except for absences due to emergencies, illness, or professional meetings. In case of an absence for vacation or other purposes which does not exceed 30 days, the owner shall ensure director coverage by designating an acting director who is qualified to direct that blood bank.

b) In case of an absence which is more than 30 days, the owner shall designate an acting director to direct the blood bank in the directors' absence who meets the qualifications set forth in Section 490.120 of this Part. The owner shall submit to the Department immediately after 30 days has elapsed, a personnel form for the acting director. The acting director may continue to function as director for a period of 90 days after the Laboratory Personnel Qualification Appraisal Form (See Section 490.40 (c)(6)) is received. This individual may be the same individual designated in accordance with Section 490.230(a) or another individual.

c) An acting director may not serve as director for a period of time exceeding 120 days, 90 days after the personnel form was received by the Department, unless a

new license application is submitted to the Department to change the acting director to director.

Section 490.230 Number of Blood Banks Permitted to Operate

a) The medical director of a blood bank shall not direct more than three blood banks and/or laboratories. This limitation does not preclude a director from serving additional blood banks as a consultant, general supervisor, or acting director. Blood bank drawing stations licensed under this Act do not count with respect to this limitation (See Section 6-103 of the Act).

b) The medical director of a blood bank must actively participate in the activities and programs of the blood bank; therefore, attendance of brief duration sufficing only for signature of reports or other nominal administrative duties will not constitute compliance with Section 6-103 of the Act.

SUBPART C: LOCATION, CONSTRUCTION, SANITATION, AND SAFETY

Section 490.310 Location

Before approval, each initial license application and each license application for a change of location shall be accompanied by a letter from the blood bank owner indicating that the owner has checked with a zoning authority having jurisdiction and the zoning authority has found that the blood bank location meets local requirements or will meet local requirements within a time frame acceptable to the zoning authority. If no zoning authority has jurisdiction, the letter shall state that fact and the license shall state that fact.

Section 490.320 Conformance to Local Ordinances

Before approval, each initial license application and each license application for a change of location shall be accompanied by or followed within 90 days by a letter from the blood bank owner indicating that the blood bank has been inspected and approved by local authorities to ensure that the blood bank meets applicable building safety and plumbing codes, fire codes, ordinances, or by-laws. If there are no local codes, ordinances or by-laws relating to plumbing, the owner shall submit documentation that the blood bank premise has been inspected and approved by a State license plumber within the last year.

Section 490.330 Safety and Sanitation

The blood bank director shall establish a Safety and Sanitation Manual. This manual shall be consistently implemented throughout the facility and contain signed or initiated documentation that it has been reviewed at least annually to ensure that the requirements of this Part are met. The manual shall include, but need not be limited to the following items.

a) General Sanitation and Safety with respect to:

1) minimum clearance in passageways to assure that exit from and access to the blood bank are not impeded;

2) the selection of and the schedule for the use of cleaning supplies for floors, walls, ceilings, bench tops, and sinks;

3) hand washing protocol;

4) requiring that all items which are disposed of and which can cut or puncture the skin shall be placed in containers which are impervious to the flow of liquids, rigid to prevent the container from collapsing when handled in the blood bank, and puncture proof to prevent needles from penetrating the container;

5) safe storage, transport, and use of compressed gases which includes the requirements that each cylinder is shipped with a valve safety cover which shall remain in place when regulators are not attached; that gas cylinders shall be secured at all times; and that empty containers shall be labeled and removed from the laboratory;

6) requiring that smoking, eating, and drinking shall be prohibited in all areas where laboratory work is performed;

7) requiring that mouth pipeting shall be prohibited;

8) requiring that all electrical outlets shall be grounded, electrical equipment be maintained in condition to prevent shock and fire hazards, and protective fuses not be bypassed; and

9) requiring that all blood letting and collection devices shall be both sterile

and disposable.

b) Warning signs shall indicate "Hazardous Materials" (radioactive, flammable, poison, irritant, carcinogen, etc.) with precautions in the use and storage of those materials.

c) Fire prevention and control with respect to:

1) the use of open flames, flammables, safety cans, safety cabinets, etc.;

2) requiring that a fire extinguisher of the CO_2 or dry chemical type shall be in the blood bank;

3) actions to be taken in case of fire; and

4) requiring that provisions for unimpeded egress from the building shall be posted.

d) Chemical and radiation hazards with respect to:

1) maintenance of a list of all chemicals used in the laboratory categorized as corrosive, flammable, toxic, carcinogenic, explosive, radioactive, and mutagenic;

2) actions to be taken in the event of an accidental break or spill;

3) ventilation in accordance with the kinds of chemical fumes encountered;

4) storage requirements for chemicals which are caustic, poisonous, flammable, carcinogenic, etc.;

5) requiring that wastes discharged to any sewer shall be in accordance with the general requirements for liquids, solids, or gases as well as specific requirements for mercury and cyanide as established by the Illinois Environmental Protection Agency (35 Ill. Adm. Code 307).

6) safe use of radioactive materials, if used in the laboratory, by having a registration certificate from and validated by the U.S. Nuclear Regulatory

Commission or a license from the U.S. Nuclear Regulatory Commission for the use of radioactive materials.

e) Biological hazards with respect to:

1) handling of specimens to avoid infection by air, ingestion, direct inoculation, and skin contact;

2) providing biological safety hoods and other appropriate barriers (i.e. plastic gloves) in accordance with the types of organisms encountered; and

3) disposal of cultures, specimens, and other potentially infectious materials which shall be completely incinerated or sterilized or sealed in a container as indicated below to render the materials innocuous before disposal or removal from the premises.

A) 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 724).

B) 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.

C) The disposal or removal of materials outside of the facility shall be done in the following manner:

i) Incinerated or sterilized materials shall be disposed of through routine waste disposal methods without precautions against possible contamination.

ii) 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). These materials 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 and 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 or blood bank.

f) Handling and Disposal of HIV Contaminated Blood and Human Tissue

1) *Any blood* or blood components, organs, semen or other human tissue *showing exposure to HIV* as evidenced by two of 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 Blood Labeling Act, Ill. Rev. Stat. 1987, ch. 111½, par. 620-3.1) Any such blood or human tissue shall be disposed of in accordance with Section 490.330(f) (2) when no longer being used for research purposes.

A) A research facility, for the purposes of this Section, shall mean any clinical laboratory licensed under the Illinois Clinical Laboratory Act, any blood bank licensed under the Blood Bank Act or any hospital licensed under the Hospital Licensing Act.

B) *Any person delivering such blood* or blood components, organs, or semen or other human tissue *to research facilities pursuant to such a request shall file with the Department a report which shall include at least the following information:*

i) *a copy of the request for blood* or human tissue;

ii) *the quantity of blood* for human tissue *delivered*;

iii) *the name and location of the research facility to which the blood* or human tissue *was delivered;* and

iv) *the date and time of delivery*. (Section 620-3.1 of The Blood Labeling Act.)

2) Any such blood and blood components or human tissue, or any materials or paraphernalia exposed to or contaminated by such blood and blood components or human tissue shall be disposed of in accordance with the provisions of subsection (e) of this Section.

SUBPART D: QUALIFICATIONS OF PERSONNEL

Section 490.410 General Supervisor – Laboratory

a) Duties
There shall be at least one qualified medical director or supervisor on the blood bank premises during all hours of laboratory operation. In the absence of the director, the supervisor shall supervise technical personnel and reporting of findings, perform tests requiring special scientific skills commensurate with education, training, and experience of the individual and be held responsible for the proper performance of all procedures. During periods of time when the blood bank is open for emergencies only, a director or supervisor is not required to be on the premises provided a qualified technologist (Section 490.420 of this Part) performs the emergency work and director or supervisor who is responsible for the work reviews and documents the review during the next duty period when the blood bank is open to provide other than emergency work or within 24 hours. An emergency shall be determined by the medical director or his physician designee. There shall be a written policy defining an emergency.

b) An individual who meets one of the following qualifications shall qualify as general supervisor. These qualifications must be documented on the Department's form entitled "Laboratory Personnel Qualifications Appraisal" (See Section 490.40 (c)(6)).

1) The individual is a physician licensed to practice medicine in all of its branches or has an earned doctoral degree from an accredited institution in a medical laboratory science such as microbiology and clinical chemistry and subsequent to graduation has had at least 1 year of full-time experience in one of the laboratory specialties in an approved clinical blood bank.

2) The individual has a Master of Arts or Master of Science degree from an accredited institution in a medical laboratory science such as microbiology or clinical chemistry and subsequent to graduation has had at least 1 year of full-time laboratory experience in an approved blood bank.

3) The individual is qualified as a medical technologist pursuant to the provisions of Section 490.420 of this Part. If the individual qualifies as a medical technologist because the individual has successfully passed the United States Public Health Service exam, that individual shall have an associate degree or at least 60 semester hours of academic credit from an accredited institution, including at least 12 semester hours in chemistry and biology courses. Subsequent to the date of qualifying as a medical technologist, the individual shall have at least four years of pertinent full-time laboratory experience in an approved clinical laboratory.

c) Exception to Section 490.410(b)
An individual serving as general supervisor of a blood bank laboratory on September 15, 1970 and having had at least 15 years of pertinent laboratory experience prior to September 15, 1970 may continue to serve as supervisor of said laboratory: provided, that a minimum of 30 semester hours credit toward a Bachelor's degree with a chemical or biological science as the major subject shall reduce the required years of experience by 2 years, with an additional hours further reducing the required years of experience at the rate of 15 hours for 1 year.

Section 490.420 Medical Technologist

a) An individual who meets one of the following qualifications shall qualify as a technologist. These qualifications must be documented on the Department's form entitled "Laboratory Personnel Qualifications Appraisal" (See Section 490.40 (c)(6)).

1) The individual has an earned Bachelor's degree in Medical Technology from an accredited college or university.

2) The individual has successfully completed 3 academic years of study (a minimum of 90 semester hours or equivalent) in an accredited college or university which meets the specific requirement for entrance into, and successful completion of a course of training of at least 12 months, in a school of medical technology accredited by one of the agencies recognized by the U.S. Office of Education for the accreditation of training programs for medical technologists, as distinguished from training programs for medical laboratory technicians.

3) The individual has an earned Bachelor's degree from an accredited college or university in one of the chemical or biological sciences and in addition at least 1 year of laboratory experience and/or training in an approved blood bank or clinical laboratory (See 77 Ill. Adm. Code 450.10).

4) The individual has successfully completed 3 years (90 semester hours or equivalent in quarter hours) in an accredited college or university with a distribution of courses as shown below, and, in addition, successful experience and/or training covering several fields of medical laboratory work of such length (not less than 1 year), and of such quality that this experience or training in an approved blood bank or approved clinical laboratory (See 77 Ill. Adm. Code 450.10). The specified courses must have included lecture and laboratory work. Survey courses are not acceptable.

   A) For those whose training was completed prior to September 15, 1963: Academic training must include at least 24 semester hours in chemistry and biology courses of which not less than 9 semester hours must have been in chemistry and must have included at least 6 semester hours in inorganic chemistry, and not less than 12 semester hours must have been in biology courses pertinent to the medical sciences.

   B) For those whose training was completed after September 15, 1963. Academic training must include 16 semester hours in chemistry courses which must have included at least 6 semester hours in

general chemistry and the remaining semester hours in analytical chemistry, organic chemistry and/or physical chemistry and which are acceptable toward a major in chemistry; 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in biological sciences; and 3 semester hours of mathematics.

b) An exception to the requirement of subsection (a) of this Section will be made if an individual who has successfully passed the United States Public Health Service exam in order to qualify under Medicare and Medicaid as a Clinical Laboratory Technologist provides documentation to the Department.

Section 490.430 Technician

An individual who meets one of the following qualifications shall qualify as a technician. These qualifications must be documented on the Department's form entitled "Laboratory Personnel Qualification Appraisal." (See Section 490.40 (c)(6)). The individual:

a) has successfully completed 60 semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution or has an associate degree based on a course of study including those subjects from an accredited institution; or

b) is a high school graduate or equivalent such as a General Education Degree (GED), and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by the U.S. Office of Education; or

c) is a high school graduate or equivalent such as a General Education Degree (GED), and has successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and has held military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

Section 490.440 Phlebotomy and Patient Care Personnel

a) A phlebotomist must be a high school graduate with documentation that the individual has completed a training program for proper patient care in blood drawing as established in writing by the medical director.

b) Patient Care Personnel
A medical director or a registered nurse licensed under The Illinois Nursing Act of 1987 (Ill. Rev. Stat. 1987, ch. 111, pars. 3501 et seq.) shall be physically present when blood or blood components are infused or reinfused into an individual. The medical director shall have a written policy which states the availability of adequate medical care.

SUBPART E: EQUIPMENT

Section 490.510 Facilities and Equipment

The blood bank must document that the physical facilities, equipment, and instruments are in proper operating condition for performance of the procedures and tests for which the blood bank is requesting a license (See Subpart C of this Part).

Section 490.520 Preventive Maintenance of Equipment and Instruments

a) Preventative Maintenance Program

1) The blood bank must establish a written preventive maintenance program for each piece of equipment. The program shall be documented and implemented on a regularly scheduled basis (i.e. at least semi-annually). It shall provide for instrument function verification and equipment maintenance.

2) The preventive maintenance programs shall at minimum coincide with the manufacturer's recommendations.

b) Service Contract

1) A service contract from an outside source for preventive maintenance is acceptable, provided there is a description of the services to be performed for each piece of equipment or instrument and a statement of the frequency of maintenance to be performed.

2) A service contract does not negate the blood bank's responsibility to perform other routine maintenance as required by the written program.

3) The blood bank must maintain records of preventive maintenance whether performed by the blood bank staff or by an outside source.

c) Specific Laboratory Equipment

1) Automatic dilutors and samplers, except those checked by use of a calibrator or reference material included in each run, shall be checked for accuracy and reproducibility at least once per month.

2) A serum/cell calibration shall be performed on a serofuge when first put into operation and after any adjustments or repairs which affect the speed, or balance during the operation of the instrument. Accuracy of the timer and RPM shall be checked at least quarterly.

3) Volumetric glassware (pipets, flasks) that is not designated "class A" by the manufacturer, shall be calibrated to confirm its designated volume.

4) Thermometer readings for temperature controlled spaces and instruments shall be recorded each day of use.

5) All thermometers in the blood bank shall be checked against a reference thermometer (certified by the National Bureau of Standards or guaranteed by the manufacturer to meet the National Bureau of Standards criteria) before being placed into use and annually thereafter.

6) Donor scales shall be checked for accuracy each day of use.

7) Glassware shall be free from scratches and cloudiness, and graduations shall be legible. "To contain" and "to deliver" pipettes shall be separated.

8) Analytical balances shall be checked for accuracy at least annually, and accuracy of weights verified by using "Class A Weights".

SUBPART F: PROFICIENCY TESTING AND INSPECTION OF FACILITIES

Section 490.610 Inspections

a) All blood banks subject to licensure shall be open to inspection by representatives of the Department during regular business hours unless otherwise directed. The premises and operation of all blood banks shall be inspected to study and evaluate the effect of the location, operation, supervision and procedures of such facilities on the health and safety of the people of this State. Routine inspections will be made annually and may be announced or unannounced. These inspections may include on-site review of records and reports pertaining to the technical operations of the blood bank.

b) The Department may submit forms such as check lists to be completed by the director of the blood bank in advance of inspection in situations, such as but not limited to, changes in key personnel of the blood bank, changes in ownership, or additons to testing procedures offered in the testing menu of the blood bank. These forms shall include questions, such as but not limited to, relating to the construction, sanitation, equipment, procedures, and records which will be reviewed by the Department and will assist it in making inspections to determine compliance with the Act and this Part.

c) A blood bank which elects to be accredited by the American Association of Blood Banks will routinely be inspected by the Department every other year, provided the blood bank director notifies the Department in writing prior to the first day of March of the interim year, that the American Association of Blood Banks has or will inspect that blood bank during that calendar year. Such inspections will be conducted using the "Standards for Blood Banks Transfusion Service;" (See Section 490.40(c)(7) of this Part). The blood bank director shall make provisions to send to the Department, within 60 days after the inspection by the American Association of Blood Banks, a copy of the inspection report and an indication of deficiencies found. If the Department does not receive an inspection report for the interim year, that blood bank will be inspected annually by the Department.

Section 490.620 Proficiency Survey Program

a) The Department shall require the "demonstration of proficiency" in the performance of each test performed by the blood bank by means of State-operated or State/approved proficiency testing programs. The Department shall exclude some specific tests from this requirement when the proficiency testing is not available.

b) Requirements for Testing Service Approval

1) The State-approved proficiency testing service must cover all specialties and subspecialties in which the blood bank performs tests as they are made available and are proven feasible for proficiency testing.

2) The approved proficiency testing service must provided to the Department an annual list of subscribers among Illinois blood banks authorizing the proficiency testing service to report their proficiency testing results to the Department.

3) The approved proficiency testing service must supply exception reports (cumulative survey management reports-cumulative deviancy reports) covering at least the immediately previous two years of testing and documenting the unsatisfactory results during that minimum two year period. This report must be continuously updated with each new testing period and must be made available to both the participating blood bank and to the Department after each testing period.

4) The approved proficiency testing service must provide at least the following statistical parameters: mean or median, standard deviation or coefficient of variation, and some discussion and/or indication of accuracy and precision.

5) The approved proficiency testing service must document, in writing, the bases for establishing acceptable limits of performance. This documentation must be supplied to the Department and to each participating blood bank at least annually and must cover each test for which proficiency testing is provided. The yearly revision must include all changes made in the criteria for acceptable performance which are to prevail for the ensuing year.

6) The approved proficiency testing service must provide proficiency testing materials to blood banks not less than four times a year.

c) A list of the State-approved proficiency testing programs may be obtained from the Department of Public Health.

d) The costs of such State-approved proficiency testing must be borne by the blood bank.

e) The laboratory shall keep on file a copy of the results of proficiency testing for review by the State laboratory evaluators.

f) Requirements For Blood Bank Testing

1) The participating blood bank must test applicable materials each time they are distributed by the approved proficiency testing service.

2) Those procedures performed by the blood bank for which test materials are provided by the approved proficiency testing service and which are not excluded by the Department from the "demonstration of proficiency" requirement must be proficiency tested by the participating blood bank each time test materials are received.

3) The participating blood bank must authorize the approved proficiency testing service to report proficiency test results to the Department.

4) The participating blood bank must test applicable materials only in the blood bank to which the license and the proficiency testing requirement applies, using personnel and equipment used in that facility in providing services.

5) A blood bank shall be required to discontinue providing a service in a procedure or category of procedures (hematology, chemistry, bacteriology-mycology, parasitology, immunology-serology, immunohematology, etc.) if:

A) For two consecutive testing periods the blood bank fails to report on test materials received for procedures for which the blood bank is required to be proficiency tested, or

B) For two consecutive testing periods the blood bank demonstrates unsatisfactory performance in a procedure or category of procedures. A determination of satisfactory performance for a procedure for a testing period shall be based upon all results being

within acceptable limits established by the proficiency testing service for that procedure and approved by the Department. A determination of satisfactory performance for a category of procedures shall be based upon 75% or more of the results in that category over three consecutive testing periods being within acceptable limits established by the proficiency testing service and approved by the Department.

6) A blood bank whose services have been disapproved because of unsatisfactory performance shall be reapproved by the Department to provide these services after meeting one of the following conditions, provided that proficiency testing is the only problem preventing reapproval.

A) The blood bank results for an unsatisfactory discontinued procedure shall be within acceptable limits established by the proficiency testing service for two consecutive testing periods subsequent to the testing periods which resulted in the discontinuance of the procedure. The blood bank results for a disapproved category of procedures shall have 75% or more of the results within acceptable limits established by the proficiency testing service for two consecutive testing periods subsequent to the testing periods which resulted in discontinuance of the category of procedures.

B) On-site Testing

i) The blood bank director may request that the Department provide proficiency testing specimens for purposes of retesting. The cost of such proficiency testing specimens shall be borne wholly by the blood bank. The Department shall ship or cause to be shipped, hand carry or otherwise convey to the blood bank such proficiency testing specimens within three weeks after receipt of such request. The Department shall provide an on-site visit by a laboratory evaluator for the purpose of determining deficiency correction.

ii) Successful analysis (100% of specific analysis or 75%of the results of a category are within acceptable limits as established by the testing service) shall be based upon test results of specimens similar in number and purpose to those normally received by the blood bank where performance has been judged unsatisfactory.

iii) Successful analysis and site visit findings shall be used to reapprove either a category of procedures or a given procedure.

g) Renewal of license may be denied for failure to maintain an acceptable standard of proficiency in the program and services provided by a blood bank (See Section 490.620(f) of this Part).

SUBPART G: BLOOD BANK PROCEDURES

Section 490.710 General

a) The definition of a "blood bank" is interpreted to include facilities operating or located in Illinois, fixed or mobile, used for the collection, processing, storage, distribution, and/or administration of human blood or any of its derivatives prior to transfusion including plasma, packed red blood cells, platelets, or leukocytes. (See Section 490.30 of this Part)

b) Any changes in the program or services of a blood bank shall be reported to the Department in writing within 30 days. This includes the discontinuance or addition of a service as well as a change in the use of any reference or research facility by the blood bank.

c) All phases of the selection of blood donors and of the collection, storage, processing, and administration of blood or blood components shall be the responsibility of the medical director.

d) Provisions for medical care and hospital services for donors who sustain adverse reactions shall be established by written policy.

e) A written standard operating procedure manual shall be maintained and followed

and shall include all steps in the collection, processing, compatibility testing, storage and distribution of blood and blood components for homologous and autologous transfusion purposes in accordance with FDA standards (21 CFR 60.100)(1987).

Section 490.720 Donors and Donor Blood – Criteria for Donor Selection

The following rules shall be applied on the day of donation by trained persons and results shall be recorded (See Section 490.440 of this Part).

a) The following requirements shall apply to determine donor suitability.

1) Prospective donors with a history of chronic disease of the heart, kidneys, lungs, liver, etc.; or with a history of cancer, except minor skin cancer; or abnormal bleeding tendencies; shall be excluded subject to evaluation by a physician on the day of donation.

2) The interval between individual donations shall be at least 8 weeks.

3) The amount of whole blood (not including anticoagulant) removed from a donor during a plasmapheresis procedure or in any 48-hour period, shall not exceed 1,000 ml unless the donor's weight is 80 kg (176 pounds) or greater. If the donor's weight is 80 kg or greater, the amount of whole blood removed during a plasmapheresis procedure or in any 48-hour period shall not exceed 1,500 ml. Within a 7-day period, the amount of whole blood removed shall not exceed 2,000 ml. unless the donor's weight is 80 kg (176 pounds) or greater, in which case it shall not exceed 2,400 ml.

4) Whole blood donations shall be deferred for at least 48 hours after plasmapheresis.

b) 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. (See subsection (c) of this Section).

c) If the following requirements are not met, the donor shall be rejected.

1) General Appearance
The donor shall appear to be in good health and free from acute respiratory diseases.

2) Age
Blood donor shall be between the ages of 17 through 75 (up to 76th birthday) provided:

A) that the donor is 17 years of age or older

B) 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 they meet all other criteria for acceptability (See Section 490.40(c)(5) of this Part).

3) Temperature
The oral temperature shall not exceed 99.6 degrees Fahrenheit (37.5 degrees Centigrade)

4) Hemoglobin or hematocrit

The measurement of either value is acceptable.

A) The hemoglobin shall be no less than 12.5 grams per dl.

B) The hematocrit value shall be no less than 36 percent for females, and no less than 38 percent for males.

5) Pulse
The pulse shall reveal no pathological cardiac irregularity and shall be between 50 and 100 beats per minute.

6) Blood Pressure
The systolic blood pressure shall be between 90 and 180 mm of mercury, and the diastolic shall not exceed 100 mm of mercury.

7) Pregnancy

Known existing pregnancy shall preclude donation. A prospective donor shall be excluded for 6 weeks postpartum.

8) Receipt of blood or blood components
Prospective donors who during the preceding six months have received blood or human blood components known to be a possible source of hepatitis, shall be excluded.

9) Infectious Diseases
A donor shall be free from infectious diseases known to be transmissible by blood insofar as can be determined by usual examinations and history as indicated below.

A) Viral Hepatitis

i) Prospective donors with a history of viral hepatitis shall be excluded.

ii) A prospective donor shall be excluded permanently if the donor's blood was the only unit of blood or blood component administered to a patient who within six months developed posttransfusion hepatitis and who received no other blood derivative known to transmit vital hepatitis and there was no other probable source of infection.

iii) A prospective donor shall be excluded permanently if the donor has a history of a reactive test for hepatitis B surface antigen.

iv) 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 blood bank physician.

B) Travelers who have been in areas considered endemic for malaria by the Malaria Branch, Centers for Disease Control, U.S.

Department of Health and Human Services, may be accepted as regular blood donors six months after return to the nonendemic area, providing they have been free of unexplained febrile illnesses 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 antimalarial prophylaxis or who have been 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 derivatives devoid of intact red blood cells are exempted from these restrictions.

C) Syphilis
A donor whose blood tests positive for syphilis shall be rejected. Prospective donors may be acceptable when they become seronegative upon approval by the blood bank medical director.

D) Tuberculosis
Prospective donors with clinically active tuberculosis are unacceptable. Prospective donors with a positive tuberculin skin test, but without underlying medical conditions, may be accepted if they have not taken prophylactic medication during the preceding 48 hours.

E) HIV Infection

i) 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 490.750(b).

ii) 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.

10) Immunizations or vaccinations:

A) Persons recently immunized with toxoids and killed virus, bacterial and rickettesial vaccines are acceptable, if they are symptom-free and afebrile. These include vaccines against hepatitis B, tetanus, diphtheria, pertussis, typhoid, paratyphoid, cholera, typhus, Rocky Mountain spotted fever, influenza, polio (injection) and plague. The same rules apply for rabies vaccine (duck embryo or human diploid) unless the vaccination has been given following a bite by a rabid animal in which case the donor is deferred until 1 year after the bite.

B) After vaccination for smallpox, donors are acceptable when the scab has fallen off or 2 weeks after an immune reaction. Following inoculation with attenuated virus vaccines such as polio (oral), measles (rubeola), mumps or yellow fever, donors are deferred for 2 weeks; following inoculation for German measles (rubella), deferral is for 4 weeks.

C) Prospective donors shall be deferred for 12 months after receiving Hepatitis B Immune Globulin (HBIG).

11) Donor skin
The skin at the venipuncture site shall be free of lesions and no tattoo was performed any place on the body within six months prior to donation.

12) Alcohol, narcotics
Obvious stigmata of narcotic or alcoholic habituation or intoxication shall exclude a donor.

13) Oral medication
History of recent drug therapy shall 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.

14) 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 blood bank medical director shall decide whether the person will be bleed in the blood bank. The use of this blood for transfusion purposes shall be determined by the physician in charge of the blood bank and of the physician attending the prospective recipient.

15) 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, except that it is not necessary to reduce the amount of anticoagulant calculated for 450 ml of blood when the amount of blood drawn is 300 ml to 405 ml. Prospective donations of blood exceeding the recommended amounts shall be subject to evaluation by a physician.

16) Medical discretion
Any of the above criteria may be waived or modified by the medical director and the donor's physician, for certain medical indications related to the therapy of the donor.

d) 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 AIDS Confidentiality Act Ill. Rev. Stat 1987, ch. 111½, par. 7301 et seq.) 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 HIV 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 virus must not donate blood, except for the purpose 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 than 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 the HIV infected-persons;

C) males who have 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 490.750(b) of this Part.

Section 490.730 Collection of Blood

a) The collection of blood from the donor shall meet FDA standards (21 CFR 640) (1987).

b) Directed Blood Donations
Pursuant to Section 7-106 of the Blood Bank Act:

1) *Each blood bank licensed under the Blood Bank Act shall allow a recipient of blood to designate a donor of his choice under the following conditions*:

A) *the recipient or someone on his behalf, has solicited the donors*;

B) *the designated donor consents to such donation*;

C) *the designated donor's blood may be obtained in sufficient time to meet the health care needs of the recipient*;

D) *the designated donor is qualified to donate blood under the criteria for donor selection promulgated by the Department of Public Health under the Blood Labeling Act;*

E) *the blood of the donor is acceptable* under the requirements of Section 490.750 and *for the patient's medical needs*.

2) *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.

3) This Section shall not limit other procedures blood banks may establish to enable directed donations.

Section 490.740 Labeling

Containers holding finished products from the blood bank for infusion into humans shall be labeled in accordance with FDA standards (21 CFR 606)(1987).

Section 490.750 Laboratory Testing

All laboratory testing shall be performed on a pilot sample specimen of blood taken from the donor at the time of collection of the unit of blood and before the blood or blood components leave the blood bank. The required tests are listed below.

a) Testing for syphilis, blood grouping, Rh factors, and hepatitis B surface antigen shall be performed in accordance with FDA standards (21 CFR 610.40 and 640.5)(1987). Testing for HTLV-1 shall be performed, using a test licensed by the FDA, in accordance with the instructions accompanying the test kit. Blood or blood components intended for transfusion purposes, shall not leave the blood bank unless the tests for HTLV-1, syphilis and hepatitis B surface antigen are negative, unless, an exception is made in accordance with FDA standards (21 CFR 606.121 and 640.2)(1987). The test for HTLV-1 shall be included in the exceptions made in accordance with these FDA standards.

b) HIV Testing

1) All donor blood shall be tested for evidence of infection with the HIV virus 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 of 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 and shall be disposed of in accordance with Section 490.330 of this Part. 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).

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 either verbally or in writing, by the medical director of the blood bank or the blood bank director or his designate.

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 subsection (b)(4) of this Section.

4) Notification Requirements:

A) The donor shall be advised to contact the blood bank 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 blood bank 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 blood bank for an appointment to discuss the test results.

B) the medical director of the blood bank 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 blood bank for an appointment as described in subsection (b)(4)(A) of this Section above or if the donor has failed to follow through with the scheduled appointment, the confirmed test result(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;

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.

c) Western Blot Assay Testing Procedure
All laboratories which conduct the Western blot assay shall comply with following requirements.

1) Western blot assay Testing Procedures

A) Western blot assay kits licensed by the United States Food and Drug Administration (FDA) shall be performed on specimens which have been found to be repeatably reactive using the enzyme-linked immunosorbent assay (ELISA) test. The laboratory shall perform a Western blot assay test to determine reactivity with viral polypeptides in accordance with manufacturer's recommendations or package insert.

B) When a Western blot assay kit that is not licensed by the FDA is utilized, the testing procedure must be able to demonstrate and reproduce in a second demonstration at least the viral polypeptides in accordance with recommendations of the Centers for Disease Control, Association of State and Territorial Public Health Laboratory Directors, or American Association of Blood Banks.

C) Western blots must have clear backgrounds and lack non-specific banding; and all banding should be distinct and uniform as well as reproducible.

D) The final blots of non-licensed kits must be examined to determine if the antibodies reacted specifically with HIV polypeptides. Western blot interpretations shall be consistent with the manufacturer's recommendations or package insert.

2) Laboratory Certification and Quality Control

A) The laboratory prior to using any given lot of a non-licensed Western blot kit, shall test all lot material with control sera consisting of negative (no reaction), weakly positive (some reaction but not strong), and positive (strong, very noticeable reaction) sera. The laboratory shall ensure that the reagent lots are correctly identified with the above control sera. Any and all reagents not meeting the laboratory's specified criteria established in accordance with the quality control system methodologies in Subpart K of the Illinois Clinical Laboratory Code (77 Ill. Adm. Code 450 Subpart K) shall not be utilized for testing.

B) The laboratory shall maintain internal viral Western blot quality control for all Western blot assays. All internal Western blot quality control results shall be maintained by the laboratory for review by the Department.

C) The laboratory shall participate in at least one proficiency testing program for ELISA and Western Blot screening and supplemental testing for viral antibodies offered by the College of American Pathologists, the American Association of Bioanalysts, or the Department. A copy of all proficiency testing evaluation reports shall be made available for review by the Department.

d) Records – Quality Control

1) Records shall be maintained concurrently with performance of each laboratory procedure so steps can be clearly traced.

2) 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.

3) Equipment
The temperature of water baths, heating blocks, Rh view boxes and incubators shall be checked daily to determine that the temperature meets the requirements set forth in the procedure manual (See 77 Ill. Adm. Code 450, Subpart J). Centrifuges used for serologic testing and for separation of blood components shall be calibrated to determine optimum time and force. (See Subpart E of this Part).

4) Quality Control
All laboratory procedures performed in the blood bank shall meet all applicable requirements of 77 Ill. Adm. Code 450, Subpart K.

Section 490.760 Blood Storage

a) Refrigerators and Freezers

1) The refrigerator compartment in which blood is stored shall contain only blood, blood components donor samples, or blood bank reagents. It shall be provided with a fan for circulating air.

2) Refrigerators and freezer for storage shall have a system to monitor temperature continuously and to record the temperature at least every 4 hours.

3) Whole Blood or non-frozen Red Blood Cell components shall be stored in a refrigerator with the sensor for the temperature recording system in a container holding no more than 250 ml of liquid with heat transfer characteristics similar to those of the blood and blood container (i.e. 10% glycerol in water).

4) Alarm systems with audible signals shall be on all refrigerators and freezers. The alarm systems shall be set to activate when the temperature falls outside the acceptable 1 to 6 degrees Centigrade range.

5) Written procedures shall delineate actions to be taken when a refrigeration system fails to maintain blood or blood components within the specified temperature range (See Section 490.40(c)(7) of this Part).

b) Temperatures – containers – expiration dates
Expiration date is the last day on which the blood or blood component is considered useful for transfusion purposes. Whole blood, red blood cells, frozen red blood cells, washed and deglycerolized red blood cells, leukocyte poor red blood cells, single donor plasma, platelet concentrate, and any other blood component shall be stored within temperature ranges, in containers, and used before expiration dates as specified by Food and Drug Administration (FDA) (21 CFR 640)(1987).

c) Reissue of blood

1) Blood which has been returned to the blood bank shall not be reissued unless the following conditions have been met.

A) The container closure has not been disturbed.

B) The blood has been continuously refrigerated at 1 to 10 degree Centigrade (preferable 1 to 6 degrees Centigrade).

C) Blood bank records indicate that the blood has been reissued.

D) The pilot tube or segment has remained attached to the container if the blood has left the premises of the issuing facility.

2) If the blood has remained on the premises of the issuing facility, a removed pilot tube may be reidentified by the originally attached label and number which shall correspond with the number on the container.

Section 490.770 Preparation of Blood Components

Preparation of red blood cells, frozen red blood cells, deglycerolized red blood cells, leukocyte poor red blood cells, washed red blood cells, liquid plasma, fresh frozen plasma, cryoprecipitated AHF, platelet concentrate, granulocyte concentrate, and any other preparation separated from single units of whole blood and intended for use as final products for transfusion shall follow preparation, storage, and expiration date requirements as specified by FDA (21 CFR 640)(1987).

Section 490.780 Hemapheresis, Also Known as Plasmapheresis

a) Hemapheresis procedures for which the donor is paid, shall be performed only when a physician is physically present and repsonsible for all phases of hemapheresis. All other hemapheresis procedures shall be performed only when emergency medical care is available within 15 minutes. The medical director shall develop a written protocol specifying how emergency medical care will be available if an emergency should arise.

b) Criteria of selection and care of the donors shall be those for whole blood donations. (See Section 490.720 of this Part). Hemapheresis of donors who do not meet the donor requirements shall be performed only when a physician who is aware of the health status of the donor has certified in writing that the donor's health permits hemapheresis.

c) The consent of a prospective donor or parent or legal guardian shall be obtained after a physician or other medical director's designee explains the hazards of the procedure to the prospective donor in such a manner that he is offered an opportunity to refuse consent.

d) Donor suitability, hemapheresis procedures, donor immunization, and laboratory testing shall meet the requirement specified by FDA (21 CFR 640)(1987).

e) Therapeutic hemapheresis

1) The medical director of the blood bank, in consultation with the patient's physician, shall decide if the procedure is to be performed, the appropriate location, replacement fluids to be used, and the need for special life-support procedures.

2) There shall be a written procedure manual which describes the procedures used, as outlined in 21 CFR 640 (1987). Records shall contain patient identification, date and time when the procedure is performed, diagnosis, therapeutic procedure, hemapheresis method, amount of blood removed and returned, replacement fluids used, adverse reactions, and any medication administered.

Section 490.790 Autologous Blood and Blood Components

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED REPEALER

Blood or blood components for autologous use shall meet all requirements established under Subpart G of this Part for blood for transfusion purposes, except that a blood bank may provide blood for autologous use when the blood or blood product is positive for hepatitis B surface antigen or syphillis only upon the written, signed and dated request of the patient's physician who is licensed to practice medicine in all of its branches.

SUBPART H: PROHIBITED PRACTICES

Section 490.810 Terms Not to be Used in Names of Blood Banks

The term "certified", "approved", "qualified", or any other comparable term, indicating departmental endorsement of the blood bank, shall not be incorporated in the name of any blood bank, nor shall such terms be used in connection with any blood bank.

Section 490.820 Prohibitions in Advertising and Announcements

Since licensing under the provision of the Act does not imply approval but serves merely as notice to the Department of the location of facilities and the character of program and services, there shall be no reference in any advertisement or announcements expressing or implying approval by the Department.

Section 490.830 Acceptance of Specimens and Reporting of Results

No blood bank shall accept specimens or report results except as provided in Sections 7-101 and 7-102 of the Act.

Section 490.840 Referral of Specimens for Examination

All specimens accepted by a blood bank shall be tested on its premises. However, specimens for infrequently performed tests or confirmatory tests or tests related to non-immunohematologic processing of blood for transfusion may be forwarded for examination to another blood bank licensed under this Act, or to a clinical laboratory licensed under the Illinois Clinical Laboratory Act, or to any blood bank specifically exempt from the Act (See Section 7-103 of the Act).

SUBPART I: RECORDS

Section 490.910 Records

a) Records shall be maintained concurrently with the performance of each step in the collection, processing, compatibility testing, storage and distribution of each unit of blood or blood component in accordance with FDA standards (21 CFR 606, Subpart I)(1987).

b) Complete records in regard to each specimen examined shall be kept on file in the blood bank for not less than five years. Such records shall contain:

1) Laboratory number or other identification of the specimen;

2) The name or other means of identification of the person from whom the specimen was taken;

3) The name of the licensed physician or other authorized person, clinical laboratory, or blood bank submitting the specimen;

4) The date the specimen was collected and the date the specimen was received in the blood bank;

5) When a specimen is forwarded to another clinical laboratory or blood bank for tests, the name, the date when the specimen was forwarded to such laboratory or blood bank, the date it was tested, and the date the report of the findings of the test was received from such laboratory or blood bank;

6) In case the specimen is an unsatisfactory specimen, the condition of the specimen when received;

7) The types and numbers of tests performed annually; and

8) The result of the test conducted by the blood bank, the method used, the signature of the examiner.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED REPEALER

Section 490.APPENDIX A License Application for Blood Banks

Section 490.EXHIBIT A Initial License Application for Blood Banks

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
DIVISION OF LABORATORIES
2121 WEST TAYLOR STREET
CHICAGO, ILLINOIS 60612

INITIAL LICENSE APPLICATION FOR BLOOD BANKS

1. APPLICATION DATE: _____ / _____ / _____
Month Date Year

2. FACILITY IDENTIFICATION

A. _____
Name of Laboratory

B. _____
Address (Number and Street)

C. _____
Address (City, State, Zip Code)

D. Telephone Number: _____ / _____

E. County: _____
Area Code

F. Hours of Operation: M ____ to ____ : T ____ to ____: W____ to ___:
Th ____ to ____ : F ____ to ____ : Sa ____ to ____: Su ___ to ___.

3. OWNERSHIP

A. Check the appropriate box below:

☐ Individual ☐ Partnership* ☐ Corporation** ☐ Trust

☐ County ☐ Township ☐ City ☐ Other _____

DEPARTMENT OF PUBLIC HEALTH

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Specify

B. List owner(s), title, and address below. Use an additional sheet if necessary.
*Partnership – Provide names of all partners and percent of interest.
**Corporation – Provide corporate name, names of officers and all stockholders owning 5 percent or more of stock, with an indication of percent of stock owned. If no stockholder owns more than 5 percent, so indicate below.

EXACT NAME(S) OF OWNER(S) – IF A COPORATION PROVIDE EXACT CORPORATE NAME)	% INTEREST	ADDRESS

C. IF THE OWNER LISTED IN 3B IS A CORPORATION, INDICATE NAMES OF OFFICERS AND ALL STOCKHOLDERS OWNING 5% OR MORE OF STOCK	TITLE OF OFFICERS	ADDRESS

4. PERSONNEL – MEDICAL DIRECTOR(S)

A. The director(s) must BE PRESENT in the blood bank EACH WEEK of operation, except for defined absences. Provide the name of each blood bank director and

indicate his/her weekly regularly scheduled hours in the blood bank. A personnel form is required for each director. Use an additional sheet if necessary.

LAST NAME	FIRST NAME	HOURS e.g. 8AM – 11AM						
		M	T	W	Th	F	Sa	S

B. For each medical director, list each laboratory or blood bank (hospital, independent, or industrial) which he/she is associated with as director. Use an additional sheet if necessary.

LAST NAME OF DIRECTOR	NAME OF FACILITY	ADDRESS OF FACILITY

5. PERSONNEL – SUPERVISOR(S)

List the name of each blood bank supervisor and indicate his/her scheduled hours in this blood bank. Use an additional sheet if necessary. A personnel form must be submitted for each supervisor.

LAST NAME	FIRST NAME	HOURS e.g. 8AM – 11AM						
		M	T	W	Th	F	Sa	S

6. PERSONNEL OTHER THAN DIRECTORS OR SUPERVISORS

List the names of all technical personnel employed by this blood bank other than directors or supervisors. Use an additional sheet if necessary. A personnel form must be submitted for each individual. Use the codes below to indicate how each employee is functioning.

T = technologist TE = technician C = consultant P = phlebotomist PC = patient care

LAST NAME	FIRST NAME	INITIAL	FUNCTIONING AS:				
			T	TE	C	P	PC

7. PROGRAM AND SERVICES

Complete the attachment entitled "Program and Services". In accordance with Section 3-103 of the Illinois Blood Bank Act, the Department will issue a license to the applicant to operate a blood bank to provide the services and programs described in the application if the Department is satisfied that the applicant has complied with the provisions of the Illinois Blood Bank Act and rules and regulations pertaining thereto.

In accordance with Section 3-105 of the Illinois Blood Bank Act, you are required to notify the Department of any changes in the program or services within 30 days after the changes take place.

8. INFORMATION ITEM

A. PROFICIENCY TESTING INFORMATION

Regulations require the demonstration of proficiency in the performance of tests performed by the blood bank by means of participating in State-operated or State-approved proficiency testing programs. The Department recognizes the following as State-approved proficiency testing programs.

DEPARTMENT OF PUBLIC HEALTH

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1. College of American Pathologists
5202 Old Orchard Road
Skokie, IL 60077-1034
Phone: (312) 966-5700

2. American Association of Bioanalysts
205 West Levee
Brownsville, Texas 78520
Phone: (800) 544-3081

B. SECTION 3-106 OF THE ILLINOIS BLOOD BANK ACT

"A license to conduct a blood bank shall be issued to the owner for the premises stated in the application. The owner shall be responsible for the provision at all times of laboratory direction by a Medical Director who meets the provisions of this Act and the rules and regulations pertaining thereto: for notifying the Department prior to any change in the medical directorship; and for forwarding necessary documentation to the Department to establish that the Medical Director is qualified to direct that blood bank. The owner shall be responsible to the Department for the maintenance and conduct thereof or for any violations of the provisions of this Act obtained for each location. A license shall be valid only in the possession of the persons to whom it is issued and shall not be a subject of sale, assignment or transfer, voluntary or involuntary nor shall a license be valid for any premises other than those for which the license is issued. However, a new license may be secured for the new name, location or owner prior to the actual change provided the contemplated change Appendix A License Application for Blood Banks is in compliance with the provisions of this Act and regulations pertaining thereto. The fee for the issuance of such new license shall be $100."

9. AFFIDAVIT

State of _____ County of _____

The undersigned owner or authorized officer and blood bank medical director(s) of the facility described herein, being duly sworn on oath, depose(s) and say(s) that the statements contained in the foregoing application are true and correct to the best of _____ knowledge and belief; that no owner has been convicted of a felony or of any crime involving moral turpitude under the laws of any state or of the United States arising out of or in connection with the operation or a blood bank; and that _____ has (have) read and understand(s) this application and affidavit.

NAME TITLE

DEPARTMENT OF PUBLIC HEALTH

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Signature: _____

Type Name: _____ _____

Signature: _____

Type Name: _____ _____

Signature: _____

Type Name: _____ _____

Signature: _____

Type Name: _____ _____

Signature: _____

Type Name: _____ _____

Subscribed and sworn to
before me this ____ day
of _____, 19_____.

_____
Notary Public In and For Said State

NOTE:

This completed application along with the required license fee are to be returned to:

Fiscal and Management Services
Illinois Department of Public Health
Attn: Validation Unit
535 W. Jefferson Street
Springfield, IL 62761

DEPARTMENT OF PUBLIC HEALTH

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BLOOD BANK

PROGRAM SERVICES

BLOOD BANK NAME _____ DATE _____

A. Enter the annual volume on the lines to the left of each procedure performed.

B. Where requested, please provide the name of major pieces of equipment and the name of the manufacturer of equipment used in providing tests and services.

0210 Syphilis Serology

_____ 86592 VDRL, RPR, RST, ART

0220 Other Serology

_____ 86287 Hepatitis B antigen (HB_sAg)
_____ 86289 Hepatitis B antibody (anit-HBc)
_____ 86290 HIV antibody (anti-HIV)
_____ 86291 CMV antibody (anti-CMV)
_____ 86999 Unlisted immunology procedure (Briefly describe)

LIST MAJOR EQUIPMENT USED IN 0210 AND 0220 ABOVE

_____

_____

_____

_____

0310 Chemistry

_____ 84449 Alanine aminotransferase (ALT)
_____ 84460 Transaminase, glutamic pyruvic (SGPT)
_____ 84999 Unlisted chemistry procedures (Briefly describe)

LIST MAJOR EQUIPMENT USED IN 0310 ABOVE

_____

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_____

_____

0400 Hematology

_____ 85014 Hematocrit
_____ 85018 Hemoglobin
_____ 85999 Unlisted hematology (Briefly describe)

LIST MAJOR EQUIPMENT USED IN 0400

_____

_____

_____

0510 Blood Grouping

_____ 86080 Blood Typing, ABO
_____ 86082 Blood Typing, ABO and Rho(D)
_____ 86090 M+N typing
_____ 86095 Blood typing, RBC antigens other than ABO or Rho(D)
_____ 86105 Rh genotyping

0520 Antibody Identification

_____ 86008 Antibody, titer
_____ 86016 Antibodies, RBC, saline high protein

0530 Compatibility testing

_____ 86068 Blood crossmatch, complete (typing antibody screen-recipient and donor)
_____ 86075 Blood crossmatch, minor only

0540 Immunohematology, other

_____ 86031 Antihuman globulin test, direct (Coombs)
_____ 86032 Antihuman globulin test, (indirect Coombs)
_____ 86201 Cryoprecipitate, prep.

_____	86265	Frozen blood, prep.
_____	86346	Leukocyte poor blood, prep.
_____	86389	Plasmapheresis
_____	86392	Platelet concentrate
_____	86427	Red blood, cells, packed
_____	86500	Unlisted immunochematology procedure (Briefly describe)

LIST MAJOR EQUIPMENT USED IN 0510, 0530, AND 0540

_____

_____

_____

DIRECT PATIENT SERVICES (please list below)

_____

_____

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED REPEALER

Section 490.APPENDIX A License Application for Blood Banks

Section 490.EXHIBIT B Renewal License Application for Blood Banks

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
DIVISION OF LABORATORIES
2121 WEST TAYLOR STREET
CHICAGO, ILLINOIS 60612

RENEWAL LICENSE APPLICATION FOR BLOOD BANKS

1. DATE OF APPLICATION ____/____/____
Month Day Year

2. NAME/ADDRESS/HOURS OF OPERATION

A. If either the name or address on the mailing label above is incorrect, indicate corrections and effective date(s) below

Month Day Year

New Name Effective Date

/ /

New Address (Number and Street) Effective Date

New address (City, State, Zip Code)

B. Hours of Operation: M ____ to ____ : T ____ to ____: W____ to ____:
Th ____ to ____ : F ____ to ____ : Sa ____ to ____: Su ____ to ____.

3. OWNERSHIP

A. Check the appropriate box below:

☐ Individual ☐ Partnership* ☐ Corporation** ☐ Trust

DEPARTMENT OF PUBLIC HEALTH

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☐ County ☐ Township ☐ City ☐ Other _____

B. List owner(s), title, and address below. Use an additional sheet if necessary.

*Partnership – Provide names of all partners and percent of interest.
**Corporation – Provide corporate name, names of officers and all stockholders owning 5 percent or more of stock, with an indication of percent of stock owned. If no stockholder owns more than 5 percent, so indicate. License Application for Blood Banks

EXACT NAME(S) OF OWNER(S) – (IF A COPORATION, PROVIDE EXACT CORPORATE NAME	% INTEREST	ADDRESS

C. If the owner under 3B is a corporation, indicate names of officers and all stockholders owning 5% or more of stock

	TITLE OF OFFICES	ADDRESS

D. If a change in ownership (item 3B above) has occurred since the last license was issued, indicate below the effective date for that change.

_____
Month / Day / Year

E. List the names and addresses of other laboratories or blood banks located in Illinois which have the same ownership. If none, indicate N/A. Use additional sheets if necessary.

NAME	ADDRESS

4. PERSONNEL – MEDICAL DIRECTOR(S)

A. The director(s) must BE PRESENT in the blood bank EACH WEEK of operation, except for defined absences. Provide the name of each blood bank medical director and indicate his/her weekly regularly scheduled hours in the blood bank. Use an additional sheet if necessary.

LAST NAME	FIRST NAME	Hours e.g. 8 AM – 11 AM						
		M	T	W	Th	F	Sa	S

B. If a medical director has RESIGNED or has been HIRED after the last license was issued, list below his/her name and the effective date. A personnel form must be submitted when a director is hired. Use an additional sheet if necessary.

Name	Month	/ Day	/ Year

License Application for Blood Banks

C. For each medical director, list each laboratory or blood bank (hospital, independent, or industrial) which he/she is associated with as director. Use an additional sheet if necessary.

LAST NAME OF DIRECTOR	NAME OF FACILITY	ADDRESS OF FACILITY

5. PROGRAM AND SERVICES

Complete the attachment entitled "Program and Services". In accordance Exhibit B Renewal License Application for Blood Banks with Section 3-103 of the Illinois Blood Bank Act, the Department will issue a license to the applicant to operate a blood bank to provide the services and programs described in the application if the Department is satisfied that the applicant has complied with the provisions of the Illinois Blood Bank Act and rules and regulations pertaining thereto.

In accordance with Section 3-105 of the Illinois Blood Bank Act, you are required to notify the Department of any changes in the program or services within 30 days after the changes take place.

6. INFORMATIONAL ITEM

A. The Department recognizes the following as State-approved proficiency testing programs. Demonstration of proficiency by means of participation in State operated and/or State approved proficiency testing programs is required for laboratory tests performed by the blood bank.

1. College of American Pathologists
5202 Old Orchard Road
Skokie, IL 6007-1034
Phone: (312) 966-5700

2. American Association of Bioanalysts
205 West Levee
Brownsville, Texas 78520
Phone: 800-544-3081

B. SECTION 3-106 OF THE ILLINOIS BLOOD BANK ACT (EFFECTIVE JULY 1, 1988)

"A license to conduct a blood bank shall be issued to the owner for the premises stated in the application. The owner shall be responsible for the provision at all times of laboratory direction by a Medical Director who meets the provisions of this Act and the rules and regulations pertaining thereto: for notifying the Department prior to any change in the medical directorship: and for forwarding necessary documentation to the Department to establish that the Medical Director is qualified to direct that blood bank. The owner shall be responsible to the Department for the maintenance and conduct thereof or for any violations of the

provisions of this Act and regulations pertaining thereto. A separate license must be obtained for each location. A license shall be valid only in the possession of the persons to whom it is issued and shall not be a subject of sale, assignment or transfer, voluntary or involuntary, nor shall a license be valid for any premises other than those for which issued, or for any name of the blood bank other than that under which the license is issued. However, a new license may be secured for the new name, location or owner prior to the actual change provided the contemplated change is in compliance with the provisions of this Act and regulations pertaining thereto. The fee for the issuance of such new license shall be $100.

7. Affidavit

State of _____ County of _____

The undersigned owner or authorized officer and blood bank medical director(s) of the facility described herein, being duly sworn on oath, depose(s) and say(s) that the statements contained in the foregoing application are true and correct to the best of _____ knowledge and belief; that no owner has been convicted of a felony or of any crime involving moral turpitude under the laws of any state or of the United States arising out of or in connection with the operation or a blood bank; and that _____ has (have) read and understand(s) this application and affidavit.

	NAME	TITLE
Signature:	_____	
Type Name:	_____	_____
Signature:	_____	
Type Name:	_____	_____
Signature:	_____	
Type Name:	_____	_____
Signature:	_____	

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED REPEALER

Type Name: _____ _____

Signature: _____

Type Name: _____ _____

Subscribed and sworn to
before me this ____ day
of _____, 19_____.

Seal

NOTE:

This completed application along with the required license fee are to be returned to:

Fiscal and Management Services
Illinois Department of Public Health
Attn: Validation Unit
535 W. Jefferson Street
Springfield, Illinois 62761