**Section 490.APPENDIX A License Application for Blood Banks**

**Section 490.EXHIBIT A Initial License Application for Blood Banks**

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| 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 | | | | | | | | | | | |
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| 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 | | |  | | | | | | | | |
|  | 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| EXACT NAME(S) OF OWNER(S) – IF A COPORATION PROVIDE EXACT CORPORATE NAME) | | | | %  INTEREST | | ADDRESS |
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|  | 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 | |
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| 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 |
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|  | 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. | | | | | | | | | | |
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| LAST NAME OF DIRECTOR | | | | NAME OF FACILITY | | | | ADDRESS OF FACILITY | | | | |
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| 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 |
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| 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 |
|  |  | | | | | | | |
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| 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. |

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| 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. | | | |
|  |  | 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." | | | |

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| 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. | | | |

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|  | | NAME | | |  | TITLE |
| Signature: | |  | | |  |  |
| Type Name: | |  | | |  |  |
| Signature: | |  | | |  |  |
| Type Name: | |  | | |  |  |
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| Subscribed and sworn to  before me this \_\_\_\_ day  of \_\_\_\_\_, 19\_\_\_\_\_. | | | | | | |
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|  | | | | Notary Public In and For Said State | | |
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| 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 | | | |

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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 (HBsAg) | | | | | |
|  | | 86289 | |  | Hepatitis B antibody (anit-HBc) | | | | | |
|  | | 86290 | |  | HIV antibody (anti-HIV) | | | | | |
|  | | 86291 | |  | CMV antibody (anti-CMV) | | | | | |
|  | | 86999 | |  | Unlisted immunology procedure (Briefly describe) | | | | | |

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| LIST MAJOR EQUIPMENT USED IN 0210 AND 0220 ABOVE | | | | | |
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|  |  | | 0310 Chemistry | | |
|  | 84449 |  | Alanine aminotransferase (ALT) | |
|  | 84460 |  | Transaminase, glutamic pyruvic (SGPT) | |
|  | 84999 |  | Unlisted chemistry procedures (Briefly describe) | |

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| LIST MAJOR EQUIPMENT USED IN 0310 ABOVE | | | | | |
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|  |  | | 0400 Hematology | | |
|  | 85014 |  | Hematocrit | |
|  | 85018 |  | Hemoglobin | |
|  | 85999 |  | Unlisted hematology (Briefly describe) | |

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| LIST MAJOR EQUIPMENT USED IN 0400 | |
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|  |  | | 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 | |

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|  |  |  | 0520 Antibody Identification |
|  | 86008 |  | Antibody, titer |
|  | 86016 |  | Antibodies, RBC, saline high protein |

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|  |  | | 0530 Compatibility testing | |
|  | 86068 |  | Blood crossmatch, complete (typing antibody screen-recipient and donor) |
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|  | 86075 |  | Blood crossmatch, minor only |

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|  |  |  | 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) |

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| LIST MAJOR EQUIPMENT USED IN 0510, 0530, AND 0540 | |
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| DIRECT PATIENT SERVICES (please list below) | |
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**Section 490.APPENDIX A License Application for Blood Banks**

**Section 490.EXHIBIT B Renewal License Application for Blood Banks**

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| 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| New Name | | | | | | | | | | | | Effective Date | | | | | | | | | | | | | | | | | | |
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| New Address (Number and Street) | | | | | | | | | | | | Effective Date | | | | | | | | | | | | | | | | | | |
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|  | New address (City, State, Zip Code) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | B. | | Hours of Operation: | | | | | M |  | to | |  | : T | |  | to |  | | | : W | | |  | | to |  | | | : |
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| 3. | OWNERSHIP | | | | | | | | | | | | | | |
|  | A. | Check the appropriate box below: | | | | | | | | | | | | | |
|  |  |  | Individual | |  | Partnership\* | | |  | | Corporation\*\* | | |  | Trust |
|  |  |  | County |  | Township | |  | City | |  | | Other |  | | |

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|  | 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 |
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|  | 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 |
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|  | 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. | | | | | | | |
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|  |  | | | | 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 | | |
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| 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 | | | | | | | | | | |
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|  | 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 | | | | | | | | | |
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| 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. |

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| 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. | | |

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| 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: | | |  | | | |  | |  | |
| 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 | | | | |