**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.