**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).