§ 576. Duties and powers of the department. 1. The department may inquire into the operation of clinical laboratories and blood banks and may conduct periodic inspections and/or evaluations of facilities, methods, procedures, materials, staff and equipment to assess compliance with requirements set forth in this title, the regulations promulgated hereunder and local laws, codes or regulations as specified in subdivision three of section five hundred eighty of this title.

2. The department may require clinical laboratories and blood banks to submit, in a form prescribed by the department, periodic reports of tests performed and such other information as the department may require to carry out the provisions of this title. The department may adopt regulations to require clinical laboratories and blood banks to report all serious adverse incidents which may be connected to the clinical laboratory or blood bank services provided. Such incident reports shall be deemed confidential in the same manner as such reports submitted pursuant to section twenty-eight hundred five-m of this chapter. The department may also require clinical laboratories and blood banks to submit lists of personnel who are employed to perform laboratory procedures and to notify the department promptly of any changes in such personnel.

3. The department shall operate a reference system and shall prescribe standards for the proper operation of clinical laboratories and blood banks and for the examination of specimens. As part of such reference system, the department may review and approve testing methods developed or modified by clinical laboratories and blood banks prior to the testing methods being offered in this state, and may require clinical laboratories and blood banks to analyze test samples submitted by the department and to report on the results of such analyses. The rules and regulations of the department shall prescribe the requirements for the proper operation of a clinical laboratory or blood bank, for the approval of methods and the manner in which proficiency testing or analyses of samples shall be performed and reports submitted. Failure to meet department standards for the proper operation of a clinical laboratory or blood bank, including the criteria for approval of methods, or failure to maintain satisfactory performance in proficiency

testing shall result in termination of the permit in the category or categories of testing established by the department in regulation until remediation is achieved. Such standards shall be at least as stringent as federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight. Such failure and termination shall be subject to review in accordance with regulations adopted by the department.

4. (a) The department may adopt and amend rules and regulations to effectuate the provisions and purposes of this title. Such rules and regulations shall establish fees for clinical laboratories and blood banks in amounts not exceeding the cost of the reference system for clinical laboratories and blood banks and shall be subject to the approval of the director of the budget. For the purposes of this subdivision, standard federally established governmental cost allocation practices shall be used by the commissioner to determine the cost of the reference system. The department shall make available, on the department's website, information on the costs included in determining the permitted laboratories' fees. The department shall not deem as costs of the reference system, costs associated with federal grants and patents which are not related to the reference system. The fee paid by the department to maintain an exemption for clinical laboratories and blood banks from the requirements of the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight shall be deemed a cost of the reference system.

(b) In determining the fee charges to be assessed, the department shall, on or before May first of each year, compute the costs for the preceding state fiscal year which were expended to operate and administer the duties of the department pursuant to this title. The department shall, at such time or times and pursuant to such procedure as it shall determine by regulation, bill and collect from each clinical laboratory and blood bank an amount computed by multiplying such total computed operating expenses of the department by a fraction the numerator of which is the gross annual receipts of such clinical laboratory or blood bank during such twelve month period preceding the date of computation as the department shall designate by regulation, and the denominator of which is the total gross annual receipts of all

clinical laboratories or blood banks operating in the state during such period.

(c) Each such clinical laboratory and blood bank shall submit to the department, in such form and at such times as the department may require, a report containing information regarding its gross annual receipts for all activities performed pursuant to a permit issued by the department in accordance with the provisions of section five hundred seventy-five of this title. The department may require additional information and audit and review such information to verify its accuracy.

(d) Partial payments equal to one-quarter of the total amount billed, may be made on or before June thirtieth, September thirtieth, December thirty-first and March tenth of the fiscal year to which the billing relates.

(e) On or before September fifteenth of each year, the department shall reconcile its costs and expenses for the reference system for the preceding state fiscal year and shall, on or before October fifteenth send to each clinical laboratory and blood bank, a statement setting forth the amount due and payable by, or the amount computed to the credit of, such clinical laboratory or blood bank, computed on the basis of the above stated formula, except that for the purposes of such computation the fraction shall be multiplied against the total recomputed expenses of the department for such fiscal year. Any amount due shall be payable not later than thirty days following the date of such statement. Any credit shall be applied against any succeeding payment due.

(f) The commissioner may waive all or any part of such fee charges for clinical laboratories or blood banks operated by local governments and for nonprofit clinical laboratories or blood banks performing examinations and analyses or providing services under contract with the state or its local governments.

(g) Subject to the approval of the director of the budget, the commissioner shall charge adequate and reasonable fees for the periodic inspection of out-of-state clinical laboratories and blood banks, not exceeding the estimated additional costs incurred for out-of-state inspections under this title.

5. The department, within the amounts appropriated, may employ inspectors, investigators, assistants and other employees or may contract with the city of New York to carry out the provisions of this title, set the compensation of such employees, within limits provided by law, and prescribe the duties of such employees.

6. The commissioner may appoint one or more advisory committees of persons expert in the major categories of clinical laboratory procedures to advise the commissioner in connection with the qualifications of technical personnel employed and the use of appropriate procedures. Each such advisory committee shall include at least one designee of the commissioner of the department of health of the city of New York.

7. The department may adopt rules or regulations applicable only to or in the city of New York which are designed to address special needs or circumstances existing in such city. The department shall consider the recommendations of the city of New York, or the department or board of health of such city, concerning the adoption or amendment of any such rules or regulations.

8. The department may enter into agreements with the secretary of health and human services as authorized by the federal clinical laboratory improvement act of nineteen hundred eighty-eight and title XVIII of the social security act to perform such acts as may be necessary to assure conformance with such laws by laboratories operating in the state.