PART 19
CLINICAL LABORATORY DIRECTORS

(Statutory authority: Public Health Law, Section 573(1))

Sec.

19.1 Definitions
19.2 Clinical laboratory or blood bank; qualifications of laboratory director
19.3 Director of a clinical laboratory or blood bank; certificate of qualification
19.4 Denial of an application for a certificate of qualification

19.1 Definitions.
(a) Clinical laboratory director means the individual responsible for administration of the technical and scientific operation of a clinical laboratory or blood bank, including supervision of test procedures, the reporting of results, and the duties and responsibilities specified in section 19.3 of this Part.
(b) Acceptable laboratory means a clinical laboratory or blood bank of a hospital, health department, university, medical research institution, independent clinical laboratory or blood bank, or other facility providing equivalent training and/or experience in patient specimen testing, which has a director who meets or would meet the requirements of this Part and which meets or would meet the commissioner's standards as outlined in Part 58 of this Title.
(c) Accredited means having the approval (accreditation) conferred on schools, institutions or programs by an accrediting agency or agency or association recognized by the United States Secretary of Education and verified as such by the commissioner.
(d) Physician means a physician who is licensed and currently registered to practice medicine in New York State or in the state in which he or she practices.
(e) Dentist means a dentist who is licensed and currently registered to practice dentistry in New York State or in the state in which he or she practices.
(f) Certificate of qualification means a credential issued by the department to applicants meeting the requirements set forth in this Part.
(g) Grandfathered laboratory director means a laboratory director who qualified for and received a certificate of qualification in one or more categories of testing prior to the amendment of this regulation which became effective January 25, 1988.
(h) Category means an area, procedure, or specialty of laboratory medicine specified in section 19.3(d) of this Part.
(i) Blood banking-collection means collection of blood or blood components, or processing of blood or blood components.
(j) Referring physician means a physician or other person authorized by law to order laboratory tests and receive reports, as specified in Subpart 58-1 of this Title.
(k) Virology means isolation and other characterization of virus.
(l) Diagnostic immunology means application of immunologic techniques to detect the presence of antigens in biologic fluids and determine host-antibody responses.
(m) Transfusion service means a service which issues blood or blood components for administration into a person, but does not include a limited transfusion service, as defined in section 58-2.1(k) of this Title.
(n) Genetic testing means enzyme, substrate, and DNA-based analyses, or qualitative and/or quantitative measurement of other body analytes, undertaken to determine the genetic status (carrier or disease) of a person.

19.2 Clinical laboratory or blood bank; qualifications of laboratory director.
The director of a clinical laboratory or blood bank must possess training and/or experience, obtained within the previous six years, in generally accepted and currently used methods and techniques in one or more categories listed in section 19.3(d) of this Part, and must meet one of the following requirements:
(a) be a physician who is currently certified by the American Board of Pathology in:
   (1) clinical pathology; or
   (2) anatomic pathology; or
   (3) an area of special competence relevant to the certificate of qualification sought; or
(b) be a dentist who is currently certified by the American Board of Oral Pathology; or
(c) be a physician or hold an earned doctoral degree from an accredited institution with a relevant chemical, physical or biological science major, and:
   (1) is currently certified by:
      (i) the American Board of Medical Microbiology; or
      (ii) the American Board of Clinical Chemistry in clinical chemistry; or
      (iii) the American Board of Clinical Chemistry in toxicological chemistry; or
      (iv) the American Board of Forensic Toxicology; or
      (v) the American Board of Medical Laboratory Immunology; or
      (vi) the American Board of Internal Medicine in hematology; or
   (2) subsequent to receiving a doctor of medicine, doctor of osteopathy or earned doctoral degree has had, and has documented to the department, four years of training and/or experience in an acceptable laboratory, including two or more years of training and/or experience in methods and techniques currently in use in the certificate category or categories sought and in general laboratory management, or an equivalent combination of training and/or experience as verified by the commissioner.
(d) A transfusion facility director shall be a physician licensed to practice medicine in the State of New York.

19.3 Director of a clinical laboratory or blood bank; certificate of qualification.
(a) Certificate required. A director of a clinical laboratory or blood bank must hold a certificate of qualification issued after the commissioner has determined that the applicant meets the requirements specified in sections 19.2 and 19.3(e) of this Part,
and has demonstrated, in accordance with subdivision (c) below and section 19.4(a) of this Part, that he or she possesses the character, competence, training and ability to direct the technical and scientific operation of a clinical laboratory or blood bank, and ensure the proper supervision or performance of test procedures, adherence to the department’s quality control standards and accurate reporting of findings of tests.

(b) An applicant for a certificate of qualification must submit a complete, original, signed and sworn application in such form and manner as may be required by the department, and must supply such additional information as may be required by the department. An individual seeking renewal of a certificate of qualification must submit an application no later than 90 days prior to expiration of the current certificate.

(c) To function effectively in fulfilling his or her duties and responsibilities, a laboratory director should possess a knowledge of basic clinical laboratory sciences and operations, and should have the training and/or experience and physical capability to discharge the following responsibilities:

1. provide advice to referring physicians regarding the significance of laboratory findings and the interpretation of laboratory data;
2. maintain an effective working relationship with applicable accrediting and regulatory agencies, administrative officials, and the medical community;
3. define, implement and monitor standards of performance in quality control and quality assurance for the laboratory and for other ancillary laboratory testing programs;
4. monitor all work performed in the laboratory to ensure that medically reliable data are generated;
5. assure that the laboratory participates in monitoring and evaluating the quality and appropriateness of services rendered, within the context of the quality assurance program, regardless of where the testing is performed;
6. ensure that sufficient qualified personnel are employed with documented training and/or experience to supervise and perform the work of the laboratory;
7. set goals and develop and allocate resources within the laboratory;
8. provide effective and efficient administrative direction of the laboratory, including budget planning and controls in conjunction with the individual(s) responsible for financial management of the laboratory;
9. provide educational direction to laboratory staff;
10. select all reference laboratories; and
11. promote a safe laboratory environment for personnel and the public.

(d) Certification. Certificates of qualification are issued in one or more of the following categories, procedures or specialties:

1. one or more of the subspecialties of microbiology: bacteriology, virology, mycology, mycobacteriology, diagnostic immunology and parasitology;
2. hematology;
3. immunohematology, excluding testing performed solely for transfusion purposes;
4. one or more of the subspecialties of clinical biochemistry: clinical chemistry, blood pH and gases, endocrinology and therapeutic substance monitoring/quantitative toxicology;
histopathology, and/or the subspecialties: oral pathology and dermatopathology;
(6) cytopathology;
(7) cytogenetics;
(8) histocompatibility;
(9) cellular immunology;
(10) oncofetal antigens, and/or the subspecialties: tumor markers, maternal serum and amniotic fluids;
(11) genetic testing;
(12) transfusion services, including all pre-transfusion testing;
(13) blood banking collection-comprehensive, including all tests required in Subpart 58-2 of this Title;
(14) blood banking collection-limited, including collection of autologous blood for transfusion and excluding testing for transmissible disease markers;
(15) one or more of the subspecialties of clinical toxicology; drug analysis, blood lead, erythrocyte protoporphyrin and chlorinated hydrocarbons;
(16) forensic toxicology; or
(17) other specific categories, procedures or specialties designated by the department.

(e) Required qualifications.

(1) Applicants for a certificate of qualification in bacteriology, mycobacteriology, mycology and/or parasitology must qualify under section 19.2(a)(1), (c)(1)(i) or (c)(2) of this Part.
(2) Applicants for a certificate of qualification in virology must qualify under section 19.2(c)(1)(i) or (c)(2) of this Part.
(3) Applicants for a certificate of qualification in diagnostic immunology must qualify under section 19.2(a)(1), (c)(1)(i), (c)(1)(v) or (c)(2) of this Part.
(4) Applicants for a certificate of qualification in hematology must qualify under section 19.2(a)(1), (c)(1)(vi) or (c)(2) of this Part. Applicants qualifying under section 19.2(c)(1)(vi) of this Part must document that the required training and/or experience includes or is supplemented by six months' training and/or experience in an acceptable laboratory.
(5) Applicants for a certificate of qualification in immunohematology must qualify under section 19.2(a)(1) or (c)(2) of this Part.
(6) Applicants for a certificate of qualification in one or more of the subspecialties of clinical biochemistry must qualify under section 19.2(a)(1), (c)(1)(ii) or (c)(2) of this Part.
(7) Applicants for a certificate of qualification in histopathology must qualify under section 19.2(a)(2) of this Part.
(8) Applicants for a certificate of qualification in oral pathology must qualify under section 19.2(a)(2) or (b) of this Part.
(9) Applicants for a certificate of qualification in dermatopathology must qualify under section 19.2(a)(2) or (a)(3) of this Part.
(10) Applicants for a certificate of qualification in cytogenetics, histocompatibility, cellular immunology, oncofetal antigens and/or genetic testing must qualify under section 19.2(c)(2) of this Part.
(11) Applicants for a certificate of qualification in transfusion services must be physicians and must qualify under section 19.2(a)(3) or (c)(2) of this Part, or under section 19.2(a)(1) or (c)(1)(vi) of this Part including or supplemented by at least six months' training and/or experience in transfusion services.

(12) Applicants for a certificate of qualification in blood banking collection-comprehensive must qualify under section 19.2(c)(2) of this Part. Required experience in blood services must include at least one year's training and/or experience in collection and testing of blood for homologous transfusion.

(13) Applicants for a certificate of qualification in blood banking collection-limited must qualify under section 19.2(a)(1), (c)(1)(vi) or (c)(2) of this Part.

(14) Applicants for a certificate of qualification in one or more of the subspecialties of clinical toxicology must qualify under section 19.2(a)(1), (c)(1)(iii), (c)(1)(iv) or (c)(2) of this Part.

(15) Applicants for a certificate of qualification in forensic toxicology must qualify under section 19.2(c)(1)(iii), (c)(1)(iv) or (c)(2) of this Part.

(f) Scope and limitations.

(1) The requirements for qualification set forth in section 19.2 of this Part shall apply to all laboratory directors, regardless of prior grandfathered status, upon expiration of current certificates of qualification, if the laboratory director is no longer employed in a laboratory or in the field of laboratory medicine.

(2) Additional categories of testing may not be added to a certificate of qualification issued on a grandfathered basis. Such a certificate may not be renewed if allowed to lapse, unless extenuating circumstances prevent timely reapplication and specific departmental approval is obtained.

19.4 Denial of an application for a certificate of qualification.

(a) In determining whether to deny an application for a certificate of qualification in whole or in part, the department shall consider: the applicant's education, experience and licensure as required in sections 19.2 and 19.3 of this Part; the applicant's demonstrated ability to discharge the responsibilities set forth in section 19.3(c) of this Part; the character and competence of the applicant and the laboratory or laboratories directed; and any other factors the department considers relevant, including, but not limited to:

(1) prior sustained charges of administrative violations of state or federal laws, rules and regulations related to the provision of health care services or reimbursement for such services, against the applicant individually or any laboratory directed by the applicant;

(2) conviction of any crime, including, but not limited to, any offense relating to the furnishing of, or billing for, laboratory services and medical care, services, or supplies, or which is considered an offense involving theft or fraud;

(3) false representation or omission of any material fact in making an application in any state or city of the United States for any license, permit, certificate, or registration related to a profession or business, or in making an application for a certificate of qualification or laboratory permit to New York State or New York City;
(4) submission of a laboratory permit application which conceals an ownership or controlling interest by any person who otherwise would be ineligible for a permit;
(5) failure to supply additional documentation of training and/or experience, pursuant to a written request for such documentation, in the course of applying for a certificate of qualification;
(6) on the part of any laboratory directed by the applicant, a pattern of repetitive failures of required proficiency testing performance in one or more proficiency testing categories, excluding failure for administrative reasons such as late result submission;
(7) on the part of any laboratory directed by the applicant, a pattern of deficiencies on onsite inspection, especially in areas of quality control, quality assurance, laboratory management, and handling of regulated medical waste and radioactive materials, including refusal or inability to produce records as requested by department employees, which deficiencies are not corrected from inspection to inspection or which recur at each annual inspection despite written notice of violations by a state or federal licensing or auditing agency and which jeopardize the quality of test results and resulting patient care, even if interim corrections have occurred;
(8) on the part of any laboratory directed by the applicant, performance of any laboratory procedures not authorized by the laboratory permit issued pursuant to Article 5, Title V of the Public Health Law; or operation or direction of a laboratory without a permit; or continuing operation or failure to notify the department after a change in director, ownership or location has voided the permit;
(9) unless the laboratory is owned and operated by the State of New York, performance of tests on specimens collected in New York City while the laboratory directed by the applicant lacks a New York City permit to perform such tests;
(10) on the part of any laboratory directed by the applicant, referral of specimens collected in New York State outside of New York City to laboratories which do not possess a New York State permit;
(11) on the part of any laboratory directed by the applicant, knowing acceptance of specimens or requisitions for laboratory examination from, or issuance of reports to, a person or persons not authorized by law to submit such specimens or requisitions, or receive such reports;
(12) on the part of any laboratory directed by the applicant, issuance of reports on laboratory work, including both patient samples and proficiency testing, actually performed in another laboratory, without designating the fact that the examinations or procedures were performed in another laboratory; and/or testing and reporting results on unsatisfactory specimens as defined by the department, including unlabeled specimens or specimens of insufficient quantity to conduct the analyses requested;
(13) on the part of any laboratory directed by the applicant, failure to establish and ensure that employees follow procedures for disposal or handling of specimens or infectious or radioactive medical waste, in violation of applicable state or federal laws, rules and regulations, or in a manner which endangers the public, the laboratory's employees, or the environment;
(14) employment of unqualified technical personnel or an insufficient number of such personnel; (15) failure of the laboratory director to be responsible for adequately supervising laboratory personnel to ensure the proper performance of all tests conducted in the laboratory; and (16) any other factor having a direct bearing on the applicant's ability to provide or supervise the provision of high quality laboratory services, or to ensure compliance with statutory and regulatory requirements.

(b) If an application for a certificate of qualification is denied, the applicant shall be given written notice of the proposed denial, stating the reason or reasons for the denial. Such notice shall be sent by certified mail and shall be a final determination to be effective thirty (30) days from the date of the notice, unless a hearing is requested pursuant to subdivision (c) below.

(c) If the department gives notice of the proposed denial of an application for a certificate of qualification, the applicant may request a hearing on the proposed denial by submitting a written request for a hearing to the department within ten (10) days of the date of the notice. Submission of a request for a hearing within ten (10) days shall stay any action to deny the application for a certificate of qualification, pending the department's decision following the hearing on such proposed denial.