SUMMARY OF EXPRESS TERMS

Part 58-1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) regulates the permitting and operation of clinical laboratories and blood banks. An entity operating a clinical laboratory or blood bank located in New York State, or accepting specimens from a person or entity in New York State, is required to hold a permit issued by the New York State Department of Health (Department). The proposed amendments to sections 58-1.1 through 58-1.5 revise several aspects of the current regulation.

Section 58-1.1 specifically defines the permitting process for clinical laboratories, including criteria for a permit, allowable categories of testing, and the process for obtaining provisional permits. Amendments to paragraph 58-1.1(a)(1) clarify that testing or procedures performed under a permit must be approved by the U.S. Food and Drug Administration or the Department. Paragraph 58-1.1(a)(2) is amended to define conditions for permit denial and to define allowable owners. Subdivision 58-1.1(d) is amended to better define the conditions under which provisional permits can be issued. New subdivision 58-1.1(e) is added to define the process for voiding a permit, consistent with Public Health Law (PHL) § 575(6). New subdivision 58-1.1(f) defines the process for issuance of a "single use permit," which would allow access to testing on a patient or test-specific basis under certain circumstances, such as a during a declared state disaster emergency.

Section 58-1.2 sets forth the required availability of the laboratory director to the clinical laboratory or blood bank and his or her responsibilities. Amendments to

subdivisions 58-1.2(a)-(b) establish the title of "sole assistant director," a person responsible for one or more categories on the laboratory or blood bank permit for which the laboratory director does not hold a Certificate of Qualification. The sole assistant director would be treated as the laboratory director for those categories. Amendments to subdivision 58-1.2(b) also allow a laboratory director to serve at five different clinical laboratories or blood banks, or any combination thereof. Amendments to subdivision 58-1.2(c) set forth expectations for the onsite presence of the director and sole assistant director while also providing for exceptions.

Revisions in section 58-1.2 also include a definition of "regular part time hours," to allow onsite supervision at a reduced frequency. Subdivisions 58-1.2(d)-(e) define the responsibilities of laboratory directors and sole assistant directors. Subdivisions 58-1.2(f)-(g) set forth expectations for coverage and notification when the laboratory director's or sole assistant director's employment is terminated. Finally, new subdivision 58-1.2(g) defines the consequences of an extended absence of a director or sole assistant director when a new individual is not identified as a replacement. The proposed revisions now define that absences of greater than 60 days require prior notification and approval by the Department.

Section 58-1.3 sets forth the roles and responsibilities of a clinical laboratory supervisor. Amendments to section 58-1.3 expand supervisor titles from just clinical laboratories to blood banks, as per PHL, and allow for supervisors to oversee "procedures" in addition to "tests," as appropriate for blood banks. Amendments to subdivision 58-1.3(d) provide criteria for allowing an exception to the requirement to have a supervisor onsite during all hours of laboratory testing. Subsection 58-1.3(e) is

amended to expand the allowable areas for cytotechnologist supervision in accordance with their scope of practice as interpreted by the New York State Education Department (NYSED).

Section 58-1.4 defines the qualifications of a clinical laboratory supervisor, and section 58-1.5 defines the duties and qualifications of clinical laboratory technical staff. Amendments to section 58-1.4 define "acceptable laboratory" by describing the experience required for qualification of supervisors and staff, reducing the number of years of experience in such "acceptable laboratories" required to qualify as a supervisor, and expanding the criteria to allow certificate of qualification holders to serve as supervisors. Sections 58-1.4 and 58-1.5 are also amended to revise the duties and responsibilities of additional laboratory staff, as well as respiratory therapists, and to revise the qualifications for such staff to conform to NYSED licensure requirements. These amendments also allow supervisors and staff working in laboratories outside of New York State to qualify under the appropriate titles if they meet Department requirements or are licensed in their state or other jurisdiction. Deletions from these sections remove outdated language that is no longer applicable, simplifying the regulation overall.

A new section 58-1.14 is added clarifying reporting requirements for results of laboratory testing for certain communicable diseases. The section requires the Commissioner to designate those tests for communicable diseases that require prompt action, and to make available a list of such diseases on the Department website. It also requires clinical laboratories to immediately report positive test results for communicable diseases identified as requiring prompt attention, in a manner and format identified by the

Commissioner. Finally, the new section requires clinical laboratories to report all test results, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

Pursuant to the authority vested in the Commissioner of Health by Section 576 of the Public Health Law (PHL), Sections 58-1.1 through 58-1.5, and Section 58-1.14 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 58-1.1 Permit.

(a) Permit means a clinical laboratory or blood bank permit issued by the [Commissioner] Department of [health] Health.

(1) No clinical laboratory or blood bank shall be issued a permit in any category sought unless:

[(1)] (i) its laboratory director or assistant [director] director(s) holds a certificate of qualification, pursuant to Part 19 of this Title, in each category for which the permit is sought;

[(2)] (ii) the clinical laboratory or blood bank has been physically inspected and has [corrected any deficiencies found] provided satisfactory evidence of correction of any deficiencies found;

[(3)] (iii) the clinical laboratory or blood bank has successfully participated in all required proficiency [examinations] assessments or remedial activities in the categories sought[.];

(iv) all tests performed in New York State or on specimens from New York State are either:

(a) classified as approved, cleared, or exempt by the United States Food and Drug Administration (FDA); or

(b) approved by the Department.

(2) When reviewing an application for a permit, the Department shall consider the laboratory director's ability to discharge the responsibilities set forth in Part 19 of this Title as well as the laboratory director's and owners' character and competence, and any other factors the Department considers relevant, including but not limited to:

(i) prior administrative violations by the laboratory director or owner(s) of state or federal laws or regulations related to the provision of health care services or to the reimbursement of such services;

(ii) 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, and any offense that involves theft or fraud;

(iii) false representation or omission of any material fact in making an application for any license, permit, certificate, or registration related to a profession or business, or in making an application for a clinical laboratory permit to New York State;

(iv) submission of a laboratory permit application that conceals an ownership or controlling interest by any person who otherwise would be ineligible for a permit;

(v) performing laboratory procedures not authorized by a clinical laboratory or blood bank permit issued pursuant to Article 5, Title V of the Public Health Law and this Subpart; direction or ownership of a clinical laboratory operating without a permit; or continuing operation after a change in laboratory director, ownership or location has voided the permit;

(vi) repeated referral of specimens obtained from a person or entity in New York State to a laboratory or laboratories not possessing a New York State permit;

(vii) repeated 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;

(viii) issuance of reports on laboratory work, including both patient specimen and proficiency testing, actually performed in another laboratory, without designating the fact that the examinations or procedures were performed in another laboratory;

(ix) employment of unqualified personnel;

(x) denial, revocation, or limitation of a permit for any clinical laboratory or blood bank directed by the applying laboratory director or owned by the applying owner;

(xi) any other factor having a direct bearing on the laboratory director and/or owner's ability to provide high quality laboratory services, or to ensure compliance with statutory and regulatory requirement.

3) If an application for a permit 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 a final determination to be effective thirty (30) days from the date of the notice.

4) As used in subdivision 6 of section 575 of the Public Health Law and this Subpart, "owner" shall mean any individual, corporation, partnership, natural person, or entity holding a ten percent or greater interest or corporate membership, directly or indirectly, in the clinical laboratory or blood bank.

(b) A clinical laboratory or blood bank shall perform only those tests or procedures that are within the categories stated on its permit and that have been approved, cleared or exempted by the FDA, or approved by the Department. Specimens for all other tests or procedures shall be referred to a clinical laboratory with a permit in the appropriate category and test-specific approval. The Department shall maintain a list of available categories that is publicly accessible on the Department's website. [Categories of tests shall be designated according to the following procedures or specialties:

(1) one or more of the following subspecialties of microbiology: bacteriology, virology, mycology, parasitology, and mycobacteriology;

(2) hematology;

(3) blood services - diagnostic immunohematology collection and/transfusion;

(4) one or more of the following subspecialties of clinical biochemistry: clinical chemistry, blood pH and gases, endocrinology and therapeutic substance monitoring/quantitative toxicology;

(5) histopathology or one or more of the following subspecialties: dermatopathology and oral pathology;

(6) cytopathology;

(7) urinalysis;

(8) one or more of the following subspecialties of toxicology: drug analysis-quantitative, blood lead and erythrocyte protoporphyrin, forensic toxicology, and chlorinated hydrocarbons;

(9) cytogenetics;

(10) human immunodeficiency virus (HIV) testing;

(11) histocompatibility;

(12) diagnostic immunology;

(13) cellular immunology;

(14) oncofetal antigens;

(15) other specific tests or procedures as designated by the department.]

(c) In performance of laboratory procedures <u>within the categories</u> stated on its permit, a blood bank shall <u>also</u> meet the appropriate requirements in Subpart 58-2 [and sections 58-1.2 through 58-1.6, 58-1.9, 58-1.10, and 58-1.11 of this Subpart].

(d) A provisional permit [shall be available, which shall be valid] in one or more categories may be issued by the Department for a limited period [determined by the Department to be sufficient] of time to enable the [department] Department to assess the proficiency or lack of proficiency of the laboratory in [the categories] each category sought. [The provisional permit may be renewed pending issuance or denial of a permit if the initial proficiency test results are inconclusive.]

(1) [A clinical laboratory or blood bank initially applying for a permit may be issued a provisional permit] A provisional permit may only be issued when the clinical laboratory or blood bank meets the following conditions:

(i) a valid and complete permit application has been filed; [and]

(ii) application and reference fees have been paid; [and]

(iii) the laboratory director or assistant [director] director(s) holds a certificate of qualification in all categories sought; and

(iv) the laboratory has been inspected by the [department] Department and has provided satisfactory evidence of correction of any deficiencies found.

[(2) Provisional permits shall not be available in the categories of cytogenetics – general, mycology, mycobacteriology, human immunodeficiency virus screening and /or confirmatory testing, or virology.

(3) A clinical laboratory or blood bank which has failed to demonstrate its proficiency in testing specimens in a category may, after successful

participation in a remediation program, including proficiency testing, be granted a provisional permit.]

[(4)] (2) If the laboratory director [or any owner] of the clinical laboratory or blood bank applying for a provisional permit has ever [directed or owned a laboratory which has had its permit revoked, suspended, limited, annulled , or which has an enforcement proceeding against it pending at the time of the application for a provisional permit, a provisional permit shall not be issued] stipulated to a failure to, or been proven to have failed to, discharge his/her/their responsibilities set forth in Part 19 of this Title as described in subdivision (a)(2) of this section, the applicant shall not be eligible for a provisional permit.

(3) If the laboratory director, or any owner of the clinical laboratory or blood bank applying for a provisional permit, directs or owns a laboratory or blood bank that has an enforcement proceeding pending against it at the time of application for a provisional permit, the applicant shall not be eligible for a provisional permit.

(4) A provisional permit may be denied or terminated, without a hearing, if the Department finds that the clinical laboratory or blood bank is not operating in compliance with the Public Health Law and Parts 34 and 58 of this Title.

[(5) A provisional permit may be revoked, suspended, limited, annulled, or the holder thereof censures, reprimanded, or otherwise disciplined in accordance with Public Health Law, including section 577 thereof.]

[(6)] (5) A provisional permit [in a category] may be converted to a full permit when the laboratory has [demonstrated to the satisfaction of the [department] Department its proficiency in testing specimens in that category] met all of the requirements in subdivision (a) of this section.

(e) A permit or provisional permit shall become void immediately upon a change in laboratory director, owner, or location. However, the Department may stay the voiding of the permit or provisional permit and issue an amended permit or provisional permit, provided that:

(1) notification of such change is received by the Department no later than sixty (60) calendar days from the effective date of the change;

(2) all outstanding inspection and reference fees have been paid; and

(3) the laboratory or blood bank is either currently in good standing with the Department or demonstrates to the Department a compelling basis warranting a stay of the voiding of the permit or provisional permit. For purposes of this subdivision, "in good standing" shall mean:

(i) a pattern of compliance with fundamental standards of practice, with no significant deficiencies identified over multiple on-site surveys. A deficiency is considered significant if the Department determines that: it is of a nature, scope, or frequency that could cause unreliable results for any analysis the laboratory is authorized to perform pursuant to its clinical laboratory permit; it

may induce an erroneous diagnosis; or it may contribute to the selection of an inappropriate method of treatment;

(ii) no laboratory practices have been identified that could lead to immediate jeopardy of public health; and

(iii) no testing has been performed without the required Department approval.

(f) A single use permit may be available on a patient-specific or test-specific basis, which shall be valid for a limited period of time and/or for a limited number of tests.

(1) Single use permits may only be issued to a clinical laboratory:

(i) holding a permit but lacking test-specific approval; or

(ii) that does not possess a permit but that otherwise meets all federal requirements to perform clinical laboratory testing on specimens originating in the United States.

(2) The Department may grant a single use permit based on:

(i) medical necessity;

(ii) clinical circumstances;

(iii) test availability;

(iv) a declared state disaster emergency; or

(v) other circumstances as determined by the Department.

(3) Application for a single use permit shall be made prior to the initiation of testing, in a manner and format prescribed by the Department.

58-1.2 Laboratory director.

(a) [The] Each laboratory or blood bank shall have a laboratory director who shall serve the clinical laboratory or blood bank full-time, or on a regular part-time basis, to perform the duties listed in this Part and in Part 19 of this Title. Regular part-time basis shall mean assumption of full responsibility for direction and technical operation of the laboratory, including adherence to the [department quality control standards and training of personnel performing the testing] Department's clinical laboratory standards of practice, which shall be publicly available on the Department's website. Every laboratory director shall possess a certificate of qualification issued by the Department pursuant to Part 19 of this Title, in at least one category of testing offered by the clinical laboratory or blood bank. Individuals holding a certificate of qualification can be designated by the laboratory director as assistant directors; however, if an individual holds the sole certificate of qualification for a category or categories of testing at that facility, that individual is considered a sole assistant director, and will be held responsible for the duties listed in Part 19 for that category or those categories of testing conducted by the clinical laboratory or blood bank.

[If he serves on a regular part-time basis, he] (b) An individual shall not serve as laboratory director or sole assistant director of more than [two] five clinical laboratories or blood banks, or any combination thereof, within or outside New York State, [or more

than one clinical laboratory and one blood bank or more than two blood banks] either permitted by New York or registered in accordance with federal regulations. [Where a laboratory and a blood bank are on the same premises and are under the supervision of the same director, such laboratory and blood bank shall be deemed one laboratory for the purpose of this subdivision. Notwithstanding the foregoing provisions of this subdivision, if the commissioner finds that more than two are required to serve the needs of an area and the total volume and the types of laboratory service provided by the several laboratories or blood banks are not such as to require the services of more than one director; or, he may authorize an individual to direct more than two laboratories or blood banks or combinations thereof. Such authorization must be renewed at least every two years. The commissioner may also make an exception where the additional directorships involve only blood-holding facilities as defined in section 58-2.1(i) of this Part.]

[(b)] (c) Commensurate with the [laboratory] workload, scope and complexity of the testing procedures carried out, qualifications of onsite personnel, proximity to another clinical laboratory or blood bank under identical directorship, and availability of alternate monitoring and communications capabilities, the laboratory director and any sole assistant directors shall [spend an adequate amount of time] be on-site on at least on a regular part-time basis in the clinical laboratory or blood bank to direct and supervise the technical performance of the staff and shall be readily available [for personal or telephone consultation] at all other times by telephone and/or through synchronous two-way electronic audio-visual communication to the laboratory's staff and clients. [The adequacy of the amount of time a laboratory director is present and in active direction

shall be determined by the department based on the factors enumerated above, results of onsite inspections and proficiency testing and documentation of the director's full responsibility for direction and technical operation.] Attendance records may be required to document the adequacy of the laboratory director's or sole assistant director's presence.

(1) For purposes of this section "regular part-time" is defined as at least eight hours per week.

(2) Requests for a laboratory director to be on-site less than eight hours per week will be considered pending a review of the number of permit categories for which they are responsible, the volume and complexity of testing at the clinical laboratory or blood bank, and the performance history of the clinical laboratory or blood bank during inspections and proficiency testing.

(3) The Department may require that a laboratory director be present on a more frequent basis than previously approved based upon concerns identified during inspection or proficiency testing, or if the Department has received more than one complaint against the clinical laboratory or blood bank.

[(c)] (d) The laboratory director and any sole assistant director shall be responsible for performance of all tests or procedures carried out in the clinical laboratory or blood bank, adherence to the [department's quality assurance] Department's clinical laboratory standards of practice for such tests or procedures, [and] accurate reporting of the test results and recording of required information.

[(d) The director shall be responsible for ensuring the employment of qualified laboratory personnel, evaluation of job performance of such personnel and their in-service training.]

(e) [If the director's employment terminates or he is temporarily absent, arrangements shall be made for a qualified temporary director, which arrangements must receive the prior approval of the department. An assistant director who holds a certificate of qualification to be a director of a clinical laboratory or blood bank in the appropriate category may act for the director in the director's absence, and at such time shall fully discharge the duties and responsibilities of the director. (f) When the director's employment terminates, for whatever reason, both the owner and the director of the laboratory, or the chief executive officer of the facility, shall notify the department in writing prior to the termination. In the case of death or physical and/or mental incapacitation of the director, the owner or the chief executive officer must notify the department within 72 hours of each event.] The laboratory director and owner shall be jointly and severally responsible for clinical laboratory or blood bank operations and shall exercise authority for the design, implementation, maintenance and improvement of a quality management system for the delivery of services that meet the needs of patients and all clinical personnel responsible for patient care.

(f) Failure to notify the Department of the resignation, termination, death, or physical or mental incapacitation of the laboratory director within sixty (60) calendar days of such event shall result in the voiding of the permit. Failure to notify the Department of the resignation, termination, death, or physical or mental incapacitation of a sole assistant

director within sixty (60) calendar days of such event shall result in the voiding of the specific permit category under the sole assistant director's direction.

(g) If the laboratory director or sole assistant director will be temporarily absent for more than sixty (60) consecutive calendar days, arrangements shall be made, with the prior approval of the Department, for a new laboratory director or sole assistant director who possesses a certificate of qualification in the appropriate categories. Failure to notify the Department of the absence of a laboratory director or sole assistant director of greater than sixty (60) calendar days shall result in the voiding of the permit.

58-1.3 Clinical laboratory and blood bank supervision.

(a) A clinical laboratory or blood bank shall have one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and the reporting of findings, perform tests or procedures requiring special scientific skills, and, in the absence of the laboratory director, are responsible for the proper performance of all laboratory procedures.

(b) A laboratory director who qualifies pursuant to the provisions of section 19.2 of this Title shall also be deemed qualified as a supervisor.

(c) Depending upon the size and functions of the clinical laboratory or blood bank, the Department may authorize the laboratory director to also serve as the supervisor of the clinical laboratory or blood bank.

(d) [The] A supervisor shall be on the laboratory premises during all hours in which tests are performed. An exception to [the on-premises] this requirement shall be applicable [with respect to the performance of procedures required for emergency purposes; provided, that the person performing the test qualifies as a medical technologist pursuant to the provisions of section 58-1.5(b) of this Subpart, the results of his work are reviewed by the supervisor or director during his or her next duty period, and a record is maintained to reflect the actual review.] if all the following conditions have been met:

(i) the clinical laboratory or blood bank has not demonstrated a pattern of noncompliance with fundamental standards of practice, nor have any laboratory practices been identified that could lead to immediate jeopardy of public health;

(ii) the clinical laboratory or blood bank has not demonstrated a pattern of unacceptable and/or unsatisfactory proficiency testing performance;

(iii) the supervisor is immediately accessible by telephone or synchronous two-way electronic audio-visual communication to all testing personnel at all times testing is performed;

(iv) the supervisor is assigned on-site hours as determined by the laboratory director to ensure adequate supervision for the scope, complexity and volume of testing being carried out at each site, which shall not be less than eight hours per week;

(v) documentation is maintained that defines and delegates supervisory responsibilities including whether these responsibilities are performed on-site versus off-site;

(vi) when more than one supervisor is employed by the clinical laboratory or blood bank, documentation is maintained that defines which supervisor is responsible for a specific time period;

(vii) the individual who serves as the supervisor may only serve in this capacity at five clinical laboratories or blood banks; and

(viii) the clinical laboratory or blood bank meets any other requirements prescribed in the clinical laboratory standards of practice related to the proper supervision of testing.

(e) An individual who qualifies as a supervisor pursuant to [provisions of] section 58-1.4(d) of this Subpart, shall supervise technical personnel in the [specialty] specialties of [cytology] cytopathology and histopathology only.

58-1.4 Qualifications of laboratory supervisor.

The laboratory supervisor must meet one of the following requirements:

(a) The supervisor is a physician licensed to practice medicine or osteopathy in the State of New York or in the state or jurisdiction in which the supervisor practices or an individual who has earned a doctoral degree from an accredited institution with a chemical, physical or biological science as [his] the supervisor's major subject (*accredited*, as used herein, refers to accreditation by a nationally recognized accrediting agency or association, as determined by the United States Commissioner of Education),

and either holds a certificate of qualification or qualifies as a clinical laboratory technologist as described in section 58-1.5 of this Subpart. The supervisor shall, subsequent to graduation, have had at least [two years'] one year of pertinent experience in [one of the] an acceptable laboratory [specialties in a clinical laboratory or blood bank having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, a health department, university, medical research institution, or other institution which provides equivalent training].

(i) As used in this section, "acceptable laboratory" means a clinical laboratory or blood bank as defined in Section 571 of the Public Health Law, with a laboratory director who meets or would meet the requirements of Part 19 of this Title and where such facility meets or would meet the Department's standards as outlined in this Subpart. This may include, but is not limited to: the anatomic and clinical pathology facilities of a hospital or health department; a testing unit of a university or medical research institution; an independent clinical laboratory or blood bank; a privately operated forensic testing laboratory; or a facility providing training and/or experience in the testing of human specimens.

(b) The supervisor holds a degree of master of arts or master of science from an accredited institution with a major in one of the chemical, physical or biological sciences, qualifies as a clinical laboratory technologist as described in section 58-1.5 of this Subpart, and, subsequent to graduation, has had at least [four] two years of pertinent [laboratory] experience [of which not less than two years have been spent working in the designated laboratory specialty in a clinical laboratory having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, a health

department, university, medical research institution or other institution which provides equivalent training] in an acceptable laboratory.

(c) The supervisor is qualified as a [medical] clinical laboratory technologist pursuant to the provisions of section 58-1.5(b) of this Subpart and has had at least [six] four years of pertinent [clinical laboratory] experience in an acceptable laboratory subsequent to qualifying [of which at least two years have been spent working in a clinical laboratory having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, university, health department, medical research institution or other institution which provides equivalent training].

(d) The supervisor is qualified as a cytotechnologist pursuant to the provisions of section 58-1.5(c) of this Subpart and subsequent to qualifying, has had at least four years of pertinent [clinical laboratory] experience in cytotechnology in [a] an acceptable laboratory having a doctoral level director qualified in cytopathology. [The clinical laboratory shall be part of a hospital, health department, university, medical research institution, or other institution which provides equivalent training.]

(e) [With respect to individuals first qualifying prior to April 1, 1972, an exception to the requirements in subdivision (a), (b) or (c) of this section may be made if:] The supervisor of a respiratory therapy technician shall be a licensed physician with one year of relevant experience or a respiratory therapist possessing a license issued by the New York State Education Department to practice as a respiratory therapist, if such license is required under Article 164 of the State Education Law, with four years of relevant experience.

[(1) the supervisor was performing the duties of a clinical laboratory supervisor at any time between July 1, 1961 and September 1, 1971; and

(2) the supervisor has had at least 15 years of pertinent clinical laboratory experience prior to September 1, 1971: provided, that a minimum of 30 semester hours of credit toward a bachelor's degree with a chemical, physical or a biological science as his major subject; or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by two years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year; and

(3) he has performed the duties of a supervisor for at least two years during the qualifying 15 years in:

(i) a clinical laboratory having a director at the doctoral level, of a hospital, university, health department or medical research institution; or

(ii) in a laboratory approved under the Medicare supplementary medical insurance program, provided also, that where qualifying years in a laboratory described in subparagraph (i) of this paragraph are obtained after January 30, 1969, the laboratory meets applicable conditions under the Medicare health insurance program, or, under title 42, Code of Federal Regulations, part 74, the latter being the regulations issued pursuant to the Federal Clinical Laboratories Improvement Act of 1967.]

58-1.5 Duties and qualifications of clinical laboratory technical personnel.

(a) Duties of a clinical laboratory technologist. [The laboratory shall employ a sufficient number of qualified medical technologists, or where appropriate, cytotechnologists, to perform proficiently under general supervision the clinical laboratory tests which require the exercise of independent judgment as follows: (1) The medical technologists shall perform tests] A clinical laboratory technologist performs tests pursuant to established and approved protocols which require the exercise of independent judgment and responsibility, with [a] minimal supervision by the laboratory director or supervisor, in only those specialties or subspecialties in which they are qualified by education, training and experience.

[(2) With respect to specialties in which the medical technologist is not qualified by education, training or experience, he shall function only under direct supervision and perform only tests which require limited technical skill and responsibility.

(3) Clinical laboratory technologists shall be sufficient in number to adequately supervise the work of technicians and trainees.

(4) An individual who qualifies as a cytotechnologist under subdivision (c) of this section may supervise technicians and trainees only in the specialty of cytology.]

(b) Qualifications of [medical] a clinical laboratory technologist.

[A medical technologist must meet one of the following requirements:] A clinical laboratory technologist practicing in New York State shall possess a valid license, issued by the New York State Education Department to practice as a clinical laboratory

technologist, if such license is required under Article 165 of the State Education Law. A clinical laboratory technologist practicing in a clinical laboratory or blood bank located outside of New York State may qualify provided the clinical laboratory technologist possesses an equivalent license issued by the state or jurisdiction in which the laboratory is located, or meets one of the following requirements:

(1) Successful completion of a [full] course of study which meets all academic requirements for a bachelor's, or higher, degree in medical technology or laboratory science from an accredited [college or university.] institution; or

(2) Successful completion of [three academic years of study (a minimum of 90 semester hours or equivalent) in an accredited college or university which met the specific requirements for entrance into, and the successful completion of a course of training of at least 12 months in a school of medical technology approved by the Council on Medical Education of the American Medical Association] a course of study which meets all academic requirements for a bachelor's, or higher, degree in one of the chemical, physical, or biological sciences from an accredited institution, and, in addition, at least six months of acceptable supervised experience and/or relevant training.

[(3) Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical or biological sciences and, in addition, at least one year of pertinent laboratory experience and/or training covering the specialty(ies) or subspecialty(ies) in which he performs tests, provided the combination has given

the individual the equivalent in such specialty(ies) or subspecialty(ies) of the education and training described in paragraph (1) or (2) of this subdivision.

(4) Successful completion of three years (90 semester hours or equivalent) in an accredited college or university with a distribution of courses as shown below, and, in addition, successful experience and/or training covering several fields of medical laboratory work of such length (not less than one year), and of such quality that this experience or training, when combined with the education, will have provided the individual with education and training in medical technology equivalent to that described in paragraph (1) or (2) of this subdivision. Distribution of course work: (Where semester hours are stated, it is understood that the equivalent in quarter hours is equally acceptable. The specified courses must have included lecture and laboratory work. Survey courses are not acceptable.)

(i) for those whose training was completed prior to September 15, 1963: At least 24 semester hours in chemistry and biology courses of which not less than nine semester hours must have been in chemistry and must have included at least six semester hours in inorganic chemistry, and not less than 12 semester hours must have been in biology courses pertinent to medical sciences;

(ii) for those whose training was completed after September 15, 1963: 16 semester hours in chemistry courses, which included at least six semester hours in inorganic chemistry and are acceptable toward a major in

chemistry; 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and three semester hours of mathematics.

(5) With respect to individuals first qualifying prior to April 1, 1972, an exception to the requirements in paragraph (1), (2), (3) or (4) of this subdivision may be made if:

(i) the technologist was performing the duties of a medical technologist at any time between July 1, 1961 and September 1, 1971;

(ii) the technologist has had at least 10 years of pertinent clinical laboratory experience prior to September 1, 1971: provided, that a minimum of 30 semester hours credit toward a bachelor's degree from an accredited institution with a chemical, physical, or a biological science as his major subject; or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by two years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year; and (iii) he has performed the duties of a clinical laboratory technologist for at least two years during the qualifying 10 years:

(a) in a clinical laboratory having a director at the doctoral level, of a hospital, university, health department or medical research institution; or

(b) in a laboratory approved under the supplementary medical insurance program: Provided also, that where qualifying years in a laboratory described in clause (a) of this subparagraph are obtained after January 30, 1969, the laboratory meets applicable conditions under the Federal health insurance program, or under title 42, Code of Federal Regulations, part 74, the latter being the regulations issued pursuant to the Federal Clinical Laboratories Improvement Act of 1967.]

(c) An individual practicing as a clinical laboratory technologist outside of New York State who is licensed to practice in that state or jurisdiction, or who possesses credentials that were evaluated and deemed acceptable prior to the adoption of this section, may be qualified as a clinical laboratory technologist for the purposes of this Subpart.

(d) Duties of a clinical laboratory technician. A clinical laboratory technician performs tests pursuant to established and approved protocols, where such tests require the exercise of limited independent judgment and responsibility, and where such tests are only in those specialties or subspecialties in which the clinical laboratory technician is qualified by education, training and experience.

(e) Qualifications of a clinical laboratory technician. A clinical laboratory technician practicing in New York State shall possess a valid license issued by the New York State Education Department to practice as a clinical laboratory technician, if such license is required under Article 165 of the State Education Law. A clinical laboratory technician practicing in a clinical laboratory or blood bank located outside of New York State may

qualify provided the clinical laboratory technician possesses an equivalent license issued by the state or jurisdiction in which the laboratory is located, or meets one of the following requirements:

(1) Successful completion of a course of study which meets all academic requirements for an associate's, or higher, degree in medical technology from an accredited institution; or

(2) Successful completion of a course of study which meets all academic requirements for an associate's, or higher, degree in one of the chemical, physical or biological sciences from an accredited institution, and, in addition, at least three months of acceptable supervised experience and/or relevant training.

(f) An individual practicing as a clinical laboratory technician outside of New York State, who is licensed to practice in that state or jurisdiction, or who possesses credentials that were evaluated and deemed acceptable prior to the adoption of this section, may be qualified as a clinical laboratory technician for the purposes of this Subpart.

(g) Duties of a cytotechnologist:

A cytotechnologist makes the preliminary cytologic interpretation for gynecologic cell samples (PAP smears) and non-gynecologic cell samples and makes the final cytologic interpretation for gynecologic cell samples which are within normal limits under the general direction of a qualified pathologist and pursuant to the requirements of section 58-1.12 of this Subpart, and performs certain other tests related to gynecological health,

pursuant to Department approval, which require independent judgment and responsibility.

[(c)] (h) Qualifications of a cytotechnologist.

A cytotechnologist practicing in New York State shall possess a valid license issued by the New York State Education Department to practice as a cytotechnologist, if such license is required under Article 165 of the State Education Law. A cytotechnologist practicing outside of New York State may qualify provided the cytotechnologist possesses an equivalent license issued by the state or jurisdiction in which the laboratory is located, or meets one of the following requirements:

(1) [have successfully completed two years in an accredited college or university with at least 12 semester hours in biology courses pertinent to the medical sciences; and:] successful completion of a course of study that meets all academic requirements for a bachelor's, or higher, degree in cytotechnology from an accredited institution that prepares the applicant for professional practice as a cytotechnologist; or

[(i) must have received 12 months of training in a school of cytotechnology approved by the American Medical Association; or

(ii) received six months formal training in a school of cytotechnology approved by the American Medical Association and six months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal six months of training; or]

(2) [prior to September 1, 1971, shall have been graduated from high school, completed six months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and completed two years of full-time experience in cytotechnology.] successful completion of a course of study that meets all academic requirements for a bachelor's, or higher, degree in one of the chemical, physical or biological sciences and, in addition, 12 months of training in a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation (CAHEA) or the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or a program registered as licensure-qualifying in cytotechnology by the New York State Education Department; or

(3) An individual practicing as a cytotechnologist outside of New York State who is licensed to practice in that state or jurisdiction, or who possesses credentials that were evaluated and deemed acceptable prior to the adoption of this section, shall qualify as a cytotechnologist for the purposes of this Subpart.

(i) Duties of a histotechnician. A histotechnician processes tissues by fixation, dehydration, embedding, sectioning, decalcification, microincineration, mounting, and routine and special staining and may also identify tissue structures, cell components and their staining characteristics, and relate them to physiological functions, under the general supervision of a pathologist.

(j) Qualifications of a histotechnician. A histotechnician practicing in New York State shall possess a valid license issued by the New York State Education Department to practice as a certified histotechnician, if such license is required under Article 165 of the State Education Law. A histotechnician practicing outside of New York State shall qualify provided the histotechnician possesses an equivalent license issued by the state or jurisdiction in which the laboratory is located, or meets one of the following requirements:

(1) successful completion of a course of study that meets all academic requirements for an associate's, or higher, degree in a histotechnician program from an accredited institution; or

(2) successful completion of a full course of study that meets all academic requirements for an associate's degree, or higher, in one of the chemical, physical or biological sciences from an accredited institution; and either one of the following conditions:

(i) one year of experience and/or training in histology within the past 5 years, under the direction of a pathologist certified by the American Board of Pathology in anatomic pathology; or

(ii) successful completion of a course of training of at least nine months in an histotechnician program from an accredited institution; or

(3) successful completion in an accredited institution of a course of study that meets all academic requirements for a bachelor's, or higher, degree in one of the

chemical, physical or biological sciences, including a combination of thirty (30) hours in biology and chemistry; and, either one of the following conditions:

(i) one year of experience and/or training in histology within the past 5 years, under the direction of a pathologist certified by the American Board of Pathology in anatomic pathology; or

(ii) successful completion of a course of training of at least nine months in an histotechnician program from an accredited institution.

(4) An individual practicing as a histotechnician in another state or jurisdiction who is licensed to practice in that state or jurisdiction, or who possesses credentials that were evaluated and deemed acceptable prior to the adoption of this section, may qualify as a histotechnician for the purposes of this Subpart.

* * *

Section 58-1.14 Reporting of certain communicable diseases

(a) The commissioner shall designate those communicable diseases, as defined by section 2.1 of the Sanitary Code, that require prompt action, and shall make available on the Department's website a list of such communicable diseases.

(b) Laboratories performing tests for screening, diagnosis or monitoring of communicable diseases requiring prompt action pursuant to subdivision (a) of this section, for New York State residents and/or New York State health care providers, shall:

(i) immediately report to the commissioner all positive results for such communicable

diseases in a manner and format as prescribed by the commissioner; and

(ii) report all results, including positive, negative and indeterminate results, to the commissioner in a time and manner consistent with Public Health Law § 576-c.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 576 authorizes the New York State Department of Health (Department) to promulgate regulations to effectuate the provisions and purposes of Title V of Article 5 of the PHL, relating to the issuance of permits and the requirements for operating a clinical laboratory or blood bank.

Legislative Objectives:

Title V of Article 5 of the PHL is intended to promote the public health, safety, and welfare by requiring the permitting of clinical laboratories and blood banks and by requiring that the performance of tests and procedures employed by clinical laboratories and blood banks meet minimum standards accepted and approved by the Department.

Needs and Benefits:

Amendments to section 58-1.1 clarify that tests or procedures performed by a clinical laboratory or blood bank must be approved by the Food and Drug Administration (FDA) or by the Department; define allowable owners and laboratory directors of clinical laboratories and blood banks; specify conditions for permit denial; and better describe the conditions under which provisional permits can be issued. These amendments are beneficial to the Department and to regulated parties because they provide clarity to the permitting process. Further, during the COVID-19 public health emergency, the need for a streamlined process to issue provisional permits became evident to allow the

Department to quickly approve laboratories located in New York to initiate COVID-19 testing. For example, the current regulation specifically prohibits the issuance of a provisional permit in virology, the category under which diagnostic COVID-19 testing is performed. By removing this language and revising other criteria for provisional permit issuance, the Department will be better positioned to respond more rapidly in the event of future novel communicable disease outbreaks. Additionally, subdivision 58-1.1(e) codifies the process for voiding a permit.

The introduction of a "single use permit" will allow access to testing on a patient- or test-specific basis, when such testing is medically necessary, needed as part of a clinical trial, or as part of a declared state of emergency. Single use permits are beneficial to the public health by allowing testing to be performed by laboratories that do not hold a New York State clinical laboratory or blood bank permit, but which can nevertheless offer important services to patients. In addition to being able to be used during a pandemic, single use permits will allow testing for extremely rare disorders or where testing capacity of New York State permitted laboratories is limited and additional support is needed to meet testing demands.

Amendments to section 58-1.2 add the term "sole assistant director," which is a person responsible for one or more categories on the laboratory permit for which the laboratory director does not hold a certificate of qualification. Sole assistant directors will be treated as laboratory directors for those categories. Amendments to this section will also increase the number of allowable directorships an individual may hold and establish requirements for the onsite presence of laboratory directors, notification of

laboratory director changes and notification of laboratory director absences. These changes provide flexibility and reduce the regulatory burden on clinical laboratories.

The proposed amendments will also increase the number of directorships of clinical laboratories or blood banks allowed for a laboratory director, from two to five. This change will benefit regulated parties, especially in geographically rural areas or in specialized areas of testing where qualified individuals are scarce.

The proposed amendments establishing requirements for the onsite presence of the laboratory director and any sole assistant director are necessary to ensure the quality of testing results. Specifically, amendments to subdivisions 58-1.2(c) through (g) set forth the requirements for the onsite presence of the laboratory director and sole assistant director, while also providing criteria for exceptions to those requirements. Revisions to the definition of "regular part time hours" will add clarity to the regulations. This change will also help facilitate social distancing in clinical laboratories by reducing the in-person workforce.

New subdivision 58-1.2(e) is needed to clarify that termination, death, or incapacitation of the laboratory director will result in the voiding of the permit if not reported within 60 calendar days. This is consistent with the provision in PHL § 575(6) that stipulates that a change in director shall void a permit and the new subdivision 58-1.1(e) which requires notification within 60 days of such change to stay the permit void. The current regulations require notification to the Department of a "temporary absence" of the director, a term that was not defined and therefore led to significant ambiguity. However, new subdivision 58-1.2(g) will help to define the consequences of an extended absence of a director or sole assistant director when a new individual is not identified as a

replacement. Amendments to section 58-1.3 expand the supervisor titles used for clinical laboratories to blood banks; provide criteria for allowing an exception to the requirement to have a supervisor onsite during all hours of laboratory testing; and expand the allowable areas for cytotechnologist supervision in accordance with scope of practice interpretations from the New York State Education Department (NYSED). The revisions allow for part-time remote supervision while still requiring a minimum number of hours onsite, thereby facilitating social distancing in clinical laboratories by reducing the in-person workforce.

Amendments to section 58-1.4 are needed to codify the definition of "acceptable laboratory" in reference to experience required for qualification of laboratory supervisors and clinical laboratory testing personnel; reduce the number of years of experience in acceptable laboratories required to qualify as a laboratory supervisor; and expand the criteria to allow certificate of qualification holders to serve as supervisors. It is assumed that reducing the years of experience will increase the candidate pool of supervisors, therefore alleviating an apparent supervisor shortage. Finally, persons holding a certificate of qualification will be included as allowable supervisors to rectify an oversight in the current regulation.

Amendments to section 58-1.5 revise the duties and responsibilities of clinical laboratory testing personnel, as well as respiratory therapists; amend qualifications for such staff to comply with NYSED licensure requirements; and allow supervisors and staff working in laboratories outside of New York State to qualify under the appropriate titles if they meet either New York State requirements or are licensed in their state or

other jurisdiction. These changes provide flexibility and reduce the regulatory burden on clinical laboratories.

Finally, new section 58-1.14 is necessary to clarify clinical laboratory reporting requirements for certain communicable diseases. The section requires the Commissioner to designate those communicable diseases that require prompt action, and to make available a list of such diseases on the Department website. It also requires clinical laboratories to immediately report positive test results for communicable diseases and to report all test results, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

Costs to Regulated Parties:

Section 576 of the PHL governs the collection of fees to recoup the operating costs of the regulatory program. The proposed revisions do not impose any additional costs to the regulated parties and instead will likely reduce costs.

Cost to Local Government:

The proposed amendments will not require local governments to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Costs to the Department of Health:

The proposed amendments will not impose additional costs to the New York State Department of Health program responsible for oversight of clinical laboratories. The

program responsible for the oversight of clinical laboratories is a well-established program operated at the State level and the new language does not impact the costs of the oversight program.

Local Government Mandates:

The proposed regulations do not impose new mandates on any county, city, town or village government; or school, fire or other special district.

Paperwork:

The proposed revisions to Subpart 58-1 do not require any additional forms or paperwork from regulated parties. In fact, several revisions will reduce the necessity for regulated parties to file paperwork. The modification to subdivision 58-1.2(b), which increases the limit of laboratory directorships from two to five, will remove the need for directors to request a waiver from this section of regulation. Likewise, the modification in subdivision 58-1.2(h) increases the allowable temporary absence from the current policy-defined three weeks to a codified 60 days, which will reduce the number of required notifications to the Department.

Duplication:

The federal government also issues operating certificates to clinical laboratories (42 CFR Part 493). The Department has applied and been approved for an exemption from the federal government for this requirement continuously since 1995, granting the

Department the authority as the primary accrediting body for clinical laboratories operating in New York State. Consequently, there is no duplication.

Alternatives:

An alternative to the regulatory amendments would be to not make any changes to the regulation. However, this alternative was not adopted as the proposed amendments will provide flexibility to the clinical laboratory industry in a manner that protects the safety of New York State residents.

Federal Standards:

The Federal Code of Regulations (CFR) sets forth rules for the operation of clinical laboratories (42 CFR Part 493). Section 58-1.1 is more stringent than federal rules. The federal program issues a certificate to perform testing upon application and payment of fees. The Department issues a permit to perform testing only after all requirements have been met to include, at a minimum, payment of fees, onsite inspection, and participation in proficiency testing.

Section 58-1.3 is more stringent than federal rules. General supervisors under the federal rules must be accessible at all times to provide onsite, telephone or electronic consultation for technical staff; therefore, the supervisor may in fact never be onsite in the laboratory. The proposed amendments to section 58-1.3 require that the supervisor must be onsite for at least eight hours per week to provide oversight in addition to providing telephone or audio-visual consultation. The federal rules do not define the

number of laboratories where a general supervisor may serve. The proposed amendments limit the number of laboratories served by an individual supervisor to five laboratories.

Sections 58-1.4 and 58-1.5 are consistent with the requirements for testing personnel in the federal rules. Amendments to these sections are also in accordance with New York State Education Law.

Section 58-1.14 is consistent with a recently adopted federal rule requiring mandatory communicable disease reporting for COVID-19 test results.

Compliance Schedule:

The Department of Health expects that regulated parties will comply with the proposed regulation upon Notice of Adoption in the State Register.

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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no other compliance costs imposed on public or private entities in rural areas as a result of the amendments.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health ("Department") received comments from representatives of nine clinical laboratories and laboratory member organizations, such as the New York Clinical Laboratory Association and the American College of Medical Genetics and Genomics. These comments are summarized below along with the Department's responses. Based on the comments received, no changes were necessary to the proposed rulemaking.

Comment: A comment was received requesting that Department recognize limited service laboratories to be reimbursed for testing by the Medicaid program.

Response: The requirements for limited service laboratories are outlined in New York State Public Health Law (PHL) section 579(3). By definition, these facilities are excepted from the requirement to hold a clinical laboratory permit. The proposed revisions to Subpart 58-1 of Title 10 of the New York Code, Rules and Regulations (10 NYCRR) are applicable only to sites holding a clinical laboratory or blood bank permit. This comment is outside the scope of these regulations and was forwarded to the Department's Office of Health Insurance Programs.

Comment: A comment was received requesting the deletion of the word "physical" from the requirement in 58-1.1(ii) that a physical inspection be performed before a NY clinical laboratory permit can be issued, so that permits can still be issued when physical inspections are not possible.

Response: Provisional permits only require the performance of an inspection, not a physical inspection, so the Department has the discretion to issue provisional permits for a limited period of time based on a virtual or remote inspection until a physical inspection can be performed. No changes to the proposed regulation are necessary as a result of these comments.

Comment: A comment was received requesting that provisional permits be allowed for the category of cytogenetics.

Response: The language in the current regulation that prohibits issuance of a provisional permit in cytogenetics, mycology, mycobacteriology, HIV testing and virology was marked for deletion in the proposed regulations. No changes are necessary as a result of this comment.

Comment: Two comments were received regarding Section 58-1.1(a)(2), objecting to the potential for broad interpretation of the criteria used to measure the effectiveness of the laboratory director and owner of applying entities, due to the phrases “including but not limited to” and “any other factor.”

Response: This provision provides eleven different factors that the Department will consider when determining a laboratory director’s ability to discharge their responsibilities. The phrase “including but not limited to” is commonly used in regulations and allows the Department to use reasonable discretion should a situation arise that does not fit squarely within the eleven factors listed. No changes are required as a result of these comments.

Comment: A comment was received requesting clarity on the differences in responsibilities for a laboratory director and a sole assistant director.

Response: The designated laboratory director is responsible for the overall operations of the laboratory and must hold direct responsibility, commensurate with their Certificate of Qualification ("CQ"), for at least one category listed on the clinical laboratory permit. A sole assistant director is defined as the only CQ holder designated as responsible for a category on a permit, meaning a single person is deemed responsible for the technical oversight of the testing in that category; which may include responsibilities as outlined in 10 NYCRR Part 19 to the extent delegated by the laboratory director. This situation occurs when the laboratory offers a broad testing menu and the laboratory director does not hold the appropriate Certificate of Qualification for a particular permit category. There is no limit on the number of assistant directors that can be designated as responsible for a category on the permit. In such instances, there would be no sole assistant director. The laboratory director assumes final responsibility for testing in that category and all others on the permit. No changes are necessary as a result of these comments.

Comment: One commenter asked whether the Department could synchronize the category terminology between clinical laboratory permits and laboratory director CQs.

Response: A crosswalk document is posted on the Department's public website, https://www.wadsworth.org/regulatory/clep/certificate-requirements, which

provides a listing of the CQ categories and the permit categories that they cover. No changes to the regulation are necessary as a result of this comment.

Comment: Several comments were received expressing concern about the onsite requirements for the laboratory director and how exemptions are accepted and processed. One comment questioned Department expectation for onsite presence if two permitted-laboratories are located within walking distance of each other or resided in adjoining buildings.

Response: The Department feels strongly that active involvement of laboratory directors in laboratory operations requires a periodic on-site presence. The laboratory director is required to serve the laboratory on a full time or regular part time basis. The proposed regulations define regular part time hours as eight hours per week and additional language allows for onsite presence of the laboratory director of less than regular part time hours based on the number of permit categories for which they are responsible, the volume and complexity of testing at the clinical laboratory or blood bank, and the performance history of the clinical laboratory or blood bank during inspections and proficiency testing.

The process to request less frequent onsite hours of a laboratory director or assistant director remains the same. The onsite hours request must be submitted to the Department using the existing web-based platform, or for initially applying laboratories on forms provided on the Department's webpage, and additional information is requested as necessary to assess the criteria above. A laboratory director employed at more than one site must submit requests for less frequent onsite hours for each site.

Each request is reviewed on a case-by-case basis taking into account the criteria above as well as onsite hours of current responsible staff. If there are special considerations that preclude frequent onsite presence other than the criteria listed above, the laboratory must indicate that such other considerations exist. No changes are necessary as a result of these comments.

Comment: Two comments were received asking for clarity on consistency of state and federal regulations regarding the on-site presence of laboratory directors.

Response: The Department feels strongly that active involvement of laboratory directors in laboratory operations requires periodic on-site presence. State regulations can be more stringent than the federal regulations and it is further noted that the requirement for laboratory directors to serve the laboratory on a full-time or regular part-time basis has not changed from the current regulation. The proposed revisions provide additional clarity on the process to request onsite presence of less frequency. No changes are necessary as a result of these comments.

Comment: A comment was received asking for clarification on the review of criteria to determine if a laboratory is eligible to utilize the remote supervision exception. The commenter asked for a definition of a "pattern" as used in proposed Section 58-1.3(i) and (ii) relating to patterns of noncompliance and unacceptable proficiency testing performance. The commenter also requested "flexibility" in documenting the remote supervisory responsibilities and designation of a 'responsible' supervisor for specific timeframes.

Response: A pattern of noncompliance may occur during the course of a single onsite survey or over several survey events and will depend on the severity and nature of the noncompliance. Likewise, a pattern of unacceptable/unsatisfactory proficiency testing performance may occur based on a series of unsatisfactory performance for a number of analytes included in a single PT event, although generally not including administrative errors, or a series of unacceptable performance for the same analyte over multiple PT events; again, it depends on the specific circumstances causing the unacceptable performance.

The Department does not intend to prescribe supervisory duties as either remote or in-person. The laboratory management must define those duties and determine if they can be performed remotely. This does not preclude any specific duty from being performed in-person.

Regarding the designation of supervisors as responsible during specific timeframes, the intent of the Department is for the laboratory to ensure that testing personnel clearly understand who they can contact with questions. Therefore, it would be reasonable for more than one 'responsible' remote supervisor to be designated based on their area of expertise. No changes to the proposed regulations are necessary as a result of this comment.

Comment: A comment was received requesting inclusion of proposed paragraph 58-1.5(c) into Section 58-1.4 to ensure that currently qualified supervisors may continue to qualify as supervisors following adoption of the regulation.

Response: The Department agrees with this recommendation and intends to prepare a new rulemaking package that will incorporate this change. No changes to the proposed regulation are being made at this time.

Comment: A comment was received asking if clarification could be provided for licensed nurses qualifying as a supervisor, specifically considering the multiple education degree options. The comment suggested that only licensed 4-year RNs with 4 years of experience in non-waived testing be considered to qualify as a supervisor to be consistent with licensed clinical laboratory technologists.

Response: This comment requires consultation with the NYS Education Department; therefore, no changes are being made to the proposed regulation at this time.

Comment: A comment was received suggesting a correction to the reference in Section 58-1.4(d) regarding qualified cytotechnologists.

Response: The Department agrees with this recommendation and intends to prepare a new rulemaking package that will incorporate this change. No changes to the proposed regulation are being made at this time.

Comment: A comment was received requesting additional clarification of the duties of a histotechnician to include the task of specimen grossing.

Response: The Department agrees with the suggestion to include 'grossing' to the lists of duties performed by histotechnician. We intend to incorporate this change in a new rulemaking package that will also address the new State Education license category of

histotechnologist that will go into effect in 2024. No changes to the proposed regulation are necessary at this time.

Comment: Two comments were received requesting clarification on the acceptable credentials for histotechnicians in states other than New York. One commenter provided specific recommendations for consideration, such as allowing an associate's degree in any field with a combination of 12 semester hours (18 quarter hours) of relevant biology and chemistry; allowing for histotechnicians in training (working under the direction of a pathologist certified by the American Board of Pathology in anatomic pathology) to work on NY specimens, and recognizing experienced histotechnicians as those who have histology training within the previous 10 years. The same commenter requested a word change in the verbiage provided in 58-1.5(j)(4) from "may" to "shall."

Response: Pursuant to PHL, any laboratory, regardless of location, that accepts and examines specimens originating from New York must hold a New York clinical laboratory permit. The Department assesses the qualifications of testing personnel in these facilities against the regulations. Individuals acting as histotechnicians in NY permitted laboratories in other states must meet one of the following:

- hold licensure as required in the state with which they're working;
- have had their credentials deemed acceptable to the Department prior to adoption of this proposed revision;
- hold an associate's degree in histotechnology;
- have completed all coursework necessary for an associate's degree or higher in chemical, physical or biological science + 1 year of histotechnology experience

under a licensed pathologist within the past 5 years or completed a nine month histotechnology certificate program; or

- have completed all coursework necessary for a bachelor's degree or higher in chemical, physical or biological science, including 30 credit hours in biology and chemistry + 1 year of histotechnology experience under a licensed pathologist within the past 5 years or completed a nine month histotechnology certificate program.

Review of transcripts is generally necessary to ascertain if a histotechnician has completed the requisite coursework. The Department agrees with the suggestion to change "may" to "shall" in Section 58-1.5(j)(4) and intends to incorporate this change in a new rulemaking package that will also address the new State Education license category of histotechnologist that will go into effect in 2024. No changes to the proposed regulation are necessary at this time.

Comment: A comment was received requesting clarification on the communicable disease reporting requirements set forth in proposed section 58-1.14, specifically the definition of the term "immediately."

Response: The Department generally expects reporting of positive communicable disease results within 24 hours but intends to prepare a new rulemaking package that will also provide additional clarity on reporting expectations.