Health and Health Planning Council shall adopt rules and regulations, subject to the approval of the Commissioner of Health, governing the standards and procedures followed by nursing homes which, at a minimum, must meet federal standards.

Legislative Objectives:

The legislative objective of PHL Article 28, as set forth in PHL section 2800, includes the protection of the health of the residents of New York State through the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. This proposal, which requires nursing homes to submit weekly bed census data to the Department of Health (Department) through the Department's Health Commerce System, is consistent with that objective. Having current and accurate nursing home bed occupancy data is important in the event of natural disasters and to alert the Department to significant changes in nursing home occupancy, improving the Department's ability to take appropriate action. While facilities have already been advised administratively that they must submit this data, including the requirement in regulation will improve compliance.

Current Requirements:

The Health Commerce System (HCS), previously known as the Health Provider Network (HPN), is a highly secure, Internet-based, electronic portal for communications and critical data sharing with organizations including nursing homes and other health care providers. Section 400.10 of Title 10 (Health) of the New York Compilation of Codes, Rules and Regulations (NYCRR) requires providers, including nursing homes, to maintain and keep updated an active HPN account.

DAL #09-02, effective April 8, 2009, was issued by the Department to require nursing homes to report weekly bed census data electronically to the Department through the HPN. The DAL provided for such data to be reported each week between Wednesday 8:00 a.m. and Friday 5:00 p.m. In 2013, via a notice sent through the HCS, the Department informed nursing homes that such data should be reported between Wednesday 12:01 a.m. and the following Tuesday at 11:59 p.m.

Needs and Benefits:

It is critical that the Department have accurate nursing home census data including occupancy and availability data by bed type. Natural events such as hurricanes and floods and other emergency events such as extended power outages could cause situations in which some nursing homes may have to transfer their residents to other facilities to ensure their safety. In those situations, the Department must be able to quickly assess the number and location of nursing home residents across the affected area, as well as the number of available beds. Furthermore, the ability to monitor a facility's current occupancy data improves the Department's ability to identify a declining census and proactively take appropriate action.

Despite the current requirement for bed census data reporting, communicated via a DAL and a subsequent HCS notice, the Department often finds itself in the position of having to call some nursing homes repeatedly to obtain this information. This proposed regulation will add a new section 415.32 to Title 10 of the NYCRR to require that nursing homes submit bed census data on a weekly basis by electronically filing the Nursing Home Weekly Bed Census Survey (Survey). This will promote compliance and ensure that the Department has access to essential, current occupancy data as necessary to protect residents.

Accordingly, the proposed regulation provides that the Survey must be submitted via the HCS Health Electronic Response Data System (HERDS) application by a facility staff person assigned a Nursing Home Data Reporter role within the HCS Communications Directory. Nursing homes shall report bed census data reflecting the weekly census taken every Wednesday at 12:00 a.m. The facility's designated Nursing Home Data Reporter shall enter and transmit the survey census data to the Department between Wednesday at 12:01 a.m. and the following Tuesday at 11:59 p.m. Instructions for the Survey will be available on the HCS. The proposal further requires nursing homes, through their HCS Coordinators, to designate enough Nursing Home Data Reporters to ensure that the facility can submit surveys to the Department as required.

Costs:

Costs to Private Regulated Parties:

New York State health care facilities are already required by section 400.10 of the NYCRR to have an HCS account to exchange electronic information with the Department. Moreover, nursing homes are already expected to send bed census information to the Department as communicated in the DAL. Therefore, nursing homes should not incur any additional costs related to the electronic submission of bed census information to comply with the proposed regulation.

Costs to Local Government:

This proposal will not impact local governments unless they operate a nursing home, in which case they will be impacted to the same extent as other nursing homes. As previously noted, nursing homes are not expected to incur any additional costs related to the electronic submission of bed census information.

Costs to the Department of Health:

The Department is not expected to incur any additional administrative costs as a result of the proposed regulation. The statewide HCS infrastructure and the mechanisms for nursing home bed census data collection are already in place.

Costs to Other State Agencies:

The proposed regulatory changes will not result in any additional costs to other State agencies.

Local Government Mandates:

This proposed regulation does not impose any new mandates on local governments.

Paperwork:

Nursing homes are already expected to submit bed census information via the HCS. Accordingly, the proposal should not increase paperwork.

Duplication:

This proposed regulation reiterates and strengthens the existing requirement, set forth in the DAL, that nursing homes report census data on a weekly basis to the Department. Moreover, while federal regulations require submission of bed census data to the federal Centers for Medicare and Medicaid Services (CMS) on a quarterly basis, this regulation will ensure that the Department receive this information directly and more frequently.

Alternatives:

There are no other alternatives for the Department to reliably secure current bed census data from nursing homes.

Federal Standards:

Federal regulations require nursing homes to submit quarterly census data to CMS.

Compliance Schedule:

These regulations will be effective upon publication of a Notice of Adoption in the New York State Register. The statewide HCS infrastructure and the mechanisms for bed census reporting for nursing homes are already in place. Consequently, regulated parties should be able to comply with the proposed regulation as of its effective date.

Regulatory Flexibility Analysis

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed rule will not have a substantial adverse impact on small businesses or local governments. Nursing homes that constitute small businesses and local health departments that operate nursing homes, like all other nursing homes, are already required to have an HCS account to exchange electronic information with the Department and report bed census data.

Rural Area Flexibility Analysis

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed rule will not have an impact on nursing homes located in rural areas any differently than in any other areas. Such nursing homes are already required to have an HCS account to exchange electronic information with the Department and report bed census data.

Job Impact Statement

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of this proposed regulation.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Clinical Laboratory Directors

I.D. No. HLT-51-18-00017-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Amendment of Part 19 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 573

Subject: Clinical Laboratory Directors.

Purpose: Recognize additional accrediting boards for qualification of clinical laboratory directors to obtain a certificate of qualification.

Substance of proposed rule (Full text is posted at the following State website:www.health.ny.gov/Laws & Regulations/Proposed Rulemaking): Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 573 of the Public Health Law, Part 19 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

Section 19.1 is amended to include definitions for "assistant director," "board certified," "earned doctoral degree," "training," and "experience." The definitions of "acceptable laboratory" and "category" are also revised and clarified. Section 19.1 is further revised to expressly recognize physicians and dentists who are licensed in the countries in which they practice as being able to qualify as directors or assistant directors of clinical laboratories or blood banks.

Section 19.2 is amended to recognize additional accrediting boards for purposes of certifying that applicants meet the educational and training requirements needed to be a director or assistant director of a clinical laboratory or blood bank.

Section 19.3 is amended to provide the Department more flexibility in updating the certificate of qualification categories. Amendments to this section will also allow the Department to issue certificates of qualification with limitations based on an applicant's specific experience. In addition, this section is amended to include additional director responsibilities, such as ensuring staff competency, specifying in writing the responsibilities and duties of all laboratory personnel, having standard operating procedure manuals, and participating in acceptable proficiency testing.

Section 19.4 is amended for clarity and to remove references to New York City laboratory permits, which are obsolete.

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 60 days after publication of this notice.

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) section 573 establishes the authority of the Department to promulgate criteria for the issuance of a certificates of qualification. PHL section 573(2) specifically states that the Department shall issue a certificate of qualification to any person who meets such minimum qualifications and who otherwise demonstrates to the Department that he or she possesses the character, competence, training and ability to administer properly the technical and scientific operation of a clinical laboratory or blood bank, including supervision of procedures and reporting of findings of tests.

Legislative Objectives:

The legislature enacted PHL section 573 to protect the health and safety of the public by requiring that only properly educated and experienced individuals be issued certificates of qualification and subsequently assigned responsibility as clinical laboratory directors. Such directors are responsible for the proper operation of clinical laboratories to ensure accurate and reliable results for clinical testing. Part 19 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR), in its original adoption and all subsequent revisions, has been crafted to ensure that applicants have the necessary education, training and experience to effectively direct a laboratory. The proposed amendment is consistent with this legislative objective as it will include the recognition of additional accrediting boards that have been developed since the last regulatory amendment, in response to changes and advances in clinical laboratory testing.

Needs and Benefits:

Part 19 regulates the issuance of certificates of qualification. An individual must hold such certificate to be a clinical laboratory director or assistant director at a clinical laboratory or blood bank permitted by New York under the authority of PHL section 572. The intent of these regulations is to ensure that individuals who are granted certificates of qualification have the necessary education, experience, and training to effectively operate a clinical laboratory. Successful applicants for a certificate of qualification must demonstrate both experience in laboratory management, such as management of resources (e.g. budget allocation, staffing), implementation of a quality management system, development of standard operating procedures; and experience specific to a category of testing defined in Part 19.

Several revisions to the regulatory definitions are proposed. Most notable are the inclusion of a definition for assistant director and revision to the definition of category. Assistant directors are jointly accountable with the laboratory director for the categories of testing on the laboratory permit. In many instances, however, the assistant director may be the only individual qualified to supervise testing in a specific category on the laboratory permit.

Language is proposed in sections 19.2 and 19.3 that clarifies the role and responsibilities of assistant directors of clinical laboratories. With these revisions, assistant directors will be held to the same standards as laboratory directors.

The definition of "category" was revised to strengthen the Department's authority to limit the approval of a certificate of qualification to a subcategory, technology, method or specific procedure based on the applicant's documented experience. Extensive experience in a single method of testing does not necessarily translate to breadth of knowledge across an entire category of testing. Indeed, as innovations in laboratory medicine continue, an individual's experience in a proven technology may quickly become obsolete without continued education and training. The proposed revisions to the definition of category allow the Department to ascertain an individual's specific breadth of experience upon each application and reapplication for a certificate of qualification.

The definitions of the following terms are being proposed for the first time; board certified, earned doctoral degree, training, and experience.

A review of the accrediting boards currently recognized in Part 19 and those included in the proposed revisions was performed to ensure that the requirements for each board were consistent with the rules set forth in federal regulation. This included a review of both the educational and training requirements for the accrediting board. As noted in the proposed revisions, certain boards mandate the appropriate educational requirement of a doctoral degree, but do not specify that the candidate for the board demonstrate the required four years of post-doctoral experience. Therefore, language clarifying the post-doctoral degree experience required by the Department has been proposed for these boards (American Board of Bioanalysts High Complexity Laboratory Director and the National Registry of Clinical Chemists) to ensure that the requirements for all applicants are consistent.

The duties and responsibilities of laboratory directors and assistant directors set forth in subdivision 19.3(c) were revised to provide clarity and introduce new responsibilities. Of note are the added responsibilities of ensuring the availability of procedures for monitoring staff competency and improvement of skills. These new responsibilities are currently included in the New York State Clinical Laboratory Standards of Practice; however, formal codification in regulation is desired.

Finally, subdivision 19.3(d) has been removed since the certificate of qualification categories are repeated in the current subdivision 19.3(e), and therefore 19.3(d) was considered redundant. The Department currently maintains a list of certificate of qualification categories on its publicly accessible website, and revisions were made in proposed subdivision 19.1(i) to outline the necessary contents of this list.

Costs:

Costs to Regulated Parties:

The proposed amendment will not impose costs on regulated parties. The current regulation already requires clinical laboratories and blood banks to have directors who hold certificates of qualification.

Costs to the Agency, State and Local Governments:

The proposed amendment will not impose additional costs to the New York State Department of Health, the program responsible for oversight of clinical laboratories, or to local governments. 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 impose no new mandates on any county, city, town or village government; or school, fire or other special district.

Paperwork:

The proposed revisions to Part 19 do not require any additional forms or paperwork from applicants. All candidates are required under the current rule to provide a complete application, a curriculum vitae, and proof of licensure for physicians or granting of an earned doctoral degree. Additionally, candidates must submit proof of any accreditation by a recognized board and/or letters from third parties attesting to the candidate's training and experience. The proposed revisions expand the list of recognized accrediting boards, which may in fact reduce the paperwork needed for candidates holding those accreditations.

Duplication:

The federal government also recognizes clinical laboratory directors. The Department has applied and been approved for an exemption from the federal government continuously since 1995 that grants the Department the authority to act as the primary accrediting body for clinical laboratories and clinical laboratory directors operating in New York.

Alternatives:

The alternative to this proposal would be to maintain the existing regulatory requirements. However, the proposed amendments are necessary to update the regulations to include new definitions, update the list of acceptable accrediting boards, and clarify and expand the responsibilities of laboratory directors and assistant directors.

Federal Standards:

The Federal Code of Regulations (CFR) sets forth rules for the education and experience of clinical laboratory directors (CFR 493.1443). The proposed revisions to Part 19 will incorporate several of the accrediting boards that are already recognized under the federal rule.

Compliance Schedule:

Regulated parties are expected to comply with the proposed regulation by its effective date.

Regulatory Flexibility Analysis

No regulatory flexibility analysis is required. The proposed 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. At present the regulations require clinical laboratories and blood banks to be directed by individuals who hold a certificate of qualification. This proposed amendment would update and expand the list of acceptable accrediting boards for obtaining a certificate of qualification and is therefore anticipated to have a positive impact by increasing the number of individuals who may qualify for a certificate of qualification.

Rural Area Flexibility Analysis

No rural area flexibility analysis is required pursuant to § 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendments will not impose an adverse impact on facilities in rural areas, and will not impose any significant new reporting, record keeping or other compliance requirements on facilities in rural areas.

Job Impact Statement

No job impact statement is required pursuant to § 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

New Requirements for Annual Registration of Licensed Home Care Services Agencies

I.D. No. HLT-51-18-00018-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Amendment of sections 766.9 and 766.12(c)(4) of Title 10 NYCRR.

Statutory authority: Public Health Law, section 3605(7)

Subject: New requirements for Annual Registration of Licensed Home Care Services Agencies.

Purpose: To amend the regulations for licensed home care services agencies for the annual registration requirements of the agency.

Text of proposed rule: Subdivision (n) of § 766.9 is amended to read as follows:

(n) ensure that any franchise agreement complies with the following:

* * *

(4) An agreement which contains elements of both a franchise agreement and a management contract shall be subject to the applicable provisions of this subdivision and subdivision (m) of this section[.]*; and*

A new subdivision (o) is added to § 766.9 to read as follows and existing subdivision (o) re-lettered (p):

(o) ensure registration of the licensed home care services agency with the commissioner through submission of annual registration forms included in the annual statistical report;

(1) no licensed home care services agency shall be operated, provide nursing services, home health aide services, or personal care services, or receive reimbursement from any source for the provision of such services during any period of time on or after January 1, 2019, unless it has registered for the current period;

(2) a licensed home care services agency that fails to submit a complete and accurate set of all required registration materials by the annual deadline of November 16th is required to pay a fee of $500 for each month or part thereof that the licensed home care services agency is not registered;

(3) a licensed home care services agency that fails to register in the prior year by the deadline of the current year shall not be permitted to register for the upcoming registration period unless it submits any and all unpaid late fees;

(4) the department shall publish a listing of all licensed home care services agencies and their current registration status on its public website;

(5) the department shall institute proceedings to revoke the license of any licensed home care services agency that fails to register for two annual registration periods, whether or not such periods are consecutive; and

(6) the department shall pursue revocation of the license of a licensed home care services agency if it evidences a pattern of late registration over the course of multiple years without justification acceptable to the commissioner.

Subdivision (c) of § 766.12 is amended to read as follows:

(c) The home care services agency shall furnish annually to the department a copy of:

(1) statistical summaries of all health care services, including the type, frequency and reimbursement for services provided, including reimbursement from federal and state governmental agencies, on forms provided by the department;

(2) if a for-profit corporation, a list of the principal stockholders and the number and percent of the total issued and outstanding shares of the corporation held by each, duly certified by the secretary of the corporation as to completeness and accuracy;

(3) if a not-for-profit corporation, a list of directors, officers and corporate members, if such members number 10 or fewer;

(4) *the agency's registration in a manner prescribed by the department; and*

(5) other such records and reports as may be legally required by the department.

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 60 days after publication of this notice.

This rule was not under consideration at the time this agency submitted its Regulatory Agenda for publication in the Register.

Regulatory Impact Statement

Statutory Authority:

This proposal will implement amendments to Public Health Law (PHL) §§ 3605-a and 3605-b requiring registration of licensed home care services agencies pursuant to Article 36.

Legislative Objectives:

Public Health Law Article 36 was intended to promote the quality of home care services provided to residents of New York State and to assure adequate availability as a viable alternative to institutional care. The proposed regulation furthers this objective by developing a system for the Department of Health (Department) to identify agencies that are non-operational and aligns state regulations with the Department's strategic plan.

Needs and Benefits:

The proposed changes to 10 NYCRR §§ 766.9 and 766.12(c)(4) implement amendments to PHL §§ 3605-a and 3605-b made by Chapter 57 of the Laws of 2018, Part B, §§ 9-c and 9-d, requiring registration of licensed home care services agencies pursuant to PHL.

Annual registration of licensed home care services agencies will allow the Department, on an annual basis, to confirm operational entities in all regions of the state. The registration will confirm the number of agencies providing services in the defined services area and the types of services provided. The information will assist the Department in identifying potential gaps in provider capacity and consumer access to services, and is important as the Department develops a need methodology for licensed home care services agencies. It will also be useful to the Department's oversight and surveillance functions.

This will be integral in improving the overall quality of services provided to individuals who are receiving home care services.

Just as important, the information obtained from the licensed home care services agency registration will improve consumer access to information about licensed home care services agency availability. The information collected from the registration process will improve the currency and accuracy of provider-related information on the DOH public website, giving consumers meaningful information that can help them identify available options for home care services. Additionally, the public website will identify those agencies who are registered with the Department and those agencies who are not registered with the department, indicating their compliance with 10 NYCRR § 766.9.

To comply with the registration requirement, licensed home care services agencies will need to complete a section that will be added to the existing annual statistical report. These must be submitted during the annual data collection period, which commences in August of the preceding year of the registration deadline and ends by November 16th.

The proposed changes will provide a benefit to current licensed home care services agencies who complete the registration as required, as they will be listed on the public website as being currently registered and active.

Costs:

SUMMARY OF EXPRESS TERMS

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 573 of the Public Health Law, Part 19 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

Section 19.1 is amended to include definitions for "assistant director," "board certified," "earned doctoral degree," "training," and "experience." The definitions of "acceptable laboratory" and "category" are also revised and clarified. Section 19.1 is further revised to expressly recognize physicians and dentists who are licensed in the countries in which they practice as being able to qualify as directors or assistant directors of clinical laboratories or blood banks.

Section 19.2 is amended to recognize additional accrediting boards for purposes of certifying that applicants meet the educational and training requirements needed to be a director or assistant director of a clinical laboratory or blood bank.

Section 19.3 is amended to provide the Department more flexibility in updating the certificate of qualification categories. Amendments to this section will also allow the Department to issue certificates of qualification with limitations based on an applicant's specific experience. In addition, this section is amended to include additional director responsibilities, such as ensuring staff competency, specifying in writing the responsibilities and duties of all laboratory personnel, having standard operating procedure manuals, and participating in acceptable proficiency testing.

Section 19.4 is amended for clarity and to remove references to New York City laboratory permits, which are obsolete.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 573 of the Public Health Law, Part 19 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

19.1 Definitions.

(a) [Clinical laboratory director] 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. If a clinical laboratory or blood bank employs more than one director, the laboratory owner(s) shall designate in writing one such individual as the director of record for the laboratory.

(b) Assistant director means a director who has been designated by the owner(s) of the laboratory as having shared responsibility with a director for the technical and scientific operation of the clinical laboratory or blood bank in one or more categories and/or subcategories.

[(b)] (c) 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 standard as outlined in Part 58 of this Title.] a facility, operating lawfully, that meets the definition of a clinical laboratory or blood bank as defined in Section 571 of the Public Health Law and which has a director who meets or would meet the

requirements of this Part, including the anatomic and clinical pathology facilities of a hospital or health department, a clinical 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.

[(c)] (d) Accredited means having the approval (accreditation) conferred on schools, institutions or programs by an accrediting agency or association recognized by the United States Secretary of Education and verified as such by the [commissioner] department.

[(d)] (e) Physician means a physician who is licensed and currently registered to practice medicine in New York State or in the state or the country in which he or she practices and is not subject to any disciplinary or non-disciplinary order by the applicable state or country except as otherwise allowed by the department.

[(e)] (f) Dentist means a dentist who is licensed and currently registered to practice dentistry in New York State or in the state or the country in which he or she practices and is not subject to any disciplinary or non-disciplinary order by the applicable state or country except as otherwise allowed by the department.

[(f)] (g) Certificate of qualification means a credential issued by the department to applicants [meeting] determined by the department to meet the requirements set forth in this Part.

[(g)] (h) 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)] (i) Category means an area, [procedure, or specialty of laboratory medicine specified in section 19.3(d) of this Part.] field, or discipline of laboratory medicine or laboratory science in

which a certificate of qualification is issued. The department may issue certificates of qualification in a specified subpart of a category, including, but not limited to, a subcategory, technology, method, or specific procedure, based on the applicant's education, training, and experience and the applicant's ability to demonstrate that tests performed under their direction generate reliable results. The department shall make available a list of: categories and subcategories in which certificates of qualification are issued; minimum qualifications for each category; and the corresponding categories of testing authorized by a laboratory permit.

[(i) Blood banking-collection means collection of blood or blood components, or processing of blood or blood products.

(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.]

(j) Department means the New York State Department of Health.

(k) Board certified means having completed all requirements set forth by an accrediting board

acceptable to the department, including a passing score on any qualifying examination and completion of all the requirements for recertification whenever the certifying board mandates recertification, provided such requirements are determined by the department to provide the applicant with the ability to effectively discharge the responsibilities described in Parts 10 and 58 of this title.

(l) Earned doctoral degree means a doctor of philosophy, doctor of science, or equivalent degree as determined by the department.

(m) Training includes participation in a residency, fellowship, or post-doctoral position, or participation in a training course approved by a board acceptable to the department.

(n) Experience includes post-doctoral employment or voluntary participation in an acceptable laboratory where the applicant performed, supervised or directed testing of human clinical specimens. Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is also considered acceptable experience.

19.2 Clinical laboratory or blood bank; qualifications of laboratory director.

[The] A director and any assistant director of a clinical laboratory or blood bank [must] shall possess training and/or experience acceptable to the department, 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] Additionally, the applicant must meet one of the following requirements:

(a) be a physician who is currently certified by [the American Board of Pathology in]:

(1) the American Board of Pathology in:

[(1)](i) clinical pathology; or

[(2)](ii) anatomic pathology; or

[(3) An area of special competence relevant to the certificate of qualification sought; or] (iii) dermatopathology; or

(2) the American Osteopathic Board of Pathology in:

(i) laboratory medicine; or

(ii) anatomic pathology; or

(iii) dermatopathology; or

(b) be a physician in the State of New York who:

(1) is currently certified by the American Board of Pathology in Blood Banking and Transfusion Medicine; or

(2) is currently certified by the American Board of Pathology in Clinical Pathology or the American Board of Internal Medicine in Hematology, and possesses six months of training and/or experience in transfusion services; or

(3) possesses four years of training and/or experience in an acceptable laboratory including two or more years of training and/or experience in transfusion services and in general laboratory management.

[(b)](c) be a dentist who is currently certified by the American Board of Oral and Maxillofacial Pathology; or

[(c)](d) 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 one of the following boards and meets any supplemental requirements for experience as specified by the department:

(i) [the American Board of Medical Microbiology] the American Board of Bioanalysis as a High Complexity Laboratory Director, provided the applicant has obtained a minimum of four years of post-doctoral experience equivalent to paragraph (2) of this subdivision; 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 Dermatology; or

[(iv)](v) the American Board of Forensic Toxicology, provided the applicant has an earned doctoral degree; or

[(v) the American Board of Medical Laboratory Immunology; or]

(vi) the American Board of Internal Medicine in hematology or hematology and medical oncology; or

(vii) the American Board of Medical Laboratory Immunology; or

(viii) the American Board of Medical Microbiology; or

(ix) dual certification by the American Board of Pathology in either Anatomic Pathology or Clinical Pathology, and Molecular Genetic Pathology; or

(x) the American Board of Pathology in Medical Microbiology; or

(xi) the National Registry for Certified Chemists, provided the applicant has obtained a minimum of four years of post-doctoral experience equivalent to paragraph (2) of this subdivision; 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] department.

[(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 issuance, duties and responsibilities.

(a) Certificate required. [A]An individual serving as a director or assistant director of a clinical laboratory or blood bank must hold a certificate of qualification issued after the [commissioner] department 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) of this section 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,] To qualify for, and maintain, a certificate of qualification, a laboratory director and any assistant director [should

possess a] shall demonstrate that he or she possesses knowledge of basic clinical laboratory sciences and operations, and [should] shall have the training and/or experience and physical capability to discharge the following responsibilities:

(1) provide advice to referring [physicians] health care providers regarding the significance of laboratory findings and ensure that reports of test results include pertinent information required for the interpretation of laboratory data;

* * *

(3) define, implement, and monitor standards of performance [in quality control and quality assurance] for the laboratory and for other ancillary laboratory testing programs in conformance with the department's clinical laboratory standards of practice;

* * *

(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] a quality management system, regardless of where the testing is performed;

* * *

(7) [set goals and develop and allocate resources within the laboratory] ensure that policies and procedures are established for monitoring staff to assess competency and, whenever necessary, to provide remedial training to improve skills;

(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] specify in writing the responsibilities and duties of all laboratory personnel;

(9) provide [educational direction] continuing education to laboratory staff;

(10) [select all reference laboratories; and] ensure that a current and complete procedure manual

is available to all personnel;

(11) [promote a safe laboratory environment for personnel and the public.] set goals, develop and allocate resources within the laboratory;

(12) provide effective administrative direction of the laboratory, in conjunction with the individual(s) responsible for financial management of the laboratory, to ensure adequate resources are available to operate the laboratory in a manner consistent with all state and federal requirements;

(13) select all reference laboratories for services not offered by the laboratory;

(14) promote a safe laboratory environment for personnel and the public; and

(15) ensure that the laboratory, when applicable, is enrolled in a proficiency testing program acceptable to the department for the testing performed and that the laboratory adheres to the proficiency testing program's administrative and technical requirements.

[(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;

(5) 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 fluid;

(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)](d) 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)](a)(1)(i), (a)(2)(i), (d)(1)(i), (d)(1)(viii), (d)(1)(x) or (d)(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)](d)(1)(viii), (d)(1)(x) or (d)(2) of this Part. Applicants for a certificate of qualification in virology limited to antigen detection and molecular methods must qualify under

section 19.2(a)(1)(i), (a)(2)(i) or (d)(1)(i) 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)(2), or (c)(1)(v)](a)(1)(i), (a)(2)(i), (d)(1)(i), (d)(1)(vii), (d)(1)(viii), (d)(1)(x) or (d)(2) of this Part.

(4) Applicants for certificate of qualification in hematology must qualify under section 19.2[(a)(1), (c)(1)(vi), or (c)(2)](a)(1)(i), (a)(2)(i), (d)(1)(vi) or (d)(2) of this Part. Applicants qualifying under section 19.2[(c)(1)(vi)](d)(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)](a)(1)(i), (a)(2)(i), or (d)(2) of this Part.

(6) Applicants for a certificate of qualification in [one or more of the subspecialties of clinical biochemistry] clinical chemistry, blood pH and gases, endocrinology, or therapeutic substance monitoring - quantitative toxicology must qualify under section 19.2[(a)(1), (c)(1)(ii), or (c)(2)](a)(1)(i), (a)(2)(i), (d)(1)(i), (d)(1)(ii), (d)(1)(xi) or (d)(2) of this Part.

(7) Applicants for a certificate of qualification in histopathology and/or cytopathology must qualify under section 19.2[(a)(2)](a)(1)(ii) or (a)(2)(ii) of this Part.

(8) Applicants for a certificate of qualification in oral pathology must qualify under section 19.2[(a)(2) or (b)](a)(1)(ii), (a)(2)(ii), or (c) of this Part.

(9) Applicants for a certificate of qualification in dermatopathology must qualify under section 19.2[(a)(2) or (a)(3)](a)(1)(ii), (a)(1)(iii), (a)(2)(ii), (a)(2)(iii) or (d)(1)(iv) of this Part.

(10) Applicants for a certificate of qualification in cytogenetics, histocompatibility, cellular immunology, [oncofetal antigens, and/or] genetic testing, fetal defect markers, forensic identity,

oncology, parentage/identity testing, trace elements, and/or transplant monitoring must qualify under section 19.2[(c)(2)](d)(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)](b)(1), (b)(2) or (b)(3) 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)](d)(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]allogenic 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)](a)(1)(i), (b)(1)(i), or (d)(1)(vi) 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)](a)(1)(i), (b)(1)(i), (d)(1)(i), (d)(1)(ii), (d)(1)(iii), (d)(1)(xi), or (d)(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)](d)(1)(iii), (d)(1)(v), or (d)(2) of this Part.

(16) Applicants for a certificate of qualification in andrology must qualify under section 19.2(d)(1)(i) or (d)(2) of this Part; or under section 19.2(a)(1)(i) or (b)(1)(i) of this Part including or supplemented by at least six months' training and/or experience in andrology.

(17) Applicants for a certificate of qualification in blood lead must qualify under section 19.2(a)(1)(i), (b)(1)(i), (d)(1)(i), (d)(1)(iii), (d)(1)(v), (d)(1)(xi), or (d)(2) of this Part.

[(f)] (e) 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] will 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:

* * *

(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];

* * *

(6) on the part of any laboratory, category, or subcategory 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, category, or subcategory 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, category, or subcategory 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)](9) on the part of any laboratory, category, or subcategory 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)](10) on the part of any laboratory, category, or subcategory 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)](11) on the part of any laboratory, category, or subcategory 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)](12) on the part of any laboratory, category, or subcategory 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 and Federal laws, rules and regulations, or in a manner which endangers the public, the laboratory's employees, or the environment;

[(14)](13) employment of unqualified or unlicensed technical personnel or an insufficient number of such personnel;

[(15)](14) failure of the [laboratory director] applicant to be responsible for adequately supervising laboratory personnel to ensure the proper performance of all tests conducted in the laboratory; and

[(16)](15) 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.

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 573 establishes the authority of the Department to promulgate criteria for the issuance of a certificates of qualification. PHL section 573(2) specifically states that the Department shall issue a certificate of qualification to any person who meets such minimum qualifications and who otherwise demonstrates to the Department that he or she possesses the character, competence, training and ability to administer properly the technical and scientific operation of a clinical laboratory or blood bank, including supervision of procedures and reporting of findings of tests.

Legislative Objectives:

The legislature enacted PHL section 573 to protect the health and safety of the public by requiring that only properly educated and experienced individuals be issued certificates of qualification and subsequently assigned responsibility as clinical laboratory directors. Such directors are responsible for the proper operation of clinical laboratories to ensure accurate and reliable results for clinical testing. Part 19 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR), in its original adoption and all subsequent revisions, has been crafted to ensure that applicants have the necessary education, training and experience to effectively direct a laboratory. The proposed amendment is consistent with this legislative objective as it will include the recognition of additional accrediting boards that have been developed since the last regulatory amendment, in response to changes and advances in clinical laboratory testing.

Needs and Benefits:

Part 19 regulates the issuance of certificates of qualification. An individual must hold such certificate to be a clinical laboratory director or assistant director at a clinical laboratory or blood bank permitted by New York under the authority of PHL section 572. The intent of these regulations is to ensure that individuals who are granted certificates of qualification have the necessary education, experience, and training to effectively operate a clinical laboratory. Successful applicants for a certificate of qualification must demonstrate both experience in laboratory management, such as management of resources (e.g. budget allocation, staffing), implementation of a quality management system, development of standard operating procedures; and experience specific to a category of testing defined in Part 19.

Several revisions to the regulatory definitions are proposed. Most notable are the inclusion of a definition for assistant director and revision to the definition of category. Assistant directors are jointly accountable with the laboratory director for the categories of testing on the laboratory permit. In many instances, however, the assistant director may be the only individual qualified to supervise testing in a specific category on the laboratory permit.

Language is proposed in sections 19.2 and 19.3 that clarifies the role and responsibilities of assistant directors of clinical laboratories. With these revisions, assistant directors will be held to the same standards as laboratory directors.

The definition of "category" was revised to strengthen the Department's authority to limit the approval of a certificate of qualification to a subcategory, technology, method or specific

procedure based on the applicant's documented experience. Extensive experience in a single method of testing does not necessarily translate to breadth of knowledge across an entire category of testing. Indeed, as innovations in laboratory medicine continue, an individual's experience in a proven technology may quickly become obsolete without continued education and training. The proposed revisions to the definition of category allow the Department to ascertain an individual's specific breadth of experience upon each application and re-application for a certificate of qualification.

The definitions of the following terms are being proposed for the first time; board certified, earned doctoral degree, training, and experience.

A review of the accrediting boards currently recognized in Part 19 and those included in the proposed revisions was performed to ensure that the requirements for each board were consistent with the rules set forth in federal regulation. This included a review of both the educational and training requirements for the accrediting board. As noted in the proposed revisions, certain boards mandate the appropriate educational requirement of a doctoral degree, but do not specify that the candidate for the board demonstrate the required four years of post-doctoral experience. Therefore, language clarifying the post-doctoral degree experience required by the Department has been proposed for these boards (American Board of Bioanalysts High Complexity Laboratory Director and the National Registry of Clinical Chemists) to ensure that the requirements for all applicants are consistent.

The duties and responsibilities of laboratory directors and assistant directors set forth in subdivision 19.3(c) were revised to provide clarity and introduce new responsibilities. Of note are the added responsibilities of ensuring the availability of procedures for monitoring staff competency and improvement of skills. These new responsibilities are currently included in the New York State Clinical Laboratory Standards of Practice; however, formal codification in regulation is desired.

Finally, subdivision 19.3(d) has been removed since the certificate of qualification categories are repeated in the current subdivision 19.3(e), and therefore 19.3(d) was considered redundant. The Department currently maintains a list of certificate of qualification categories on its publicly accessible website, and revisions were made in proposed subdivision 19.1(i) to outline the necessary contents of this list.

Costs:

Costs to Regulated Parties:

The proposed amendment will not impose costs on regulated parties. The current regulation already requires clinical laboratories and blood banks to have directors who hold certificates of qualification.

Costs to the Agency, State and Local Governments:

The proposed amendment will not impose additional costs to the New York State Department of Health, the program responsible for oversight of clinical laboratories, or to local governments. 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 impose no new mandates on any county, city, town or village government; or school, fire or other special district.

Paperwork:

The proposed revisions to Part 19 do not require any additional forms or paperwork from applicants. All candidates are required under the current rule to provide a complete application, a curriculum vitae, and proof of licensure for physicians or granting of an earned doctoral degree. Additionally, candidates must submit proof of any accreditation by a recognized board and/or letters from third parties attesting to the candidate's training and experience. The proposed revisions expand the list of recognized accrediting boards, which may in fact reduce the paperwork needed for candidates holding those accreditations.

Duplication:

The federal government also recognizes clinical laboratory directors. The Department has applied and been approved for an exemption from the federal government continuously since 1995 that grants the Department the authority to act as the primary accrediting body for clinical laboratories and clinical laboratory directors operating in New York.

Alternatives:

The alternative to this proposal would be to maintain the existing regulatory requirements. However, the proposed amendments are necessary to update the regulations to include new definitions, update the list of acceptable accrediting boards, and clarify and expand the responsibilities of laboratory directors and assistant directors.

Federal Standards:

The Federal Code of Regulations (CFR) sets forth rules for the education and experience of clinical laboratory directors (CFR 493.1443). The proposed revisions to Part 19 will incorporate several of the accrediting boards that are already recognized under the federal rule.

Compliance Schedule:

Regulated parties are expected to comply with the proposed regulation by its effective date.

Contact Person:

Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

No regulatory flexibility analysis is required. The proposed 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. At present the regulations require clinical laboratories and blood banks to be directed by individuals who hold a certificate of qualification. This proposed amendment would update and expand the list of acceptable accrediting boards for obtaining a certificate of qualification and is therefore anticipated to have a positive impact by increasing the number of individuals who may qualify for a certificate of qualification.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to § 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendments will not impose an adverse impact on facilities in rural areas, and will not impose any significant new reporting, record keeping or other compliance requirements on facilities in rural areas.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to § 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.