

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 225(5)(a) of the Public Health Law, Part 4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is added, to be effective upon filing with the Secretary, to read as follows:

4.1 Scope.

All owners of cooling towers, and all general hospitals and residential health care facilities as defined in Article 28 of the Public Health Law, shall comply with this Part.

4.2 Definitions.

As used in this Part, the following terms shall have the following meanings:

(a) Building. The term “building” means any structure used or intended for supporting or sheltering any use or occupancy. The term shall be construed as if followed by the phrase “structure, premises, lot or part thereof” unless otherwise indicated by the text.

(b) Commissioner. The term “commissioner” means the New York State Commissioner of Health.

(c) Cooling Tower. The term “cooling tower” means a cooling tower, evaporative condenser or fluid cooler that is part of a recirculated water system incorporated into a building’s cooling, industrial process, refrigeration or energy production system.

(d) Owner. The term “owner” means any person, agent, firm, partnership, corporation or other legal entity having a legal or equitable interest in, or control of the premises.

4.3 Registration.

All owners of cooling towers shall register such towers with the department within 30 days after the effective date of this Part. Thereafter, all owners of cooling towers shall register such towers with the department prior to initial operation, and whenever any owner of the cooling tower changes. Such registration shall be in a form and manner as required by the commissioner and shall include, at a minimum, the following information:

- (a) street address of the building at which the cooling tower is located, with building identification number, if any;
- (b) intended use of the cooling tower;
- (c) name(s), address(es), telephone number(s), and email address(es) of all owner(s) of the building;
- (d) name of the manufacturer of the cooling tower;
- (e) model number of the cooling tower;
- (f) specific unit serial number of the cooling tower;
- (g) cooling capacity (tonnage) of the cooling tower;
- (h) basin capacity of the cooling tower;
- (i) whether systematic disinfection is maintained manually, through timed injection, or through continuous delivery;
- (j) the contractor or employee engaged to inspect and certify the cooling tower; and
- (k) commissioning date of the cooling tower.

4.4 Culture sample collection and testing; cleaning and disinfection.

- (a) All owners of cooling towers shall collect samples and obtain culture testing:

(1) within 30 days of the effective date of this Part, unless such culture testing has been obtained within 30 days prior to the effective date of this Part, and shall take immediate actions in response to such testing, including interpreting Legionella culture results, if any, as specified in Appendix 4-A.

(2) in accordance with the maintenance program and plan, and shall take immediate actions in response to such testing as specified in the plan, including interpreting Legionella culture results, if any, as specified in Appendix 4-A; provided that if a maintenance program and plan has not yet been obtained in accordance with section 4.6 of this Part, bacteriological culture samples and analysis (dip slides or heterotrophic plate counts) to assess microbiological activity shall be obtained, at intervals not exceeding 90 days while the tower is in use, and any immediate action in response to such testing shall be taken, including interpreting Legionella culture results, if any, as specified in Appendix 4-A.

(b) Any person who performs cleaning and disinfection shall be a commercial pesticide applicator or pesticide technician who is qualified to apply biocide in a cooling tower and certified in accordance with the requirements of Article 33 of the Environmental Conservation Law and 6 NYCRR Part 325, or a pesticide apprentice under the supervision of a certified applicator.

(c) Only biocide products registered by the New York State Department of Environmental Conservation may be used in disinfection.

(d) All owners shall ensure that all cooling towers are cleaned and disinfected when shut down for more than five days.

4.5 Inspection and certification.

(a) Inspection. All owners of cooling towers shall inspect such towers within 30 days of the effective date of this Part, unless such tower has been inspected within 30 days prior to the effective date of this Part. Thereafter, owners shall ensure that all cooling towers are inspected at intervals not exceeding every 90 days while in use. All inspections shall be performed by a: New York State licensed professional engineer; certified industrial hygienist; certified water technologist; or environmental consultant with training and experience performing inspections in accordance with current standard industry protocols including, but not limited to ASHRAE 188-2015, as incorporated by section 4.6 of this Part.

(1) Each inspection shall include an evaluation of:

- (i) the cooling tower and associated equipment for the presence of organic material, biofilm, algae, and other visible contaminants;
- (ii) the general condition of the cooling tower, basin, packing material, and drift eliminator;
- (iii) water make-up connections and control;
- (iv) proper functioning of the conductivity control; and
- (v) proper functioning of all dosing equipment (pumps, strain gauges).

(2) Any deficiencies found during inspection will be reported to the owner for immediate corrective action. A person qualified to inspect pursuant to paragraph (a) of this section shall document all deficiencies, and all completed corrective actions.

(3) All inspection findings, deficiencies, and corrective actions shall be reported to the owner, recorded, and retained in accordance with this Part, and shall also be reported to the department in accordance with section 4.10 of this Part.

(b) Certification. Each year, the owner of a cooling tower shall obtain a certification from a person identified in paragraph (a) of this section, that such cooling tower was inspected, tested, cleaned, and disinfected in compliance with this Part, that the condition of the cooling tower is appropriate for its intended use, and that a maintenance program and plan has been developed and implemented as required by this Part. Such certification shall be obtained by November 1, 2016, and by November 1 of each year thereafter. Such certification shall be reported to the department.

4.6 Maintenance program and plan.

(a) By March 1, 2016, and thereafter prior to initial operation, owners shall obtain and implement a maintenance program and plan developed in accordance with section 7.2 of Legionellosis: Risk Management for Building Water Systems (ANSI/ASHRAE 188-2015), 2015 edition with final approval date of June 26, 2015, at pages 7-8, incorporated herein by reference. The latest edition of ASHRAE 188-2015 may be purchased from the ASHRAE website (www.ashrae.org) or from ASHRAE Customer Service, 1791 Tullie Circle, NE, Atlanta, GA 30329-2305. E-mail: orders@ashrae.org. Fax: 678-539-2129. Telephone: 404-636-8400, or toll free 1-800-527-4723. Copies are available for inspection and copying at: Center for Environmental Health, Corning Tower Room 1619, Empire State Plaza, Albany, NY 12237.

(b) In addition, the program and plan shall include the following elements:

- (1) a schedule for routine bacteriological sampling and analysis (dip slides or heterotrophic plate counts) to assess microbiological activity and a schedule for Legionella sampling and culture analysis; provided that where the owner is a general hospital or residential health care facility, as defined in Article 28 of the Public Health

Law, routine testing shall be performed at a frequency in accordance with the direction of the department.

(2) emergency sample collection and submission of samples for Legionella culture testing to be conducted in the case of events including, but not limited to:

- (i) power failure of sufficient duration to allow for the growth of bacteria;
- (ii) loss of biocide treatment sufficient to allow for the growth of bacteria;
- (iii) failure of conductivity control to maintain proper cycles of concentration;
- (iv) a determination by the commissioner that one or more cases of legionellosis is or may be associated with the cooling tower, based upon epidemiologic data or laboratory testing; and
- (v) any other conditions specified by the commissioner.

(3) immediate action in response to culture testing, including interpreting Legionella culture results, if any, as specified in Appendix 4-A; provided that where the owner is a general hospital or residential health care facility, as defined in Article 28 of the Public Health Law, the provisions shall additionally require immediately contacting the department for further guidance, but without any delay in taking any action specified in Appendix 4-A.

(c) An owner shall maintain a copy of the plan required by this subdivision on the premises where a cooling tower is located. Such plan shall be made available to the department or local health department immediately upon request.

4.7 Recordkeeping.

An owner shall keep and maintain records of all inspection findings, deficiencies, corrective actions, cleaning and disinfection, and tests performed pursuant to this Part, and certifications, for at least three years. An owner shall maintain a copy of the maintenance program and plan required by this Part on the premises where a cooling tower is located. Such records and plan shall be made available to the department or local health department immediately upon request.

4.8 Discontinued use.

The owner of a cooling tower shall notify the department within 30 days after removing or permanently discontinuing use of a cooling tower. Such notice shall include a statement that such cooling tower has been disinfected and drained in accordance with the same procedures as set forth in the shutdown plan, as specified in the maintenance program and plan required pursuant to this Part.

4.9 Enforcement.

(a) An officer, employee or agent of the department or local health department may enter onto any property to inspect the cooling tower for compliance with the requirements of this Part, in accordance with applicable law.

(b) Where an owner does not register, obtain certification, clean or disinfect, culture test or inspect a cooling tower within the time and manner set forth in this Part, the department or local health department may determine that such condition constitutes a nuisance and may take such action as authorized by law. The department or local health department may also take any other action authorized by law.

(c) A violation of any provision of this Part is subject to all civil and criminal penalties as provided for by law. Each day that an owner remains in violation of any provision of this Part shall constitute a separate and distinct violation of such provision.

4.10 Electronic registration and reporting.

(a) (1) Within 30 days of the effective date of this Part, and thereafter within 10 days after any action required by this Part, owners shall electronically input the following information in a statewide electronic system designated by the commissioner:

- (i) registration information;
- (ii) date of last routine culture sample collection, sample results, and date of any required remedial action;
- (iii) date of any legionella sample collection, sample results, and date of any required remedial action;
- (iv) date of last cleaning and disinfection;
- (v) dates of start and end of any shutdown for more than five days;
- (vi) date of last certification and date when it was due;
- (vii) date of last inspection and date when it was due;
- (viii) date of discontinued use; and
- (ix) such other information as shall be determined by the department.

(2) The commissioner may suspend this requirement in the event that the electronic system is not available.

(b) The data in the system referenced in paragraph (a) shall be made publicly available, and shall be made fully accessible and searchable to any local health department. Nothing in this Part shall

preclude a local health department from requiring registration and reporting with a local system or collecting fees associated with the administration of such system.

4.11 Health care facilities

(a) All general hospitals and residential health care facilities, as defined in Article 28 of the Public Health Law, shall, as the department may determine appropriate:

- (1) adopt a Legionella sampling plan for its facilities' potable water distribution system;
- (2) report the results of such sampling; and
- (3) take necessary responsive actions.

(b) With respect to such general hospitals and residential health care facilities, the department shall investigate to what extent, if any, requirements more stringent than those set forth in this Part are warranted.

4.12 Severability.

If any provisions of this Part or the application thereof to any person or entity or circumstance is adjudged invalid by a court of competent jurisdiction, such judgment shall not affect or impair the validity of the other provisions of this Part or the application thereof to other persons, entities, and circumstances.

Appendix 4-A

Interpretation of Legionella Culture Results from Cooling Towers	
Legionella Test	Approach
Results in CFU ¹ /ml	

<p>No detection (< 10 CFU /ml)</p>	<p>Maintain treatment program and <i>Legionella</i> monitoring.</p>
<p>For levels at ≥ 10 CFU /ml but < 1000 CFU /ml perform the following:</p>	<ul style="list-style-type: none"> ○ Review treatment program. ○ Institute immediate <u>online disinfection</u>² to help with control ○ Retest the water in 3 – 7 days. <ul style="list-style-type: none"> ▪ Continue to retest at the same time interval until two consecutive readings show acceptable improvement, as determined by a person identified in 10 NYCRR 4.5(a). Continue with regular maintenance strategy. ▪ If < 100 CFU /ml repeat <u>online disinfection</u>² and retest. ▪ If ≥ 100 CFU /ml but < 1000 CFU /ml further investigate the water treatment program and immediately perform <u>online disinfection</u>.² Retest and repeat attempts at control strategy. ○ If ≥ 1000 CFU /ml undertake control strategy as noted below.
<p>For levels ≥ 1000 CFU /ml perform the following:</p>	<ul style="list-style-type: none"> ○ Review the treatment program ○ Institute immediate <u>online decontamination</u>³ to help with control ○ Retest the water in 3 – 7 days. <ul style="list-style-type: none"> ▪ Continue to retest at the same time interval until two consecutive readings show acceptable improvement, as determined by a person identified in 10 NYCRR 4.5(a). Continue with regular maintenance strategy. ▪ If < 100 CFU /ml repeat <u>online disinfection</u>² and retest;

	<ul style="list-style-type: none"> ▪ If ≥ 100 CFU /ml but < 1000 CFU /ml further investigate the water treatment program and immediately perform <u>online disinfection</u>.² Re-test and repeat attempts at control strategy. ▪ If ≥ 1000 CFU /ml carry out <u>system decontamination</u>⁴
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¹ Colony forming units.

² Online disinfection means – Dose the cooling tower water system with either a different biocide or a similar biocide at an increased concentration than currently used.

³ Online decontamination means – Dose the recirculation water with a chlorine-based compound equivalent to at least 5 mg/l (ppm) free residual chlorine for at least one hour; pH 7.0 to 7.6.

⁴ System decontamination means – Maintain 5 to 10 mg/l (ppm) free residual chlorine for a minimum of one hour; drain and flush with disinfected water; clean wetted surface; refill and dose to 1 – 5 mg/l (ppm) of free residual chlorine at pH 7.0 – 7.6 and circulate for 30 minutes. Refill, re-establish treatment and retest for verification of treatment.

Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council (PHHPC) is authorized by Section 225 of the Public Health Law (PHL) to establish, amend and repeal sanitary regulations to be known as the State Sanitary Code (SSC) subject to the approval of the Commissioner of Health. PHL Section 225(5)(a) provides that the SSC may deal with any matter affecting the security of life or health, or the preservation or improvement of public health, in the state of New York.

Legislative Objectives:

This rulemaking is in accordance with the legislative objective of PHL Section 225 authorizing the PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety by amending the SSC to address issues that jeopardize health and safety. Specifically, these regulations establish requirements for cooling towers relating to: registration, reporting and recordkeeping; testing; cleaning and disinfection; maintenance; inspection; and certification of compliance. Additionally, these regulations require general hospitals and nursing homes to implement a *Legionella* sampling plan and take necessary responsive actions, as the department may deem appropriate.

Needs and Benefits:

Improper maintenance of cooling towers can contribute to the growth and dissemination of *Legionella* bacteria, the causative agent of legionellosis. Optimal conditions for growth of *Legionella* include warm water that is high in nutrients and protected from light. People are exposed to *Legionella* through inhalation of aerosolized water containing the bacteria. Person-

to-person transmission has not been demonstrated. Symptoms of legionellosis may include cough, shortness of breath, high fever, muscle aches, and headaches, and can result in pneumonia. Hospitalization is often required and between 5-30% of cases are fatal. People at highest risk are those 50 years of age or older; current or former smokers; those with chronic lung diseases; those with weakened immune systems from diseases like cancer, diabetes, or kidney failure; and those who take drugs to suppress the immune system during chemotherapy or after an organ transplant. The number of cases of legionellosis reported in New York State between 2005-2014 increased 323% when compared to those reported in the previous ten year period.

Outbreaks of legionellosis have been associated with cooling towers. A cooling tower is an evaporative device that is part of a recirculated water system incorporated into a building's cooling, industrial process, refrigeration, or energy production system. Because water is part of the process of removing heat from a building, these devices require disinfectants—chemicals that kill or inhibit bacteria (including *Legionella*)—as means of controlling bacterial overgrowth. Overgrowth may result in the normal mists ejected from the tower having droplets containing *Legionella*.

For example, in 2005, a cooling tower located at ground level adjacent to a hospital in New Rochelle, Westchester County resulted in a cluster of 19 cases of legionellosis and multiple fatalities. Most of the individuals were dialysis patients or companions escorting the patients to their dialysis session. One fatality was in the local neighborhood. The cooling tower was found to have insufficient chemical treatment. The entire tower was ultimately replaced by the manufacturer in order to maintain cooling for the hospital and to protect public health. In June and July of 2008, 12 cases of legionellosis including one fatality were attributed to a small evaporative condenser on Onondaga Hill in Syracuse, Onondaga County. An investigation

found that the unit was not operating properly and this resulted in the growth of microorganisms in the unit. Emergency biocide treatment was initiated and proper treatment was maintained. No new cases were then detected thereafter.

Recent work has shown that sporadic cases of community legionellosis are often associated with extended periods of wet weather with overcast skies. A study conducted by the New York State Department of Health that included data from 13 states and one United States municipality noted a dramatic increase in sporadic, community acquired legionellosis cases in May through August 2013. Large municipal sites such as Buffalo, Erie County reported 2- to 3-fold increases in cases without identifying common exposures normally associated with legionellosis. All sites in the study except one had a significant correlation, with some time lag, between legionellosis case onset and one or more weather parameters. It was concluded that large municipalities produce significant mist (droplet) output from hundreds of cooling towers during the summer months. Periods of sustained precipitation, high humidity, cloud cover, and high dew point may lead to an “urban cooling tower” effect. The “urban cooling tower” effect is when a metropolitan area with hundreds of cooling towers acts as one large cooling tower producing a large output of drift, which is entrapped by humid air and overcast skies.

More recently, 133 cases of legionellosis, which included 16 fatalities, occurred in Bronx, NY (July-September, 2015). This event was preceded by an outbreak in Co-Op City in the Bronx, from December 2014 to January 2015, which involved 8 persons and no fatalities. Both of these outbreaks have been attributed to cooling towers, and emergency disinfection of compromised towers helped curtail these outbreaks. These events highlight the need for proper maintenance of cooling towers.

The heating, ventilation, and air-conditioning (HVAC) industry has issued guidelines on how to: seasonally start a cooling tower; treat it with biocides and other chemicals needed to protect the components from scale and corrosion; set cycles of operations that determine when fresh water is needed; and shut down the tower at the end of the cooling season. The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) has recently released a new Standard entitled *Legionellosis: Risk Management for Building Water Systems* (ANSI/ASHRAE Standard 188-2015). Section 7.2 of that document outlines components of the operations and management plan for cooling towers. The industry also relies on other guidance for specific treatment chemicals, emergency disinfection or decontamination procedures, and other requirements.

However, none of the guidance is obligatory. Consequently, maintenance deficiencies such as poor practice in operation and management can result in bacterial overgrowth, increases in *Legionella*, and mist emissions that contain pathogenic legionellae. This regulation requires that all owners of cooling towers ensure proper maintenance of the cooling towers, to protect the public and address this public health threat.

Further, these regulations requires that all owners of cooling towers ensure proper maintenance of the cooling tower *Legionella* sampling plan for their potable water system, report the results, and take necessary actions to protect the safety of their patients or residents, as the Department may deem appropriate. The details of each facility's sampling plan and remedial measures will depend on the risk factors for acquiring Legionnaires' disease in the population served by the hospital or nursing home.

Most people in nursing homes should be considered at risk, as residents are typically over 50 years of age. In general hospitals, persons at risk include those over 50 years of age, as well

as those receiving chemotherapy, those undergoing transplants, and other persons housed on healthcare units that require special precautions. Additional persons who might be at increased risk for acquiring Legionnaires' disease include persons on high-dose steroid therapy and persons with chronic lung disease. Certain facilities with higher risk populations, such as those with hematopoietic stem-cell transplant (HSCT) and solid organ transplant units, require more protective measures.

An environmental assessment involves reviewing facility characteristics, hot and cold water supplies, cooling and air handling systems, and any chemical treatment systems. The purpose of the assessment is to discover any vulnerabilities that would allow for amplification of *Legionella* and to determine appropriate response actions in advance of any environmental sampling for *Legionella*. Initial and ongoing assessment should be conducted by a multidisciplinary team that represents the expertise, knowledge, and functions related to the facility's operation and service. A team should include, at a minimum, representatives from the following groups: Infection Control, Physical Facilities Management, Engineering, Clinicians, Laboratory, and Hospital Management.

Costs:

Costs to Private Regulated Parties:

Building owners already incur costs for routine operation and maintenance of cooling towers. This regulation establishes the following new requirements:

- Routine Bacteriological Culture Testing – The regulations require routine bacteriological testing pursuant to their cooling tower maintenance program and plan. The cost per dip

slide test is \$3.50. Assuming that some plans may require tests be performed twice a week, this could result in an annual cost of \$364. If heterotrophic plate count analysis is used the cost per sample on average is \$25.

- Emergency *Legionella* Culture Testing – Owners of cooling towers are required to conduct additional testing for Legionella in the event of disruption of normal operations or process control, or when indicated by epidemiological evidence. The average cost of each sample analysis is estimated to be approximately \$125.00.
- Maintenance Program and Plan Development – The formulation of a cooling tower program and sampling plan would require 4 to 8 hours at \$150 per hour (\$600 to \$1200). The range represents the cost for reviewing and modifying an existing plan versus the preparation of a new plan.
- Inspection – Owners of cooling towers shall obtain the services of a professional engineer (P.E.), certified industrial hygienist (C.I.H.), certified water technologist, or environmental consultant with training and experience performing inspections in accordance with current standard industry protocols including, but not limited to ASHRAE 188-2015, for inspection of the cooling towers at intervals not exceeding 90 days while in use. The cost of such services is estimated to be approximately \$150.00 per hour and estimated to take approximately eight (8) hours.
- Annual Certification – The same persons qualified to perform inspections are qualified to perform annual certifications. The certification can follow one of the required inspections and requires some additional evaluation and considerations. The cost of such services is estimated to be approximately \$150.00 per hour and is estimated to take approximately four (4) hours.

- Emergency Cleaning and Disinfection – If emergency cleaning and disinfection is required, owners of cooling towers are required to obtain the services of a certified commercial pesticide applicator or pesticide technician who is qualified to apply biocide in a cooling tower, or a pesticide apprentice under the supervision of a certified applicator. The cost of such services is estimated to be approximately \$5,000.00 for labor, plus the cost of materials.
- Recordkeeping and Electronic Reporting – Owners of cooling towers are required to maintain certain specified records and to electronically report certain specified information. The costs of these administrative activities are predicted to be minimal.
- Health Care Facilities – The cost of adopting a sampling plan for Article 28 facilities is dependent upon any existing plan and the status of existing record keeping. It is estimated that with prior records and a maintenance plan the time required should a consultant be hired would be 6.5 hours at \$150 per hour (\$975). Without a prior plan and poor maintenance documentation the time required would be 13 hours at \$150 per hour (\$1950). It is anticipated that facilities may develop the plan using existing staff.

Costs to State Government and Local Government:

State and local governments will incur costs for administration, implementation, and enforcement. Exact costs cannot be predicted at this time. However, some local costs may be offset through the collection of fees, fines and penalties authorized pursuant to this Part. Costs to State and local governments may be offset further by a reduction in the need to respond to community legionellosis outbreaks.

Local Government Mandates:

The SSC establishes a minimum standard for regulation of health and sanitation. Local governments can, and often do, establish more restrictive requirements that are consistent with the SSC through a local sanitary code. PHL § 228. Local governments have the power to enforce the provisions of the State Sanitary Code, including this new Part, utilizing both civil and criminal options available. PHL §§ 228, 229, 309(1)(f) and 324(1)(e).

Paperwork:

The regulation imposes new registration, reporting and recordkeeping requirements for owners of cooling towers.

Duplication:

This regulation does not duplicate any state requirements.

Alternatives:

The no action alternative was considered. Promulgating this regulation was determined to be necessary to address this public health threat.

Federal Standards:

There are no federal standards or regulations pertaining to registration, maintenance, operation, testing, and inspection for cooling towers.

Compliance Schedule:

On August 17, 2015, when this regulation first became effective, owners were given until September 16, 2015, to register their cooling towers and perform bacteriological sampling. Now that the deadline has past, all owners should have registered their cooling towers, and any owners that have not registered their cooling towers must come into compliance immediately. All owners must register such towers prior to initial operation.

By March 1, 2016, all owners of existing cooling towers must obtain and implement a maintenance program and plan. Until such plan is obtained, culture testing must be performed every 90 days, while the tower is in use.

All owners must inspect their cooling towers at least every 90 days while in use. All owners of cooling towers shall obtain a certification that regulatory requirements have been met by November 1, 2016, with subsequent annual certifications by November 1st of each year.

Owners must register cooling towers and report certain actions, using a statewide electronic system. Reportable events include date of sample collections; date of cleaning and disinfection; start and end dates of any shutdown lasting more than five days; dates of last inspection and when due; dates of last certification and when due; and date of discontinued use. These events must be reported to the statewide electronic system within 10 days of occurrence.

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The rule will affect the owner of any building with a cooling tower, as those terms are defined in the regulation. This could include small businesses. At this time, it is not possible to determine the number of small businesses so affected. This regulation affects local governments by establishing requirements for implementing, administering, and enforcing elements of this Part. Local governments have the power to enforce the provisions of the State Sanitary Code, including this new Part. PHL §§ 228, 229, 309(1)(f) and 324(1)(e).

Compliance Requirements:

Small businesses that are also owners of cooling towers must comply with all provisions of this Part. A violation of any provision of this Part is subject to all civil and criminal penalties as provided for by law. Each day that an owner remains in violation of any provision of this Part shall constitute a separate and distinct violation of such provision.

Professional Services:

To comply with inspection and certification requirements, small businesses will need to obtain services of a P.E., C.I.H., certified water technologist, or environmental consultant with training and experience performing inspections in accordance with current standard industry protocols including, but not limited to ASHRAE 188-2015. Small businesses will need to secure laboratory services for routine culture sample testing and, if certain events occur, emergency *Legionella* culture testing.

To comply with disinfection requirements, small businesses will need to obtain the services of a commercial pesticide applicator or pesticide technician, or pesticide apprentice under supervision of a commercial pesticide applicator. These qualifications are already required for the properly handling of biocides that destroy *Legionella*.

Compliance Costs:

Costs to Private Regulated Parties:

Building owners already incur costs for routine operation and maintenance of cooling towers. This regulation establishes the following new requirements:

- Routine Bacteriological Culture Testing – The regulations require routine bacteriological testing pursuant to industry standards. The cost per test is \$3.50. Assuming tests are performed twice a week, this would result in an annual cost of \$364.
- Emergency *Legionella* Culture Testing – Owners of cooling towers are required to conduct additional testing for *Legionella* in the event of disruption of normal operations. The average cost of each sample analysis is estimated to be approximately \$125.00.
- Inspection – Owners of cooling towers shall obtain the services of a professional engineer (P.E.), certified industrial hygienist (C.I.H.), certified water technologist, or environmental consultant with training and experience performing inspections in accordance with current standard industry protocols including, but not limited to ASHRAE 188-2015; for inspection of the cooling towers at intervals not exceeding once every 90 days while the cooling towers are in use. The cost of such services is estimated to be approximately \$150.00 per hour and estimated to take approximately eight (8)

hours.

- Annual Certification – The same persons qualified to perform inspections are qualified to perform annual certifications. The cost of such services is estimated to be approximately \$150.00 per hour and is estimated to take approximately four (4) hours.
- Emergency Cleaning and Disinfection – If emergency cleaning and disinfection is required, owners of cooling towers are required to obtain the services of a certified commercial pesticide applicator or pesticide technician who is qualified to apply biocide in a cooling tower, or a pesticide apprentice under the supervision of a certified applicator. The cost of such services is estimated to be approximately \$5,000.00 for labor, plus the cost of materials.
- Recordkeeping and Electronic Reporting – Owners of cooling towers are required to maintain certain specified records and to electronically report certain specified information. The costs of these administrative activities are predicted to be minimal.
- The formulation of a cooling tower program and sampling plan would require 4 to 8 hours at \$150 per hour (\$600 to \$1200). The range represents the cost for reviewing and modifying an existing plan versus the preparation of a new plan.
- Formulation of a sampling plan for Article 28 facilities is dependent upon any existing plan and the status of existing record keeping. It is estimated that with prior records and a maintenance plan the time required should a consultant be hired would be 6.5 hours at \$150 per hour (\$975). Without a prior plan and poor maintenance documentation the time required would be 13 hours at \$150 per hour (\$1950). It is anticipated that facilities may develop the plan using existing staff.

Costs to State Government and Local Government:

State and local governments possess authority to enforce compliance with these regulations. Exact costs cannot be predicted at this time. However, some local costs may be offset through the collection of fees, fines and penalties authorized pursuant to this Part. Costs to State and local governments may be offset by a reduction in the need to respond to community legionellosis outbreaks.

Economic and Technological Feasibility:

Although there will be an impact of building owners, including small businesses, compliance with the requirements of this regulation is considered economically and technologically feasible as it enhances and enforces existing industry best practices. The benefits to public health are anticipated to outweigh any costs. This regulation is necessary to protect public health.

Minimizing Adverse Impact:

The New York State Department of Health will assist local governments by providing a cooling tower registry and access to the database, technical consultation, coordination, and information and updates.

Small Business and Local Government Participation:

Development of this regulation has been coordinated with New York City.

Cure Period:

Violation of this regulation can result in civil and criminal penalties. In light of the magnitude of the public health threat posed by the improper maintenance and testing of cooling towers, the risk that some small businesses will not comply with regulations justifies the absence of a cure period.

Rural Area Flexibility Analysis

Pursuant to Section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas. The proposed rule will not impose an adverse economic impact on rural areas, nor will it impose any disproportionate reporting, record keeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

Nature of the Impact:

The Department of Health expects there to be a positive impact on jobs or employment opportunities. The requirements in the regulation generally coincide with industry standards and manufacturers specification for the operation and maintenance of cooling towers. However, it is expected that a subset of owners have not adequately followed industry standards and will now hire firms or individuals to assist them with compliance and to perform inspections and certifications.

Categories and Numbers Affected:

The Department anticipates no negative impact on jobs or employment opportunities as a result of the proposed regulations.

Regions of Adverse Impact:

The Department anticipates no negative impact on jobs or employments opportunities in any particular region of the state.

Minimizing Adverse Impact:

Not applicable.

Emergency Justification

Improper maintenance of cooling towers can contribute to the growth and dissemination of *Legionella* bacteria, the causative agent of legionellosis. Legionellosis causes cough, shortness of breath, high fever, muscle aches, headaches and can result in pneumonia. Hospitalization is often required, and between 5-30% of cases are fatal. People at highest risk are those 50 years of age or older, current or former smokers, those with chronic lung diseases, those with weakened immune systems from diseases like cancer, diabetes, or kidney failure, and those who take drugs to suppress the immune system during chemotherapy or after an organ transplant. The number of cases of legionellosis reported in New York State between 2005-2014 increased 323% when compared to those reported in the previous ten year period.

Outbreaks of legionellosis have been associated with cooling towers. A cooling tower is an evaporative device that is part of a recirculated water system incorporated into a building's cooling, industrial process, refrigeration, or energy production system. Because water is part of the process of removing heat from a building, these devices require biocides—chemicals that kill or inhibit bacteria (including *Legionella*)—as means of controlling bacterial overgrowth. Overgrowth may result in the normal mists ejected from the tower having droplets containing *Legionella*.

For example, in 2005, a cooling tower located at ground level adjacent to a hospital in New Rochelle, Westchester County resulted in a cluster of 19 cases of legionellosis and multiple fatalities. Most of the individuals were dialysis patients or companions escorting the patients to their dialysis session. One fatality was in the local neighborhood. The cooling tower was found to have insufficient chemical treatment. The entire tower was ultimately replaced by the

manufacturer in order to maintain cooling for the hospital and to protect public health. In June and July of 2008, 12 cases of legionellosis including one fatality were attributed to a small evaporative condenser on Onondaga Hill in Syracuse, Onondaga County. An investigation found that the unit was not operating properly and this resulted in the growth of microorganisms in the unit. Emergency biocide treatment was initiated and proper treatment was maintained. No new cases were then detected thereafter.

Recent work has shown that sporadic cases of community legionellosis are often associated with extended periods of wet weather with overcast skies. A study conducted by the New York State Department of Health that included data from 13 states and one United States municipality noted a dramatic increase in sporadic, community acquired legionellosis cases in May through August 2013. Large municipal sites such as Buffalo, Erie County reported 2- to 3-fold increases in cases without identifying common exposures normally associated with legionellosis. All sites in the study except one had a significant correlation, with some time lag, between legionellosis case onset and one or more weather parameters. It was concluded that large municipalities produce significant mist (droplet) output from hundreds of cooling towers during the summer months. Periods of sustained precipitation, high humidity, cloud cover, and high dew point may lead to an “urban cooling tower” effect. The “urban cooling tower” effect is when a metropolitan area with hundreds of cooling towers acts as one large cooling tower producing a large output of drift, which is entrapped by humid air and overcast skies.

More recently, 133 cases of legionellosis, which included 16 fatalities, occurred in Bronx, NY (July-September, 2015). This event was preceded by an outbreak in Co-Op City in the Bronx, from December 2014 to January 2015, which involved 8 persons and no fatalities. Both of these outbreaks have been attributed to cooling towers, and emergency disinfection of

compromised towers helped curtail these outbreaks. These events highlight the need for proper maintenance of cooling towers.

The heating, ventilation, and air-conditioning (HVAC) industry has issued guidelines on how to seasonally start a cooling tower; treat it with biocides and other chemicals needed to protect the components from scale and corrosion; and set cycles of operations that determine when fresh water is needed; and how to shut down the tower at the end of the cooling season. The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) has recently released a new Standard entitled *Legionellosis: Risk Management for Building Water Systems* (ANSI/ASHRAE Standard 188-2015). Section 7.2 of that document outlines components of the operations and management plan for cooling towers. The industry also relies on other guidance for specific treatment chemicals, emergency disinfection or decontamination procedures and other requirement.

However, none of the guidance is obligatory. Consequently, poor practice in operation and management can result in bacterial overgrowth, increases in legionellae, and mist emissions that contain a significant dose of pathogenic legionellae. This regulation requires that all owners of cooling towers ensure proper maintenance of the cooling towers, to protect the public and address this public health threat.

Further, these regulations require all general hospitals and residential health care facilities (i.e., nursing homes) to develop a sampling plan, report the results, and take necessary actions to protect the safety of their patients or residents. The details of each facility's sampling plan and remedial measures will depend on the risk factors for acquiring Legionnaires' disease in the

population served by the hospital or nursing home.

Most people in nursing homes should be considered at risk, as residents are typically over 50 years of age. In general hospitals, persons at risk include those over 50 years of age, as well as those receiving chemotherapy, those undergoing transplants, and other persons housed on healthcare units that require special precautions. Additional persons who might be at increased risk for acquiring Legionnaires' disease include persons on high-dose steroid therapy and persons with chronic lung disease. Certain facilities with higher risk populations, such as those with hematopoietic stem-cell transplant (HSCT) and solid organ transplant units, require more protective measures.

An environmental assessment involves reviewing facility characteristics, hot and cold water supplies, cooling and air handling systems and any chemical treatment systems. The purpose of the assessment is to discover any vulnerabilities that would allow for amplification of *Legionella* spp. and to determine appropriate response actions in advance of any environmental sampling for *Legionella*. Initial and ongoing assessment should be conducted by a multidisciplinary team that represents the expertise, knowledge and functions related to the facility's operation and service. A team should include, at a minimum, representatives from the following groups: Infection Control; Physical Facilities Management; Engineering; Clinicians; Laboratory; and Hospital Management.

These regulations, which originally became effective on August 17, 2015, implemented important requirements that protect the public from the threat posed by *Legionella*. To ensure that protection is maintained, the Commissioner of Health and the Public Health and Health

Planning Council have determined it necessary to file these regulations on an emergency basis. Public Health Law § 225, in conjunction with State Administrative Procedure Act § 202(6) empowers the Council and the Commissioner to adopt emergency regulations when necessary for the preservation of the public health, safety or general welfare and that compliance with routine administrative procedures would be contrary to the public interest.