SUMMARY OF EXPRESS TERMS

The following summarizes the purpose and impact of each section. The summary is for convenience, and it is not a substitute for the express terms of the regulation.

- 4-1.1 Scope.
    - Provides that the regulation applies to all owners of cooling towers.
- 4-1.2 Definitions.
    - This section defines key terms.
    - In particular, a "cooling tower" is now defined as: "a cooling tower, evaporative condenser, fluid cooler or other wet cooling device that is capable of aerosolizing water, and that is part of, or contains, a recirculated water system and is incorporated into a building's cooling process, an industrial process, a refrigeration system, or an energy production system."
    - The definition of "owner" is now defined as follows: "any person, agent, firm, partnership, corporation or other legal entity having a legal or equitable interest in, or control of, a cooling tower or the premises where the cooling tower is located. In all instances, the legal owner of the building shall be deemed an owner within the meaning of the Subpart. Further, where a tenant owns a cooling tower that services the tenant's leased premises, the tenant is an "owner" within the meaning of this Subpart. Additionally, if a tenant does not own the cooling tower but has a lease or contractual arrangement to maintain the cooling tower, the tenant shall be deemed an agent having control of the cooling tower, and thus an "owner," for purposes of this Subpart."
- 4-1.3 Electronic registration and reporting.

- Requires owners of cooling towers to register such towers with the Department using a statewide electronic system. Required registration fields have been slightly revised.
- Establishes a schedule for routine Legionella culture sampling and analysis, which includes reporting intervals not exceeding 90 days.
- Requires reporting of certain events, including:
    - last bacteriological culture sample collection date and result;
    - last *Legionella* culture sample collection date and result;
    - date of any required remedial action;
    - last inspection date;
    - last certification date;
    - date of removal or permanent discontinued use of a cooling tower; and
    - cooling tower system volume (including any piping, basin, and sump).
- The proposed regulations generally require reporting of certain events every 90 days. This is a change from the emergency regulations, which required reporting within 10 days.
- Affords public access to the statewide electronic system, as appropriate, and requires such system to be accessible and searchable to local health departments.
- Clarifies that where both a landlord and a tenant are considered "owners" of a cooling tower pursuant to Section 4-1.2, then either the owner or the tenant shall register the cooling tower. Both parties, however, are obligated to ensure that registration and reporting are completed.

- 4-1.4 Maintenance program and plan.

- Requires owners to obtain or update the maintenance program and plan for all operational cooling towers by September 1, 2016, and prior to the startup of newly installed cooling towers. The plan must include the following elements:
    - A schedule for routine bacteriological culture sampling and analysis to assess microbiological activity. The proposed regulation establishes a new, minimum sampling requirement, in which such sampling and analysis must be conducted: (1) at intervals not to exceed 30 days while the cooling tower is in use; and (2) at additional times, as needed, to validate process adjustments. The component that specifies a minimum sampling interval is a new requirement.
    - The emergency regulation contained a requirement for a schedule of routine *Legionella* culture sampling and analysis. The new regulation requires sampling within two weeks of seasonal start-up and thereafter at intervals not to exceed 90 days. In addition, the new regulation requires that year-round use towers be sampled at intervals not to exceed 90 days and within two weeks after start-up following maintenance. These are new requirements.
    - Provisions for immediate *Legionella* culture sampling and analysis following specified conditions, such as power failure, loss of biocide of sufficient duration to allow for the growth of bacteria, and if the State or local health department determines that one or more cases of *Legionella* is or may be associated with the tower. In addition to the conditions above, the proposed regulation describes conditions whereby the department or local health department may require sampling.

        - Provisions requiring immediate and appropriate action, including any necessary remedial action, in response to bacteriological and *Legionella* culture analyses.
        - Provisions requiring that any and all *Legionella* culture analysis must be performed in accordance with Section 4-1.5. This is a new requirement.
        - Provisions for shutdown and for removing or permanently discontinuing use of a cooling tower. These are new requirements.
        - Provisions requiring appropriate actions during idle conditions. This is a new requirement.
        - Provisions requiring cleaning and disinfection of a cooling tower that has been shut down without treatment for more than five days. This is a new requirement.
- 4-1.5 Legionella culture analysis.
    - Requires that *Legionella* culture analysis be performed by a laboratory that is approved to perform such analysis by the New York State Environmental Laboratory Approval Program (ELAP). This is a new requirement.

- 4-1.6 Notification.
    - Requires an owner of a cooling tower to notify the local health department within 24 hours of receipt of a *Legionella* culture sample result that exceeds 1,000 Colony forming units (CFU) per milliliter. The owner must also notify the public of the test result in a manner determined by the local health department or by the department, if the department elects to determine the manner of public notification. This is a new requirement.

- 4-1.7 Disinfection.
    - Establishes qualifications of persons who may disinfect a cooling tower.
    - Requires that the name and certification number of the applicator or the business name and registration number of the company providing the disinfection be maintained on-site in accordance with Section 4-1.9. This is a new requirement.
    - Permits only biocide products registered by the New York State Department of Environmental Conversation to be used in disinfection.
    - "Disinfection" is clarified to exclude the cleaning of a cooling tower through application of detergents, penetrants, brushes or other tools, high-powered water, or any other method that does not involve the use of a pesticide, as defined in 6 NYCRR Part 325.
- 4-1.8 Inspection and certification.
    - Inspection.
        - Requires that all owners of cooling towers ensure that such towers are inspected prior to seasonal start up and at intervals not exceeding every 90 days while in use. Year-round towers shall be inspected at intervals not exceeding every 90 days and prior to start up following maintenance. The inspection requirement prior to start up is new.
    - Certification.
        - By November 1, 2016, and by November 1st of each year thereafter, the owner of a cooling tower must obtain a certification that the cooling tower has a maintenance program and plan, and that all activities within that plan or required by this Subpart were implemented.

- Reporting.
    - All inspection findings, deficiencies, and corrective actions, and all certifications, must be reported to the owner. This section is new to the regulation.

- 4-1.9 Recordkeeping.
    - Describes the records and documentation that the owner must maintain onsite for at least three years. Such records must be made available to the department or local health department upon request.

- 4-1.10 Enforcement.
    - Provides that the department or local health department may require any owner to conduct *Legionella* culture sampling and analysis, following a determination, based upon epidemiologic or laboratory testing, that one or more cases of legionellosis are or may be associated with a cooling tower. This is a new provision.
    - Permits an officer or employee of the department or local health department to enter onto any property to inspect a cooling tower for compliance with the requirements of this Subpart. The proposed regulation clarifies that such officers or employees may take water samples.
    - Provides that a violation of any provision in this Subpart is subject to all civil and criminal penalties as provided for by law. Further, every day that an owner remains in violation of any provision constitutes a separate and distinct violation of such provision.

- 4-1.11 Variances and waivers.
    - Grants local health departments authority to issue variances from this regulation, upon approval of the New York State Department of Health. The local and State health department must be satisfied that the variance will not present a danger to public health.
    - The department may also grant general or specific waivers where it is satisfied that a waiver will not present a danger to public health.

- 4-1.12 Severability.
    - Standard severability clause is included.

- Appendix 4-A
    - This Appendix describes required responsive actions for *Legionella* culture test results. As compared to the emergency regulations, these regulations raise the threshold level for detecting *Legionella* in laboratory culture analyses, from ≥ 10 colony forming units per milliliter (CFU/mL) to ≥ 20 CFU/mL.
    - Responsive actions have been updated and clarified. The term "acceptable improvement" was changed to an actual quantitative target of "< 20 CFU/mL." Also, where an owner receives a laboratory *Legionella* culture analyses result ≥ 1000 CFU /mL, the owner must provide appropriate notifications per section 4-1.6.
    - The footnotes for *on-line decontamination* and *system decontamination* were modified to allow the use of a halogen-based compounds (chlorine or bromine).

SUBPART 4-2 Covered Facilities

- 4-2.1 Scope.
    - This Subpart addresses *Legionella* exposure in general hospitals and residential health care facilities (collectively, "covered facilities"). This area was addressed through section 4.11 of the emergency regulation.
- 4-2.2 Definitions.
    - Defines key terms.
- 4-2.3 Environmental assessment
    - Requires covered facilities to perform an environmental assessment of the facility, using forms provided or approved by the department, no later than September 1, 2016, unless an environmental assessment was performed on or after September 1, 2015.
    - Requires an annual update of the environmental assessment, and in specified conditions.
    - Requires that copies of the completed environmental assessment form be retained in accordance with Section 4-2.6.
- 4-2.4 Sampling Plan
    - Requires that all covered facilities adopt and implement a sampling plan for their potable water systems by December 1, 2016, and that new covered facilities must adopt such plan prior to providing services.
    - In addition to any sampling required by the sampling plan, *Legionella* culture sampling and analysis of the potable water system must occur immediately, as

directed by the department, where (1) the department determines that one or more cases of legionellosis are, or may be, associated with the facility; and (2) under any other condition specified by the department.

- The sampling plan must be reviewed and updated annually, and in specified conditions.
- The proposed regulation requires that the sampling plan and sampling results be retained in accordance with Section 4-2.6 of this Subpart.

- 4-2.5 *Legionella* culture analysis.
  - Legionella culture analyses must be performed by a laboratory approved to perform such analyses by the New York State Environmental Laboratory Program (ELAP).

- 4-2.6 Recordkeeping.
  - Specifies that all records related to the environmental assessment, sampling plan, and associated sampling results must be retained for three years and must be made available immediately to the department upon request.

- 4-2.7 Enforcement.
  - Authorizes the department to conduct an assessment and/or a *Legionella* culture sampling and analysis of the potable water system at any time.
  - Provides that where an owner of a covered facility does not comply with any provision contained within this Subpart, the department may determine that such condition constitutes a violation and may take such action as authorized by law.

Further, each day an owner is in violation of a provision constitutes a separate and distinct violation.

- 4-2.8 Variances and waivers.
  - Grants the department authority to issue variances and waivers from this regulation, subject to specified conditions.

- 4-2.9 Severability.
  - Standard severability clause is included.

- Appendix 4-B
  - This new appendix contains a table with comparison thresholds for routine *Legionella* culture sampling results. However, in the event that one or more cases of legionellosis are, or may be, associated with the facility, the sampling interpretation shall be in accordance with the direction of a qualified professional and the department.

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 publication of a Notice of Adoption in the State Register, to read as follows:

PART 4: Protection Against *Legionella*

SUBPART 4-1 Cooling Towers

§ 4-1.1 Scope.

All owners of cooling towers shall comply with this Subpart.

§ 4-1.2 Definitions.

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

(a) *Bacteriologic culture sampling and analysis.* The term *bacteriologic culture sampling and analysis* means the collection of a water sample for the measurement of live culture growth of the aerobic bacterial populations by heterotrophic plate count (HPC), dip slides, or similar method used by the industry and according to the manufacturer's directions.

(b) *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.

(c) *Cooling Tower.* The term *cooling tower* means a cooling tower, evaporative condenser, fluid cooler or other wet cooling device that is capable of aerosolizing water, and that is part of, or contains, a recirculated water system and is incorporated into a building's cooling process, an industrial process, a refrigeration system, or an energy production system.

(d) *Legionella culture sampling and analysis.* The term *Legionella culture sampling and analysis* means the collection of a water sample for the measurement of the live culture of *Legionella* involving the use of specialized media and laboratory methods for growth to determine the species and serogroup.

(e) *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, a cooling tower or the premises where the cooling tower is located. In all instances, the legal owner of the building shall be deemed an owner within the meaning of the Subpart. Further, where a tenant owns a cooling tower that services the tenant's leased premises, the tenant is an "owner" within the meaning of this Subpart. Additionally, if a tenant does not own the cooling tower but has a lease or contractual arrangement to maintain the cooling tower, the tenant shall be deemed an agent having control of the cooling tower, and thus an "owner," for purposes of this Subpart.

§ 4-1.3 Electronic registration and reporting.

(a) *Registration.* All owners of cooling towers shall register such towers with the department, using a statewide electronic system designated by the department, prior to initial operation, and whenever any owner of the cooling tower changes. Such registration shall include, at a minimum, the following information:

(1) street address of the building at which the cooling tower is located, with building identification number, if any;

(2) name(s), addresses(es), telephone number(s), and email address(es) of the owner(s) of the cooling tower;

(3) name of the manufacturer of the cooling tower;

(4) model number of the cooling tower;

(5) specific unit serial number of the cooling tower, if available;

(6) cooling capacity of the cooling tower;

(7) cooling tower system volume, inclusive of all piping, basin(s), and sump;

(8) intended use of the cooling tower;

(9) whether the cooling tower operates year-round or seasonally and, if seasonally, start and end date of operation;

(10) whether systematic disinfection in accordance with section 4-1.7 of this Subpart is maintained manually, through timed injection, or through continuous delivery;

(11) whether maintenance is performed by in-house personnel, by a contractor, or by other parties; and

(12) year the cooling tower was placed into service.

(b) *Reporting.* Effective upon adoption of the regulation, at intervals of no more than 90 days while a cooling tower is in use, the owner of the cooling tower shall report to the department using the statewide electronic system:

(1) date of last bacteriological culture sample collection, the analysis result(s), and date of any required remedial action, pursuant to section 4-1.4(b)(1) of this Subpart;

(2) date of last *Legionella* culture sample collection, the analysis result(s), and date of any required remedial action, pursuant to section 4-1.4(b)(2) - (4) of this Subpart;

(3) date of last inspection, pursuant to section 4-1.8 of this Subpart;

(4) date of last certification, pursuant to section 4-1.8 of this Subpart;

(5) date of removal or permanent discontinued use of the cooling tower, if applicable; and

(6) such other information as shall be determined by the department.

(c) The department shall make data in the statewide electronic system publicly available, as appropriate. The statewide electronic system shall be made fully accessible and searchable to any local health department. Nothing in this Subpart 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.

(d) Where both a landlord and a tenant are considered "owners" of a cooling tower pursuant to Section 4-1.2 of this Subpart, either the owner or the tenant shall register the cooling tower. However, both parties are obligated to ensure that registration and reporting are completed as required by this Subpart.

§ 4-1.4 Maintenance program and plan.

(a) By September 1, 2016, and thereafter prior to initial start-up of a newly installed cooling tower, the owner shall obtain or update a maintenance program and plan for each cooling tower, 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 maintenance program and plan shall include the following elements:

(1) a schedule for routine bacteriological culture sampling and analysis to assess microbiological activity at intervals not to exceed 30 days while the cooling tower is in use, and that requires additional bacteriological culture sampling and analysis, as needed, to validate process adjustments;

(2) a schedule for routine *Legionella* culture sampling and analysis within two weeks of seasonal start-up and, thereafter, at intervals not to exceed 90 days while the cooling tower is in use. Cooling towers in use year-round must sample at intervals not to exceed 90 days, and within two weeks after start-up following maintenance;

(3) in addition to the routine *Legionella* culture sampling and analysis required by paragraph (2) of this subdivision, conditions that require immediate *Legionella* culture sampling and analysis, which shall include, but are not limited to:

(i) power failure of sufficient duration to allow for the growth of bacteria;

(ii) loss of biocide treatment of sufficient duration to allow for the growth of bacteria;

(iii) failure of conductivity control, or any other control methods, to maintain proper cycles of concentration;

(iv) a determination by the department or local health department 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 department or local health department.

(4) provisions requiring immediate and appropriate action, including remedial action, in response to bacteriological and *Legionella* culture analyses. For *Legionella* culture analyses, such provisions shall include, but not be limited to, taking all responsive actions

required by Appendix 4-A, including contacting the local health department within 24 hours pursuant to the conditions specified in section 4-1.6 of this Subpart;

(5) provisions requiring that any and all *Legionella* culture analyses must be performed in accordance with section 4-1.5 of this Subpart;

(6) a shutdown and disinfection plan for removing or permanently discontinuing use of a cooling tower;

(7) provisions requiring manual or automated flushing of any piping, basin, sump, or wetted surface during idle conditions; and

(8) provisions requiring cleaning and disinfection prior to startup of a stagnant cooling tower that has been shut down without treatment and recirculation for more than five consecutive days.

§ 4-1.5 *Legionella* culture analysis.

All *Legionella* culture analyses must be performed by a laboratory that is approved to perform such analysis by the New York State Environmental Laboratory Approval Program (ELAP).

§ 4-1.6 Notification.

(a) The owner of a cooling tower shall notify the local health department within 24 hours of receipt of a *Legionella* culture sample result that exceeds 1,000 Colony forming units (CFU) per milliliter. The local health department shall notify the state department of health with 24 hours of receipt of such a report.

(b) The owner shall notify the public of such test results in a manner determined by the local health department or, in the event that the department elects to determine the manner of public notification, by the department.

§ 4-1.7 Disinfection.

(a) Any person who disinfects a cooling tower 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.

(b) The name and certification number of the applicator or the business name and registration number of the company providing the disinfection shall be maintained on-site in accordance with section 4-1.9 of this subpart.

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

(d) The term "disinfection" shall not include the cleaning of a cooling tower through application of detergents, penetrants, brushes or other tools, high-powered water, or any other method that does not involve the use of a pesticide, as defined in 6 NYCRR Part 325.

§ 4-1.8 Inspection and certification.

(a) Inspection.

(1) All owners of cooling towers shall ensure that such towers are inspected prior to seasonal start-up and at intervals not exceeding every 90 days while in use. Year-round

towers shall be inspected at intervals not exceeding every 90 days and prior to start-up, following maintenance.

(2) All inspections shall be performed by a: New York State licensed professional engineer; certified industrial hygienist; certified water technologist; environmental consultant or water treatment professional 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 4-1.4 of this Subpart.

(3) Each inspection shall include an evaluation of the:

(i) cooling tower and associated equipment for the presence of organic material, biofilm, algae, debris and other visible contaminants;

(ii) general condition of the cooling tower basin, remote sump, packing material, and drift eliminators;

(iii) water make-up connections and control, including backflow protection and/or airgaps as needed;

(iv) proper functioning of the conductivity control; and

(v) proper functioning of all water treatment equipment, including, but not limited to, pumps, timers, valves, and strain gauges.

(4) Any deficiencies found during inspection shall 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.

(b) *Certification.* By November 1, 2016, and by November 1st of each year thereafter, the owner of a cooling tower shall obtain a certification from a person identified in paragraph (a) of this

section, that such cooling tower has a maintenance program and plan, and that all activities within that plan or required by this Subpart were implemented, including but not limited to:

(1) all bacteriological culture sampling and analysis;

(2) all *Legionella* culture sampling and analysis, including any immediate *Legionella* culture sampling and analysis performed pursuant to paragraphs (b)(3) and (b)(4) of section 4-1.4 of this Subpart;

(3) any disinfection performed pursuant to section 4-1.7 of this Subpart; and

(4) all inspections performed pursuant subdivision (a) of this section.

(c) *Reporting.* All inspection findings, deficiencies, and corrective actions, and all certifications, shall be reported to the owner, who shall retain such information, in accordance with section 4-1.9 of this Subpart.

§ 4-1.9 Recordkeeping.

The owner of a cooling tower shall maintain records for at least three years of all sampling and analyses; disinfection schedules and applications; inspection findings, deficiencies, and corrective actions; and certifications. An owner shall maintain a copy of the maintenance program and plan required by this Subpart 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.

§ 4-1.10 Enforcement.

(a) The department or local health department may require any owner to conduct *Legionella* culture sampling and analysis, following a determination, based upon epidemiologic data or

laboratory testing, that one or more cases of legionellosis are or may be associated with a cooling tower.

(b) An officer or employee of the department or local health department may enter onto any property to inspect a cooling tower for compliance with the requirements of this Subpart, in accordance with applicable law, and may take water samples as part of such inspections.

(c) Where an owner does not register, obtain certification, disinfect, perform or obtain culture sampling and analysis, or inspect a cooling tower within the time and manner set forth in this Subpart, 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.

(d) A violation of any provision of this Subpart 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 Subpart shall constitute a separate and distinct violation of such provision.

§ 4-1.11 Variances and waivers.

(a) Variances. In order to allow time for compliance with this Subpart, an owner may submit a written application to a local health department for a variance from any provision of this Subpart, for a period not exceeding 90 days, accompanied by an explanation of why such variance will not present a danger to public health. With the approval of the department, the local health department may approve such application for a variance in writing, subject to any conditions that the department or local health department may deem appropriate to protect public health. The local health department or department may revoke such variance upon a determination that the variance may present a danger to public health.

(b) Waivers. The department may issue a written general or specific waiver with respect to any provision of this Subpart, subject to any conditions the department may deem appropriate, where the department is satisfied that such waiver will not present a danger to public health. The department may revoke such waiver upon a determination that the waiver may present a danger to public health.

§ 4-1.12 Severability.

If any provisions of this Subpart 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 Subpart or the application thereof to other persons, entities, and circumstances.

Appendix 4-A

Interpretation of *Legionella* Culture Results from Cooling Towers	
Legionella Test Results in CFU/mL[1]	Approach
No detection (< 20 CFU/mL)	Maintain treatment program and *Legionella* monitoring in accordance with the maintenance program and plan.
For levels at ≥ 20 CFU/mL but < 1000 CFU/mL perform the following:	○ Review treatment program. ○ Institute immediate *online disinfection*[2] to help with control ○ Retest the water in 3 – 7 days. ▪ Continue to retest at the same time interval until one sample retest result is < 20 CFU/mL. With receipt of result < 20 CFU/mL, resume routine maintenance program and plan. ▪ If retest is ≥ 20 CFU/mL but < 100 CFU/mL, repeat *online disinfection*[2] and retest until < 20 CFU/mL attained. ▪ If retest is ≥100 CFU/mL but < 1000 CFU/mL, further investigate the water treatment program and immediately perform *online disinfection*.[2] Retest and repeat attempts at control strategy until < 20 CFU/mL attained. ○ If retest is ≥ 1000 CFU/mL, undertake control strategy as noted below.

For levels ≥ 1000 CFU/mL perform the following:	○ Review the treatment program and provide appropriate notifications per section 4-1.6 of this Subpart. ○ Institute immediate *online decontamination*[3] to help with control ○ Retest the water in 3 – 7 days. ▪ Continue to retest at the same time interval until one sample retest result is < 20 CFU/mL. With receipt of result < 20 CFU/mL, resume routine maintenance program and plan. ▪ If any retest is ≥ 20 CFU/mL but < 100 CFU/mL, repeat *online disinfection*[2] and retest until < 20 CFU/mL attained. ▪ If any retest is ≥ 100 CFU/mL but < 1000 CFU/mL, further investigate the water treatment program and immediately perform *online disinfection*.[2] Re-test and repeat attempts at control strategy until < 20 CFU/mL attained. ▪ If any retest is ≥ 1000 CFU/mL: • carry out *system decontamination*[4].

[1] Colony forming units per milliliter.

[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 halogen-based compound (chlorine or bromine) equivalent to at least 5 milligrams per liter (mg/l) or parts per million (ppm) free residual halogen for at least one hour.

[4] System decontamination means – Maintain between 5 to 10 mg/l (ppm) free residual halogen 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 halogen and circulate for 30 minutes. Refill, re-establish treatment and retest for verification of treatment.
For chlorine treatment the pH range should be 7.0 to 7.6; for bromine treatment the pH range should be 7.0 to 8.7. At higher pH values the treatment times may need to be extended.

NOTE: Stabilized halogen products should not be used for remediation.

SUBPART 4-2 Health Care Facilities

§ 4-2.1 Scope.

All general hospitals and residential health care facilities as defined in Article 28 of the Public Health Law (collectively, "covered facilities") shall comply with this Subpart.

§ 4-2.2 Definitions.

(a) *Covered facilities*. The term *covered facilities* means all general hospitals and residential health care facilities as defined in Article 28 of the Public Health Law.

(b) *Legionella culture sampling and analysis.* The term *Legionella culture sampling and analysis* means the collection of a water sample for the measurement of the live culture of *Legionella* involving the use of specialized media and laboratory methods for growth to determine the species and serogroup.

(c) *Potable water system.* The term *potable water system* means a building water distribution system that provides water intended for human contact or consumption.

§ 4-2.3 Environmental Assessment.

(a) By September 1, 2016, all covered facilities must perform an environmental assessment of the facility using forms provided or approved by the department, unless an environmental assessment was performed on or after September 1, 2015.

(b) Environmental assessments shall be updated annually and under the following conditions:

(1) in the event that one or more cases of legionellosis are, or may be, associated with the facility;

(2) upon completion of any construction, modification, or repair activities that may affect the potable water system;

(3) expansion or relocation of a facility's hematopoietic stem cell transplant and solid organ transplant units; or

(4) any other conditions specified by the department.

(c) The facility shall retain copies of the completed environmental assessment form in accordance with section 4-2.6 of this Subpart.

§ 4-2.4 Sampling Plan.

(a) By December 1, 2016, all covered facilities shall adopt and implement a *Legionella* culture sampling plan for their potable water systems. New covered facilities shall adopt such a plan prior to providing services. The plan must include at a minimum:

(1) *Legionella* culture sampling sites as determined by the environmental assessment;

(2) provisions requiring *Legionella* culture sampling and analysis at intervals not to exceed 90 days for the first year following adoption of the sampling plan. Thereafter, the plan shall include provisions for annual *Legionella* culture sampling and analysis; provided that the plan shall further require that those portions of any potable water system that serve hematopoietic stem cell transplant or solid organ transplant patients shall continue to be sampled and analyzed at intervals not to exceed 90 days.

(3) provisions requiring actions in response to *Legionella* culture analysis results, including all responsive actions required by Appendix 4-B, and specific time frames for such actions.

(b) In addition to the sampling required by the facility's sampling plan, a covered facility shall conduct *Legionella* culture sampling and analysis of the potable water system in a timeframe to be determined by the department upon:

(1) a determination by the department that one or more cases of legionellosis are, or may be, associated with the facility, or

(2) any other conditions specified by the department.

(c) A covered facility shall review its sampling plan annually and under the following conditions:

(1) in the event that one or more cases of legionellosis are, or may be, associated with the facility;

(2) upon completion of any construction, modification, or repair activities that may affect the potable water system;

(3) upon expansion or relocation of a facility's hematopoietic stem cell transplant and solid organ transplant units; or

(4) any other conditions specified by the department.

(d) A copy of the sampling plan and sampling results shall be retained in accordance with section 4-2.6 of this Subpart.

§ 4-2.5 *Legionella* culture analysis.

All *Legionella* culture analyses must be performed by a laboratory that is approved to perform such analysis by the New York State Environmental Laboratory Approval Program (ELAP).

§ 4-2.6 Recordkeeping.

A covered facility shall maintain the environmental assessment required by section 4-2.3 and the sampling plan required by section 4-2.4 of this Subpart, and any associated sampling results, on the facility premises for at least three years. Such records shall be made available to the department immediately upon request.

§ 4-2.7 Enforcement.

(a) The department may conduct an assessment and/or *Legionella* culture sampling and analysis of the potable water system at any time.

(b) A violation of any provision of this Subpart 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 Subpart shall constitute a separate and distinct violation of such provision.

§ 4-2.8 Variances and waivers.

(a) *Variances.* In order to allow time for compliance with this Subpart, a facility may submit a written application to the department for a variance from any provision of this Subpart, for a period not exceeding 90 days, accompanied by an explanation of why such variance will not present a danger to public health. The department may approve such application for a variance in writing, subject to any conditions that it may deem appropriate to protect public health. The department may revoke such variance upon a determination that the variance may present a danger to public health.

(b) *Waivers.* The department may issue a written general or specific waiver with respect to any provision of this Subpart, subject to any conditions the department may deem appropriate, where the department is satisfied that such waiver will not present a danger to public health. The department may revoke such waiver upon a determination that the waiver may present a danger to public health.

§ 4-2.9 Severability.

If any provisions of this Subpart 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 Subpart or the application thereof to other persons, entities, and circumstances.

Appendix 4-B

Interpretation of Routine[1] *Legionella* Culture Results from Covered Facilities	
Percentage of Positive *Legionella* Test Sites	Approach
< 30%	Maintain environmental assessment and *Legionella* monitoring in accordance with the sampling plan.
≥ 30%	• Immediately institute short-term control measures[2] in accordance with the direction of a qualified professional,[4] and notify the department. • The water system shall be re-sampled no sooner than 7 days and no later than 4 weeks after disinfection to determine the efficacy of the treatment. o Retreat and retest. If retest is ≥ 30% positive, repeat short-term control measures.[2] o With receipt of results < 30% positive, resume monitoring in accordance with the sampling plan. • For persistent results, as determined by the department, showing ≥ 30% positive sites, long-term control measures[3] shall be implemented in accordance with the direction of a qualified professional[4] and the department.
[1] In the event that one or more cases of legionellosis are, or may be, associated with the facility, the sampling interpretation shall be in accordance with the direction of a qualified professional[4] and the department.	

[2] Short-term control measures are temporary interventions that may include, but are not limited to, heating and flushing the water system, hyperchlorination, or the temporary installation of treatment such as copper silver ionization (CSI).

[3] Long-term control measures may include, but are not limited to, continuous low-level chlorination, CSI, chlorine dioxide or chloramination.

[4] Control measures shall be conducted in accordance with the direction of a qualified professional. A qualified professional is a New York State licensed professional engineer; certified industrial hygienist; certified water technologist; environmental consultant or water treatment professional with training and experience performing assessments and sampling in accordance with current standard industry protocols.

SUMMARY OF REGULATORY IMPACT STATEMENT

Needs and Benefits:

Legionellosis describes any illness caused by exposure to *Legionella* bacteria, including Legionnaire's Disease and Pontiac Fever. Potential sources of exposure to *Legionella* bacteria include water in the home, workplace, healthcare facilities or aerosol-producing devices in public places. Improper maintenance of cooling towers can contribute to the growth and dissemination of *Legionella* bacteria. Inadequate surveillance for *Legionella* bacteria in the potable water systems at general hospitals and residential health care facilities can also increase the risk of legionellosis.

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 and 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 and 2014 increased 323%, compared to those reported in the previous ten-year period.

Outbreaks of legionellosis have been associated with cooling towers, as well as with the potable water systems of general hospitals and residential health care facilities. Subpart 4-1 of these regulations establish requirements for cooling towers relating to: registration, reporting and recordkeeping; testing; disinfection; maintenance; inspection; and certification of compliance. Subpart 4-2 of these regulations require general hospitals and residential health care facilities to

implement an environmental assessment and *Legionella* sampling plan for their potable water systems and take necessary responsive actions.

These proposed regulations incorporate important clarifications and revisions from the emergency regulations initially adopted by the Public Health and Health Planning Council on August 17, 2015. In general, the Department organized and streamlined the language for concision and clarity. Certain sections were renumbered and related provisions consolidated. Further, the proposed regulations have been divided into two Subparts.

Costs:

Subpart 4-1

Building owners already incur costs for routine operation and maintenance of cooling towers. There will be some increased costs associated with sampling, inspection, and certification of cooling towers. These costs are detailed in the Regulatory Impact Statement.

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.

Subpart 4-2

General hospitals and residential healthcare facilities already incur costs associated with running infection control programs. The regulations would incur new costs for those facilities that are not already conducting annual environmental assessments, and would require all such facilities to adopt and implement a *Legionella* sampling plan. In many instances, facilities can

complete the environmental assessment using existing hospital staff (maintenance, operations, and nursing staff). The cost of these requirements is expected to be offset by the reduced risk of Legionellosis in such facilities.

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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 PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety by amending the SSC to address issues that jeopardize such health and safety. Subpart 4-1 establishes requirements for cooling towers relating to: registration, reporting and recordkeeping; testing; disinfection; maintenance; inspection; and certification of compliance. Subpart 4-2 establishes requirements for potable water systems for general hospitals and residential health care facilities.

Needs and Benefits:

Legionellosis describes any illness caused by exposure to *Legionella* bacteria, including Legionnaire's Disease and Pontiac Fever. Symptoms of legionellosis may include cough, shortness of breath, high fever, muscle aches, and headaches, and can result in pneumonia. 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 and 2014 increased 323%, compared to those reported in the previous ten-year period.

Illnesses caused by the *Legionella* bacteria are a serious public health threat, as these cases often require hospitalization, and between 5 and 30% of cases are fatal. Optimal conditions for *Legionella* growth 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. Outbreaks of legionellosis have been associated with cooling towers, as well as with the potable water systems of hospitals and residential health care facilities.

The proposed regulations govern operation and maintenance of cooling towers, as well as potable water systems for general hospitals and residential healthcare facilities. These proposed regulations incorporate important clarifications and revisions, as compared to the emergency regulations adopted by PHHPC on August 17, 2015. In general, the Department has organized and streamlined the language for concision and clarity. Certain sections were renumbered and related provisions consolidated. Further, the proposed regulations have been divided into two Subparts: the first regulates cooling towers, and the second regulates potable water systems of general hospitals and residential health care facilities.

Subpart 4-1

Improper maintenance of cooling towers can contribute to the occurrence of *Legionella*. 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. Water is part of the process of heat transfer, and these devices require disinfectant to kill or inhibit the

growth of bacteria (including *Legionella*) in such water. The mists normally aerosolized from the tower contain any bacteria growing in this water, including *Legionella*.

Notably, cooling tower manuals typically contain warnings that *Legionella* and other bacteria may be amplified and disseminated if the cooling tower is not properly maintained. Manuals typically recommend that the cooling tower be located at a distance and direction that avoids contaminated discharge from being drawn into fresh air intakes.

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 either dialysis patients, or companions escorting patients to their dialysis session. The cooling tower was found to have insufficient chemical treatment to control bacterial overgrowth. The tower was ultimately replaced by the manufacturer in order to maintain cooling for the hospital and to protect public health.

Additionally, in June and July of 2008, 12 cases of legionellosis, including one fatality, were attributed to a small cooling tower in Syracuse, New York. After an investigation, it was determined that the unit was not operating properly, resulting in the growth of microorganisms in the unit. No new cases were detected after emergency biocide treatment was initiated and proper treatment was maintained.

Recently, 133 cases of legionellosis, which included 16 fatalities, occurred in the Bronx, New York (July-August, 2015). Epidemiologic, environmental, and laboratory investigations of the Legionnaires' disease outbreak in the South Bronx identified a hotel cooling tower as the source of this outbreak. The investigation included a DNA comparison of isolates cultured from cooling towers in the South Bronx and case-patients who lived, worked or visited the area. DNA

from the hotel cooling tower isolates and the outbreak-associated cases were indistinguishable.

In both situations, emergency disinfection of compromised cooling towers helped curtail these outbreaks. These outbreaks highlight the need for proper operation, monitoring, on-going treatment and maintenance of cooling towers. Prior to the issuance of the emergency regulation in August 2015, cooling towers were unregulated in New York State.

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.

Absent regulation, however, this industry guidance is not obligatory. Consequently, maintenance deficiencies, such as poor practice in operation and management, can result in bacterial overgrowth and mist emissions that contain pathogenic *Legionella* bacteria. This regulation requires that all owners of cooling towers ensure that such towers are properly maintained, to protect the public and address this public health threat.

Subpart 4-2

The proposed regulations require that all general hospitals and residential healthcare facilities perform an environmental assessment of their facility. The facilities must also adopt a *Legionella* sampling plan for their potable water system, report the results, and take necessary actions to protect the safety of their patients and/or residents. Additionally, facilities must perform immediate *Legionella* culture sampling and analysis of potable water systems, in a manner directed by the Department, where the Department determines that one or more cases of legionellosis are, or may be, associated with the facility. The Department may also require immediate sampling and analysis based upon any other conditions it specifies.

Most healthy people do not get Legionnaires' disease after being exposed to *Legionella*. In both general hospitals and nursing homes, the risk for disease increases in people who are: over 50 years of age; receiving chemotherapy; undergoing or who have undergone transplants; or receiving immunosuppressive therapy for other conditions. Hospitals will often group these patients together due to the requirements for special precautions. General hospitals who have patients within hematopoietic stem-cell transplant (HSCT) and solid organ transplant units are especially at risk. Accordingly, the potable water systems serving such patients require more frequent sampling under the regulations.

Additionally, people with chronic lung disease are at increased risk for acquiring Legionnaires' disease. Many residents of nursing homes are at risk for legionellosis, as the risk increases with increasing age, especially in the presence of underlying chronic disease.

From 2007 to date, the Department has been involved with the environmental assessment or investigation of 230 Legionellosis events that involved one or more cases, located in 173 hospitals and nursing homes. These cases have demonstrated the need for general hospitals and

nursing homes to conduct regular environmental assessments, implement a sampling plan for the potable water systems, and to take necessary responsive action.

Costs:

Costs to Private Regulated Parties:

Subpart 4-1

Building owners already incur costs for routine operation and maintenance of cooling towers. The proposed regulation, however, establishes certain requirements that have associated costs, to the extent these actions are not already being performed.

- *Routine Bacteriological Culture Sampling and Analysis.* The regulations require routine bacteriological sampling and analysis using dip slides or heterotrophic plate counts (HPC).
    - The cost per dip-slide test is $3.50. Assuming these tests are performed once each month, this would result in an annual cost of $42 for year-round towers. For seasonal towers, the approximate cost for this sampling is $24.50.
    - The cost per HPC test would average $20. Assuming HPC is performed once each month, this would result in an annual cost of $240 for year-round cooling towers. For seasonal towers, the approximate cost would be $140.
- *Routine and Immediate Legionella Culture Sampling and Analysis.* Owners of cooling towers are required to conduct *Legionella* culture sampling and analysis at intervals not to exceed every 90 days while the cooling tower is in use, and immediately in the event of disruption of normal operations. The average cost of each sample analysis is estimated to be approximately $125. If four samples are collected per year for a year-round cooling tower, the approximate cost is $500. In the case of a seasonal tower, if three samples are

collected per year, the approximate annual cost is $375.

- *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 or water treatment professional 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 per hour and estimated to take approximately eight (8) hours. For year-round towers, the approximate annual cost of inspection is $4,800, and for seasonal towers, the approximate annual cost of inspection is $3,600.
- *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 per hour and is estimated to take approximately four (4) hours. The approximate cost of annual certification for both year-round and seasonal towers is $600.
- *Disinfection.* If 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 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 maintenance program and plan is estimated to 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.
- Where power producers and industrial facilities disinfect a cooling tower using halogenation, they may be required to dehalogenate discharge streams from cooling towers to meet State Pollutant Discharge Elimination permit System (SPDES) permit conditions. Piping, and attendant monitoring equipment (e.g., conductivity probes, continuous halogen monitors), may require design and capital expenditures in accordance with the unique operating conditions of the tower.

Subpart 4-2

General hospitals and residential healthcare facilities already incur costs for routine operation and maintenance of infection control programs. This regulation establishes the following requirements, which have associated costs:

- *Annual Environmental Assessment.* In many instances, physical facilities staff can complete the environmental assessment in cooperation with other hospital staff (maintenance, operations, and nursing staff). The work can normally be completed in 2 to 3 hours. In the event that a consultant is used, these costs range between $300 and $450.
- *Sampling Plan.* If the facility already has a sampling plan and maintains proper maintenance records, but requires a consultant to determine compliance with these new requirements, the associated cost would be 6.5 hours at $150 per hour ($975). Without a prior plan, and with poor maintenance documentation, the associated cost would be 13 hours, or more, at $150 per hour (approximately $1,950). In some cases, facilities may be

able to develop a sampling plan using existing staff. Further, these costs will have already been realized by those facilities following the department's guidance documents issued prior to the emergency regulations.

- *Routine and Immediate Legionella Culture Sampling and Analysis.* Covered facilities are expected to sample at intervals not to exceed every 90 days for the first year after adoption of the sampling plan. If ten samples were to be collected during each sampling round, and the cost of each sample analysis is estimated to be approximately $125.00, the total cost per year of such sampling is estimated to be $5,000. This would be an annual cost for facilities with hematopoietic stem-cell transplant (HSCT) and solid organ transplant units. For facilities without such units, the annual cost of sampling is estimated to be $1,250, as sampling may be performed on an annual basis.

Costs to State Government and Local Government:

State and local governments will incur costs for administration, implementation, and enforcement of Subpart 4-1. 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.

State government will incur costs for enforcement of Subpart 4-2 for general hospitals and residential healthcare facilities. However, the cost is expected to be outweighed by the benefit of reduced cases of legionellosis at these facilities.

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 Subpart 4-1, utilizing both civil and criminal options available. PHL §§ 228, 229, 309(1)(f) and 324(1)(e). With respect to Subpart 4-2, the Department, rather than local governments, will conduct enforcement.

Paperwork:

The regulation imposes new registration, reporting and recordkeeping requirements for owners of cooling towers. Additionally, general hospitals and residential healthcare facilities will be required to perform periodic environmental assessments and to adopt and implement a *Legionella* sampling plan. The regulation imposes new recordkeeping requirements for general hospitals and residential healthcare facilities related to the environmental assessment, the sampling plan and sample results.

Duplication:

This regulation does not duplicate any state requirements.

Alternatives:

No alternatives were considered, as promulgating this regulation was determined to be necessary to address the public health threat.

Federal Standards:

There are no federal standards or regulations pertaining to registration, maintenance, operation, testing, and inspection for cooling towers, or to *Legionella* sampling of potable water systems for general hospitals or residential healthcare facilities.

Compliance Schedule:

These permanent regulations, which incorporate revisions to the emergency regulations currently in effect, will be effective upon publication of a Notice of Adoption in the State Register.

Subpart 4-1

All owners of existing cooling towers should already be complying with the current emergency regulations. By September 1, 2016, all owners of existing cooling towers must begin routine bacteriological sampling analysis every 30 days while the tower is in use, and *Legionella* culture sampling and analysis every 90 days while the tower is in use. As in the emergency regulations, owners of cooling towers must 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 dates of sample collection; dates of disinfection; date of last inspection; date of last certification; and date of discontinued use. Reporting must be made through the electronic registry in intervals not exceeding 90 days.

Subpart 4-2

By September 1, 2016, all covered facilities must perform an environmental assessment of the facility using forms provided, or approved, by the department, unless an environmental assessment was performed on or after September 1, 2015. The assessment shall be updated annually and updated in the event of a case of facility-acquired legionellosis, facility repair, new construction, changes in the potable water system, and upon any other conditions specified by the department.

Additionally, all covered facilities must adopt and implement a *Legionella* sampling plan for the facilities' potable water system by December 1, 2016. The plan must include *Legionella* culture sampling and analysis at intervals not to exceed 90 days for the first year after the adoption of the sampling plan. Thereafter, sampling is to be performed annually, at a minimum, provided that general hospitals with hematopoietic stem cell and solid organ transplant units must continue to sample at intervals not to exceed 90 days. The sampling plan must be reviewed annually and updated in the event of a case of facility-acquired legionellosis, significant construction, repair work, or changes to the potable water system and/or facilities' use that may affect hematopoietic stem cell and solid organ transplant units, and any other conditions specified by the department.

In addition to the sampling required by a facility's sampling plan, immediate Legionella culture sampling and analysis of the potable water system must occur, at the direction of the department, when (1) a determination is made by the department that one or more cases of legionellosis are, or may be, associated with the facility; or (2) any other conditions specified by the department.

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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, which could include small businesses and local governments. Any general hospitals and residential health care facilities owned or operated by a local government or that qualifies as a small business will be required to complete an environmental assessment, adopt and implement a *Legionella* sampling plan for the facilities' potable water system, and take appropriate responsive actions. At this time, it is not possible to determine the number of small businesses or local governments affected.

Local governments must also enforce Subpart 4-1, relating to regulation of cooling towers. 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:

Compliance requirement for small businesses and local governments are the same as those requirements set forth in the Regulatory Impact Statement.

Professional Services:

To comply with inspection and certification requirements with respect to cooling towers, small businesses and local governments 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 and local governments will need to secure laboratory services for *Legionella* culture analysis. To comply with disinfection requirements with respect to cooling towers, small businesses and local governments will need to obtain the services of a commercial pesticide applicator or pesticide technician, or pesticide apprentice under supervision of a commercial pesticide applicator.

Compliance with the provisions that apply to general hospitals and healthcare facilities may require expertise in areas such engineering, physical facility management, water treatment methods, and monitoring of the environmental conditions of their potable water distribution systems.

Compliance Costs:

Compliance costs for small business and local government are consistent with the costs outlined in the Regulatory Impact Statement.

Economic and Technological Feasibility:

Although there will be an impact on building owners, including small businesses and local governments, compliance with the regulation is considered economically and technologically feasible, in part because the requirements are consistent industry best practices. This regulation is also necessary to protect public health, and it is expected to reduce cases of legionellosis in communities around cooling towers, as well as for patients and residents in general hospitals and residential healthcare facilities. Accordingly, the benefits to public health are anticipated to outweigh any costs.

Minimizing Adverse Impact:

The Department provides a cooling tower registry, technical consultation, coordination, and information and updates. In addition, the Department has issued guidance for general hospitals and cooling towers, which is consistent with the proposed regulations. Covered facilities that have followed the guidance will already be in compliance with most of the new regulations.

Small Business and Local Government Participation:

Development of the emergency regulations, upon which these regulations were based, was coordinated with New York City.

Cure Period:

Violation of this regulation can result in civil and criminal penalties. However, the regulations allow for time to adopt plans and performed required actions. Accordingly, and in light of the magnitude of the public health threat posed by *Legionella*, no cure period is warranted.

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, recordkeeping or other compliance requirements on public or private entities in rural areas.

JOB IMPACT STATEMENT

Nature of the Impact:

The New York State Department of Health (NYSDOH) 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 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 employment opportunities in any particular region of the state.

Minimizing Adverse Impact:

Not applicable.