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TO: **Memo Distribution List**

LeadingAge New York

FROM: Hinman Straub P.C.

RE: Final Adopted Regulation Establishing Requirements to Prevent the Spread of Legionella

DATE: July 6, 2016

NATURE OF THIS INFORMATION: This is information explaining new requirements you need to be aware of or implement.

DATE FOR RESPONSE OR IMPLEMENTATION: The Final Regulation was adopted on July 6, 2016 and is effective immediately.

HINMAN STRAUB CONTACT PEOPLE: Sean Doolan and Michael Paulsen

THE FOLLOWING INFORMATION IS FOR YOUR FILING OR ELECTRONIC RECORDS:
Category: #4 Regulatory Process Suggested Key Word(s):

On July 6, 2016, the Public Health and Health Planning Council (PHHPC) and the Commissioner of Health formally adopted the regulations currently in effect relating to protections against the spread of Legionella bacteria. As you may recall, the emergency regulations required all Article 28 general hospitals and residential health care facilities (RHCFs) ("covered facilities") to develop a Legionella sampling plan for its facilities' potable water distribution system and take necessary actions to protect the safety of their patients or residents.

The adoption of the final regulation follows the issuance of regulatory guidance by the Department of Health and the adoption of the emergency regulation. The final adopted regulations include components of both the emergency regulation and provisions contained in the DOH-issued guidance "Health Advisory: Prevention and Control of Legionellosis (Legionnaires' disease) in Healthcare Facilities", resulting in the final adopted regulation now containing specific requirements for Article 28 covered facilities in relation to Legionella assessment, testing, sampling, and reporting.

It is important to note that the final adopted regulations are substantially similar to the DOH-issued guidance and should not result in significant changes to your facility's policies and procedures developed in 2015 as required by the emergency regulation. For those facilities that did not implement policies and procedures as a result of the emergency regulation, the final adopted regulation now establishes specific timeframes that must be met in order to ensure compliance with the regulation.

For your reference, copies of the following documents are attached:

- The **text** of the final adopted regulation;
- **Our memorandum** providing an overview of the initial emergency regulation;
- DOH-issued "**Health Advisory**: Prevention and Control of Legionellosis (Legionnaires' disease) in Healthcare Facilities"; and
- **DOH-presentation** "Nursing Home Guidance for Prevention and Control of Legionnaires' Disease".

Background

In 2015, DOH issued emergency regulations to prevent the spread of Legionella bacteria by requiring registration, testing, inspection, and certification of cooling towers located in New York State. The emergency regulations further required all Article 28 general hospitals and residential health care facilities (RHCFs), regardless of whether the facility owns or operates a cooling tower on its premises, to develop a Legionella sampling plan for its facilities' potable water distribution system and take necessary actions to protect the safety of their patients or residents. Specifically, the emergency regulations required that all Article 28 covered facilities:

- Adopt a Legionella sampling plan for its facilities' potable water distribution system and report the results of such sampling conducted pursuant to the adopted sampling plan; and
- Take necessary responsive actions to protect the safety of their patients or residents.

While the emergency regulation did not specify the actions that must be undertaken to meet these requirements, the Department subsequently issued updated guidance for Article 28 facilities through a Health Advisory following the implementation of the regulation and posted a

PowerPoint presentation providing guidance to nursing homes. To comply with the first requirement under the regulation, the Department recommended that the facility develop a policy that contains a water sampling plan that includes periodic testing and an appropriate response to a positive test.[1] For the second requirement, the Department recommended that the facility develop a policy to address clinical criteria for identifying patients that may have been infected by Legionnaires' disease.

As previously noted, any facility that is the owner of a cooling tower is already subject to the registration, testing, inspection and reporting requirements contained in the initial emergency regulation.[2]

Summary of Provisions

1. Covered Facilities

The final adopted regulation, in relation to health care facilities, applies to all Article 28 general hospitals and RHCFs in New York State, regardless of whether the facility owns or operates a cooling tower.

2. Environmental Assessment

The final adopted regulation requires all covered facilities to perform an environmental assessment of the facility by September 1, 2016, and annually thereafter, using forms provided or approved by DOH.[3] The requirement to perform an environmental assessment by September 1, 2016 does not apply to any facility that performed an assessment on or after September 1, 2015.[4] The Regulatory Impact Statement (RIS) provides that environmental assessments should be completed by individuals, or members of an internal multi-disciplinary team, that have the knowledge related to the facility's components, operations, and contract services.

In addition to the completion of an annual environmental assessment, the final adopted regulation will require covered facilities to perform an environmental assessment under the following conditions:

- in the event that one or more cases of legionellosis are, or may be, associated with the facility;
- upon completion of any construction, modification, or repair activities that may affect the potable water system;
- expansion or relocation of a facility's hematopoietic stem cell transplant and solid organ transplant units; or
- any other conditions specified by the department.

[1] The Health Advisory contains a recommended sampling plan that can be used for the sampling policy for a facility
[2] The provisions applicable to buildings with a cooling towers remain unchanged in the final adopted regulation.
[3] In prior guidance, DOH recommended that facilities use the "Environmental Assessment of Water Systems in Healthcare Settings", originally developed by CDC and modified for use in New York State, available on the Health Commerce System (HCS).
[4] A facility that performed an environmental assessment on or after September 1, 2015 would be required to complete their annual environmental assessment 1-year from the date the initial assessment was performed.

It is important to note that DOH-issued "Health Advisory: Prevention and Control of Legionellosis (Legionnaires' disease) in Healthcare Facilities" contains information and guidance on performing and completing the environmental assessment.

3. Sampling and Management Plan

The final adopted regulation requires all covered facilities to adopt and implement a *Legionella* culture sampling plan for their potable water systems by December 1, 2016. Covered facilities will be required to review the facility's sampling and management plan annually, or upon the occurrence of a condition that requires the performance of an environmental assessment.

The management plan must include at a minimum:

- *Legionella* culture sampling sites as determined by the environmental assessment;
- Provisions requiring *Legionella* culture sampling and analysis at intervals not to exceed 90 days for the first year following adoption of the sampling plan, and annually thereafter;
- For portions of any potable water system that serve hematopoietic stem cell transplant or solid organ transplant patients, the plan must provide for this water system to continue to be sampled and analyzed at intervals not to exceed 90 days;
- Provisions requiring actions in response to *Legionella* culture analysis results and specific time frames for such actions.

Similarly, DOH-issued "Health Advisory: Prevention and Control of Legionellosis (Legionnaires' disease) in Healthcare Facilities" contains information and guidance on developing and implementing a Legionella sampling plan.

4. Recordkeeping

Facilities are required to maintain on-site for a period of at least 3 years: (1) completed environmental assessment forms; (2) a copy of the sampling and management plan; and (3) any associated sampling results.

5. Enforcement

The final adopted regulations provide DOH with the authority to conduct an assessment and/or *Legionella* culture sampling and analysis of the potable water system at any time.

A violation of any of the provisions and requirements of this regulation is subject to all civil and criminal penalties as provided for by law. Each day that an owner remains in violation of any provision constitutes a separate and distinct violation of each such provision.

6. Variances and Waivers

In order to allow time for compliance with this regulation, a facility may submit a written application to DOH for a variance from any provision of the regulation, for a period not

exceeding 90 days, accompanied by an explanation of why such variance will not present a danger to public health. Further, DOH is authorized to issue a written general or specific waiver with respect to any provision, 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.

Please contact us with any questions that you may have.

4831-5494-9940, v. 2

Protection Against Legionella

Effective date: 7/6/16

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 legionellosis 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 per milliliter (CFU/mL). 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 Conservation for use in cooling towers or pesticidal devices in a USEPA registered establishment to be used in disinfection.
    - Clarifies the terms “disinfect” and “disinfection” to mean the control of microorganisms or microbial growth. The term “disinfection” is also 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 and Management Plan

- Requires that all covered facilities adopt and implement a sampling and management 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 and management plan must be reviewed and updated annually, and in specified conditions.
- The proposed regulation requires that the sampling and management 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 and management 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 14 days 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 treatment and 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 per milliliter (CFU/mL). 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 for use in cooling towers or pesticidal devices produced in a USEPA registered establishment may be used in disinfection.

(d) The terms “disinfect” and “disinfection” in this Part means the control of microorganisms or microbial growth. 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 subdivision (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 subdivsion (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, have a maintenance program and plan, 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 each 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]	Response
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:	o Review treatment program. o Institute immediate *online disinfection*[2] to help with control o 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. o If retest is ≥ 1000 CFU/mL, undertake control strategy as noted below.

For levels ≥ 1000 CFU/mL perform the following:	o Review the treatment program and provide appropriate notifications per section 4-1.6 of this Subpart. o Institute immediate *online decontamination*[3] to help with control o 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 online decontamination or system decontamination as defined in this Appendix per footnotes 3 and 4.

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 and Management Plan.

(a) By December 1, 2016, all covered facilities shall adopt and implement a *Legionella* culture sampling and management plan for their potable water systems. New covered facilities shall adopt such a plan prior to providing services. The sampling and management 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 and management 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 and management 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 and management 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 and management 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 and management 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 each 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	Response
< 30%	Maintain environmental assessment and *Legionella* monitoring in accordance with the sampling and management plan.
≥ 30%	o Immediately institute short-term control measures[2] in accordance with the direction of a qualified professional,[3] and notify the department. o 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. ▪ Retreat and retest. If retest is ≥ 30% positive, repeat short-term control measures.[2] ▪ With receipt of results < 30% positive[4], resume monitoring in accordance with the sampling and management plan. o For persistent results, as determined by the department, showing ≥ 30% positive sites, long-term control measures[5] shall be implemented in accordance with the direction of a qualified professional[3] 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 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] 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.

[4] Positive samples should be minimized.

[5] Long-term control measures may include supplemental disinfection treatments.

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 and management 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 and management 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 and managment 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 and management 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 and Management Plan.* If the facility already has a sampling and management 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 and management 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 and management 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 and management plan. The regulation imposes new recordkeeping requirements for general hospitals and residential healthcare facilities related to the environmental assessment, the sampling and management 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 and management 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 and management 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 and management 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 and management 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 and management 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.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

This assessment summarizes and responds to the comments received on proposed regulations for Subparts 4-1 and 4-2 of Title 10 of the New York State Code of Rules and Regulations, which address protection against *Legionella* in cooling towers and in the potable water systems of general hospitals and residential health care facilities. The Notice of Proposed Rulemaking was published in the *State Register* on April 20, 2016. The public comment period for this proposal was open from April 20, 2016 until June 6, 2016.

The Department of Health ("DOH" or the "Department") received approximately 80, letters and emails, containing over 200 comments and questions from various stakeholders, including but not limited to, manufacturers of cooling towers, cooling tower operators, consultants, power production consortia, analytical laboratories, healthcare facilities and associations, local health departments, and other organizations representing the interests of the affected parties. While the Department processed every comment and each one received equal consideration, in providing responses, the Department grouped together similar comments. The Department made some technical revisions to the regulations in response to these comments, as further explained below. No substantive changes were made to the regulations.

The Assessment of Public Comment presents and responds to all of the comments; this serves as a summary of the most frequent comments and the Department's corresponding responses. The full text of the regulations, as well as the full Assessment of Public Comment, are available on the Department's website.

Scope of the Regulation

Several comments recommended the Department broaden the scope of the regulations to include management of entire building water systems, through incorporation of the ANSI/ASHRAE Standard 188-2015. The commenters urged the Department to require the management of the entire building water system for "high-risk" buildings.

The Department acknowledges there are many potential sources of exposure to *Legionella* bacteria including water in the home, workplace, healthcare facilities or aerosol-producing devices in public places. Part 4 addresses two of those sources—cooling towers and potable water systems in general hospitals and residential health care facilities. 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 increase the risk for exposure. Findings from a recent Centers for Disease Control and Prevention (CDC) review of legionellosis between 2000 and 2014 (CDC; *Morbidity and Mortality Weekly Report*, Vol. 65, June 7, 2016) support the Department's focus on cooling towers and potable water systems in health care facilities. The Department will continue to consider whether and how to regulate other sources of *Legionella* but does not intend to expand the regulation at this time. Dividing Part 4 into Subparts enables the Department to amend the regulations to address other sources.

Cost of the Regulation

The Department received several comments concerning the cost of the regulation associated with the requirements in both Subparts. The Department will work with local health departments as well as the regulated parties to identify methods to streamline implementation.

Subpart 4-2 will be implemented by the Department and will not impact local health departments.

SUBPART 4-1 Cooling Towers

Bacteriological and Legionella culture sampling and analysis

The Department received several comments requesting additional specificity for the sampling methods and conditions describing when additional *Legionella* culture sampling and analysis must occur. The Department declined to add additional specificity to accommodate new sampling and analytical technologies, professional judgment, and differences between cooling towers and their conditions. No change was made to the regulation.

The Department also received several comments suggesting modification to the bacteriological and *Legionella* culture sampling and analysis frequency to provide more flexibility. The Department believes the sampling intervals are reasonable and attainable and no change was made to the regulation.

Differences between power production plant cooling towers and those used by other industries

The Department received several comments describing the differences between power production plant cooling towers and those used for other purposes. The Department has had substantial discussions with power production consortia and with the New York State Department of Environmental Conservation (DEC) to discuss the unique issues involving disinfection and discharge permits for power production plant cooling towers.

The Department will continue to address these concerns through guidance. No change was made to the regulation.

Registry

The Department received several comments regarding coordination with New York City Department of Health and Mental Hygiene (DOHMH), given the recently adopted DOHMH regulations pertaining to cooling towers. The Department continues to work with DOHMH to address reporting and data sharing. No change was made to the regulation.

Environmental Laboratory Approval Program (ELAP)

The Department received comments concerning the requirement that *Legionella* culture analysis be performed by a New York State Environmental Laboratory Approval Program (ELAP) certified laboratory. On June 1, 2016, the Department made application materials available for laboratories to apply for certification for *Legionella* culture analysis and has begun receiving applications for laboratories. No change was made to the regulation.

Public Notification

The Department received comments concerning the public notification requirement, requesting clarification and a standard approach for notification. The Department will work with local health departments to ensure a standard approach for public notification.

Disinfection

One commenter raised a concern over the technical accuracy of the disinfection language in 10 NYCRR 4-1.7. The Department, in consultation with the DEC, made technical clarifications to the regulation to specify that the terms “disinfect” and “disinfection” mean the control of microorganisms or microbial growth. Further, the regulation permits only biocide

products registered by the DEC for use in cooling towers or pesticidal devices in a US EPA registered establishment to be used in disinfection.

Inspection and Certification

The Department received several comments and questions related to the inspections and certification requirements in 10 NYCRR 4-1.8. Several commenters requested changes to the inspection interval. The Department believes the inspection interval is reasonable and attainable, and no change was made to the regulation. Additional clarification was provided in the full Assessment of Public Comment. The Department will publish additional guidance as needed.

Appendix 4-A

The Department received several comments recommending revisions to Appendix 4-A. In particular, commenters requested a revision to the language prohibiting the use of halogen-based compounds. In response, the Department provided a technical revision to a footnote to address that online disinfection may involve the use of stabilized halogens that are part of normal operations. In addition, the Department revised the second column heading in Appendix 4-A from “Approach” to “Response,” as suggested.

SUBPART 4-2 Health Care Facilities

Environmental Assessment

The Department received several comments concerning the environmental assessment form, including how to access the form, who should prepare it, and when must it be updated. The forms are currently available to local health departments in the Health Commerce System and will be posted on the Department’s website. Assessments should be completed by individuals, or

members of an internal multi-disciplinary team, that have the knowledge related to the facility's components, operations, and contract services. As stated in the regulation, the environmental assessment needs to be updated annually or when major construction is conducted at the facility. This means that the environmental assessment must be revised whenever building or plumbing modifications occur that will affect the remainder of the potable water system. No changes were made to the regulation.

Sampling and Management Plan

The Department received comments stating that a comprehensive management program and plan is necessary for healthcare facilities. Specifically, some commenters requested that Subpart 4-2 incorporate ANSI/ASHRAE 188-2015, Annex A, by reference.

The Department did not make substantive amendments to 10 NYCRR 4-2.4 in response to these comments. Elements of Annex A are contained in Department guidance issued as a Health Advisory sent to Article 28 facilities on August 10, 2015 (Health Advisory). In addition, the Department clarified the regulation by changing the term "Sampling Plan" to "Sampling and Management Plan." Inclusion of "Management" in the title better represents the intent of the plan.

The Department also received several questions concerning when samples must be collected, from where, how many, and other details. Many of these answers are available in a Department's Health Advisory, and responsive details are provided in the full Assessment of Public Comment. In addition, the Department will issue updated guidance with additional information. No changes were made to the regulation in response to these comments.

Appendix 4-B

The Department received several comments concerning the sampling result interpretation and response actions for *Legionella* culture results. The Department revised the second column heading in Appendix 4-B from “Approach” to “Response,” as suggested. The Department provided a technical revision to a footnote to remove mention of specific treatment alternatives. Specific answers to the questions received are provided in the full Assessment of Public Comment.

ASSESSMENT OF PUBLIC COMMENT

This assessment responds to the comments received on proposed regulations for Subparts 4-1 and 4-2 of Title 10 of the New York State Code of Rules and Regulations, which address protection against *Legionella* in cooling towers and in the potable water systems of general hospitals and residential healthcare facilities. The Notice of Proposed Rulemaking was published in the State Register on April 20, 2016. The public comment period for this proposal was open from April 20, 2016 until June 6, 2016.

The Department of Health ("DOH" or the "Department") received approximately 80 comment letters and emails from various stakeholders, including but not limited to manufacturers of cooling towers, cooling tower operators, consultants, power production consortia, analytical laboratories, healthcare facilities and associations, local health departments, and other organizations representing the interests of the affected parties.

The comments are summarized below with responses. The Department made some technical revisions to the regulations in response to these comments, as further explained below. No substantive changes were made to the regulations.

SUBPART 4-1 Cooling Towers

§ 4-1.1 Scope

Comment: The Department received several comments concerning the incorporation of the American National Standards Institute/American Society of Heating, Refrigeration, and Air Conditioning (ANSI/ASHRAE) Standard 188-2015:

- A commenter recommended that the regulation should include full incorporation of the ANSI/ASHRAE Standard 188-2015 to cover the entire building water system for "high-risk" buildings, defined as all hospitals or healthcare facilities where patient stays exceed 24 hours; buildings that are more than 10 stories high; and multiple housing units with centralized potable water heater systems.
- A commenter recommended incorporating section 6 of ANSI/ASHRAE Standard 188-2015, as well as the Hazard Analysis Critical Control Point (HACCP).
- A commenter requested the inclusion of ANSI/ASHRAE Standard 188-2015 section 7 and National Science Foundation (NSF) Standard 453.
- A commenter asked why ANSI/ASHRAE Standard 188-2015 was included but not the 188 Appendix.
- A commenter suggested that incorporating ANSI/ASHRAE Standard 188-2015 conflicted with the federal Clean Water Act (CWA).
- A commenter asked that the Department incorporate recent guidelines from the Centers for Disease Control and Prevention ("CDC"), relating to *Legionella* control.

Response: Full incorporation of the Standard would not be appropriate. However, the Department's guidance—specifically, a Health Advisory sent to Article 28 facilities on August 10, 2015 (Health Advisory)—includes certain elements of ANSI/ASHRAE Standard 188-2015 that are not incorporated by reference into the regulation.

With respect to the comment on the Clean Water Act, this regulation does not conflict with that federal law, as it does not relate to discharges of pollutants or regulatory water quality standards for surface waters.

The CDC published a toolkit entitled *Developing a Water Management Program to Reduce Legionella Growth and Spread in Buildings: A Practical Guide to Implementing Industry Standard*, on June 6, 2016. The toolkit is consistent with the Department's Health Advisory; however, the Department may update its guidance to more closely track certain elements of this recent publication.

No changes were made to the regulation in response to these comments.

Comment: Commenters suggested that the regulation unduly singles out cooling towers at the source of legionellosis.

Response: Over the last 10 years, the Department has been involved with legionellosis investigations across the state associated with cooling towers and healthcare facilities, as well as other sources. A recent CDC review of legionellosis between 2000 and 2014 (CDC; *Morbidity and Mortality Weekly Report*, Vol. 65, June 7, 2016) showed that even though potable water was the most frequent source of exposure (56%), cooling towers accounted for the next highest exposure source (22%). Significantly, however, outbreaks related to cooling towers were associated with the larger numbers of cases. In addition, healthcare associated outbreaks accounted for 57% of the cases (essentially the bulk of the potable water cases) and 85% of fatalities. These data are consistent with Department experience and demonstrate that the

regulation focuses on the appropriate sources of *Legionella*. The Department's experience and this recent publication support the focus of the regulation.

No change was made to the regulation in response to these comments.

Comment: A commenter suggested that power plants and electricity producing systems should be regulated in a separate Subpart, given their unique operations and State Pollutant Discharge Elimination Systems (SPDES) requirements.

Response: Although the Department believes that the regulations are appropriate for power plants, the Department acknowledges that cooling towers for power plants operate differently than those for other uses, and may require additional considerations. The Department will continue to work with the power production consortia and the Department of Environmental Conservation ("DEC") to address the concerns. However, no change to the regulation is warranted at this time. These may be addressed through future guidance.

Comment: A commenter suggested that the regulation include a requirement to test other water sources including: construction and street sweepers; hydro-seeding operations; unusual municipal distribution system activity; and private water suppliers.

Response: The Department has existing authority to evaluate potential sources associated with cases of legionellosis. During the course of an investigation, this may include taking samples from appropriate sources other than cooling towers and potable water systems at health care facilities. No change was made to the regulation.

§ 4-1.2 Definitions

Comment: The Department received comments concerning the definition of *bacteriological culture sampling and analysis*. A commenter questioned whether dip slide culture tests or laboratory culture tests are required to validate process adjustments, per section 4-1.4(1). The commenter recommended that Heterotrophic Plate Count (HPC) dip slides should not be used, suggesting that studies demonstrated inaccurate, highly variable, and non-reproducible dip side results. Further, the commenter requested that the regulation clarify the method due to variability between dip slide culture results and laboratory culture results. Finally, the commenter suggested that if laboratory culture tests are required for HPC, a method should be specified.

Response: The definition intentionally allows for "similar method used by the industry" that are used "according to the manufacturer's directions." This definition allows the use of alternate methods that are considered acceptable by industry and supporting laboratories. Over-specification of methods would cause additional expense and unnecessary changes in operations. Finally, the regulation allows for new sampling and analytical technologies that are determined to be reliable measures of biological growth. No change was made to the regulation.

Comment: The Department received comments concerning the definition of *Legionella culture sampling and analysis.* A commenter questioned why specific *Legionella* serogroups must be identified. In addition, a commenter suggested that the definition clarify that dip slide tests for *Legionella* will not be allowed because they would not achieve a quantitation limit of 20 colony forming units per milliliter (CFU/mL). A commenter also noted that *Legionella* dip slide tests often have false negative results.

Response: Identification of serogroups is recommended—and may be required during an outbreak—because *L. pneumophila* 1 is responsible for the majority of illnesses and, further, a link between environmental isolates and patient isolates may need to be performed under outbreak conditions. When an outbreak is not due to *L. pneumophila* 1, knowing the general category of the legionellae present may also be critical to the environmental response.

The regulations do not refer to use of dip slides for *Legionella* spp. Rather, testing must performed pursuant to a method approved by the Department's Environmental Laboratory Approval Program (ELAP; see section 4-1.5) for *Legionella* sampling and analysis. At this time, ELAP has approved ISO 11731 for *Legionella* quantitation, which does not include dip slides.

No change was made to the regulation.

Comment: The Department received a comment expressing support for the revised definition of *owner* in the proposed regulation, as compared to the original definition in the emergency regulation. The commenter asked for the following clarifications:

- Are two separate maintenance program and plans required for the tenant tower (owner and tenant)?
- Will both entities be fined in the case of a violation or just the tenant or just the owner?
- Will sampling have to be done by both the owner and the tenant?

Response: The definition is intended to cover the variety of arrangements between owners of buildings, owners of cooling towers, and tenants. Only one maintenance program and plan is necessary for a given cooling tower. Like other compliance requirements, the required sampling

is the responsibility of any party deemed an "owner" of a cooling tower. However, either party may satisfy the requirement. Any party deemed an "owner" may be liable for fines.

Comment: The Department received a comment asking that definitions be added for *water treatment professional*, as used in Section 4-1.8, and *water management program*, as used in certain parts of ANSI/ASHRAE Standard 188-2015.

Response: The term *water treatment professional* used in the regulation in section 4-1.8(a)(2) is intentionally broad and includes many types of professionals who have appropriate experience and follow industry standards. Because the Department has not incorporated all of ANSI/ASHRAE Standard 188-2015, there is no need to define *water management program*. Accordingly, no change was made to the regulation.

Comment: The Department received a comment asking whether the definitions found in the emergency regulation will remain valid once Part 4 Title 10 is adopted and published.

Response: Upon adoption of the permanent regulation, the emergency regulation will no longer be in effect. The definitions contained in the adopted regulation will supersede earlier versions.

§ 4-1.3 Electronic registration and reporting

Comment: The Department received a comment suggesting that less specific data about registered cooling towers be publically available on the internet.

Response: Transparency is an important element of the Department's regulatory program, and the Department has not identified a public interest in making less data available. No change was made to the regulation.

Comment: The Department received a comment requesting that all testing results be accessible through the online database—not just the most current results.

Response: The database reflects the current status of cooling towers across the state. The Department will review this comment and determine whether the database should be modified to display more data. As this feature of the database is not governed by the regulation itself, no change was made to the regulation.

Comment: A commenter indicated that the regulation should require that owners update the registry within a specified number of days after performing certain actions, in addition to the 90-day update requirement.

Response: The Department determined that such a requirement would be overly burdensome and hamper compliance, and that a 90-day reporting cycle is more appropriate. No change was made to the regulation.

Comment: The Department received comments recommending that registration requirements include certain specifics regarding the disinfection and treatment system, including biocide, corrosion inhibitor and dispersant. A commenter also suggested that the location of the cooling tower within the context of the building should be included.

Response: Disinfection and treatment system specifics should be included in the maintenance program and plan. The Department may further examine whether additional fields are needed in the registry. No change was made to the regulation at this time.

Comment: The Department received a comment requesting a separate reporting requirement for power production plant owners. Power production companies also raised concern with cooling system capacity and other fields within the registry, requesting several amendments to the registry.

Response: The Department acknowledges the differences in power plant cooling tower use, operation, and capacity. The Department will explore updating the registration system in response to these concerns. However, at this time the Department believes that the registration requirements are reasonable, and that any necessary clarifications can be handled through guidance. Accordingly, no change was made to the regulation at this time.

Comment: The Department received a comment stating that the exact start-up and shut down is difficult to determine precisely in advance, due to weather conditions.

Response: The date of start-up and shut down should be entered after those events occur, and not estimated in advance.

§ 4-1.4 Maintenance program and plan

Comment: The Department received a comment stating that there is no mention in the permanent regulation of the emergency regulation's deadline for completion of the maintenance program and plan and asked if the emergency regulation requirement is no longer enforceable.

Response: If the permanent regulations are adopted, the date for completion of the maintenance program and plan will be extended to accommodate the need for modifications based on additional provisions included in the permanent regulation.

Comment: The Department received a comment recommending that the reference to ANSI/ASHRAE Standard 188-2015 include Section 6 and Figure 1.

Response: The Department does not intend to expand the incorporation of ANSI/ASHRAE Standard 188-2015 beyond 7.2 (pages 7-8) at this time. Section 6 of ASHRAE Standard 188-2015 applies to building operations and is not appropriate for Subpart 4-1. No change was made to the regulation.

Comment: The Department received a comment suggesting that the maximum 30-day interval for bacteriological testing of operational cooling towers will require at least 13 tests per year. The commenter suggested the regulation be modified to testing "every calendar month during which tower operates for any period of time, not to exceed [e.g.] 45-days between tests."

Response: The requirement to test every 30 days will establish consistency, and is both reasonable and attainable. No change was made to the regulation.

Comment: The Department received several comments concerning the *Legionella* sampling requirement:

- A commenter stated the routine *Legionella* sampling requirement “within two weeks” of start-up should be changed to “two weeks before or after start-up,” to be consistent with New York City regulations.
- A commenter requested clarification as to whether the initial sampling for *Legionella* culture “within two weeks after start-up following maintenance” counts toward the quarterly sampling requirement.

- Several commenters requested that the 90-day *Legionella* sampling and analysis requirement be replaced with 100 days, or some other alternative, to better facilitate quarterly sampling. Another commenter suggested that *Legionella* sampling and analysis should not be a periodic requirement, but should be conducted only under certain specified conditions.

Response: With respect to requirement to perform *Legionella* sampling within two weeks of start-up, the sampling must be performed following start-up. The analysis of the *Legionella* samples within two weeks of start-up will provide data to validate initial treatment conditions. Upon this initial sampling, the 90-day interval for sampling requirements begins. The Department believes that a 90-day sampling interval is reasonable and attainable. No change was made to the regulation.

Comment: Section 4-1.4(b)(3)(v) provides that the maintenance program and plan must specify that *Legionella* sampling must be immediately performed pursuant to "any other conditions specified by the department or local health department." A commenter requested clarification of what such conditions might be.

Response: It is not possible to enumerate all of the emergency conditions that may warrant immediate *Legionella* testing. In general, however, immediate testing may be required when an outbreak has occurred or is suspected.

Comment: The Department received a comment requesting that the location for sampling be specifically defined as from the cooling tower basin. The commenter indicated that all sampling points should be approved by the State or local health department.

Response: Generally, a *Legionella* sample is collected from the tower basin or from a bottom drain (after voiding a pipe run). The maintenance program and plan should specify appropriate sampling locations. It would not be feasible for the State or local health department to identify all sampling locations for each cooling tower. No change was made to the regulation.

Comment: The Department received a comment stating that water samples should not be collected or analyzed by companies or persons who are also selling water treatment chemicals or disinfection devices to the owners of cooling towers.

Response: Cooling tower owners should use their discretion when selecting companies or persons to assist with their sampling and disinfections needs. No change was made to the regulation.

Comment: The Department received comments requesting clarification concerning the duration of events that may lead to bacteria growth that would require *Legionella* sampling (e.g., power failure, loss of biocide treatment or failure of other control methods). One commenter suggested that a duration of three days be specified.

Response: There is no single duration that would apply to all towers, and professionals in the field should use their informed judgment. This issue may also be addressed in future guidance. No change was made to the regulation.

Comment: The Department received a comment asking at what level of conductivity control loss is a “failure” determined to exist. The commenter asked whether it would be sufficient to

advise their customers that this situation is handled on a case-by-case basis and validated by the culture sampling included in their maintenance program and plan.

Response: Conductivity set-points are established by a water treatment provider. Therefore, each unit should be evaluated on a case-by-case basis.

Comment: The Department received a comment requesting the regulation clarify the distinction between "stagnant" and "idle," as used in Section 4-1.4(b)(7) and (8).

Response: A cooling tower system is considered idle, but in service, when it is not removing heat loads but the system components are wet, circulated, and properly treated according to the maintenance program and plan. When cooling tower systems are stagnant, shut down status without treatment or circulation for more than five days, the tower is considered out of service and requires cleaning and disinfection.

Comment: The Department received a comment stating the maintenance program and plan should include provisions for immediate and appropriate action in response to positive culture analyses. Further, a commenter suggested the Department require that the first response be to re-evaluate the system to determine the root cause of the bacteria growth.

Response: The maintenance program and plan should specify immediate and appropriate follow-up actions. No change was made to the regulation.

Comment: The Department received a question concerning whether cooling towers require routine physical cleanings, beyond what is specified in Appendix 4-A.

Response: The permanent regulation does not specify an interval for physical cleaning of cooling towers. The frequency should be guided by industry guidance, professional judgment,

sampling and inspection results, and other indicators. The maintenance program and plan should include provisions for cleaning. No change was made to the regulation.

§ 4-1.5 *Legionella* culture analysis

Comment: The Department received several comments concerning the requirement that *Legionella* culture analyses must be performed by a laboratory that is approved to perform such analysis by the New York State Environmental Laboratory Approval System (ELAP).

Response: The majority of these comments have been addressed in a *Legionella* Frequently Asked Question document, available on the Department's ELAP webpage: http://www.wadsworth.org/sites/default/files/WebDoc/Legionella%20FAQ_0.pdf

Before June 1, 2016, application materials were made available on the Department's website for laboratories to apply for ELAP certification to conduct *Legionella* culture analysis in the categories of non-potable water and potable water. Any laboratories currently performing *Legionella* culture analysis on samples originating from New York State were required to submit an application for ELAP certification, including supporting documentation, by June 29, 2016. For the purposes of compliance with the permanent regulations, any laboratory currently performing *Legionella* analysis that has submitted a timely application for certification will be granted interim approval until the application is fully processed by ELAP. Interim approval should mitigate concerns regarding the availability of laboratories to perform testing.

As any laboratory performing *Legionella* culture analysis as part of this regulatory requirement must be ELAP certified. Although ELAP is part of a national organization that will recognize other state environmental lab testing programs, recognition is only for those analyses that are regulated nationally. Since *Legionella* culture analysis is not regulated nationally, reciprocity has not been established with other states. Cooling tower owners will not need to re-sample if inspections and *Legionella* sampling has been completed on schedule under the emergency regulation and prior to the adoption of the permanent regulation. After adoption of the permanent regulation, the next required sampling and any emergency sampling that is performed must be done by laboratories with ELAP certification for *Legionella* culture.

Comment: The Department received several comments asking why the Environmental *Legionella* Isolation Techniques Evaluation (ELITE) program offered by the Centers for Disease Control and Prevention (CDC) is not acceptable as part of the ELAP certification process.
Response: The CDC ELITE program is a proficiency testing (PT) program, and certification by this program is only based on PT performance. ELAP is a comprehensive regulatory program and, to be certified by ELAP, other requirements need to be met in addition to PT. ELAP certification requires the laboratory to have a qualified laboratory technical director and quality assurance officer, have an appropriate standard operating procedure manual, submit data demonstrating that staff are capable of performing testing (demonstration of capability), and have a successful on-site inspection.

Comment: The Department received a comment asking what initial demonstration of capability NYS will accept with the submission of the application for certification in the potable water category.

Response: ELAP is offering certification for *Legionella* culture analysis in both non-potable and potable water. The PT requirements that need to be met are dependent on the type of certification being sought. PT samples need to be obtained from an organization accredited by a Proficiency Testing Provider Accreditor that meets National Environmental Laboratory Accreditation/TNI (NELAC/TNI) requirements, where there is a PT provider available.

At this time, the Department is not aware of a PT provider for *Legionella* that meets the NELAC/TNI requirements for potable water. Therefore, laboratories seeking certification for *Legionella* culture analysis in the category of potable water will not need to submit PT data. In the absence of a PT, an initial demonstration of capability (DOC) will be required with the submission of the application for certification in the potable water category. The procedures for initial DOC is to analyze at least 4 sample aliquots. Additional information on initial DOC can be obtained from ELAP.

For certification for *Legionella* culture analysis in non-potable water, the Department is aware of one PT provider for *Legionella* that meets the NELAC/TNI requirements. This is Sigma-Aldrich RTC. Since the CDC ELITE program PT does not meet the NELAC/TNI requirements, results from these studies cannot be used for certification for non-potable water. A laboratory should make every effort to submit documentation to demonstrate passing scores in at least two (2) of three (3) consecutive PTs performed at least fifteen (15) days apart. For purposes of compliance with the *Legionella* regulations, a laboratory that submits an application for certification for *Legionella* culture analysis in the category of non-potable water with documentation showing a passing score in one PT event will be granted interim approval provided that documentation is

submitted that indicates steps have been taken to perform additional PT studies, including an expected date of completion. A laboratory that has been granted interim approval with one (1) passing PT event will be required to submit documentation to demonstrate passing scores in at least two (2) of three (3) consecutive proficiency tests performed at least fifteen (15) days apart by July 29, 2016.

Comment: The Department received a comment suggesting a 24 hour hold time between sampling and lab testing for HPC that is allowable in SM be used in place of the NYS ELAP required 8-hour hold time.

Response: The Department does not intend to change the 8-hour holding time; the HPC method and *Standard Methods* will continue to apply. In addition, any ELAP laboratory certified for HPC can be used.

Comment: The Department received a comment requesting more clarification regarding the "*Legionella* Culture Method" that specifies using the CDC method/ISO method.

Response: Scientific subject matter experts in the Department were consulted to determine the appropriate methods for *Legionella* culture analysis. It was determined that laboratories will be required to use International Standard Method 11731 Water quality-detection and enumeration of *Legionella* (ISO 11731) for non-potable water. For potable water, laboratories will be required to use International Standard Method 11731 Water quality-detection and enumeration of *Legionella* (ISO 11731), or International Standard Method 11731-2 Water quality-detection and enumeration of *Legionella* Part 2: Direct membrane filtration method for waters with low

bacterial counts (ISO 11731-2). These methods should allow for the enumeration of *Legionella*. Certification for subtyping or speciation is not required.

Comment: The Department received a comment asking if a hospital already licensed to analyze *Legionella* cultures may be permitted to perform the analysis of water samples, for the purposes of this regulation. Another commenter indicated that their microbiology lab has participated in the ELITE program but has moved to performing a different method for proficiency testing. Based on the new ELAP requirement, their microbiology lab will no longer be able to perform this testing in house. The commenter indicated this requirement will result in a significant cost increase and may impact the current *Legionella* sampling frequency.

Response: Any laboratory, including hospital laboratories, can apply for ELAP certification.

Comment: The Department received a comment noting the differential in numerical analysis for *pneumophila* or other serotypes is not provided.

Response: Identification (for example, serotyping) is highly recommended because *L. pneumophila* 1 is responsible for the majority of illnesses and, further, a link between environmental isolates and patient isolates may need to be performed under outbreak conditions. When an outbreak is not due to *L. pneumophila* 1, knowing the general category of the legionellae present may also be critical to the environmental response. It is recommended that three groups be identified: *L. pneumophila* 1, *L. pneumophila* 2 -14, and the non-*pneumophila* species.

Comment: The Department received a comment asking whether cooling tower owners that have already complied with the emergency regulation will be required to re-inspect/re-test their cooling towers once laboratories gain this accreditation. A commenter voiced concern with the availability and capacity of laboratories to conduct this required statewide sampling.

Response: Cooling tower owners will not need to re-inspect or re-sample if inspections and *Legionella* sampling has been completed on schedule under the emergency regulation and prior to adoption of the final regulation. After final adoption of the regulation, the next required sampling and any emergency sampling that is performed must be done by laboratories with ELAP certification for *Legionella* culture. Laboratory capacity will increase as interim approvals are issued to expedite the process.

Note: Many of these responses are also relevant to Section 4-2.5.

§ 4-1.6 Notification

Comment: The Department received several comments concerning notification of *Legionella* culture sample results that exceed 1,000 CFU/mL:

- A commenter requested contact information for the local health department.
- A commenter suggested that owners report directly to the Department and not to the local health departments.
- A commenter suggested uniformity in notification for all local health departments responsible for public notification.

- A commenter suggested that notification to the local health department also occur upon receipt of excessive dip slide results and that public notification generally should include newspaper, radio, TV, social media, and specific individuals.
- A commenter stated that it is not necessary to notify the local health department or general public when elevated *Legionella* is detected, in the absence of two or more cases of legionellosis.

Response: Contact information for each local health department is publically available. The Department will work with the local health departments to ensure a standard and uniform approach. However, some decisions related to public notification will need to be made on a case-by-case basis.

The Department did not expand the notification requirements to include bacteriological culture results, which are used to validate adjustments to process control and not colonization and growth of potentially pathogenic organisms.

The Department believes that the current notification requirements are reasonable and appropriate. No changes were made to the regulation in response to these comments.

Comment: The Department received a comment suggesting that the reference to 1,000 CFU/mL be noted in scientific notation (e.g., 10^3).

Response: Some members of the public may not be familiar with scientific notification. No change was made to the regulation.

§ 4-1.7 Disinfection

Comment: The Department received comments requesting clarification of the term "disinfection":

- A commenter stated that there are no products currently registered for disinfection of cooling tower water.
- A commenter asked whether the regulation requires cooling towers to be cleaned with a disinfectant. Another commenter asked whether the proposed regulation requires any routine physical cleaning or disinfection.
- A commenter suggested that because disinfection, as defined, does not to include cleaning, a specific section noting minimum cleaning methods should be included.
- A commenter stated that some SPDES and other permits prohibit the addition of biocides to the towers because of discharge restrictions.
- A commenter recommended that the regulation be amended to clarify that continuous disinfection is needed where sampling and inspection shows it is needed, or its obverse; allow a system to demonstrate that continuous disinfection is not needed based on a three month sampling period over the summer of weekly sampling to demonstrate the problem is not present.

Response: In response to this comment, the Department made technical clarifications to the regulation to specify that the terms "disinfect" and "disinfection" mean the control of microorganisms or microbial growth. Further, the regulation permits only biocide products registered by the NYS DEC for use in cooling towers or pesticidal devices in a US EPA registered establishment to be used in disinfection.

The Department's regulation does not specify the frequency at which cleaning must occur. The frequency should be guided by industry guidance, professional judgment, sampling and inspection results, and other indicators. Any discharges from cooling towers to waters of the State must comply with applicable SPDES permitting requirements. Discharges from cooling towers to publicly owned treatment works (POTWs) or municipal sewage systems must comply with all applicable local and pre-treatment requirements set forth by the owner of the POTW or sewerage system. The Department, in consultation with the DEC, is available to assist any party that is concerned with compliance with SPDES permits.

Industry best practices for the maintenance of cooling towers includes regular, if not continuous, disinfection. Start-up and shut down procedures should contain cleaning steps in the maintenance program and plan, and additional cleaning is dependent on the results of sampling and regular inspections.

Comment: The Department received comments concerning 7G certified pesticide applicators:

- A commenter suggested the requirement for a 7G applicator be modified since facilities may have an apprentice but the vendor has the 7G certified applicator.
- A commenter stated that for many facilities, it is impractical to employ a certified pesticide applicator, but it is practical to train staff to apply biocides under the supervision of a certified applicator.

Response: Pursuant to 6 NYCRR Part 325, supervision of an apprentice involved in the application of a pesticide to a cooling tower requires that the apprentice to be supervised by a 7G applicator employed by the same business or agency. No change was made to the regulation.

§ 4-1.8 Inspection and certification

Comment: The Department received a question asking how far back the Department wants a certifying professional to assess compliance efforts. Further, a commenter stated that the certifying professional should not be required to certify compliance with laws and regulations outside of their field experience.

Response: Section 4-1.8 indicates that the person qualified to do regular inspections should certify that the elements contained in the maintenance program and plan, and any related activities responsive to the plan, were completed over the course of the previous year.

Comment: The Department received a question asking what should occur if the qualified person finds that some items were not properly performed, and whether a certification can be provided in this instance.

Response: If qualified person finds that some items were not performed, corrective actions should be taken and documented. Guidance will address whether a conditional certification can be provided in these instances.

Comment: The Department received a comment requesting adequate time and training be provided to get individuals "up to speed" on the substance of the regulations.

Response: These regulations contain many provisions that are similar or identical to the emergency regulations, which have been in place for nearly a year. To the extent the request asks for a delay in implementation of the regulations, the Department declines.

Comment: The Department received comments that expressed concern about whether there are enough qualified individuals to implement this regulation and included:

- There may not be enough qualified companies or representatives to serve a region;
- Water treatment companies may be experts in heating, ventilating, and air conditioning (HVAC) water treatment only;
- A Certified Pesticide Technician or Applicator (7G) should be added to the list of qualified individuals to perform inspections and provide annual certifications.

Response: Section 4-1.8(a)(2) is sufficiently broad to include 7G certified applicators. The definition ensures certifiers have the appropriate experience and follow industry standards without excluding a particular group that may be qualified. There have been no reported complaints under the emergency regulations regarding a lack of inspectors or certifiers. No change was made to the regulation.

Comment: The Department received a comment suggesting the inclusion of a trained auditor from a public health organization certified under ISO/IEC 17020:2012, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*, in the list of qualified professionals.

Response: Section 4-1.8(a)(2) is sufficiently broad to include such auditors, where they have the requisite experience. No change was made to the regulation.

Comment: The Department received a comment suggesting that a water treatment professional should be required to document deficiencies, rather than an environmental consultant. The commenter stated that the water treatment professional is qualified and less expensive.

Response: An environmental consultant is only one of several professionals who may perform the required tasks under Section 4-1.8. No change was made to the regulation.

Comment: The Department received several comments concerning the rate of inspections:

- Inspections should be required once per year.
- Inspections should be done no sooner than 30 days and no later than 120 days after start-up.
- Inspections should be required at least four times a year at intervals not exceeding every 100 days.
- The maximum 90 day interval for inspections and *Legionella* testing will require at least five inspections per year. Consequently, inspecting and testing should occur every calendar quarter during which cooling tower operates for any period of time, not to exceed 105 days between tests.

Response: The Department believes that inspections at intervals not exceeding every 90 days is reasonable and attainable. No change was made to the regulation.

Comment: The Department received a comment recommending the regulation be revised to require that the November 1st certification be submitted to the State or local health Department.

Response: Because the certification must be retained on-site for three years and the certification date must be entered into the cooling tower registry, this change is not necessary. No change was made to the regulation.

Comment: The Department received a comment suggesting the November 1st annual certification date be changed to March 1st.

Response: The Department believes that November 1st date is reasonable, and changing it to March would unnecessarily delay certification by six months. No change was made to the regulation.

Comment: The Department received a comment suggesting that "treatment method" and "cycles of concentration" be incorporated into the certification requirements.

Response: This information can be included in the maintenance program and plan. No change was made to the regulation.

Comment: The Department received a comment stating that the costs of regulatory compliance may lead to the use of less efficient cooling systems, in turn leading to great electricity use, higher greenhouse gas emissions, and more pollution.

Response: The Department believes that the benefit to public health is greatly outweighed by any theoretical increase to emissions. Additionally, diligent operation and maintenance of cooling towers will ensure efficient heat transfer, lower electrical consumption, and reduced production of greenhouse gasses.

§ 4-1.9 Recordkeeping

No comments were received.

§ 4-1.10 Enforcement

Comment: The Department received comments suggesting that an enhanced testing requirement be included in the enforcement section for a source suspected of causing legionellosis.

Response: Section 4-1.10(a) requires *Legionella* culture sampling and analysis whenever the State or local health department determines that one or more cases of legionellosis are or may be associated with a cooling tower. This provision is sufficient to address this concern. No change was made to the regulation.

§ 4-1.11 Variances and waivers

Comment: The Department received comments requesting the addition of specific variances and waivers for power plants.

Response: The provision is sufficiently broad to address variance and waiver requests from power plants. No change was made to the regulation.

Comment: The Department received requests for clarification as to whether the Department's regulations will supersede local regulations that are more stringent.

Response: Cooling tower owners must comply with both local and state regulations related to cooling towers. Local jurisdictions are permitted to have more stringent regulations.

Comment: The Department received comments suggesting that local health departments should make determinations with respect to variances and waivers. Another commenter suggested that the responsibility of variances and waivers should be the sole responsibility of the Department.

Response: The Department believes that the variance and waiver provision strikes an appropriate balance between State and local involvement. No change was made to the regulation.

§ 4-1.12 Severability

No comments were received.

Appendix 4-A

Comment: The Department received a comment suggesting a new Appendix 4-A based upon a recent CDC toolkit, entitled *Developing a Water Management Program to Reduce Legionella Growth and Spread in Buildings: A Practical Guide to Implementing Industry Standard,* published on June 6, 2016.

Response: The CDC toolkit, in general, is consistent with the Department's Health Advisory; however, the Department will consider elements of the CDC toolkit for inclusion in guidance associated with elements of Subpart 4-1.

Comment: The Department received several comments related to the *Legionella* detection levels and thresholds specified in Appendix 4-A. One commenter indicated that it did not seem appropriate for cooling towers to be held to a higher standard than hospital drinking water supplies. One commenter supported the detection level of <20 CFU/mL, while other commenters recommended the replacement of Appendix 4-A with alternate threshold levels and approaches for both bacteriological and *Legionella* culture results. One commenter suggested adding numerical thresholds for dip slide test results and subsequent required actions for those thresholds similar to those specified for *Legionella* results.

Response: Cooling towers are not being held to a higher standard compared to hospital drinking water supplies. Facilities analyzing potable water samples for *Legionella* must include any positive sample in their calculation of percent positivity regardless of the number of CFU/mL. Cooling towers must only respond to values ≥ 20 CFU/mL.

The Department believes that the detection level <20 CFU/mL is reasonable and appropriate. The Department declines to add requirements related to results from dip slide testing, as there are sufficient thresholds available in industry guidance. The bacteriological results for dip slides should be used by cooling tower operators to validate treatment efficacy. No change was made to the regulation.

Comment: The Department received questions concerning the expression of *Legionella* test results. Two commenters believed the regulation would be improved by changing the table to log values. Additionally, a commenter noted the differential in numerical analysis for *pneumophila* or other serotypes is not provided.

Response: Using the log notation would obscure important information. As proposed, *Legionella* test results of 1,000 CFU/mL and 8,000 CFU/mL could both be reported as 10^3. The Department believes that important quantitative information would be lost if log notation was used for reporting instead of CFU/mL. While the numerical analysis for *pneumophila* or other serotypes may be useful and necessary during outbreak conditions, it is not required by the regulation. No change was made to the regulation.

Comments: The Department received comments concerning halogen based compounds. One commenter suggested the Department reconsider the note to Appendix 4-A that states stabilized halogen products should not be used for remediation. A second commenter believes that disinfection should not be limited to the use of halogen based compounds and that the regulation should allow the option for new treatment if it is demonstrated effective and approved by the Department.

Response: The Note to Appendix 4-A was clarified to read "Stabilized halogen product should not be used for online decontamination or system decontamination as defined in the Appendix per footnote 3 and 4." This acknowledges that online disinfection may involve the use of stabilized halogens that are or were part of normal operations. The Department believes the use of halogen-based compounds for *Legionella* control is appropriate at this time.

Comment: The Department received comments related to the pH ranges specified in footnote 4. One commenter stated that the pH range 7 to 7.6 could be an issue and asked if the range could be extended. Another commenter suggested a modification to the footnote that would allow at higher pH levels, the extension of treatment times and/or higher residuals.

Response: The Department believes that the pH ranges are reasonable and appropriate. The cooling tower treatment provider would know the dominant pH in the cooling tower and should select the appropriate halogen, based on that pH. The regulation does not preclude the treatment provider from either extending the contact time or increasing the concentration of the halogen, to address these concerns. No change was made to the regulation.

Comment: The Department received several comments requesting changes to the definitions used in the Appendix. One commenter indicated the term “monitoring” as used is not consistent with the definition with ANSI/ASHRAE Standard 188-2015. Another commenter suggested changing “monitoring” to “testing”. One commenter suggested a change from “Approach” to “Response” in the column heading, while another requested replacement with “Recommended Actions.” One commenter suggested changing “Online decontamination” to “Online remediation,” while another commenter suggested changing “Online disinfection” to “Remedial treatment.”

Response: All recommended wording changes were evaluated. The second column heading in Appendix 4-A was changed from “Approach” to “Response” as suggested by commenters. Given the conflicting suggested alternative wording for the definitions by commenters, the Department has chosen not to change the terms “Online disinfection” and “Online decontamination.”

Comment: The Department received comments suggesting more prescriptive detail in the treatment protocols, including citing analytical methods for documenting biocide residuals and excluding the use of specific methods such as Oxidation Reduction Potential.

Response: The Department believes that the treatment protocols are reasonable and appropriate as written. The Department may issue guidance to clarify requirements. No change was made to the regulation.

Comment: A commenter asked: If a cooling tower contains *Legionella* culture at 850 CFU/mL and, after cleaning and disinfection, the next two consecutive readings are at 5 CFU/mL, is tower disinfection complete?

Response: Yes.

SUBPART 4-2 Health Care Facilities

§ 4-2.1 Scope

Comment: The Department received several comments expressing concern that the regulations are more burdensome to the healthcare community than necessary.

Response: The Department believes that the regulations are reasonable and appropriate. The Department is committed to working with the regulated entities to provide guidance to assist with implementation of the regulations.

Comment: The Department received several comments stating that a comprehensive maintenance program and plan is necessary for healthcare facilities. Specifically, some commenters stated that Subpart 4-2 should be implemented using the HACCP-based maintenance program and plan, by incorporating by reference ANSI/ASHRAE 188-2015, Annex A. One commenter recommended use of a program designed using both ANSI/ASHAE Standard 188-2015, Annex A and NSF Standard 453.

Response: The Department clarified the regulation by changing the term "Sampling Plan" to "Sampling and Management Plan." Inclusion of "Management" into the title better represents the

intent of the plan. In addition, elements of the Annex A are contained in Department guidance. However, the Department declines to incorporate Annex A in full into the regulation at this time. Certain elements of Annex A and the CDC toolkit published on June 6, 2016, will be considered for inclusion in guidance associated with elements of Subpart 4-2.

Comment: The Department received a question asking why the regulations are only focused on cold water and how many people have been known to contract *Legionella* from cold water systems.

Response: The regulations do not focus on cold water only. The permanent regulation applies to "potable water," which is defined as "water intended for human contact or consumption." This includes both hot and cold water.

§ 4-2.3 Environmental Assessment

Comment: The Department received a question as to when the forms specified under this section will be released. The commenter asked what the approval process will be for forms developed by outside companies.

Response: Environmental assessment forms will be posted on the Department's website. The forms are currently available to local health departments in the Health Commerce System.

Comment: The Department received a question asking who is qualified to perform an environmental assessment.

Response: Assessments should be completed by individuals, or members of an internal multi-disciplinary team, that have the knowledge related to the facility's components, operations, and

contract services. The assessment involves reviewing facility characteristics, hot and cold water supplies, cooling and air handling systems, and any chemical treatment systems.

Comment: The Department received a comment recommending language that more precisely quantifies the need to revisit the environmental assessment, so that facilities will not continually be revising and modifying their plan.

Response: As stated in the regulation, the environmental assessment needs to be updated annually or when major construction is conducted at the facility. This means that the environmental assessment must be revised when building/plumbing modifications occur that will affect the remainder of the potable water system. No change was made to the regulation.

Comment: The Department received a comment that stated that many facilities have multiple systems within the meaning of "covered facility" and, as such, the Department should consider whether an assessment is needed for each system and whether duplication of sampling is required.

Response: An environmental assessment is needed for each facility or building that has one or more hot water system. If a building has more than one hot water system that serves completely different areas (e.g., separate wings), separate forms must be completed. Campuses with multiple buildings that may share hot water systems from a centralized plant would need to prepare an assessment for each building in order to evaluate water age and its impact. Some consideration must also be given to multiple cold water supplies entering a building or a campus.

§ 4-2.4 Sampling and Management Plan

Comment: The Department received a comment asking for a definition of potable water, because in certain industries it is used synonymously with drinking water.

Response: A potable water system is defined in Section 4-2.2(c) as "a building water distribution system that provides water intended for human contact or consumption."

Comment: The Department received a question asking whether changing a faucet would be classified as a "repair activity" necessitating review of the sampling plan.

Response: Significant or major changes to a facility's infrastructure will warrant a review and update of the environmental assessment form and sampling and management plan. Those repairs that may impact the remainder of the potable water system need to be considered. Changing water faucets is a minor repair that will not impact the potable water system.

Comment: The Department received a comment stating that a sampling plan for *Legionella* testing and prescriptive responses based on results is not sufficient to ensure effective water management of potable water systems in healthcare facilities.

Response: The Department made a technical change to the section title, revising "Sampling Plan" to "Sampling and Management Plan." This modification clarifies that the sampling plan is included in the facilities' overall program for maintaining effective management of their potable water system.

Comment: The Department received a comment requesting that this section be modified to remove the sampling requirement associated with a positive sample when the healthcare facility infection prevention and control (IC) program, which has an infection preventionist certification

in infection control (CIC) by certification board of infection control and epidemiology (CBIC), determines there is no risk to the facility's population.

Response: A sampling event with a single water sample that is positive for *Legionella* would not necessarily result in additional sampling. Appendix 4-B explains that ≥ 30% of sampling sites should be positive to continue sampling. Although a target of < 30% positive samples sites is noted as a threshold, it is recommended that the number of positive samples be minimized. In addition, the infection preventionist should be part of the multi-disciplinary team outlined in the Department's August 10, 2015 Health Advisory guidance. The sampling requirement is reasonable and appropriate. No change was made to the regulation.

Comment: The Department received a comment stating that treating cold water is costly, increases liabilities, and brings many social issues to the forefront. Accordingly, this commenter recommended testing domestic cold water only in areas which are dormant for more than five days.

Response: This change is unnecessary, as the regulation makes no specific reference to the treatment of cold water systems. Culture sampling of potable water systems and other monitoring in healthcare facilities is currently included in the Department's August 10, 2015 Health Advisory guidance. No change was made to the regulation.

Comment: The Department received a comment stating the regulations do not offer a recommendation on the appropriate number of *Legionella* samples that should be collected based on a facilities size, complexity of patients, and other risk factors. The commenter further stated that the Department provided an example in the Regulatory Impact Statement of ten samples

collected every 90 days; however, Appendix 4-B indicates that a facility must respond to 30% positive samples, which would mean three positive out of only 10 samples. The commenter feels that this may not be an adequate representation of what is occurring within a building water system and it would be difficult for facilities to equally and consistently respond to these criteria without more guidance on sample size. Further, a commenter stated that the number and location of sampling sites is not specified, but the August 10, 2015 Department Health Advisory guidance has more information. This commenter asked whether the Department expects this guidance to inform the sampling plan requirements.

Response: Sample size and location is part of the Department's August 10, 2015 Health Advisory guidance, which informs sampling plan requirements. The minimum recommended sample size is 10 samples.

Comment: The Department received a question asking why it was necessary to perform four sets of samples for the first year (i.e., every 90 days), if the first set is negative.

Response: Sampling at intervals not to exceed 90-days will cover an entire year and is only required the first year of sampling. This sequence of sampling may reveal seasonal differences as well as low-flow or vulnerable areas to guide future sampling.

Comment: The Department received a question asking what sites would typically be included under this provision. Specifically, the commenter asked whether these sites would fall under "medical facilities" in the guidelines issued by the Department. Further, the commenter asked if ASC clinics, urgent care, and stand-alone emergency departments would also be included.

Response: The facilities for which the requirements within Subpart 4-2 apply include all general hospitals and residential health care facilities as defined in Article 28 of the Public Health Law.

Comment: The Department received a comment expressing concern that there will be insufficient qualified individuals to set-up a proper sampling plan, due to the lack of knowledge of individual plumbing systems.

Response: Facility staff should be familiar with the potable water system in the building. The Department's August 10, 2015 Health Advisory guidance includes convening a multi-disciplinary team comprised of staff from infection control, physical facilities, and engineering. An essential element of this team is a consultant that can assist the multi-disciplinary team with the formulation of a sampling and management plan.

§ 4-2.5 *Legionella* culture analysis

Comment: The Department received recommendations that the regulation include a requirement that persons or firms sampling water for microbial testing, and the laboratories performing such tests, be independent and unaffiliated with the persons or firms treating the water.

Response: This comment may be addressed in future guidance. No change was made to the regulation.

Note: Many questions concerning this Section were responded to in the Section 4-1.5 above.

§ 4-2.6 Recordkeeping

No comments were received.

§ 4-2.7 Enforcement

No comments were received.

§ 4-2.8 Variances and waivers

No comments were received.

§ 4-2.9 Severability

No comments were received.

Appendix 4-B

Comment: The Department received several suggestions requesting modification to the threshold levels (percent positive *Legionella* culture action levels). One commenter suggested that any detection of *Legionella* should trigger re-evaluation of the treatment program. Another commenter asked that the "Percentage of Positive" thresholds be replaced with *Legionella* concentrations, specifically "*Legionella* detected (>20 CFU/mL)." Finally, a commenter suggested that ≥ 30% positive results trigger a requirement for immediate notification of and consultation with the Department.

Response: A decade of experience in hundreds of hospitals and nursing homes indicates that the ≥ 30% threshold for action, in combination with patient surveillance, has minimized the occurrence of legionellosis in impacted facilities. When facilities have ≥ 30% positive *Legionella* results, the permanent regulations and current guidance involve notification of the Department. No change was made to the regulation.

Comment: The Department received a question as to what is considered a "Positive *Legionella* Test Site."

Response: A positive *Legionella* site is one which, upon culture analysis, results in the recovery of any level of legionellae. The facility should aim for the lowest possible number of positive sites (at minimum <30%) and lowest level of CFU/mL possible.

Comment: The Department received a question as to whether action beyond continued implementation of the monitoring program are needed when sampling results are below the percent positivity threshold. Another commenter asked whether only flushing could be used if the percent positivity threshold is exceeded and flushing is demonstrated as effective.

Response: If sampling results are below the percent positivity threshold, regular monitoring continues and any other applicable elements of the sampling and management plan. If flushing is successfully used, continued implementation of the sampling and management plan and clinical surveillance should continue based upon the results.

Comment: The Department received a comment suggesting that all of the benefits of referring to short-term and long-term control methods can be achieved by generic descriptions.

Response: Minor technical revisions were made to remove specific treatment methods from footnote 5 for long-term control measures to accommodate new treatment options that may become available in the future.

Comment: The Department received a comment requesting that local health department be made aware immediately when sampling reports trigger an investigation and/or legionellosis cases are identified at Article 28 facilities within a local health department's jurisdiction.

Response: The Department notifies local health departments as appropriate.

Comment: The Department received a comment requesting that the Department modify footnote 3 to add: "Ozone, and associated Mixed Oxidants" (as recognized by the US EPA).

Response: The Department made a technical change to the regulations to remove specific treatments from the footnote for long-term control measures to accommodate new treatment technologies.

Regulatory Impact Statement (RIS)

Comment: The Department received comments concerning general compliance costs for private regulated parties, including healthcare facilities. These comments included the following:

- The size of the facilities and the number of samples that will be required;
- Burden of costs on small healthcare facilities;
- Many hospitals have several distinct systems, each with different hot water generators, flow rates, dormant legs, etc.;
- Follow-up costs;
- Actual costs of hiring a professional water treatment service company;
- Differences in costs throughout the state;
- The amount of time for healthcare facilities to complete an environmental assessment;

- By providing the length of time estimated to perform services, this may force some individuals to feel cheated if someone completes a service in less time; and
- The Department's reporting requirement specification should dictate the length of time needed to perform such professional services.

Response: Costs will vary depending upon the complexity of the cooling tower or the potable water system. There may also be variation in costs across the state.

With respect to covered facilities, the time required to prepare a sampling and management plan or to complete other services is affected by potable water system complexity and whether there is currently existing sampling and management protocols in place.

The Department's August 10, 2015 Health Advisory guidance includes consideration of sample size, sample locations, dormant legs, and other vulnerable areas. The duration of the assessment is dependent on the size and complexity of the facility and can be completed by facility staff. The Health Advisory recommends convening a multi-disciplinary team to evaluate vulnerabilities comprised of staff from infection control, physical facilities, and engineering. The frequency of sampling and the need for other water quality assessment would be at the discretion of the multidisciplinary team and a consultant. Costs will vary depending upon the role of facility staff.

With respect to cooling towers, most consultants will train on-site staff to perform routine maintenance and monitoring. Instituting management or maintenance programs and plans can vary from approximately $2,000 to $6,000. Hourly or daily rates and culture sampling and analysis costs vary; estimates included in the RIS were made based on discussions with industry.

Comment: The Department received several comments related to cost estimates at healthcare facilities:

- Initial cost estimates ranged from $30,000 to $85,000, with one commenter noting that these costs would be associated with employing continuous water treatment in the form of chlorine dioxide. Several healthcare facilities commented that the risks (e.g., stating cold water is not a significant threat) does not justify the costs, which are burdensome at a time when many small and/or rural hospitals are struggling to survive. This cost may result in reduced services to the community.
- There are recurring costs to consider, with one commenter estimating such costs to be $9,000 annually for salary, training and daily monitoring.
- A commenter estimated an additional $10,000 in costs annually for a third party service.

Response: The comments above are noted. The need for long-term treatment is not a requirement in all cases. The environmental assessment will help determine vulnerabilities in the potable water system and the sampling and management plan will determine the extent of colonization. After assessment and culture sampling and analysis, the need for long-term treatment can be examined, if warranted.

Comment: The Department received several comments concerning local health department costs:

- The resources needed to ensure compliance with these regulations are beyond the financial capabilities of the local health departments.

- This burden on local and state Environmental Health staff resources may result in unintended consequences including increasing the risk of other public health threats due to the need to reallocate resources to meet these new requirements.
- Consideration must be given to providing additional resources to state and local health departments during the 2017 state budget process and within future state budgets in order to implement these regulations.
- State resources should be provided to implement these regulations, particularly during an outbreak, which include personnel and testing resources.
- While the registry is helpful, it is incomplete and resources to identify and follow up on building owners' adherence to the new regulations are limited.

Response: State resources are regularly used for both nosocomial and community cases of legionellosis. Many resources include epidemiology, environmental health, and laboratory staff. The Department will work with local health departments as well as the regulated parties to identify methods to streamline implementation. Subpart 4-2 will not impact local health department resources, since implementation will be addressed by the Department.

Miscellaneous Comments

The Department received several comments on issues that could not be classified to a specific section. Several of the comments concern partnership and coordination with other governmental agencies and private entities to ensure compliance with the regulations.

Comment: The Department received comments urging coordination with the NYC Department of Health and Mental Hygiene (DOHMH), given the recently adopted DOHMH regulations pertaining to cooling towers. One commenter asked if there were any differences between DOHMH's cooling tower rule and the Department's regulation and, if so, which one should a NYC cooling tower owner follow.

Response: Owners must comply with both State and local regulations. The Department continues to work with DOHMH to address reporting and data sharing. This coordination will continue.

Comment: The Department received a comment from the New York State Association of County Health Officials (NYSACHO) indicating it would be advantageous to continue a scientifically-based dialogue on issues concerning *Legionella* before finalizing the regulations. NYSACHO also identified the need for continued dialogue and vigilance of *Legionella* in health care settings, because patients at such facilities are at higher risk of poor outcomes secondary to pneumonia. Another commenter suggested protocols be developed to ensure optimum coordination between state and the local health department to describe roles and procedures during investigation and sampling of sources.

Response: Since the later 1990s, the Department has issued scientifically-based guidance, advisory letters, held presentations, and trained staff in the central and regional offices to respond to legionellosis investigations and sampling. To ensure coordination between the Department and the local health departments, the Department is developing guidance documents that will define roles and responsibilities for implementing the regulation and conducting investigations. These guidance documents will be developed in consultation with the local health departments.

Comment: The Department received a comment recommending that all reported cases of Legionnaires' disease be the subject of a preliminary investigation, which should include basic culture sampling of an individual's home. Further, this commenter asserted that a majority of outbreaks (and cases) are caused by potable water, and it is therefore imperative that all cases be investigated to identify the source and take action before others become sick.

Response: The Department will continue to investigate nosocomial and community cases of legionellosis. Epidemiology, environmental health, and laboratory staff will continue to be used to support this effort. Tracking legionellosis cases is standard practice and will continue.

On August 17, 2015, the Public Health and Health Planning Council (PHHPC) and the Commissioner of Health adopted emergency regulations, effective immediately, to prevent the spread of Legionella bacteria by requiring registration, testing, inspection, and certification of cooling towers located in New York State. The regulations further require all Article 28 general hospitals and residential health care facilities (RHCFs) to develop a Legionella sampling plan for its facilities' potable water distribution system and take necessary actions to protect the safety of their patients or residents. A copy of the emergency regulation is **attached**.

As a result, all Article 28 general hospitals and RHCFs located in New York State will be required to comply with the provisions contained in Section 4.11 of the emergency regulation (see Section 1 under Summary of Emergency Regulation). In addition, any facility that is the owner (corporation or other legal entity having a legal interest in, or control of, the Article 28 facility) of a cooling tower[1] will also be required to meet the registration, testing, and inspection, requirements contained in the emergency regulation by September 16, 2015.

Background

Recent outbreaks of legionellosis have been associated with cooling towers. 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.

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*.

In response to recent outbreaks of legionellosis in New York City, the Commissioner of Health and the PHHPC have adopted emergency regulations, under their authority to adopt regulations when necessary for the preservation of the public health, safety or general welfare. The emergency regulations have been adopted to prevent the spread of Legionella bacteria and protect the public from future outbreaks of Legionnaires' disease.

Summary of Emergency Regulation

1. Requirements for All Article 28 General Hospitals and RHCFs in New York State

The emergency regulations contain a provision applicable to all Article 28 general hospitals and RHCFs in New York State, regardless of whether the facility owns or operates a cooling tower

[1] 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.

on its premises. Specifically, the emergency regulations require that all Article 28 general hospitals and RHCFs:

- Adopt a Legionella sampling plan for its facilities' potable water distribution system;
- Report the results of such sampling conducted pursuant to the adopted sampling plan; and
- Take necessary responsive actions to protect the safety of their patients or residents.

The emergency regulations currently do not identify the process for general hospitals and RHCFs to report the results of sampling its facilities' potable water distribution system. It is possible that this reporting will be conducted through the statewide electronic system that will be used for registering cooling towers to be developed by the Department of Health (DOH). The regulation requires DOH to investigate whether more stringent requirements for general hospitals and RHCFs are warranted.

It is important to note that at this time, the emergency regulation does not require Article 28 diagnostic and treatment centers (D&TCs) to meet the requirements contained in this regulation. However, if a licensed D&TC owns a building that uses a cooling tower, the requirements identified in Section 2 of this memorandum would apply.

2. **Requirements for Facilities in New York State That Own A Cooling Tower**

In addition to the mandatory sampling and reporting of a facilities' potable water distribution system, any facility that owns a cooling tower would be subject to additional requirements contained in the emergency regulation. The requirements identified in this section only apply to the owners of buildings and facilities in New York State that operate a cooling tower.

a. Registration

Any owner of a building with an existing cooling tower must electronically register the tower with the Department of Health by September 16, 2015 (30 days following the enactment of the emergency regulation). All new cooling towers must be registered prior to initial operation. There is no cost to register a cooling tower with the State.

b. Culture Sample Collection and Testing

Any owner of a building with a cooling tower must collect samples and obtain culture testing within the next 30 days. Thereafter, testing must be performed every 90 days, or in accordance with a maintenance program and plan prepared by the building owner. The owner is required to take immediate actions in response to such testing as specified in the plan, including interpreting Legionella culture results. Owners are required to clean and disinfect any cooling tower that is shut down for more than five days.

In the event the results of the culture testing require cleaning and disinfection of the cooler tower, the owner may only use 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. Further, only biocide products

registered by the New York State Department of Environmental Conservation may be used in disinfection.

c. Inspection and Certification

All cooling towers must be inspected within the next 30 days, unless such tower has been inspected within the last 30 days (on or after July 18, 2015). Following the initial inspection, all cooling towers must be inspected at intervals not exceeding every 90 days while in use. All inspections must 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.

All cooling towers must be certified as complying with all regulatory requirements by November 1, 2016, and thereafter annually by November 1 of each year. The certification must provide that such cooling tower was inspected, tested, cleaned, and disinfected in compliance with the emergency regulation, 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 by the owner.

d. Maintenance Program

Any owner of a building with a cooling tower must implement a maintenance program and plan by March 1, 2016, developed in accordance with 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. The plan must include a schedule for routine sampling, as well as procedures for emergency testing and disinfection to destroy Legionella bacteria. Owners must maintain a copy of the plan on the premises where a cooling tower is located.

e. Recordkeeping

All owners are required to maintain records of all inspection findings, deficiencies, corrective actions, cleaning and disinfection, tests, and certifications for at least three years. In addition, an owner is required to maintain a copy of the maintenance program and plan on the premises where a cooling tower is located.

f. Electronic Registration and Reporting

All owners of buildings and facilities in New York State that operate a cooling tower will be required to electronically register their tower by September 16, 2015. In addition to registration, all actions required by the regulations must be reported to the electronic system within 10 days of such actions being taken.

Please contact us with any questions that you may have.

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

DATE: **August 10, 2015**

TO: All Article 28 Hospitals and Nursing Homes

FROM: Office of the Commissioner

Health Advisory:
Prevention and Control of Legionellosis (Legionnaires' disease) in Healthcare Facilities

Please distribute immediately to: Administration, Medical Director, Infection Prevention, Infectious Disease Service, Pulmonologists, Hospitalists, Nursing Administration, and Engineering and Facilities Maintenance

The New York State Department of Health (NYSDOH) and the New York City Department of Health and Mental Hygiene (NYCDOHMH) are currently investigating a cluster of cases of Legionnaires' disease in the Bronx. From 7/8/2015 through 8/7/2015, 100 persons have been infected and there have been 10 deaths associated with this outbreak. Given the distribution of cases in the community and preliminary laboratory data, it is believed that cooling towers in the area contaminated with legionella bacteria may have contributed to the outbreak. This outbreak underscores the importance for all healthcare facilities to conduct surveillance for *Legionella* infections and to ensure proper maintenance of potable water systems and cooling towers.

This advisory provides information on the prevention and control of healthcare facility-associated Legionnaires' disease, including:

- Guidance for clinicians on diagnosis and laboratory testing (Attachment 1);
- Guidance for infection control activities for prevention, surveillance, investigation, and control (Attachment 2); and
- Guidance for routine environmental care and maintenance within a facility, and response to possible or confirmed healthcare facility-associated Legionnaires' disease cases (Attachment 3).

NYSDOH regulations require hospitals and nursing homes to ensure the safety of patients and residents. The following actions will help ensure the safety of patients/residents from Legionnaires' disease. NYS urges healthcare facilities to:

- Review and update their facility's *Legionella* prevention, surveillance and control policies based on the attached NYSDOH guidance documents and the facility's patient population, facility design, and available methods for control of *Legionella.* This process should include convening a multi-disciplinary team (to include clinicians, infection control practitioners, plant facility technicians and engineers, nurses, laboratorians, and administrators) to review the NYSDOH guidance and to evaluate the risk for

Legionnaires' disease based upon patient population, physical plant, and other relevant factors.

- Distribute these guidance materials to clinicians, infection control practitioners, and plant facility technicians and engineers. To assist you in this endeavor, NYSDOH has published separate guidance sheets for clinicians (Attachment 1), infection control practitioners (Attachment 2) and facility physical plant managers (Attachment 3).
- Regularly monitor adherence to facility policies for controlling healthcare facility-associated Legionnaires' disease.

Legionella species are naturally occurring, ubiquitous aquatic organisms. They prefer warm water temperatures with the ideal temperature for growth ranging from 77 to 115° F (25 to 46° C). The ten-year average number of cases of Legionnaires' disease reported to New York State annually is 539 (including NYC). Cases may be community or healthcare facility-associated, and may result from exposure to contaminated water aerosols or from aspirating contaminated water. Outbreaks of Legionnaires' disease have been reported throughout the world. Numerous articles in medical literature describe the link between Legionnaires' disease and potable water or aerosol-generating devices, such as nebulizers, cooling towers, showers, faucets, hot tubs, whirlpool spas, respiratory therapy equipment, and room-air humidifiers.

Legionellosis is a bacterial disease that is associated with two distinct illnesses: Pontiac fever (a self-limited, influenza-like illness with a 1 to 2 day incubation period, also known as non-pneumonic legionellosis) and Legionnaires' disease (a progressive pneumonia with a 2 to 10 day incubation period that may be accompanied by cardiac, renal and gastrointestinal involvement).
The extent of measures taken to prevent healthcare facility-associated Legionnaires' disease will depend largely on the risk factors for acquiring Legionnaires' disease in the population served by the hospital or nursing home. Some patients/residents at risk, including those receiving cancer chemotherapy or undergoing transplants, may be housed on special units that warrant special precautions. Many other patients/residents who are not on specialized units might also be at increased risk for acquiring Legionnaires' disease, such as persons 50 years of age or older, persons on high-dose steroid therapy, and persons with chronic lung disease. For this reason, in some facilities a generalized prevention and control approach may be easier to operationalize and more successful. Certain facilities with higher risk populations, such as those with hematopoietic stem-cell transplant (HSCT) and solid organ transplant units, require more protective measures.

The Department will review compliance with these practices as part of its surveillance of facility operations. Questions regarding healthcare facility-associated Legionnaires' disease should be directed to the NYSDOH Regional Epidemiologist in your area (See contact list at the end of this document).

Thank you for your prompt attention to this important health matter.

NYSDOH Regional Offices:

Western Regional Office	(716) 847-4503
Central New York Regional Office	(315) 477-8166

Capital District Regional Office	(518) 474-1142
Metropolitan Area Regional Office	(914) 654-7149

Enclosures

Attachment 1: Prevention and Control of Legionnaires' disease, Guidance for Clinicians: Background and Diagnosis
Attachment 2: Prevention and Control of Legionnaires' disease, Infection Control Guidance: Surveillance, Investigation and Control
Attachment 3: Prevention and Control of Legionnaires' disease, Environmental Guidance and Engineering Measures

Attachment 1

NEW YORK STATE DEPARTMENT OF HEALTH
PREVENTION AND CONTROL OF LEGIONNAIRES' DISEASE
GUIDANCE FOR CLINICIANS: BACKGROUND AND DIAGNOSIS

Background

Legionellosis is a bacterial disease that is associated with two distinct illnesses: Pontiac fever (a self-limited, influenza-like illness with a 1 to 2 day incubation period, also known as non-pneumonic legionellosis) and Legionnaires' disease (a progressive pneumonia with a 2 to 10 day incubation period that may be accompanied by cardiac, renal and gastrointestinal involvement). The causative agent in 90% of infections is *L. pneumophila. L. pneumophila* is further classified into serogroups, of which serogroup 1 is most common. Many other *Legionella* spp. can cause disease in humans, including *L. micdadei, L. bozemanii, L. dumoffii,* and *L. longbeachii*.

Legionella species are naturally occurring, ubiquitous aquatic organisms. They prefer warm water temperatures with the ideal temperature for growth ranging from 77 to 115° F (25 to 46° C). The ten-year average number of cases of Legionnaires' disease reported to New York State annually is 539 (including NYC). Cases may be community- or healthcare facility-associated and result from exposure to contaminated water aerosols or aspirating contaminated water. Outbreaks of Legionnaires' disease have been reported throughout the world. Numerous citations have appeared in the medical literature describing the link between Legionnaires' disease and potable water or aerosol-generating devices, such as nebulizers, cooling towers, showers, faucets, hot tubs, whirlpool spas, respiratory therapy equipment, and room-air humidifiers.

Certain host factors will place persons at greater risk for acquiring Legionnaires' disease. Persons with severe immunosuppression from organ transplantation or chronic underlying illness, such as hematologic malignancy or end-stage renal disease, are at the **greatest risk** for acquiring, and dying from, Legionnaires' disease. Persons with diabetes mellitus, chronic lung disease, non-hematologic malignancy, HIV, the elderly, and persons who smoke cigarettes are at **moderately increased risk**. The disease is rare among children. Healthcare facility-associated Legionnaires' disease may be underestimated in facilities where clinicians do not perform routine specific diagnostic testing for the disease.

Legionnaires' disease cannot be distinguished clinically from pneumonia caused by other agents. Therefore, clinicians should maintain a heightened awareness and include *Legionella* as a causative agent in the differential of all healthcare facility-associated pneumonia that occurs in patients/residents who are at moderately increased risk or greatest risk for acquiring Legionnaires' disease. Additionally, *Legionella* should be considered in the differential diagnosis in adults admitted from long term care facilities to the hospital with signs and symptoms consistent with pneumonia. Pneumonia that develops after 48 hours of hospitalization is considered healthcare facility-associated (see Attachment 2).

Diagnosis

- Obtain chest x-ray as clinically indicated.
- Test patients/residents by **both**:
  - **Culture** of respiratory specimens for *Legionella* spp., and
  - Detection of *Legionella* **urinary antigen**.
- Alert the laboratory when requesting culture for *Legionella* spp. as special media must be used for isolation of the organism.
- Save isolates from respiratory specimens since they are necessary in facility-associated Legionnaires' disease investigations to match with other clinical and environmental isolates.

Laboratory testing

- Bacterial culturing of *Legionella* spp.:
  - Alert the laboratory that *Legionella* is being considered as a causative agent. (Buffered charcoal yeast extract (BCYE) agar is required for culture.)
  - Save isolates of *Legionella* for the epidemiologic investigation.
- *Legionella* urinary antigen
  - Enzyme-linked immunosorbent assay (ELISA),radioimmunoassay, or rapid lateral flow immunoassay is performed on a urine sample.
  - Antigen testing is not reliable to detect *Legionella* spp. other than *L. pneumophila* serogroup 1.
- Other methods of identification include:
  - Direct fluorescent antibody (DFA) staining.
  - Polymerase chain reaction (PCR).
    - PCR testing will identify non-viable as well as viable organisms which presents a challenge in diagnosis and comparison of clinical and environmental isolates.
  - Serologic tests require acute and convalescent phase sera obtained 2 – 4 weeks apart.
    - Serology is not helpful in establishing the diagnosis in a timely manner. A single positive titer does not distinguish patients/residents with Legionnaires' disease from patients/residents with other etiologies of pneumonia.
    - Immunohistochemical staining is available at the Centers for Disease Control and Prevention (CDC).

- When cultures are positive for *Legionella* spp.:
  - Isolates should be submitted to the NYSDOH Wadsworth Laboratories (or New York City Department of Health and Mental Hygiene Public Health Laboratory for NYC facilities) as per the NYSDOH Laboratory Reporting of Communicable Disease Guidelines, located on the Wadsworth Center Website at: http://www.wadsworth.org/labcert/regaffairs/RAindex.htm.
  - The public health laboratory will perform confirmation, serogrouping, and pulsed-field gel electrophoresis if indicated.

Clinicians should notify the Department of Infection Control in their facility if a suspected or confirmed case of *Legionella* is diagnosed in one of their patients/residents. Clinicians should also maintain a high index of suspicion for

legionellosis in the setting of community-onset or healthcare facility-associated pneumonia to ensure early therapy, particularly in high risk individuals.

References

1. Tablan OC, Anderson LJ, Besser R, Bridges C, Hajjeh R. Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2003;53(No. RR-3):1-36.

2. Sehulster L, Chinn RYW. Guidelines for environmental infection control in health-care facilities, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2003;52(No. RR-10):1-44.

3. American Thoracic Society. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. Am J Respir Crit Care Med 2005;171:388-416.

4. Goetz, A.M.; Muder, R.R. *Legionella pneumophila*. In: APIC text of infection control and epidemiology. 2nd ed. Washington, D.C.: Association for Professionals in Infection Control and Epidemiology, Inc.;2005:76-1−76-8.

Attachment 2

NEW YORK STATE DEPARTMENT OF HEALTH
PREVENTION AND CONTROL OF LEGIONNAIRES' DISEASE
INFECTION CONTROL GUIDANCE:
SURVEILLANCE, INVESTIGATION AND CONTROL

A close collaboration among clinicians, patient/resident care staff, plant facility engineers and technicians, laboratorians, and the infection control department is necessary to prevent and control facility-associated Legionnaires' disease. The recommendations below should be incorporated in your facility policies and procedures.

Surveillance for Legionnaires' disease

- Ensure the availability of laboratory tests for *Legionella* (i.e., culture and urinary antigen). Determine your facility's strategy for clinically identifying cases of facility- associated cases of Legionnaires' disease. All patients/residents who are at greatest risk or moderately increased risk for acquiring Legionnaires' disease (see Attachment 1) should be tested for *Legionella* if they develop a facility-associated pneumonia. This can be operationalized by either:
    - Educating all clinicians to perform testing for *Legionella* for all patients/residents who develop a facility-associated pneumonia who are at moderately increased or greatest risk for Legionnaires' disease or in patients/residents not in these risk categories who are not responding to typical community- or healthcare facility-associated pneumonia treatment ; **OR**
    - Culturing all respiratory specimens received by the laboratory for *Legionella.*
- At least semiannually, review the availability and clinicians' use of laboratory diagnostic tests for *Legionella* in the facility. If testing is assessed as inadequate, implement measures to enhance clinicians' use of the tests.
    - If all respiratory specimens are cultured for *Legionella,* the facility does not have to measure adequacy of testing.
- The following surveillance definitions apply for assessing community- versus healthcare facility-associated Legionnaires' disease, given an incubation period of 2 to 10 days:
    - Community-associated Legionnaires' disease: the patient/resident was in the community for the entire incubation period and presented with onset of illness within 48 hours of admission.
    - Possible healthcare facility-associated Legionnaires' disease: the patient/resident was not in the facility during the entire incubation period.
    - Definite healthcare facility-associated Legionnaires' disease: the patient/resident was in the facility for the entire incubation period.
- All cases of community- and healthcare facility-associated Legionnaires' disease should be reported to the appropriate public health authority within 24 hours of diagnosis:
    - All cases of Legionnaires' disease are to be reported to the local health department where the patient/resident resides by submitting a confidential

case report form DOH 389 (NYC residents are reported to the NYCDOHMH by submitting a confidential case report on the NYCDOHMH Universal Reporting Form).

- Possible or definite healthcare facility-associated cases of Legionnaires' disease are to also be reported to the NYSDOH Healthcare Epidemiology and Infection Control program by submitting a report on the Nosocomial Outbreak Reporting Application (NORA) system located on the Health Commerce System (HCS; formerly Health Provider Network or HPN) at: https://commerce.health.state.ny.us/hcs/index.html
  - If you already have access to NORA, click the NORA link under "My Applications" at the left of the page. The appropriate NYSDOH Regional Epidemiology office or New York City Department of Health and Mental Hygiene (NYCDOHMH) office will follow up with the facility after the electronic submission of the report is received.
  - If you need access to NORA, contact your facility's HCS (formerly HPN) coordinator and ask to be assigned the 'Infection Control Practitioner' role in the Communications Directory. A paper NORA report must be completed and submitted by fax while your access to NORA is being processed. The paper NORA report form can be downloaded at: http://www.health.ny.gov/forms/doh-4018.pdf

Prevention of Legionnaires' disease: Use and care of respiratory equipment

Tap water should never be used for rinsing semi-critical respiratory devices or filling reservoirs of respiratory equipment or devices that create aerosols due to the risk of exposing patients/residents to waterborne organisms. The following recommendations are consistent with the CDC's *Guidelines for Preventing Healthcare-associated Pneumonia, 2003*:

- Use sterile water for rinsing nebulization devices and other semicritical respiratory-care equipment after they have been cleaned and disinfected.
- Use sterile water for filling reservoirs of devices used for nebulization.
- Do not routinely use large volume room-air humidifiers that create aerosols. If use of such a device is deemed medically necessary, the following recommendations apply:
  - Follow the above recommendations regarding rinsing and filling with sterile water.
  - Subject the device to sterilization or high-level disinfection daily.
- The same standards of care for respiratory equipment in healthcare facilities apply to respiratory equipment brought in by the patient/resident or family (e.g., humidifiers, CPAP, BiPAP) for use during an in-patient stay. Facility staff should be assigned to:
  - Assess equipment brought in from the patient's/residents' home.
  - Clean and reprocess devices brought in from home.
  - Educate patient/resident and family regarding proper use and maintenance of equipment brought in from home.
  - Document the following:

- The use of the device was recommended by the patient's/resident's clinician;
- The use of the device was cleared by the designated person(s);
- Education of the patient/resident and family occurred;
- Adequate supplies of sterile water are in the patient/resident room for use; and
- Daily cleaning and processing has occurred as above.

Prevention of Legionnaires' disease: Protective environments/transplantation units

Protective environments are specialized patient care areas that have a positive air flow relative to the corridor that can safely accommodate persons that have undergone allogeneic hematopoietic stem cell transplant (HSCT). Patients who have received HSCT or a solid organ transplant are at highest risk for acquiring and dying from Legionnaires' disease. The following additional recommendations are for this population. Facilities may choose to expand this recommendation, and utilize these measures for other patient/resident care units that service population groups they assess are at high risk for Legionnaires' disease (e.g., oncology patients receiving chemotherapy).

- Culturing for *Legionella* spp. in potable water samples from HSCT or solid organ transplant units shall be performed at least quarterly as part of a comprehensive strategy to prevent Legionnaires' disease.
- If *Legionella* spp. are determined to be present in the water supply of the unit:
    - Decontaminate the water supply as recommended in Attachment 3.
    - Remove faucet aerators from patient/resident care areas if environmental sampling yields positive results for *Legionella* spp.
    - Restrict patients/residents on the unit from taking showers.
    - Provide patients/residents with sterile water for tooth brushing, drinking, flushing nasogastric tubing and dilution of enteral nutrition for administration via a nasogastric tube.
    - Notify patients/residents and family members of the need and the rationale for the water restriction on the affected unit.
    - If the above recommendations are in place and a case of facility-associated Legionnaires' disease is identified, reinforce adherence to above recommendations, and additionally consider:
    - Not utilizing sinks in patient/resident rooms. If this is initiated, the facility must ensure:
        - Hand hygiene products are available (e.g., alcohol-based hand rubs), and
        - There is reasonable access to a sink if hands are visibly soiled (i.e., the employee does not have to thread their way through doorways and/or stairs to access a sink).
        - Do not use tap water for patients'/residents' sponge baths.

Investigation and control of Legionnaires' disease

If a single case or multiple cases of Legionnaires' disease are detected:

- Report to the NYSDOH and local health department as described in "Surveillance for Legionnaires' disease" above.
- The NYSDOH will open an investigation and provide consultation for facilities reporting a possible and/or definite case(s) of healthcare facility-associated Legionnaires' disease. Investigations in New York City facilities will be conducted jointly with the New York City Department of Health and Mental Hygiene.
- Recommendations for control will vary depending on the types of patients/residents the facility services, whether the case is a probable or definite healthcare facility-associated case, and certain elements of the physical plant. The recommendations will cover:
    - Retrospective and prospective surveillance to identify additional cases;
    - Obtaining *Legionella* urinary antigen for cases identified on retrospective surveillance (if causative agent is *L. pneumophila* serogroup 1);
    - Assessment of physical plant, potable water systems, construction activities, and current water treatment and maintenance;
    - Environmental culturing;
    - Molecular analysis of patient/resident and environmental isolates;
    - Reinforcement of recommendations described in "Use and care of respiratory equipment for the prevention of Legionnaires' disease" in this document;
    - Tap water restrictions for immune compromised populations; and
    - Notification to patients/residents and family members if a water restriction is indicated, including the rationale for the restriction.

References

1. Tablan OC, Anderson LJ, Besser R, Bridges C, Hajjeh R. Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2003;53(No. RR-3):1-36.

2. Sehulster L, Chinn RYW. Guidelines for environmental infection control in health-care facilities, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2003;52(No. RR-10):1-44.

3. Goetz, A.M.; Muder, R.R. *Legionella pneumophila*. In: APIC text of infection control and epidemiology. 2nd ed. Washington, D.C.: Association for Professionals in Infection Control and Epidemiology, Inc.;2005:76-1−76-8.

Attachment 3

NEW YORK STATE DEPARTMENT OF HEALTH PREVENTION AND CONTROL OF LEGIONNAIRES' DISEASE ENVIRONMENTAL GUIDANCE AND ENGINEERING MEASURES

Environmental Assessment

The New York State Department of Health (NYSDOH) recommends that facilities proactively perform an environmental assessment of their water systems. This 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 structure a response in advance of any environmental sampling for *Legionella*. Factors to be considered include, but are not limited to:

- Facility Characteristics
  - Types of care
  - Age of buildings
  - Floor space and numbers of beds/population capacity

- Source of water supply and treatment
  - Hot and cold water temperature profiles
  - Free chlorine residuals
  - Presence and location of thermostatic mixing valves
  - Presence and service of water softener systems
  - Supplemental (long-term) water treatments for microbial contamination
  - Other water quality parameters (pH, TOC, etc.)

- Heating and Cooling
  - Age and types of heating and cooling components
  - Service records, warranties and manufacturer recommendations
  - Locations
  - Service contracts and vendors
  - Chemical treatments, shut-down and start-up procedures

- Construction Issues
  - Internal plumbing repairs or construction
  - External construction
  - Water main breaks or repairs
  - Colored water issues
  - Sprinkler system service or malfunction/repair.
  - Potential cross-connections

For specific information on additional factors to be considered during this review process, an assessment form entitled "Environmental Assessment of Water Systems in Healthcare Settings", originally developed by CDC and modified for use in New York State, is available from NYSDOH on the Health Commerce System. A similar, regularly updated, form is also available from CDC on their website (www.cdc.gov). Once the

assessment is completed, it should be reviewed and updated at least one time per year.

Updates to the environmental assessment form, and attendant files or information, should accompany any significant construction or repair work that is done in the facility. Initial or ongoing assessment should be conducted by a multidisciplinary team composed of key individuals in each facility that represent the expertise, knowledge and functions related to the facility operations and service.

Multidisciplinary teams should include at a minimum:

- Infection Control
- Physical Facilities Management
- Engineering
- Clinicians
- Laboratory
- Hospital Management.

As part of the assessment process itself, environmental sampling for *Legionella* sp. could be performed to determine the extent of colonization, including the possibility of extensive biofilm involvement and areas of concern.

The response to sampling results should be based on decision-making strategies outlined below and on the percentage of culture positive sites. This information will help guide the facility to the next steps for continued monitoring, initiating treatment, and/or retaining a consultant.

Recommended Actions for Legionnaires' disease in a Healthcare Facility

If a case of Legionnaires' disease is linked to a NYSDOH regulated nursing home or hospital, the facility **in consultation with NYSDOH** should consider disinfection of the implicated water system following an assessment of the facility (Refer to the 'Environmental Assessment Section'). **Complete eradication of *Legionella* may not be feasible and, without long-term control measures, re-growth will likely occur**. Therefore, long-term control measures, or other barriers such as point-of-use microfiltration, may be needed. Environmental surveillance, such as collecting water samples or plumbing system swab samples for *Legionella,* is necessary to ensure that the recommended disinfection and long-term control measures are appropriate to the system. Sampling periods should be determined in consultation with NYSDOH.

Routine sampling and environmental assessment as a prevention strategy

In hematopoietic stem cell transplant (HSCT) and solid organ transplant units the environmental sampling frequency should be at least quarterly and in conjunction with the recommendations discussed below and with current NYSDOH guidance. Prior to sampling, a facility plan should be in place to address any positive environmental samples. In the absence of disease, environmental surveillance of any other units considered to be more vulnerable than the general facility census (e.g. oncology, ICU/CCU involving cardiopulmonary patients, etc.) could be initiated as determined by

the *Legionella* policy that was formulated by the facility's multi-disciplinary team or as part of a routine facility assessment (see 'Environmental Assessment Section').

OPERATIONS AND MAINTENANCE

The items noted below are suggested elements of an environmental management plan. Elements can be added or deleted depending upon the outcome of a facility environmental assessment.

Heating and Cooling

- Hot water heating systems (non-potable) and cooling towers should be maintained according to the manufacturer's recommendations and current industry standards (ASHRAE; CTI, 2008). This should include annual start-up and shut-down procedures.
- The operation and maintenance of the cooling tower should be conducted under the guidance of a water treatment expert experienced in cooling tower design and operation.
- A daily operation log and maintenance manual reflecting the latest standards should be developed and maintained for your cooling tower and hot water systems (e.g. flushing hot water tanks, instantaneous heaters, mixing valves, etc.).
- Cooling tower documentation should include written details regarding the proper use of corrosion inhibitors, biocides, and disinfectants, and records on repairs, alterations, operating times, monitoring, routine disinfection, and inspections.
- Operations should follow current industry practice (ASHRAE; CTI, 2008) Documentation should be reviewed on a periodic basis to assure it is consistent with current standards of practice.
- Operational changes to the system(s) may also warrant a review of existing materials.

Construction and Repair

- When planning new construction, facilities should consider installing anti-scald valves on hot water outlets, so that water temperatures in the recirculation lines and distribution system may be set high enough to control *Legionella* growth. This would also include the use of instantaneous heaters to maintain higher temperatures.
- When the hot water distribution system is opened for repair/construction or subject to water pressure changes, the system should, at the minimum:
    - Be thoroughly flushed before being returned to service.
    - On a case-by-case basis, be evaluated for disinfection using a high temperature or chlorination flush before being returned to service.
    - If only a portion of the system is involved, disinfection may occur on only that portion of the system.
    - Precautions should be taken to prevent patient/resident exposure to aerosols, high temperatures or high concentrations of chlorine during flushing.

Storage and Premise Distribution

- Store and distribute potable cold water at <68°F (20°C).
- If your facility has the necessary mixing valves and/or anti-scald valves, hot water should be stored above 140°F (60°C) and circulated with a minimum return temperature of 124°F (51°C; Darelid, 2002). Instantaneous water heaters can also provide and maintain high water temperatures without storage. Mixing valves and/or anti-scald valves are necessary on such systems to reduce the final water temperature to no more than 120° F (49°C) in patient/resident areas to prevent scalding.
    - Recirculation loops with high temperatures do not guarantee a reduction in *Legionella* colonization at distal sites that are supplied via risers which result in lower temperatures (Chen, 2005).
    - Anti-scald valves need to be operated according to manufacturer's recommendations, which include periodic testing of outlet temperatures and documentation of results.
- Facilities that do not have the necessary mixing valves and/or anti-scald valves to operate according to the temperatures described above, or have not implemented other long-term control measures, should: [1] Perform an environmental assessment (which could include *Legionella* sampling); [2] Update the environmental assessment annually.
- "Dead ends", capped lines, and the location of water hammer arrestors should be documented. If they appear to be a source of corrosion, microbiologically influenced corrosion or biofouling, then they should be removed or altered to prevent recurrence of the problem. Old water hammer arrestors may need periodic replacement.
- Water lines in patient/resident areas that have been dormant or unused should be flushed or disinfected before being placed back into service. Periodic running of water in empty patient/resident rooms is recommended.
- Electronic (also known as "on-demand" or "hands free") faucets should be monitored along with other sites in a *Legionella* sampling plan.
- Hot water storage tanks should be drained, cleaned and disinfected at least annually.
- Hematopoietic stem cell transplant (HSCT) and solid organ transplant units could implement the following additional measures. These measures will not have any long-term positive impact on the control of *Legionella* unless they are done in conjunction with a good operations and maintenance scheme or long-term treatment methods.
    - Use point-of-use filters where necessary or appropriate (showers, sinks, nursing stations used for supplying patients/residents water and ice)[1] ;
    - Remove sink aerators from patient/resident room sinks if environmental sampling persistently yields positive results for *Legionella* spp.

These latter measures may also be considered for other patients that are considered more vulnerable than the general facility census (e.g. oncology, ICU/CCU involving cardio-pulmonary patients, etc.).

DISINFECTION

Disinfection should be performed if indicated by the results of an environmental

[1] Establishment of water stations where drinking water and ice can be produced using filters with pore sizes of no more than 0.2 microns. In addition, shower wands with these 0.2 micron filters could serve as an alternative to shower restrictions and dry baths.

assessment or in response to disease. If multiple possible or definite case(s) of legionellosis are identified, it is advisable to consider immediate disinfection. This may require that the facility hire a consultant. The disinfection and culture sampling should be done in consultation with NYSDOH.

When possible, a baseline assessment or an updated Environmental Assessment should be completed prior to disinfection. Acute disinfection options may only have a temporary positive effect or they may be ineffective (Chen, Y., 2007). It should be noted that repeated use of these methods can mobilize biofilm and may be destructive to facility piping and hardware. The facility's multidisciplinary team should be involved in all disinfection decision making. Appropriate education and control measures need to be implemented prior to disinfection to prevent injuries.

Short Term Control Measures

Heat and Flush

The literature suggests bringing hot water temperatures to 160 F (71 C) and flushing each tap for a minimum 30 minutes to be effective (Best, 1984). Many facilities cannot achieve these temperatures or exposure times. Under less-than-optimum circumstances a facility should attain temperatures of 160 F (71C) for greater than 5 minutes (Sehulster and Chin, 2003). Lower temperatures and shorter exposure times will be less effective (Darelid, 2002; Chen, 2005; Van der Mee-Marquet, 2006). For example, temperatures of 140 F (60 C) may require greater than 30 minutes exposure times to be effective (Freije, 1996)

Failure of heat and flush protocols may require the use of hyperchlorination. The water system should be re-sampled no sooner than 7 days and no later than 4 weeks after disinfection to determine the efficacy of the treatment and the rate of re-occurrence of legionellae.

Hyperchlorination

Performing hyperchlorination is usually a more difficult short-term treatment to implement. It may be necessary to contact a consultant that can assist with the hyperchlorination of an entire building.

- Hyperchlorination should target a minimum free chlorine residual of 2.0 ppm for no less than two hours but no more than 24 hours.
- Free chlorine residual should be confirmed at multiple locations throughout the system.
- Current literature also suggests that an initial concentration of 10 - 20 ppm for two hours should be followed by reducing the concentration to > 2.0 ppm (A range of 2.0 to 6.0 ppm is required for control of *Legionella*) for up to 24 hours, after which the system should be thoroughly flushed.

The hot water system should be sampled no sooner than 7 days and no later 4 weeks after disinfection to determine the efficacy of the treatment and re-occurrence of legionellae. If additional culture analysis determines that acute treatment does not succeed in lowering the concentration of *Legionella* in your hot water system the treatment may be repeated. In some instances long-term continuous treatment methods may be needed

(chlorine dioxide or copper-silver treatment).

Low Level Continuous Chlorination

As an intermediate treatment, when either heat and flush or hyperchlorination are contraindicated, another option is to continuously treat both hot and cold water with supplemental chlorine until a permanent control measure is implemented. The target concentration should be 0.5 ppm free chlorine residual at the most distal locations from the treatment location. After implementation, culture of legionellae should be performed within 7 to 10 days.

Other Short-Term Control Measures

Empirical data indicate that the application of copper-silver on a temporary basis has been successful in controlling the re-growth of *Legionella* spp. Typical implementation requires a 30-day (or longer) treatment period with frequent culture monitoring. Cultures should be collected just prior to application of copper-silver, at a mid-point and at the presumed end of the treatment period. Inordinately high numbers of positive sites (>30%) at the end of 30 days would result in an additional 30-day (or more) treatment. The long-term efficacy of this type of treatment may be limited (e.g. up to six months) but it would allow the facility time to examine long-term treatment options (Lin, et al, 2011).

Long-Term Control Measures

Long-term control measures are complex and should be individualized. Expert advice should be sought when developing and implementing long-term control measures. If consultants are retained, they should assess corrosion, scaling, biofilm, pH, temperature profile and other physical parameters that may negatively affect treatment.

The primary treatment methods used for long term control of *Legionella* in hot water systems include silver/copper ionization and chlorine dioxide. Consultants, or other experts, should provide sufficient data to justify selection of the long term treatment selected. When applying these long-term treatments localized flushing may help attain target chemical concentrations in problem areas. Additional steps that could be used in conjunction with these long-term measures include:

- Installing anti-scald valves on all outlets and maintaining a minimum return temperature of 124°F (51°C).
- Continuous chlorination to maintain a free chlorine residual of 0.2 ppm at the outlets.
- Periodic superheating and flushing.
- Use a combination of the preceding treatment methods.
- When evaluating primary treatment methods, consultants, or other experts, should determine whether other preventative measures are needed for long term control. These measures may include:
    - Installing mixing or anti-scald valves to allow higher temperatures in all or part of the system;

- Replacing hot water tanks with instantaneous heaters;
- Removing or replacing 'shock absorbers' (i.e., water hammer arrestors);
- Periodically flushing to improve treatment at distal outlets;
- Modifying hot water re-circulation system or adding automated temperature controls;
- Replacing shower heads.

- In HSCT and solid organ transplant units, and any other units your facility has designated as having at-risk patients (e.g., oncology and cardiopulmonary ICU/CCU), consideration should be given to point-of-use filtration. The use of microporous filters may be used as a temporary additional barrier or a long-term control measure for targeted at risk areas. Alternatively, a single drinking water/ice machine station, using point-of-use filters, could be established to prepare water and ice for delivery to patient/resident rooms.
- After long-term control measures have been implemented, facilities should develop, and regularly re-evaluate, an environmental surveillance plan for *Legionella* (routine water monitoring) along with their plan for active case surveillance.

ENVIRONMENTAL SURVEILLANCE FOR *LEGIONELLA*

Culturing the Environment in the Absence of Disease

- Culturing for *Legionella* spp. in potable water samples from HSCT and solid organ transplant units should be performed at least quarterly as part of a comprehensive strategy to prevent Legionnaires' disease.
- Facilities housing less vulnerable patients/residents than those listed above should convene their multidisciplinary team to determine the need for environmental sampling by using available empiric literature and their facility's risk and environmental assessment to guide their decision. When the decision to perform environmental testing is made, the NYSDOH recommends that the following issues be addressed before the sampling commences:
    - Methodology for collecting samples should be consistent with current guidance. See the Guidelines for Environmental Infection Control in Health-Care Facilities: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee, June 2003, Appendix p. 43, and Box 2 p.18.
    - Culture is the gold standard for environmental testing for *Legionella*. The laboratory chosen for culturing should be proficient in culturing environmental samples for *Legionella*. Laboratory participation in the CDC ELITE program for proficiency testing is highly recommended (http://www.cdc.gov/legionella/elite-intro.htm).
    - Although PCR protocols to detect *Legionella* spp. are not standardized, PCR can be very useful to guide culture and remediation efforts. Please see *Culturing the Environment in the Presence of Disease* below for further details.
    - **The facility should decide what measures will be taken in response to positive environmental results in the absence of disease.** Refer below to "Interpretation of Culture Results".

Culturing the Environment in the Presence of Disease

- Recommendations regarding environmental sampling for *Legionella* spp. should be made in consultation with the NYSDOH if a case of possible or definite healthcare facility-associated Legionnaires' disease has been identified or in the context of an ongoing outbreak of Legionnaires' disease in the surrounding community Answers to the following questions will help determine what recommendations will be made:
    - Possible or definite healthcare facility-associated case?
    - Previous history of healthcare facility-associated Legionnaires' disease?
    - Patient/resident populations the facility serves?
    - Location of the facility relative to any community outbreak?
    - Physical plant structure (hot water flow, complexity of the system, blue prints)?
    - Availability of patient/resident culture(s)?
    - Completion of an environmental assessment form?
- Environmental sites appropriate for sampling should be chosen in consultation with the NYSDOH Center for Environmental Health and/or consultants/experts.
- Environmental culturing should be performed by a laboratory that is experienced in culturing *Legionella* spp. from environmental samples. The NYSDOH does not certify laboratories for environmental *Legionella* analysis at this time. However the CDC ELITE program is available for culture proficiency testing of laboratories.
- Laboratories should be able to distinguish *L. pneumophila* from other *Legionella* species.
- Polymerase chain reaction (PCR) and direct fluorescent antibody (DFA) methods used for environmental sampling may detect non-viable organisms, and thus, have value limited to screening for the potential presence of viable organisms.

RECOMMENDED SAMPLING PLAN

If a potable hot/cold water sampling plan is required as a result of disease, or is done as part of a routine environmental assessment, the recommended sampling sites should include but not be limited to:

- One water sample of the inlet of the heating system(s)
- One water sample of the outlet of the heating system(s)
- One sample of the inlet of the cold water supply
- Floors that housed ill patients/residents, as well as additional floors, should be sampled. Three samples should be collected from each floor. This is normally done in the following fashion:
    - Tap closest to first delivery of hot water from the riser
    - One sample from the middle of the system
    - One sample from the last outlet before the water returns to heaters
- Where multiple risers supply hot water to a limited number of rooms from a circulation loop, several locations corresponding to the loop should be sampled.
- One additional random sample should be collected from each floor when wings have extensive lengths of piping and complex paths. Good judgment should be

used to determine representative sites (e.g. if cold water taps frequently yield "tepid" water).
- For initial building assessment it is suggested that a surface sample (swab) be performed at locations representing the middle or end of the hot water line on each floor.

Sampling Technique

- Water samples should be first draw samples. First draw hot water samples are used to determine "percent positivity" (see below).
- Temperature, pH and residual chlorine levels should be obtained with all water samples (immediately after the first draw). Temperatures should be obtained with first draw sample and after a three minute flush. The temperature profile for hot or cold water systems will help delineate low flow/poor flow areas.
- Aseptic technique should be used in collecting the water samples and filling vessels.
- Thiosulfate, to inactivate free chlorine, should be used in all samples.
- Store samples at 4°C for transport to the lab. (Dry ice is NOT recommended. Ice or "blue" ice bricks and a cooler are preferred).
- Surface samples should be collected with sterile cotton swabs that are dipped in water from the sample site. The swab is aseptically broken off into the bottle containing sample water. Cotton swabs prepared with buffers or alginate swabs are not recommended.

There may be variations of this sampling scheme. Most consultants, vendors, and other experts will make similar recommendations or add suspect sites (dead legs, infrequently used areas, low flow zones, water softener equipment, roof top tanks, ice machines, etc.) depending upon the level of suspicion. At least 10 sites (taps/showers) are recommended in hospitals with <500 beds; 2 sites per 100 beds is recommended for facilities with >500 beds.

Use of ATP methods will also help determine the background microbial populations and increase, or decrease, the index of suspicion with regard to water system microbiological quality. However, high ATP values with high heterotrophic plate counts do not always correlate with the occurrence of high levels of legionellae.

Interpretation of Culture Results

Culture results would be assessed based on the number of positive sites with some special consideration given to the *L. pneumophila* serotypes and secondarily to *Legionella* species. Although some current literature suggests that colony counts (colony forming units (CFU)) are not useful information, in combination with the data on the number of positive sampling sites, this additional information may be very useful in determining a level of concern and how to react to that concern. Any location with double-digit levels of legionellae per 100 ml, when linked together with >30%-positive sampling sites, should be considered an area of concern.

If the number of positive sampling sites is:

>30% - THEN acute treatment is often recommended; follow NYSDOH guidelines to protect patients/residents. If this was already done as part of an outbreak response, the system needs to be reassessed to determine the efficacy of the treatment. It may need to be repeated.

=30% - THEN treatment may need to be considered (dependent upon *Legionella* species and facilities assessment information). This is a borderline condition; therefore, if the number of colony forming units is quite high (generally double-digit colony count values per 100 ml sample), even if the number of positive sites is 30%, an acute treatment may be advisable.

<30% - THEN continue to monitor the facility on a quarterly basis. This should be done in combination with patient/resident surveillance measures. If there is no change after one year, reduce routine monitoring to 2 (or three) times per year.

When assessing the number of positive sampling sites the following is a guideline for the level of concern for the species of the isolates recovered*:

- Primary concern is *Legionella pneumophila* 1;
- Secondary concern is *L. pneumophila* serotypes 2 – 6;
- Less concerning are sporadic isolates of *L. pneumophila* 7-16 and non-*pneumophila* species; exceptions to this lower level of concern are:
    - When a facility is extensively colonized with any *L. pneumophila* 7-14 and/or non-*pneumophila*;
    - There is extensive occurrence of *L. anisa*, *L. micdadei* or *L. bozemanii***.
    - Disease is caused by *L. pneumophila* 7-16 or any non-*pneumophila* species.

*Composed from Benin, et al, 2002, and data reported to the CDC from 1980 – 1998

**Each of these organisms has caused disease in New York State.

As noted earlier, it may be advisable to implement point-of-use microfiltration for the establishment of water stations where drinking water and ice can be produced using filters with pore size of no more than 0.2 microns. In addition, shower wands with microporous filters are also available as an alternative to shower restrictions and dry baths. Point-of-use microfiltration may be a useful barrier during the period between the determination of facility vulnerability and a final solution. Point-of-use microfiltration can also be used as an added barrier in locations serving compromised patients/residents.

A version of a *Legionella* management/action plan is attached (cooling tower sampling should be done by your vendor; refer to the appropriate industry guidance such as ASHRAE Standard 188).

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CONTACTS

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2. Cooling Technology Institute; www.cti.org; Phone: (281) 583-4087.

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Central New York Regional Office	(315) 477-8166
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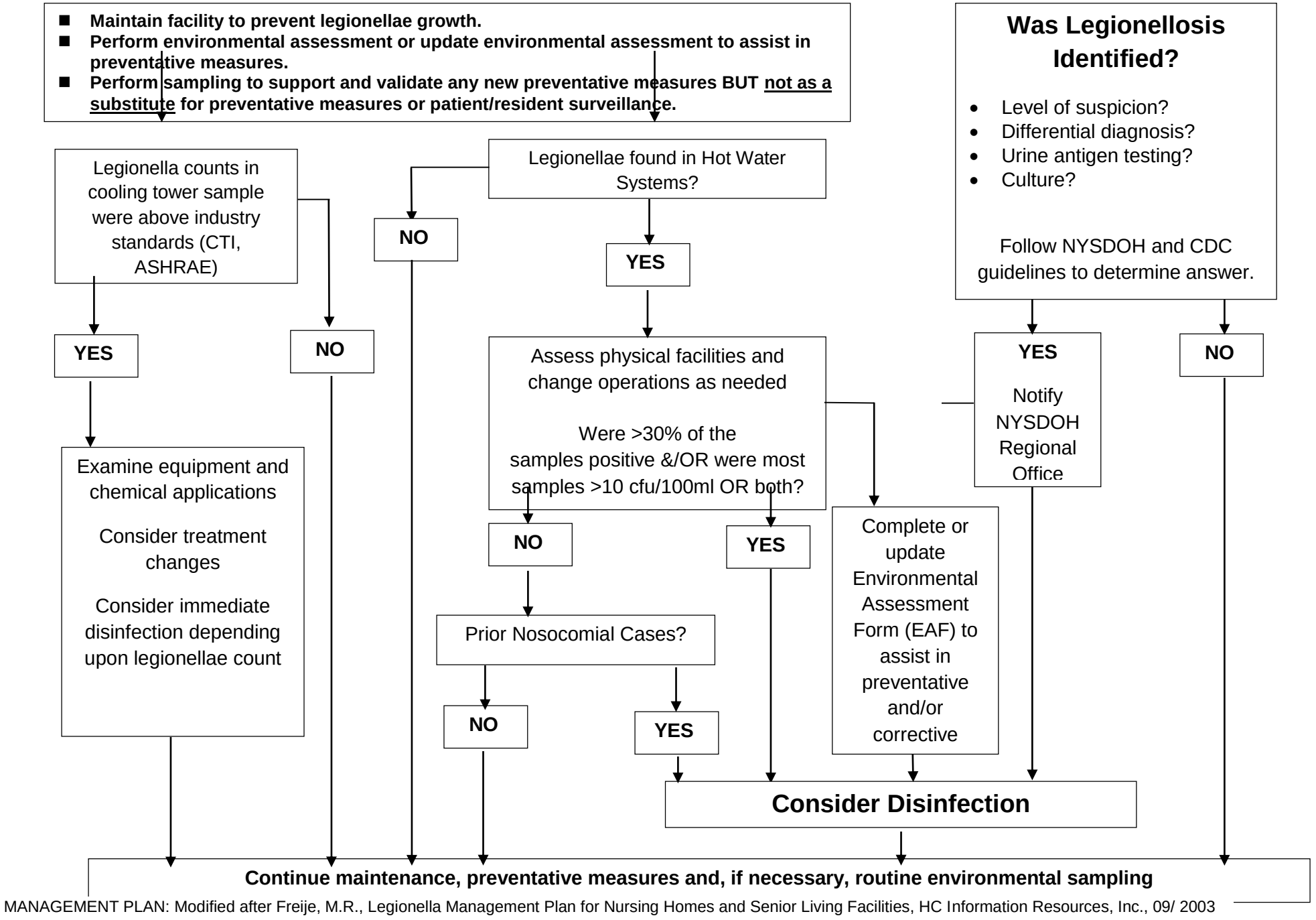


MANAGEMENT PLAN: Modified after Freije, M.R., Legionella Management Plan for Nursing Homes and Senior Living Facilities, HC Information Resources, Inc., 09/ 2003

Nursing Home Guidance for Prevention and Control of Legionnaires' Disease

Outline

- Emergency *Legionella* regulation
- Brief overview of *Legionella* and Legionnaires' disease
- Clinical guidelines
- Infection prevention and control guidelines
- Environmental guidelines
- References and resources

NEW YORK STATE OF OPPORTUNITY. Department of Health

New Regulation

- Approved as an emergency regulation by the Public Health and Health Planning Council on August 17, 2015
- Available on NYSDOH website
  - http://www.health.ny.gov/diseases/communicable/legionellosis/docs/emerg_regs.pdf

New Regulation

- Focus on cooling towers
- However, includes a section for general hospitals and nursing homes
  - *Legionella* sampling plan for potable water systems

NEW YORK STATE OF OPPORTUNITY. Department of Health

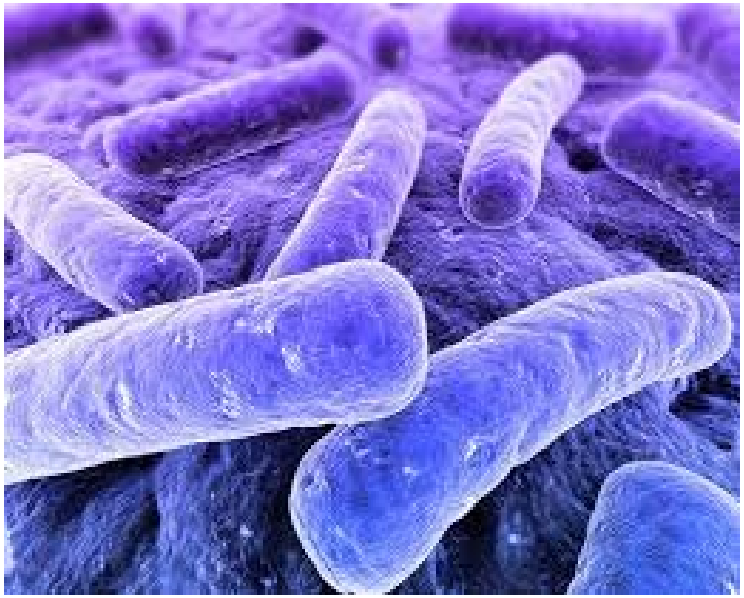
Legionellosis

- A bacterial infection causing:
  - Legionnaires' disease
    - Progressive pneumonia
    - 2-10 day incubation period
  - Pontiac Fever
    - Self-limiting, flu-like illness (no pneumonia)
    - 1-2 day incubation period
  - Rarely, can infect other sites

NEW YORK STATE OF OPPORTUNITY. Department of Health

Legionella

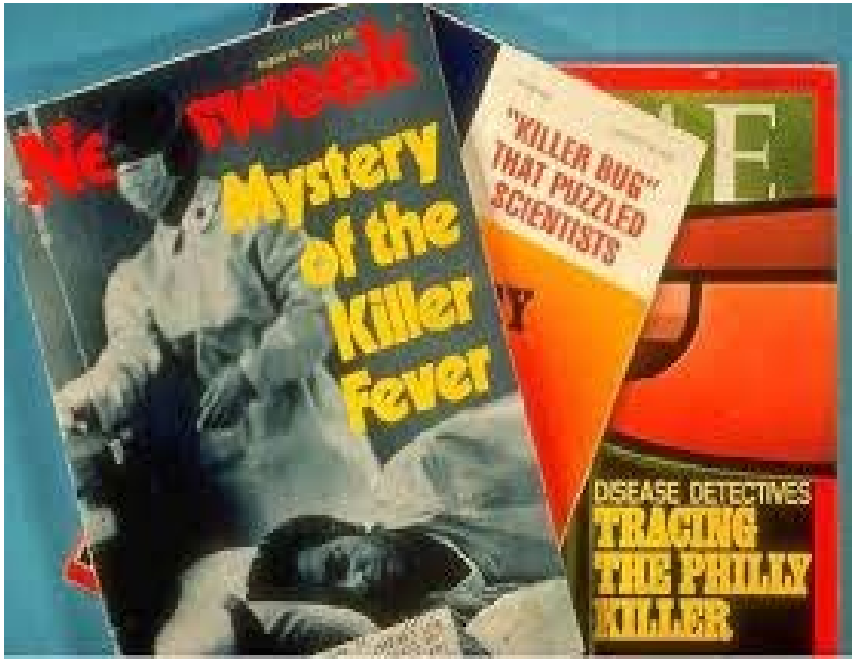
- Ubiquitous, aquatic organism
- First isolated in the lab in 1943
- Facultative intracellular parasite



NEW YORK STATE OF OPPORTUNITY. Department of Health

Legionnaires' Disease (LD)

- American Legion convention in Philadelphia, 1976
  - 200+ ill
  - 20+ deaths
  - Illness linked to hotel air conditioning system

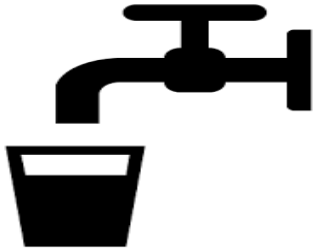


NEW YORK STATE OF OPPORTUNITY. Department of Health

Epidemiology

- *L. pneumophila* causes 90% of infections
  - Serogroup 1 most common cause of disease
  - Serogroups 2-6 also can cause disease
- *L. micdadei, L. bozemanii, L. dumoffii, L. longbeachii, L. anisa* also cause human disease

Epidemiology



- *Legionella* prefers aquatic environments
  - Ideal growth at 77-115° F (25 - 46° C)
- LD cases have been linked to:
  - Potable water systems
  - Cooling towers
  - Showers/faucets
  - Hot tubs, whirlpool spas
  - Respiratory therapy equipment
  - Room-air humidifiers

NEW YORK STATE OF OPPORTUNITY. Department of Health

Epidemiology

- Human host factors
  - Greatest risk group: Immunosuppression
    - Organ transplant, hematologic malignancies, end-stage renal disease
  - Moderate risk group: Other factors
    - Diabetes mellitus
    - Chronic lung disease
    - Non-hematologic malignancies
    - HIV
    - Elderly (>= 50 years)
    - Tobacco smoking
  - Rare among children

Clinical Considerations

- LD is not clinically distinguishable from pneumonia caused by other agents
  - Incubation period 2-10 days
  - Pneumonia developing 48+ hours after admission is considered healthcare facility-associated
  - Maintain heightened awareness in all healthcare facility-associated pneumonia, especially persons at greatest or moderate risk

Clinical Considerations

- Diagnostic work up should include the following:
  - Chest radiograph
  - Respiratory cultures for *Legionella* spp.
    - Requires special laboratory techniques; routine sputum culture will not grow *Legionella* spp.
    - Alert lab that *Legionella* is suspected!
  - *Legionella* urinary antigen test (UAT)
    - Not reliable for serogroups other than *L. pneumophila* 1

Clinical Considerations

- Additional lab testing
  - Direct fluorescent antibody (DFA) staining
  - Polymerase chain reaction (PCR)
    - Identifies both living and dead organisms
    - Presents challenge in diagnosis and comparison of clinical and environmental isolates
  - Serology
    - Requires acute and convalescent phase sera 2-4 weeks apart
    - Not helpful in a timely manner

Clinical guidelines

- When isolates are positive for *Legionella* spp.:
  - Submit to NYSDOH Wadsworth Laboratories
    - Facilities within NYC should submit to NYCDOHMH Public Health Laboratory
  - Notify infection control within the facility

Infection Control

- Close collaboration with multidisciplinary team is essential
  - Infection control
  - Physical facilities management
  - Engineering
  - Clinicians
  - Laboratory
  - Hospital Management

Infection Control

- Residents at greatest or moderate risk should be tested for *Legionella* if they develop a healthcare facility-associated pneumonia
- Report all community- and healthcare facility-associated cases to public health within 24 hours of diagnosis

Infection Control

- Respiratory devices/equipment
  - Use sterile water for rinsing or filling reservoirs
  - If reusable, follow manufacturer instructions for cleaning and disinfection
  - This includes patient equipment brought from home

NEW YORK STATE OF OPPORTUNITY. Department of Health

Infection Control

- Guidelines for “protective environments” are outlined in the NYSDOH document released 8/10/15
  - Does not apply to most nursing homes
  - Pertain to protecting patients with stem cell and solid organ transplants from exposure to potentially contaminated water

New Regulation

- Emergency regulation requires:
  - "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 the Part are warranted."

Infection Control

- If single or multiple cases of LD detected
  - Report to NYSDOH and local health department
    - NYSDOH will provide consultation
    - Investigations in NYC conducted jointly with NYCDOHMH

Surveillance

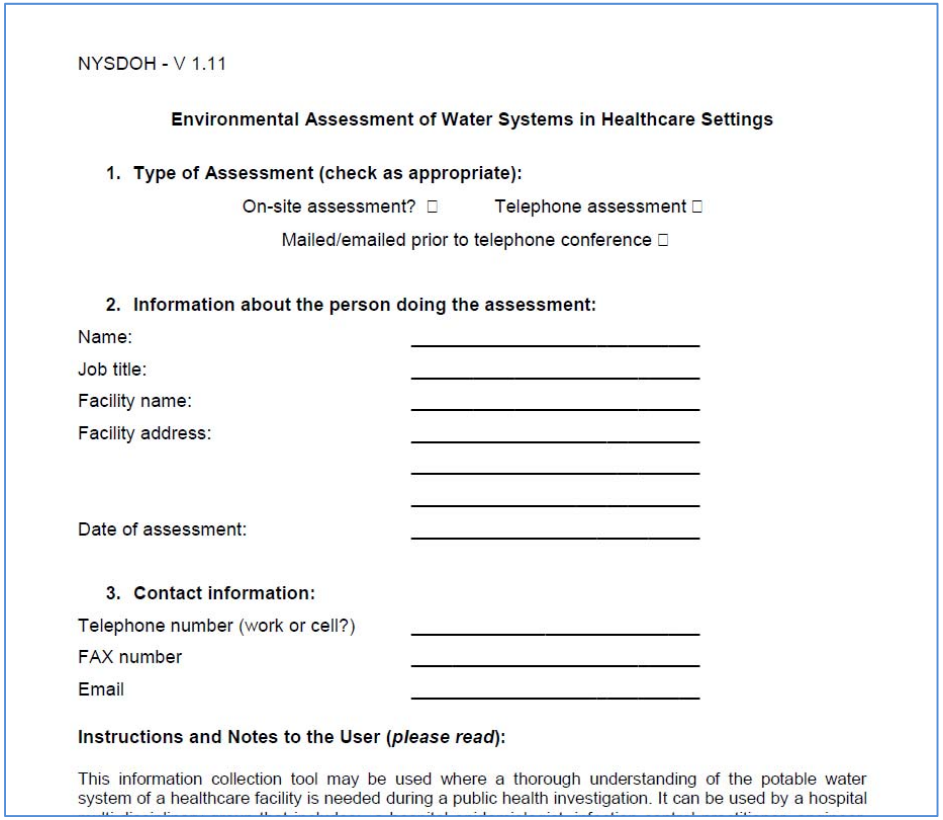
- Investigations of one or more healthcare facility-associated cases might involve:
  - Retrospective and prospective surveillance for additional cases
  - Review of facility's potable water and cooling systems
  - Molecular analysis of clinical and environmental cultures
  - Reinforcement of published prevention guidelines
  - Tap water restrictions for immunocompromised residents
  - Resident notification

Environmental Assessment

A complete environmental assessment includes:

- Facility characteristics
- Source of water supply and treatment
- Heating and cooling components
- Construction issues

Environmental Assessment Form (EAF)



NYSDOH - V 1.11

Environmental Assessment of Water Systems in Healthcare Settings

1. **Type of Assessment (check as appropriate):**

On-site assessment? ☐ Telephone assessment ☐

Mailed/emailed prior to telephone conference ☐

2. **Information about the person doing the assessment:**

Name: _____

Job title: _____

Facility name: _____

Facility address: _____

_____

_____

Date of assessment: _____

3. **Contact information:**

Telephone number (work or cell?) _____

FAX number _____

Email _____

Instructions and Notes to the User (*please read*):

This information collection tool may be used where a thorough understanding of the potable water system of a healthcare facility is needed during a public health investigation. It can be used by a hospital

Available on the Health Commerce System
https://commerce.health.state.ny.us/hcsportal/docs/Source/hin/hinapps/envhlt/water/EAHealthcare.pdf

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Control Measures – Short Term

- Heat and Flush:
  - 160° F (71° C) for > 5 minutes at each tap
- Hyperchlorination
  - Minimum 2.0 ppm free chlorine residual for no less than two hours but no more than 24 hours.

To determine re-growth for the above: Re-sample at least 7 days but no later than 4 weeks after above treatments.

- Low level continuous chlorination:
  - Target concentration level – 0.5 ppm at most distal locations
  - Re-sample in 7 to 10 days.
- Copper-silver ionization (CSI)
  - Usually 30 – 60 days of treatment
  - Re-sample over the next 4 months to confirm continued efficacy
  - Reapply or decide on another long-term treatment

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Control Measures – Long Term

- Copper-silver ionization (CSI)
- Chlorine dioxide
- Additional steps in conjunction with the above:
  - Maintaining a minimum return temperature of 124° F (51° C) with anti-scalding valve installation
  - Continuous chlorination – maintain free chlorine residual of 0.2 ppm at outlets
  - Periodic superheating/flushing
  - Automated temperature control (balancing hot water delivery)
  - Other (chloramination, UV disinfection)

Environmental surveillance for *Legionella*

- Culture is the gold standard for environmental surveillance
  - Use a CDC certified ELITE lab
- Culturing in the absence of disease
  - Be prepared to respond to positive sample results.

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Environmental surveillance for *Legionella*

- Considerations for culturing in the presence of disease
  - Sampling locations based on
    - History of disease in facility
    - Physical plant structure (EAF)
    - Cases definitely or possibly associated with the facility
- Distinguish between *L. pneumophila* and other *Legionella* spp.

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Culture Interpretation

If the number of positive sampling sites is:

>30% - acute (short-term) treatment is often recommended; the system needs to be reassessed to determine the efficacy of the treatment

=30% - treatment may need to be considered, dependent upon *Legionella* species. This is a borderline condition if the number of colony forming units is quite high (generally double-digit colony count values per 100 ml sample), even if the number of positive sites is 30%, an acute treatment may be advisable.

<30% - continue to monitor the facility.

Guideline for *Legionella* spp. Levels of Concern

- Primary concern: *Legionella pneumophila* serotype 1
- Secondary concern: *Legionella pneumophila* serotypes 2-6
- Less concerning: sporadic isolates of *L. pneumophila* serotypes 7-16 and non-*pneumophila* spp.
- Exceptions from above rules:
  - A facility is extensively colonized with any *L. pneumophila* 7-14 and/or non-*pneumophila;*
  - Extensive occurrence of *L. anisa, L. micdadei, L. bozemanii*
  - Disease in the facility has been caused by *L. pneumophila* 7-16 and any non-*pneumophila* spp.

Questions

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Contact Us

NYSDOH Bureau of Healthcare Associated Infections

Email: icp@health.ny.gov

Phone: 518-474-1142

NYSDOH Bureau of Water Supply Protection

Email: ceheduc@health.ny.gov

Phone: 518-402-7650

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Resources

NYSDOH Legionella Website:
https://www.health.ny.gov/diseases/communicable/legionellosis/

CDC Legionella Website: http://www.cdc.gov/legionella/index.html

American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE): www.ashrae.org