



Department  
of Health

# 10 NYCRR Part 4

Protection Against *Legionella*



# Today's Presentation

- Part 4 regulatory requirements
  - Subpart 4-1: Cooling Towers
  - Subpart 4-2: Healthcare Facilities
- Guidance for Subpart 4-2

# Background

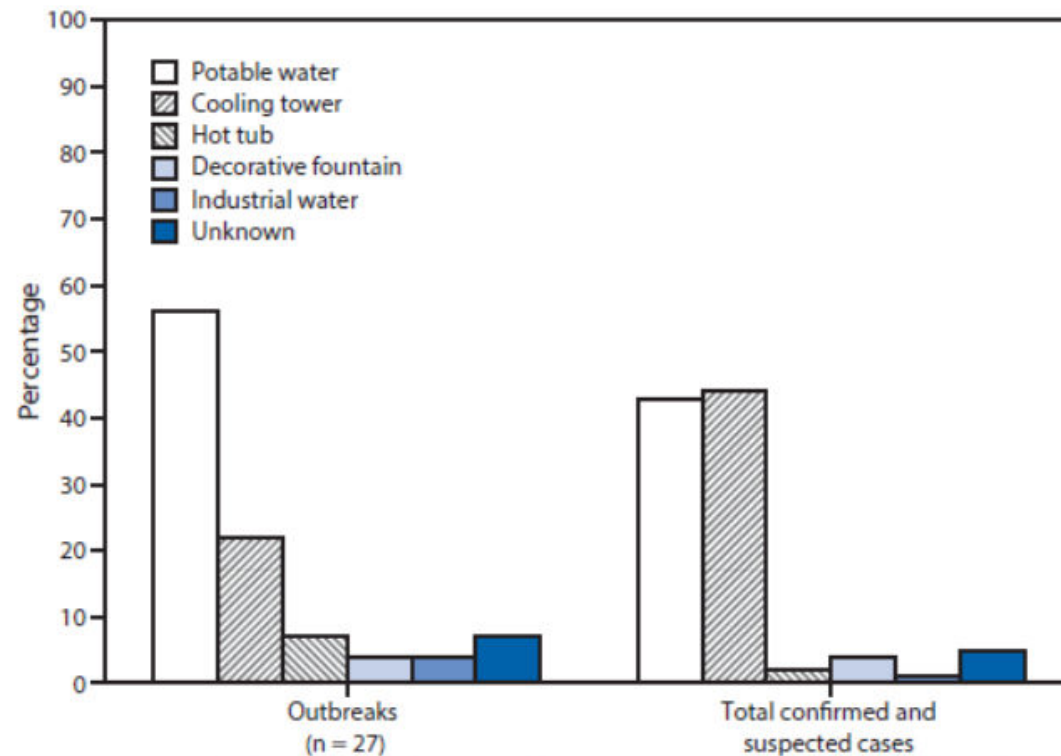
## Why is it important to regulate *Legionella*?

Water in healthcare facilities or aerosol-producing devices in public places can be potential sources of exposure to *Legionella*.

- **Cooling towers (Subpart 4-1):** Proper maintenance is needed to prevent the growth and dissemination of *Legionella*.
- **Healthcare facilities (Subpart 4-2):** Patient surveillance along with the proper monitoring for *Legionella* in the potable water systems at general hospitals and residential health care facilities can help decrease patient exposures and illness.

# CDC Data

## Percentage of Outbreaks and Cases of Legionnaires' Disease, by Environmental Source – North America, 2000-2014



# 10 NYCRR Part 4 Subpart 4-1

# Definitions

## Cooling Towers

- Evaporative condensers, fluid coolers, or other wet cooling devices
- Capable of aerosolizing water
- Part of **or contain** a recirculated water system
- Incorporated into a building's cooling process, an industrial process, a refrigeration system, or an energy production system

## Owners

- A variety of arrangements between the owners of buildings, owners of cooling towers, and tenants
- Any party (person, agent, etc.) may satisfy the definition of owner and be liable for fines



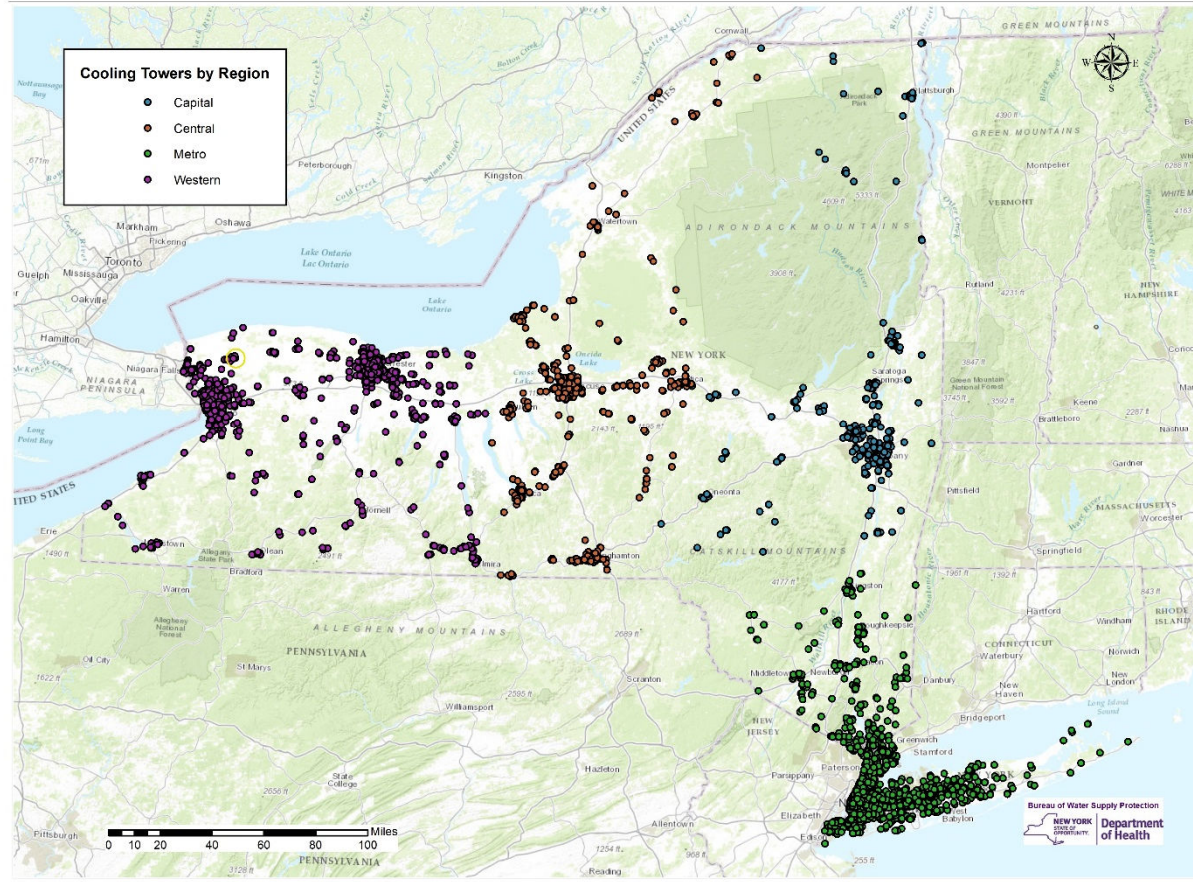
# Registration & Reporting

## Requirements

- All owners of cooling towers shall register their towers, using the Department's statewide electronic system
- The owner shall report data into the statewide electronic system at intervals not to exceed 90 days while a cooling tower is in use
- Items that need to be reported within the 90 day timespan include
  - Last inspection date
  - Last routine bacteriological sample collection date and test result
  - Last *Legionella* sample collection date and test result
- Annual certification is due by November 1 of each year
  - The most recent certification date should be entered into the registry
- Seasonal start-up and shut-down dates should be entered as needed



### NYS Cooling Tower Registry Feb. 2017





# Maintenance Program and Plan

- Each cooling tower is required to have a maintenance program and plan (MPP) in place
  - The document should be kept on site and be available for review
  - Components include treatment, flushing, cleaning, and disinfection protocols
- Sampling while tower is operational
  - Routine bacteriological culture sampling and analysis (intervals not to exceed 30 days)
  - Routine *Legionella* culture sampling and analysis (upon start-up and at intervals not to exceed 90 days)
  - Non-routine sampling provisions following disease, power failure, and other conditions
- *Legionella* culture analysis
  - To be performed by an NYS ELAP approved laboratory

# Maintenance Program and Plan

## Elements should include:

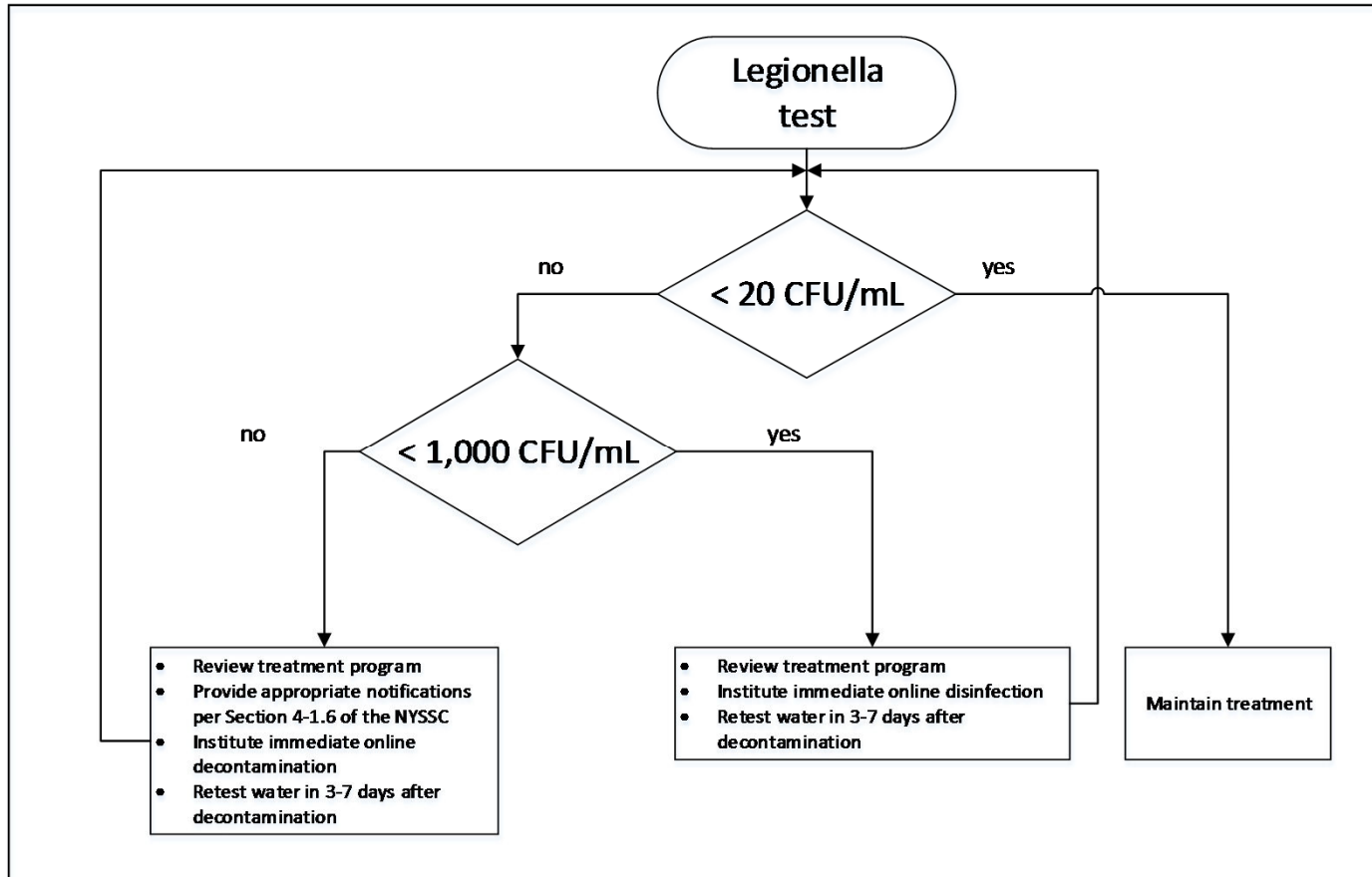
- Tower identification;
  - Developer of the plan, affiliations and effective dates;
  - Process diagrams with control elements;
  - Personnel roles and responsibilities.
- Contact information for personnel;
  - Program chemistry;
  - Culture sampling and analysis schedule;
  - Inspection schedule;
  - Monitoring and maintenance.

## *Legionella* Culture Results (Appendix 4-A)

- No detection (<20 CFU/mL\*)
  - Maintain treatment program and monitoring in accordance with plan
- $\geq 20$  CFU/mL but < 1000 CFU/mL
  - Institute online disinfection
  - Retest in 3-7 days
- $\geq 1000$  CFU/mL
  - Institute immediate online decontamination
  - Notify local health department & NYSDOH ([cooling.tower@health.ny.gov](mailto:cooling.tower@health.ny.gov))
  - Retest in 3-7 days

\*CFU/ml = Colony Forming Units per milliliter

## Appendix 4-A Schematic



# Notification

## 1 - Owners

The regulation indicates that the owner should notify the local health department within 24 hours of receipt of a *Legionella* culture sample result that exceeds 1,000 CFU/mL

## 2 - Local Health Departments

Notify the Department within 24 hours

## 3 - Owners

Notify the public in a manner determined by the local health department (or by the Department in the event that the department elects to determine the manner)

- Templates for public notification are available from the Department
- Additional guidance and coordination will be provided on a case-by-case basis

# Additional Provisions

## Disinfection

- Must be performed by a certified biocide applicator or a pesticide apprentice under the supervision of a certified applicator (Environmental Conservation Law)

## Inspection

- Performed prior to seasonal start-up and at intervals not to exceed 90 days while a tower is in use
- 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 cooling tower inspections

## Certification

- Obtained by the owner from a qualified person identified to perform inspection of cooling towers by November 1 of each year; qualifications are the same as for inspectors.

# Recordkeeping

- Owners shall maintain records of the following items on-site for at least three years
  - All sampling results
  - Disinfection schedules and applications
  - Inspection findings, deficiencies, corrective actions, and certifications
- A copy of the maintenance program and plan should be available on-site

# Enforcement

## Requirement

- The Department or local health department may require any owner to conduct *Legionella* culture sampling and analysis based on one or more cases of legionellosis
- An officer or employee of the Department or local health department may enter onto any property to inspect a cooling tower and may take water samples

## Fines

- A violation of any provision is subject to all civil and criminal penalties as provided for by law
- Each day that an owner remains in violation of any provision shall constitute a separate and distinct violation of each provision
- Primary jurisdiction for administering fines and other penalties lies with the local health departments.

The Department may administer fines if the local health department does not



# Variations and Waivers

## Variance

An owner may submit in writing an application to the local health department or NYSDOH 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

## Waiver

NYSDOH may issue a written general or specific waiver for any provision of the Subpart, where the department determines the waiver does not present a danger to public health

# 10 NYCRR Part 4 Subpart 4-2

# Definitions

## Covered Facilities

- General hospitals
- Residential healthcare facilities
- Defined in Article 28 of Public Health Law

## Potable Water System

- A building water distribution system
- Provides water intended for human contact or consumption

# Regarding Article 28 Facilities

In accordance with the definitions of “general hospital” and “residential healthcare facility” set forth in section 2801 of the Public Health Law, 10 NYCRR Subpart 4-2 applies to:

- Buildings of general hospitals that provide in-patient services or to buildings of residential healthcare facilities providing a “health related service,” such as lodging, board, and physical care.
- 10 NYCRR Subpart 4-2 does not apply to administrative buildings of such facilities, general hospital buildings that only provide out-patient services, or to diagnostic and treatment centers providing only out-patient services.

# Environmental Assessment

- All covered facilities must perform or update an environmental assessment by September 1 of each year
- The environmental assessment must be updated annually or under certain conditions, including completion of construction or repair activities that may affect the potable water system
- The Environmental Assessment Form (EAF) is posted on the Health Commerce System (HCS) and can also be found on the Department's website at: <http://www.health.ny.gov/forms/doh-5222.pdf>

## 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

PFI (Permanent Facility Identifier)

Facility address

Date of assessment

## 3. Contact information

Telephone number (work and/or cell)

FAX number

Email

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

Please complete this form and keep it with your records. You do not need to submit it to NYSDOH. You will need to produce this form at the request of NYSDOH as part of a routine inspection or during the investigation of an outbreak.

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 multi-disciplinary group that includes: a hospital epidemiologist, infection control practitioner, engineer, facility manager or other individual(s) engaged in efforts to reduce the risk of legionellosis associated with the facility. It may also be used to assist the facility in efforts to minimize the risk of legionellosis in the absence of evidence of human disease or when a facility is reviewing/implementing the NYSDOH guidance document on hospital-associated legionellosis. It should be completed in as much detail as possible. Some information requested by the tool may not be applicable for every healthcare facility.

For very large, complex healthcare facilities, completing the form may take several hours. Please keep in mind that this initial investment of time is quite important and will be a time-saving device during periodic re-assessments. If follow-up with the facility is needed in subsequent months or years, the information contained in this form will be very valuable. **Please do not leave sections blank. If a question doesn't apply, write N/A. If a question can't be answered please explain why.** Where applicable, please specify the unit of measurement being used (e.g., ppm). It is recommended that if you are completing the form electronically, you use a different font and/or italics for your answers. This will make the form much easier to read if additional information is added in the future to an existing form.

# Environmental Assessment Form



# Sampling and Management Plan

## Implementation and Updating

- Plans for covered facilities should have been implemented by December 1, 2016
- New facilities must adopt a plan prior to providing services
- The plan must be updated annually and following specific conditions

## Requirements

- Routine *Legionella* culture sampling and analysis at intervals not to exceed 90 days for the first year and annually thereafter (with the exception of hematopoietic stem cell transplant or solid organ transplant patient units)
- Provisions for non-routine sampling for *Legionella* culture sampling and analysis following disease, construction, and other conditions
- Culture analysis by a NYS ELAP-approved laboratory

## Expected Elements – Sampling and Management Plan (S&MP)

Additional elements of the S&MP include details regarding, for example:

- Facility information
- Personnel roles and responsibilities
- Description of the building water system
- Monitoring / Environmental culture sampling
- Response to >30% *Legionella* culture results
- Preventative measures



## ***Legionella* Culture Results (Appendix 4-B)**

< 30% of *Legionella* test sites positive

- Maintain environmental assessment and *Legionella* monitoring

≥ 30% of *Legionella* test sites positive

- Immediately institute short-term control measures
- Report to NYSDOH via [HCF.legionella@health.ny.gov](mailto:HCF.legionella@health.ny.gov)
- Resample in 1 to 4 weeks
- For persistently positive culture results, implement long-term control measures

## Health Advisory *Guidance* – Attachment 3 August 10, 2015

*Guidance* on environmental sampling is provided in Attachment 3 of the Advisory:

- 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.
- During outbreaks and investigations the number of sampling events, and samples, would likely be increased

## Health Advisory *Guidance* – Attachment 3

### August 10, 2015

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 from the outlet side 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. 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 heater(s)

# Additional Provisions

## Recordkeeping

- The EAF, sampling and management plan, and sampling results shall be retained on-site for three years

## Enforcement

- The Department may conduct an assessment or *Legionella* culture sampling of the potable water system at any time

## Variations and Waivers

- A facility may submit a written application to the Department for a variance from any provision, for a period not to exceed 90 days
- The Department may issue a written general or specific waiver, where the Department is satisfied that such a waiver will not present a danger to public health

# Questions?

## *Email*

**Subpart 4-1**

**[cooling.tower@health.ny.gov](mailto:cooling.tower@health.ny.gov)**

**Subpart 4-2**

**[HCF.legionella@health.ny.gov](mailto:HCF.legionella@health.ny.gov)**

**(518) 402-7650**