

 **Department of Health**

## 10 NYCRR Part 4 - Protection Against *Legionella*

**Subpart 4-2, Health Care Facilities**

---

---

---

---

---

---

---

---

2

### Today's Presentation

- Brief overview of *Legionella* and Legionnaires' disease
- Clinical guidelines
- Infection prevention and control guidelines
- Part 4 regulatory requirements
  - Subpart 4-2: Healthcare Facilities
- Some guidance for Subpart 4-2

 **Department of Health**

---

---

---

---

---

---

---

---

3

### 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

 **Department of Health**

---

---

---

---

---

---

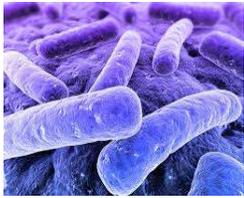
---

---

4

## Legionella

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



---

---

---

---

---

---

---

---

5

## Legionnaires' Disease (LD)

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



---

---

---

---

---

---

---

---

6

## 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



---

---

---

---

---

---

---

---

7

## 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





---

---

---

---

---

---

---

---

8

## 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



---

---

---

---

---

---

---

---

9

## 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



---

---

---

---

---

---

---

---

10

### 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



---

---

---

---

---

---

---

---

11

### 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



---

---

---

---

---

---

---

---

12

### 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



---

---

---

---

---

---

---

---

13

## Infection Control

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



---

---

---

---

---

---

---

---

14

## 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



---

---

---

---

---

---

---

---

15

## 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



---

---

---

---

---

---

---

---

16

## 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



---

---

---

---

---

---

---

---

17

## 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



---

---

---

---

---

---

---

---

18

## 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



---

---

---

---

---

---

---

---

## Regulatory Background

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

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

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




---

---

---

---

---

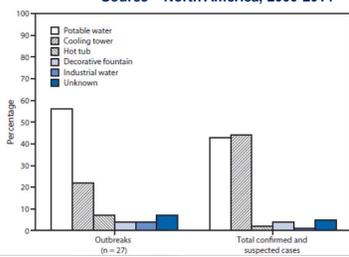
---

---

---

## CDC Data

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




---

---

---

---

---

---

---

---

## 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>



---

---

---

---

---

---

---

---

### NEW YORK STATE DEPARTMENT OF HEALTH Bureau of Water Supply Protection Environmental Assessment of Water Systems in Healthcare Settings

1. Type of Assessment (check as appropriate)  
 On-site assessment  Telephone assessment  Not applicable prior to telephone conference

2. Identify the person doing the assessment

Name: \_\_\_\_\_  
Job Title: \_\_\_\_\_  
Facility Name: \_\_\_\_\_  
FPI (Personnel Safety Identifier): \_\_\_\_\_  
Facility Address: \_\_\_\_\_

Date of Assessment: \_\_\_\_\_

3. Contact Information  
Telephone number (area and unit): \_\_\_\_\_  
EAX number: \_\_\_\_\_  
Email: \_\_\_\_\_

Instructions and Notes to the User (please read)

Please complete this form and keep it with your records. This does not need to be submitted to NYSDOH. This will be produced by NYSDOH as part of a routine inspection or during the final inspection of an outbreak.

This information collection tool may be used when 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 licensed lead inspector or a public health inspector, a hospital epidemiologist, infection control practitioner, engineer or other public health expert or others to reduce the risk of Legionnaires' disease associated with the facility. It may also be used by healthcare facilities to efforts to minimize the risk of Legionnaires' by the absence of evidence of other disease or when the facility is under construction or other circumstances.

For very large, complex healthcare facilities, completing the form may take several hours. Please keep in mind that this initial assessment of risk is a public health requirement and will be a time saving device for future assessments. Facilities with the facility's history of Legionnaires' disease or other waterborne outbreaks should be given priority. Please do not complete another check. If a question does not apply, write "N/A." If a question pertains to the assessment please explain why. When applicable, please specify the unit of measurement being used in a question. Do not check "not applicable" if you are completing this form electronically, you will see different text under "N/A" for your answers. This will save the form and ensure that additional information is added to the form as an existing form.

D09-5222 (09-15) v. 1.0

## Environmental Assessment Form



---

---

---

---

---

---

---

---

25

## 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




---

---

---

---

---

---

---

---

26

## 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




---

---

---

---

---

---

---

---

27

## 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
  - Resample in 1 to 4 weeks
  - For persistent results, implement long-term control measures




---

---

---

---

---

---

---

---

28

**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 the number of samples would likely be increased



---

---

---

---

---

---

---

---

29

**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 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. 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



---

---

---

---

---

---

---

---

30

**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

**Variances 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



---

---

---

---

---

---

---

---

31

## Questions?

<p><u>Environmental</u></p> <ul style="list-style-type: none"><li>• Subpart 4-1: <a href="mailto:Cooling.tower@health.ny.gov">Cooling.tower@health.ny.gov</a></li><li>• Subpart 4-2: <a href="mailto:HCF.legionella@health.ny.gov">HCF.legionella@health.ny.gov</a></li><li>• Phone: (518) 402-7650</li></ul>	<p><u>Clinical</u></p> <ul style="list-style-type: none"><li>• <a href="mailto:ICP@health.ny.gov">ICP@health.ny.gov</a></li><li>• Phone: (518) 474-1142</li></ul>
---	---



---

---

---

---

---

---

---

---