# CMS REQUIREMENTS TO REDUCE LEGIONELLA: RISK IN HEALTHCARE FACILITY WATER SYSTEMS

May 21, 2018



# LEGIONELLOSIS AND PUBLIC HEALTH

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# OUTLINE

- Ecology of Legionella
- Transmission
- Legionellosis disease
- Surveillance
- Prevention
- CMS Memo
- Water management programs
- Healthcare-associated cases
- Outbreak investigations
- Control measures



# LEGIONELLA BACTERIA

- Gram-negative bacillus
- Legionella are ubiquitous in natural and artificial fresh water environments
- Intracelluar parasite of free-living protozoa primarily found in fresh water
  - Legionella multiplies inside free-living amoeba
- Grows best in warm temperatures, 77°-110°F
  - Dormant under 77°F and killed above 124°F when temp held
- Legionella pneumonophila serogroup 1 causes majority of human illness (~90%), but other serogroups do cause disease



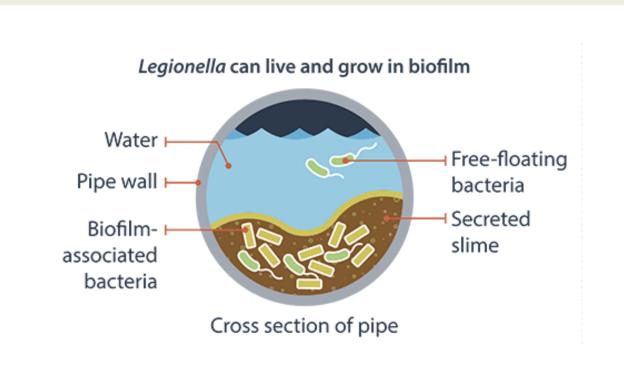


### FAVORABLE CONDITIONS FOR LEGIONELLA AMPLIFICATION

- Large, complex water systems
- Grow at warm temperatures 77°-110°F
- Stagnation
- Scale and sediment
- Biofilms
- Presence of amoebae and protozoa
- Natural rubbers, wood, some plastics support growth

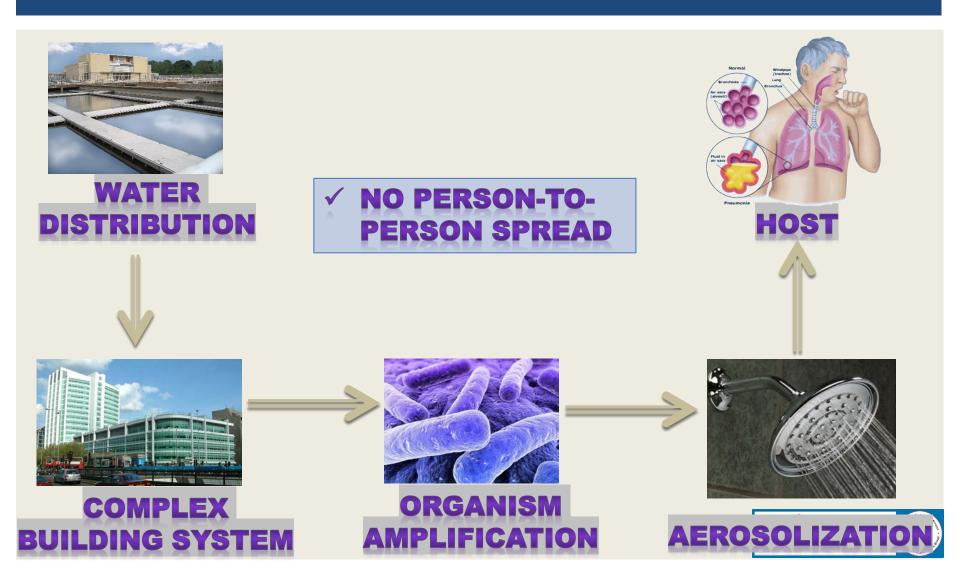


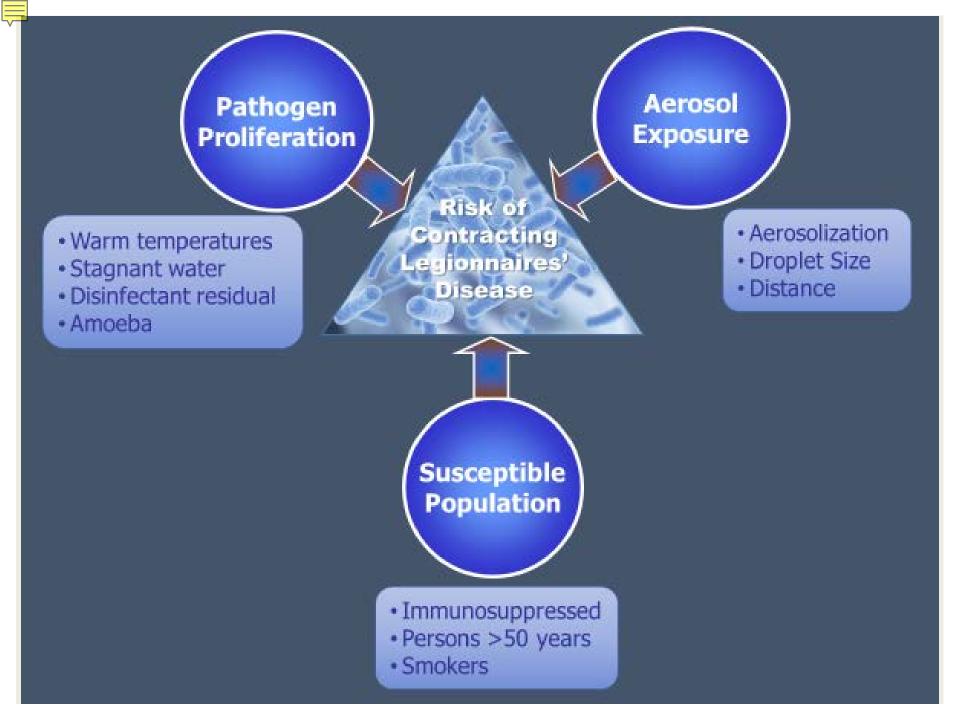
#### WHAT IS BIOFILM?





### TRANSMISSION





# LEGIONELLOSIS

#### Legionnaires' Disease

- Low attack rate: 5%
- High mortality: 5-30%
- Incubation: 2-14 days
- Fever: 102-105 °F
- Breathing difficulty
- Cough (dry, phlegm)
- Chills
- Chest pain

#### Pneumonia

#### **Pontiac Fever**

- High attack rate: 90%
- No mortality
- Incubation: 1-3 days
- Muscle aches
- Flu-like symptoms
- Self-limiting



# WHO IS AT RISK FOR LEGIONELLOSIS?

- Most healthy individuals do not become infected with Legionella bacteria after exposure. People at higher risk of getting sick are:
  - Older people (usually 50 years of age or older)
  - Current or former smokers
  - Those with a chronic lung disease (like COPD or emphysema)
  - Those with a weak immune system from diseases like cancer, diabetes, kidney failure, or HIV/AIDS
  - People who take drugs that suppress (weaken) the immune system (like after a transplant operation or chemotherapy)



# WHO TO <u>TEST</u> FOR LEGIONELLOSIS?

- Patients who have failed outpatient antibiotic therapy
- Patients with severe pneumonia, in particular those requiring intensive care
- Immunocompromised host with pneumonia
- Patients with pneumonia in the setting of a legionellosis outbreak
- Patients with a travel history (patients that have traveled away from their home within two weeks before the onset of illness)
- Patients suspected of healthcare-associated pneumonia



# WHAT TEST SHOULD BE USED??

#### Two tests are preferred for diagnosing Legionnaires' disease

- Legionella urine antigen test
  - Detects Legionella pneumophilia serogroup 1
- Culture of lower respiratory secretions (e.g. sputum) on selective media
  - Isolation on culture is important for detection on non-Lp1 species
  - Cultures are using for comparing clinical to environmental isolates during an investigation

#### BOTH urine antigen AND culture should be ordered







# PUBLIC HEALTH INVESTIGATIONS



# NATIONAL DISEASE BURDEN

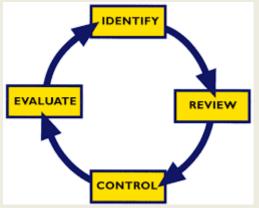
- Number one cause of atypical community-acquired pneumonia among patients admitted to ICU
- 8,000-18,000 hospitalizations in the U.S. each year
- Inpatient cost estimates \$92-582 million each year
- About 10-20% of cases are outbreak associated
- More than 20% of cases reported to CDC are travelassociated
- Nationally, the rate of legionellosis cases has quadrupled 2000-2015
- If Legionnaires' disease is healthcare associated, the fatality rate is 25% (1 in 4 patients)



From the Centers for Disease Control and Prevention

### SURVEILLANCE RATIONALE

- Monitor and describe incidence and trends of cases
- Rapidly recognize cases that occur in similar locations or with similar exposures
- Identify opportunities for control and prevention





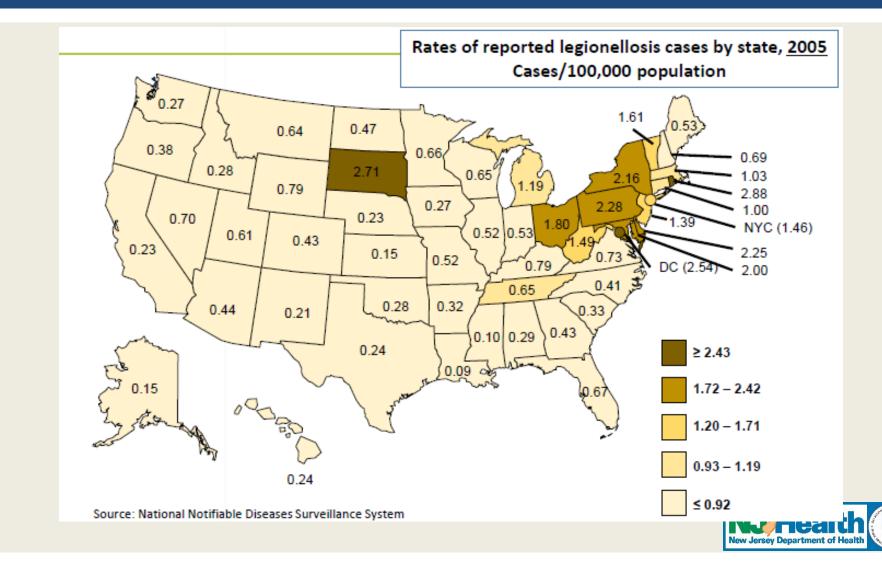
# **CASE DEFINITIONS**

#### **Confirmed Legionnaires' Disease:**

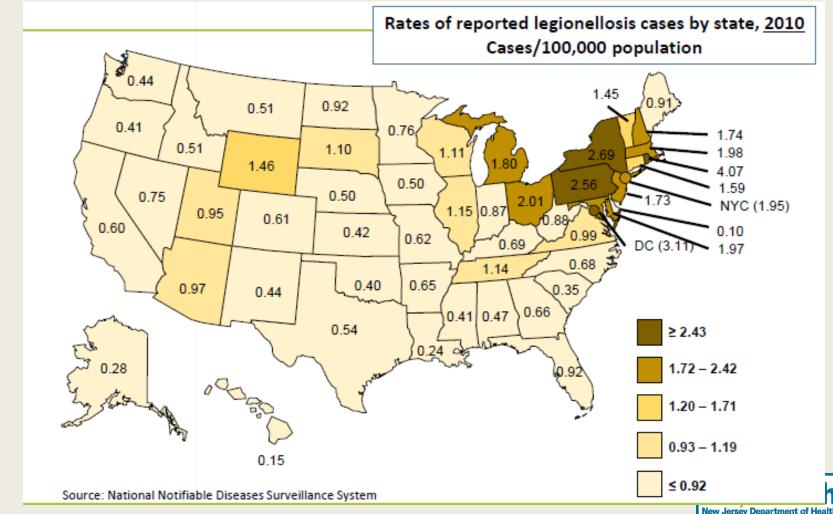
- Clinical: fever, myalgia, cough and clinical or radiographic pneumonia (Pontiac Fever- no pneumonia)
- Laboratory:
  - By culture: isolation of any Legionella from respiratory, lung tissue, other sterile site
    - By urinary antigen: detection of L. pneumophila serogroup 1 in urine
    - By seroconversion: fourfold or greater rise in antibody titer to L. pneumophila serogroup 1
- Suspect (no Probable Case)



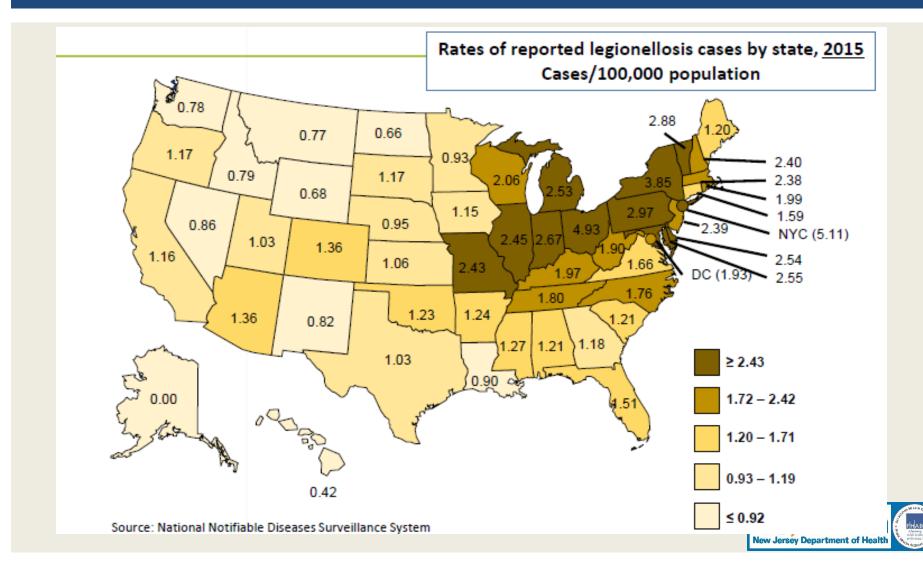
# INCREASES ACROSS THE COUNTRY 2005



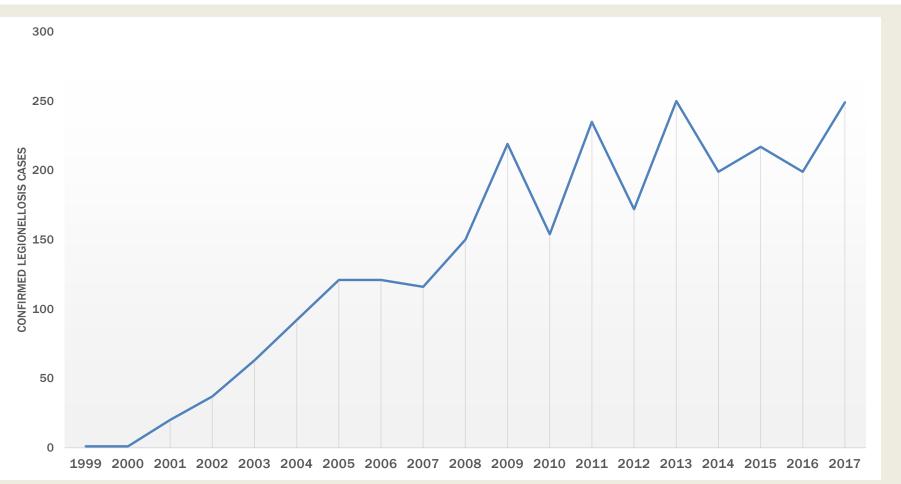
# **INCREASES ACROSS THE COUNTRY** 2010



# INCREASES ACROSS THE COUNTRY 2015

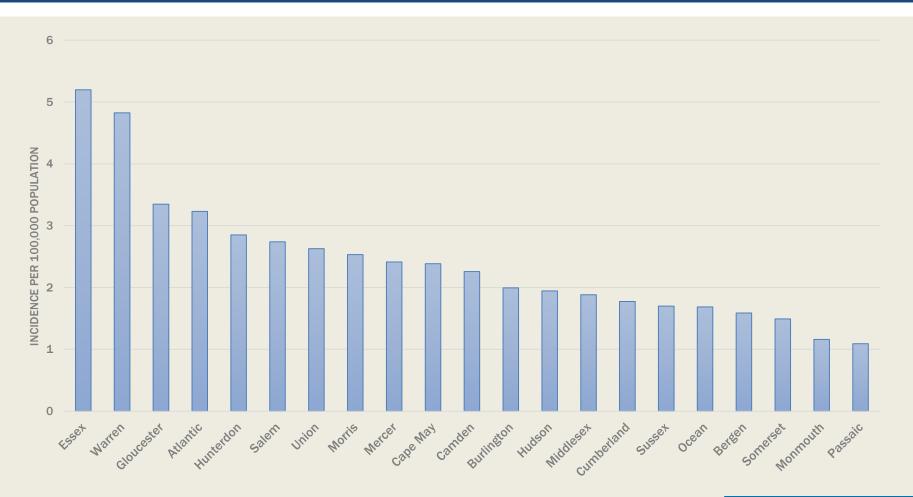


# CONFIRMED LEGIONELLOSIS CASES IN NEW JERSEY, 1999-2017



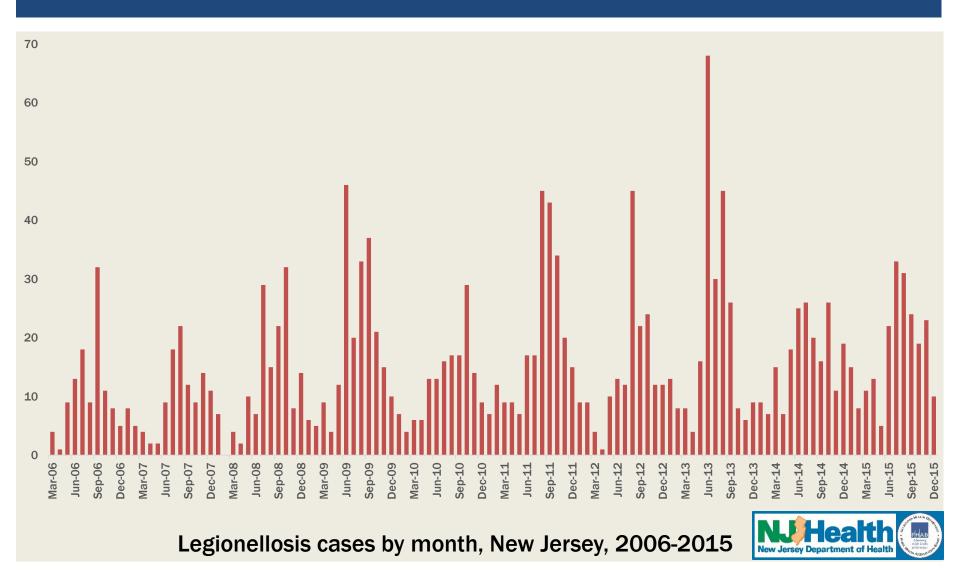


#### AVERAGE ANNUAL INCIDENCE OF REPORTED LEGIONELLOSIS CASES PER 100,000 POPULATION, BY NJ COUNTY, 2008-2017





#### SEASONALITY OF LEGIONELLOSIS



# **REPORTING OF CASES**

- Cases are reported into NJ's Communicable Disease Reporting and Surveillance System (CDRSS)
- Local Health Departments are responsible for performing a disease investigation into each case reported for their residents
- Information needed includes:
  - Illness onset
  - Incubation period
  - Potential exposures (include water, LTC resident, over-night travel, decorative fountains)

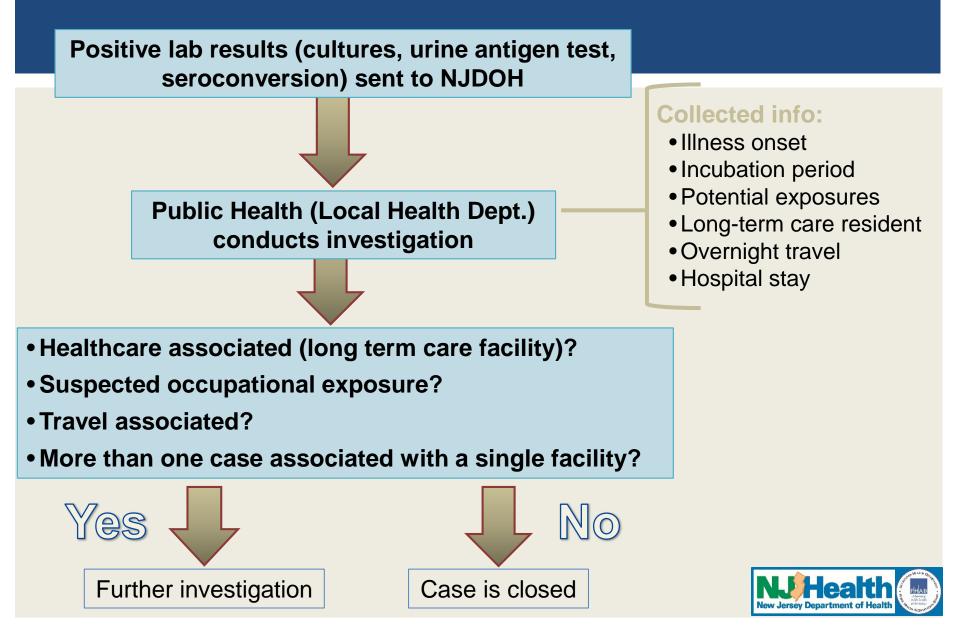


# **OUTBREAKS AND CLUSTERS**

- Public health identifies cases through
  - Surveillance
  - Healthcare
  - Other states
  - CDC
- Case may be identified to be:
  - Travel-associated
  - Healthcare-associated
  - Community-associated



# **PUBLIC HEALTH RESPONSE**



# **PERFECT PARTNERSHIP**

- Public Health
  - LHD
  - NJDOH
- Healthcare Stakeholders
  - Acute care
    - Patients being seen who may be cases
    - IPs obtaining pertinent info
  - Long-term care
    - Residents with pneumonia
    - Building investigations





# PREVENTION: WATER MANAGEMENT PROGRAMS

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### CMS S&C 17-30-HOSPITALS/CAHS/NHS

S&C revised 06-09-2017

Provides background on Legionella infections

Applicable to Hospitals and Nursing Homes

Provides expectations for Healthcare Facilities



## **HOSPITAL REGULATORY AUTHORITY**

42 CFR 482.42 (Infection Control - Condition of Participation)

"The hospital must provide a sanitary environment to avoid sources and transmissions of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases."



# SKILLED NURSING FACILITIES REGULATORY AUTHORITY

42 CFR 483.80 (Infection Control - F880)

"The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections".



# FACILITY EXPECTATION

- Conduct a facility risk assessment to identify where Legionella and other opportunistic waterborne pathogens could grow and spread in the facility water system
- Implement a water management program that considers ASHRAE industry standard and the CDC toolkit
- Specify testing protocols and acceptable ranges for control measures



### FACILITY RISK ASSESSMENT

Conduct a facility risk assessment for potential areas for growth and spread of *Legionella* or other opportunistic waterborne pathogens which includes:

- Conducting environmental assessment
- Identifying buildings at increased risk for Legionella
- Considering patient risk groups and healthcare reservoirs



# FACILITY RISK ASSESSMENT

Conduct environmental assessment/identify at risk buildings:

- Age/condition of building
- Age/condition of water system
- Place in water systems where legionella could amplify or biofilms could form
- Places in water systems that create aerosols

https://www.cdc.gov/legionella/downloads/environ-assess-instrument.pdf https://www.cdc.gov/legionella/maintenance/wmp-risk.htm



# FACILITY RISK ASSESSMENT

Consider patient/resident risk groups and healthcare reservoirs:

**Occupant characteristic:** 

- Age
- Pre-existing disease
- Immune status

Healthcare reservoirs:

- Patient care devices
- Medical equipment



### WATER MANAGEMENT PROGRAM

Implement a water management program that considers ASHRAE industry standard and the CDC toolkit

- Establish a water management team
- Describe the building water systems
- Identify areas where Legionella could grow and spread
- Decide where to apply and how to monitor control measures
- Establish ways to intervene when control limits aren't met
- Ensure program is running as designed and is effective
- Document and communicate all activities



### WATER MANAGEMENT PROGRAM

- Establish a water management team: Consider who among your employees, partners, and outside experts can provide the skills needed to develop and implement your Legionella water management program.
  - Facility Director
  - Facility Administrator
  - Medical Director
  - Health and Safety
  - Infection Control
  - Environmental Services
  - Chief Engineer
  - Maintenance Director

#### Describe the building water systems:

 Use a flow diagram or schematic and a written description which includes where the building connects to the municipal water supply, how water is distributed, and where water heaters/boilers, and cooling towers are located.



#### HOW IS WATER PROCESSED AND USED

#### How is water processed?

- Heated
- Cooled
- Stored
- Disinfected
- Distilled
- Filtered
- How is water used?
  - Food prep and sanitation
  - Patient care, showering, bathing
  - Housekeeping and environmental services
  - Drinking fountains and ice machines
  - Fire suppression/emergency eye wash
  - Process water, heating & cooling
  - Decorative fountains
  - Pools, spas, hydrotherapy
  - Dental



#### WATER MANAGEMENT PROGRAM

#### Identify areas where Legionella could grow and spread:

- Identify where potentially hazardous conditions could occur such as areas where water temperatures could promote Legionella or where water flow may be low.
- Decide where to apply and how to monitor control measures:
  - Establish control measures and limits for each hazardous condition, as well as plans for where and how to monitor. Control measures are heating, adding disinfectant, or cleaning. Control limits are the range of values that are acceptable for the control measures you are monitoring to reduce Legionella growth.



#### WATER MANAGEMENT PROGRAM

#### Establish ways to intervene when control limits aren't met:

 Determine what corrective actions or contingency responses to take when control measures are outside of the control limits you established.

#### Ensure program is running as designed and is effective:

 Establish procedures, both initially and on an ongoing basis, to verify that your team is implementing the water management program as designed.



#### WATER MANAGEMENT PROGRAM

#### Document and communicate all activities:

- Document all the activities and communicate with building occupants, employees, and colleagues on a continual basis.
- If an event triggers you to review or update your water management program:
  - Update the flow diagrams, associated control points, control limits, and corrective actions. Update the written description of your building water system, train those responsible for implementing and monitoring the updated program.



### **TESTING PROTOCOLS**

- Specify testing protocols and acceptable ranges for control measures:
  - Water quality management parameters such as disinfectant and temperature levels should be monitored regularly to ensure that building water systems are operating in a way to minimize hazardous conditions that can promote growth of Legionella.
  - It is up to the team to determine how to validate the effectiveness of the program. Sampling plans are unique to each facility and dependent on several factors such as baseline test results, overall performance of water management program, building characteristics, and sites of possible exposure to aerosolized water.



# RESPONSE: CONFIRMED HAI CASES

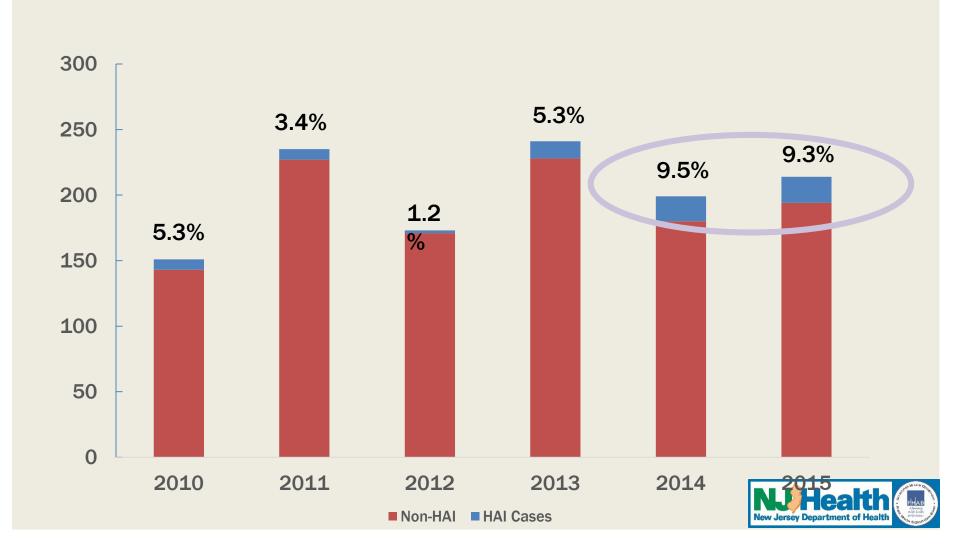


#### **HEALTHCARE-ASSOCIATED CASES**

- Notification from Infection Preventionist in healthcare setting (patients usually very ill)
  - Long term care facility, assisted living, nursing home
  - Acute care hospital
- Public health response differs depending on patient's exposures, extent of outbreak, capability of facility
- One case of healthcare-associated legionellosis leads to a full epidemiologic and environmental investigation if the case spend their entire incubation period in the facility



## HEALTHCARE ASSOCIATED CASES NEW JERSEY, 2010-2015



#### **INITIAL STEPS IN HAI INVESTIGATIONS**

- One confirmed case of legionellosis in LTC resident or acute care stay = FULL INVESTIGATION
- LHD to verify the person meets confirmed case definition
- LHD to establish illness onset date and incubation period
- LHD needs to confirm patient was only in LTC (or healthcare facility) during incubation period



## **INVESTIGATION CONTINUES**

- Once case is linked to the building, NJDOH generates an Outbreak Number (E-number)
- LHD and NJDOH to set up conference call with facility
  - Facility Administrators
  - Director of Nursing
  - Infection Preventionist
  - Facility Manager and Maintenance
- Information needed on initial conference call:
  - Clinical information on the case (nebulizer, oxygen, aspiration risk?)
  - Possible water exposures of the case
  - Building information (age, size, number of water outlets)



#### **IMMEDIATE ACTIONS FOR FACILITY**

- Immediate prevention actions: shower filters, bottled water, removing aerators from sinks
- Hiring water consultant with experience in Legionella control
- Schedule building walk-through with consultant, LHD and NJDOH represented
- On-going surveillance for clinical pneumonias
- Review of water management program in-place
- Water sampling for Legionella culture
- Risk communication to residents/families
- Remediation
- Follow-up testing



## **BUILDING INFORMATION**

- Age, size & construction, room configurations
- Renovation History
- Plumbing system
  - Design
  - Number & type of water outlets
  - Preventive Maintenance
  - Connection to fire sprinkler system
- Heating/Cooling System
- Occupancy rate
- Water management program documentation





#### **BUILDING ASSESSMENT**

- Water condition (CI, Temp & pH)
- Whirlpool spas and hot tubs, tubs
- Decorative fountains
- Cooling towers and evaporative condensers
- AC drip pan drainage
- Recent or ongoing construction/renovation
- Repair or construction of public water system









#### SOURCES OF EXPOSURE

#### Breath mist

- Cooling tower mist
- Showers & aerators
- Nebulizer
- Hot tub/whirlpool
- Decorative fountain
- Aspiration of water
  - Ice machines
  - Drinking tap water
  - Eating food made with tap water









#### **BIOFILMS IN HEALTHCARE**

#### Piping

- Water hammer arrestors
- Shower heads and hoses
- Aerators and flow restrictors
- Sink basins, drains and traps
- Devices attached to or filled with potable water supply
  - Ice machines
  - Automated endoscope reprocessors
  - Humidifiers
  - Heater-cooler units



#### **PLUMBING SYSTEM RISK FACTORS**

- Tanks sediment & temp stratification
- Biofilm & scale in plumbing
- Deadlegs" stagnant water
  - Pipes inappropriately capped off
  - Unused rooms (sections closed off, rooms unoccupied)
- Rubber gaskets & expansion tank lining
- Water temperature & CI at outlets





#### **PRE-REMEDIATION SAMPLING**

- Use a CDC certified ELITE Laboratory (http://www.cdc.gov/legionella/elite.html)
- Sample & process 1 liter
- Approximately 10% of outlets
  - Rooms associated with case
  - Rooms distal to the case room
  - Unused & underused outlets
- All tank(s) top & bottom
- Hot water return(s)
- Incoming water



#### **PRE-REMEDIATION ACTIONS**

- Identify and remove dead legs
- Drain, clean, and flush water heater
- Remove and disinfect faucet aerators & shower heads
- Eliminate/minimize rubber, plastic, and silicone washers and gaskets
- Eliminate other points of stagnation
- Inspect sprinkler backflow preventers
- Biocides
  - protozoans & biofilms pose barriers



## **REMEDIATION-SHOCK TREATMENT**

## Superheat

- Post warnings
- Hot H<sub>2</sub>O tank
  - drain & flush
  - Raise temp to 160 °F
  - hold 3 hrs.
- Flush outlets
  - 140 °F @ 2 min
  - hold 2 hrs.
  - 140 °F @ 2 min
- Reduce temp

## Hyperchlorinate

- Post warnings
- Isolate H<sub>2</sub>O tank
  - drain & flush
  - Raise Cl<sub>2</sub> to 50 ppm
  - hold 3 hrs.
  - circulate & test: 30 ppm
- Flush outlets
  - draw & test: 30 ppm
  - hold 16 hrs.
  - draw & test: 10 ppm
- Reduce Cl<sub>2</sub>
  - < 2 ppm</p>



#### SAMPLING RECOMMENDATIONS

- 3-5 days after remediation
- Same locations as pre-remediation
- Can change after >3 consecutive NDs.
- Every 2 weeks for 3 months
- Monthly for 3 months
- Quarterly for 1.5 years



## CONTROL ACTIONS

- Implement flushing program
  - Hot water heater
  - Operational deadlegs
  - Back-flow prevention
- Monitor water Temp, CI & pH
- Install point-of-use water heaters
- Test water for Legionella on-going
  - Is organism controlled?
- Implement periodic remediation program
- Install secondary disinfection system?
- Install thermostatic mixing values at outlets



## BUILDING-ASSOCIATED OUTBREAKS (N=27): COMMON CAUSES (2000-2014)

- 65% (about 2 in 3) were due to process failure
- 54% (about 1 in 2) were due to human error
- 35% (about 1 in 3) were due to equipment failures
- 35% (about 1 in 3) were due to unmanaged external change
- 48% (about 1 in 2) were due to more than one of the above problem

# Water management problems can lead to Legionnaires' disease outbreaks



#### **PREVENTION IS THE KEY**

- Water management programs reduce the potential for Legionella and other waterborne pathogens to amplify in building water systems.
- Reduce potential building occupants to be exposed to water containing Legionella bacteria.
- If Legionnaires' disease is healthcare associated, the fatality rate is 25% (1 in 4 patients)
- "Legionella is easier to prevent than control"
- A multi-step, dynamic, continuous process!



#### **REPORTING REQUIREMENTS**

8:43E-10.11 (e) Other reporting requirements unrelated to the Patient Safety Act

A health care facility shall report incidents of infectious and communicable diseases to the Department pursuant to N.J.A.C. 8:57

#### 8:57-1.5 (b) Reportable communicable diseases

Health care providers and administrators shall report within 24 hours of diagnosis as set forth at NJ.A.C. 8:57-1.6 confirmed cases of the following reportable communicable diseases: Legionellosis (Legionella spp.)



#### RESOURCES

- CDC, Considerations when working with Legionella Consultants <u>https://www.cdc.gov/legionella/wmp/consultant-considerations.html</u>
- CDC, Legionella <u>https://www.cdc.gov/legionella/index.html</u>
- CDC, Toolkit to Developing a Water Management Program <u>https://www.cdc.gov/legionella/downloads/toolkit.pdf</u>
- CDC, Monitoring Water Quality <u>https://www.cdc.gov/legionella/wmp/monitor-water.html</u>
- CDC, Environmental Investigation Resources <u>https://www.cdc.gov/legionella/health-depts/environmental-inv-resources.html</u>
- CMS, Requirement to Reduce Legionella Risk in Healthcare <u>https://www.cms.gov/Medicare/Provider-Enrollment-and-</u> <u>Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-30.pdf</u>
- ASHRAE 188: Legionellosis Risk Management for Building Water Systems <u>https://www.cdc.gov/legionella/health-depts/ashrae-faqs.html</u>
- Department of Veteran Affairs, Prevention of HAI Legionella disease <u>https://www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=303</u>



## **THANK YOU!**

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