# Reducing *Legionella* Risk in Your Buildings

March 29, 2017

# Speakers

Ray Petrisek,
Director of Environmental Microbiology

HP Environmental
An AIHA accredited Environmental Microbiology laboratory

Dan Broder, PhD
Lead Scientist, Legiolert R&D Team

IDEXX
Global provider of water microbiology testing solutions.

# Agenda

*Legionella* and the Industrial Hygienist (Ray)

*Legionella* Basics (Dan)

Tools for Reducing the Risk of Legionnaires' disease
- Water Management Plans (Ray)
- Routine Monitoring (Dan)

Questions (Ray and Dan)

# Where is the hazard?

"In the United States, Legionnaires' disease has proven to be the most lethal building-related illness associated with water-borne bacteria."

"The New Age of *Legionella*"
The Synergist, July 2015

# The Industrial Hygiene approach

Anticipation

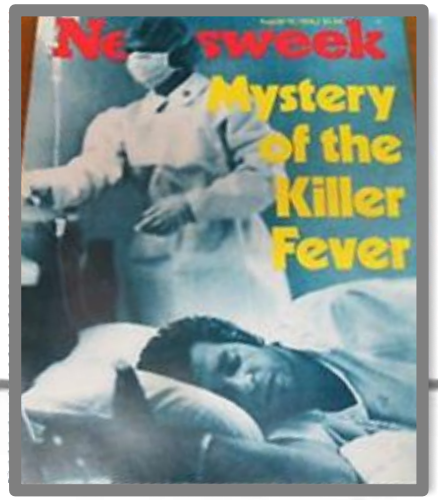
Recognition

Evaluation

Control

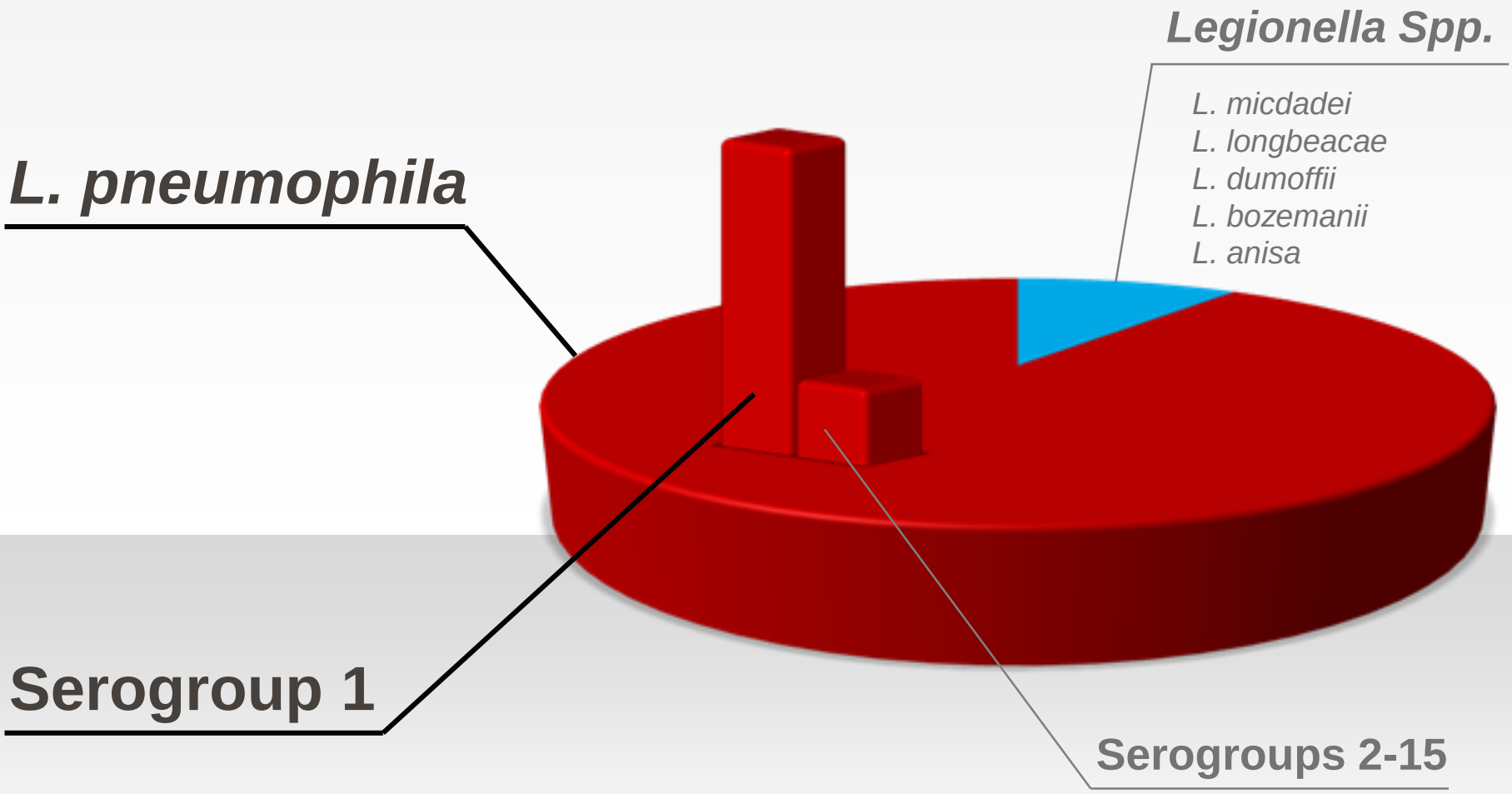
of workplace and environmental hazards, including *Legionella*

# What is *Legionella*?

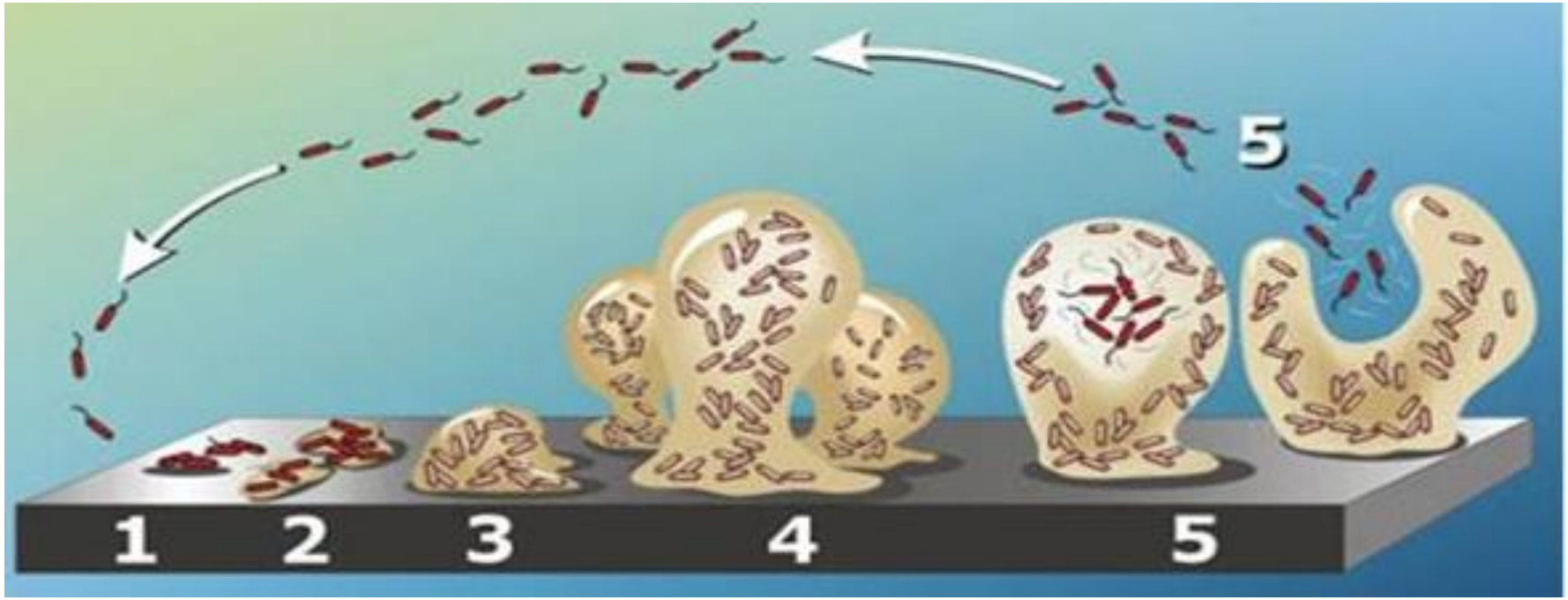





# *Legionella* Species



# Biofilm – stable structures and breeding grounds




# Where does *Legionella* live?

## Potable Water

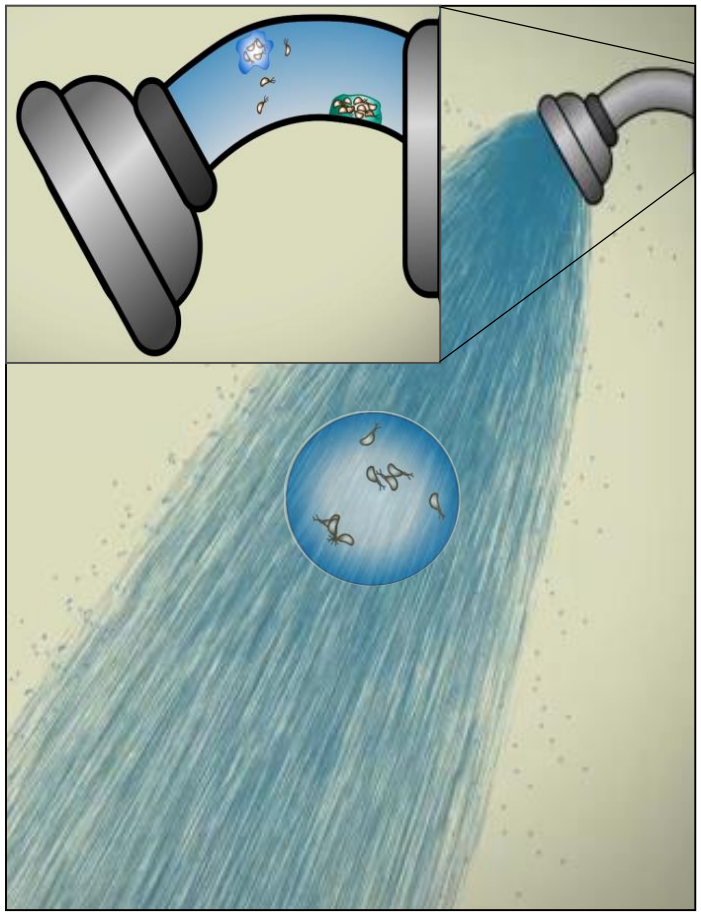
# Where does *Legionella* live?

## Nonpotable Water

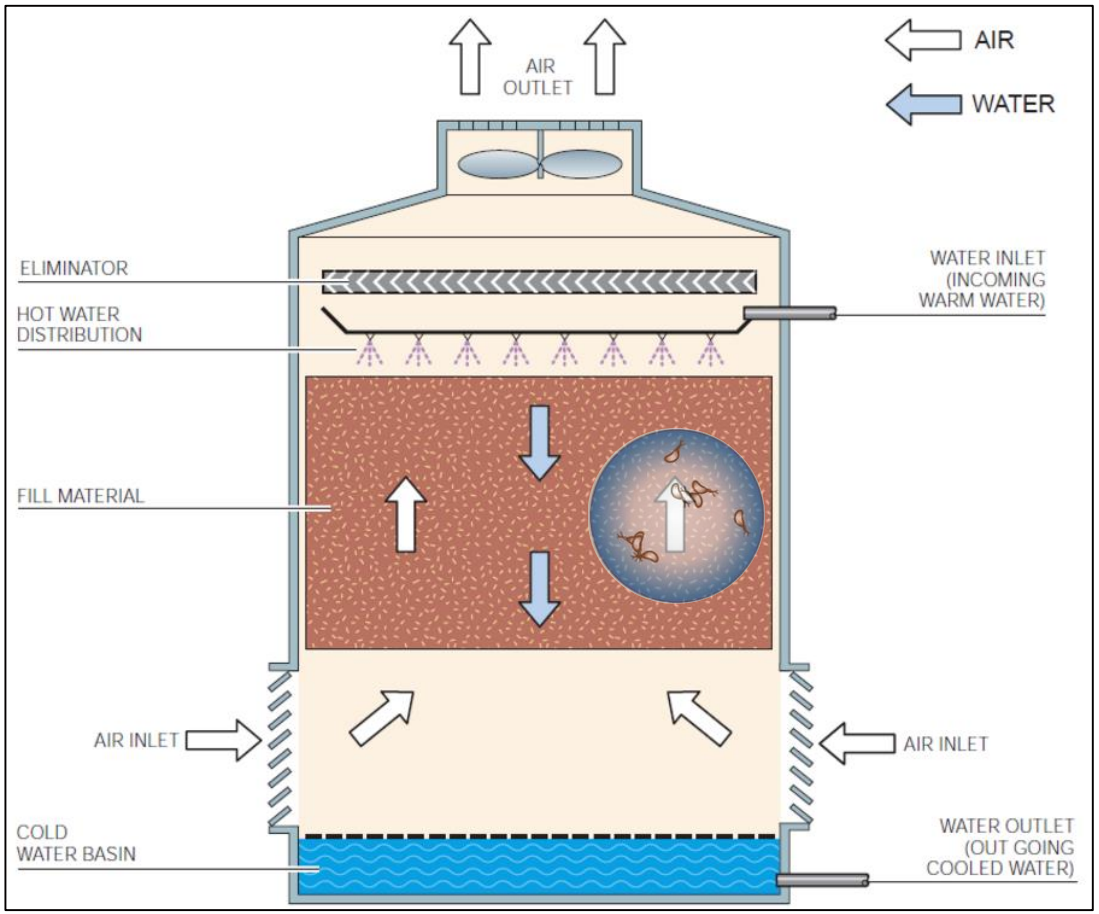





# Infectivity – *Legionella* are aerolized

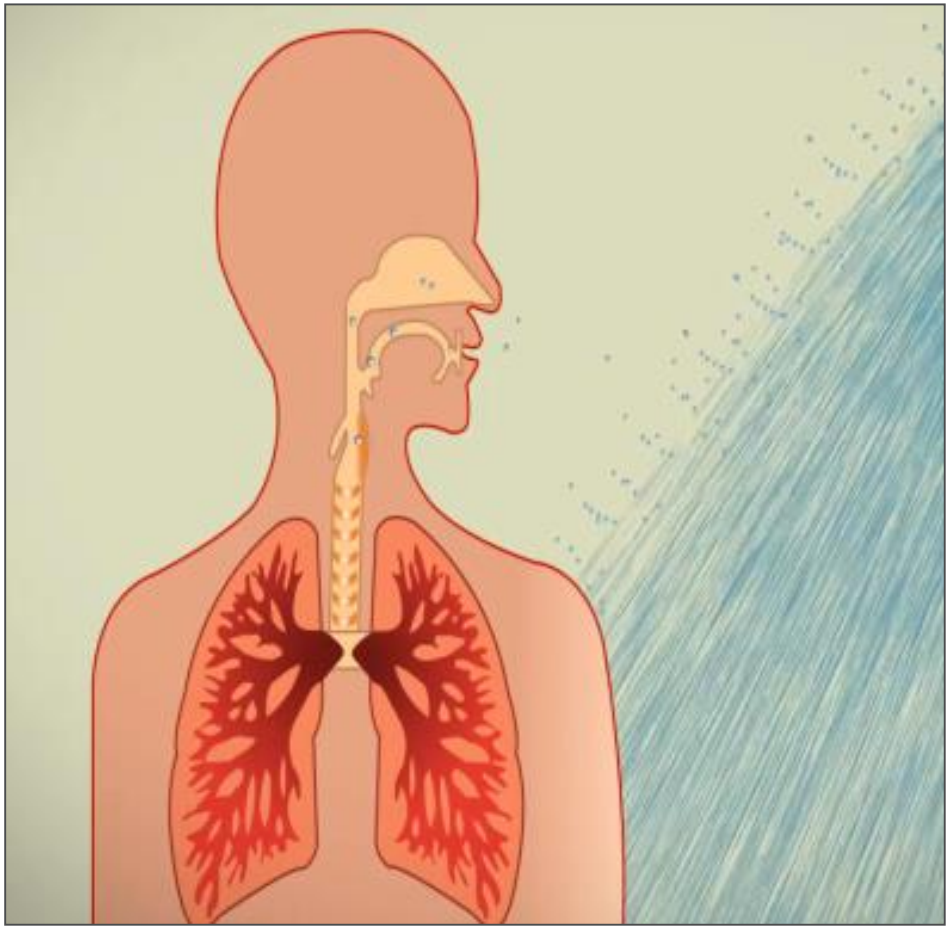


Shower aerosol




Cooling tower aerosol

# Infectivity – Infected water droplets are aspirated into the lungs.



# Risk Groups

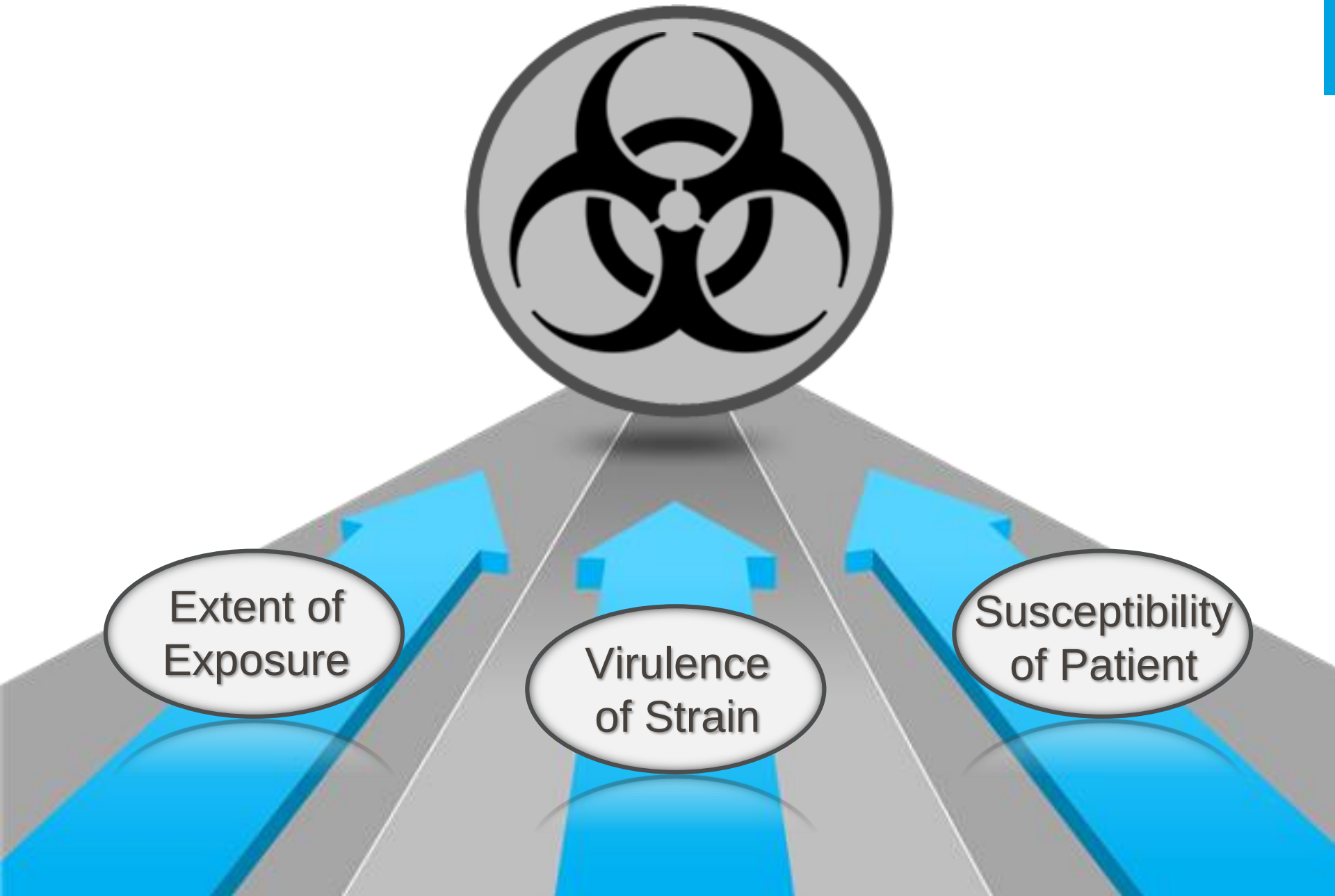
Chronic Lung Disease

Smokers

Immunocompromised

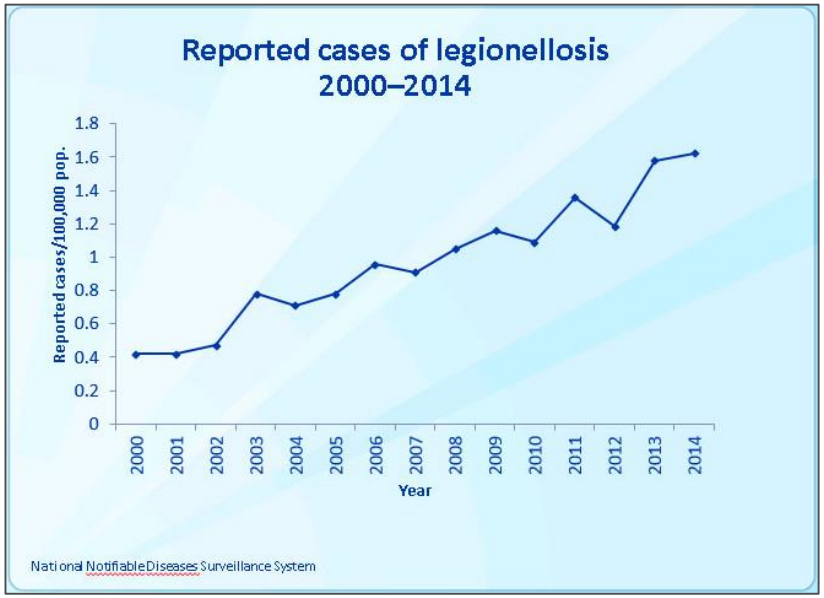
> 50 years

# Risk Factors



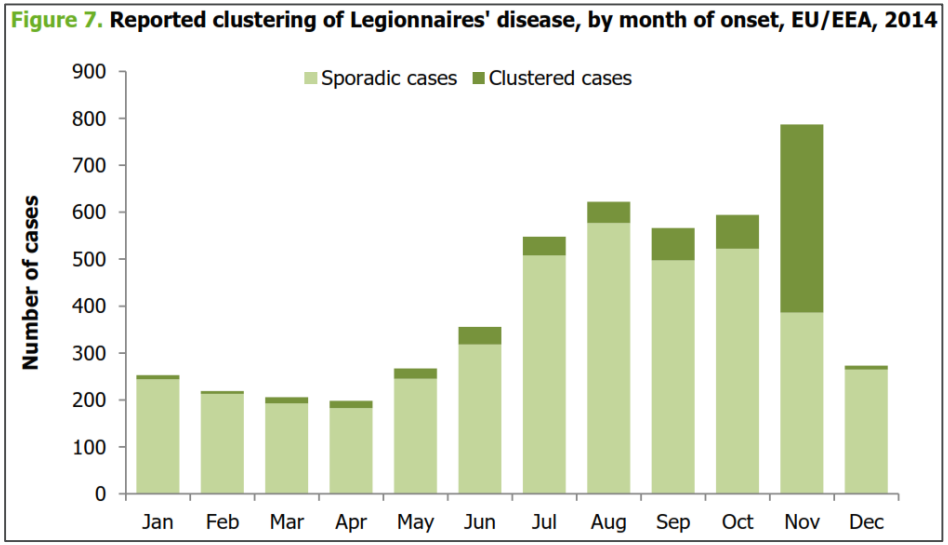
# Why should you be concerned with *Legionella*?

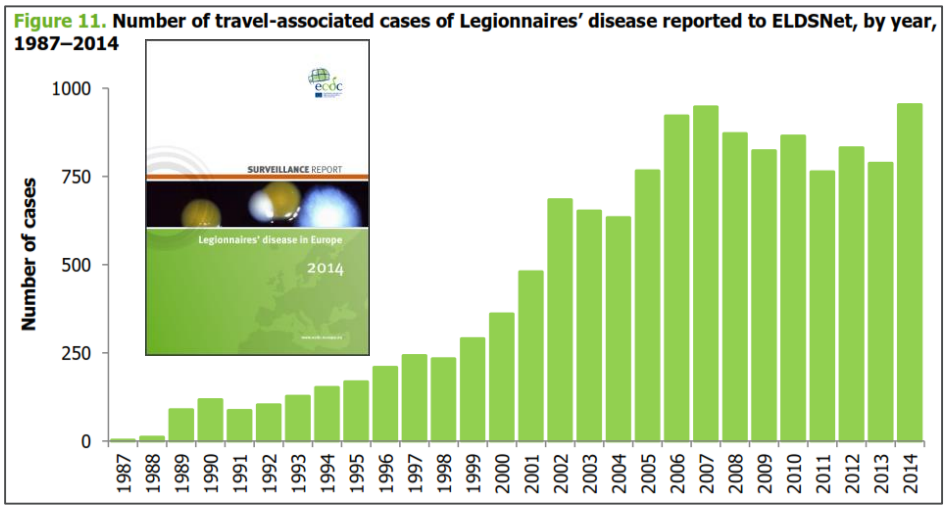
- The # of cases of legionellosis have increased 286% over the past 14 years
- 8,000 to 18,000 people contract legionellosis in the U.S. each year (estimated)
- 5-15% of the known cases of legionellosis are fatal




http://www.cdc.gov/legionella/surv-reporting.html

*"During 2000–2014, passive surveillance for legionellosis in the United States demonstrated a 286% increase in reported cases per 100,000 population"*

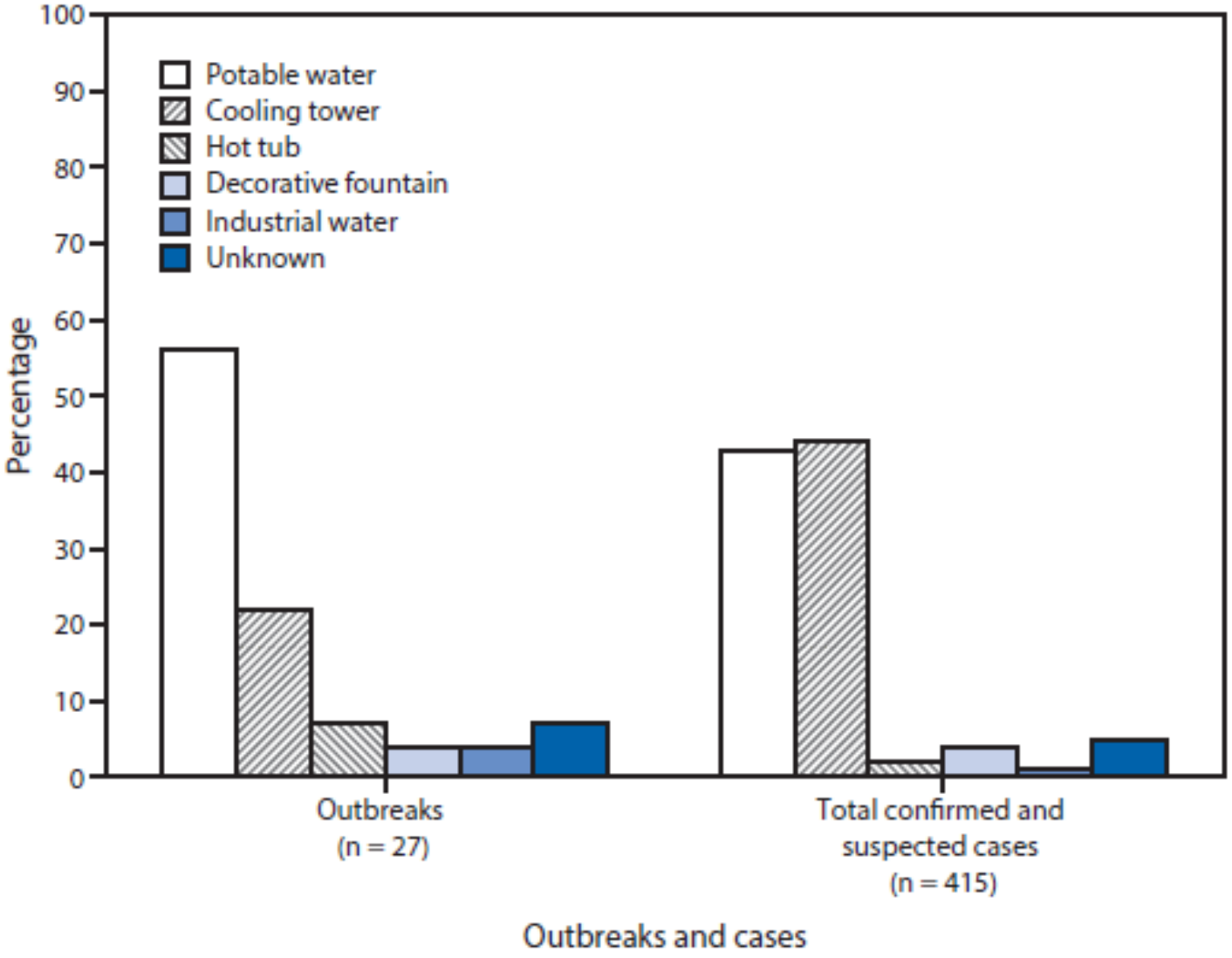


# Significant *Legionella* Outbreaks 2000 – 2016, N. America

| Year | Month | TYPE | CITY | STATE | CAUSE | CASES | DEATHS |
|---|---|---|---|---|---|---|---|
| 2005 | April | Hospital | New York | NY | Distrib. Syst. | 4 | 2 |
| 2006 | June | Hospital | San Antonio | TX | Distrib. Syst. | 10 | 2 |
| 2006 | February | Hotel | Daytona | FL | Distrib. Syst. | 3 | 1 |
| 2007 | September | Long-term Care | Roslyn Heights | NY | Unknown | 5 | 3 |
| 2007 | July | Hospital | Grand Rapids | MI | Distrib. Syst. | 1 | 1 |
| 2008 | September | Hospital | New Brunswick | NJ | Distrib. Syst. | 8 | 3 |
| 2008 | March | Hospital | Rochester | NY | Distrib. Syst. | 3 | 1 |
| 2008 | June | Community | Syracuse | NY | Distrib. Syst. | 13 | 1 |
| 2009 | October | Long-term Care | Baltimore | MD | Unknown | 7 | 1 |
| 2009 | November | Long-term Care | Vernon Hill | IL | Unknown | 4 | 2 |
| 2009 | July | Hospital | Utica | NY | Unknown | 3 | 2 |
| 2009 | December | Hotel | Miami | FL | Unknown | 3 | 1 |
| 2010 | May | Hospital | Des Moines | IA | Distrib. Syst. | 2 | 1 |
| 2010 | January | Long-term Care | Kingston | NY | Unknown | 2 | 1 |
| 2011 | September | Longterm Care | Turtle Creek | PA | Distrib. Syst. | 8 | 1 |
| 2011 | September | Longterm Care | Turtle Creek | PA | Distrib. Syst. | 3 | 1 |
| 2011 | October | Long-term Care | Plant City | FL | Unknown | 3 | 1 |
| 2011 | November | Long-term Care | Ellicott City | MD | Unknown | 1 | 1 |
| 2011 | March | Hospital | Dayton | OH | Unknown | 10 | 1 |
| 2011 | April | Hospital | Spokane | WA | Distrib. Syst. | 3 | 1 |
| 2012 | January | Hotel | Las Vegas | NV | Unknown | 3 | 1 |
| **2012** | **August** | **Hotel** | **Quebec City** | **CA** | **Cooling tower** | **180** | **13** |
| 2012 | November | Hospital | Pittsburgh | PA | Distrib. Syst. | 16 | 5 |
| 2013 | October | Hospital | South Whitehall Township | PA | Unknown | 6 | 1 |
| 2013 | July | Longterm Care | Reynoldsburg | OH | Distrib. Syst. | 35 | 4 |
| **2014** | **June** | **HALD and Community** | **Genesee County** | **MI** | **Flint water system** | **91** | **12** |
| 2014 | May | Hospital | Birmingham | AL | Distrib. Syst. | 8 | 2 |
| 2014 | May | Hospital | Pittsburgh | PA | Ice Machine | 3 | 1 |
| 2014 | February | Hospital | Indianapolis | IN | Unknown | 2 | 2 |
| 2015 | November | Community Acquired | Hannibal | MO | Not determined | 3 | 1 |
| 2015 | October | Healthcare | Syracuse | NY | Building water system | 3 | 1 |
| **2015** | **August** | **Community** | **South Bronx** | **NY** | **Cooling Tower** | **127** | **12** |
| 2015 | July | Rehab Center | Chicago | IL | Not determined | 1 | 1 |
| 2016 | August | Healthcare | Seattle | WA | Not confirmed | 4 | 2 |

# Outbreaks: potable vs. nonpotable water




https://www.cdc.gov/mmwr/volumes/65/wr/mm6522e1.htm

# *Legionella* is ubiquitous, but it can be managed

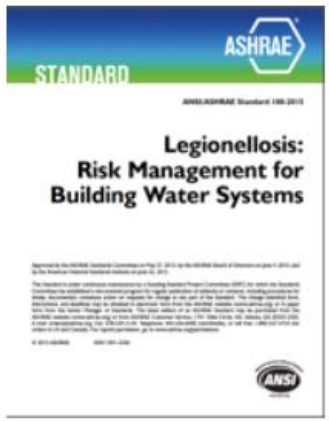
Up to 70% of all building water systems are contaminated with *Legionella*

Both utility (i.e., cooling towers, air conditioning systems, etc.) and potable waters are potential sources of *Legionella* contamination

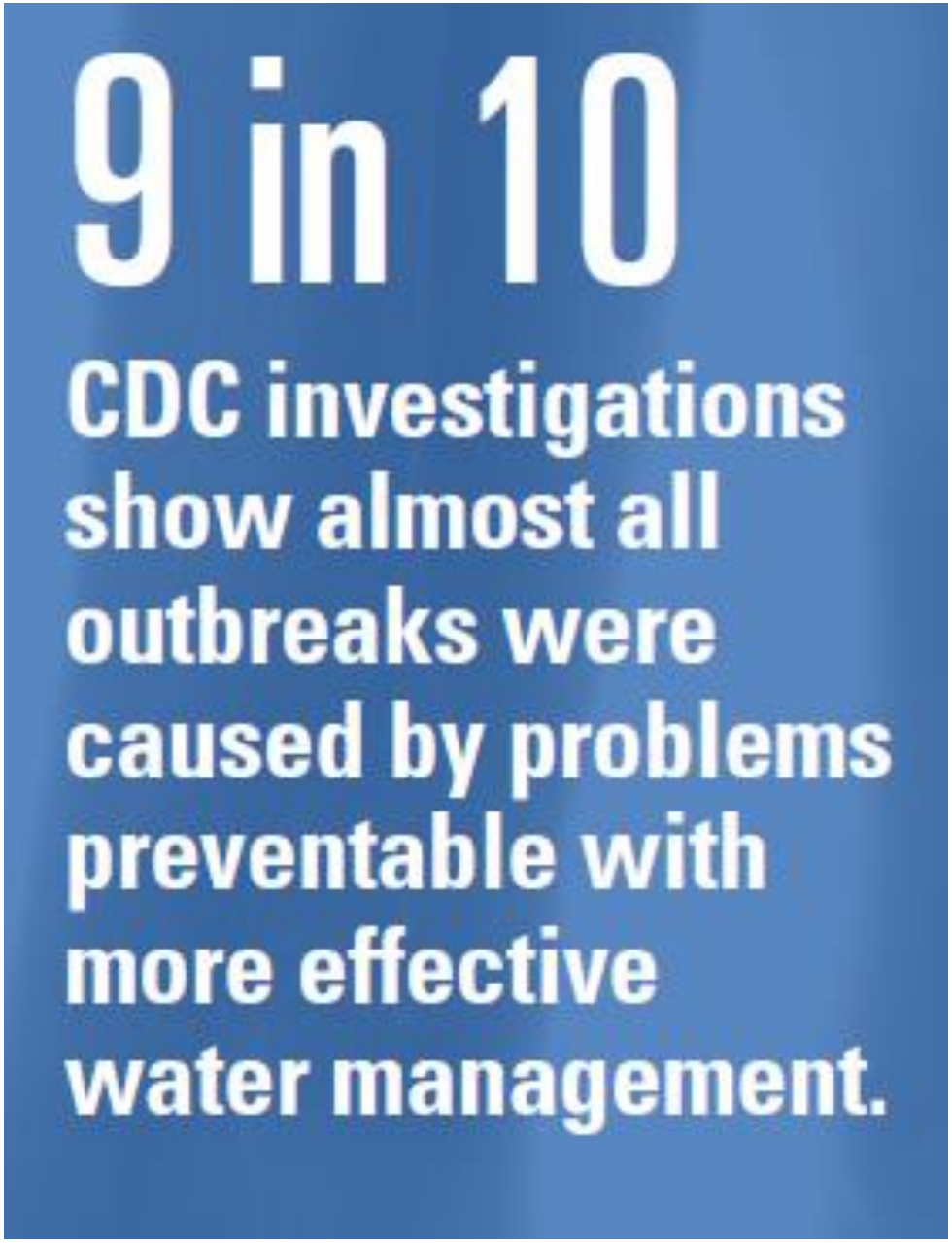
Building owners & managers are potentially liable and may incur considerable financial penalties

Legionellosis is a **growing public health issue** that **is preventable**

What can be done to reduce the risk of exposure to Legionella bacteria?

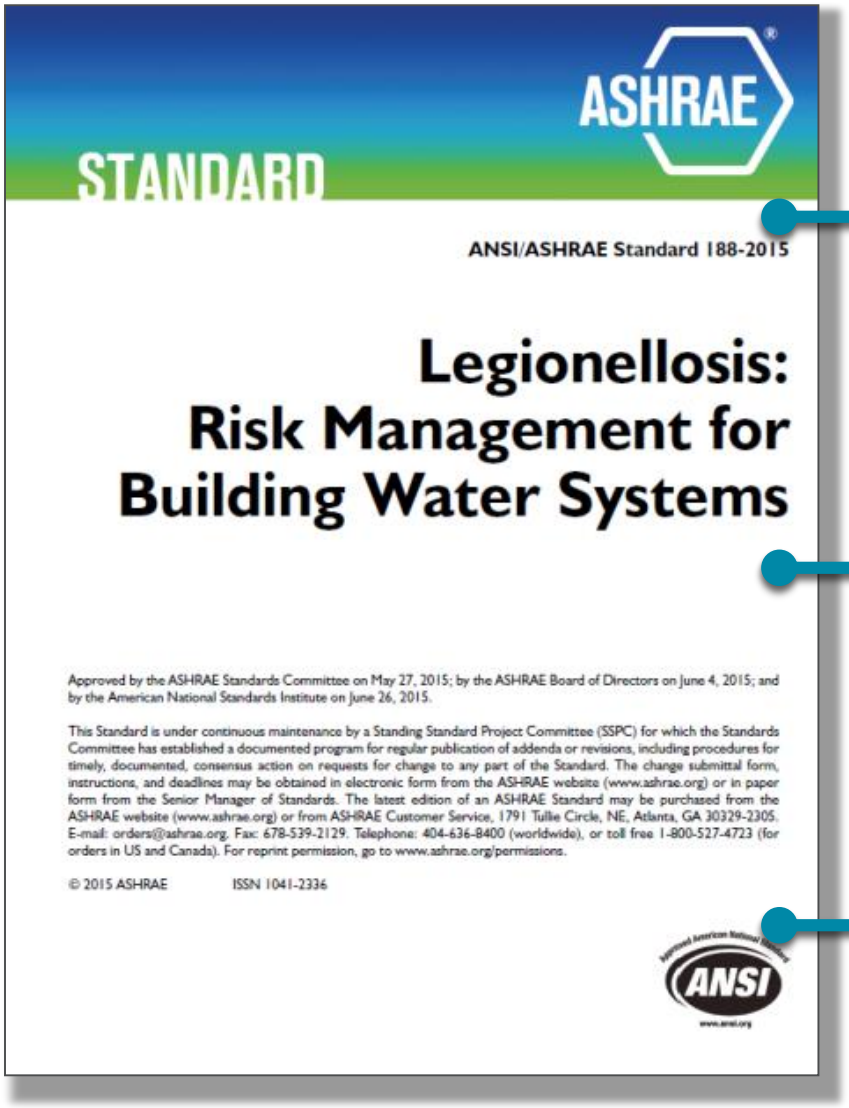



Perform a **RISK ASSESSMENT** of your building



# Regulatory: ASHRAE *Standard 188-2015*




Recommended Water Safety Plan

First NA Standard for *Legionella*

Annex C is Specific to Testing

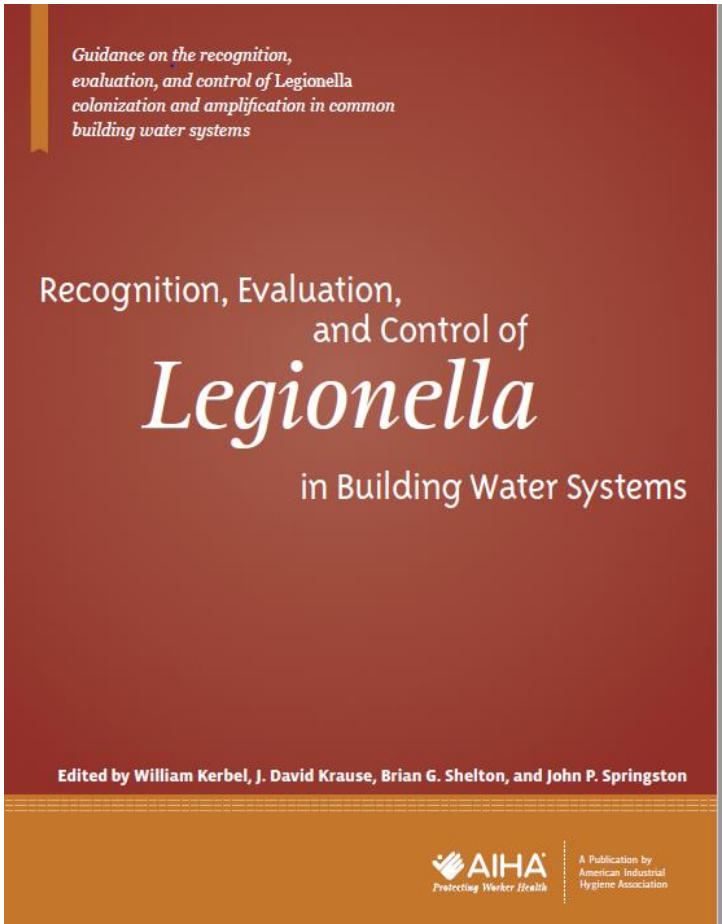
# Tools: CDC *Legionella* Toolkit


- Yes/No Worksheet to examine risky building areas
- Walk through of *Legionella* mgmt. program
- Example problem scenarios
- Healthcare-specific guidance

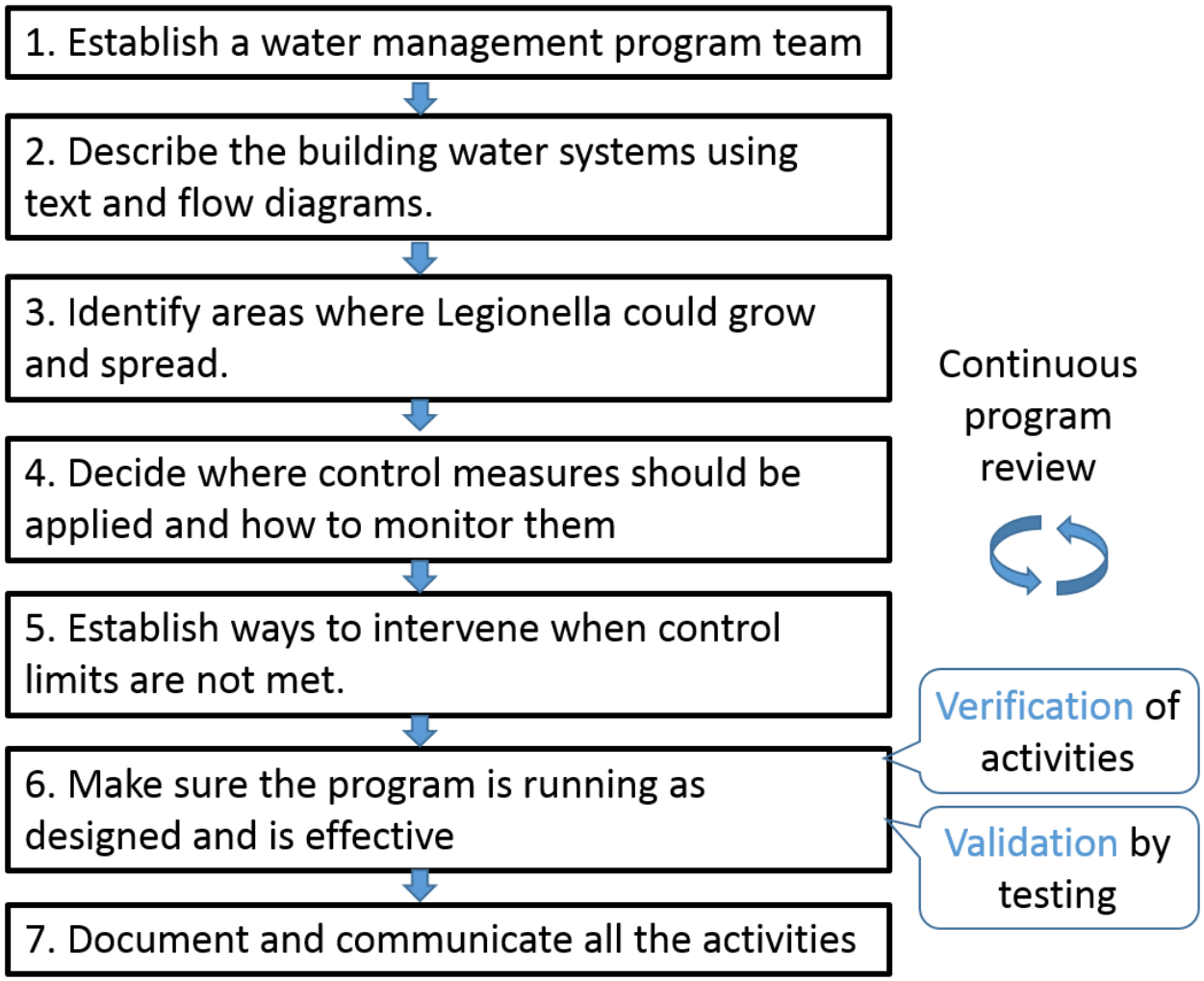
# The Industrial Hygiene Approach

"Proactive efforts to recognize and evaluate *Legionella* hazards and strives to prevent disease through

- source identification
- risk assessment
- control"



# Water Management/Risk Management Plans




Source: "Developing a *Legionella* Water Management Program", CDC, 2016. p. 23

# Developing a *Legionella* Risk Management Plan

## PLAN DEVELOPMENT

HPE sends out Questionnaire & Water Systems Inventory

↓

Documentation (questionnaire, inventory, process flow diagram) returned to HPE for review

↓

HPE schedules site visit with OM to inspect building

↓

HPE performs risk assessment & prepares draft RMP

↓

RMP sent to team members for comment/review

↓

HPE revises plan (as needed) & issues to management for implementation

## PLAN IMPLEMENTATION

**Education**

1. Initiation of the Plan
2. New employees & vendors
3. Refresher every 2 years

↓

**Engineers perform RMP Steps**

1. Inspection/Monitoring
2. System Maintenance
3. Chemical Treatment
4. Testing (validation)

↓

Engineers survey building to ensure compliance with RMP (annually)

↓

Team members schedule conference call (annually) to discuss plan implementation, evaluate building risk factors, CCPs, CMs, scientific findings & new technologies

↓

HPE revises/updates RMP

## PROGRAM REVIEW

Comprehensive Program Review (every 2 years)

↓

**Risk Assessment Review**

1. Changes to the water system or its use
2. Changes in the utilization of the building
3. Availability of new info about risks, CCPs & control measures
4. Results of checks indicate that CMs are not effective
5. A case of Legionellosis is linked to the building
6. Changes in key personnel

↓

RMP Revised/Updated (as needed)

# Plan Example:

Includes Scope of Services, Risk characterization, team members, building water system description, water source information

**Legionella Risk Management Plan For Building Water Systems**

ACME Property Group
**1234 Crystal Drive**
(ACME Park 3)
Arlington, Virginia 55555

December 24, 2015

| | |
|---|---|
| Number of Buildings | 1 |
| Construction Date | 1986 |
| Building Type | Commercial |
| Total Number of Floors | 15 |
| Above grade | 12 |
| Below grade | 3 |
| Total square footage of the building | 400,000 ft² |
| Total # of Cooling Towers (location) | 4 (penthouse) |

**Table of Contents**



**Scope of Services**
The scope of services performed by HP Environmental, Inc. (HPE) was to provide consulting services to assist in the development of a risk management plan for the control of *Legionella* in building water systems at 1234 Crystal Drive (ACME Park 3), in Arlington, Virginia. This plan does not address resident installed water systems (domestic/utility water) that are, by design, not the responsibility of ACME Property Group.

**Risk Characterization**
*Building has one or more SYSTEMS that may relate to legionellosis:*
- **Open- & closed-circuit cooling towers or evaporative condensers that provide cooling and/or refrigeration for the HVAC&R system or other systems or devices in the building;**

*Building has one or more FACTORS that relate to legionellosis:*
- **It is more then 10 stories high (including any levels that are below grade)**

**Disclaimer Statement**
HPE has used its best efforts in preparing this risk management plan and makes no warranty of any kind, expressed or implied, nor assumes any legal liability or responsibility for any 3rd party's use, with regard to the content, quality, performance, transmission or any other aspect of the information contained herein. The information provided herein is based on a general walkthrough performed by HPE and an evaluation of information provided by ACME Property Group on the Water Systems Inventory and the Plan Questionnaire. The Plan is designed to control the risk of *Legionella* and no other pathogens. HPE shall not be liable for any damages, including consequential damages, in connection with, or arising in any manner related to information offered herein. The mention of trade names or commercial products does not constitute endorsement or recommendation for use.


Prepared by:
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**MEMBERS OF THE TEAM**

| *Engineering Supervisor* | *Engineering Supervisor* | *Operations Manager* |
|---|---|---|
| TBD | TBD | TBD |
| *Assistant Director of Engineering* | *Quality Control Manager* | *Senior VP of Engineering Services* |
| TBD | TBD | TBD |
| *Microbiologist Consultant* | *Environmental Consultant* | *Building Consultant* |
| Ray Petrisek, MS, ASCP(MT), SM, HEM<br>HP Environmental, Inc.<br>104 Elden Street, Herndon, VA<br>(703) 471-4200<br>rpetrisek@hpenviron.com | Jonathon Hall, MPH, CIH<br>HP Environmental, Inc.<br>104 Elden Street, Herndon, VA<br>(703) 471-4200<br>jhall@hpenviron.com | William Kilpatrick, PhD, MEng, PE, LEED AP ID+C<br>HP Environmental, Inc.<br>104 Elden Street, Herndon, VA<br>(703) 471-4200<br>wkilpatrick@hpenviron.com |

**DESCRIPTION OF THE BUILDING'S WATER SYSTEMS**

| System | Water System | # of Systems | Location/POE |
|---|---|---|---|
| Fire Protection Systems (FPS) | Utility | 3 (1 wet, 2 dry) | G1 Level & Loading Dock |
| Cooling Towers (CT) | Utility | 4 | Penthouse |
| Boilers | Utility | 2 | Penthouse |
| Chillers | Utility | 3 | G1 Level |
| Swimming Pools | Utility | None | - |
| Potable Water Main Taps (PWMTs) | Potable | 1 | West side of building |
| Points of Entry (POE) | Potable | 1 | West side of building |
| Domestic Hot Water Systems (DHWs) | Potable | 2 | Penthouse |
| Bottled Water Dispensers | Potable | None | - |
| Supplemental Filters | Potable | Various | Ice & coffee machines, hot & cold water dispensers |

Points of use (POU) domestic water systems identified at the building include:

| | | |
|---|---|---|
| • Coffee machines | • Faucets in employee areas | • Drinking fountains |
| • Refrigerator icemaker | • Faucets in public restrooms | • Hot & cold water dispensers |
| • Dishwashers | • Faucets in other areas | • Water coolers |
| • Faucets in janitor's closets | • Ice machines | • Toilets |

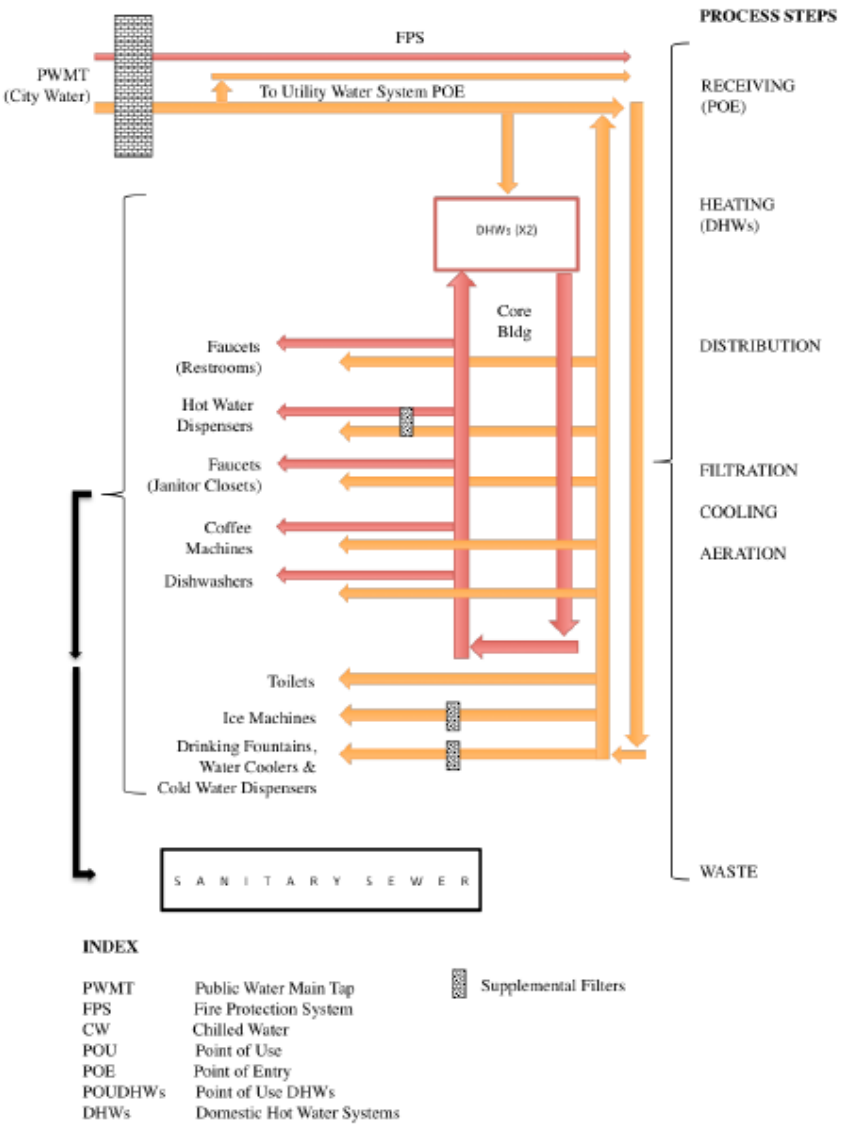
Where does the Building's water come from and how is it treated?

| | |
|---|---|
| **Source** | Potomac River |
| **Treatment Plant** | Dalecarlia Water Treatment Plant |
| **Disinfection Process** | Chloramine / Chlorine |
| **Additional Information** | http://water.arlingtonva.us/water/ |

# Process Flow Diagram

- Promotes a complete assessment of risk
- Illustrates the most appropriate sampling points

**Figure 2.** Process Flow Diagram for Potable Water Systems at ACME Park 3



# Hazard Analysis

Potential for harboring and/or transmitting *Legionella* bacteria if not properly maintained.

**Table 1.** Hazard Analysis for Water Systems identified at ACME Park 3

| System/ Device | Significant *Legionella* Risk (Y/N) | CCP (Y/N) | Reasoning |
|---|---|---|---|
| CT | Y | Y | Potential for *Legionella* growth and exposure. |
| DHW (central) | Y | Y | *Legionella* growth in DHWs will affect exposure at POUs. |
| POU | Y | Y | Contamination of piping & plumbing systems (e.g., dead legs, aerators faucets, showers, standard mixing valves, thermostatic mixing valves, electronic faucets, etc.) will affect exposure to *Legionella* at the POU. Control measures are not necessary at some POU devices (e.g., toilets; dishwashers) because exposure to *Legionella* is low. |
| POUFLTR | Y | Y | *Legionella* can grow on filters and can be released into water, potentially contaminating other parts of the domestic water system and affecting exposure at POUs. |

# Critical Control Point Identification

**Control Point**

**Risk Severity**

**Potential Controls**

| CCP | Severity/Basis for Risk Characterization | What controls could be applied to eliminate, reduce or prevent the Legionella hazard from causing harm? |
|---|---|---|
| CT | Moderate to high risk; poorly maintained CTs can and are known to harbor *Legionella* & provide transmission to cause disease | • Develop a water treatment program<br>• Maintain & monitor chemical applications to reduce biofilm<br>• Perform regular maintenance (clean system, maintain & clean UV and/or supplemental filtration)<br>• Perform semi-annual *Legionella* testing (May - Oct) |
| DHW | Medium risk; Poorly maintained DHWs can harbor *Legionella* | • Flush system regularly to remove the build up of sediment & remove any accumulated biofilm<br>• Chlorinate system if level is below 0.5 ppm for > 1 month |
| POU | Medium risk; Contamination of plumbing systems will affect exposure to *Legionella* at the POU. | • Check aerators for sediment and/or biofilm twice/year<br>• Replace/clean aerators as needed or at time of turnover<br>• Use laminar flow aerators<br>• Maintain POU hot water temperature at 110 - 120°F<br>• Check & verify mixing valve operation<br>• Ozone application<br>Copper/silver drip ionization system |
| POUFLTR | Medium risk; Poorly maintained filters can harbor *Legionella* & can contaminate other parts of the DWS & exposure at POU. | • Check filters for sediment and/or biofilm<br>• Replace filters or clean, as needed |

# Control Measure Examples

## Inspection, maintenance & corrective action

| Process/ Device | Keyword | Control Measure | Frequency (Inspection, Maintenance or Testing) | Notes |
|---|---|---|---|---|
| Backflow Preventers | N/A | Inspect working condition; install where needed & repair, as needed | Annually | 11 |
| Check Valves | N/A | Inspect condition regularly; remove debris & drain as needed; thoroughly clean & disinfect all surfaces | Annually | 97 |
| Dead legs, abandoned piping | N/A | Remove piping & fixtures no longer used or flush often to minimize stagnation; Cut or valve off where pipe joins main, or at the last accessible point of flow | Quarterly (includes inspection & maintenance of vacant space plumbing lines) | 22 38 54 55 |
| Drinking Fountains | Aerators | Flush system & disinfect aerator | Biannually | 78 |
| Eyewash Stations | Aerators | Flush piped eyewash stations per ANSI or OSHA requirements; repeat if requirements not met | Biannually | 12 |
| Faucets | Aerators | Run hot & cold water faucets; replace or clean aerators as needed or at time of tenant turnover | Biannually | 31 |
| Filters | Ice & coffee machines, hot & cold water dispensers | Inspect condition regularly; check filters for sediment and/or biofilm & replace/clean, as needed | Biannually (increase frequency of maintenance if filter is heavily loaded w/ sediment/biofilm) | 14 26 |
| Ice Machines | N/A | Inspect condition of supply line filters & replace, as per manufacturers recs; clean & disinfect the machine regularly | Biannually | 15 83 |
| Hose Reels/Bibs | Supply lines, aerators | Flush infrequently used hose bibs | Biannually | 31 |
| Showers | Head | Flush showerhead | Biannually | 12 |
| | Hose | Drain shower hoses or hang to drain without touching the floor when not in use | Flush hoses biannually | 51 |

Establish frequency

Remove Dead Legs

Flush and Clean

Inspect, Clean, Disinfect

# Environmental Testing

*"Environmental monitoring that includes sampling for viable Legionella is essential to validate the effectiveness of control measures in eliminating or minimizing Legionella growth."*

The AIHA *Legionella* Work Group of the
AIHA Indoor Environmental Quality Committee
Letter to the CDC, May, 2016

# Testing for *Legionella*

"By implementing administrative, engineering and protective measures, based upon empirical measurement of the organism responsible for the disease in question, **health risks to worker and building occupants can be reduced**.

Proactive sampling and analysis for *Legionella* should be included as an integral part of any building water program."

- American Industrial Hygiene Association Comments on BSR/ASHRAE Standard 188P Legionellosis: Risk Management for Building Water Systems. (Nov, 2014)

# Global Action limits – Guidance & Legislation

## Potable Water

| Country | Entity | Type of rule | Potable water limit |
|---|---|---|---|
| United States | CDC | Guidance | Depends on Risk Mgmt Plan |
| | ASHRAE | Guidance | Depends on Risk Mgmt Plan |
| | AIHA | Guidance | ≥ 10 cfu/mL |
| | OSHA | Guidance | ≥ 10 cfu/mL |
| | VHA Directive 1061 | Guidance | Any positive |
| | New York State Dept. of Health | Legislation | ≥ 30% “positive” outlets (healthcare facilities only) |
| France | Ministry of Health | Legislation | ≥ 1 cfu/mL |
| Germany | Trinkwasserverordnung TrinkwV 2001 | Legislation | ≥ 1 cfu/mL |

# Global Action Limits – Guidance & Legislation

## Nonpotable water

| Country | Entity | Type of rule | Nonpotable water limit |
|---|---|---|---|
| United States | CDC | Guidance | Depends on Risk Mgmt Plan |
| | ASHRAE | Guidance | Depends on Risk Mgmt Plan |
| | AIHA | Guidance | ≥ 100 cfu/mL |
| | OSHA | Guidance | ≥ 100 cfu/mL |
| | New York State Dept. of Health | Legislation | ≥ 10 cfu/mL |
| France | Ministry of Health | Legislation | ≥ 1 cfu/mL |
| Germany | Trinkwasserverordnung TrinkwV 2001 | Legislation | ≥ 1 cfu/mL |
| Canada | Quebec | Legislation | ≥ 10 cfu/mL |

# Actions from positive results: AIHA Guidelines

**Table 3.2** — Recommended Actions

| Action Level | Recommended Actions |
|---|---|
| 1 | Continue monitoring as per the site specific plan based upon risk assessment results. Continue maintaining the system and source and consider reassessment if conditions change to favor *Legionella* colonization or amplification. |
| 2 | If no cases of Legionellosis (LD or PF) are suspected, reassess maintenance and treatment practices, implement remedial cleaning or disinfection protocols, and schedule for retesting. Based upon professional judgment and the history of the water source, consider increasing the frequency and/or intensity of sampling efforts in order to identify any contributing amplification source(s) or implement prophylactic cleaning or biocide treatment protocol. Re-examine secondary parameters (pH, residual disinfectant levels, temperature, etc.) to identify potential cause of elevated *Legionella* levels, and make any necessary adjustments.<br>If one or more cases of Legionellosis (LD or PF) are suspected, notify appropriate management and public health authorities of test results and coordinate further efforts. Take immediate steps to prevent further exposure to occupants, workers and the public. Interim measures to restrict water use, filter the organism from the water, or prevent aerosolization can effectively prevent exposure until terminal measures are implemented. Coordinate and implement cleaning, and/or disinfection protocols with any proposed testing by public health officials. Continue water use restrictions and/or interim measures until post-treatment sample results are received from the laboratory and reviewed by a competent professional.<br>If an amplification site is identified in the course of further investigation and implement measures to remediate the source and prevent its reoccurrence.<br>Perform post-remediation testing to verify and document the effectiveness of remediation protocols (see 4.3 Section d) and implement follow up monitoring using a strategy based upon Routine Assessments as described in 3.1.1 and 3.1.3. |
| 3 | If no cases of legionellosis (LD or PF) are suspected, take immediate steps to prevent further exposure to occupants, workers and the public. Interim measures to restrict water use, filter the organism from the water, or prevent aerosolization can effectively prevent exposure until terminal measures are implemented. Implement cleaning, and/or disinfection protocols. Continue water use restrictions and/or interim measures until post-treatment sample results are received from the laboratory and reviewed by a competent professional. Reassess maintenance and treatment practices, implement remedial cleaning or disinfection protocols, and schedule for retesting. Re-examine secondary parameters (pH, residual disinfectant levels, temperature, etc.) to identify potential cause of elevated *Legionella* levels, and make any necessary adjustments.<br>If one or more cases of Legionellosis (LD or PF) are suspected, notify appropriate management and public health authorities of test results and coordinate further efforts. Coordinate any cleaning and/or disinfection protocols with any proposed testing by public health officials.<br>If an amplification site is identified in the course of further investigation, implement measures to remediate the source and prevent its reoccurrence.<br>Perform post-remediation testing to verify and document the effectiveness of remediation protocols (see 4.3 Section d) and implement follow up monitoring using a strategy based upon Routine Assessments as described in 3.1.1 and 3.1.3. |
| 1A | Verify water treatment operation and, if deemed necessary, increase biocide treatment levels. Review cleaning and scale control program to determine if it should be enhanced. Re-test until the *Legionella* levels are consistently below 10 CFU/mL. |
| 2A | Disinfect and clean, as per recommendations described in the Cooling Technology Institute Legionellosis Guideline: Best Practices for Control of *Legionella* WTB-148 (08) within 30 days. Review cleaning and scale control program to determine if it should be enhanced. Re-test until the *Legionella* levels are consistently below 10 CFU/mL. If an amplification site is identified in the course of further investigation, implement measures to remediate the source and prevent its reoccurrence.<br>Perform post-remediation testing to verify and document the effectiveness of remediation protocols (see 4.3) and implement follow up monitoring using a strategy based upon Routine Evaluations as described in 3.1.1 and 3.1.3. |

## Range of Actions:

- Increase of biocides
- Cleaning and/or disinfection
- Water restrictions
- Notification of officials if suspected case of Legionellosis
- Remediation
- Post-Remediation testing

# Regulations, Guidance, and Liability

- Regulations = Less common, but on the rise

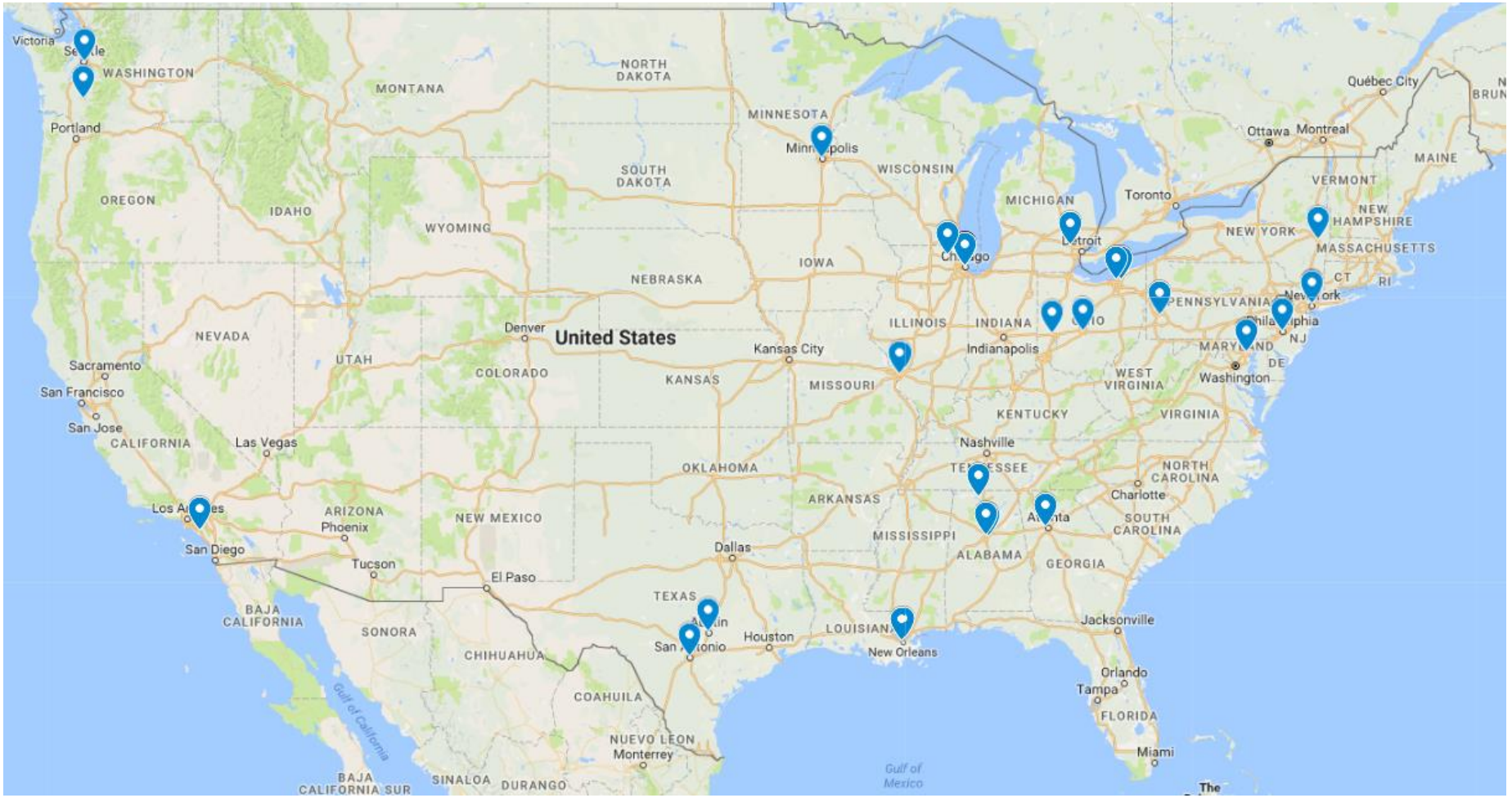
- Guidance = More common (ASHRAE, OSHA, etc.)
  - Conforming to guidance reduces risk and illness; when illness occurs there may be direct responsibility/liability

- Who is to blame?  Who is liable?
  - **Owner or operator** of a public building (hospital, hotel, etc.)
  - **Building engineers and maintenance personnel** depending on the specific circumstances

# The impact of liability

## Legionnaires' Disease lawyers in the United States

Not a comprehensive list!



# Litigation and costs

- ✓ People sue for getting Legionnaires' Disease
- ✓ Settlements, awards, and legal fees can be significant

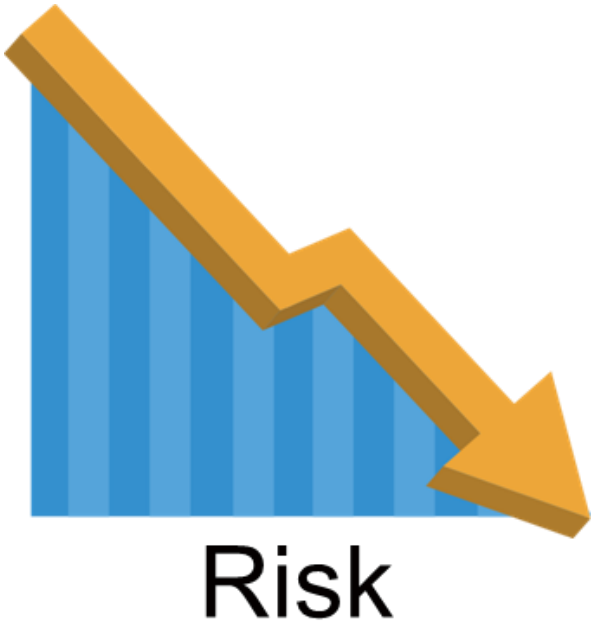
| Year | Source | Amount |
|---|---|---|
| 2007 | Hot tub/cruise ship | $15.1 million |
| 2010 | Hot tubs/pools | $490K |
| 2010 | Drinking water | $1.2 million |
| 2010 | Hotel hot tub | $4.5 million |
| 2010 | Hot tub | $2.4 million |
| 2014 | Decorative fountain | $2.3 million |
| 2013 | Not determined | $3 million sought |
| 2014 | Hospital | $228K |

# How do you reduce the health and legal risks?

There will be ramifications if there is an incident, so protect individuals and yourself:

How?

- Test regularly to confirm risk management practices are working properly
- Perform corrective actions if needed and retest to confirm actions have reduced the risk
- Keep records of your test results and corrective measures!



# Testing for *Legionella*: What do most labs do?

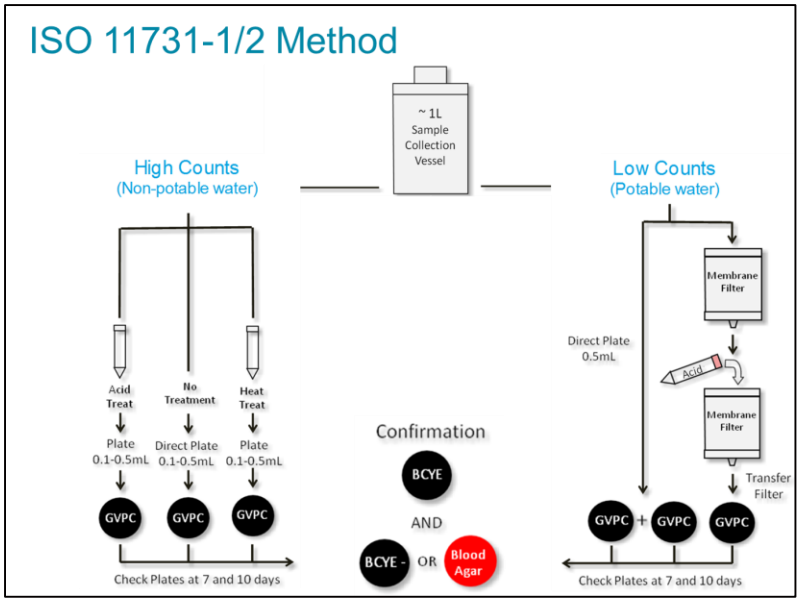
## The Gold Standard = Culture

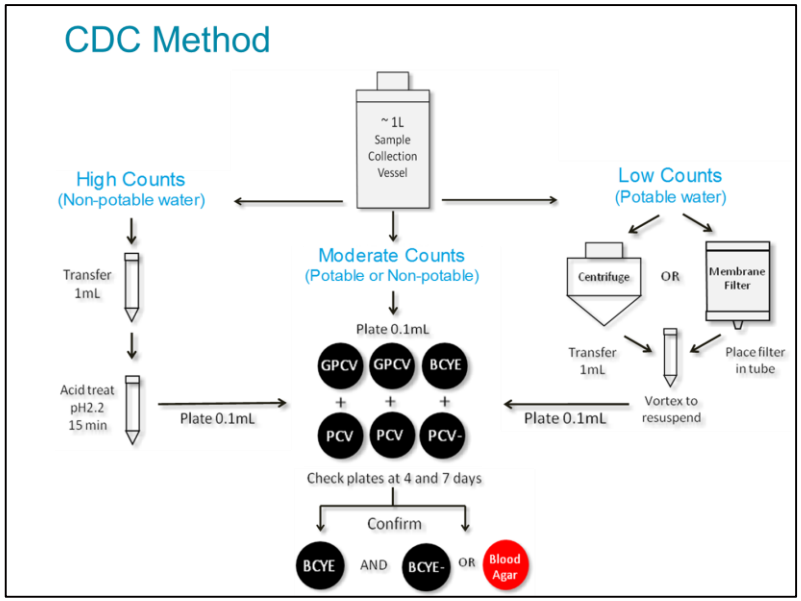
# But which culture method? There are many!

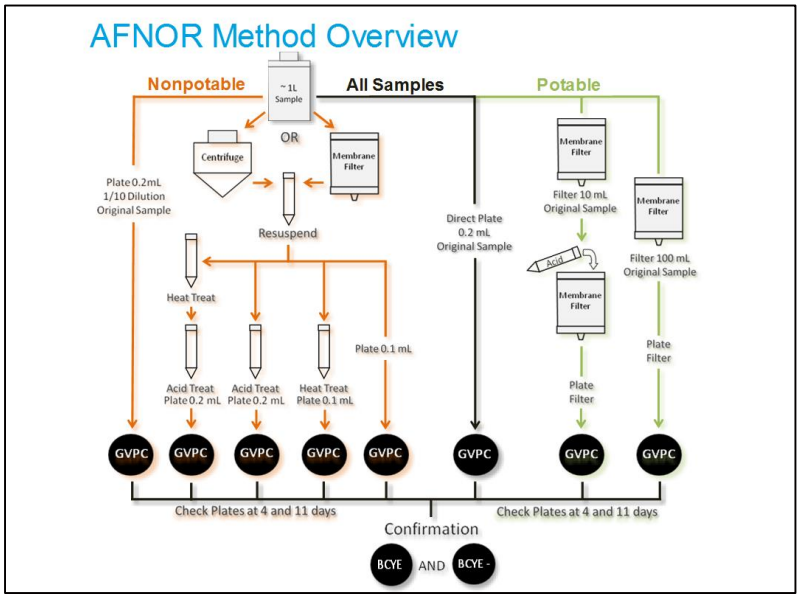
## Labs choose from many possible protocol options

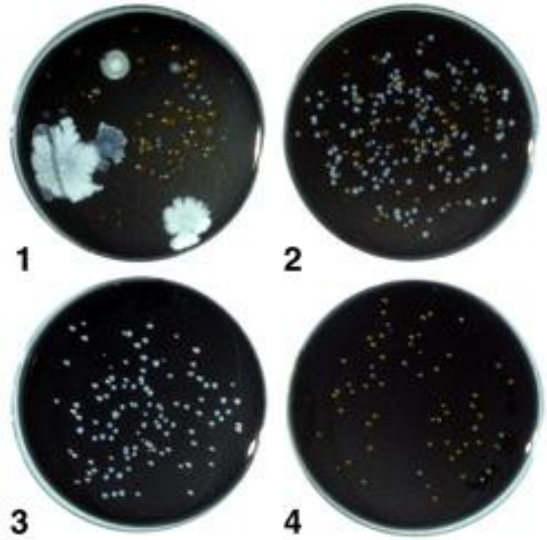
1. Concentration
   - Membrane filtration
   - Centrifugation
2. Pretreatments (to reduce the background)
   - Acid
   - Heat
3. Media formulas
   - GVPC, PVC, MWY, DGVP, CCVC, etc.
4. Follow up/ confirmation methods
   - Plate media
   - Serotype - latex agglutination
   - Direct fluorescence antibody microscopy
   - Sequencing

# Different methods = different results



# What about other “rapid” tests?

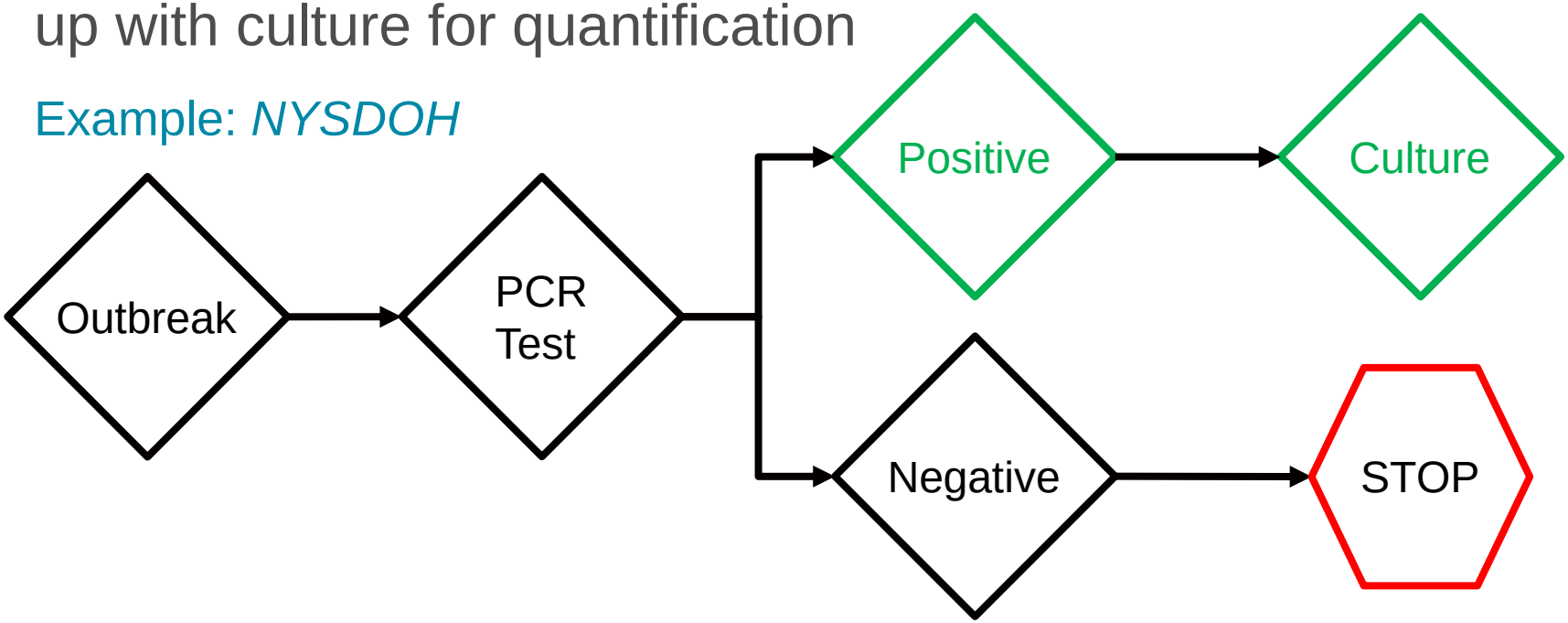
| Method | Fast? | Quantitative | Problems |
|---|---|---|---|
| Culture | No | Yes | • Labor intensive<br>• Subjective<br>• High variability from method variations and expertise |
| PCR | Yes | Sort of: Reports out in Genomic units which are not equivalent to CFU or MPN | • Cross reaction from matrix issues<br>• Live vs. dead can’t be resolved |
| DFA | Yes | Not reproducibly | • Live vs. dead can’t be resolved<br>• High degree of variability<br>• Requires concentration |
| Lateral flow antibody test | Yes | No | • Limited range of serotypes (Lp1 only)<br>• Not very sensitive<br>• High false negative rage |
| Antibody capture | Yes | Yes, but accuracy varies | • Highly labor intensive<br>• Expensive<br>• High variability from method difficulty |

# Do you need a same day test result?

No, not for routine monitoring – the key to a risk management plan is trending / outliers

Same day tests are good for outbreaks, but are also followed up with culture for quantification

Example: *NYSDOH*



# Legiolert™, the next generation culture test
# Ideal for routine monitoring and compliance

- Detects all serogroups of *Legionella pneumophila*
- Highly specific, little background interference
- Simple to use, color reaction similar to Colilert®
- Reproducible and repeatable
- Can be used for potable and nonpotable matrices
  - Matrix-specific protocols
- Uses most probable number (MPN) to quantify, which is the same quantification as CFU
- Counts of up to 2,272 per test, much higher than petri plates
- Incubates for 7 days to yield a confirmed result

# Legiolert platform

- Unique 100 mL “Quanti-Tray” device
  - 6 large wells (overflow)
  - 90 small wells (resolution)
  - Counts *L. pneumophila;* from 1-2272 MPN/ Quanti-Tray
- Blister pack reagent

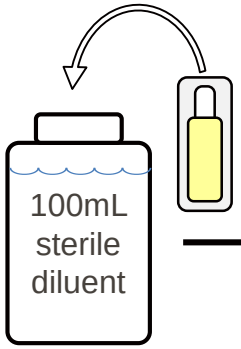

Reaction with *L. pneumophila*

Negative Sample

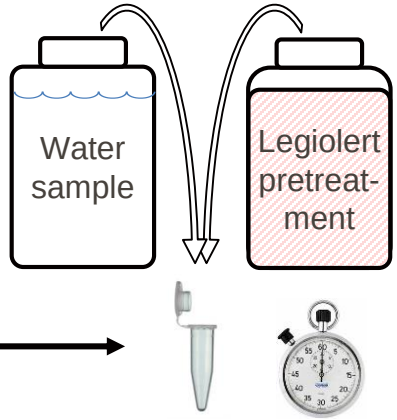
# Legiolert protocols: potable and nonpotable water

| Application | Incubation |
|---|---|
| Nonpotable | 37°C |
| Potable | 39°C |

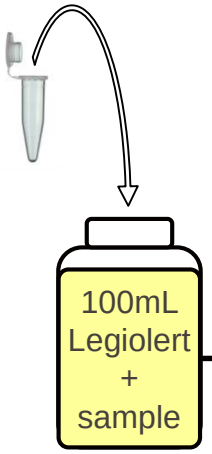
## Nonpotable




Add Legiolert reagent to 100 mL sterile diluent

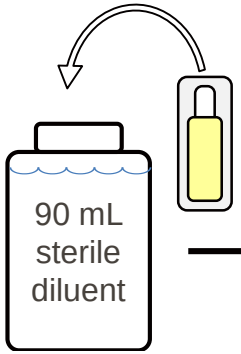



Mix 0.2 mL sample with 0.2 mL pretreatment, wait 60 seconds

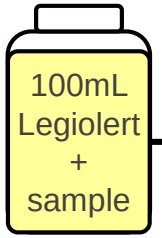



Add 0.2 mL treated water sample

## Potable




Add Legiolert reagent to 90 mL sterile diluent




Add 10 mL water sample

Pour into Quanti-Tray, seal, and incubate

Count @ 7 days
=
**Confirmed result**

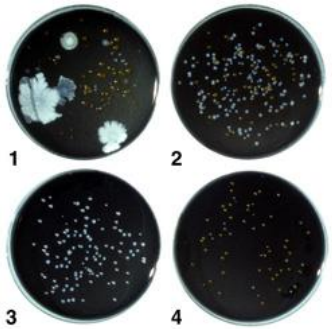
# Legiolert performance — ISO 13843 Method Validation

## Validation of Legiolert

ISO/TR 13843:2000(E) Water Quality – Guidance on validation of microbiological methods

| Metric | Value |
|---|---|
| Sensitivity | 98% |
| Specificity | > 99% |
| False positive rate | < 0.01% |
| False negative rate | 4.20% |
| Efficiency | > 99% |
| Repeatability | < 0.01 |
| Reproducibility | < 0.01 |

# *Legiolert* Field Trials



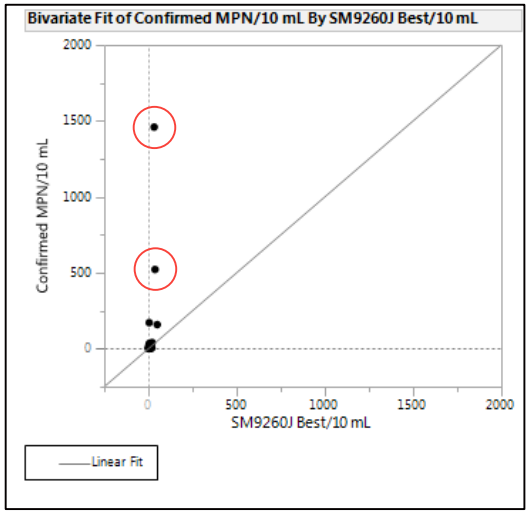

- Potable and nonpotable water
- Independent laboratories
- Regions
  - Germany
  - North America (U.S. and Quebec)
- All methods confirmed by secondary culture and serotyping when necessary
- Split samples analyses
  - Samples were obtained from sites/customers during routine business/laboratory operations in order to mimic performance in a real world scenario
- Data segregated for *L. pneumophila* by isolate speciation

# North American Beta Trial Evaluation – Potable Water

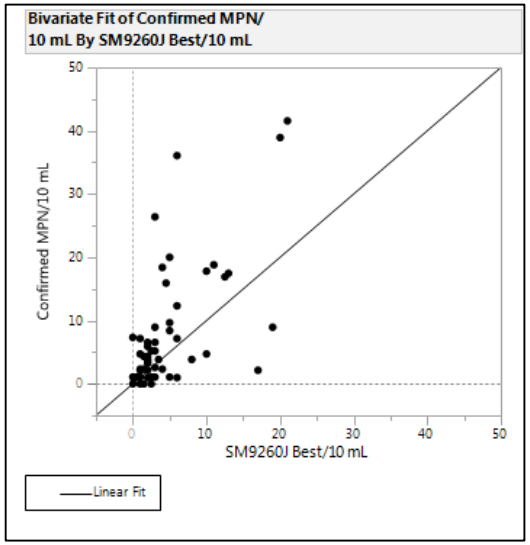
## Legiolert vs. Standard Methods SM9260J: Detection of Pathogenic Bacteria: *Legionella*

| Statistical method | Statistic | vs. SM9260J: Best |
|---|---|---|
| T-Test | N | 74 |
| | Prob > \|t\| | 0.120 |
| | Prob > t | 0.060 |
| | Prob < t | 0.94 |
| Wilcoxon Signed Rank Test* | Prob > \|S\| | **<.0001** |
| | Prob > S | **<.0001** |
| | Prob < S | 1 |
| p < 0.05 indicates a significant difference | | |
| % False positive = 0% | | |
| *Statistical method for non-parametric data | | |

Legiolert is equal to or more sensitive than standard methods for potable water




All Data

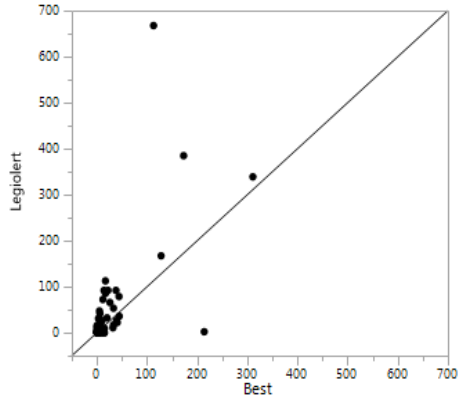


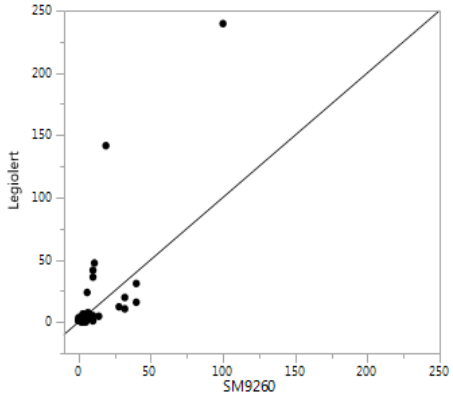

Zoom

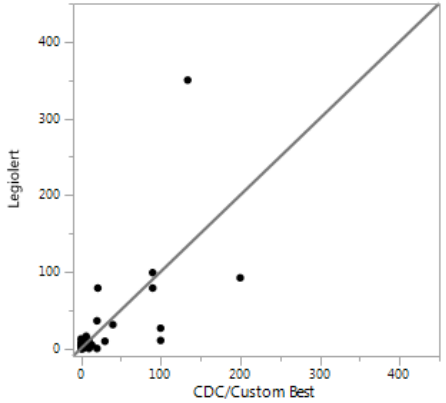
# North American Beta Trial Evaluation – Nonpotable Water

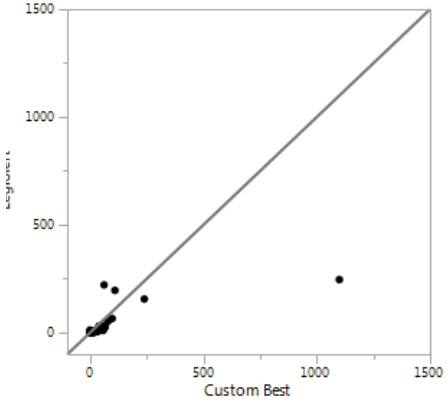
| Lab A CDC GVPC | Lab B SM9260J CCVC | Lab C Custom PCV | Lab D Custom DGVP |
|---|---|---|---|

## All Data

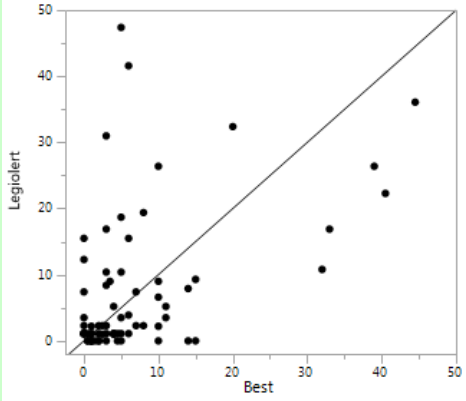


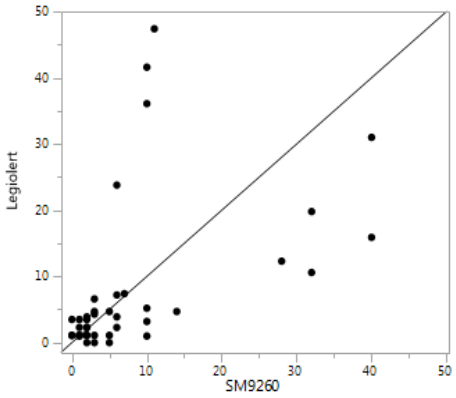



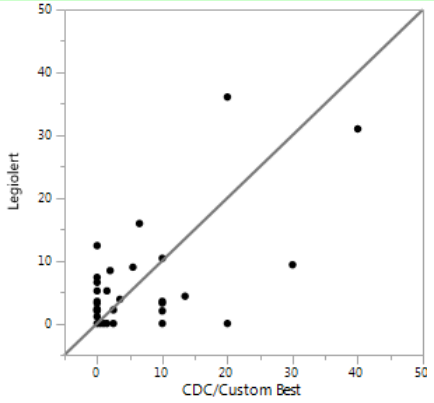



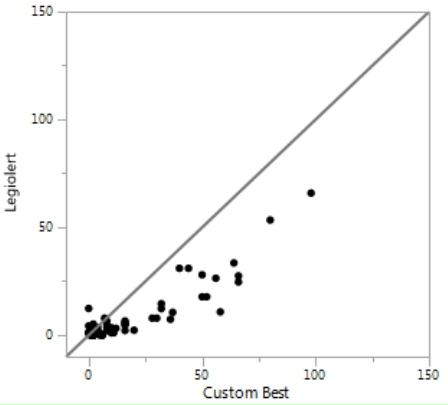




## Zoom



# North American Beta Trial Evaluation – Nonpotable Water

## Sensitivity statistics for all trial sites

| Statistical method | Statistic | vs. CDC: Best | vs. SM9260J: Best | vs. CDC/AFNOR: Best | vs. Laboratory custom method Best |
|---|---|---|---|---|---|
| T-test | N | 92 | 49 | 74 | 76 |
| | Prob > \|t\| | 0.076 | 0.201 | 0.326 | 0.130 |
| | Prob > t | 0.038 | 0.100 | 0.163 | 0.935 |
| | Prob < t | 0.962 | 0.899 | 0.837 | 0.065 |
| Wilcoxon Signed Rank Test* | Prob > \|S\| | 0.258 | 0.728 | 0.924 | <.0001 |
| | Prob > S | 0.129 | 0.636 | 0.462 | 1.0000 |
| | Prob < S | 0.871 | 0.363 | 0.363 | <.0001 |
| $p < 0.05$ indicates a significant difference | | | | | |
| *Statistical method for non-parametric data | | | | | |

## Specificity: True/false positivity

| | |
|---|---|
| Legiolert wells sampled | 671 |
| Legiolert wells confirmed as *L. pneumophila* | 652 |
| Cumulative false positivity rate | 3.6% |

# My test results show there is *L. pneumophila* in the water. Is this really bad??

# Not necessarily…

There are other factors besides presence/absence!

1. How much is there?
2. Is this a change from a previous test cycle?
   - Results from test to test must be accurate to know this!
3. Are many locations within the building positive?
   - For example, New York State Dept. of Health rules stipulate that action should be taken if ≥ 30% of outlets are positive above the minimum threshold

# Legionnaires' Disease - final thoughts

Legionnaires' disease is preventable with a risk management plan
Regulations and guidance/liability make it your responsibility to carry out that risk management plan **and make sure it's working**
There are tools to help you!

**Legiolert**

- Accurate and consistent for Risk Management Plan assessment
- Detects *L. pneumophila*, the primary clinical and environmental disease agent
- Easy test means
  - More labs will offer this
  - Industrial hygienists and premise owners can react with the best information to protect the public as soon as *Legionella pneumophila* is found

# Thank you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