Managing Legionnaires' Disease
Outbreak readiness

Disclaimer:

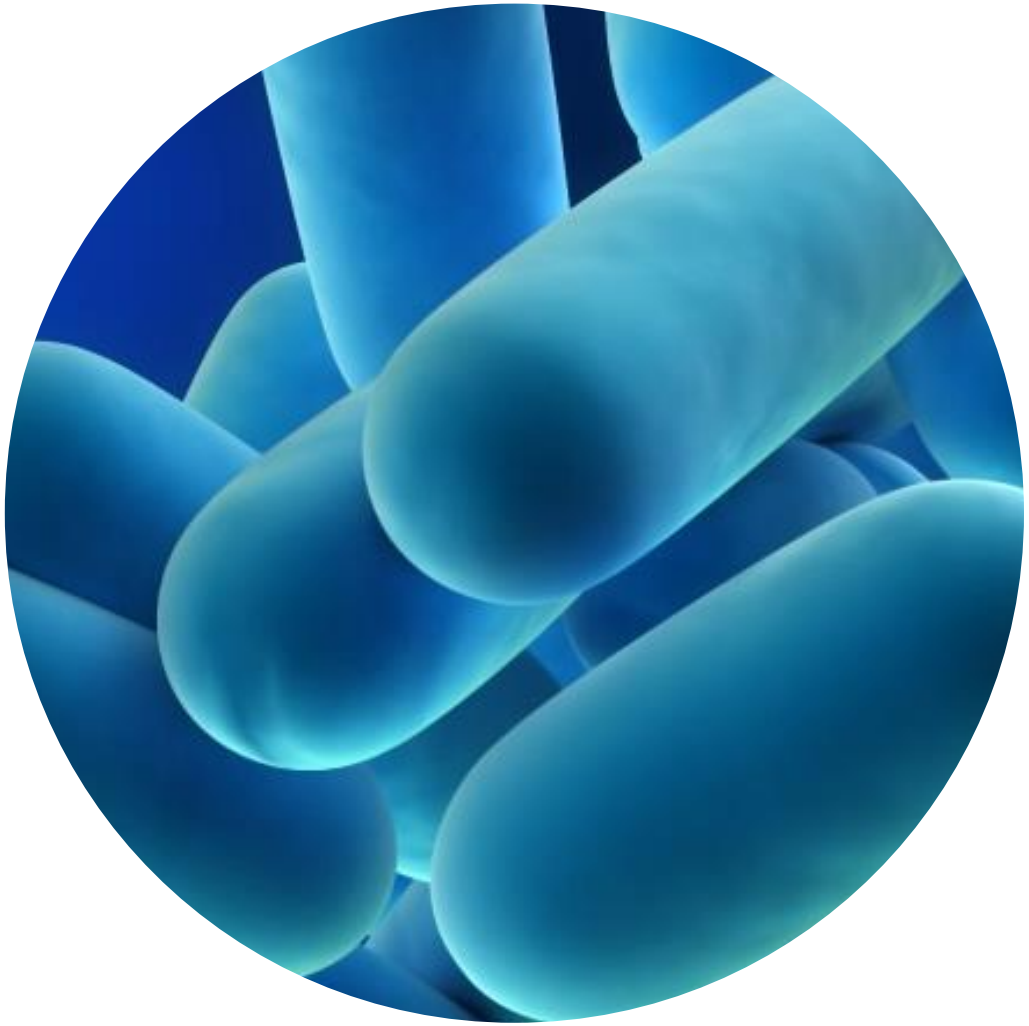
This presentation is intended to introduce you to general principles based on current guidance and suggested practices from government agencies and industry groups. As with any overview program, these materials and our guidance are general, and you should always consult your own advisors as appropriate for your circumstances.

Agenda

- Characteristics and ecology of *Legionella*
  - Where *Legionella* can live/grow in a building system
- What defines a Legionnaires' disease outbreak; when to report an outbreak
- How to identify sample sites in an outbreak
- Criteria for choosing a testing laboratory and analytical methods
- Prevention: use of ASHRAE 188/CDC Toolkit to manage *Legionella*

Characteristics and Ecology of *Legionella*

Legionella Characteristics



- Aerobic
- Normal aquatic bacteria
- Gram-negative (do not stain well)
- Nonspore-forming
- Flagellated
- Pleomorphic
- Facultative intracellular bacteria
- The causative agent of legionellosis including:
  - Legionnaires' Disease
  - Pontiac fever

Where *Legionella* live

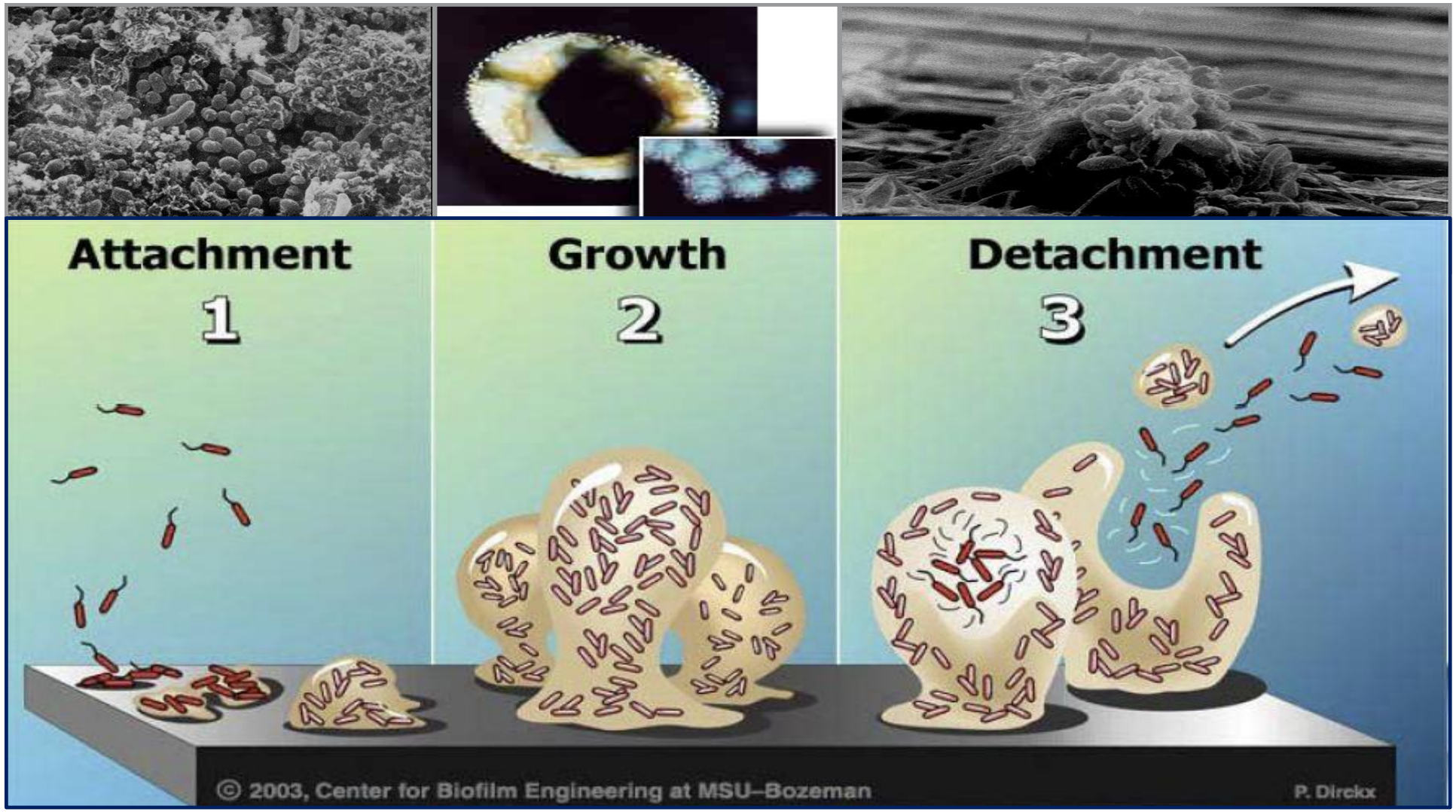
Potable Water



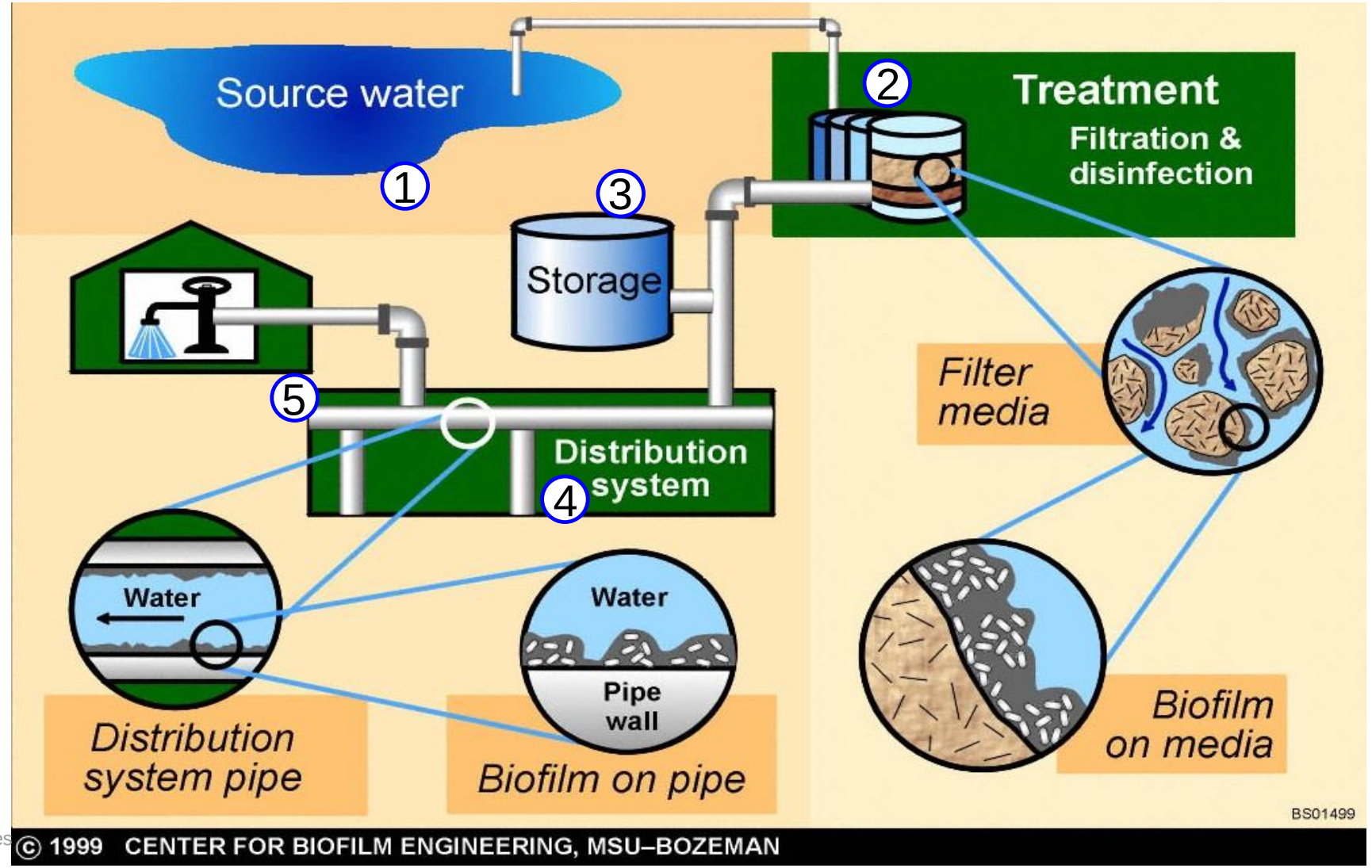

Nonpotable Water




Biofilm harbors bacteria, including *Legionella*

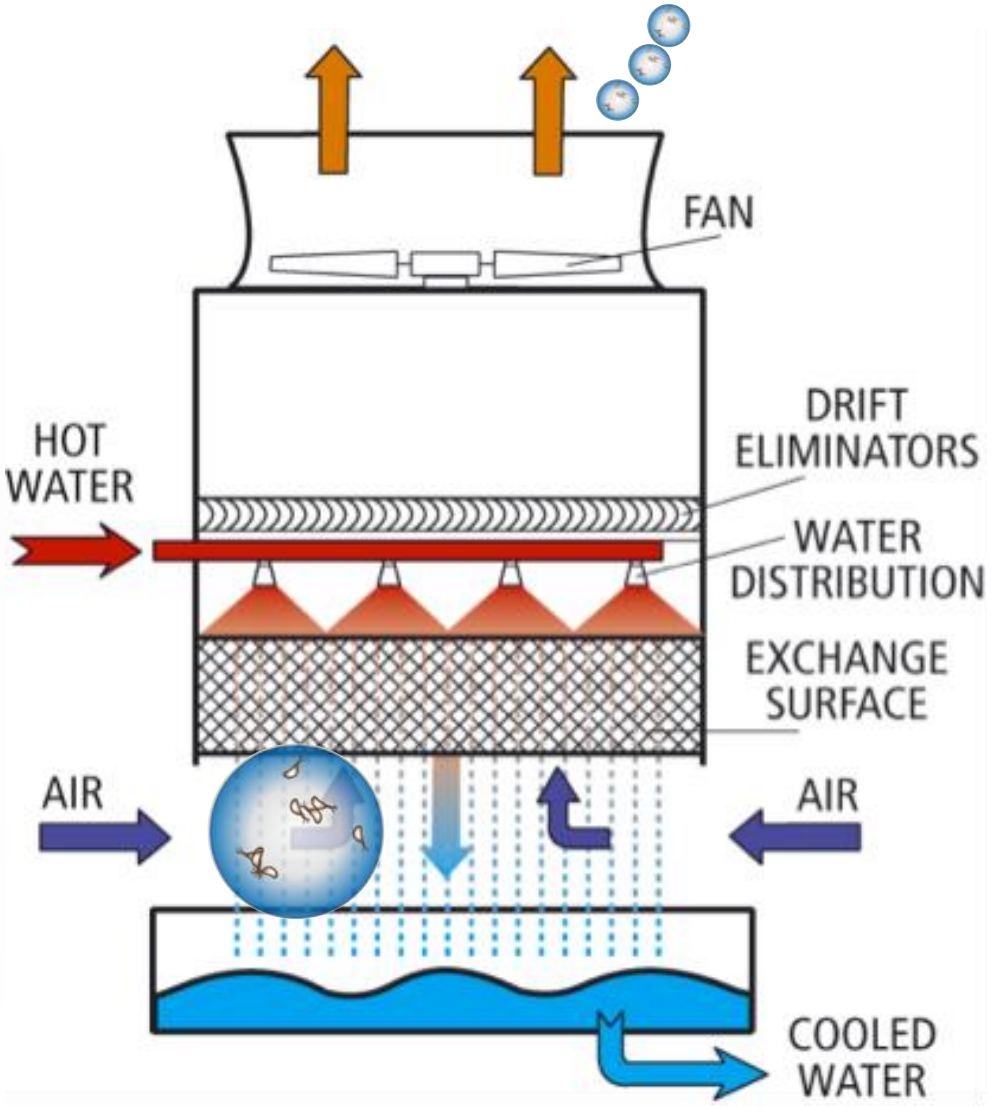


Biofilm is pervasive, not easily removed and regrows



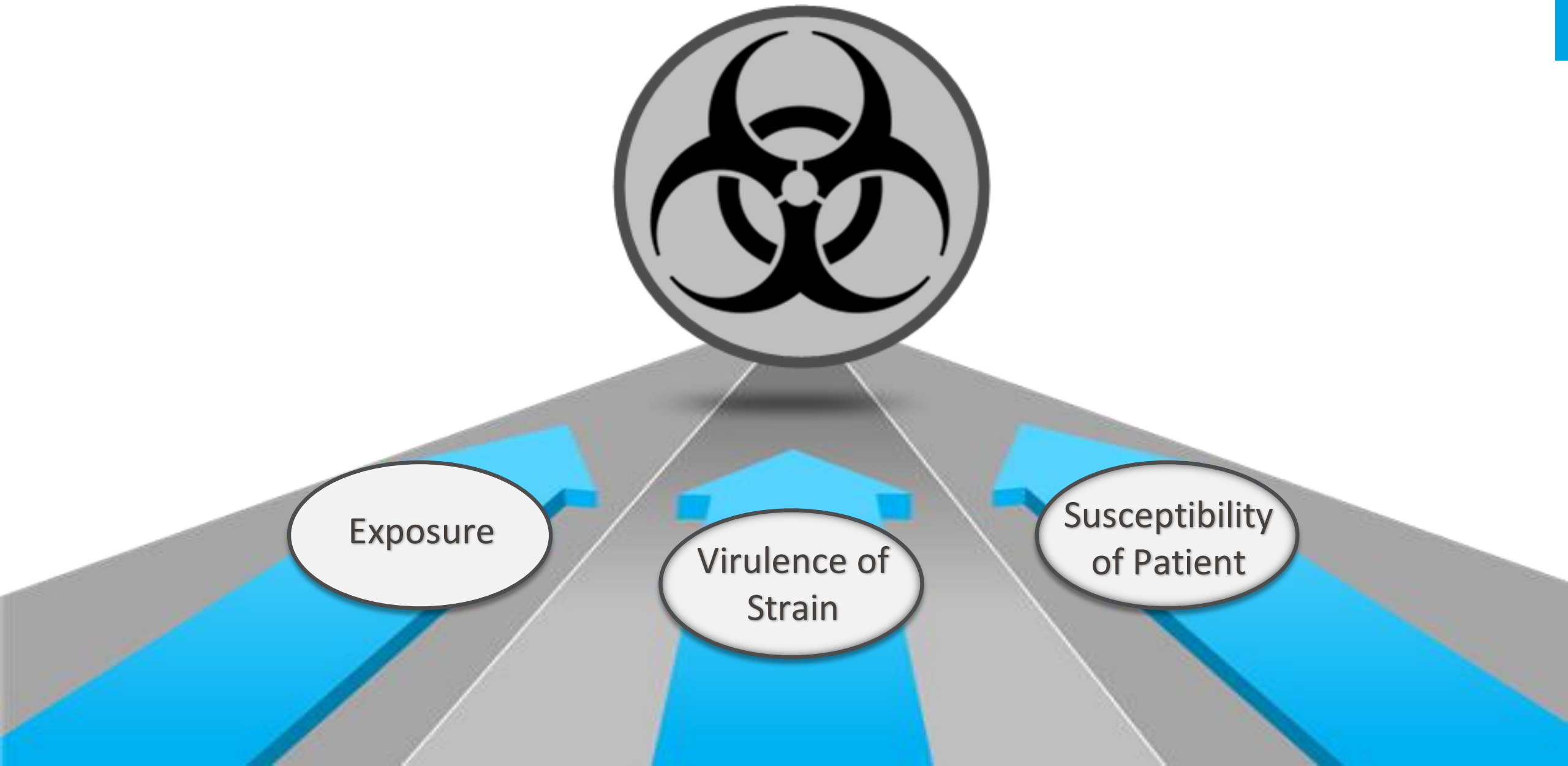
Infectivity – *Legionella* Aerosolization

Shower aerosol



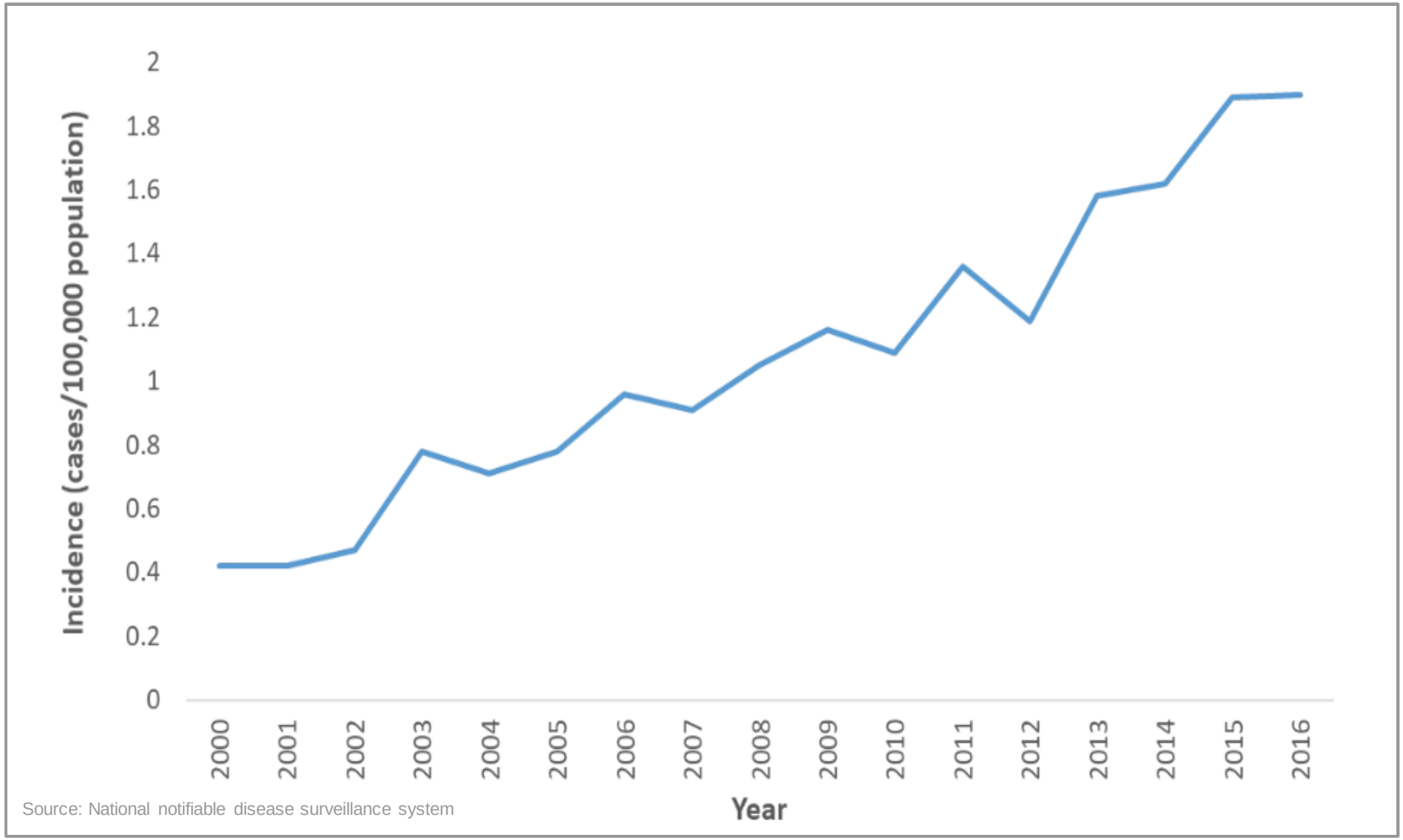
Cooling tower aerosol

Infectivity Risk Factors – Need All 3



Legionnaires' disease is on the rise

- Reported cases have increased more than 550% in the last 15 years
- 8,000 to 18,000 people contract legionellosis in the U.S. each year (est.)
- ~10% of known cases are fatal, but **25%** if contracted in healthcare setting



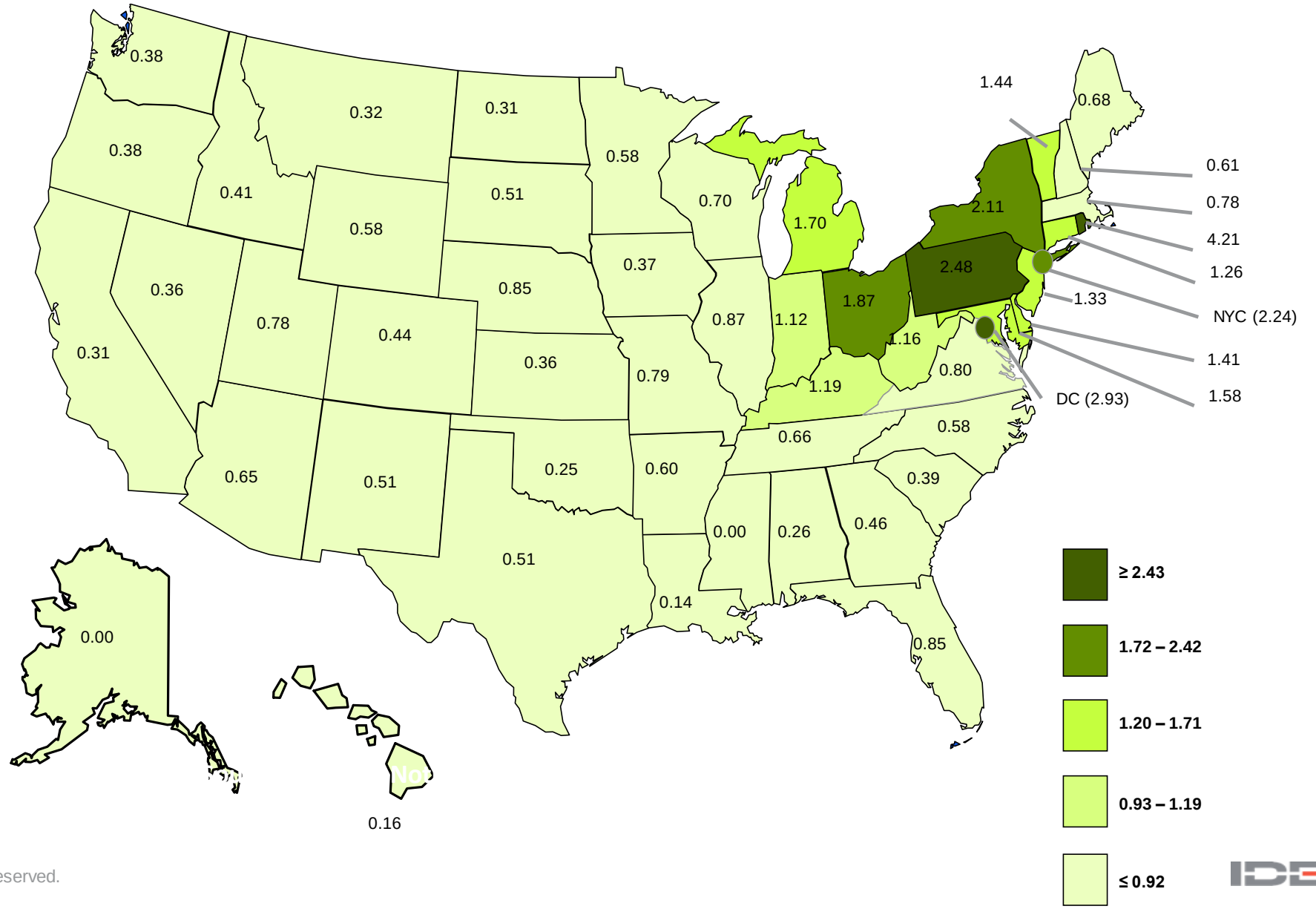
Source: National notifiable disease surveillance system

Legionellosis: US case rates

Reported cases by state

2007

Cases/100,000 population

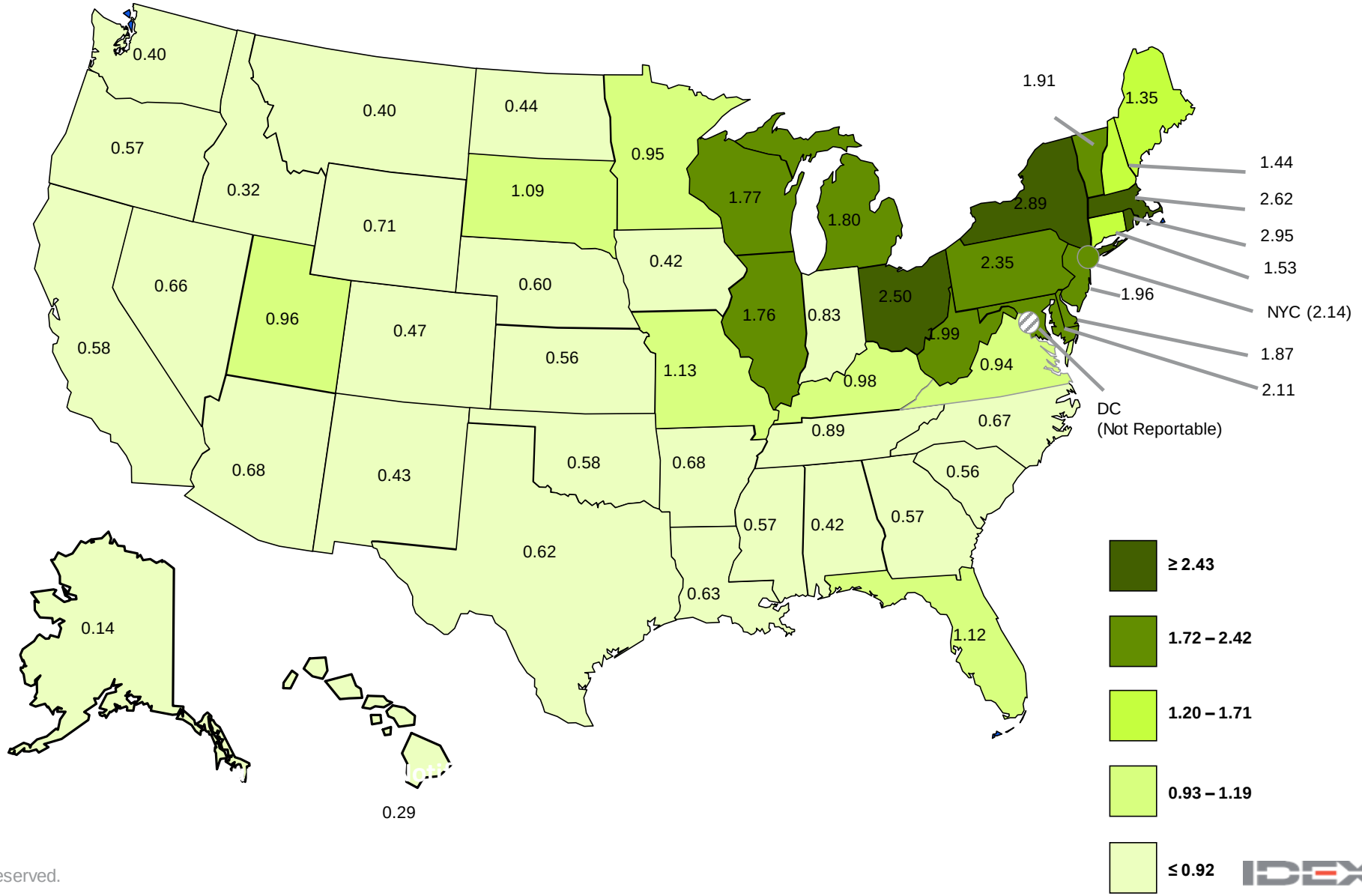


Legionellosis: US case rates

Reported cases by state

2012

Cases/100,000 population

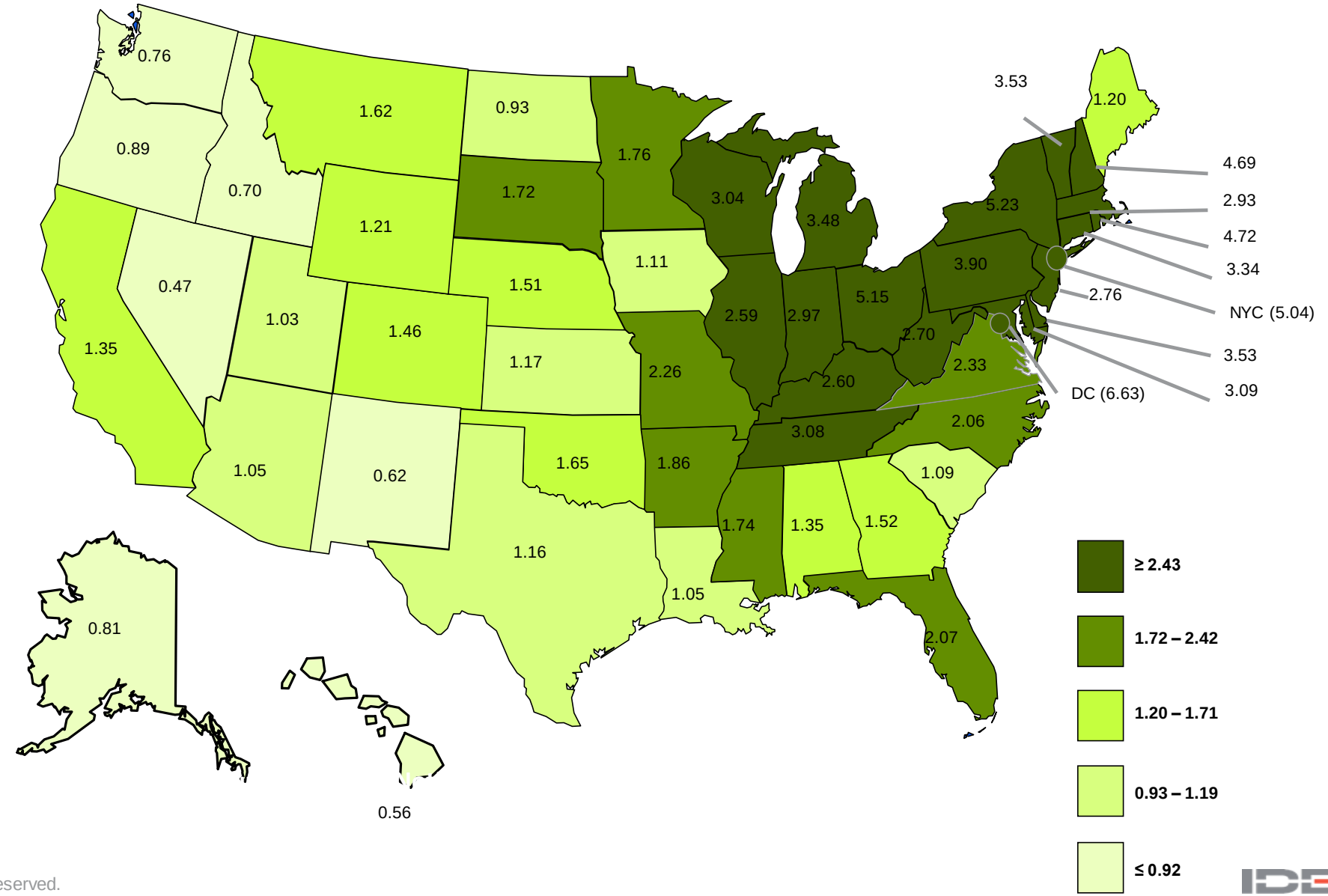


Legionellosis: US case

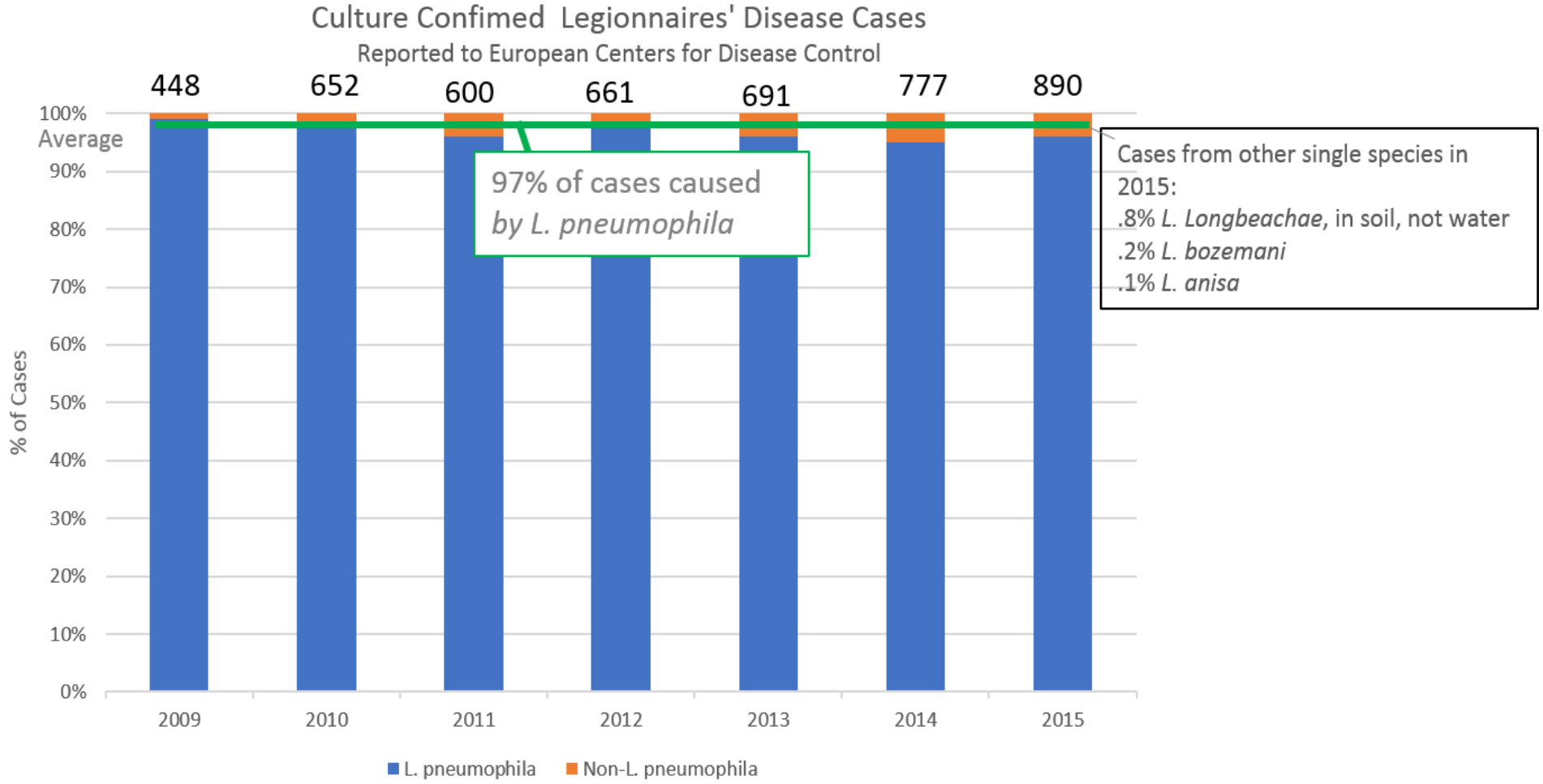
Reported cases by state

2017

Cases/100,000 population



L. pneumophila is the cause of 97% of Legionnaires' disease cases

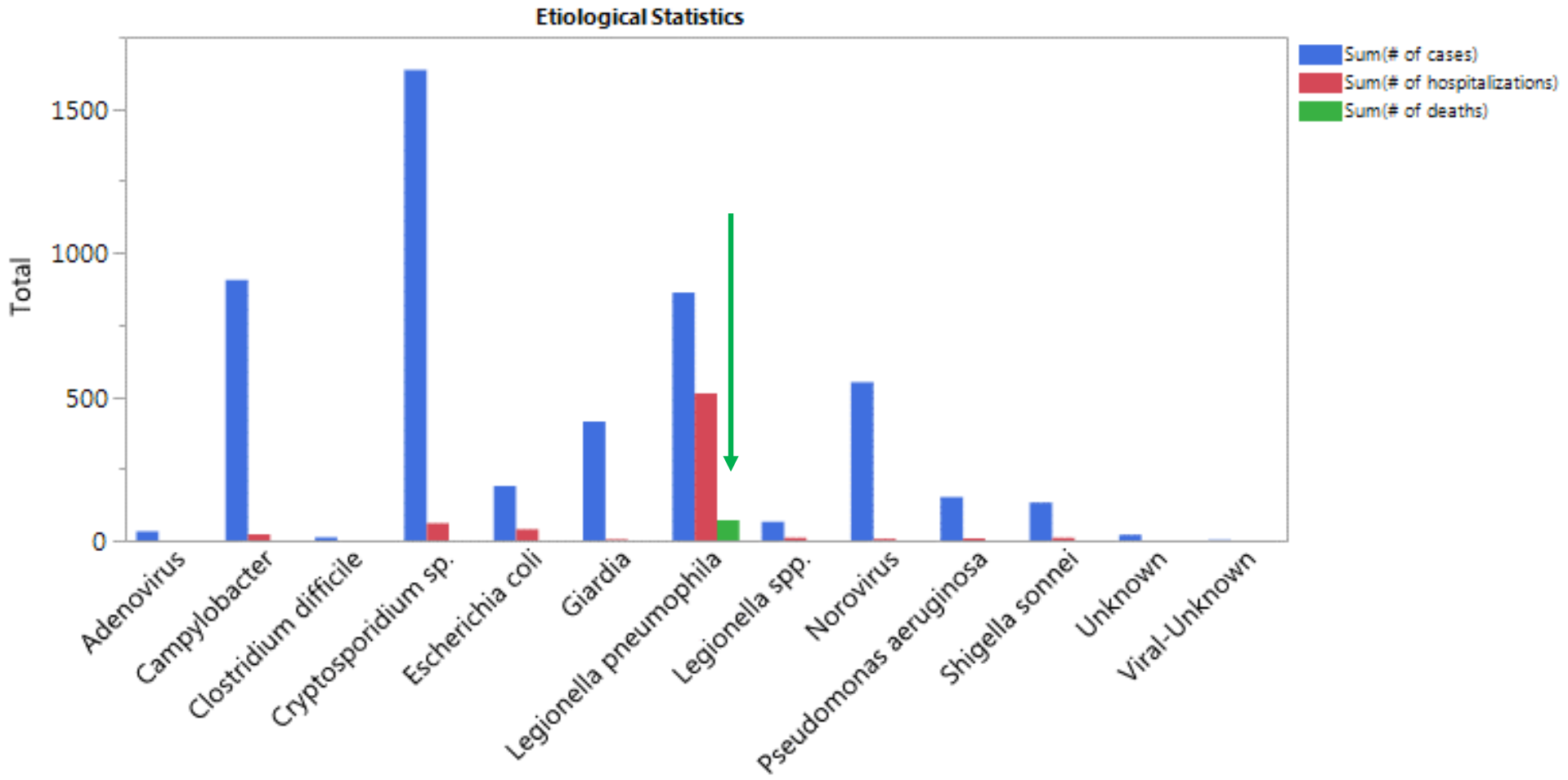


Data from clinical cultures of 4,719 patients over seven years in 17 countries

Source: https://ecdc.europa.eu/en/publications-data/legionnaires-disease-europe-2015

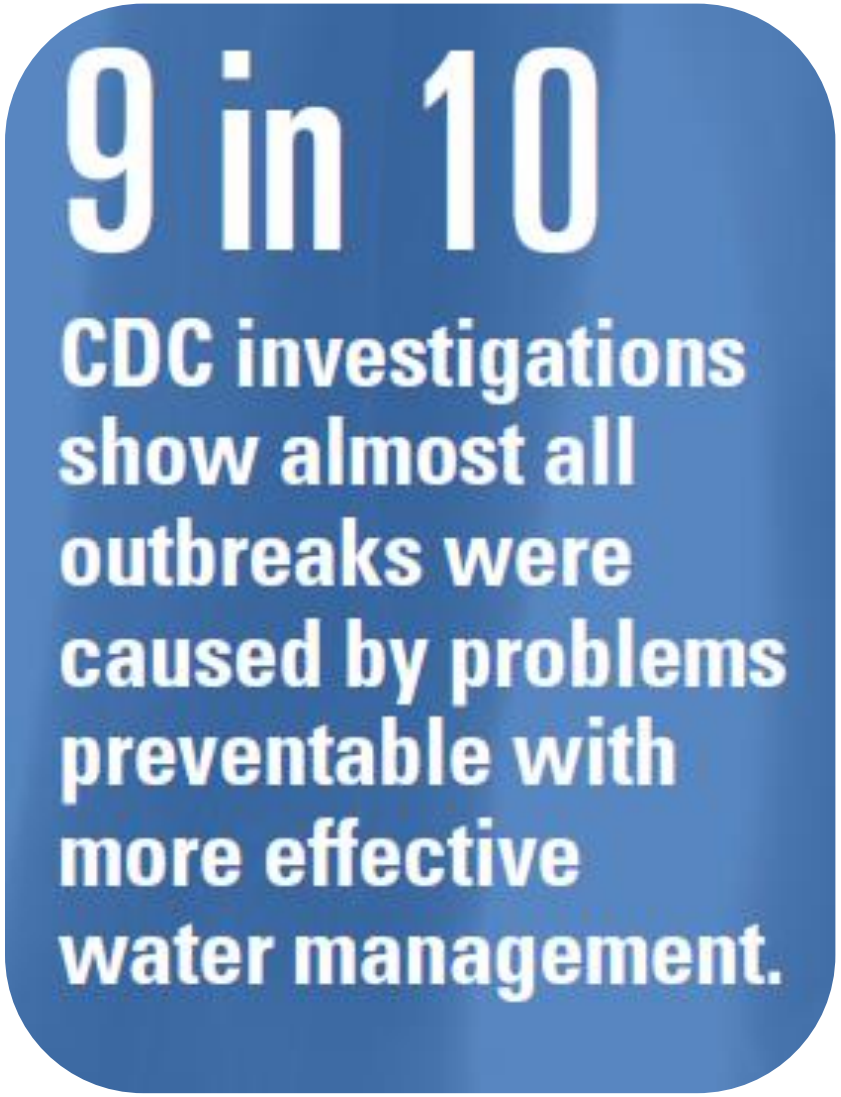
L. Pneumophila - the most dangerous waterborne pathogen

Waterborne outbreaks associated with drinking water, 2013-2014



Benedict KM, Reses H, Vigar M, et al. Surveillance for Waterborne Disease Outbreaks Associated with Drinking Water — United States, 2013–2014. MMWR Morb Mortal Wkly Rep 2017;66:1216–1221

Legionnaires' disease is preventable

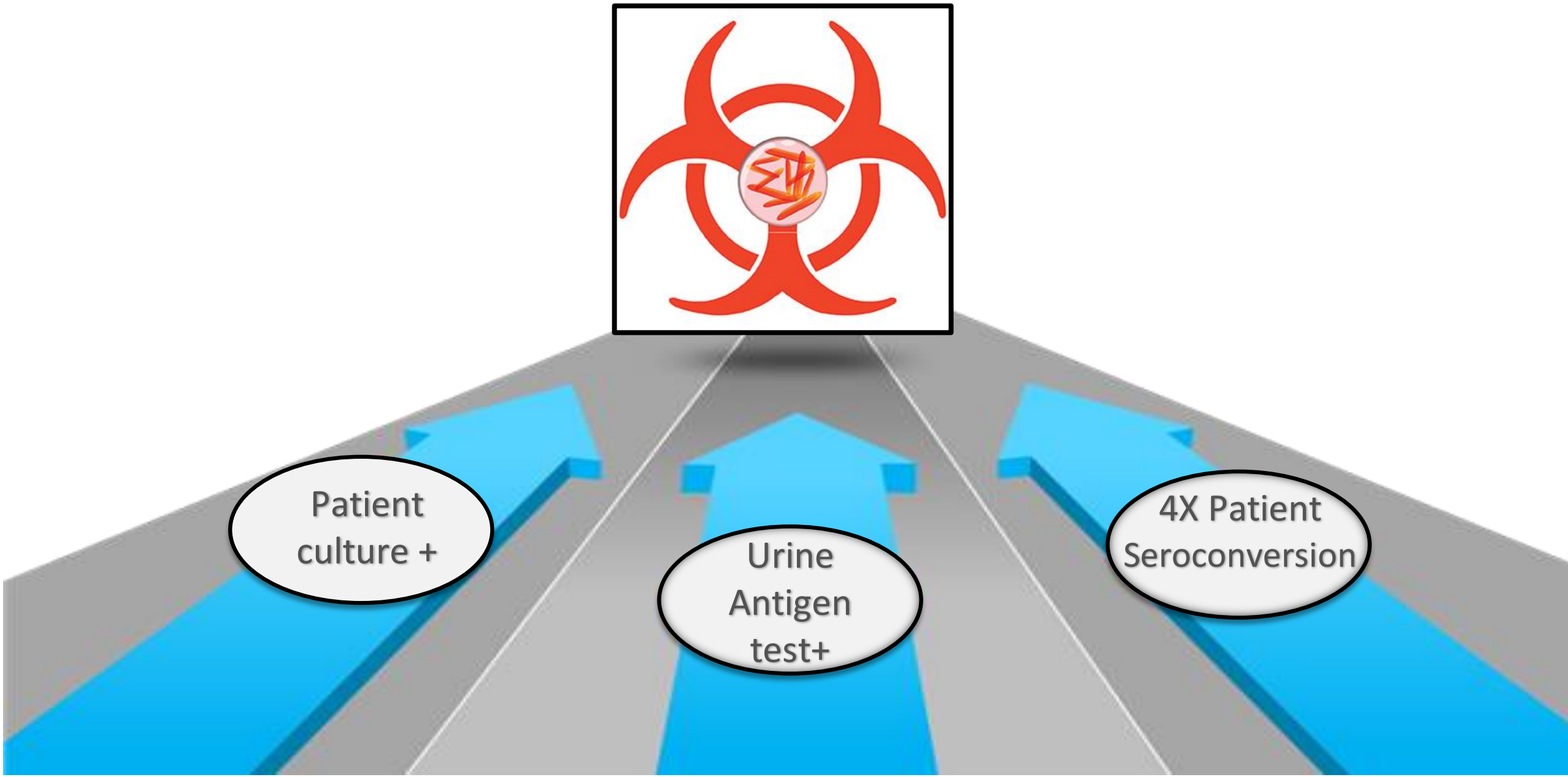


Adapted from CDC *vital*Signs June 2017
https://www.cdc.gov/vitalsigns/pdf/2017-06-vitalsigns.pdf

Many organizations focus on managing *L. pneumophila*

Defining a legionellosis outbreak

Defining legionellosis case



Legionellosis case reporting

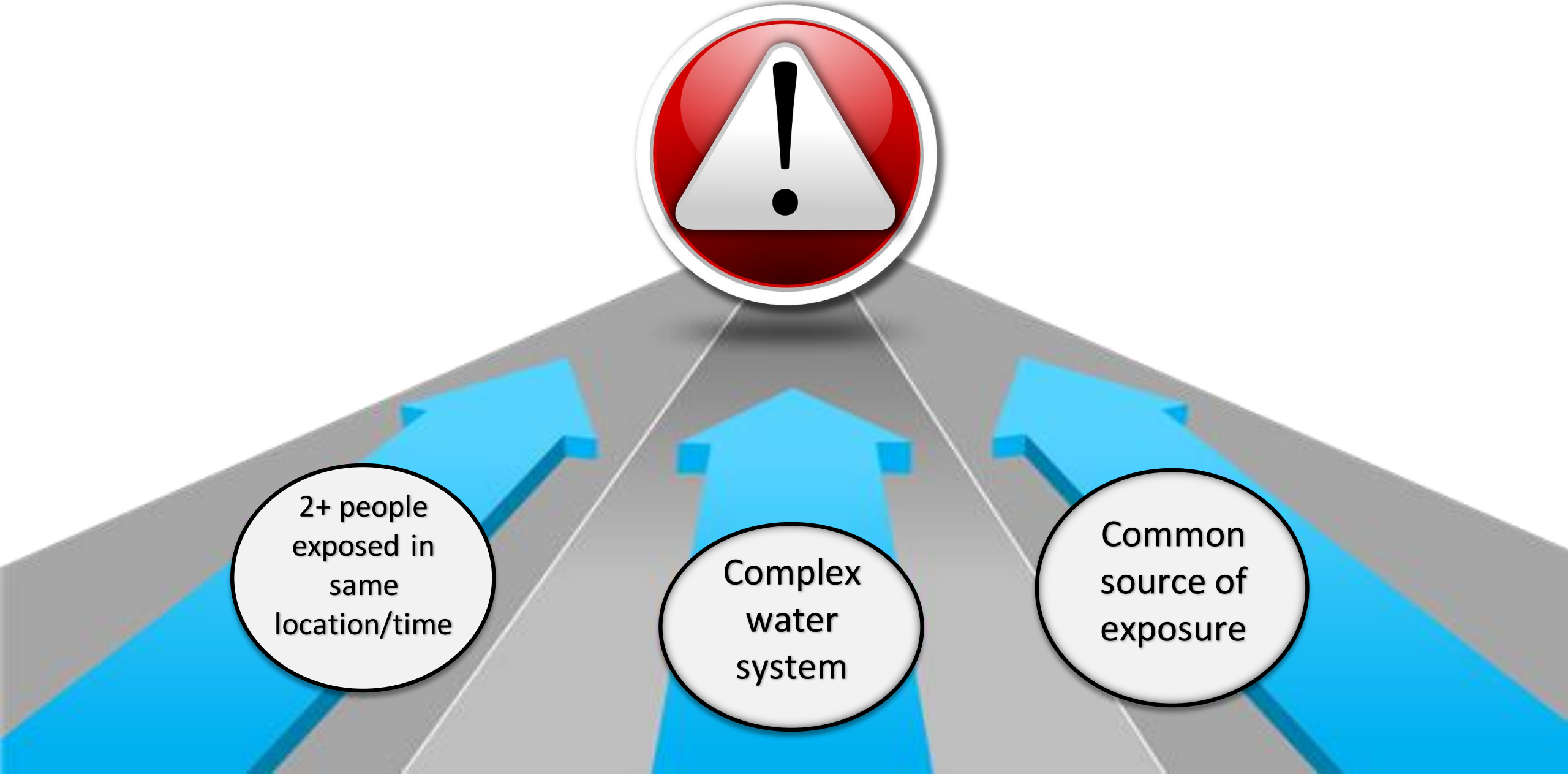
Confirmed cases of legionellosis are to be reported to CDC using:

1. National Notifiable Diseases Surveillance System (NNDSS)
2. Supplemental Legionnaires' Disease Surveillance System (SLDSS) contact Dr Claressa Lucas

Resources:

- Reporting a case: https://www.cdc.gov/legionella/health-depts/surv-reporting/report-cases.html
- Case reporting Form: https://www.cdc.gov/legionella/downloads/case-report-form.pdf
- Report travel-associated cases within 7 days to: travellegionella@cdc.gov

Defining Legionnaires' disease outbreak



Defining a legionellosis outbreak

Cases and outbreaks can include two types of exposure routes:

Travel-associated

Hotel, spa, cruise ship

File EPI-X Request to alert other states. Email travellegionella@cdc.gov.

Community acquired

Building water system at a hospital, nursing home, office, apartment complex

Will you need to do a full investigation??

Legionnaires' disease outbreak investigation tools

1. Obtain a Detailed Exposure History and Identify Pattern
   - CDC's Legionnaires' Disease Hypothesis-generating Questionnaire Template Cdc-word
   - CDC's Line List Template is a tool to summarize case demographic, clinical, and exposure information specific to a community-associated outbreak

2. Conduct Additional Case Finding for Community-associated Case(s)
   - Notify local clinical laboratories and healthcare providers for additional case finding (e.g., issue a health advisory notification [HAN]) Provide guidance for appropriate diagnostic testing

Legionnaires' disease outbreak investigation tools

Other Considerations

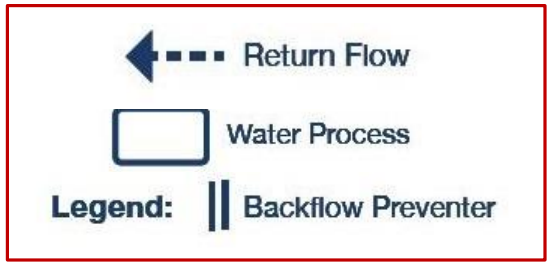
- Map all patient residences and sites for daily activities
- Identify any possible common exposures through conducting patient interviews
- Contact the local water authority to determine changes that could have contributed to *Legionella* growth (e.g., modifications to potable water disinfection, water main breaks, major construction activity, water service interruptions)
- Consider cooling towers as a possible source if cases are tightly clustered in time and neighborhood but patients lack common potable water exposures

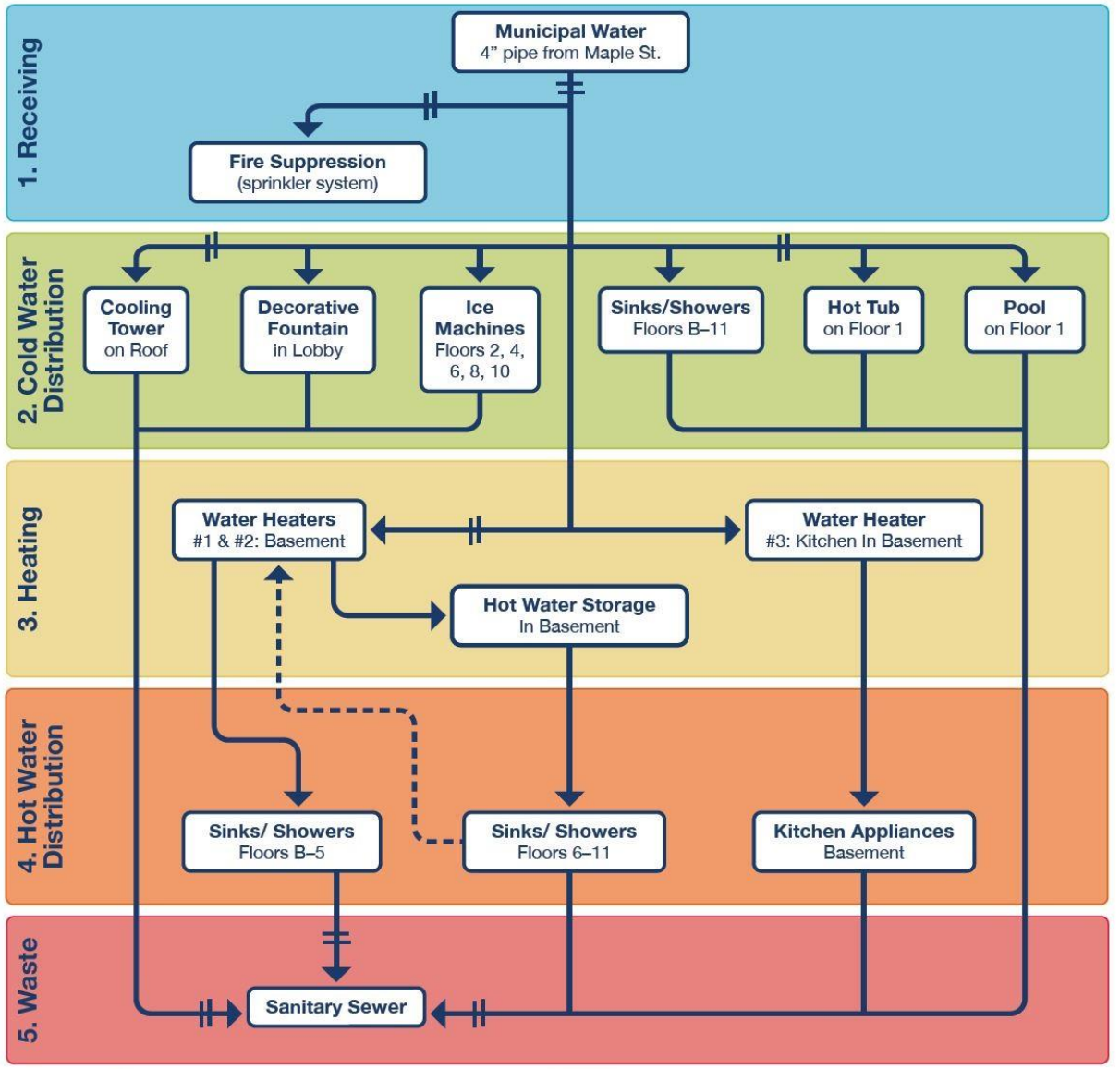
Where to sample for *L. pneumophila*

Risk areas are already defined in a WSP

Process Flow Diagrams

ASHRAE 188
CDC Toolkit





Water Safety Plan (WSP) 7 step program

WATER SAFETY (RISK) MANAGEMENT STEPS

ROLES & RESPONSIBILITIES

DESCRIBE THE SYSTEM

IDENTIFY RISK AREAS

DETERMINE CONTROLS

MONITORING & CORRECTIVE ACTIONS

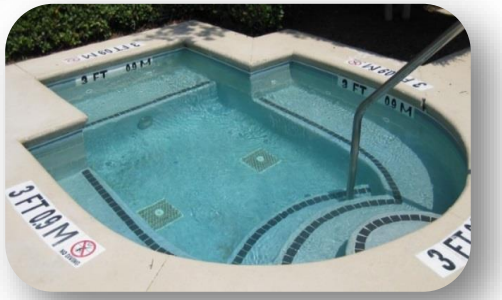
VERIFY & VALIDATE THE PLAN

DOCUMENT

Components in the WSP to consider sampling in an outbreak

Consider sampling these part of the building water system:

- Cooling Towers
- Evaporative condensers
- Whirlpool spas
- Ornamental fountains
- Misters, air washers, atomizers, humidifiers
- Devices that aerosolize and release fine water droplets, including CPAP other respiratory/surgery devices



Choosing a testing laboratory

Have a laboratory response plan now

Public Health Offices should coordinate with their partner Laboratories to create a plan for:

1. Routine testing as part of any water safety plan at a building, hospital, nursing home, etc.

1. Outbreak investigation assistance, for when a case or outbreak has been identified, requires connecting clinical to environmental samples to identify route cause for intervention. CDC Laboratory Response Plan

CDC Laboratory Response toolkit helps your prepare for an outbreak investigation

The laboratory response toolkit includes:

- A checklist to assess current *Legionella* testing capacity
- Templates for identifying response team and determining roles and responsibilities
- Templates for a plan to test clinical specimens and environmental samples in your laboratory
- Templates for a plan to refer samples to an outside laboratory
- A sample Legionnaires' disease Laboratory Response Plan
- An example response scenario with a sample workflow and timeline
- Sample worksheets to document laboratory results
- Example instructions for specimen storage and shipping

Criteria for choosing an outside testing laboratory

The laboratory should demonstrate proficiency in subject method and be either or both:

- CDC ELITE, should consider an ELITE laboratory if there is a case or outbreak
- National/State accredited laboratory should be used for routine testing such as testing as part of a water safety plan

What is the difference between ELITE certified and National/State accredited laboratories?

CDC ELITE Certified Vs. National/State accreditation

CDC ELITE Requirements	Accreditation Requirements
• Be able to perform some version of spread-plate culture • Pass 2 test samples per year via presence/absence (P/A)	• Specifically list S.O.P. for each method on Scope • Pass at 1-2 accredited Proficiency Tests (PTs) per year • Have a Quality Management System • Have a QAPP for each client • Have sample Chain of Custody, sample receipt and data reporting forms signed by staff/QA officer • Have regular 3rd party audits to determine compliance to accreditation processes

Interviewing an outside laboratory

Ask to see these items:

- Accreditation Certificate
- Scope of Accreditation
- S.O.P. for each *Legionella* method on their Scope; will give insight into TAT and if they can ID *L. pneumophila* and serotypes
- Do they have a Quality Management System and write a QAPP for each client
- A blank Chain of Custody and redacted Data Report, learn how they report their test results

Example Data Report

MONTEREY COUNTY HEALTH DEPARTMENT

Consolidated Chemistry Laboratory

1270 Natividad Road, Salinas, CA 93906
Phone (831)755-4516 Fax (831) 755-4552

ELAP Certification Number: 1395

[redacted]

[redacted]

Lab Number: AC19872 **Client Code:** [redacted]

Sample Description: [redacted] Collection Date/Time: [redacted] 11:25
Source Code: Submittal Date/Time: [redacted] 14:27
Sample ID: Sample Collector: [redacted]

Sample Comments: [redacted] Water. Receiving temperature 17.0°C.

Analyte	Method	Unit	Result	PQL	Analysis Start Date/Time
L. pneumophila - Culture	CDC	Present/Absent	**ABSENT**	Variable	[redacted] 10:44
Analysis Comments: A 500ml portion of the water sample was tested by membrane filtration followed by culture. Legionella pneumophila was not present.					
Legionella spp. - Culture	CDC	Present/Absent	**INDETERMINATE**	Variable	[redacted] 10:44

Analysis Comments: A 500ml portion of the water sample was tested by membrane filtration followed by culture. No Legionella spp. were detected by culture methods. The laboratory also performed a nucleic acid amplification assay on concentrated sample for internal investigative purposes, and Legionella spp. DNA was detected. Discrepancies between PCR and culture methods is not uncommon. PCR detects viable and non-viable organisms; culture methods only detect viable organisms. Non-detection by culture may occur due to lower sensitivity, non-culturability of injured organisms, overgrowth of other bacteria, and absence of viable organisms. Recommend submission of additional samples for further testing.

Report approved by: Donna Ferguson

Donna Ferguson, Ph.D, P.H.M
Laboratory Director

Chain of Custody Example

ENVIRONMENTAL ANALYSIS REQUEST FORM
MONTEREY COUNTY CONSOLIDATED CHEMISTRY LABORATORY
1270 NATIVIDAD ROAD, SALINAS, CALIFORNIA 93906 Phone (831) 755-4516

Shaded areas for laboratory use only

Chain of Custody:

Collected by (Print & sign):	Received by:	Date & Time:
Relinquished by:	Received for Laboratory:	Date & Time:

Client Name:	Email Address (if applicable):	ANALYSIS REQUESTED
Address:	Copy to: ☐ Monterey Co EH ☐ State: _____ ☐ Other: _____	
City, State, Zip:	Phone: Results delivery: ☐ Mail ☐ E-Mail	

Laboratory Number	Sample ID or System #	Sample Site or Description	Collection Date & Time	Matrix(1) 1-Routine 2-Repeat 3-Replacement	Number of Containers	Coliform	MMO (P/A) ☐ Quanti ☐	Nitrate (N)					

(1) D=Drinking Water (Specify as routine, repeat, replacement, special, or other) W=Wastewater (Specify as grab or composite) I=Irrigation S=Storm

[ ] Payment received with delivery	Amount: _____	Sample comments (irregularities/preservation, billing information if different than reporting):
Check: _____	Initials: _____	
Receipt #: _____	Date: _____	Receiving Temp: _____ °C Blank/Sample

Analytical Testing Methods

qPCR for *L. pneumophila* and L. species

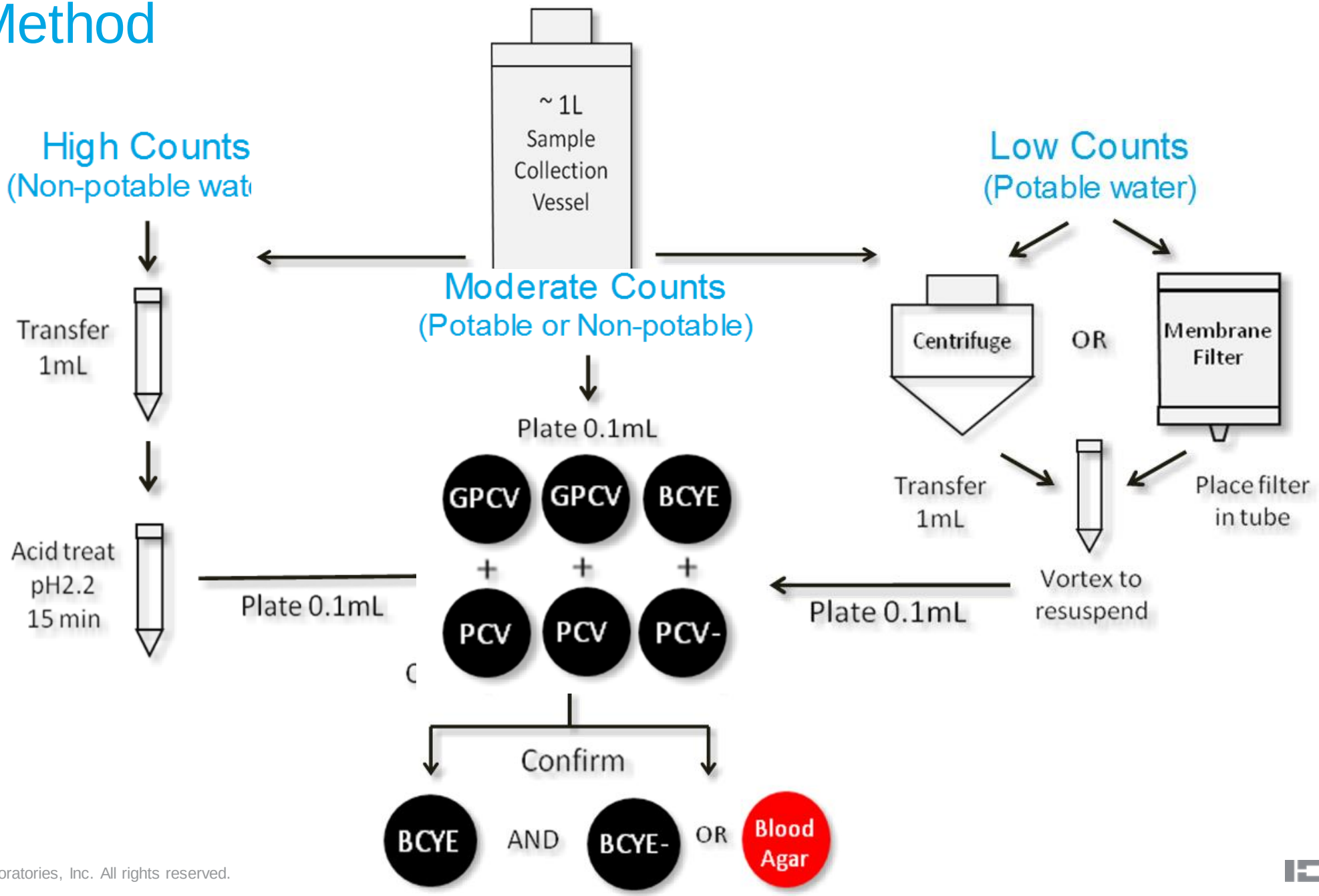
Some laboratories use qPCR, or molecular detection of *Legionella*, to screen samples that should be cultured. In case or outbreak, you will need to retain the live culture for future testing, so PCR is a tool, *but not a substitute* for culture.

Culture Methods for water Testing

Liquid Culture

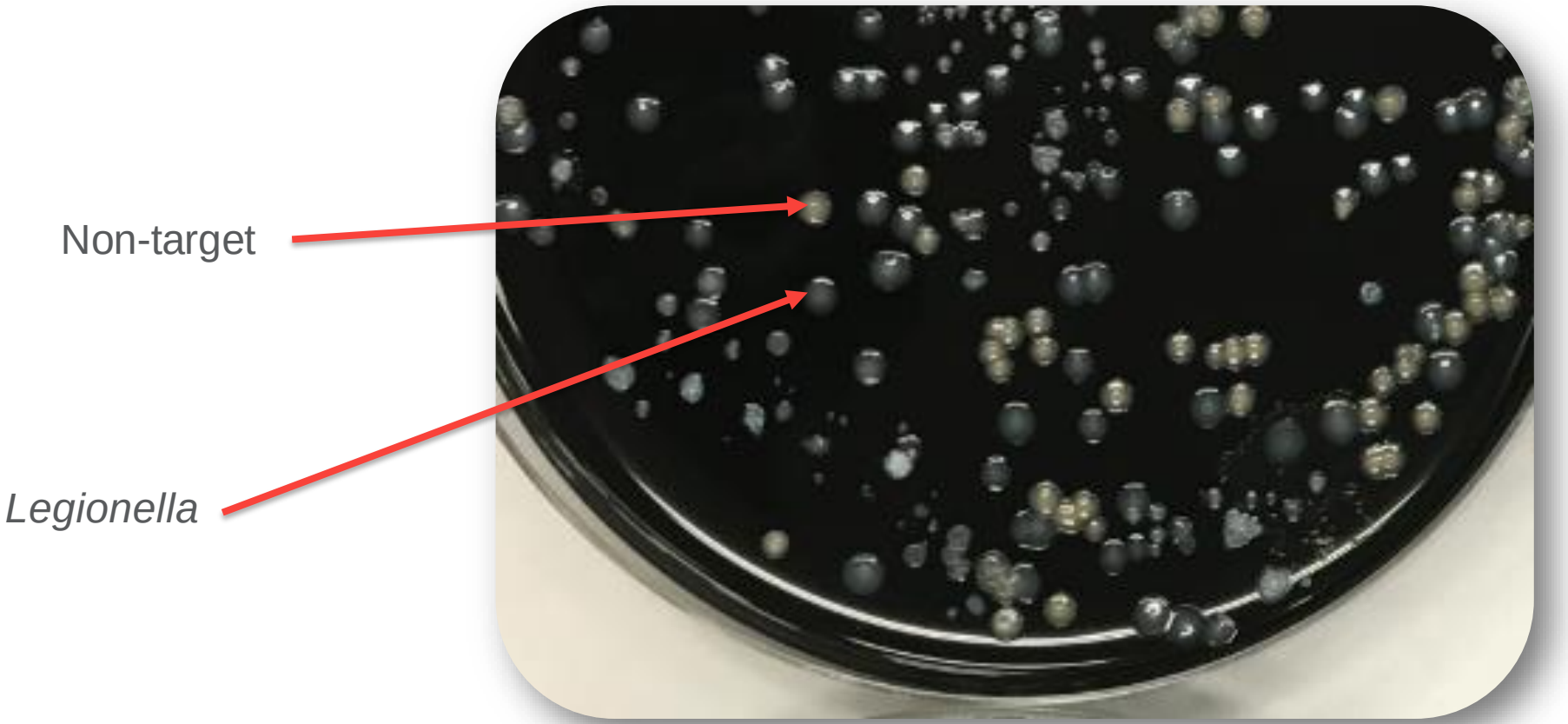
Solid media Culture

CDC Method

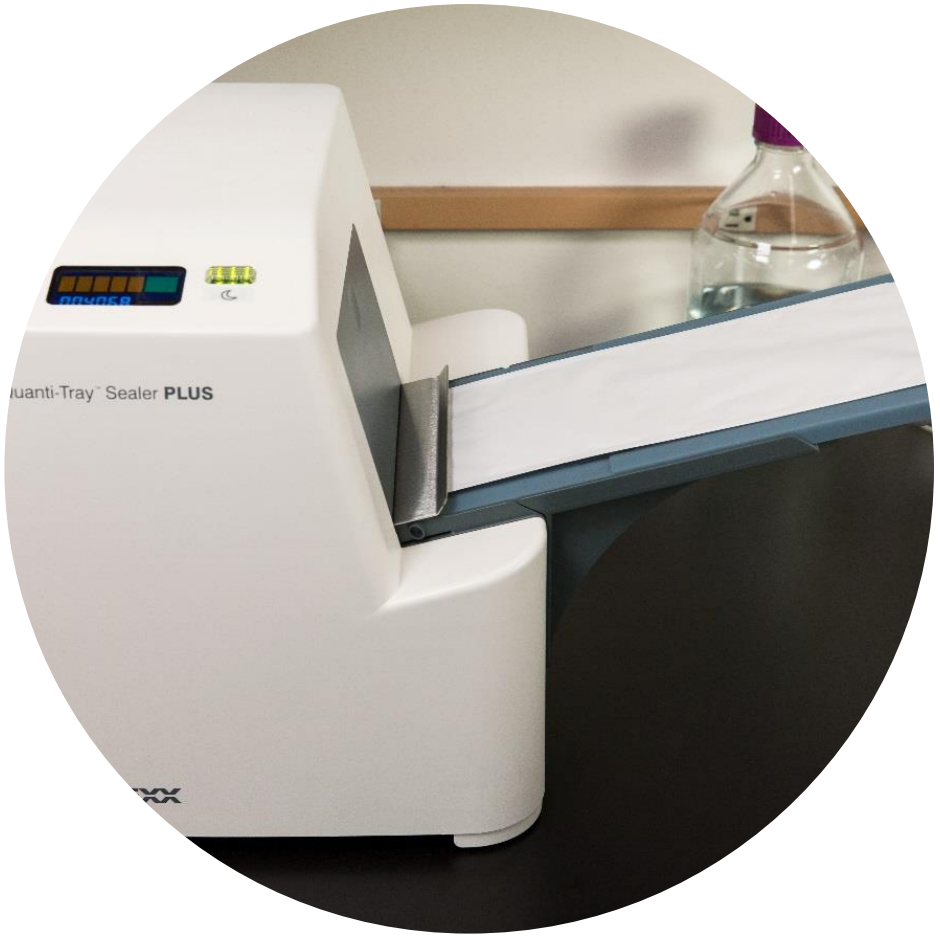


Spreadplate methods are not easy to interpret or reproduce

- Subjectivity of colony interpretation
- Interference of non-*Legionella* organisms
- Analyst experience level



Legiolert liquid culture method



Detection of *L. pneumophila* by Legiolert

- Confirmed results without additional tests
- A positive result can be confirmed without additional incubation
- Detects and quantifies all serogroups of *Legionella pneumophila (Sg1 – 15)*
- 99% reproducibility and repeatability
- Smaller sample size of 100 mL
- Quicker TAT, results in 7 days

Spread-plate culture vs Legiolert

Spread-Plate Culture

- 250 ml or 1000 ml sample
- Detects/quantifies *Legionella* species (but not all)
- Can detect *L pneumophila* with extra steps
- Serogrouping and speciation direct from plate
- 7-12 day TAT
- Higher variability in processing
- Lower repeatability
- Media can vary per vendor
- Interference from background bacteria, yeasts and filamentous molds
- Possibility of co-culture with *Legionella*

Legiolert Culture

- 120 ml sample
- Detects and quantifies LP missed by spread-plate cultures
- 7-day TAT
- Serogroup directly from wells
- 99% Repeatability
- 99% Reproducibility
- High specificity for all LP serogroups 1-15
- Reduce the need to re-test because of overgrowth (vs. TNTC plates)

Legionella speciation and latex agglutination

Culture for live organisms is the gold standard, additional steps needed for spread-plate culture can include determining species and serotype of *L pneumophila*:

Agglutination will determine if you have L pneumophila serotype 1 or 2-14

Used to determine the species of *Legionella*. Alternative that is more often used is to serotype *L pneumophila*

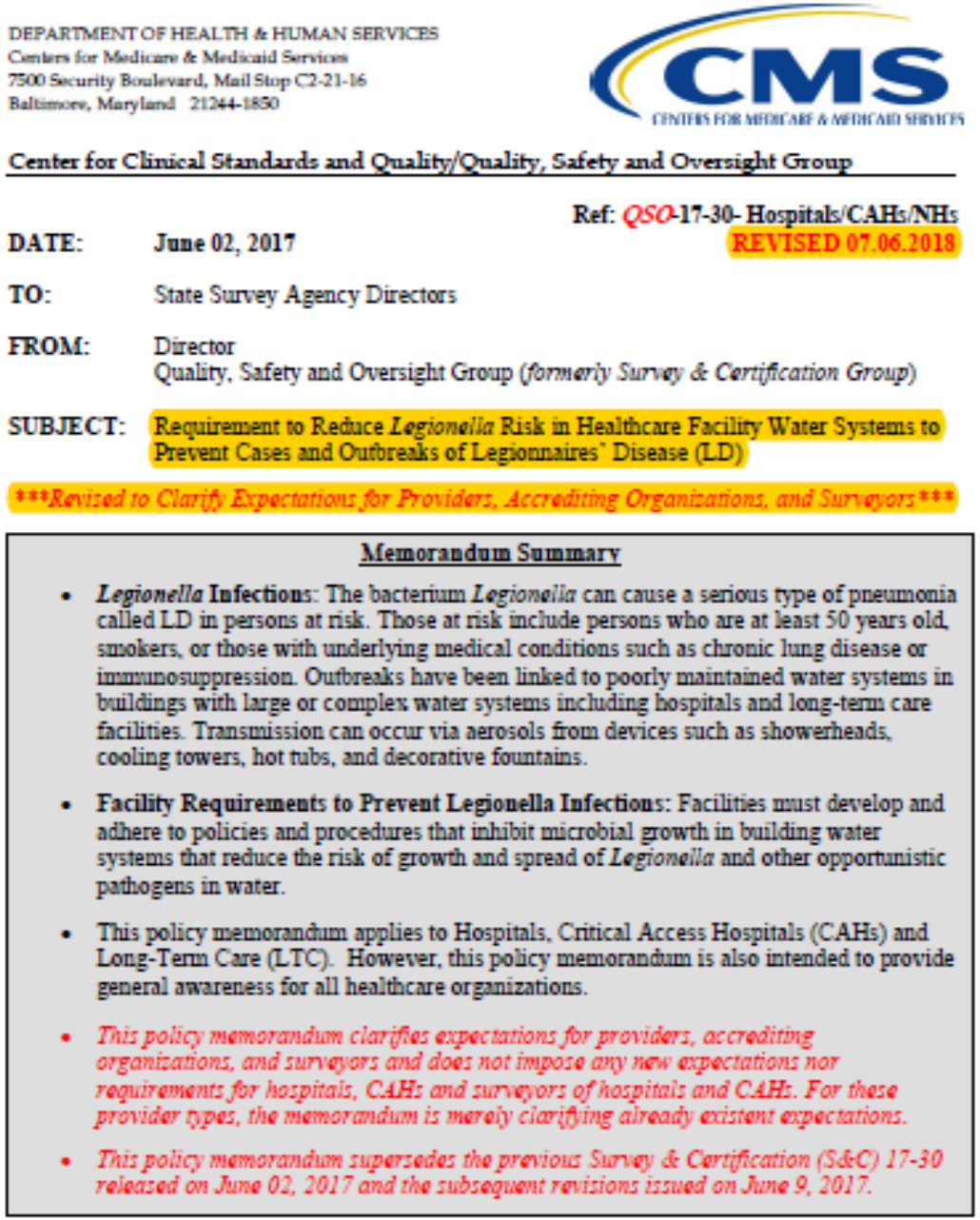
Preventing Legionnaires' Disease

Centers for Medicare & Medicaid Service (CMS) Memo

Memo June 2017
Updated July 2018

Sent to:
State Survey Agency Directors

Subject:
Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease (LD)



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety and Oversight Group

Ref: *QSO*-17-30- Hospitals/CAHs/NHs
REVISED 07.06.2018

DATE: **June 02, 2017**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety and Oversight Group (*formerly Survey & Certification Group*)

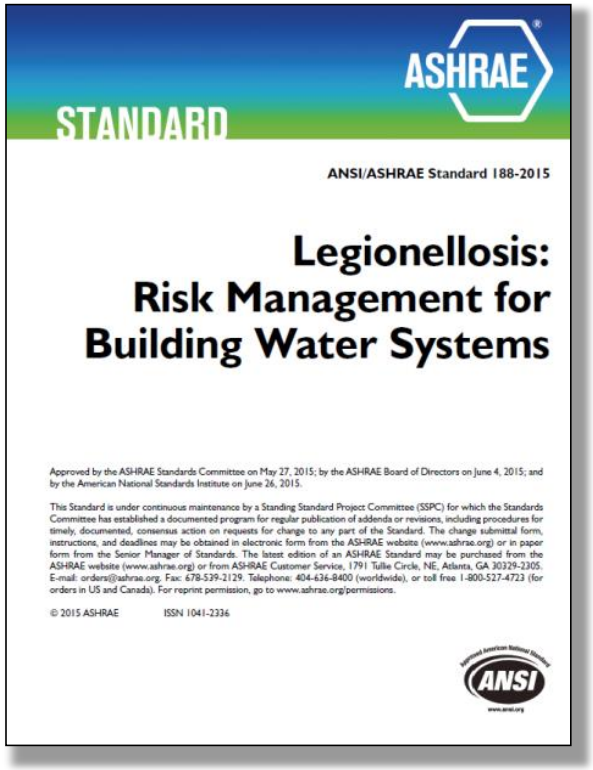
SUBJECT: Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease (LD)

Revised to Clarify Expectations for Providers, Accrediting Organizations, and Surveyors

Memorandum Summary

- ***Legionella* Infections**: The bacterium *Legionella* can cause a serious type of pneumonia called LD in persons at risk. Those at risk include persons who are at least 50 years old, smokers, or those with underlying medical conditions such as chronic lung disease or immunosuppression. Outbreaks have been linked to poorly maintained water systems in buildings with large or complex water systems including hospitals and long-term care facilities. Transmission can occur via aerosols from devices such as showerheads, cooling towers, hot tubs, and decorative fountains.
- **Facility Requirements to Prevent Legionella Infections**: Facilities must develop and adhere to policies and procedures that inhibit microbial growth in building water systems that reduce the risk of growth and spread of *Legionella* and other opportunistic pathogens in water.
- This policy memorandum applies to Hospitals, Critical Access Hospitals (CAHs) and Long-Term Care (LTC). However, this policy memorandum is also intended to provide general awareness for all healthcare organizations.
- *This policy memorandum clarifies expectations for providers, accrediting organizations, and surveyors and does not impose any new expectations nor requirements for hospitals, CAHs and surveyors of hospitals and CAHs. For these provider types, the memorandum is merely clarifying already existent expectations.*
- *This policy memorandum supersedes the previous Survey & Certification (S&C) 17-30 released on June 02, 2017 and the subsequent revisions issued on June 9, 2017.*

ASHRAE 188:2018 Standard and the CDC Tool Kit: Resources to create WSM plans



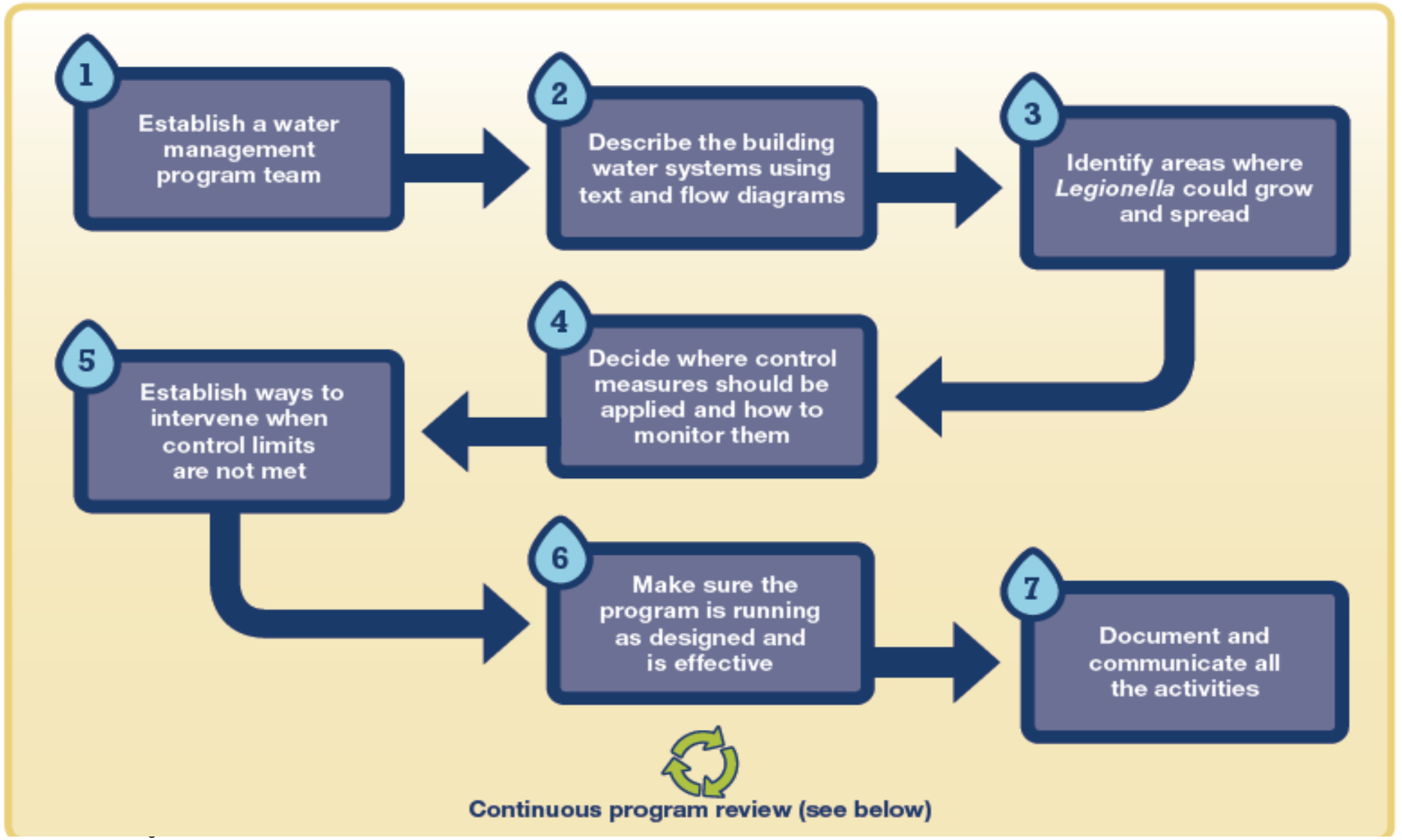
ASHRAE 188

- First NA standard
- Only ANSI Accredited Standard
- Consensus view of the best practices for managing Legionnaires' risk in building water systems
- Recommended Water Safety Plan
- Testing specific section

CDC Toolkit

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

CDC Tool Kit WSM Plan: 7 core activities



Source: CDC **Developing a Water Management Program to Reduce *Legionella* Growth & Spread in Buildings Version 1.1**

Additional Water Safety Management resources

- **Association of Water Technologies** (AWT) Certified Water Treaters list WWW.AWT.org
- **HC Info:** WSM Templates, checklists & technical information https://hcinfo.com/home/
- **ASHRAE:** Guidance on Reducing the Risk of Legionella www.ASHRAE.org
- **Centers for Disease Control (CDC):** Information on Legionella and the CDC Tool Kit www.cdc.gov/legionella
- **IDEXX:** information on *L. pneumophila* and a directory of testing laboratories www.idexx.com/legiolert

Accreditation Standards and Analytical Method Resources

TNI Accreditation Bodies: http://www.nelac-institute.org/content/NELAP/accred-bodies.php

AIHA/EMLAP: https://www.aihaaccreditedlabs.org/LabAccreditationPrograms/EMLAP/Pages/default.aspx

ISO 11731: 2017 https://www.iso.org/standard/61782.html

Legiolert: https://www.idexx.com/en/water/water-products-services/legiolert/

Question and Answer Session

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
	VA 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

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	≥ 20 cfu/mL
	New York City Dept. of Health	Legislation	≥ 10 cfu/mL
France	Ministry of Health	Legislation	≥ 1 cfu/mL
Germany	Trinkwasserverordnung TrinkwV 2001	Guidance	≥ 1 cfu/mL
Canada	Quebec	Legislation	≥ 10 cfu/mL