

WATER MANAGEMENT ESSENTIALS

Why Verification and Validation Testing Matter

Ten myths about waterborne pathogen testing,
and what the standards actually say



YASMINE HADDAD
Regional Business Development Manager
Phigenics

What we just measured

Ten beliefs. One underlying question.

"How do we know the program is working?"



01

THE WHY'S AND HOW'S

Water Management Overview

Why do we develop Water Management Programs?



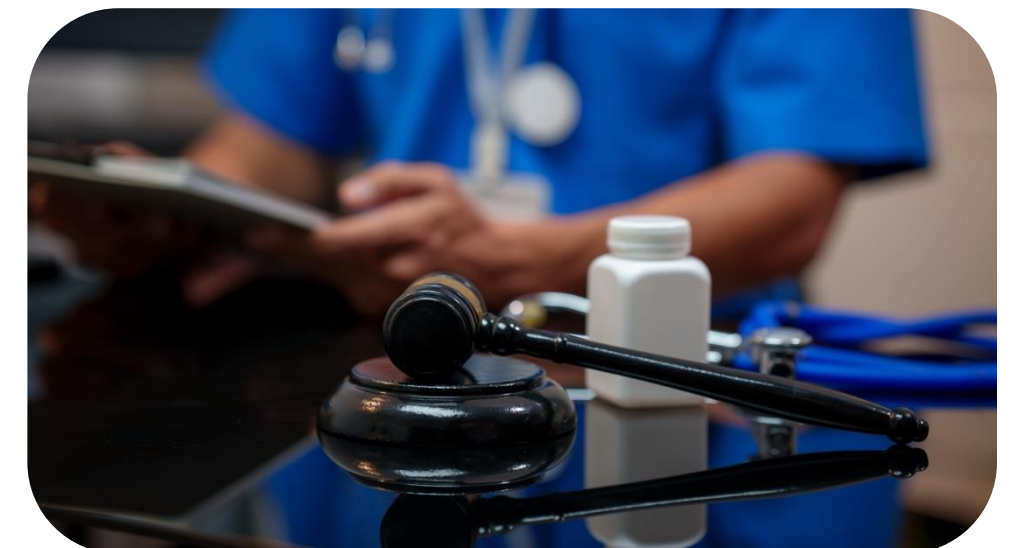
KEEP Patients Safe

From acquiring Legionellosis



ACHIEVE Compliance

With accreditation and surveys, e.g. CMS, JC



DRIVE Defensibility

Against litigation and unnecessary costs

WATER MANAGEMENT OVERVIEW

The Standards:

Requires

Supports

CMS MEMO S&C 17:30

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1909

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

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)

Ref: **OSCA17-30-Hospitals/CAHs/NHs**
REVISED 07.06.2018

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.**

Background

LD, a severe sometimes fatal pneumonia, can occur in persons who inhale aerosolized droplets of water contaminated with the bacterium *Legionella*. The rate of reported cases of legionellosis, which comprises both LD and Pontiac fever (a milder, self-limited, influenza-like illness) has

JC PE.04.01.05

JOINT COMMISSION

R3 Report
REQUIREMENT, RATIONALE, REFERENCE

A supplementary publication of Joint Commission

June 12, October 17, 2021
UPDATED November 16, 2021

New Standard for Water Management Program — Hospitals, Critical Access Hospitals, and Nursing Care Centers

The new water management standard R3C: EC.02.05.01, EPs 1 through 4 (CAH and NAC were renumbered to PE.04.01.05, EPs 1 through 4) will go into effect January 1, 2022. This standard will appear in the July 1, 2021 spring update so that organizations will have the opportunity to become familiar with the requirements and begin planning for the additional expectations. EC.02.05.01, EP 14 (for hospitals and critical access hospitals) and EP 6 (for nursing care centers) will continue to be utilized for scoring purposes until January 1, 2022 and will then be deleted from these programs.

Currently, EC.02.05.01, EPs 6 and 14 address the need for organizations to minimize pathogenic biological agents in cooling towers, domestic hot and cold water systems, and other aerosolizing water systems. The expectation is that this process includes a risk assessment, water management plan, and testing protocols and acceptable ranges.

The new standard and EPs are designed to further improve the quality and safety of care provided to hospital patients and nursing care residents who are immunocompromised. This new standard incorporates the latest research and best practices with the primary goal of improving quality and safety in these settings.

Joint Commission evaluated expert literature to determine what additional requirements were needed to help protect immunocompromised patients and residents from waterborne pathogen-related diseases. The literature review revealed that in addition to the need for a risk assessment, water management plan, and testing protocols and acceptable ranges, there was a need for more specific requirements related to a water management program. The new standard requires that an individual or team be responsible for the oversight and implementation of the water management program, including but not limited to development, management, and maintenance activities. It also specifies required elements to be included in the water management program, such as a basic diagram that maps water supply sources, treatment systems, processing steps, control measures, and end-use points. The water risk management plan is based on the information in the diagram and includes an evaluation of the physical and chemical conditions of each step of the water flow diagram. There is also a requirement for an annual review of the water management program and when any changes have occurred.

R3 REPORT 1, ISSUE 32, OCTOBER 17, 2021
UPDATED NOVEMBER 16, 2021

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ANSI/ASHRAE
Std. 188-2021

ASHRAE

STANDARD

ANSI/ASHRAE Standard 188-2021
(Supersedes ANSI/ASHRAE Standard 188-2018)
Includes ANSI/ASHRAE addenda listed in Appendix D

**Legionellosis:
Risk Management for
Building Water Systems**

The Standard is under continuous maintenance by a Standing Standard Project Committee (SSPC) for which the Standards Committee has established a documented program for regular publication of addenda or revisions, including provisions for timely documented, consensus action on requests for change to any part of the Standard. Instructions for how to submit a change can be found on the ASHRAE® website (www.ashrae.org/continuous-maintenance).

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ANSI

ANSI/AAMI
ST108:2023

American National Standard

ANSI/AAMI
ST108:2023
Water for the processing of medical devices

AAMI

ANSI/ASHRAE Std.
514-2023

ASHRAE

STANDARD

ANSI/ASHRAE Standard 514-2023

**Risk Management for
Building Water Systems:
Physical, Chemical, and
Microbial Hazards**

Approved by the ASHRAE Standards Committee on June 24, 2023 and by the American National Standards Institute on July 31, 2023.

This Standard is under continuous maintenance by a Standing Standard Project Committee (SSPC) for which the Standards Committee has established a documented program for regular publication of addenda or revisions, including provisions for timely documented, consensus action on requests for change to any part of the Standard. Instructions for how to submit a change can be found on the ASHRAE® website (www.ashrae.org/continuous-maintenance).

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ANSI

REQUIRES Hospitals
to have a WMP

Accreditation based on
4 EPs modeled after
ANSI/ASHRAE Std 188

Definitive standard for
Legionella WMPs

Water quality standards
for sterile processing

Expands WMP hazard
scope beyond *Legionella*

Definition Verification and Validation

6. VERIFICATION:

Testing, auditing, or reviewing to confirm that the water management program is **being implemented exactly as designed**.

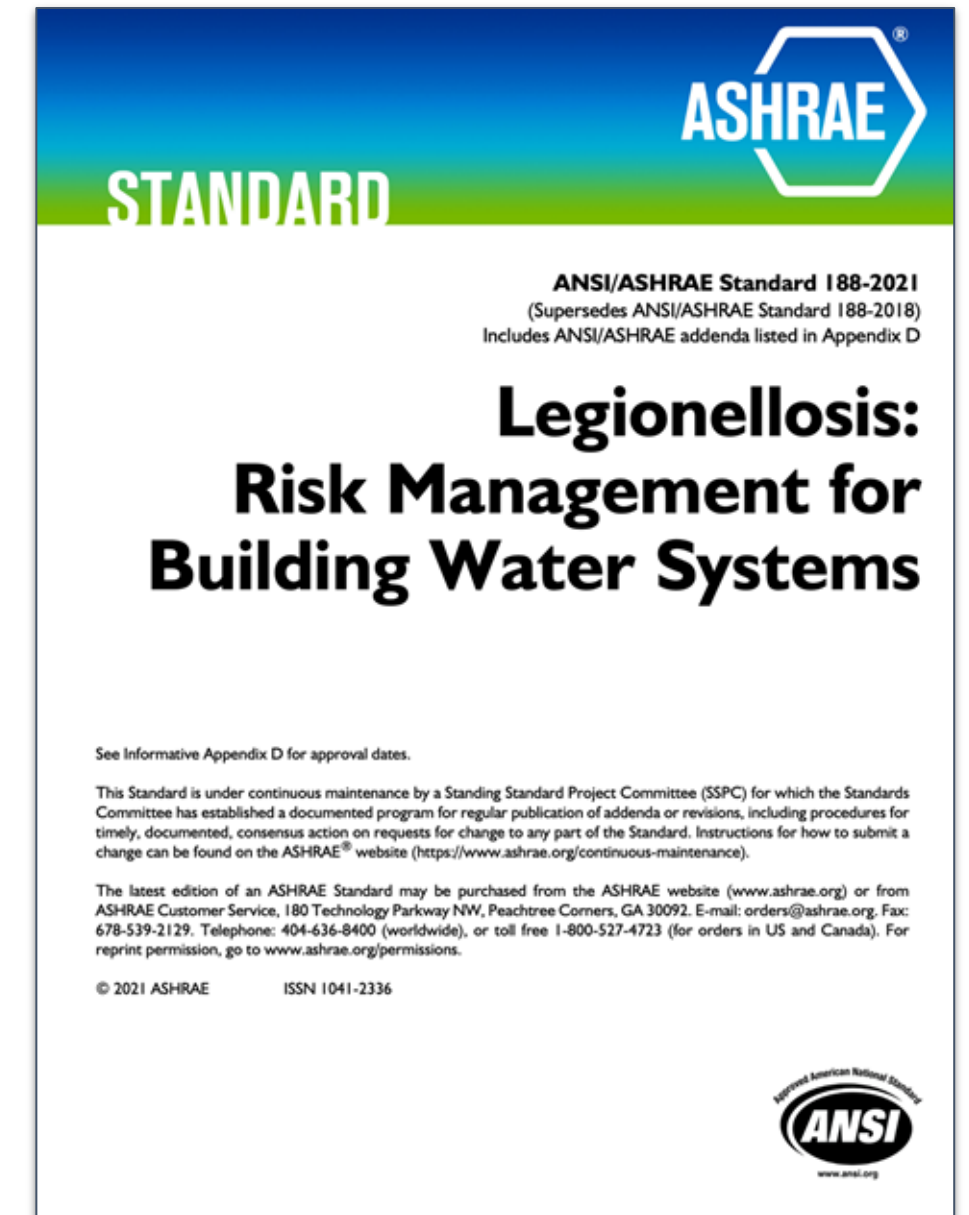
"Are we doing what we said we would do?"

7. VALIDATION:

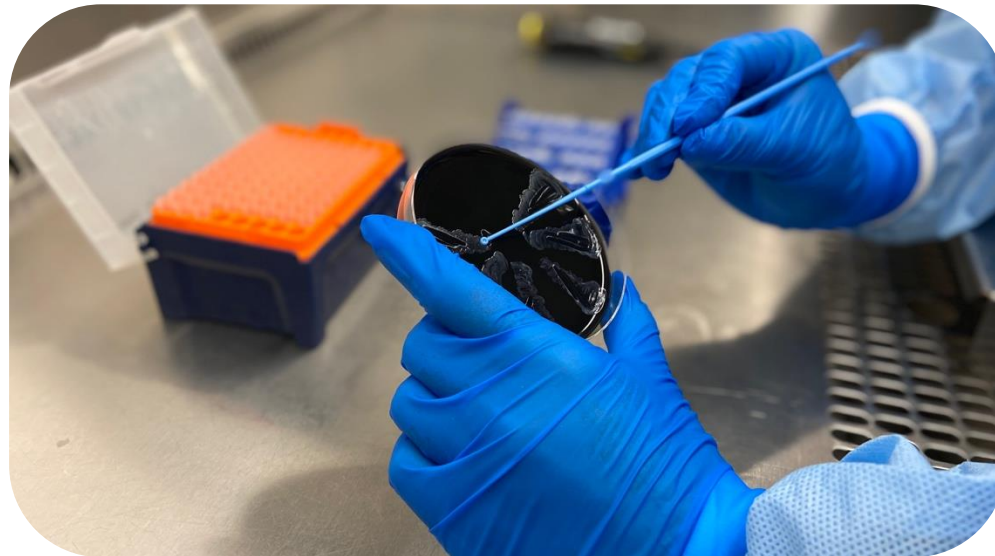
Testing, monitoring, or reviewing to confirm that the water management program is **actually effective at controlling the hazard**

Is our plan actually working to manage *Legionella* growth?

Both require documentation,
if you didn't document it then you didn't do it



Types of Environmental Tests for *Legionella*



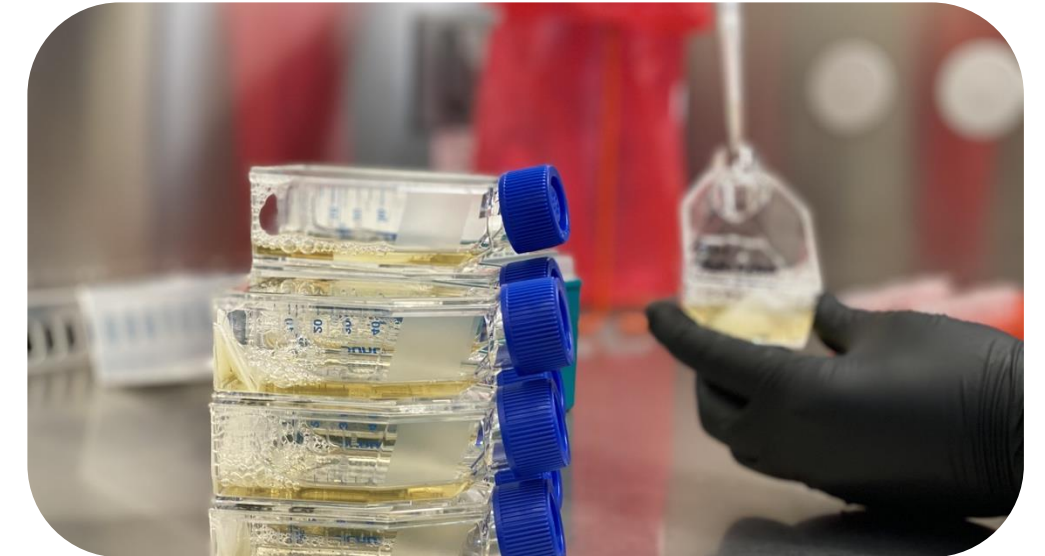
Culture Based

Captures slow growing, viable cells in low concentrations. Usually have reporting times of 10+ days.



Molecular Based

DNA PCR methods that can detect the presence of *Legionella* (living or dead) which can be a rapid negative screen. Reports in within 24 hours.

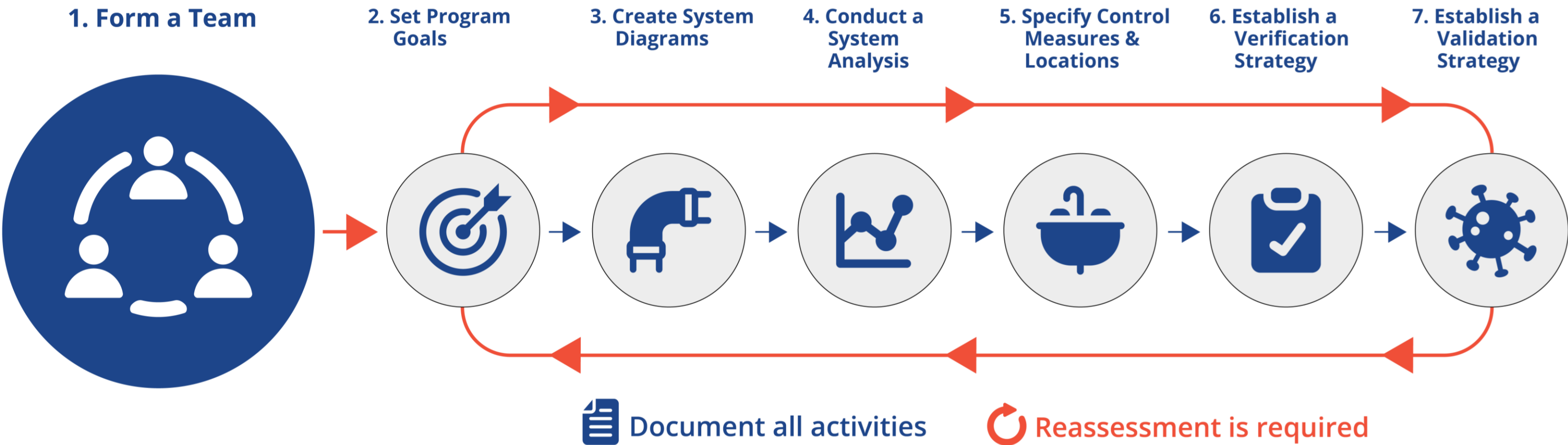


Hybrid Methods

Utilizes both Culture and Molecular methods to improve sensitivity and detect viable-but-non-culture *Legionella*.

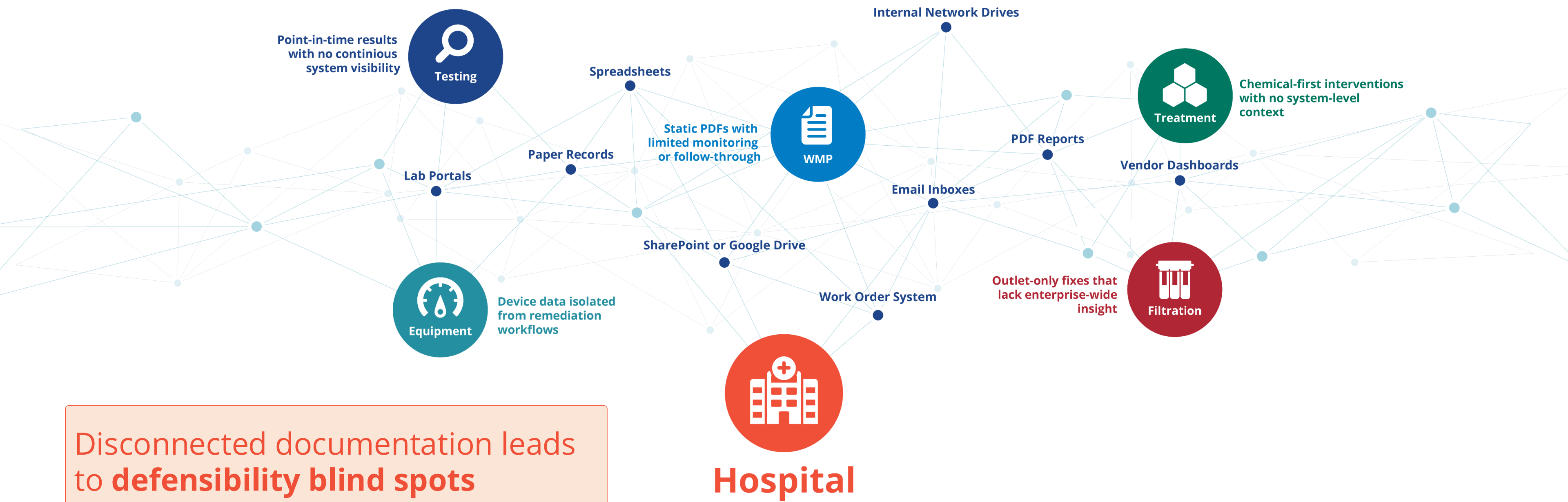
How Programs are designed and implemented:

7-Steps of Water Management



Designed for alignment with ANSI/ASHRAE Std. 188, CDC, CMS, and Joint Commission PE.04.01.05

Common Challenges to Program Implementation and Defensibility



DEMYSTIFYING WATER MANAGEMENT

Myths vs Facts

MYTH 1

“We check temps and residuals every month and everything is in range. Our program is validated.”

Myth

Routine monitoring of control measures means the water management program has been validated.

Fact

That is **verification**, not validation. Verification asks whether your control measures are holding, measured at the control locations against control limits. **Validation** asks whether hazards are controlled throughout the distribution system, measured at representative points against target ranges.

Same instruments. Different locations, different benchmarks, different questions.



01

WHY IT MATTERS

Verification and validation are not synonyms

	 Verification	 Validation
The question it answers	Are we doing what we said?	Is it actually working?
Where you measure	At the control measures	At representative points throughout the system
What you measure against	Control limits	Target ranges, plus clinical surveillance
What a control limit can be	A chemical or physical parameter only. A microbial count cannot be a control limit, which is why microbial testing is a separate documented decision.	

Same two words, different definitions across standards. ST108 uses ISO 11139 definitions.

MYTH 2

“If we test for it, we’ll find it!”

Myth

Testing for *Legionella* in our water systems means finding it every time.

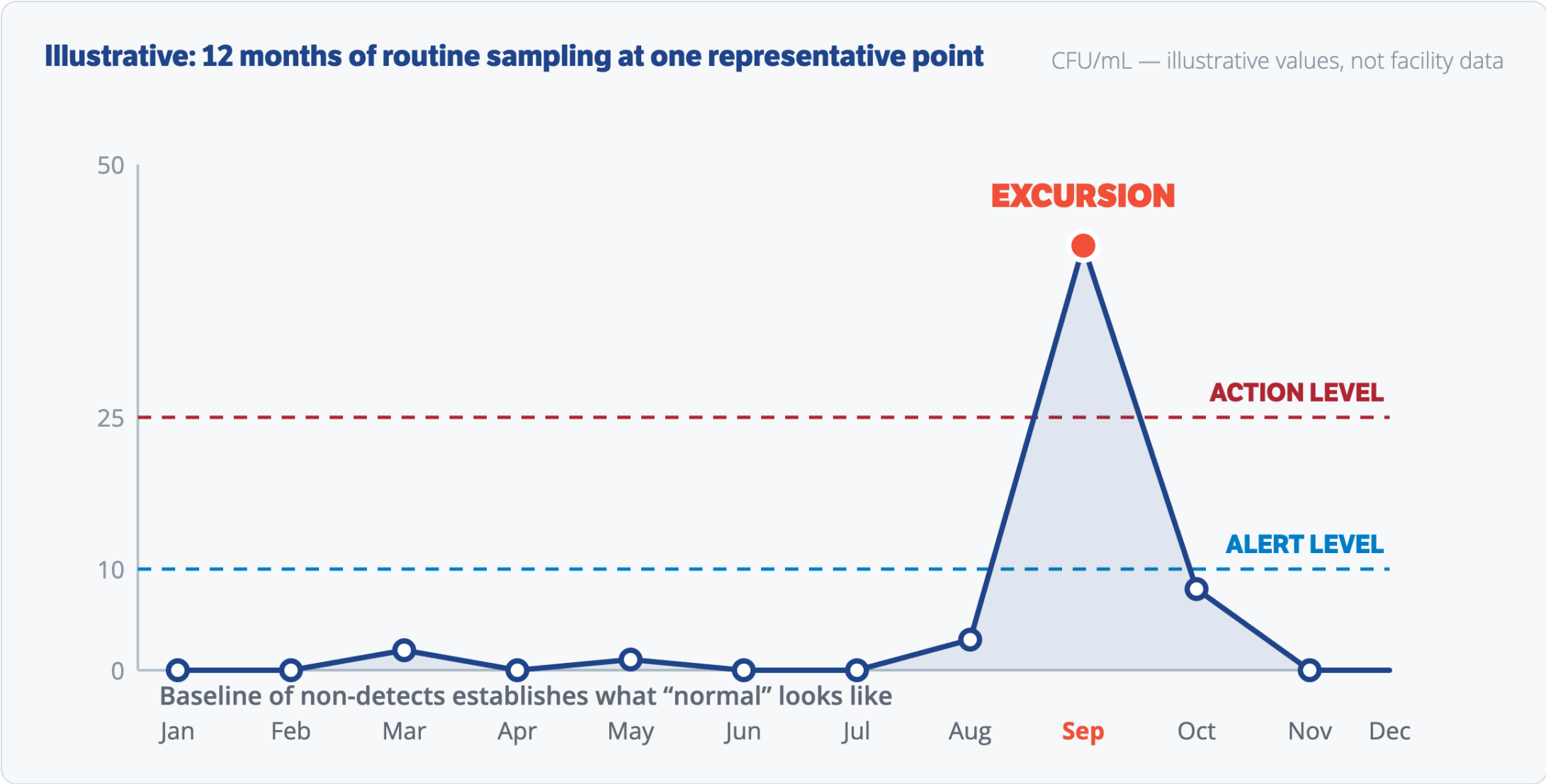
Fact

A well-designed program can and should produce **non-detects**. Under a functioning water management program, routine sampling that returns non-detectable results confirms if the program is successful at managing *Legionella* bacteria.



WHY IT MATTERS

Non-detects are how you recognize an excursion later



BASELINE

Non-detects build the baseline. No history means no way to recognize an excursion.

ROUTINE VALIDATION

Confirms the water quality at points of use.

TREND BEATS THRESHOLD

Alert levels are set from your own baseline data, not borrowed from someone else's.

CAVEAT

A non-detect only means something if the sampling design could detect the hazard.

MYTH 3

“It costs too much, so we do not test.”

Myth

Legionella and waterborne pathogen testing is too expensive to justify in the budget.

Fact

The proactive investment of environmental data outweighs the cost of a disease case, investigation, or death.

A documented risk analysis lets you target and scale sampling instead of sampling uniformly, which is what makes the budget line defensible.

03

WHY IT MATTERS

What a case costs, and where the deaths concentrate

COST OF CASE

\$37,100

Direct cost per Legionnaires hospital stay.

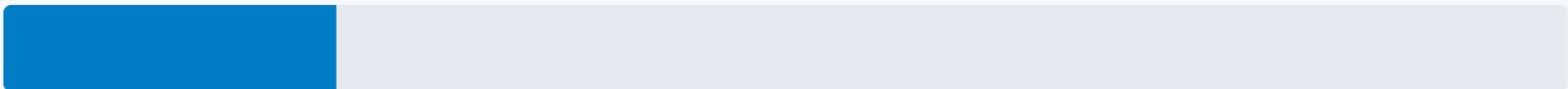
~\$76,000

Once lost work and premature death are counted.

One published UK investigation: patient treatment about **86%** of total cost, the investigation about **14%**.

WHERE DEATHS CONCENTRATE

Cases in health care settings **21%**



456 of 2,140 reported cases

Deaths in health care settings **85%**



75 of 88 reported deaths

Source: CDC drinking water outbreak surveillance, 2015–2020.



ASHRAE 514 and ST108 both require a **documented risk analysis** — that is what lets you concentrate sampling rather than spread it uniformly. ST108 specifies water quality, not treatment hardware: assessment precedes procurement.

MYTH 4

"We only care about *Legionella*."

Myth

Other waterborne pathogens are not reportable, so they do not need to be in the water management program.

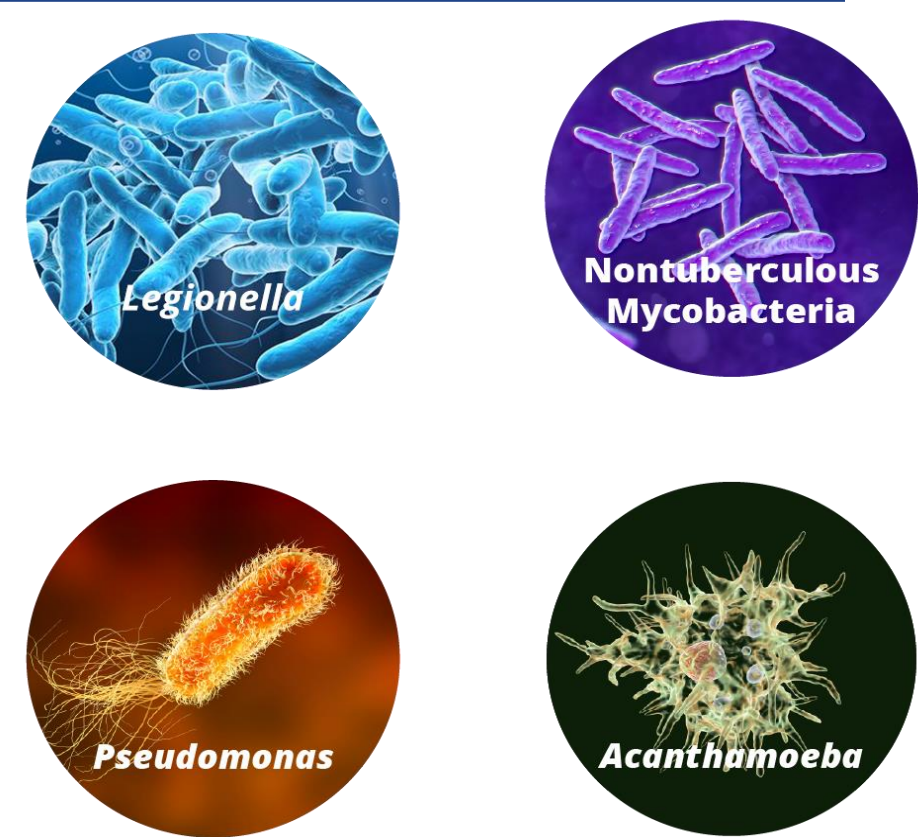
Fact

CMS survey expectations name other opportunistic waterborne pathogens by genus. The Joint Commission standard requires a program addressing *Legionella* and other waterborne pathogens. ASHRAE 514 names ten clinically significant waterborne microbial hazards in health care environments in addition to *Legionella*, and extends the framework to physical and chemical hazards as well.

WHY IT MATTERS

Beyond *Legionella*: what Standard 514 actually names

PRIMARY



ADDITIONAL



WHERE THE HARM LANDS
~\$2.39B a year. CDC attributes most waterborne hospitalizations and deaths to biofilm pathogens. *Legionella* is not the largest of the three.

WHY THE MISCONCEPTION PERSISTS
Legionella is notifiable and investigated. NTM is not, and rarely produces a reportable outbreak.

MYTH 5

“514 is just 188 with a longer pathogen list, and we already do 188.”

Myth

Standard 514 supersedes or duplicates Standard 188, so a facility already following 188 has nothing further to do.

Fact

Standard 514 was developed as a companion to Standard 188 and mandates the use of 188 for Legionellosis risk management. It does not replace it. It extends the framework to physical and chemical hazards, and to microbial hazards beyond *Legionella*, across potable and non-potable systems.

WHY IT MATTERS

Three things Standard 514 requires that 188 alone does not



Broader hazard scope

Physical, chemical, and microbial hazards. Design through renovation.



Clinical surveillance is not optional

Required as part of validation in health care facilities.



Three factors for the testing determination

Control measures not maintained. At-risk or immunocompromised inpatients. History of illness.

MYTH 6

“ST108 is not required, so why test?”

Myth

ANSI/AAMI ST108 is not a Joint Commission survey requirement, so there is no value in qualification or routine testing.

Fact

Alignment with ANSI/AAMI ST108 is at the facility's discretion unless law or regulation says otherwise— however, sterile processing continues to be a vital component of a hospital's operation.

Qualification and routine testing ensure defensibility and efficiency for medical device processing, preventing water from being a limiting factor to operating room schedule and general central sterile operations.



WHY IT MATTERS

No mandate to test. A clear mandate to document.

REQUIRED TODAY

CMS QSO-17-30

- Risk assessment
- Water management program
- Testing protocols and acceptable ranges
- Documented results and corrective actions

TJC PE.04.01.05

- Named oversight
- Water system diagram
- Risk management plan
- Patient population evaluation
- Monitoring protocols
- Annual review



NOT REQUIRED

Neither AHJ requires testing. Testing protocols are at facility discretion unless law requires otherwise.

ST108 is a **voluntary consensus standard**, not a survey element.

MYTH 7

“Our city water has always been good.”



Myth

Municipal water meets drinking water standards, it is suitable for medical device processing.

Fact

Municipal water is the starting point, not the specification.

In addition seasonal changes or disruptions may cause significant fluxes in incoming water, that without monitoring, leads to processing using inappropriate water quality, up o temporary shutdowns or costly mitigation.

WHY IT MATTERS

Drinking water standards are not device processing standards

TIER 1

Utility water

Flushing, washing, intermediate rinsing.

Specified for pH, hardness, alkalinity, conductivity, bacteria, and ionic contaminants.

TIER 2

Critical water

Final rinse for devices contacting bloodstream or sterile tissue.

Same parameters, tighter limits, plus TOC and endotoxin.

TIER 3

Steam

Monitored as condensate.

Carries its own pH and ionic contaminants.

Why an IP should care

ST108 Section 5.2 links inadequate water quality to device malfunction during a patient procedure, toxic effects and tissue irritation from residuals, infection risk from contaminated devices, pyrogenic reactions from endotoxin, and ineffective cleaning and disinfection.

MYTH 8

“We are not involved, facilities manages the plan.”

Myth

Facilities handles the water management program, so infection prevention does not need to be involved.

Fact

ST108 names infection prevention and control among the disciplines the multidisciplinary team should include, with defined responsibilities. ASHRAE 514 makes clinical surveillance part of validation for health care facilities. The Joint Commission requires an evaluation of patient populations to identify immunocompromised patients. Both of these examples highlight the critical importance of clinical leadership in these programs.

WHY IT MATTERS

Named responsibilities, not optional participation

Core Members — Every Team Meeting

- ✓ **Facility Management**
- ✓ **Infection Prevention**
- ✓ Sterile Processing
- ✓ Environmental Services

Support Members — Brought in as needed

- ✓ Admin Representative
- ✓ Risk Management
- ✓ Construction Management
- ✓ 3rd Party Vendors (non-voting)



SUMMARY

Why We Verify, Validate and Document

Keep Patients Safe

Identify Clinical and Environmental risks, proactively implement risk mitigation before an infection occurs

Achieve Compliance

Meet accreditation and survey requirements (CMS/TJC/CDC NHSN)

Drive Defensibility

Documented data supports decisions and withstands scrutiny after the fact.

SUMMARY

Where to find everything cited today

ANSI/AAMI ST108:2023

Water for the processing of medical devices

ANSI/ASHRAE Standard 514-2023

Risk management for building water systems

ANSI/ASHRAE Standard 188-2021

Legionellosis risk management

ANSI/ASHRAE Guideline 12-2023

Managing the risk of legionellosis

CMS QSO-17-30

Revised July 6, 2018

The Joint Commission PE.04.01.05

Hospitals and critical access hospitals · R3 Report Issue 32

CDC

Legionella control toolkit · drinking water outbreak surveillance · waterborne disease burden estimates

Questions

Why Verification and Validation Testing Matter



YASMINE HADDAD

Regional Business Development Manager
Phigenics